



Monash University

**Global Health and Justice in International Biomedical
Research:**

**A Moral Defence of the Contribution Model of
Intellectual Property Rights**

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Abstract

Access to existing essential medicines is severely inadequate in the developing world. To address the global burdens of diseases access to medicine has been considered by the United Nations since 1948 to be part of meeting basic human rights. The obstruction of access to medicine directly affects human health rights and the livelihood of the poor. A lack of health (i.e. ill-health) is considered to result in a lack of capabilities that are linked with the basic social infrastructure of a nation. There are various ways of ameliorating these problems and increasing access to medicines. International biomedical (IB) research is considered one of the promising initiatives to offer reasonable opportunities for advancing global health rights, and for promoting increased access to medicines in developing countries.

Considerable IB research is conducted in collaboration with developing nations and significant numbers of the global poor help to improve global health conditions by participating in IB research. They contribute to the process of drug development and they donate their biological samples and other resources to health research, which helps to advance knowledge. However, these participants in this research currently have no legal rights, (i.e. they are not usually given IP rights) to access these medicines equitably on a long-term basis, because the current distribution system of benefits and burdens of IB research (specifically, the international intellectual property (IP) rights system) creates problems for fair access to medicine in developing nations. The Intellectual Property and patents derived from such research are exclusively owned by

the developed nations, or by the pharmaceutical companies sponsoring the research. Thus, lack of access to medicines in developing countries remain as a key moral challenge for global health rights. The current Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), instituted by the World Trade Organization (WTO), poses significant additional challenges to the health of the poor in developing nations. IB research and development typically yield a net benefit to sponsors but not to the co-contributor-host nations, who often bear enormous burdens in this process. What principle of justice might achieve a fairer distribution of IP rights (patent rights) in IB research? More specifically, are there any compelling moral grounds or reasons to confer IPR (property rights) to M (Medicine produced via IB research) for X (Clinical Trial Participants)?

Therefore, in this thesis first, I investigate questions about whether the currently accepted meaning and application of IP rights by global and national institutions provide a morally justifiable foundation for the fair distribution of the benefits and burdens of IB research. In the early chapters, I aim to develop a principle of justice (though not a full theory of justice) based on an inclusive notion of contribution. Instead of rejecting the very idea of patents themselves, I argue that the basic principle of justice in frameworks designed to ensure fairness in distributing benefits from IB research should include a recognition of developing nations' human resource contributions by sharing the IP rights (Patent) to successfully tested drugs as their due return. Consequently, the TRIPS should be shaped by a principle of just property acquisition based on a more inclusive notion of contribution than that which is currently assumed in the distribution of IP rights

in this context. Drawing on the notion of Adding Value from Lockean labour theory, this project highlights the nature of host nations' contributions, for establishing the moral rights of developing nations for a fair share of pharmaceutical IP rights (Patent). In developing what I will call this 'contribution model', I also draw from Nozick's principles of acquisition, Kantian ideas of moral worth, and Sen and Nussbaum's notion of freedom from inequalities/injustices. I argue that where research participants have contributed to research in relevant ways, it is unjust not to grant them and their host nations a proportionate share of patent rights in the drug, which would allow them to claim benefits in the form of royalty *rights*. Consequently, I also argue that developing nations are also legally entitled to claim a fair share of the derived benefits of this IP.

In addition to the UN Universal Declaration on Human Rights, different international covenants, declarations, protocols, and treaties have bestowed upon governments the responsibility of providing basic healthcare (Singer & Schroeder, 2009, p.16). For example, in the 2030 Agenda for Sustainable Development adopted at the United Nations Sustainable Development Summit on 25 September 2015 devolved to states the responsibility for human rights to health. However, many developing nations unfortunately still lack the capacities necessary for fulfilling such a responsibility. I, therefore, argue for granting royalty rights to host nation governments.

Furthermore, developing nations have completely failed in their negotiations to establish their rights to increased access to medicines and treatment technologies for the poor in

the WTO's TRIPS Agreement (Drahos, 2001). In response to such failures, Peter Singer and Doris Schroeder (2008, 2009) have argued for TRIPS reform both for moral and practical reasons.

In this thesis, secondly, I investigate whether developing nations currently have the necessary capacity to re-negotiate the TRIPS Agreement or IB research protocol that provide for a fairer distribution of IB research benefits to help achieve global health rights. My answer to this question is negative. Most researchers (such as Peter Drahos and Angela Ballantyne) argue that the existence of an asymmetric power relationship between the parties is an insurmountable barrier to fairness in negotiation, and therefore in IB research. My view is that achieving global health rights also requires, specifically, improving the negotiation capabilities of developing nations- i.e., providing them with fair access to information (knowledge and thus more power) and better input into decision-making (political power). These capabilities are vital for poor nations to be able to claim their global health rights (Millum, 2010) and for implementing the benefit sharing principle, as I argue.

Revisiting negotiations, I argue that the fundamental principle of justice as *equal opportunity* for all parties involved in negotiation should play a crucial role in bringing fairness. The individuals and groups whose negotiating capabilities I am discussing here includes research trial participants, local researchers, or higher-level officials as employed representatives for negotiation, but for simplicity in my chapters discussing negotiation I will usually refer to all of these as included in developing nations' negotiation capabilities.

What does enhancement of this negotiation capability involve in the context of IB research? In my view, such capability involves having both the requisite abilities and opportunities. Enhancing the negotiation skills of developing nations is important because if any research proposal is not responsive to the host community's health needs, or is not based on an acceptable moral principle of justice, or is exploitative, then the host community would be in a better position to reject the proposal or alternatively, could be in a position to and have the skills to negotiate an appropriate level of compensation for any harm that occurs because of participation in the research. They also would be able to negotiate fair level of benefits for their participation in the research.

To combat suffering, and to address global burdens of diseases, reform of the TRIPS Agreement, rectification of historical injustices, social infrastructure development, more IB research into neglected diseases, along with drug donation, seem to me inadequate for achieving global health justice. Unequal distributions of benefits and burdens in international biomedical research raises concerns about injustices in global health. Thus, in this thesis, I argue for IP rights sharing as a morally superior and more useful way of bringing greater fairness in IB research, and of increasing access to medicines in developing countries.

Declaration

This thesis contains no materials which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no previously published or written by another person, except where due reference is made in the text of the thesis.

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Finally, I would like to dedicate my thesis for the freedom fighters of Bangladesh, Martyrs and Others who sacrificed themselves in many ways in the liberation war of Bangladesh in 1971.

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Chapter One

Access to Medicines: An Exploration of Justice in International Biomedical (IB)

Research

1.1 Introduction

The World Trade Organization's (WTO) international recognition of intellectual property (IP) rights via the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994 raised serious concerns among people around the globe. Especially concerning was the effect that this agreement could have on the "accessibility and affordability¹" of essential lifesaving medicines for the poor (Cullet, 2007, In Segelid & Pogge, 2010, p.261). In the past (i.e., prior to 1994), developing nations' own pharmaceutical companies had a broader scope of opportunity to copy and produce generic medicines, and had access to global markets to provide cheaper generic medicines. Each government had protected this access in various ways according to their own jurisdictions. The idea of innovation is used by governments of developing nations, for example India, in a restricted sense to facilitate generic medicine production (<https://www.theguardian.com/sustainable-business/patent-wars-india-takes-on-big-pharma/16/05/2019>).

¹ "Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them (Cullet, 2007, p.261)."

Scholars have started to argue that the TRIPS Agreement constitutes an injustice to Low and Middle-Income Countries (LMIC²), because this agreement conflicts with global health rights (see e.g., Cullet, 2007, Forman and Kohler, 2012, p.4, Alkoby, 2012 in Forman and Kohler, 2012, p.47). Some of the key provisions of the TRIPS Agreement poses a substantial challenge to fair access to medicine and medical technologies in developing nations. And restricting fair access to medicine and medical technologies is a violation of the health rights of the citizens of these countries, rights that are recognized in the United Nations' Universal Declaration of Human Rights 1948.

The aim of this PhD research is first to develop a principle of justice (though not a full theory of justice) based on an inclusive notion of contribution. Secondly, I aim to show that by using this principle of justice a reasonable intellectual property (IP) regime can be developed and promoted for fairer access to healthcare, and for the protection of the IP and patents rights of the participant contributors to international biomedical (IB) research³ (particularly, drug development research), as well as of the rights of the poor

² I will use developing nations to refer low and middle-income countries and Developed nations to refer high income countries in this thesis interchangeably.

³ Biomedical or Clinical Research is a type of health research that requires human participants to test therapeutic or diagnostic products such as testing drug dosage regime or drug safety or efficacy to contribute to the development of generalizable knowledge (Macklin, 2004, p.109, Ballantyne, 2006, p.26). The aim of this research is to focus on international biomedical/clinical research. The Council for International Organizations of Medical Sciences (2002) guideline 3 defines international biomedical research as,

“...Research undertaken in a host country but sponsored, financed, and sometimes wholly or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions and personnel of the host country.” For this research, international biomedical research refers to the type of research which is sponsored by a developed country government agency such as NIH or multinational pharmaceutical company such as GlaxoSmithKline (GSK) but carried out in a developing country. The research sponsor can be one or multinational pharmaceutical company or one or more national/ international government/agencies. For simplicity, I will use the term as only entity from the developed world.

nations, in the process of innovation. The argument I intend to develop in this thesis is that it is unjust not to grant host nations and research participants (in those cases where they have made contributions of the relevant kinds) a share of patent rights, which would then allow them to claim benefits in the form of royalty *rights*.

In this respect, I discuss the applicability of John Locke's theory of property rights as a basis for the allocation of intellectual property rights in the patentable discoveries resulting from IB research. I argue that the apparent Lockean grounding of the TRIPS Agreement justifies a more expansive allocation of property rights to the contributors to biomedical innovation than that which the TRIPS Agreement recognises. In IB research, providing a proportionate share of IP rights to the host nations will both enhance procedural fairness and will distribute the benefits and burdens of this research more equitably. In turn, sharing the benefit of IP rights with contributors will promote fair access to global health rights and human dignity, by helping to '*create capabilities*' for the poor (Nussbaum, 2011).

1.2 Background to the Research

In 1946, the World Health Organization (WHO) recognized health as a fundamental right of humans and adopted a definition of health in their declarations. According to the WHO definition, "health is a state of complete physical, mental, and social well-being

and not merely the absence of disease or infirmity” (WHO, 1946⁴). The WHO constitution also affirms that

“the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being...(<http://www.who.int/about/mission/en/visited> 26/11/2017)”

The WHO therefore urges states not to interfere directly or indirectly with individuals’ enjoyment of the right to health – for example, it strongly advises states to refrain from limiting access to health-care services and marketing unsafe drugs (WHO, 2010).

In 1948 the UN Universal Declaration of Human Rights also adopted health as a right in article 25:1. The UN (1948) Declaration states that,

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control”⁵.

That improving access to lifesaving medicines and essential medicines is an essential step for ensuring health rights⁶ is recognized by the International Covenant on Economic, Social, and Cultural Rights (ICESCR)⁷. Access to essential medicines in developing nations is severely inadequate and the health conditions of the poor in these countries are often critical. From a health rights point of view, this situation is morally

⁴ The definition is stated in the preamble to the Constitution of WHO as adopted by the International Health Conference, New York, 19 June - 22 July 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of WHO, No. 2, p. 100) and entered into force on 7 April 1948, <https://www.who.int/about/who-we-are/frequently-asked-questions/21/04/2019/>

⁵ <http://www.un.org/en/universal-declaration-human-rights/>

⁶ The fundamental principle of health rights is that everyone has the right to be able to access health care (<http://www.safetyandquality.gov.au/wp-content/uploads/2012/01/Charter-PDf.pdf>/01/08/2014).

⁷ http://www.who.int/medicines/areas/human_rights/en/

untenable and unacceptable. More than 30% of global deaths, or some 18 million deaths annually, occur mostly in developing nations from diseases, and 90% of these deaths are easily preventable, or treatable and/or curable (Chuan and Schaefer, 2008, Hollis and Pogge, 2008, p.113, Selgelid and Pogge,2010). Typically, communicable diseases are one of the important reasons for these deaths (WHO, 2004, Pogge, Rimmer and Rubenstein, 2010, p.4)⁸. Because of these diseases many hundreds of millions are suffering, and many more hundreds of millions of people are devastated due to premature deaths or severe illness in their families (Hollis and Pogge, 2008, p.113). Furthermore, according to the WHO⁹, more than 2 billion people suffering from cancer, tuberculosis, malaria, HIV¹⁰ and other diseases in developing nations simply cannot afford the medicines required to adequately treat their diseases and other medical conditions.

Factors that are affecting access to medicines in LMIC include the lack of medicines that are required to treat diseases that affect people of developing nations (Hunt, 2009, p.21). One of the reasons for this is that pharmaceutical companies do not do enough research into new drugs specifically required to fulfil the health needs of developing countries, and do not develop/manufacture and market necessary medicines require for LMIC countries, despite the appeal from the United Nations General Assembly “to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies.” Consequently, this has been adopted as a goal in the

6. World Health Organization.2004. *The Global Burden of Diseases:2004 Update 10*, pp.17-18.

⁹ http://www.who.int/whr/1998/media_centre/50facts/en/01/08/2014.

¹⁰ HIV-Human Immunodeficiency Virus

Millennium Development Goals (Resnik, 2006, p.89, Macklin, 2012, p. 118, Hunt, 2009)¹¹. Lack of research into the health needs of LMIC is evident from “the fact that over a twenty-five-year period only 0.1 percent of new drugs have been developed for ‘tropical diseases’” and tuberculosis, which are “primarily experienced in the [LMIC]” (Forman and Kohler, 2012, p.8). Further, *The Economist* also (16th June, 2005) reports that “Of the 1,500 or so drugs launched over the past 30 years, fewer than 20 deal specifically with tropical disease” (<https://www.economist.com/node/4054002/07/01/2018>).

Developing nations are often too economically weak to conduct biomedical research specifically for their own health needs and/or lack the purchasing capacity/power to buy such medicines required to treat these diseases. On the other hand, Resnik points out that it is not cost-effective for developed nations’ pharmaceutical companies to develop new medicines specifically required for low- and middle-income countries (Resnik, 2001, p.15). For example, in OECD¹² states, per head spending on drugs is at about US\$239 per annum, while in developing nations, per head per annum spending is less than US\$20 on all health programs which also include drugs expenditure. In contrast to developed nations per head expenditure for purchasing drugs, in sub-Saharan Africa, is

¹¹ World Health Organization. Regional Office for the Western Pacific. (2016). Sustainable development goals (SDGs) : Goal 3. Target 3.b : Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all [poster]. Manila : WHO Regional Office for the Western Pacific. <http://www.who.int/iris/handle/10665/208289>

¹² OECD - the Organisation for Economic Co-operation and Development. In 1960, The OECD is founded aiming to grow in trade and economy as an intergovernmental economic organization. Currently, the OECD consists of 35-member countries.

less than US\$6 (Mills, Werhane and Gorman, 2006, p.33, Khosla and Hunt, 2012, p.26 in Forman and Kohler, 2012). The investment opportunities, i.e., monetary profit, for drugs in developing nations are so relatively small compared to the OECD market that fails to attract necessary research interest of multinational pharmaceutical companies.

The following example illustrates another type of disparity in global health research. According to the Novo Nordisk Annual Report (2008)¹³, more than 40 percent of clinical trials in developing countries are designed to mainly benefit people living in developed nations. For instance, in early 1990, the Thailand' Ministry of Public Health allowed a hepatitis A vaccine trial known as the Havrix Trial to be conducted in Northern Thailand. The trial was a success, and the results of the trial showed that the vaccine is effective and mostly safe against hepatitis A. However, the vaccine was not made available to Thai people, because it was not cost-effective for the pharmaceutical company (Smith-Kline Beecham Biologicals) to make available the vaccine to this population. The cost of vaccine is 160,000 Bath (4571 US\$ approximately) per QALY. The Thailand government cannot allocate fund for this vaccine. The people of Thailand cannot afford the vaccine as their annual income per capita is 1100 US\$. Ensuring that the vaccine is available to the people of industrialised countries who travel to developing nations was the main aim of the study (Hawkins and Emanuel, 2008, pp. 55-58, Macklin, 2004, p.106). Thus, according to Macklin (2012), much of the biomedical research conducted in developing nations addresses the health needs of developed nations, neglecting

¹³Novo Nordisk Annual report 2008, <http://annualreport2008.novonordisk.com/how-we-perform/responsible-business-practices/bioethics/clinical-trials.asp/01/08/2014>.

diseases that mostly affect the health of populations in developing nations (Chuan and Schaefer, 2008, Macklin, 2012).

Even though IB research is conducted through international collaborations with developing nations, most of the patents derived from such trials are owned exclusively by the pharmaceutical companies and multinational corporations based in developed nations. A high percentage of all the clinical drug trials conducted in developing nations are led by corporations based in developed nations (See also Ballantyne, 2006 pp.22-24). This was accurately reflected in the statement of an employee of a developed nation pharmaceutical company, Juan Pablo Guzman of Searle and Pharmacia. In reference to Latin America in 2000, Mr Guzman said at the Drug Information Association meeting in San Diego:

“We are colonizing a region for clinical trials”¹⁴

Another factor affecting access to medications in developing nations is that pharma companies don't lower the prices of existing drugs or allow cheaper generic versions to be sold in these markets. Grover et al. (2012) expressed a similar view and they note that pharmaceutical companies' interest in profit intensifies this lack of access to medicines as they strive for a greater return on their drug development investments.

14 DeYoung, K., Nelson, D.2000. Latin America is ripe for trials and fraud, *Washington Post*, 21 December: A01.

Making profit is one of the main objectives of pharmaceutical companies to meet the expenses and give incentives for innovation. The profit-maximising objective of pharmaceutical companies are critically examined by global health justice researchers when global health rights are affirmed in the international arena (Lexchin, 2006, pp.11-21, in Cohen et al. 2006). The claims of profit intensification against pharmaceutical industries can be further demonstrated from the following statement of the WHO's past Director General Margaret Chan. For Chan, "the R&D incentive is virtually non-existent". She continued, "a profit driven industry does not invest in products for markets that cannot pay (Time, 2014)." Further, according to a report of *Sydney Morning Herald*, some year 11 high school pupils of Sydney Grammar recreated a drug called Daraprim (anti-parasitic medication). This drug (Daraprim) is used to treat Malaria and Aids patients. The students claimed that they could recreate a dose of Daraprim at a cost of AU \$ 2 only. However, the same drug was priced \$US750 a dose by the Turing Pharmaceuticals Company of Mr. Shkreli. In defence of charging high price for Daraprim, Mr Shkreli claimed that the price was high to extract money to fund future research and development of better drugs. The Executives of pharmaceutical companies typically use such reason for high price of drugs, but Mr Shkreli is known as a figure of exceptional greed. James Wood, a student of Sydney Grammar School, rejected Shkreli's justification for the high price of the drug and claimed that

"He was clearly trying to justify something driven by the profit motive"

(<http://www.google.com/amp/samp.smh.co..au/technology/sci-tech/martin-shkreli-responds-after-sydney-grammer-boys-make-daraprim-20161201-gt1n3q.html/visited> 01/10/2017). In this particular case, it seems to me that the Sydney Grammar boys have

unquestionably demonstrated the profit maximization¹⁵ interest of pharmaceutical companies.

Despite the ongoing lack of adequate access to essential medications in developing countries, in 1994 the WTO introduced a legally binding treaty known as the TRIPS Agreement, recommending strong patent protection for pharmaceutical products across the globe. The TRIPS Agreement incorporates a strong intellectual property (IP) rights regime for protecting the profit maximization interests of developed nations. This regime also requires all member states of the WTO to adopt, reform or introduce new domestic regulations to satisfy the TRIPS requirements (Drahos, 2003, Muzaka, 2011, p. 38, Hollis, Pogge, Schroeder, 2013, p.209 in Schroeder and Lucas ed. 2013). This global mandate for IP protection means that the developing world will no longer have access to generic versions of patented drugs before the patent expires (drug patents usually last for 20 years). Patented drugs are expensive for consumers compared to generic versions, and approximately three-quarters of the global population cannot afford patented drugs (Hollis & Pogge, 2008, p. 7). Poor people in LMIC will, therefore, be further disadvantaged by their governments complying with the Agreement as it will exacerbate existing limits on their access to medicines. In this polarised context, the current TRIPS regime poses significant additional threats to the health of the poor in developing nations (Schuklenk, 2000, p. 64). For critics, the TRIPS Agreement is a

¹⁵ See also Lexchin, J. 2006. The pharmaceutical industry and the pursuit of profit in Cohen, J., Illingworth, P. and Schuklenk, U. (ed.). 2006. *The Power of Pills social, ethical and legal issues in drug development, marketing, and pricing*, London: Pluto Press.

flawed “one-size-fits-all”¹⁶ legal global governance mandate of the WTO that overlooks the developmental differences between member nations, as well as the WHO’s global push for health rights (Muzaka, 2011, p. 38).

To promote justice and better access to essential medicine for the developing world, many have argued for abolishing such strong patent protection systems (Mannan & Story, 2006). On the other hand, reforming IP rights themselves is another way of addressing health problems for the poor of the developing nations (Schroeder & Singer, 2008). For example, Selgelid (2006) and Pogge and Hollis (2008) have proposed developing a new socially responsive IP system and new medicines through the Health Impact Fund (HIF¹⁷). The HIF would be created by a non-profit organization called ‘Incentives for Global Health’ to provide rewards for pharmaceutical companies for their drug based on its actual impact on global health (i.e. On the Global Disease Burden). In addition, the HIF will create a global patent system owned by the global community, which will help to rescue people in developing nations from unbridled pharmaceutical profit-making, and will incentivize pharmaceutical companies to address neglected

¹⁶ Mannan & Story (2006) claim that patent protection for both Product and Process of any invention under the TRIPS is a one –size-fits-all standard. In pharmaceuticals, patent protection of the chemical of a drug is called product patent and patent on a drug’s specific way of administering and manufacturing method is called process patent. Both types of patent are protected under the TRIPS Agreement (1994) and the member states of the WTO should follow the TRIPS. Malhotra (2010, pp. 180) also similarly acknowledges that the TRIPS is a one-size-fits-all standard when he was exploring the TRIPS Agreements’ appropriateness in the context of developing nations and product patenting of pharmaceutical.

¹⁷ The HIF is a performance-based reward system for pharmaceutical innovations. If any pharmaceutical company decides to register their product with HIF to receive funds, they are required to provide their drugs at accessible rates which developing nations can afford. By doing so, the affordability of medicine for the poor will be addressed to help meet their health rights. URL: <http://healthimpactfund.org/>

diseases of developing nations to increase access to medicine for poor, and will help compensate pharmaceutical companies for the high costs of research.

Risse (2012) has proposed a different view of intellectual property rights, i.e., common ownership in IP for essential drugs based on the idea of Grotius's "humanity's collective ownership"/common ownership of sea. Grotius's view of property in relation to sea routes is that discovering a new sea route does not necessarily give rise to private ownership of that sea route, and Grotius argues that no one can justifiably claim that the sea route is his or her property (pp.89-107). The sea is common property for all; thus, the sea routes are common property for all. For Risse and Grotius, the use of a sea route by people other than the discoverer does not obstruct the discoverer from getting benefits from it. Similarly, the use of an idea by others besides the inventor does not necessarily obstruct the inventor from getting benefits from that idea. So, ideas can coherently be regarded as common property. Risse's view of intellectual property rights, together with the HIF initiative, could provide the basis for a more just global regime for securing global health rights. Risse (2012) throughout the chapter 12 of his book *On Global Justice* also argued for fair access to essential medicines based on the notion human rights and global justice. For Risse, since developing nations are members of global institutions, such as UNs, WHO, WTO, IMF, the World Bank, the global poor deserve access to medicines and rich nations have obligation/duty to ensure their access to essential medicines.

Recently, to reduce global health disparities and to strengthen the research capacities of developing nations, developed nations have engaged themselves in partnerships models, such as product development partnerships (hereafter PDP). The PDP connects private, philanthropic, academic, and public organisations to develop new products (drugs, vaccines, and diagnostics) to provide in LMIC. Unlike the pharmaceutical industry, PDPs are not aimed at maximizing profits. The Drugs for Neglected Diseases Initiative (DNDI) and the Medicines for Malaria Venture (MMV) are two PDPs currently working in developing countries to secure access to medicines and capacity building¹⁸ initiatives for individuals and institutions. The Institute for One World Health (OWH) is another PDP working on issues of access to medicines (Pratt and Loff, 2013). However, the senior staff and head offices of PDPs are from the United States and Europe, meaning that the decision-making power and financial control of these PDPs rest with developed nations. Thus, even in the PDP model, the power inequity (Pogge, 2008, p.16) and research disparity between developed and developing nations remains (Pratt and Loff, 2013, p.1969).

Philanthropic approaches, and approaches by NGOs and other government organisations have also been undertaken to assist capacity building in developing countries hosting IB research, with the aim of reducing exploitation in research and achieving justice. For example, the Bill and Melinda Gates Foundation, the Joint United Nations Programme on HIV/Aids (UNAIDS) and the National Institutes of Health through

¹⁸ According to Mary Lansang and Rudolfo Dennis, “capacity building as the ongoing process of empowering individuals, institutions, organisations and nations to define and prioritize problems systematically, develop and scientifically evaluate appropriate solutions, and share and apply the knowledge generated” (WHO, 2004).

the Fogarty International Center have all contributed to bridging the gap between developed nations and conducting health research for the developing world.

In response to the lack of access to essential medicines for patients who mostly reside in LMIC, and the affordability issues of medicines in these countries, big pharmaceutical companies have begun offering drug donations to the poor on request from global institutions as expressions of “corporate social responsibility”. For example, Pfizer and GlaxoSmithKline (GSK) donated pneumonia vaccines in 2014, and they have also stated that they are willing to donate¹⁹ drugs to LMIC. However, donations of drugs or medical products are not a sustainable solution to the affordability and accessibility issues of essential medicines for the global poor. In making such donations, pharmaceutical companies decide when, how and to which community and to which geographic location the drug donation should go. This means that any drug donation depends upon the mind-set of an agent for a pharmaceutical company, and in most cases, conditions are attached to the drug donation. Pharmaceutical companies continue to offer donations of drugs instead of pursuing long-term solutions to the problems of access to medicines. According to the Executive Director of Doctors without Borders in the United States, Jason Cone,

“Donation can also undermine long-term efforts to increase access to affordable vaccines and medicines” (<http://www.doctorswithoutborders.org/article/there-no-such-thing-%E2%80%9Cfree%E2%80%9D-vaccines-why-we-rejected-pfizer%E2%80%99s-donation-offer-pneumonia/visited> 26/11/2017).

¹⁹ <https://www.afairshot.org/articles/2016/10/10/there-is-no-such-thing-as-free-vaccines-why-we-rejected-pfizers-donation-offer-of-pneumonia-vaccines>.

Therefore, most global health organizations such as UNICEF, WHO, the Vaccine Alliance and GAVI have developed recommendations against drug donation from pharmaceutical companies. Medecins Sans Frontieres (MSF) has recently rejected an offer of pneumonia vaccines donation from Pfizer, stating that

“There is no such thing as “FREE” vaccines” (ibid)”.

By offering drug donations to some developing countries including philanthropic organizations, pharma companies seek to justify continuing to charge high prices for their drugs to others. Cone further said, “donations are often used as a way to make others ‘pay up’ (ibid, p.1)”.

Lack of access to medicine for the global poor is also addressed through a system known as ‘compulsory licensing’. The Doha Declaration (2001)²⁰ urges the granting of compulsory licensing²¹ of patented drugs to address the problem of access to medicine for an affordable price for LMIC in emergency situations, i.e., a pandemic of influenza virus. Compulsory licensing is an international legal measure for global public health laid

20 World Trade Organization.2003. Doha Declaration,
https://www.wto.org/english/res_e/booksp_e/ddec_e.pdf

²¹ In this situation, patent owner is forced to lose rights for taking action against copying, which means it is not an option that pharmaceutical companies are willingly sharing with the developing nations to address problems of access to medicines for the global poor. This is completely different from sharing benefits of international collaborative research. Compulsory license can be obtained by any nation whether they have contributed in the drug development process or not (Ballantyne, 2006, Schroeder and Singer, 2009, Drahos, 2007). However, some scholars have argued for such provision, as Schuklenk and Ashcroft (2002) believe that compulsory licensing is morally and pragmatically better solution over drug donation or price cut option.

In this regard, I would like to point out that there are two issues: one is access to health care for the global poor and another is international clinical research benefit sharing. As this research is focusing on the international clinical research benefit sharing, compulsory license cannot be a solution to the problem of benefit sharing rather it is more relevant to the problem of access to global health care.

out in Article 31 of the TRIPS Agreement. A compulsory license can be obtained by any state with domestic manufacturing capacities and is a way for states to manufacture drugs while paying minimum royalties. A Compulsory license means a state has the power to authorize an experienced government generic producer to produce generic copies of a patented drug as an emergency response to a pandemic in the state. According to the compulsory license system, a patent holder is required to sell a license to a WTO member with minimum royalties even if the remuneration is not equivalent to the patent's economic value.

The WTO took a further initiative to assist least developed nations (LDCs) to meet the health needs of their citizens. In November 2015, all of the LDCs were granted further exemptions from key provisions of the WTO's intellectual property agreement until 1 January 2033 (WHO, 2015, Rahman²², 2015).” The LDCs can be benefited from non-compliance with the TRIPS requirements until 2033. For example, developing nations would be able to produce generics of patented drugs without the permission of patent holders or without obtaining compulsory license (https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm).” However, this extension or liberalization of IP protection rule does not give any guarantee for LMIC nations to have access to medicines or assurance of doing research to develop drugs for neglected diseases in developing nations, or they may get compensation for past IB research similar to pharmaceutical companies.

²² Rahman, M. WTO Decision on Pharma: An Opportunity, *The Daily Star*, 19 November 2015, Bangladesh. Accessed on 12/08/2016.

But low and middle income countries need to develop and/or update national legislation in order to comply with the WTO's demands by then. However, the WTO members also left open the possibility of a further extension. However, no discussion took place about when to give IP rights on products developed through IB research. The exemption is a kind of *gratis* to promote and protect global health rights. However, it is expected that all developing nations will be able to develop human resources and economically to be able to comply and fully respect the TRIPS provision by 2033. This seems a very optimistic expectation about the pace of development of the developing nations. What will happen if most of these countries are unable to reach the expected level of development by then, and those countries who lack domestic manufacturing capacities, or have little capacity or inadequate capacity, are unable to address the problem effectively?

Therefore, first, our commitment towards global health rights protection requires considering access to medicine on a long-term basis. Secondly, we need to explore further morally reasonable options besides compulsory licensing. Thus, it seems to me that a fair distribution of benefits and burdens cannot be achieved when the research contributions of developing nations are not properly recognized, and when the research contributions of developing nations continue to be measured through conventional perspectives of justice. If finding a sound moral basis of IB research is a critical and crucial step of an innovative process, then we need to consider all its contributors as partners, rather than some of these as mere *labourers*. The relationship of both parties

cannot be measured in terms of the conventional dichotomy: investor and labourer. Here the relationship is not only a symbiotic relationship like mother and child, earth and humans. The relationship is more than these conventional relationships. It relates to our continued existence and flourishing of life on earth. In addition, IB research is seen by many philosophers as one of the ideas for social sustainability, world peace and security.

As was mentioned above, a large percentage of the biomedical trials undertaken globally are conducted in collaboration with developing nations. In this regard, bioethics researchers have emphasized the importance of researchers sharing the benefits of IB research with the host nations - their collaborative partners - to avoid injustice or exploitation. For example, Emanuel, Wendler, Killen and Grady (2004²³, p. 932) have argued that,

“...collaborative partnership requires a fair distribution of the tangible and intangible rewards of research amongst the partners.”

Some researchers have also proposed certain ways for researchers to share the benefits of IB research studies with the nations and/or communities which hosted those studies. For example, Annas and Grodin (1998, p. 561) argue that any drugs or interventions made available to disadvantaged participants during a clinical trial should also be made available to trial participants after the clinical trials have concluded. This would avoid exploiting the disadvantaged people who participate in clinical trials in order

²³ Emanuel, E.J., Wendler, D., Killen, J., Grady, C.2004. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis*, 189 (5): 930-7.

to access drug or medical treatment. Regarding the sharing of such post-trial benefits, the US National Bioethics Advisory Commission (NBAC) urged the adoption of a responsive mechanism to address health needs of poor developing nations. The NBAC argued that “Making the [post-trial] benefits responsive to the health needs of the participants provides an additional way to ensure that research participants are not exploited (NBAC²⁴, 2001)”. Norman Daniels (in Macklin, 2004, p.76) argued that “access to basic health care is a requirement of justice, as it is necessary in order for human beings to function in a way that is normal or typical for the species.” In this circumstance, those advocating post-trial access to participants believe that such access helps to avoid exploitation of participants, because exploitation involves an unfair transaction, and that such access removes this unfairness. The above view of Daniels demonstrates relationship between access to medicine as part of basic health care and justice.

Similarly, Alex London (2005) has argued that pharmaceutical companies should provide drugs resulting from collaborative research to the host countries of the research and should also make these drugs accessible to other poor countries through differential pricing or voluntary licensing. Differential pricing, along with attention to host countries’ health needs and sufferings, has the potential to become an important mechanism to address global health rights. If the call for post-trial benefit sharing

²⁴ National Bioethics Advisory Commission (NBAC).2001. *Ethical and Policy issues in International Research: Clinical Trials in Developing Countries* Volume 1. Bethesda, Maryland: National Bioethics Advisory Commission: 60.

becomes more widely recognised, then IB research would become more responsive to the health needs of host countries (London, 2005).

Angela Ballantyne (2006) has suggested that the problem of unjust distribution of benefits and burdens can be addressed by introducing an infrastructure charge to the sponsors of the research for the host community of a clinical trial. For her, by introducing an infrastructure charge to the sponsor of the IB research, the international community can agree to a standard rate. This infrastructure charge can be applied on top of the existing costs of the research. This charge provides a guaranteed benefit for the host community and it should be deposited/transferred to a trustee fund before the completion of the research. This charge should be used to develop health related infrastructure to address the lack of health care facilities. Lack of this structure makes them vulnerable to participate in the research trial, thus they can get access to the health care services through participating in a trial.

Ballantyne (2006) also explained why she proposed this infrastructure charge on top of the total trial costs. She argues that a sponsor of an IB research study can save huge amount of money just by relocating the trial to a LMIC or developing country, instead of conducting a trial in the USA where costs of clinical research is three times higher than a developing nation. Ballantyne (2006) uses an example to illustrate the savings of the sponsors. If a Tuberculosis drug trial is conducted in Uganda, then it would require originally \$8.2 million, and if 10% of infrastructure charge is added to the original cost it

would require only \$9.02 million. Even if 90% of the infrastructure charge is added to the original cost, it would only require \$15.58 million whereas if the same drug trial is conducted in the USA, it would require \$22.6 million originally. It is much cheaper for a sponsor to conduct the trial in Uganda. By doing so, the sponsor of the trial saves a huge amount in their investment. To support her claim, Ballantyne argues that it is relatively easy to add an international standard rate of infrastructure charge on top of the total costs of the trial (See Ballantyne, 2006, pp.255-261)²⁵.

In addition to participants sharing in the benefits of clinical trials, some researchers suggest that justice in IB research requires ensuring that all participants have provided their informed and voluntary consent to participate in the study in question (Hawkins and Emanuel, 2008, p.7). Macklin argues that the informed and voluntary consent of participants should be the core value for achieving justice in IB research in the developing world, and so on this view, it is a requirement of justice to ensure that IB research participants are not being coerced or forced to take part in the study in question (Macklin, 2004, p.76).

²⁵ Beside the net saving in clinical research, relocating the trial in a LMIC or developing country sponsor of biomedical research can recruit research participants faster than that of the USA. This means IB research in developing nations helps to get faster regulatory approval (ie. FDA approval) for marketing of the successful intervention which resulted from the trial. There can be other benefits also from relocation of a clinical research in a developing nation. For instance, this also contributes to fixing the price of the medicine a bit lower price, and this contributes to the economy of the developed nation. Consequently, health needs of nation are addressed timely. Another benefit can be noted that there is a shortage of human resources in developed nations due to decreasing birth rate and increase in the number of aged people. On the other hand, ill health reduces number of workers/human resources required for the industry and pose threat to national economy and security. Therefore, to avoid this panic situation it is practically beneficial for developed nations if they locate clinical research in developing nations. This also open market for them.

Another justice debate in IB research concerns whether the standard of care for research participants in developing nations should be equivalent to the standard of care that is available locally, or whether the standard of care in developing nations should meet global standards. Macklin argues that providing research participants with care that does not meet global standards at the time of conducting the research constitutes an injustice (Macklin, 2004, p.76). The standard of care is an important issue of justice in IB research. However, it is beyond the scope of this thesis to discuss this issue further.

Past and recent IB research has been required by guidelines such as *the International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS²⁶, revised in 2016), *Ethical and Policy issues in International Research: Clinical Trials in Developing Countries Volume 1* (NBAC, 2001), *Declaration of Helsinki-Ethical Principles for Medical Research involving Human Subjects* (revised in 2013) (WMA²⁷, 2013) to consider different types of benefits for host countries and participants in response to their specific disadvantaged circumstances²⁸.

²⁶ CIOMS-Council for International Organisations of Medical Services.

²⁷ World Medical Association

²⁸ Instead of supporting the property rights that the developing nations deserve, other researchers propose gifts or donations. On the basis of what I have been arguing, this appears insufficient and undermines universal human rights and human dignity. It is the contribution of research participants which enables new treatment to be brought to market quickly. The developed nations use the knowledge which is gained from the clinical trials for their own benefits (Annas & Grodin, 1998, p.561). Drug companies are only receiving the patent rights for marketing the drug quickly because research participants have made an extremely positive contribution towards the process of development of a new drug or kind of medical intervention.

However, the idea that the distribution of benefits in IB research be carried out according to need seems to be based on an ethic of compassion, and is an expression of sympathy, and these are often framed as matters of justice. For example, Mill in chapter 5 of his book *Utilitarianism* argued that justice ‘implies something which is not only right to do, and wrong not to do, but which some individual person can claim from us as a moral right (Mill, 1863, p.49).’ On some occasions, beneficence appears as a requirement of justice alongside rectification and giving due return. Mill here tried to argue that justice has nexus with claim rights. Mill’s view on justice indicates that justice or injustice is not merely a kind of labelling action of someone or performing moral utterance. Rather it implies substantive action, and obligation. If X is a person and she has a claim for Y, then she must claim it as her right to claim Y; denial of which is to be termed as injustice and morally wrong. Justice implies obligation for/responsibility of Z’s (pharmaceutical companies/sponsoring clinical trial) to respect X’s right to royalty and ensure similar types of access to medicine produced from the collaborative research (i.e. in drug development process), hosting a clinical trial for a sponsor.

Later, in chapter 2 and 3, I will demonstrate that approaches of this kind, for example utilitarian conception of justice, while good as far as they go, fail to recognise the intellectual, financial, bio resources sharing and others contributions of the various participants in IB research, and thus do not sufficiently appreciate certain moral implications of the acquisition of property rights, as these rights are taken for granted. To address this morally troubling situation, each IB research project requires closer investigation.

It is crucial to the argument for sharing drug patents with the host nation of research to recognise that the contributions made by the participants in IB research typically differ significantly from the contributions made to a business by people selling goods in a shop or working in a drug manufacturing plant. This is because clinical trial participants typically contribute to the uncovering of various properties of the tested drugs, which serves to create opportunities for future research for the scientific communities. As Hawkins and Emanuel (2008, p.12) correctly claim that, "All research "uses" the participants to gain information that, hopefully, will improve the health of others whether directly or indirectly through additional research." Similarly, Emanuel, Wendler and Grady (2000, p.2701) claim that "the overarching objective of clinical research is to develop generalizable knowledge to improve health and/or increase understanding of human biology; subjects who participate are the means to securing such knowledge." Research participants assist to advance researchers scientific quests when they (research participants) recognise, define and report about their level of functioning of a drug or intervention or their illness experience. Researchers use information or learned lessons about treatment related disease or toxicity from the trial participants to direct their quests further (Bottomley and Aaronsons, 2007). In this way, research participants are in an important sense, partners in the development of intellectual property. By contrast, ethical approaches that portray participants' contributions to clinical research as equivalent to these other types of contributions focus on the largely moral issue of the broad social and economic disadvantages common to developing nations.

This research is about sharing the benefits of international clinical research, yet I acknowledge the global wealth and health disparities between High income countries (HIC) and LMIC nations are strongly connected to this issue. These disparities play a crucial role in my argument for health justice, and there is considerable overlap between the issue of access to medicine for the global poor and the question of sharing the benefits of international collaborative research.

If the benefits of IB research are to be distributed fairly - that is, according to the actual nature of the contributions made by research participants, then we need to focus on the morally significant factors. In this case, a key morally significant factor is the *contribution* by participants and host nations who bear much of the burden of the research. From my analysis of the available literature, I have concluded that there is injustice in international biomedical research, because these contributions are neither adequately recognised in the distributions of benefits and burdens nor have such contributions been properly recognised in the relevant literature on international research ethics. This is the basis upon which I have developed my research questions.

1.3 The Significance and the Scope of this Research

Claims of injustice in international biomedical (IB) research have appeared forcefully in the relevant literature for different reasons (Macklin, 2004). Existing IP regimes distribute the benefits and burdens of IB research- disproportionately, that is in ways that fail to reflect the significant contributions of various parties. This is not only an

injustice to the host nations of IB research, but it also significantly undermines global health rights, especially in LMIC.

Addressing my research question will be helpful in achieving fairness in IB research and for promoting universal health rights. Existing research in bioethics has produced recommendations that address access to medicines for global health rights, and frameworks that address exploitation in IB research. For example, CIOMS (2002) and others have argued for reasonable access to the fruits of research conducted in developing nations to bring fairness to IB research. However, these existing approaches either overlook the significant role of developing nations in IB research, and/or consider justice as in this context as an expression of compassion. Such an attitude undermines global justice even though respectful relationships are affirmed in United Nations' declarations (<http://www.un.org/en/documents/udhr/>)²⁹

My research in this thesis is based on the hypothesis that *there is injustice in international biomedical research*, and the aims of my research are twofold. First, I will address key questions to help clarify what fairness and injustice in IB research are usually thought to involve. I will examine the present frameworks of justice for the distribution of benefits and burdens to address fairness in IB research and global health rights. I will show that there are gaps in existing frameworks. Whether such gaps, if there are any, can be filled by appealing to the principle of contribution advanced by Locke will be another question for investigation. An answer to these questions will be

²⁹ Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice, and peace in the world.

helpful for developing an ethical framework for IB research that has enormous potential to increase access to medicines, reduce global disparities in the promotion of universal health rights, and to act as a prerequisite for human development and freedom (Sen, 1999, Nussbaum, 2011).

1.4 Justice as Recognition of Contribution: Analytical Framework of the Thesis

In the previous sections, I have indicated that the contributions of IB research participants and host countries is a morally significant factor that plays a key role in the fair distribution of the benefits of the research. In this section, I analyse the meaning of justice to demonstrate how it fits with the thesis aims.

The concept of justice has evolved, and the meaning of the term has been debated, since Plato's *Republic*. For example, *The Making of the TRIPS Agreement- personal insight from Uruguay Round negotiations* recounts how representatives of different nations in the WTO negotiations attempted to argue for some ways in which the TRIPS Agreement could be a fair agreement from their national perspectives³⁰. These representatives mostly tried to explain the meaning of justice by considering the specific context of a real-world problem. Justice researchers, especially global health rights advocates, also explore the meaning of justice by referring to real life cases or by

³⁰ Watal, J & Taubman, A. 2015. *The Making of the TRIPS Agreement- personal insight from Uruguay Round negotiations*, Geneva, World Trade Organization.

introducing thought experiments. From their analyses, the concept of justice has accrued several meanings and so there seems to be no universally accepted definition of justice that can be used as basis of the thesis.

Indeed, the sphere of justice has more recently been extended to non-human species. Such a broad application of justice further complicates the meaning of the term. In this regard, Low and Gleeson³¹ rightly claim that the concept of justice is not only a contested term but is also complex to explain and understand. Philosophers have identified that the concept of justice is linked with human needs, rights, merit, and desert. For example, according to Feinberg³², justice denotes equality, desert, distribution according to merit, contribution, effort, achievement. This term is used to define our relationship with other (human and non-human) entities also. Instead of debating such a broad notion of justice, in this thesis, I will try to define justice in international biomedical research by reference to global health rights.

For example, I will assume that lack of access to medicine is a key impediment to ensuring global health rights in LMIC and poor communities. Since health is a prerequisite for human development, global health rights need proper attention. International health and biomedical research can play a crucial role in addressing global health inequalities and in increasing access to medicine, helping to ensure justice for LMIC and addressing the health needs of the global poor (Commission on Health for

³¹ Low, N & Gleeson, B.1998. *Justice, Society, and Nature- an exploration of political ecology*, p. 29, London, Routledge.

³² Feinberg, J.1973. *Social Philosophy*, New Jersey, Prentice-hall.

Development, 1990). Therefore, equitable distribution of IB research benefits and burdens can be considered as required by fairness and justice.

My argument in this thesis takes a different approach. I argue that the TRIPS³³ Agreement poses a significant threat to global health rights. This agreement obstructs fair access to medicine and health technologies, as they do not acknowledge patent rights for host nations or their contributions to IB research. The TRIPS Agreement, which come into being from the perception that IP should be protected globally within the legal systems of each nation, gives unilateral access to benefits for the sponsoring nations of IB research, while host nations bear a substantial portion of the burdens. Another consequence of the TRIPS Agreement is limited access to essential medicines for poor nations. Such unequal access to IP benefits and limited access to essential medicines for poor nations are arguably an injustice, as every human being has right to healthcare. At least the deleterious effects, as I mentioned above, of the TRIPS Agreement on LMIC is also arguably a violation of global health rights. Therefore, for the governments of these countries, respecting and protecting global health rights require ensuring fair access to essential medicine for their citizens. From this perspective justice also requires the fulfilment of basic human health needs, as this has been enshrined in the Universal Declaration of Human Rights 1948.

United Nations Universal Declarations of Human Rights considered health rights as fundamental human rights. These are inclusive rights that contains freedom and

³³ The Trade-Related Aspects Intellectual Property Rights (TRIPS) remind us Thrasymachus who said justice is the interest of stronger in Plato's *The Republic*.
For further information: https://www.wto.org/english/res_e/publications_e/trips_agree_e.htm

entitlement of “essential medicines” (WHO & UNHCHR, 2008, p.3). Health rights are also interrelated, interdependent and indivisible. Health rights also entail non-discrimination and equal treatment (ibid, p.3). Thus, the violation of such rights is considered an injustice as this may obstruct the enjoyment of other fundamental natural and human rights, such as a right to life, education, work and living dignified life³⁴. According to John Rawls, health rights such as access to essential medicines and technologies for treatments are considered a primary good (See also Ballantyne, 2006). Rawls view of justice, therefore, tell us unequal access to these provisions and lack of protection from violation of these rights are therefore considered injustices. For philosophers such as, Kant, each human being has equal intrinsic worth, and thus has the same claim to fundamental human rights as any other person. When applied to the framework of global health rights, this means that person is entitled to an equal level of access to essential medicines. Therefore, for me, barriers to certain groups of people accessing lifesaving essential medicines or treatment technologies constitute an injustice. From this point of view equality becomes a principle of justice for global health rights that I accept, and am pursuing in this thesis, and it appears that the TRIPS Agreement is a barrier to justice in IB research and global health rights.

Equal access to essential medicine is therefore to be regarded as a part of global health rights, and the non-recognition of such rights is a violation of the equality principle of justice. However, equal treatment in the distribution of IP rights may still be unjust, in the

³⁴ World Health Organization and Office of the United Nations High Commissioner for Human Rights (2008), *The Right to Health, Fact Sheet No. 31*, pp. 1-45. <https://www.who.int/gender-equity-rights/knowledge/right-to-health-factsheet/en/02/12/2019>.

same way that giving equal money to a family comprising 6 members and a member family comprising a single member is unjust (Feinberg, 1973). The needs of six people are more than that of a single person, and this must be considered if the distribution of resources is to be just. In this regard, philosophers often argue for distributing benefits according to each person's contribution or their need. Likewise, the benefits of IB research should be distributed according to contribution and need. For example, the sponsoring nation/s of an international clinical trial may invest 60 percent of the total cost, while the host nation bears the remaining costs of conducting the trial. In this case, justice arguably requires that the host nation should get 40 percent of the benefits while the sponsoring nation gets 60 percent of the benefit. In such case, equal treatment, where each party receives 50 percent of the benefits, may be considered a violation of rights. Thus, applying this concept of justice can result in unequal distribution in the context of contribution.

For this thesis, I have adopted the meaning of justice as giving 'due return' for contribution, whoever contributes to which ever amount in whichever way (intellectual, labour, funds etc.) should be recognized in the distribution of the derived benefit³⁵. The

³⁵ This view has great similarity with French Political Philosopher Pierre-Joseph Proudhon who argued that "property is theft" in his famous book *What Is Property? An Inquiry into the Principle of Right and of Government published in 1840*. I am not saying that property is theft but arguing to reconsider conventional benefit-sharing model of collaborative creation. I am also arguing for equitable distribution of the benefits and burdens. Here I would also like to give some credit to Nozick who argued for fairness in acquisition, transfer, and compensation. I also disagree with Marx that people should enjoy according to their needs. Rather, I agree with Risse (2012, p.111) that ("The core idea of common ownership is that all co-owners ought to have an equal opportunity to satisfy basic needs to the extent that this turns on obtaining collectively owned resources.") each person have right to access essential medicines as this is related to their basic needs. However, I am not considering his theory of collective ownership as the ground of justice although I argue for IP rights of all parties involved in the clinical research process.

governments of developing nations, for example via the International Centre for Diarrhoeal Disease Research in Bangladesh (ICDDR,B), provide opportunities for HICs' pharmaceutical industries and researchers to conduct clinical trials. The governments of developing nations, in this case Bangladesh, as the host nation invest a lot to organize human resources, and to conduct the trial with high levels of precision. In the process, the host nations provide available infrastructure for the development of the drug or for final approval of the technology. The types of contributions made by host nations are discussed in detail in chapter three. I argue that many of the contributions of host nations to IB research are such that it is unjust for host nations to be denied access to medicines and technologies that they have helped to develop, while sponsoring nations who collaborated with the host nations enjoy the benefits of these medicines and technologies. In this regard, I am not arguing for an equal share of benefits to be allocated to each contributor, or for involving every participant in decision-making processes (though these might sometimes turn out to be justified in certain circumstances). Rather, I argue that a proportionate distribution of benefits (i.e. proportionate to each party's contribution) is fairer, and that it is justifiable for the governments and people of host nations to jointly negotiate protocols for fairness in the

For Proudhon, "The results of the labor performed by this generation are ...products are the legitimate property of those who have created them by their activity.... Second class. —Not only has this generation created the products just mentioned (objects of consumption and instruments of labor), but it has also added to the original value of the soil by cultivation, by the erection of buildings, by all the labor producing permanent results, which it has performed. This additional value evidently constitutes a product—a value created by the activity of the first generation; and if, BY ANY MEANS WHATEVER, the ownership of this value be distributed among the members of society equitably, —that is, in proportion to the labor which each has performed, —each will legitimately possess the portion which he receives. He may then dispose of this legitimate and private property as he sees fit, —exchange it, give it away, or transfer it; and no other individual, or collection of other individuals, —that is, society, —can lay any claim to these values." http://www.gutenberg.org/files/360/360-h/360-h.htm#link2H_4_0013) See also, The General Idea of Proudhon's Revolution, <https://theanarchistlibrary.org/library/robert-graham-the-general-idea-of-proudhon-s-revolution>

distribution of benefits, as well as for fair monitoring of the clinical trial process. Fairness requires the recognition of host nations' contributions, and the provision of due return for each party's contribution. Each of these may be considered to be aspects of justice.

In the context of international collaborative clinical research, patent and data exclusivity for a certain limited period is a possible derived benefit from a successful trial, whereas direction for the further development of generalizable knowledge is a possible benefit from an unsuccessful trial. The contribution of host nations of clinical trials as collaborative partners in generating these benefits should be documented and sharing patent rights with them is an intellectually plausible and in-principle ethically justifiable option for promoting justice in IB research. If sponsoring nations can enjoy the benefits of patent and data exclusivity, then host nations also have a reasonable claim to similar benefits, given the nature of the contributions that they have made. These contributions can take many forms. A developing nation may not have significant research capacity, but their researchers might work in a high-income country and can contribute to a drug development research project. Similarly, a developing nation may not have the industrial capacity to produce a drug, but they can facilitate the clinical trials of wealthier nations.

IB research is a complex process that contributes in various ways to closing gaps in public health. This means that problems of distribution and the protection of various types of rights cannot be addressed by a single notion of justice. A complex framework

is required to achieve fairness in IB research and global health rights, one that draws on different concepts of justice.

As I mentioned above, justice is a “complex and contested term”, and so it needs to be contextualized for this thesis. IB research is a dynamic field, and I will argue that acknowledgement of the abovementioned contributions is a possible way to bring fairness to the distribution of benefits derived from internationally sponsored collaborative clinical research. However, delivering justice in IB research seems to require more than following procedural justice principles- that is, justice also requires following a fair process. Justice here requires focusing on the equitable distribution of the research outcome, which means designing substantive distributive justice principles for this context. Developing mutually respectful collaborative partnerships between the sponsors and the host nations of clinical trials should also be considered an integral part of this process. In this regard, interactional justice- at interactions between involved parties are transparent and based on mutual intercultural respect can also play a significant role in IB research.

The complex nature of IB research and its stringent nexus with global health rights suggests that a pluralistic³⁶ notion of justice would be the most useful here. Procedural

³⁶ There is view of expressed by Michael Walzer in his book *Spheres of Justice: A Defense of Pluralism and Equality* in 1983. In this book Walzer claimed that in different societies different goods are distributed in different ways. Secondly, meanings of justice are “embedded and embodied in societies (Williams, 1996).”

[Reviewed Work: *Pluralism, Justice, and Equality*. by David Miller, Michael Walzer Review by Williams, M.1996. *The Journal of Politics*, Vol. 58, No. 3, pp. 897-900].” This implies that meanings of justice are socially constructed. Thus, there are many principles of justice in different political culture.

justice is essential for IB research to protect research participants from harm, as it ensures that the formal structure of the process is fair- for example that informed consent is required, and that no particular group of people, or nation, is excluded without giving justification. Ethics approval of research protocols by an institutional ethics review board run by an independent committee is another important safeguard to protect research participants from harm. Furthermore, distributive justice is necessary to ensure that the outcome of the research is distributed fairly and equitably, and interactional justice will be useful for dealing with intercultural issues, respect, and possible social sensitivity issues that arise when parties interact with each other. Taken together, this combination of theories certainly entails going beyond the conventional procedure of justice in practice and blending the best ingredients of justice.

The advancement of global health rights may require more than the acknowledgement of contributions to IB research. Here we might turn to Rawls (1971), who argued for his influential “difference principle”, which holds that the greatest priority should be given to the most disadvantaged people. That is, according to Rawls, “social and economic inequalities are to be arranged so that they are both: (a) to the greatest benefit of the least advantaged, consistent with the just savings principle, (Rawls, 1971, p.302)”. This approach might in the context of IB research be taken to suggest that the developing nations who host IB research, being more disadvantaged than the sponsor countries, are entitled to a greater share of the benefits of that research than would be justified by the level of their contribution alone. Some followers of the Rawlsian approach argue that it should be applied at global level, although in his book *A Theory of Justice* Rawls did

not apply it to this context himself. Advocates of global justice in IB research have struggled to expand Rawls' framework of justice from the local level to a global level by giving additional benefits to host nations, without properly acknowledging the contribution of these nations. Nevertheless, redistributing such additional benefits is taken to be justified in many cases by appealing to historical injustice, considering the global nature of diseases (Macklin, 2004, pp.81-82; Selgelid, 2008).

As a preliminary demonstration of this point, let us imagine A and B are two nations which seek to conduct a clinical trial for drug X. Suppose that A is a developed nation like the USA and B is a developing nation consisting mostly of Muslim people. Both nations have distinct cultural heritages and ways of life. The trial involves the participation of women, and the observation of any skin colour changes before and after drug X is used. The participating women are required to show their arms for this observation³⁷. However, this is against Islamic tradition and culture. The concept of interactional justice suggests that, in this case, the researchers should value the Muslim cultural setting and so employ women personnel to observe arms of the participants. Another factor to consider is that the participating country B has a distinct financial system. Instead of receiving benefits in the form of money, participants may be able to accept only goods. Participants may also need breaks for their prayer time. Lastly, participants may not be interested in taking benefits individually, and might prefer to choose benefits for their community. These indicate that several principles are to be

³⁷ Hussain-Gambles M¹.2004. "South Asian patients' views and experiences of clinical trial participation" *Fam Pract.* 2004 Dec;21(6):636-42. <https://www.ncbi.nlm.nih.gov/pubmed/15528290>

considered as bases of decision making and require utilization of different notion of justice in each case. This gives us an impression that the concept of justice is truly a complex term and is contested in every society.

A widely accepted principle of justice requires that contributors receive their 'due return' from what they have produced collaboratively, by adding their labour (Proudhon, 1840). 'Due return' can be interpreted in two possible ways. Firstly, it can be based on Proudhon's idea of equity, mutual respect, and reciprocity, where contributors develop a partnership to accomplish something collaboratively and the derived benefit of this collaboration will be distributed proportionately/equitably among stakeholders. Respecting the opinions of all stakeholders (sometimes known as a 'bottom up approach') involves sharing not only legal obligations but also moral obligations, despite power differences in society, and this requires mutual respect and mutual understanding of each other's worldviews.

The second way to interpret the notion of 'due return' is where collaborators will work for an entrepreneur and receive wages for their labour, while the outcome of their labour belongs to the entrepreneur. This approach is supported by the idea that not only labour but also capital plays a crucial role in producing wealth. An entrepreneur may provide capital for research, or fund new marketing strategies for the product, thus increasing profits or funding an ingenious idea of a new technology.

However, this second interpretation of due return might be thought unjust, as it allows one party to exploit the labour of others to receive a greater share of benefits, depriving those who contributed to the development of the product or bore various types of burdens in the development process. In response it may be argued that receiving a greater share is not unjust so long as this is a result of a prior agreement between the involved parties, and that this agreement was entered into through the autonomous choices of all involved. This might be thought to apply even in cases where, following the agreement, one party believes or finds that he has been taken advantage of, or has signed a deal which has placed him in a disadvantageous position.

In the second interpretation, the positive law³⁸ seems to have been taken as authoritative, and therefore, whatever the distribution is- i.e., proportionate or disproportionate should not be considered as an injustice. This is a somewhat Hobbesian view, as Hobbes thought that “No law can be unjust” (quoted in Bedau, 1971, P.9). From this perspective, the TRIPS Agreement would also likely be regarded as justified insofar as they were developed through proper processes as developed nations wish to incentivize the inventors of new drug or technologies for their labour and enable them to enjoy the fruits of their labour globally. However, as we will see, the justifiability of this agreement is questionable (see chapter 6).

³⁸ Positive law is considered as command and no distinction cannot be made between law and justice. This implies that law cannot be evaluated by moral values as morality is subjective. Law is either effective or ineffective. For example, the TRIPS is a binding treaty for all nations who signed the document. Through a series of meeting from various interest groups, the TRIPS Agreement is passed. This treaty cannot be evaluated from a moral point of view of a nation. The positive law theorists argue that examining law from a moral perspective is subjective. For them, the TRIPS Agreement is reached through consensus. This is adequate to provide moral ground of a law. This leaves open the door of irrationalism. Any unjust law can be imposed anywhere in the world and people like Socrates is bound to obey.

For me, the above second interpretation of 'due return' raises an important moral question of fairness. The second interpretation diminishes the worth of the individual and undermines the dignity of a person, as this allows a person to be used as a mere means of production only. To support my above claim, I would like to draw from Kant's moral philosophy. According to Kant, no person can be used as a mere means to an end, as this would violate human dignity, for Kant human worth. Kant's view has reappeared in Allen Wood (1995, pp.150-151), who argued that "Proper respect for others is violated when we treat their vulnerabilities as opportunities to advance our own interests or projects. It is degrading to have your weakness taken advantage of and dishonorable to use the weakness of others for your own ends." Dave Wendler (2000, p.312) also noted that "... all research subjects face some risk of exploitation. They face the possibility that researchers may regard them purely as a means to benefit society..." I think most of us will agree with the moral principle of Kant and it can be taken as providing a defensible basis of my thesis statement, i.e., that the present IP system is morally unjust, and an inclusive notion of contribution is essential for fairness in the distribution of IB research and fair access to medicine. The circumstances under which an individual agrees to take part in IB research may lead a person to believe that he/she is under compulsion or has some form of obligation to accept an unfair deal. While apparently giving autonomous consent to the venture, he/she may lack the options required to freely make this choice. Similarly, a nation may desperately admit a trial under duress. Indeed, there is evidence that the TRIPS Agreement was signed by low

and middle-income countries under duress³⁹ (as discussed in chapter 6). For Gerhart (2000, p.358) “TRIPS is the first of the WTO treaty obligations that imposes wholly positive obligations on states.”

Therefore, in this research, I propose a moral principle of justice by focusing my attention on global health rights protection, examining the relationship between global health rights and the TRIPS Agreement, and establishing a nexus between global health rights and IB research. Finally, I use Locke’s theory of contribution, which emphasizes how an individual can add labour and value, as the foundation of my justice theory in this context. I also appeal to John Rawls’ liberal theory of justice, and I examine Nozick’s critique of this theory. In some cases, I also base my thesis statements on Nussbaum’s capability theory of justice⁴⁰ for human dignity. Thus, not only human needs, or rights, but also dignity appears as a basis of justice here.

I will argue that lack of access to health care, such as lack of access to essential medicines, is a kind of injustice. Therefore, global health rights imply a positive role for the governments in facilitating access to essential medicines as an aspect of justice;

³⁹ See Sell, S.K.1995.Intellectual property protection and antitrust in the developing world: crisis, coercion, and choice, *International Organization*,49(2), pp.315-49.

⁴⁰ In an article “Capability Approach to Justice as a Virtue” published in *Ethical theory and Moral Practice*, Volume 15, Issue 1, PP. 23-38, Jay Drydyk explored six dimensions of Amartya Sen’s idea of justice. For Drydyk, “six dimensions of acting justly are identified: (1) reducing capability shortfalls; (2) expanding capabilities for all; (3) saving the worst-off as a first step towards their full participation in economy and society, (4) which is also to be promoted by a system of entitlements protecting all from social exclusion; while (5) supporting the empowerment of those whose capabilities are to expand; and (6) respecting ethical values and legitimate procedures (Drydyk, 2012,p.23).” In my thesis, I used these ideas referring Alex London and Martha Nussbaum.

failure to do so yields injustices. Global health rights likewise implicate global institutions to, at the very least, not obstruct access to essential medicines.

As I argued above, the TRIPS Agreement invariably obstructs access to medicines for citizens of developing nations. On the other hand, IB research increases access to medicines for poor and makes immeasurable positive impacts in the realisation of global health rights. For example, some communities lacking health care facilities gain access to these through IB research; participants may be provided with free health check-ups and care and gain access to investigational drugs. But recognition of the contribution of host nations will lead to fairer distribution of the benefits of IB research, which could increase the capabilities of these nations and create more opportunities for state organizations to further global health rights. Thus, I argue that application of an inclusive notion of Locke's labour theory can reduce and redress the suffering of the global poor and can dispense justice in the distribution of benefits and burdens of IB research.

1.5 Outline of the Thesis Chapters

In this chapter, in the above four sections, I presented an exposition of the problems of Justice in IB research and attempted to establish a link between IB research and access to medicines for global health rights.

In chapter two, I discuss different conceptions of intellectual property (IP) rights and their moral implications for IB research. While many drugs and medical technologies are the products of international collaborative research, the conferral of IP rights (i.e. patent rights) only to sponsors, researchers, or pharmaceutical companies in recognition of their contribution to the development of innovative products is left unquestioned by researchers, bioethicists, and others. Does the accepted meaning and application of IP rights by global and national institutions provide a morally justifiable foundation for the fair distribution of the benefits and burdens of human research? Chapter two will explore concepts of rights, property rights and intellectual property rights to identify the moral foundation of IP rights. I will focus on John Locke's labour theory of property rights, and Robert Nozick's theory of just acquisition. The claim that adding labour can also be adding value is crucial to both these theories of property rights, and also for the development of my argument that pharmaceutical IP rights should be shared with the host nations of clinical trials based on the inclusive contribution principle.

In chapter three, I attempt to identify in more detail the contributors to IB research and I discuss how their contributions can influence the outcome of the research. The current research and development (R&D) process yields a net benefit to sponsors but not to the host nation, which not only contributes to the research but also typically bears enormous burdens. This situation lacks moral justification and should be considered a global injustice to host nations. The critical question, therefore, is why sponsors from wealthy nations are commonly thought to have no moral obligations to share patent rights with host nations? This chapter will explore the *intellectual* contributions of

research participants, local medical personnel, as well as the *financial, bio resources* sharing and other contributions made by the host nations to IB research. I will argue that it is unjust for these contributions not to be acknowledged in the distribution of the benefits of the research. The acknowledgement of all contributions will pave the way for greater fairness in IB research.

In chapter four, I present a critique of existing benefit sharing models as a part of a justification of my proposed model (I also offer a reply to critics of my proposal in chapter 8, who question why participants should be given IP rights if they could negotiate a benefit sharing protocol other than IP). It seems to me that despite having certain merits, the moral principles that justify the existing benefit sharing models have serious flaws. In general, the official models of global health concerns and researchers' responses to these overlook some key moral rights of developing nations. The benefit sharing models proposed thus far are based on compassion, and focus on global wealth and disparities. The proponents of benefit sharing models overlook some key moral obligations of developed nations as informed citizens. An informed person has an additional responsibility to share the benefits of social goods, in this case the benefits of collaborative biomedical research, to achieve fairness in IB research. The conferral of IP rights to IB research participants should be seen as a recognition of the moral rights of these participants, and carrying this out is a prime responsibility of informed people. In chapter four, I clarify the meaning of the term 'benefit-sharing' and I then critique the reasonable availability and fair benefit approaches to benefit sharing based on reciprocity principles of justice.

In chapter five, I argue that the influential human development (HD) approach advanced by Alex London and others is inadequate to achieve fairness in IB research and global health rights. For London, broader issues of social justice are centrally linked to the health needs of a particular community. Thus, we are required to adopt a broader view of justice in the distribution of benefits and burdens of IB research. I argue that the HD approach correctly acknowledges that both the existing asymmetries of power (Pogge, 2008, p.16) and the economic conditions between developed and developing nations need to be addressed, when developing a justice framework for benefit sharing in IB research. Thus, by considering and taking account of existing asymmetries of power and economic conditions between developed and developing nations, the HD framework recommends meaningful public participation so that host nations' participants can argue their case. However, the relative lack of negotiation capabilities in developing nations remains a key barrier to this process, and this has not been addressed by existing models.

Therefore, in chapter six, I discuss increasing the negotiation capabilities of host nations to promote the fair distribution of the benefits of IB research through sharing patent rights⁴¹. I will argue that the ability to negotiate a fair distribution of the benefits of international biomedical research is a key capability to achieving global justice in health.

⁴¹ In order to do so it also requires collaborative partnership this can enhance mutual respect for each other and sharing the post-trial benefits (London, 2010). Gradually, they (host community) will be dignified and become aware of injustice and build capacities for bargaining potential against any potential injustice and exploitation.

The aim of this chapter is to argue for creating capabilities of host communities by providing fair access to justice, information, and involvement in the decision-making process. I demonstrate how the lack of various capabilities of host nations can be addressed through benefit sharing and respecting participants' contributions.

To redress and remedy past injustices, the global poor should receive additional protection irrespective of their colour, nationality, and race. Research should be carried out to address the neglected diseases of poor nations. In addition, developing nations lack various capabilities. Their lack of negotiation capabilities should be addressed, and procedural fairness should be exercised in international negotiation. There should also be scope to empower poor nations' negotiation representatives. People of the world expect a global framework, which must be responsive to global health rights and in no way undermine human dignity in decision-making and practice.

In chapter seven, I argue that the development of a global framework for global health rights requires the recognition of the key roles, trust and power play in negotiation, and therefore justice in IB research. Abuse of trust, and power imbalance, serve to influence negotiation, and affect respect for protocol and agreements. The TRIPS Agreement is an unjust global framework of IP distribution and protection organized by the WTO, as this agreement is a product of exploitation, the abuse of trust, and power. The WHO's IHR 2005 (originally adopted 25 July, 1969 in twenty second (22) World Health Assembly) is another framework ostensibly aimed at promoting global health rights, but it is wrongly exploited by developed nations. Therefore, I present two cases: H1N1 virus

sharing and the TRIPS, in chapter seven to facilitate the discussion of injustice in global health.

In chapter eight, the possible strengths and criticisms of my proposed contribution model of benefit sharing are discussed. For example, Resnik (2003) argues that the contribution theory of Locke fails to reward other contributions, as rewards go to the first inventor. If two people invent something, only the first will receive the IP rights regardless of whether another person has added value, or how much labour or contribution they have added. In response however, I argue that awarding IP rights only to the first inventor helps to avoid repetitive research and encourages researchers to further innovation. I will also examine other models of the attribution of IP rights based on a utilitarian calculus. Finally, I will discuss how to address implementation and monitoring problems with contribution models.

In this thesis, I argue that the lack of a fair benefit-sharing framework based on an impartial principle of justice at global level is a barrier for fair access to medicines and paves the way for exploitation and injustice. I explore the steps necessary to prevent injustices like the exploitation of trust and abuse of the vulnerability of developing nations' clinical trial participants, and the reasons for neglecting diseases of LMIC countries by IB researchers that afflict developing nations health and wellbeing while the health problems of rich countries are given priority. I also look at the need to overcome the lack of access to information in the process of negotiation, and to create capabilities for overcoming developing nations' lack of bargaining potential. Finally, presenting a summary of all the chapters, I reaffirm the recommendation that the introduction of an IP

distribution principle of justice based on recognition of the contributions of involved parties, will help to achieve justice in IB research and global health rights.

Chapter Two

A Lockean Theory of Intellectual Property (IP) Rights and Moral Implications for International Biomedical (IB) Research

2.1 Introduction

In the first chapter, I explained that access to medicine is important for global health rights. IB research, in this regard, is a viable option to increase access to medicine and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is a potential barrier to achieve global health rights. In both cases, the meaning of the term “intellectual property rights” plays a principal role. Therefore, in this chapter, I focus on the question of whether the meaning of intellectual property rights currently accepted by global and national institutions provides a fair foundation to distribute benefits and burdens proportionately among the contributors to IB research.

Current use of the term “IP rights”, as I argue below, raises a serious question of fairness. The affirmation and authorisation of the term in the present frameworks of IP rights, in the first place, fail sufficiently to protect the health rights of the poor people of the globe. The meaning of IP rights currently adopted in international law-making systems promotes injustice as it paves the way for unjust distributions of intellectual property (hereafter IP) rights and economic benefits among high income countries (hereafter referred to as developed nations) and low and middle-income countries (hereafter referred to as developing nations). As a result, the poor of the developing

countries, who live in high-risk societies (Beck, 1992) and suffer from various diseases remain exposed to various types of health risks. In some cases, they are further marginalized and forced to bear the burdens of diseases and drug development processes disproportionately.

Ang (2014) argues that IP rights generally would be morally justified if such rights are regarded in conjunction with a duty to share resources specifically with the people who provide the labour. But although people in poor developing nations contribute their labour to the research and development of medicine and medical technologies, IP rights as they are expressed through Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) ultimately impose barriers to the “accessibility and availability” of medicine in the poor developing nations (Schroeder & Singer, 2009). The current IP rights regime therefore forces the people of developing nations, who are historically marginalized, to bear unjust health burdens, increasing their vulnerability and poor quality of life.

Second, many of the biomedical research projects that are carried out in collaboration with developing nations focus on diseases that predominantly affect the health of people in developed nations, rather than the diseases that affect the nations where the research is carried out (Pogge, 2008). The results of such research ultimately return higher benefits to the economies of developed nations than to the developing nations that collaborate in it. For example, the oral saline that is used to prevent and cure diarrhoea caused by rotavirus is the product of research carried out in Bangladesh (and in what was previously called East Pakistan) by international researchers with the

assistance of the Bangladeshi government and Bangladeshi researchers (Ruxin, 1994). The International Centre for Diarrhoeal Disease Research Bangladesh (ICDDR, previously known as Pakistan-SEATO Cholera Research Laboratory), a multinational research centre, conducted this research during the 1970s, and it has since saved millions of lives globally (https://www.who.int/gho/epidemic_diseases/cholera/cases_text/en/10/05/2015⁴²). The initial protocol (therapy) was developed by a Bangladeshi doctor. The second successful protocol was devised by an American researcher (Ruxin, 1994). Later, this oral solution was patented in the USA. Recently, the US drug company earned a huge amount of money from selling the oral solution to the US army deployed in the Middle East. However, no benefits are given to the Bangladeshi people who contributed to the clinical trials that produced these treatments. As a result, the people of Bangladesh are still exposed to various types of diseases that prevent them from living a healthy happy life.

Given this historical background of injustices in low and middle-income countries, in this thesis I aim to elucidate various types of global health related injustices and advance arguments for fairness in global health systems to promote and protect universal health rights. So, in the following sections of this chapter, I argue that the theory of intellectual property rights currently accepted by global and national institutions based on John Locke's classical labour theory provides a generally fair foundation to distribute benefits and burdens proportionately among the contributors to IB research. More specifically, my argument is that greater recognition of developing nations' contribution to IB

⁴² According to this estimate about 4 million people were affected by cholera in 2015 and 30-142 thousand people died. https://www.who.int/gho/epidemic_diseases/cholera/cases_text/en/10/05/2015

research within the IP rights frameworks will bring more fairness in distribution and will increase access to medicine for the poor. By meeting the health needs and protecting universal health rights of people in developing nations, this recognition will further contribute to these nations' economies and will allow them to carry out health research to address the neglected diseases that disproportionately affect their people.

Justice in international biomedical research is taken to imply fairness in the process of research, fair treatment of research participants, proper acknowledgement of contributions of all involved parties, and fair distribution of benefits and burdens that are generated from a research project. Therefore, to ensure fairness and justice in IB research, bioethicists have suggested different principles and methods of interventions for benefits sharing. They have also tried to devise governance frameworks to preserve the ethical integrity of the process. Policies that focus only on informed consent are a poor fit for IB research, as poor and vulnerable research participants people often lack the capacity to negotiate a research protocol or articulate the ethical dilemma that emerges from the application of conflicting human rights i.e., intellectual property rights and health rights. These governance frameworks also attempted to address different exploitation concerns using classical ethical principles (Macklin, 2004). However, the contribution of participants in IB research has been ignored by ethicists. As a result of this, the benefits and burdens of IB research are distributed unjustly.

Recently, a group of researchers, under the leadership of Pogge (2010 in Selgelid & Pogge, 2010) attempted to find ways to ensure fair access to medicine through the

Health Impact Fund (HIF). The HIF is a compensation model that considers global poverty as a contributing factor to lack of accessibility and affordability of essential medicines (Liddell, 2010), but which otherwise work within the current regime of patent and intellectual property rights. By contrast, Singer & Schroeder (2008) suggest reforming the existing IP rights model, however, they acknowledge the win-win benefits of HIF since it addresses both *accessibility* and *availability* problems of medicine (Selgelid, 2006).

One of the common concerns of these researchers is that access to medicine for all should be considered as a basic universal human right. This right imposes a duty on developed nations to contribute to increasing access to medicine for developing nations. However, it also ensures that IP rights are kept almost intact, as this (i.e., keeping IP rights almost intact) has consequential benefits for the alleviation of poverty and access to medicine that affect the health of the poor (Singer & Schroeder, 2008, 2009). But these researchers overlook the crucial contributions of host nations and participants in IB research, which ultimately pave the way for huge profits for the sponsoring nations and pharmaceutical companies. As a result, these researchers fail to address the question of whether it is appropriate for IP rights and patent rights to a drug or technology that is a product of collaborative research to be conferred solely to the sponsoring nations or companies. In this thesis, therefore, I focus on issues of fair recognition of the host nation's contribution based on the process of IB research that ultimately unjustly distributes benefits and burdens among developed and developing nations.

Some researchers have identified the lack of bargaining potential of developing nations as one of the key factors of such inequitable distribution of benefits (Ballantyne, 2006). There are suggestions that access to fruits of the research, for example, via a price differentiating mechanism (CIOMS, 2002), could be applied as developing nations are incapable of paying full price for drugs or technologies for meeting their health needs. There are also arguments that research community should be responsive to the host nations' health needs and rights (London, 2005), and that an infrastructure charge can be provided for capacity building (Ballantyne, 2006) to balance the burdens and benefits of IB research. Most of these suggestions have been put forward to redress various claims of injustice, and in particular to address charges of exploitation which it is claimed create barriers to meeting the health needs of developing nations and to the promotion of the rights to health. However, the conferral of IP rights to the proposed researchers for the recognition of contribution to innovation has been left unquestioned. If we are serious about overcoming exploitation and meeting the health needs of developing nations, we should explore the processes of IB research and the conferral of the resulting IP rights to ensure that all contributors involved in the research share its benefits justly.

Many researchers have argued, for example, against the conferral of patent rights to pharmaceutical companies, as this might be a potential source of exploitation and an important factor of injustice. By contrast, instead of arguing against patenting itself, I will argue that an IP rights process that fairly acknowledges developing nations'

contributions to research would not only provide economic benefits but would also help to ensure access to medicine for the global poor. This acknowledgement could also create the ground for negotiating a fair patent rights treaty, and would empower developing nations to make the health care services more affordable without compromising incentives for innovation. For this reason, I argue that fair recognition of contribution of the developing nations through IP rights should be a basic principle of justice in IB research and the TRIPS Agreement. If IP rights are based on a flawed conception of contribution and a defective principle of acquisition, then they may become a source of injustice and a barrier to achieving global health rights. Therefore, to achieve fairness in the distribution of the benefits of IB research, intellectual property rights should address a principle of justice of acquisition based on liberty and contribution, as has been advanced by Locke and his advocates. The following section examines what is generally meant by the IP rights, especially in the context of biomedical research.

2.2 What are Intellectual Property (IP) Rights?

The argument in this chapter differs from past researchers by suggesting that giving royalties and sharing IP rights is the first step in ensuring fairness in the distribution of benefits and burdens of IB research. The IP rights which I am supporting for recognition are a modern extension of conventional property rights and have four elements: contribution, rights, property and intellect. Defining IP rights requires specifying the

meanings of these elementary concepts. Therefore, next section of this chapter explores these core concepts in detail.

(a) Meanings of Rights

From ancient times⁴³ (quoted in Sen, 1999 [3rd century B.C period of emperor Ashoka.]) to contemporary socio-political discussions, rights have been considered a basis of justice and a means of assessing claims of injustice. Both in national dialogues and international debates political leaders, scientists, philosophers and civil societies attempt to define rights to justify their arguments for and against claims of injustice.

In the international political spheres, the notion of rights is considered universal in UNs character (UN, 1948) and is called on when framing conventions and treaties. In philosophical discussions as well as economic policy-making processes, rights are regarded as key instruments for developing arguments. Like other international organizations, the World Trade Organization (WTO) has adopted rights as the foundations of trade agreements, in the same spirit as nation states have adopted rights as principles of their constitutions and foundations of their laws.

In every human society, the notion of rights is used by common people to frame injustice. For many, injustice implies violation of human rights. In the 17th century, the

⁴³ Plato raised the issue of private property rights and argued for community ownership of property in his *The Republic*. So, a discussion on rights of private property originates in ancient time. In Republic Plato notes that one of the participants in his dialogue named Shiphalas owns huge property. He also described the benefits of property. So, I assume that the rights of property are considered a topic of discussion in ancient time.

meanings of the term 'right' have been regarded as a physical power for action based on natural rights first, from the use of the term by Thomas Hobbes (Wolf, 2006, p.17) and Benedict Spinoza (Martin, 2013). The concept of 'right' is further interpreted and conceptualized in 1690 by John Locke in his *Two Treatises of Government*, whereby rights are not only the rights holder's privilege but also oblige others to respect these privileges. A review of rights literature indicates that most influential political philosophers adopted John Locke's notion of natural rights as a foundation to define all other human rights (Locke, [1689] 1988, Gewirth, 1982, Waldron, 2007, p. 745, UDHR, 1948, UN Charter, 1945, International Bill of Rights, Nozick, 1974, pp. 28-51, Raz, 1986, Alston, 1987, Glendon, 1991). There are also non-philosophical meanings of the term rights. When people say that they have the rights to express their feelings without any restrictions is one example of non-philosophical use of the term.

In recent time, as a successor to Locke's theory of property rights, Robert Nozick has specified the nature, meaning, force and power and dimensions of rights from a libertarian perspective through his expositions in *Anarchy, State, and Utopia* (1974). Beside rights as civil liberties, he also based his theory of justice on the notion of rights since rights can be taken to justify natural acquisition, the transfer of non-human worldly things, and claims of compensation for historical injustice (Nozick, 1974).

John Rawls has advocated an egalitarian notion of human rights as a basis for a flourishing human life (1971). Rawls' first principles of justice articulates equality as a

core value. This has been used to support the intellectual property rights of individual researchers whereas the second principle of justice, which is known as the difference principle, has been thought to provide moral grounds for benefit sharing for disadvantaged people and reasons for global justice (ibid, 1971, Resnik, 2003). The second principle is also used to address the health needs of the poor (Ballantyne, 2006). However, neither Rawls nor his followers have observed subtle steps and contributions of different participants as well as the collaborative nature of IB research.

Amartya Sen has further extended the concept of rights, linking rights to development with freedom and capabilities (1999). Sen argues that it is a violation of human freedom if rights of access to information for one's livelihood is obstructed. Such an obstruction violates the right to life. In this respect, barriers imposed by IP rights regimes can be demonstrated as violation of human rights (this will be discussed later). In addition to these theories of rights, a non-philosophical notion is also advanced in many cultures by basing rights on religious texts. However, this is beyond the scope of this thesis.

Theorists explain rights by analysing their elements⁴⁴, functions and explaining the justification or grounds on which rights rest (Becker, 1977, Waldron, 2007 Martin, 2013).

The concept of 'rights' implies a form of power or strength of doing something – in Sen's

⁴⁴ Becker argues that there are ten elements of a right. Among them, who owns the right depends on the following three of those elements. First, it is required specifying the general nature of the relation between right-holder and right-regarder. The specification of the act, forbearance, status, or benefit owed to or possessed by the right-holder is the second element of right. And, the third element is the specification of the conditions under which a right-claim may be said to be sound (Becker, 1977, p.10).

term, *capabilities* (Sen, 1999, Nussbaum, 2003). This also implies a justification of action and gives a normative direction of conduct to a second party (Martin, 2013, p.2). The concept of rights also encompasses someone's power to redress and remedy some injustices that occur at local, national, and global levels.

According to Feinberg, rights are generally considered to be morally justified claims (Feinberg, 1980, 155). On the other hand, Becker argues that a "right" 'is "the existence of a state of affairs in which one person (the right holder) has a claim on an act or forbearance from another person (the duty-bearer) in the sense that, should the claim be exercised or in force, and the act or forbearance not be done, it would be justifiable, other things being equal, to use coercive measures to extract either the performance required or compensation in lieu of that performance (Becker, 1977,p.8)". Martin (2013) advocates a correlation thesis based on a historical development of the notion rights. His analysis is based on Locke's tradition and draws arguments from recent theories of rights. For Martin, rights are justified valid claims that also ascribe responsibility to others to comply with (Martin, 2013). For instance, patent rights legalize pharmaceutical companies to extract benefits according to their wishes and share royalties with innovators. On the other hand, such legal authorization in turn impose responsibilities to others, i.e., member nations of the WTO /signatories of the TRIPS Agreement to follow/comply with the TRIPS Agreement even though their people may be in desperate in need of access to affordable medicines (i.e. developing nations). Rights essentially imply a duty to others, and so it is argued by Wenar (2015) that global health rights mean it is the duty of researchers and pharmaceutical companies to consider the health

needs of the poor (O'Neil⁴⁵, 2005, pp.427-439). It can also be argued that it is a violation of rights if the global community undermines the health needs of poor nations.

Feinberg (1980) defines rights as *entitlements* based on Locke's natural rights theory (as discussed below). This also echoes Nozick's idea of rights. For example, Feinberg states, "All rights seem to merge entitlements to do, have, omit, or be something with *claims against* others to act or refrain from acting in certain ways (p. 155)." For him there are some governing rules and moral principles that concur with a claim which is a person's right. The concurrence of governing rules and moral principles makes the claim plausible and permit someone to act in a certain way. If rights are regarded as entitlements, then my argument can be expressed as holding that poor nations are entitled and justified to claim that IB research benefits should be distributed fairly considering their contributions.

Furthermore, Feinberg (1973, p.56) notes that legal professionals and academics apply the notion of right in what he calls a strict and narrow sense which is different from privileges and licenses. The strict and narrow conception of rights is defined as a claim-right: "A claim-right is such that it can be urged, pressed, or rightly demanded against other persons. In appropriate circumstances the "right-holder can urgently, peremptorily, or insistently" call for his rights, or assert them authoritatively, confidently, unabashedly

⁴⁵ O'Neill, Onora.2005. The Dark Side of Human Rights, *International Affairs* (Royal Institute of International Affairs, Vol. 81, No. 2, pp. 427-439

(Feinberg, 1973, p.58).” Claim rights can be strongly justified by legal rules or institutions for implementation. On the other hand, claim rights on something can also be morally justified by moral principles and therefore the claim-rights they justify, do not always rest on institutions for implementation; people can justify them through reason (Kant, 1787). Lyons argues that “rights do not presuppose social recognition or enforcement (2006, pp.2-4).” Therefore, along with Kant and Lyons it can be argued that rights are justified claims.

Feinberg further argues that

“When that to which one has a right is not forthcoming, the appropriate reaction is indignation; when it is duly given there is no reason for gratitude, since it is simply one’s own or one’s due that one received. A world with claim-rights is one in which all persons, as actual or potential claimants, are dignified objects of respect, both in their own eyes and in the view of others. No amount of love and compassion, or obedience to higher authority, or noblesse oblige, can substitute for those values (Feinberg, 1973, pp.58-59).”

An action that disregards someone’s right is not only a source of indignation but is also a hindrance and demonstrates contempt of the social systems or law. I agree with Feinberg that ‘[r]ights are not mere gifts or favors, motivated by love or pity, for which gratitude is the sole fitting response’ (Feinberg, 1980, p.142). This conception of rights appears to represent the actual meaning of the term. I will adopt this conception of rights to develop my argument.

According to Feinberg, rights function as a basis to *stand* on for the right holder, allowing safeguards to his/her interests from others and against interferences of state (Feinberg, 1973, Martin, 2013). If people have rights to something, it allows them to claim their interests confidently without any guilt, shame or feelings of humiliation because rights work as morally justified powers in this regard. For example, a patent right protects pharmaceutical companies' significant interests against state interests and other people's demand for access to affordably priced medicines.

Claim-rights have been classified as both positive and negative rights. A positive right implies that someone (A) has a duty to do something for another (B). On the other hand, a negative right implies A's duty to *refrain* from doing something to B. For example, research participants' have a negative right not to be exploited, and this right implies that researchers have a duty to refrain from exploiting the vulnerability of research participants. In the same context, participants' positive right to recognition implies that it is a duty of the host nation and research community to acknowledge the contributions of all involved parties in the research or so I will argue below.

Rights provide two main functions for the right holder, the power to demand freely and control his/her rights (Wellman, 1995, p.7), and the power to issue normative directions to the behaviour of the rights holder without interference. For example, drug companies have the power to claim property rights over their patented drugs, to control these rights and to prevent others from selling, manufacturing, or marketing their drugs.

Others as rights holders cannot interfere with the exercise of this right even though they may need these drugs.

However, a critical question arises at this stage when it is argued that rights imply duties. The question is: Do the pharmaceutical companies or sponsoring nations of IB research have the obligation to comply with global health rights? If this is the case, then Risse (2012) is right to argue that the affirmation of global health rights implies a responsibility on the part of drug companies and researchers who hold the rights of acquisition and transfer to provide the drugs to those who are in need.

There is another critical question that calls for our attention. Why do the contributing nations and their participants in international biomedical research claim the IP rights? Before answering such a complex question, I will discuss Locke's property theory and Nozick's entitlement theory. As their analysis of rights indicate that it is significantly connected with justice and property rights. A critical reconceptualization of Locke's view is essential for further specification of rights. For that reason, the following section discusses on the definition and practical justification of property rights.

(i) Nature of Property Rights

Property⁴⁶ is an important interest of individuals and a central element of legal, political, and economic systems. According to Reeve (2007), contemporary discussions about

⁴⁶ According to Resnik (2003, p. 320), property is a kind of object which may be "alienable, commensurable or fungible". It is a kind of relationship between an object, a person and a society or an organisation. Without property people may subject to others property in themselves in society (i.e. daily

property rights in political philosophy either focus on the philosophical analyses of Locke or Hegel⁴⁷, or take an integrated approach to property that includes socio-economic, political, legal and psychological aspects of property (p.717). The idea of property rights entails that “people are entitled to hold, as property, whatever they produce by their own initiative, intelligence, and industry” (Becker, 1977, p.32). This view of property can be justified according to either natural rights or the labour theory of property rights. The labour theory derives from John Locke’s *Second Treatise of Government* (Locke, 1690/1976), which is essential in legal applications and articulations of property (Hughes, 1989). To sketch all the types of property rights is not the objective of this research and so is far beyond the scope of the thesis. Rather, I will explore the moral foundations of property rights – Locke’s and Nozick’s theories are commonly used in pharmaceutical IP discussions (Hughes, 1989; Resnik, 2003; Hollis & Pogge, 2008), and will therefore form the basis of the following discussion. Nozick advanced his theory of entitlement comprehensively in his book *Anarchy State and Utopia* (1974), a theory that was itself based on Lockean property theory. Nozick elucidated how Locke’s theory could be applied to present-day circumstances. The following section outlines Locke’s theory of property rights in order to explore the basis upon which one acquires property rights.

labourer). In order to avoid that Karl Marx does not support private property. According to him, property should belong to the state not to any individual. Laws to promote and protect such interests have been instituted to secure and uphold peoples’ various interests. A. M. Honore (1961) developed the most influential legal theory of property rights. For him, a group of legal rights to something to control individuals’ interests is called property rights. It is not intended that a detailed exploration of legal theory of property will be developed here, though, as my objective is to address the moral foundations of property right rather than legal theory.

⁴⁷ Friedrich Hegel developed his theory in his book *Philosophy of Right* ([1821] 1942). For him, “A person must translate his freedom into an external sphere in order to exist as Idea... The rationale of property is to be found not in the satisfaction of needs but in the supersession (sic) of the pure subjectivity of personality. In his property a person exists for the first time as reason. Even if my freedom is here realized first of all in an external things...by immediacy” (Hegel, 1976, pp. 41-42).

(ii). John Locke's Property Rights Paradigm

According to Locke, there are common beliefs that God has given the earth in common for mankind so that people can utilise it for their own benefit. Such beliefs are justified by referring to religious texts such as the Bible and the Al-Quran. Moreover, God has given reason in common to people to utilise according to their capacities (Locke, 1976, Secs.25-26). If everything in "nature" is common for all humankind, then how can people acquire private ownership of property? Locke argued that even though everything in the Earth is common to all, every man has a property that is his own body. For him, "No one else has any right to his body except himself" (Sec. 27). As Locke explains:

The labour of his body and the work of his hands we may say are properly his. Whatsoever, then, he removes out of the state that nature hath provided and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property. It being by him removed from the common state nature placed it in, it hath by this labour something annexed to it that excludes the common right of other men. For this labour being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough and as good left in common for others (Locke, 1976, Sec. 27, p. 15).

Here Locke clearly explains the distinctive features of his view on acquiring property rights, as well as the limits of such rights. In the first part of the passage he categorically states that a person is owner of her own body, so whatever she might produce through using her body must also belong to her. This is because the object which she removes from its natural state is changed as a result of her labour, and so becomes her private property.

Next, Locke seems to be aware that the acquisition of property rights in this way may lead to inequalities in a society. Subsequently, he argued for leaving enough and as good of the resources in question in common for others. The reason for such limitations may be that people should consider others' needs as well, and so refrain from voracious acquisition. Later, he pointed out that people should also consider their level of consumption, and that once something is appropriated it should not be destroyed or allowed to perish without being used, as wasting something violates the law of nature. This concern with waste includes not only perishable goods but also the energy it takes to produce them (Hughes, 1989).

In addition, there is a proviso about the extent of the property appropriation in that Locke wants to ensure that "There is enough and as good left in common for others" (Locke, 1976, p.15). This proviso, first, allows space for others, and second, property acquisition should be reasonably limited so that the non-waste condition can be met.

In summary, key features of the Lockean theory of property acquisition are:

- (a) The labour of individuals;
- (b) Whenever someone changes a thing from its natural state, by his labour- to make it more useful or beneficial to him he has 'mixed' his labour with it: that is, 'has joined to it something that is his own'.
- (c) He 'thereby makes it his property,' for 'it hath, by this labour, something annexed to it that exclude the common right of all other men. For this labour being the unquestionable property of the labourer, no man but he can have a

right to what that is once joined to...' (Locke: 1924:27-30 also quoted in Becker: 1977:33).

(d) In addition, there is a proviso about the quantity of the property appropriation that is "leave enough and as good left in common for others". This proviso first, allows space for others so that they can exercise their rights and second, property acquisition should be reasonably limited so that non-waste condition can be met.

Consequently, fulfilling these conditions enables a person to claim a private right to something that they have produced. This view of contribution as a principle of justice has evolved over time, and it has been argued by philosophers that not only persons but also organisations should be considered as property rights holders. It is now well established that an organisation can be treated as an entity and accepted as a holder of property rights (<https://www.alrc.gov.au/publications/2-patent-system/economic-benefits-patent-system>).

The next section discusses further developments by examining how Nozick's theory of entitlement is based on the Lockean theory of property rights.

(iii) Robert Nozick's Reinvention of Property Rights

Nozick's entitlement theory agrees with Locke's classical view of property: i.e. that the initial acquisition of property is morally justified. In addition, Nozick addresses the issue of property transfer and reconceptualises the proviso that ascribes responsibility to the person who makes the approach for an appropriation of property. The crucial question

is what a plausible natural rights-based theory of property would look like in the context of complex and dynamic global relationships and between states and organisations. For Nozick, any acquisition is *just* if it meets three basic conditions:

Firstly, similarly to Locke, Nozick argues that *initial* acquisitions of previously unowned objects are legitimate only when someone discovers them or mixes her labour with them. For example, X has a legitimate claim to a certain fish if X catches that fish while on the seashore. Another example can be drawn from Locke as he also emphasised adding value through the mixing of labour with natural objects. For him, one acre of abandoned land has no value compared to one acre of cultivated land, as the farmer uses her labour to change abandoned land into farmland that can produce a livelihood. In his way, the farmer enjoys the fruits of her labour. As a result of her adding labour to produce valuable goods, she can then also exclude others from controlling those valuable goods. Therefore, on this approach, mixing labour and adding value provides a strong moral basis for the appropriation of property rights.

Secondly, according to Nozick just acquisitions can arise through *transfer*. i.e., if someone gives up their holding right to something and willingly transfers it to another. For example, if X gives the fish to her friend Y, then Y enjoys ownership rights over the fish. X has no more right to what Y might do to it as X willingly gave up her right. Therefore, someone's acquisition is legitimate when the right is acquired through voluntary transfer. For Nozick, a voluntary transfer is just only when it derives from a just initial acquisition.

The third, legitimate category of acquisition is through *rectification*, which depends on the acknowledgment of wrongful acquisition. Consider the above fish example: if

instead of catching the fish, X snatched or stole the fish from Z, then X's initial acquisition of the fish would be wrong, and X's friend Y's acquisition of the fish would also be unjust. X and Y may acknowledge that snatching the fish from Z was an unjust act and then return the fish to Z, or do something else to compensate for the unjust act. Consequently, rectification allows somebody to reflect upon previous actions to right past injustices. Therefore, acquisition through rectification is also just (Nozick, 1974, pp.150-53).

Nozick also tried to develop a principle of transfer of property based on the Lockean proviso that enough should be left for others. This has some similarities with the idea of the "social minimum"⁴⁸. For Nozick, if any acquisition of property appears to have violated the provision that ensures just appropriation, then transfer of such property would not be morally justifiable. If an initial appropriation is completed without considering possible harm and/or deprivation to others in the way the proviso specifies, the transfer of this property would become a violation of Nozick's appropriation principle. This implies that the principle of non-harm/waste/deprivation/social minimum should be addressed when someone seeks to acquire property or to transfer something already accrued.

(iv) Identifying Problems of Classical Labour Theory

The classical natural rights theory of Locke encounters several criticisms. One such criticism asks why Locke's mechanism for acquiring ownership of something unowned,

⁴⁸ In *Stanford Encyclopedia of Philosophy*, Stuart White writes, "a "social minimum" as that bundle of resources which suffices in the circumstances of a given society to enable someone to lead a minimally decent life (White, 2015, p.1: <https://plato.stanford.edu/entries/social-minimum/#FaiObj>).6/9/2018

i.e. through mixing one's labour with it, results in ownership rather than simply lost labour. Nozick attempted to defend this point:

Why does mixing one's labour with something make one the owner of it? Perhaps because one owns one's labour, and so one comes to own a previously unowned thing that becomes permeated with what one owns. Ownership seeps over into the rest. But why isn't mixing what I own with what I don't a way losing what I own rather than a way of gaining what I don't? If I own a can of tomato juice and spill it in the sea so that its molecules (made radioactive, so I can check this) mingle evenly throughout the sea, do I thereby come to own the sea, or have I foolishly dissipated my tomato juice? (Nozick, 1974, pp.174-75).

In response to such criticisms, Nozick tried to distinguish between foolish acts and productive acts. For him, if a person simply pours a can of juice into the sea this does not imply that the person has right to claim the whole sea as her own property even though the person has mixed their owned property with the unowned. Mixing labour does seem to justify a claim that a sea can be appropriated as personal property following the principle of mixing labour. However, for Nozick, it is morally unjustifiable to claim the sea on the basis of just adding a can of juice. This implies that adding labour does not necessarily mean that one can own a property by simply walking on it, as Neil Armstrong walked on the moon. For Nozick, the key to this question is whether the mixing of labour has some value, or none at all.

Nozick argued that "[p]erhaps the idea, instead, is that labouring on something improves it and makes it more valuable; and anyone is entitled to own a thing whose value he has created" (ibid, p.175). Through this argument, Nozick has clearly specified the meanings and implications of mixing labour: that is, improving and *adding* value to an object besides just adding labour should be the basis of a claim in relation to property rights. Some labour may not be able to improve or add value in the ways required for the

granting property rights. For example, a chemist who uses a pre-existing formula to prepare a drug to serve over the counter is not considered the inventor of the drug. However, in the laboratory, a pharmacologist who conducts research to find a molecule to cure a disease can claim at least a significant part of the ownership of the new treatment. In this sense, ownership should be determined by the value that has been generated, though as Nozick has pointed out, there is as yet no agreed measure for determining the exact value added by labour.

On the other hand, according to Nozick, if A finds a pearl in a shell while walking along the sea shore, A has a legitimate claim to that pearl according to Lockean property rights as A's ownership of the pearl does not limit others' right to such property in the given circumstance (i.e., because there may well be other oysters with pearls to be found there). In this way, the Lockean theory of property rights as it has been developed by Nozick offers a plausible account of not only how mixing labour in a productive way justifies property claims, but also explains how the appropriation of a certain property X should not in any way obstruct any person P or exhaust opportunities for similar appropriations by others.

(v) Revisiting the Proviso

As Nozick points out, Locke tried to universalise his principle of the acquisition of property by allowing others to exercise their property rights on the proviso that "enough and as good be left for others" (Locke, 1976, Sec.27). This proviso restricts aggressive

acquisition of vast amounts of property when it would not be used. This condition also encourages respect for the similar rights of others. Nozick gave credit to Locke for insisting that there is no justification for claiming an amount of property that leaves no scope for others to acquire private property or enjoy the benefits of nature. This reminds us that all members of a society deserve to be treated in basically similar ways, which is the fundamental basis of a state-based justice system.

Nozick argued that individual freedoms should not be compromised by the ownership of property. For him, X should think when considering adding their labour to natural things to acquire them that Y can also approach such things in the same way. That an appropriation should not harm others is also in the spirit of Nozick's theory. This allows people to accept some limitations to their rights in order to maintain a harmonious social life.

However, the Lockean proviso has also been criticised for neither justifying the initial appropriation nor corroborating the rights secured through transfer. Nozick (1974) describes this reverse argument as "*Zip back from Z to A*" (p. 176). According to this argument, if Y's appropriation leaves nothing for Z to acquire, then Z is obviously in a worse condition. However, this may be the result of X's appropriation leaving enough for Y but not for Z, so X's appropriation is also responsible for Z's worse condition. If we were to refer back to each initial acquisition in a similar way, A's original acquisition cannot be justified if the proviso has to be satisfied (Nozick, 1974, p.176). According to Thomson (1990), "If the first labor-mixer must literally leave as much and as good for others who come along later, then no one can come to own anything, for there are only

finitely many things in the world so that every taking leaves less for others” (p. 330). In other words, because resources are usually scarce (Fried, 1995, p.230), most appropriation is going to leave someone in a worse condition (Waldron, 1979, p.325). As a result, Locke’s theory may only be applicable in an imaginary state of nature where resources are infinite.

However, Nozick argued that there are only two ways someone’s acquisition may leave others in a worsened situation: first, when one is prevented from changing or improving their own condition due to existing ownership rights; and, second, when people could previously use resources freely, but this becomes impossible afterwards. For Nozick, if we accept such arguments in a stringent way then not only private ownership but also collective ownership is unjustified. Therefore, Nozick suggests that it is better to treat such arguments as justification only for a non-waste requirement on just acquisition (Nozick, 1973, 1974).

I believe that Nozick drew attention to the Lockean proviso to remind us that, on the one hand, we should have the right to appropriate, and, on the other hand, we also have responsibilities to others when exercising our rights (Schmidtz, 2011). Without such limitations, it is difficult to maintain social harmony. For example, the right to freedom of speech allows people to express various opinions while at the same time constraining them not to use abusive or racist words. The proviso reminds us that we are social beings and so have a responsibility to also preserve the rights of others. If we do not

allow scope to others for acquisition, social conflict may prevail. Without this proviso a theory of property rights may become a source of social injustice and an instrument of exploitation that societies neither desire nor support.

In the previous sections, I have discussed different theories of property rights. It has been argued that property rights are morally justifiable when the acquisition of property is based on generating value by mixing labour with natural objects. It has also been argued along with Nozick, that adding labour without adding value is not a morally justifiable form of property acquisition. Furthermore, acquisitions should leave enough for others so that they also have an opportunity for acquisition, so long as there is a reasonable expectation that there will be no harm to others from that acquisition. In the next section I attempt to employ this theory to define intellectual property rights, as these have been used as a basis for IP governance both at national and international levels.

2.3 Meanings of Intellectual Property rights

According to the World Intellectual Property Organisation (WIPO), “Intellectual property refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce” (WTO, 2007; WIPO, 2013; Letterman, 2001). IP is an intangible idea which may be developed in a tangible form (Letterman,

2001). For instance, the idea of a certain arrangement of chemicals is intangible, but this intangible idea can be developed into a tangible form as medicine.

Intellectual property rights can therefore be granted to those who create the intangible idea and to those who develop that idea into a tangible form. In the context of biomedical research, IP rights are granted to rights holders for their contributions to the development of new technologies. An IP right also allows the right holder to claim benefits as compensation for bearing the costs of research that leads to new technologies (WTO, 2013, p.17).

IP rights are divided into two categories: *industrial property*, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source (for example, Champagne and Parmesan); and *copyright*, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs⁴⁹ (WTO, 2013). These different types of IP rights can be justified by appealing to different social aims. For example, granting copyrights rewards the concrete results of creative artists, and inspires others to create. On the other hand, protected trademarks, industrial design and geographic indications of source allow people to make informed decisions regarding goods and services, and keeps business competition for these goods and services fair (WTO, 2013). The aim of patent protection, on the other hand, is to stimulate innovation, recoup the cost of research and secure further investment for research and development (R&D) (WTO, 2013).

⁴⁹ Rights related to copyright also include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

Patents and other forms of IP rights guarantee monopoly rights for a rights-holder, usually for 20 years. During this time, the rights holder prevents others from selling, using, replicating or creating and importing the patented products without the permission of the rights holder (WIPO, 2013; Letterman, 2001; Cullet, 2003, Gibson, 2009). The rights holders can also take action against others for unauthorised use. In theory, this right is given to the inventors to encourage further investment in R&D. However, in practice it means that inventors can commercialise their inventions and prevent others from doing so. After a certain period of time when the patent lapses, this invention will be available for use by all. By doing so, inventors are sharing their scientific developments with the wider community (Cullet, 2003).

The patent system was introduced to provide incentives for the private sector to invest in R&D. Pharmaceutical industry representatives argue that this sector invests heavily in R&D, and that they need some kind of protection in order to recoup their costs. The development of a new drug is an uncertain and costly process, and far more so than simply copying an existing drug for generic production. Also, providing patent protection on a new drug allows the owner of the patent to charge a higher price than the marginal production cost. This allows them to recoup their R&D cost by, for example, targeting patients in wealthy countries. Once a patent expires, others can produce generic versions of the drug. As a result, the price of drugs comes closer to the marginal costs and so become more affordable to the wider community.

2.4 Implications of IP Rights in the Light of the Labour Theory of John Locke in International Biomedical (IB) Research

Locke linked bodily labour with property rights. According to Hughes's interpretation of Locke, "our handiwork becomes our property because our hands and the energy, consciousness, and control that fuel their labor are our property" (1989, p. 57). Locke discussed the role of physical labour in acquiring tangible property, but he did not mention the kind of mental work involved in creating intellectual property. Hughes, however, argues that although mental work and physical labour may be different in nature similar weight should be granted to both when considering the generation of property. This is because mental work requires the application of energy, consciousness and control just as physical labour does. And the creation of many kinds of property involves both kinds of labour. For example, the drug development process clearly includes both physical and mental labour.

According to Hughes⁵⁰(1989, pp.287*) three conditions need to be satisfied before the mental work involved in the production of ideas can be taken into account when granting IP rights under the Lockean theory. These are as follows: that producing ideas requires labour; that ideas should be removed from common; that ideas meet the non-waste condition. Hence, we can apply Locke's theory of labour to the drug development process to identify rights holders, including the sponsoring nations of IB research:

⁵⁰ Hughes, J. 1989. "The Philosophy of Intellectual Property" 77 *Georgetown Law Journal*. Pp.287*

1. Firstly, like other research projects, researchers in IB research use existing knowledge and technological developments (this existing knowledge can be considered as a state of nature which is common to all). For example, hypotheses are constructed out of existing knowledge.
2. Secondly, the appointment of personnel, using infrastructure to support the research to find the potential benefits of the research is physical work which seems to match the labour in Locke's theory.
3. Thirdly, as soon as it seems potentially beneficial, the sponsor patents the research discovery (whether this patent then belongs to government research organisations or to pharmaceutical companies). This is the stage when ownership is granted as recognition of the added value. In the context of pharmaceutical IP, presumably the added value criterion is met by making projections based on initial data, since the drug in question has not yet been made available to the population at large. It can be questioned whether it is just to ascribe exclusive ownership at this stage when it is yet to go through further investigation.
4. Fourthly, clinical trials are conducted to confirm investigational findings in human populations in a variety of possible destinations (the host country or countries)
5. If the trials are successful, this is followed by regulatory approval from the regulatory body - i.e. the Food and Drug Administration (FDA). The drug then goes into production and is marketed for the use of the wider community. On the other

hand, unsuccessful trial results may lead to further developments which can add to global knowledge for future use.

6. Finally, for all these stages the sponsors provide funds. According to Resnik (2001), research would not be possible without the financial contribution of commercial organisations (p.14).

In summary, to obtain patent rights, which is a kind of IP right, sponsors make contributions to the development of drugs in the following ways: contributing knowledge, employing personnel (i.e. scientists, doctors, administrators), and providing infrastructure and financial support for the research.

2.5 Conclusion

In the previous section, I discussed how Locke's labour theory of property rights is applicable to the case of intellectual property in general, and specifically to the case of intellectual property rights in international biomedical research. The labour theory of property also provides the ground for a corporation to acquire the status of rights holder. As a corporate body, the drug company is adding its labour and financial contribution to the formula that has been developed by a researcher. I will argue in what follows that host nations also add significant value and contribute to the delivery of final products in ways that enrich the market and/or global health knowledge systems.

IP rights are positive private rights which give their holders power to "urgently, peremptorily, or insistently" make a claim for his/her rights. With this power the holder

can assert his or her claims authoritatively, confidently, and unabashedly (Feinberg, 1973). This is something, as Feinberg (1973) has argued, on which a person can 'stand'. In this case, recognition of IP rights involves the dignity of both the holders of the right and the bearers of such a right. It gives due respect to contributors and places the bearer in a dignified position and so ensures that s/he has not been exploited. In addition, according to Locke's theory of property rights this is not a gift or favour that is motivated by love or pity and delivered or accepted with gratitude.

This interpretation of Locke's theory specifies the conditions under which a rights-claim may be said to be valid. I will argue that ascribing IP rights to the research host nation (participants) requires satisfying two specific conditions: (a) whether the participants are contributing to the development of the drug as required by Locke; and (b) whether their contributions added value. If research participants satisfy these two broad requirements, then from this perspective they should be recognised as part-owners of the resulting intellectual property. And, if they are part-owners of the property, they have the right to claim and enjoy the benefits the property accrues. The strength of the argument supporting this thesis is substantially based on a clear understanding of the drug research and development process, which is the focus of the next chapter and I will explore the role of the host nation in the IB research for drug development.

Chapter Three

Contributors to International Biomedical (IB) Research: how do their contributions influence in the final outcome of the research?

3.1 Introduction

Access to lifesaving medicines is severely limited in developing nations partly as a result of poverty. In this context, the current TRIPS regime, for example, has significantly threatened the health of the poor of developing nations. Many critics regard the TRIPS Agreement as a flawed “one-size-fits-all”⁵¹ legal global governance mandate of the World Trade Organisation (WTO) which pays little regard to developmental differences within member nations (Muzaka, 2011, p 38, May, 2010). Many researchers argue for amendment and reform of the TRIPS Agreement because it is considered a potential barrier for achieving fulfilment of universal human health rights (Singer & Schroeder, 2008). Along with these critics of TRIPS Agreement, I would also argue that TRIPS Agreement is a powerful global instrument of domination, purposefully concluded to establish a global power regime led by developed nations. In addition, I would argue that TRIPS Agreement inflicts a significant global injustice on developing nations, along with a moral wrong that is taken by the WTO to justify unjust acquisition of patent rights. The TRIPS Agreement also aims to increase the profit maximisation interests of the

⁵¹ Patents can be granted for both products and process of any inventions. In pharmaceuticals, patent protection of the chemical of a drug is called product patent and patent on a drug's specific way of administering and manufacturing method is called process patent. Both types of patent are protected under the TRIPS Agreement (1994) and the member states of the WTO should follow the TRIPS Agreement. Mannan & Story (2006), claim that protection of two types of patent under the TRIPS Agreement is a one-size-fits-all standard.

pharmaceutical industry in developed nations to create scope for taking advantage of vulnerability of the global poor whose access to medicines is lacking or severely limited. The TRIPS Agreement not only poses barriers to meeting the health needs of the global poor but also marginalizes them substantially by depriving the acquisition rights of participants and the host nation in IB research which is a key contributor to the drug and medical technology development process. This unequal distribution of benefits and burdens also reduces the bargaining potential of the global poor who are experiencing various types of risks. It creates another level of limit against their development instead of helping to emancipate them from poverty, diseases and death.

The Doha Declaration 2001 resulted from such debate over the TRIPS Agreement. Access to medicines through compulsory licensing was recognized in the TRIPS Agreement that made a provision for poor nations to address their health needs based on compassion rather than rights of ownership, to address public health issues. Earlier, I have argued that unmet health needs of the developing nations pose a potential threat to economies of the developed nations as a huge quantity of commodities are produced in developing nations to provide consumer goods at a cheaper price for the developed world. To ensure effective access to medicines for public health through compulsory licensing, member states of the WTO will need to have an adequate domestic pharmaceutical manufacturing capacity. However, most of the developing countries either lack such capacity or may have inadequate capacity for production. Due to continuous pressure from civil society and NGOs' forum, the DOHA declaration was revisited in 2003 and the Amendment of 2005 was embraced to address developing

nations' lack of access to medicine (Muzaka, 2011). Such a solution, i.e., compulsory licensing, and framework, i.e., the TRIPS, are inadequate to capture the reality and ignore the contributions of the host nations in the clinical trials, which I have argued is a morally relevant consideration based on Lockean tradition, i.e., the principle of contribution. The conception of "contribution" that prompts ascription of IP rights to the researcher or the pharmaceutical company in IB research needs reinvestigation first. The developing nations host clinical trials and contribute to the drug Research and Development (R&D) process but the critical question is why the sponsoring nation has no moral obligations to share the patent rights with them? More specifically, are there any compelling moral grounds or reasons to confer IPR (property rights) to M (Medicine produced via IB research) for X (Clinical Trial Participants of a host country)? Addressing this question has potential to overcome claims of injustice and achieve fairness in the IB research.

The previous chapter investigates the labour theory of Locke in the acquisition of property rights which substantially influenced the idea of the rise of private property rights (Hughes, 1989, Haddad, 2003). The previous chapter also focused on Nozick for reconceptualizing Locke's theory to understand what is meant by IP rights in the 20th century. This chapter will apply the principle of justice developed in the previous chapter to address the above question of fairness. While the nature of IB research is collaborative, the IP rights at present are essentially distributed to the sponsoring groups of the developed nations only. Consequently, these research results are patented in the developed nations (e.g., diarrhoea oral vaccine is patented in the USA

(Ruxin, 1994). The benefits of these rights are enjoyed by developed nations. Therefore, in this chapter, I argue that the current pattern of IP rights system is a source of injustice to developing nations as it violates one of the basic human rights, i.e., property rights and also poses a threat to health rights and individuals' right to life.

To this purpose, in this chapter, first, I outline the drug research and development (R&D) process briefly. Next, I investigate the contributions of the host nations and participants of clinical trials of IB research to explain how the moral claim of IP rights is thought to be justified for the host nations. Next, considering the significant contributions of the host nations of clinical trials, based on Locke's property rights theory, I argue for ascribing an equitable portion of IP rights to the host nations. Because, the value-added criteria of Locke's theory are applicable to the drug R&D process (Hughes, 1989, Resnik, 2003), therefore, as recognition of their contributions, sharing patent rights with the host nation of the clinical trials is plausible and has the potential to deliver justice and preserve integrity in IB research. Sharing patent rights will be effective also for providing equitable access to health care gradually to meet the health needs of the poor of developing nations.

3.2 Brief Description of a Drug Research and Development (R&D) Process:

The identification of different persons' and parties' contributions plays a crucial role when granting patent rights in collaborative research. A clear understanding of the drug

R&D process provides the basis for identifying contributors who have a moral right to claim patent rights according to our principle of justice. New drug development typically requires long periods of time, huge financial investment, and requires collaboration with various kinds of individuals and organisations as well (PhRMA, Home page, 2014). Thus, a drug is a product of a collaborative process.

According to Angell (2004), a new drug R&D process consists primarily of two steps. The first step is conducting basic research for the disease. The second step is the further development of the basic research findings, which itself is divided into two steps: the pre-clinical and clinical, which are mostly interdependent (PhRMA, 2014).

Without a comprehensive understanding of a given disease, neither a cure nor a preventative is likely to be discovered. Initially the primary research phase starts by studying conditions of the disease (PhRMA, 2014, Angell, 2004, P. 22). At this stage, researchers share information, biological materials and samples of the disease in order to understand it within the research community⁵² and for the advancement of global health knowledge often from an altruistic non-profit standpoint, i.e., on the basis of good will (Quoted in Goozner, 2004, p. 65). For example, in 1975, a Japanese researcher Takaji Miyake gave Eugene Goldwasser 2,550 litres of urine which contained eight milligrams of pure human Erythropoietin (EPO) sample (Goozner, 2004, p. 18). Later the EPO sample was used in experiments to develop Epozen, a drug to treat patients

⁵² Researcher community may include from various level of global academia, governments, NGO's or industries and private research organisations (PhRMA, 2014).

suffering from anaemia (lack of red blood cells). Epozen helped sufferers avoid or reduce otherwise required blood transfusions due to chronic kidney disease. Avian Influenza Virus sharing is another instance of such global cooperation (Pogge, Rimmer & Rubenstein (eds.), 2010). Moreover, previous researchers' knowledge and contributions to earlier innovations provided a basic and essential "foundation" for any invention or creation of new knowledge (Scotchmer, 1991).

Once the basic research is done, the next stage is to use its findings in the search for new medicines. At this stage, researchers or the basic research organisation may lack the resources to take a new drug through clinical phases in order to demonstrate its safety and efficacy, as well as to satisfy the regulatory requirements that all successful pharmaceutical products must meet before going to the market. Then, they often can sell or transfer their right (IP right) to another organisation which possesses the further capacities required, often through technology transfer⁵³ and usually to a pharmaceutical company (PC). Drug companies may be involved sometimes early in the basic research or sometimes vary late in the process (Angell, 2004). This new form of ownership is a contractual legal relationship between the owner of the basic research findings and the pharmaceutical company through a license agreement (Mendes, 2002).

⁵³ According to Mendes (2002), "In the exploitation of pharmaceutical products, technology transfer by partnering in the way to bring a pharmaceutical product to market is a common feature of the industry" See also for Technology Transfer:

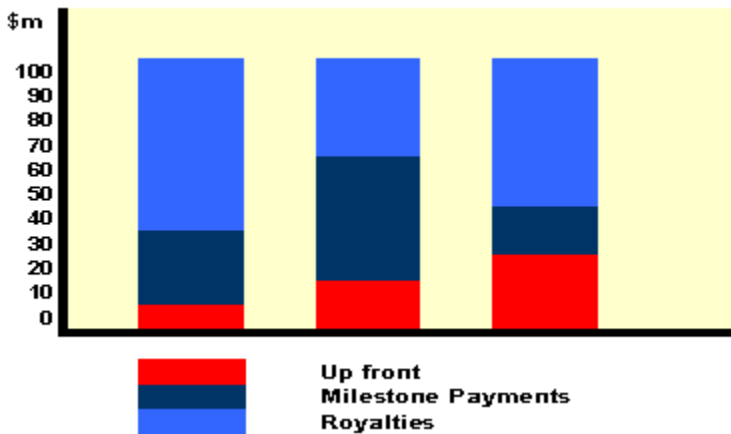
http://www.federallabs.org/ContentObjects/Publications/T2_Desk_Reference.pdf).

Further, Angell (2004) explains that in the pre-clinical stage, researchers start rapidly screening thousands of drug compounds to identify potentially relevant molecules. Once researchers find promising target molecules, they study their properties in animals and cell cultures. They complete rigorous laboratory and animal studies for toxicology to determine suitable molecule compounds to apply to humans as potential drugs in clinical testing (PhRMA, 2014).

The basic research stage provides knowledge about the underlying causes of the disease and prepares researchers with elementary knowledge about the prospective biological targets for potential medicine which may be a synthesised molecule to ameliorate or cure the disease (FDA, 2014). At this stage, health researchers use knowledge gained from other disciplines such as physiology, chemistry and anatomy etc.

Angell also explains that before the clinical stage, a patent for a new drug is obtained by drug companies (2004, p. 28). Patent rights secure the monopoly interests of the owner for maximum of 20 years. Hence, other companies cannot exploit such research findings unless the permission of the owner is obtained (WIPO, 2017). It is assumed that during clinical trials, some drug information will be disclosed to the scientific community. Consequently, the clinical trials period is a part of the granted patent life. The following graph was taken from the WTO which represents the combination of

financial benefits of sharing information between the owner of the basic research findings and the new license owner of the pharmaceutical company.



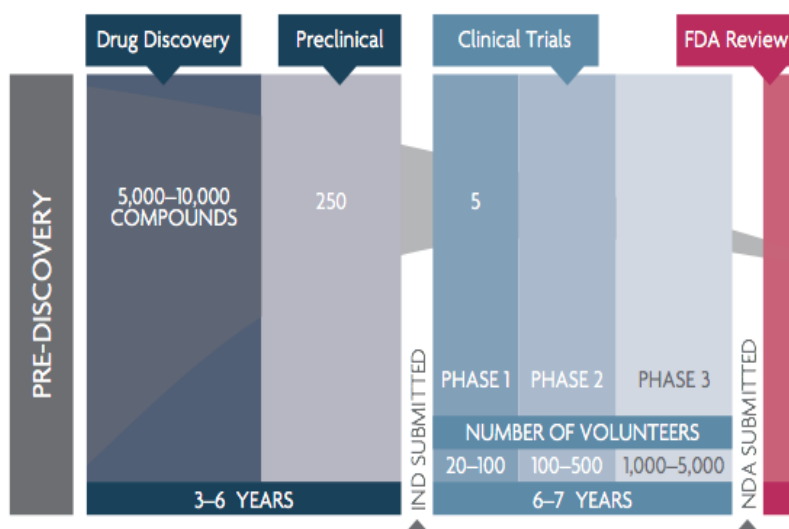
[Source: WTO]

Upfront payments are made during the license signing time. Milestone payments are made after achievement of each clinical or regulatory stage of development. In contrast, royalties are paid upon sales of a product in the market (Mendes, 2004). Consequent to the granting of patent rights, researchers and her (their) basic research organisation enjoy these payment stages from the pharmaceutical company.

It seems that researchers from universities or governmental research organisations such as the National Institute of Health (NIH) undertake most basic research funded by tax payer's money (Angell, 2004). Pharmaceutical companies do not conduct extensive basic research although they eventually become patents rights holders. There are also discussions of scenarios whereby IP resulting from publicly funded research ends up in the hands of private organisations (Pharmaceuticals Companies). Private organisations

in these cases acquire huge benefits from the research and deprive the public of enjoying the result of their contributions. Ironically, the public has to pay tax for the basic research as well as paying high prices for the final product yielded from such research. This results in a conflict between private rights and public rights. The enjoyment of such benefits appears to lack sufficient ethical justification. It is not anticipated to discuss such debates yet.

The next phase of the process is clinical testing. The PC often contribute to this stage of the research by sponsoring clinical trials and must submit applications for an investigational new drug (IND) to the Food and Drug Administration (FDA) to obtain approval for the clinical trials. At a glance, the following diagram demonstrates the drug development process, approximate duration and number of trial participants for each phase and other information.



[Source: PhRMA Industry Profile, 2009]

According to Yang, (2012), in phase I trials, 20-100 healthy or sick volunteers (depending on the diseases i.e., trials recruit cancer patients) are recruited to evaluate dosage, and safety. Similarly, in phase II, refinement of doses, risks and the short-term effects of the drug is evaluated usually within a population of 100-500 trial participants. Phase III then aims to assess the drug's overall risks-benefits profile and to monitor side effects in order to confirm its effectiveness when compared with commonly used treatments if any exist (Angell, 2004). According to Yang's interpretation, phase I, II and III are interdependent on each other for the final assessment of the drug. After completion of all the trial phases, a company submits a new drug application (NDA) to the FDA. In the NDA application, the company must include all the clinical trials data of safety and efficacy regarding specific uses and doses for approval. The FDA reviews safety and effectiveness data of the drug. Broadly speaking, companies obtain FDA approval for marketing if the benefits of the drug outweighs the risks (FDA, 2014). Hence, clinical trials may take several years.

In essence, patients suffering from a disease describe their symptoms and seek advice from a doctor or the scientific community. This is the initial point of a drug development process. Final approval of drug safety and effectiveness also depends on information provided by patients or participants of clinical trials. Thus, research participants' knowledge of the disease, the nature of their symptoms, and their reflective capacity to provide information about the effects of the drug to the scientific community play a significant role in the drug development process.

3.3 The contributions of the host nations: are the host nations of international biomedical (IB) research contributing and adding value to the research too? If so, how are they?

Do these contributions add value to the development of drugs or other interventions? If host nations of IB research contribute and add value to this process, what form does it take?

A critical discussion and analysis of drug and medical technology R&D processes reveal that host nations often contribute significantly to the development and advancement of global medical science knowledge, through their contributions to and participation in clinical trials.

IB research is often a collaborative activity involving government and non-government institutions of two or more nations with different levels of resourcing, governance and culture. When a patent is granted before clinical trials, the contributions of participants and host nations are overlooked and devalued. Schuklenk & Ashcroft (2010, p. 290), argued that “developing nations have moral obligations to contribute to research efforts just as much as some commercial organisations do”. If a developing nation has a moral duty to contribute to drug development for the benefit of humanity, then sponsors are reciprocally obliged to appropriately value the contributions of developing nations. In the next section, I discuss the nature of the contributions by host nations to drug development.

(a) Knowledge Sharing

Does the host nation contribute to the generation of knowledge in clinical trials?

In IB research, researchers, sponsors, and personnel and participants from host nations contribute their knowledge and distinctive capacities to accomplish the joint goal. Appiah-Poku, Newton and Kass (2011) conducted a study in Africa which found that 72% of non- ill relatives and 68% of patients believed that obtaining new knowledge is the greatest benefit of international collaborative research. As one participant responded (Quoted in Appiah-Poku, Newton & Kass, 2011):

From the findings of the research the doctors will gain more knowledge to treat people in the future so they will benefit more than us even (p.131).

Another participant was quoted as saying that,

If you want to know a benefit of research I will say that for example when I came here my blood was tested to find the cause of my disease, which is a benefit: finding the cause of diseases....The researcher will get to know the root cause of the disease and that is their benefit (p.131).

Further, a survey conducted by the German Association for Applied Human Pharmacology (GAAHP) to represent the participant perspective in a phase I study found that 40% of all trial participants affirmed that they contribute to improvements in pharmacotherapy (Hermann et al., 1997).

The participants in IB research convey their personal knowledge gained either through suffering from a disease or through close caring of seriously ill patients. That information

may be missing from the scientific record and figure in the research undertaking. This requires them to use their cognitive processes which helps researchers or scientists to rethink the safety, efficacy or toxicity of the study drug for further adjustment for development.

The development of the anti-oestrogen drug tamoxifen provides a relevant example of this. Based on animal and laboratory research findings, some researchers predicted that tamoxifen would not benefit patients who do not have oestrogen receptors. As a result, tamoxifen trials excluded women suffering from breast cancers as they lack oestrogen receptors. However, subsequent research revealed that tamoxifen is actually beneficial for them. Without the participation of some participants suffering from breast cancer scientists would have been ignorant of breast cancer (Chalmers, 1995, p.1317). Such omissions would leave research findings incomplete.

The results of research may also bring changes to clinical practice. For example, during pregnancy, if mothers take certain medicines this may result in their delivering larger babies, complications, or other additional risks. This type of knowledge might not be apparent to researchers or sponsors. Participants, community representatives and researchers from host nations share ideas, the effects of previously studied projects or previously neglected areas to formulate new investigation agenda which guide the research. For example, a British researcher, Chalmers, claims that when a researcher requested that local people comment on a study of low-dose aspirin for women during

pregnancy to address hypertension related problems, the local people suggested following-up the babies of participants to assess the effects of the drugs. It was subsequently found that taking aspirin might be harmful for their babies, and now doctors advise pregnant women not to take aspirin (Chalmers, 1995, p.1317).

By way of contrast, in animal experiments, researchers have to observe reactions and predict the outcome where no effective communication occurs between them and their test subjects. However, whether promising findings in animal models will translate to humans remains uncertain unless the findings are repeated in humans. In 1999, the death of 18 year old Jesse Gelsinger demonstrated once again that applying the findings of research in animals to humans can be extremely dangerous (Steinbrook, 2008). This is evident from the study findings in relation to the sparse fur mouse (animal model), that by transferring a gene to the liver, an enzyme deficiency resulting from a defective gene can be corrected. Gelsinger who had partial Ornithine Transcarbamylase (OTC⁵⁴) deficiency was enrolled in a gene transfer study. He participated in the research to help the doctors to find a way to save sick babies such a deficiency, even though his sickness was already mostly under control. After receiving the gene transfer therapy dose, Gelsinger developed disseminated intravascular coagulation, systemic inflammatory response syndrome, acute respiratory distress syndrome and multiple organ system failure, and he died within 98 hours. According to Steinbrook (2008), “when given higher doses of the vector (1×10^{13} particles/kg), rhesus monkeys developed disseminated intravascular coagulation and liver failure;

⁵⁴ OTC is a type of genetic defect disorder which interrupts the liver for metabolism of ammonia.

some died. However, at the dose administered to Gelsinger (6×10^{11} particles/kg), which was about 15-fold less, only minor toxicities to the liver were observed in the monkeys (p. 114).” Further, in 2006, six healthy participants were injected with TGN1412⁵⁵. They all suffered “a cytokine release syndrome” that includes several organ failures and life-threatening illness which required treating them in intensive care unit over a few weeks. The study of TGN1412, which was expected to target B-cell chronic lymphocytic leukemia, is another example where successful preclinical research on animals was not replicated in clinical trials (Wood & Darbyshire, 2006). Host nations in IB research provide access to participants and bear the crucial burden of the research, and without such support it is unlikely that any benefits will be extracted from the research to recoup R&D costs within the required time-frame (Gibson, 2009, pp.26-7).

According to Dresser, “during clinical trials researchers evaluate the effects of drugs and other interventions in patients” (2013, p.831). In order to obtain reliable data, researchers sometimes require trial participants to refrain from taking other medicines or refrain from having certain food or drinks (e.g., alcohol, caffeine) which may influence the findings of the trial. For example, the GAAHP survey found that participants were asked about their dietary and alcohol, nicotine and caffeine intake before being recruited as participants (Hermann et al., 1997, p.210).

⁵⁵ According to Wood & Darbyshire (2006), “TGN1412 –a humanized monoclonal antibody designed as an agonist of the CD28 receptor on T lymphocytes, which stimulates the production and activation of T lymphocytes”

Host nation research participants are qualitatively different to participants of developed nation as they are 'treatment naïve'. This means that most of them have not been exposed to any medicine previously. The marketing director of Johnson & Johnson said that medical deprivation makes patients "better for our purposes, it is very pessimistic outlook but a very true one" (Flaherty, Nelson & Stephens, 2000, pp.1-9). In contrast, research participants in developed nations typically have access to alternative treatments which can complicate or jeopardise results of the investigational agents. This means that research participants in developing countries support the generation of more consistent and accurate results of the experimental agents (Wood et al., 2003). The Director of the Sponsored Research Programs, Tufts University, Kenneth Getz, suggests in general that the clinical research process should include and engage participants as partners because no trials can be conducted for new medicine without them (PhRMA, 2013).

(b) Participants' Contribution Towards the Efficacy of a Drug

(Do these contributions add value to the evidence-based development of drugs or other interventions?)

Drug efficacy is considered an important factor when granting patents as it is set forth in the TRIPS Agreement (TRIPS, 1994). This is also important for patent protection in some countries such as the United Kingdom and India. Patent protection provides exclusive marketing rights to the innovators. Why is efficacy an important criterion for granting patents? Patents cannot be granted if the new substance is a form of a previously known substance unless the new substance is significantly different in its

effectiveness. If the contributions of the clinical trial participants were taken into consideration when granting patents, the benefits of selling such drugs would yield benefits to a host nation's economy and prosperity.

In this regard, accuracy plays a crucial role in science. The host nation participants take many of the risks associated with the clinical trials (Ballantyne, 2005, pp.487-88). They are exposed to the study drugs and so provide information on the positive and negative effects that help researchers identify an accurate dosage regime. Any drug approval based on inaccurate data may impose excessive risks on future patients. Dresser also claims that, "inaccurate findings can prematurely halt drug development, too, depriving patients of potentially beneficial new drugs" (Dresser, 2013, p.833). The collaboration of participants is essential in a clinical trial. Therefore, to enhance collaboration, some researchers argue for participatory research models in health research which include patients and the broader community (Dresser, 2008; Hermann et al., 1997; Cornwall & Jewkes, 1995; Chalmers, 1995; Goodare & Savage, 1995, see also pp.39-40 of this thesis for further).

(c) How does a host nation provide other supports (hospitals, personnel and community representative)?

As Harvard Multi-Regional Clinical Trials Center (MRCT) Executive Director, Rebecca Li, said, "Clinical trials data represent important scientific resources" (PhRMA, 2013, 1). For her, the importance of clinical data-sharing with researchers for greater benefits of

public health is paramount (PhRMA, 2013). Personnel from host nations collect biological samples and data. They also monitor data collection and preserve collected data, transcribe and interpret research data, and sometimes analyse the data of clinical trials for principal investigators or to hand over to pharmaceutical companies (Ruxin, 1994). These are also an integral part of the contribution of developing nations to IB research. Host nations play a vital role in supplying clinical data. Host nations also contribute to the implementation and evaluation of research (Dresser, 2008). For example, in terms of facilitating the research, they provide hospital resources and trained personnel.

Host nations also employ the most experienced personnel such as doctors, nurses and laboratories technicians to provide services in order to support the trial as a requirement of the sponsors (Flaherty, Nelson and Stephens, 2000). When resources are limited, the concentration of such local resources may be unjust insofar as community members are deprived of services, although this may be beneficial to the participants of the trial (Ballantyne, 2006).

Further, Cornwall and Jewkes (1995, pp. 1667-76) claim that, "Researchers and local people working together as colleagues with different skills to offer is a process of mutual learning where local people have control over the process." Indeed, Dresser argued that "Members of the study population possess knowledge that is as essential to a project's success as the scientific and medical knowledge researchers contribute" (2008, pp.233-

234). Host nations become part of the research enterprise. As collaborative partners they assist sponsors in planning, recruiting participants, guiding and conducting the research in local settings (Ruxin, 1994). Without such support R&D would not proceed as effectively. Such contributions no doubt add value to the product. Without proper acknowledgement of participants' and host nations' contributions, and without giving them their due return on these, a global governance of patent rights (i.e. TRIPS Agreement) cannot sufficiently address distributive justice issues.

Moreover, participants take part in a trial for various reasons. Some may participate from altruistic motives such as a commitment to social responsibility (Jansen, 2009; Hermann et al., 1995) and get a sense of satisfaction that they are contributing to science. Capitalising on such humanistic motives can be another crucial factor in questions of fairness⁵⁶, though this is beyond the scope of this research.

Finally, host nations bear the psychological, physical and financial burdens that arise directly or indirectly from the investigational agents or procedures. The risks of allowing investigational drugs can be fairly significant and these risks which may be short or long term, are often unknown at the time. On occasion, because participants permit researchers access to their bodies, participants may die as a result of their participation in clinical trials (e.g., the death of Jesse Gelsinger), which comes at a cost of human

⁵⁶ Individuals, social organizations motivate people to participate in clinical trials for the sake of others. The participants of clinical trial volunteer only for the sake of humanity, not for any reciprocal benefit or for kin. So, it can be argued as injustice to the society if any pharmaceutical company extracts benefits from such noble contributions of research participants. Seelig, Beth J. & Dobelle, William H. 2001. Altruism and the Volunteer: Psychological Benefits from Participating as a Research Subject, *ASAIO Journal*: Volume 47 - Issue 1 - p 3-5.

resources for host nations. For example, the FDA claims that 3 deaths resulted from the Lotronex study for irritable bowel syndrome by Glaxo pharmaceuticals (Flaherty, Nelson & Stephens, 2000). The host nation has to manage the fall-out from these kinds of risks.

Generally, in practice, IP⁵⁷ (patent) is granted to the sponsor, researcher, or PC on the grounds of their financial contribution to the R&D process so that they can recoup their investment by exercising monopoly controlling power over the market. From this, it may well appear that host nations make no financial contribution. To clarify host nations' contribution to IB research, we need to determine whether they only provide labour and support services, or whether they also contribute financially to the drug development process. In the following section, I discuss how host nations, throughout the history, are in various occasions contributing financially to the IB research process.

(d) Financial Contribution

How does a host nation contribute financially in the R&D process?

IB research is mutually advantageous for both parties. For example. Ballantyne argues that an equal or similar amount of money to that required to conduct research in a developed nation should be considered as the financial cost of conducting research in developing nations (Ballantyne, 2006). I agree with her and argue that the funds

⁵⁷ In theory, patentability criteria are novel, inventive process and industrial utility. Patent is granted, whether invention is a product or a process, as a recognition of contribution (TRIPS, 1994). However, in practice, granted pharma IP is aiming to exercise a monopoly power to control market so that pharmaceutical companies can recoup their financial investment (Cullet, 2003).

required to conduct research in a developed nation should determine the value of the contribution of the host nation. If the balance of the conducting research cost is extremely inconsistent between the sponsoring and the host nations of the research, then it would not be conceivable as fair⁵⁸. Host nations' constrained financial resources often prevent them spending on R&D. They provide their services at a *minimum rate* compared with developed nations. Subsequently, the host nations can access research opportunities.

For the sponsors, financial gains rest on many factors. These include the time to negotiate regulatory processes, how quickly the research can be done to obtain the safety and efficacy of results, and how quickly new products can be manufactured and made available for marketing. It is commonly argued that sponsors from developed nations and pharmaceutical companies are choosing developing nations as research locations to exploit the poor, their vulnerability, and weak regulatory systems for research. According to Ballantyne (2006), pharmaceutical companies obtain three types of direct benefits from IB research in developing nations: lower costs, placebo control trial acceptance, and research subjects' availability.

(i) Cost savings in IB research from foreign personnel which includes doctors, nurse, administrative staff, and recruited participants:

⁵⁸ The transaction violates basic principles of justice as fairness. In this case contributions of sponsoring nations are taken as basis of granting IP and host nations contribution is undermined seriously as this has been discuss through out the thesis.

Pharmaceutical company do not publicly disclose the actual financial costs of their R&D, and so I must rely on very limited data to assess the financial contributions of host nations.

An investigational new drug (IND) is not designed to treat people. Rather, it is designed to test the safety and efficacy of new treatments, or to identify their dose toxicity reaction levels. Therefore, it is difficult to recruit enough participants in developed nations within a reasonable timeframe, due to availability and accessibility of alternative treatments. In the United States, the FDA requires data on drug safety and efficacy from approximately 4000 participants when considering whether to grant approval for marketing (Flaherty, Nelson & Stephens: 2000). According to Jean-Pierre Garnier (2004, Quoted in Ballantyne, 2006),⁵⁹

We do about 60,000 patients in total trials each year- so the savings per person if you switch, say, 20,000 of those patients to India is in excess of US\$1's saving of US\$200 million right there (p. 209.)

Further, according to an executive of Bristol-Myers Squibb, in Russia the cost per participant is \$3,000, whereas in Western Europe the cost is \$10,000 (Flaherty, Nelson & Stephens, 2000). In most developing nations, enough participants can be recruited more quickly than in the USA or other developed nations. In addition, according to the Global Alliance for TB Drug Development (2001), the comparative cost per participant in Phase III trials in US Dollars between Uganda and the USA are \$1,500 and \$ 22,540 respectively. The following table represent the significant savings to sponsors when

⁵⁹ CEO of GlaxoSmithKline stated with *Business Week* in an interview. (Also quoted in Ballantyne, 2006).

trials are outsourced to a developing nation. This also represents a significant financial contribution by developing nations to the development of new treatments.

Comparative Estimates of Clinical Trial Costs for a New TB Drug in US Dollars

Status of Trial	No of Participants	Costs in Host Country of clinical trials	
		Uganda	the USA
Phase I	104	\$162,651	\$644,957
Phase II	264	\$1,595,708	\$3,387,765
Phase III	1000	\$8,179,228	\$22,600,924
Total	1368 participants	\$9,937,586	\$26,633,646

Table 1, Source: Economics of TB Drug Development (2001, p.56-57)

Moreover, Flaherty, Nelson and Stephens (2000) claim that each day of delay in bringing major new drugs to the market costs \$1.3 million. Obtaining trials results is a matter of “the sooner the better” when it comes to the commercialisation of new drugs as it enables companies to recoup their investments in R&D more rapidly (Juan Pablo Guzman quoted in Flaherty, Nelson & Stephens, 2000). Delays in trials make it tougher for companies to recoup R&D costs and so to achieve financial gains. Both parties are therefore vulnerable in different ways: sponsors are vulnerable due to recruitment difficulties in developed nations, while participants in host nations are vulnerable due to their lack of access to medicines. The availability of research participants in developing nations provides financial benefits for sponsors and stimulate globalised research. Flaherty, Nelson and Stephens also claim that affluent nations can shelve some more

new drugs when clinical trials are outsourced in developing nations (2000). Consequently, outsourcing trials to developing nations provides a way for sponsors to save money which can be reallocated to further research. Such a contribution is not taken into consideration when a patent is granted. If this important contribution is considered, then participants of host nations are not only contributing to the R&D process of developed nation's pharmaceutical companies, but also strengthening the economy of developed nations. The prosperity as it accrues from such developments also assists in securing their citizens' access to high standards of health care.

In addition, personnel from host countries receive much lower payments to run clinical trials than those who work directly for sponsors. The lack of acknowledgement of these financial contributions extends the vulnerability of the developing nations in such a way where systematic injustice (i.e., process related injustice such as defective informed consent) can occur. As a result, IB research may purposefully open an avenue for an ongoing injustice. Therefore, I argue that the host nations involved in the drug development process should receive equitable access to patent rights.

(e) Bio resource sharing

IB research in developing nation commonly allows developed nations researchers to access to their biological resources. Citizens' biological resources are thereby sometimes considered as nation's resource. Providing access to biological resources, developing nations contribute a lot to developed nations' research industry. Therefore,

benefits resulted from the use of such resources yet to be considered for a benefit sharing protocol with the resources provider. For example, research participants of developing nations provide their blood samples in IB research. Contribution of biological resources by research participants may include but not limited to blood, saliva, vaginal, cervical samples etc. Clinical specimens also may include dead patients' lung biopsies, nasal and throat swabs, washes from intubated patients and if available, endotracheal aspirates of patients (Lucas et al., 2013, in Schroeder and Lucas eds. p. 108, Sedyaningish et al., 2008). In most cases, once research participants biological resources are given to the researchers, donated resources are then used by researchers for investigation or transfer abroad for exploring their commercial utilities. Obtaining individual research participants consent about whether their bio-resources are being transferred for further study or commercial use is an ethically necessary requirement. Consequently, the resources providers then do not retain any further right of ownership over their donated resources. Thus, what happens to their donated biological resources is unknown to the resources providers. As Lucas et al. (2013) accurately noted, in "most cases...the samples or the materials are taken out of the country [and] when these materials are gone we never get to know what happens to these things" (p.115).

This means biological resources providers cannot claim or access the resulting benefits derived from their donated biological samples. Yet biological resources provide rich opportunities to scientific communities for understanding epidemiology of a particular disease and accordingly often contribute to subsequent development of drugs or vaccines for it. According to Schroeder, in IB research, benefit sharing of human

biological resources yet to be considered. Achieving justice in IB research therefore also requires development of ethical and legal regulations accordingly for benefits sharing.

For example, Sex workers from Majengo slum located in Pumwani district of Nairobi in Kenya have been providing biological samples over 25 years for HIV study, which provided foundation for understanding of risks factors, epidemiology of HIV and current advancement of HIV vaccine study (Bandewar et al., 2010).

Since 1990s, the sex workers of Majengo have been providing biological samples and collaborating with the HIV/AIDS research. Immunological protection mechanisms for HIV infection has been found in some among these sex workers. This means even though these women were exposed to HIV virus on numerous occasions without precaution, they were not infected, as their body has natural protective immunity resistant against HIV infection. This finding has a significant impact on the vaccine study and design of HIV.

Majengo sex workers have received following benefits from research. Nevertheless, questions may arise: are these sex workers receiving reasonable benefits at all? In Kenya, sex work is not legal, but it remains as a legacy of British colonialization. During British ruling period in Kenya, the British government brought in sex workers from Tanzania for British soldiers (Bandewar et al., 2010, p.3). Yet, sex work is not systematized in brothels and they face various types of discrimination. There were no hospital where sex workers could access to health care, and if they went to a nearby hospital, they were confronted with discrimination because of their occupation. In 1980,

research team established a hospital in the Majengo slum to study sexually transmitted diseases (STDs). Sex workers could only access to health care through research clinic. Thus, currently they have access to health care and research participants have been recruited for various HIV studies (Lucas et al., 2013).

Research participants can choose a “Comprehensive care package” that includes antiretroviral treatments, access to full health care within reach, since 2005. As a result, reduction in HIV transmission was noticed in the community and therefore, reduction in morbidity and mortality have been decreased. A community of sex workers was formed as they were able to share their experiences in a respectful environment. They develop a sense of belonging and be part of a community to form social network. As a result, they could campaign for “NO condoms no sex services” (Bandewar et al., 2010, p.6). Subsequent progress in HIV vaccine development has resulted from the study of their donated biological sample (Bower 1998, Rowland-Jones et al., 1998b, Kaul et al., 2001a). Even though Majengo sex workers have received benefits by participating in research, these benefits

On the other hand, sex workers provided biological samples for scientific research without any provision for any future benefits. Therefore, sample donors have no property rights to their donated resources. Therefore, they do not have any right to access to the fruits of the research. Bioethicists for example Schroeder and Diaz (2006) and Sheremeta (2003) argue that to avoid exploitation of research participants of

developing nations requires sharing of biological resources should be included in benefit sharing.

In most cases, when research participation is the way to access to health care, and research participants were asked whether they would consent to transfer their biological sample abroad for analysis. It can be assumed that research participants would easily consent to transferring their biological resources. This can lead to potential exploitation of research participants in developing country.

In 2000, the media brought public attention to the dispute of HIV patent, that the process of HIV vaccine development was patented by the Oxford University without acknowledging the contribution of collaborative partners of the University of Nairobi (Turner, 2000). The scientists from the university of Nairobi protested against Oxford, after significant negotiations the disagreement was resolved. A new memorandum of understanding were enforced that outline that “collaborators will be joint applicants for, and owners of, rights, title and interests in inventions and/or patent arising from the research, and that research benefits will be shared equally between them” (Turner, 2000). The Indonesian avian influenza H5N1 virus sharing is another example which will be discussed (in chapter 7) where rigorous negotiations were needed to establish right for benefits sharing. Individual research participants often face vulnerability and they have considerable limitations in power. Thus, obtaining individual consent from participants regarding biological resources is not sufficient to ensure justice for the individual research participants and state should be authorized for acting on behalf of

the participants for benefits sharing agreements. Civil society can also play a crucial role in negotiating benefits. There are differences between individual research participants having control over their biological sample and having control of the state. It is not equivalent when it is involved negotiations for benefits sharing.

The question therefore arises as to why the host nations of IB research are not considered part of the IPRs by developed nations, which is in turn a question of justice. The IPRs pursued through TRIPS fails to address such questions. It is ironic that every year global leaders acknowledge the roles of poor nations in IB research but fail to provide a just share of the benefits gained as a result of their valuable contribution.

3.4 Justice to Developing Nations in International Biomedical Research

Ascribing IP rights as a recognition of valuable contributions to global health knowledge and the R&D process.

Several recommendations have been advanced by researchers to address the health needs of poor nations who participate in IB research. For example, Benatar argues that “Collaborative research should also include the enhancement of local capacity for grappling with these ethical problems in ways that allow the quest for universalism to include all who have something to contribute to collective understanding and to the reasoning process” (Benatar, 2002, p. 1139). On a similar basis to Benatar’s recommendation, past and recent researchers in IB research have to consider different types of benefits that could be given to a host country and/or the participants by

considering their disadvantaged circumstances. However, such recommendations are usually based on an ethic of compassion and are expressions of sympathy although they are more often framed as matters of justice. Neither do they explore the intellectual and financial contributions of participants in IB research, nor understand the moral implications of the acquisition of property as these are taken for granted. I assume that such failures have already made many immoral acquisitions of developed nations. To overcome such a morally troubling situation each IB research project requires closer investigation.

In highlighting the essential contributions of research participants, Schaefer, Emanuel and Wertheimer claim that,

Clinical investigators, research institutions and funding agencies were indispensable to the past century's medical advances. Equally important were the millions of individuals who agreed to participate in the research that proved the effectiveness of the interventions that worked and no less importantly, the ineffectiveness of those that did not (2009, p.68).

In contrast, the argument I have been developing in this thesis is that it is unjust if we do not give host nations and research participants a share of the patent rights which would allow them to extract benefits in the form of royalty *rights*. Instead of supporting the property rights that the developing nations deserve, other researchers propose gifts or donations. Since what I have been arguing, this appears insufficient and undermines universal human rights and human dignity. It is the contribution of research participants which enables new treatment to be brought to market. It is unjust for only drug companies to receive the patent rights for marketing the drug, because research

participants have made an extremely positive contribution towards the development of a new drug or kind of medical intervention.

It is crucial to this argument to recognise that the contributions made by the participants in IB research are completely different from the contributions made by selling goods in a shop or working in a drug manufacturing plant. Ethical approaches that seek to make participants' contributions to clinical research equivalent to these other types of contributions are focusing on the largely morally less relevant issues of the kinds of broad social and economic disadvantages common to developing nations.

If the benefits are to be distributed fairly, that is, according to the actual nature of the contribution made by research participants, we need to focus on morally significant factors. In this case, the morally significant factor is their *contribution* by participating and bearing much of the burden of the research. Participants have not only offered access to their body, but they have also often improved the product by contributing to public health knowledge. This involves a range of intellectual activities that deserve proper recognition in the form of the awarding of intellectual property rights: i.e., patent rights. For example, participants are required to recognise, memorise, and sometimes reflect upon and retrieve data which are essential for knowledge development. For example, suppose V is a vaccine developed by scientists from the developed nation D, but suppose that there are not enough participants available in D to properly test this vaccine. The cost of a clinical trial is also a reasonable concern for the pharmaceutical companies' nation D. Suppose that pharmaceutical company P then took the challenge

for testing the vaccine V in a developing nation B, and that P reaches an agreement with the nation B for organizing the clinical trial. Consequently, participants are selected to test vaccine V. H (a,,b,c,d,e,fx,y,z) are participants. These participants are from various educational backgrounds and have been suffering from a disease for a certain period. It is the condition for the participants that they must correctly report their experiences and feelings while involved in this trial. Based on their statements, the research team will then arrive at conclusions about the efficacy of the vaccine V. And the experiences of the participants may give new directions and clues to improve the vaccine V. There might also be other complex issues that can be solved from the statements of the trial participants. These intellectual contributions, along with other contributions to research, help to ground claim that all present frameworks of international biomedical research are unfair and distribute benefits disproportionately."

There are a number of examples of collaborative research studies targeting various health issues in this regard. Consider the following examples⁶⁰ of collaborative international clinical trials which have been completed. The clinical trials conducted in Bangladesh (then East Pakistan) for developing Oral Rehydration Saline during the 1970s; "Evaluating the Safety of and Immune Response to an HIV Vaccine in healthy, HIV-Uninfected Adults in Uganda (VRC-HIVDNA009-00-VP)", "Protocol and methods for testing the efficacy of well-being therapy in chronic migraine patients: a randomized controlled trial", "Evaluating the safety, tolerability, pharmacokinetics and efficacy of clofazimine in cryptosporidiosis (CRYPTOFAZ): study protocol for a randomized controlled trial". All participants in these trials were standardly asked to provide

⁶⁰ 1. <https://clinicaltrials.gov/ct2/show/NCT01549509>,

2. Nachipo et al. Trials (2018) 19:456 <https://doi.org/10.1186/s13063-018-2846-6>,

3. Mansueto et al. Trials (2018) 19:561 <https://doi.org/10.1186/s13063-018-2944-5>

biological samples such as sputum, blood, or urine samples (often referred to as 'bioresource') before and after the interventions or drugs were administered. And typically, participants in these trials were asked to maintain a diary, record systemic observable reactions, monitor their body temperature on daily basis and sometimes records their reactions for 7 days after the drug is injected each time. In doing so, participants are required to employ their cognitive processes, to memorize, retrieve, reflect upon, articulate, and to report these observations to the researchers. These information and data help researcher and scientific community to execute the meta-analysis of the drug or intervention to reach a decision about any drug or intervention's final outcome.

Generally, mixing of one's labour with something deserves moral consideration. If contributions are not acknowledged in the distribution of benefits, this is unjust. The acknowledgement of all contributions will pave the way to bring fairness in IB research. Host nations should be given their due return in the form of a share of property rights (patent rights) and be allowed to claim benefits extracted from the drug. I would like to add with Resnik that without the contribution of research participants and host nations a drug remains a hypothesis. Therefore, they deserve benefits for their contributions.

3.5 Conclusion

An acceptance of the moral ground of benefits sharing in IB research entails a responsibility to consider further ways in which we can overcome unfairness in the distribution of the financial benefits of IB research. I have argued that providing one-off payments without provision for long-term royalty sharing seems to cause an imbalance between knowledge-sharing and financial benefits-sharing. This means that the failure to give royalty rights to host nations when sponsors from developed nations use their personnel, co-researchers and infrastructure is unfair. Personnel from host nations contribute their knowledge and understanding when conducting trials and sometimes analysing data, which is a significant intellectual contribution towards innovation. Therefore, the results of the research should be considered as the outcome of such collaborative work. Consequently, the IP rights of such research should be treated like joint ownership. In this case, it is important to establish the contributions of each party for the fair distribution of benefits. I would like to emphasise that the initial *idea* articulated by researchers and *the final idea produced* through a collaborative clinical trial process are significantly different and should be considered when distributing property rights.

To promote justice as fairness in IB research we need to affirm that the contributions of both parties, i.e., host nation and sponsoring, should be the basis of sharing benefits. In this respect, I argue that developing nations deserve better moral recognition of their contribution and have the right to claim a portion of the benefits of IB research by receiving a portion of the patent rights which would allow them to receive royalties for

their contributions. Additionally, research subjects are entitled to enjoy the benefits of the trials to which they have contributed so much through the awarding of a share in the patent rights that result from the clinical trials both in the successful and unsuccessful trials.

Chapter Four

The Moral Justification of Benefit Sharing Approaches- A Critique

4.1 Introduction

In the previous chapter, I argued that sharing IP rights to post-trial products with host nations of clinical trials would contribute to a more just distribution of international biomedical (IB) research benefits. In this regard, a counter argument could be developed that benefit sharing through IP rights is actually incompatible with the conception of economic liberty advanced by John Locke, whose notion of property rights has been used as the basis of my claim. According to this counter-argument, because people's liberty allows them to freely choose to trade their labour for whatever benefit package (salary, accommodation) they are happy to accept in return, participants should be given IP rights if participants manage to successfully bargain for such rights in individual cases, though it is up to participants whether they take advantage of such right or accept other forms of benefit in return for their contribution.

The concept of liberty implies freedom of choice. The question is, without giving all available options, including IP rights to the participant in a clinical trial, it might be argued that through other means, such as one-off payments, compulsory licensing, infrastructure charge, drug sharing, differential pricing, etcetera, we can avoid

complaints of injustice and can claim fairness in distribution of benefits and burdens. Is it morally more reasonable if host nations' rights to claim post-trial benefits of a collaborative clinical trial via IP are met in an alternative way, for example, through some types of one-off/lump-sum benefits prior to determining the contribution by the host nation and potentially concealing the potential possible profits to be made through marketing the product? Or is the obligation to host nations fulfilled by sponsoring nations if for example, given the unaffordability of drugs for the global poor, a "differential pricing system" is exercised as means to give benefits by making those drugs cheaper for developing country host nations and their citizens? Some bioethics researchers such as, Annas and Grodin (1998, p. 561) argued for making drugs reasonably available to the host community after the completion of a successful trial. If host nations were being told that there is a possibility that the TRIPS will replace existing law and will impose barriers to further access to medicine by increasing the price of drugs, even when those drugs are produced through their contribution, then how could developing nations justifiably be expected to reconsider a lump-sum or one-off payment for their participation in the research? The intention of the new economic order under the TRIPS Agreement is morally questionable, as it suddenly distributes unequal burdens to the shoulder of developing nations (Pogge, 2002). After extracting huge benefits from previous IB research, developed nations have introduced the binding agreement the TRIPS to ensure that they can unilaterally extract benefits in the future. For example, during the middle east war in Kuwait oral rehydration saline is sold at a high price to the US army. Bangladesh as a contributor to the successful development of this ORS did not ever receive any benefits from it subsequent to this development.

Should developing nations morally deserve a similar binding benefit-sharing treaty like the TRIPS, as this has been argued by Andanda et. al. (2013) to secure benefits of IB research if reciprocity, and equality are taken into consideration?

Similar to the TRIPS, the sharing of health-related information and pathogens that might potentially be relevant to threats to public health are part of the mandatory obligations to all 196 countries and all member states of WHO, as they all agreed to the International Health Regulation (IHR) 2005 agreement (WHO, 2016). All countries were required by the IHR to comply with the requirement to develop essential capacities of public health events detection, assessment and reporting by 2012. Nevertheless, only one third of the countries (64 countries) were able to comply with this requirement by 2014.

Developed nations argue for the sharing of such information for reasons such as securing the public health interests of global people, considering the global nature of diseases and the threats associated with such diseases. This sounds morally reasonable. However, there is currently no equivalent moral or legal obligation to share information as part of benefit sharing agreements with developing nations in the context of international collaborative research (Sedyaningish et al., 2008). Such a condition keeps open the door of injustice and exploitation. Therefore, I proposed IP sharing for securing benefits for low and middle-income countries (LMIC) engaged in IB research.

To be sure, it is often the case that some researchers themselves do not receive IP rights for their contribution to the development of new treatments or technology. Instead of claiming IP rights, many researchers trade their labour and expertise for salary or for a benefits package. It might be objected that there is no good reason for research participants to expect IP rights, because they do not know that their labour has contributed to the development of innovative treatments. If participants freely trade their labour for an agreed benefit, establishing a legal regime whereby the benefit available is IP rights, this might be thought to be an unjustified restriction on their liberty. From this perspective, other methods of benefit sharing, such as- access to successful interventions after the completion of the trial through drug donation, or infrastructure charges for capacity building might be regarded as preferable. In this chapter, I respond to these criticisms and objections in the light of benefit sharing models available in the bioethics literature and the notion of justice that they instantiate are based on reciprocity or distribution of benefits proportionate to burdens. First, I explore the concept of benefit sharing in international biomedical (IB) research as a means of ensuring the just distribution of its benefits and burdens. This does not seem entirely morally unjustifiable if the current pattern of benefits sharing remain in operation as part of historical injustice or compensation. However, IP sharing is a more morally defensible option to ensure fairness in IB research.

4.2 Meanings of Benefit Sharing

Bioethics researchers and others from around the world have proposed several frameworks for the fair distribution of the benefits of international clinical research, virus/information sharing and invented products as a means of respecting global health rights and avoiding the exploitation of host populations. In IB research, the term benefit sharing is commonly viewed as a way of compensating a developing nation's research participants and research communities for their time off and for any harm that occurs due to their participation in the research, whereas in genetic research, benefit sharing is often viewed as notion of solidarity to include everyone (Dauda and Dierickx, 2013). As a member of the human species, everyone shares the same genetic makeup. The following section focuses on how benefit sharing has been interpreted as a means of promoting justice in IB research.

A principle of "Benefit Sharing" was adopted in the Convention on Biological Diversity (CBD) in 1992 at the Earth Summit in Rio de Janeiro, Brazil (CBD, 1992, accessed on September 2015, Schroeder and Pogge, 2009, Hartle and Weisbaum, 2010, p. 5). Ever since, "Benefit Sharing" is a hotly debated topic in bioethics, international law, political philosophy, and economy (Schroeder, 2007, Dauda and Dierickx, 2013). For example, Macklin (2004,2012) argues that the poor people of developing nations bear disproportionate risks and burdens as health research participants of international collaborative research "without any provision [for] enjoying the long-lasting benefits

[that] may results from such research” (Macklin, 2004, p.71)”. Similarly, the Declaration of Cordoba (2008) has acknowledged that the absence of firm post study obligations for benefit sharing can negatively affect the rights and wellbeing of research participants in clinical trials (Garrafa, Solbakk, Vidal and Lorenzo, 2010). Such justice-based concerns have received much attention in the research ethics literature, without there being a definition of benefit sharing which is specific enough and can be used universally without confusion. Nonetheless, benefit sharing has been considered a crucial aspect of distributive justice in international clinical research, which Schroeder (2007, p.208), for example, has defined in the following way in the context of genetic research:

Benefit sharing is the action of giving a portion of advantages/profits derived from the use of genetic resources to the resources providers to achieve justice in exchange, with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services without providing unethical inducements.

This definition regards benefit sharing as being a consequence of some previous action. Typically, in international clinical research, participation is required to gain benefits. This participation, in the first place, often results in innovation that advances public health knowledge. Secondly, participation in research also contributes to making profits from marketing the resultant products/new drugs if the trial is successful. If other researchers want to use such knowledge once it is published, they are expected to reference the source of the information in order to avoid charges of fraud or plagiarism. In many cases, participants in clinical trials contribute to innovation in unique and original ways (e.g., the invention of oral saline for the treatment of Diarrhoea, as discussed later in the chapter). The host country’s research participants assist in meeting the quest of

scientists by taking the burden of testing the investigational drug. Prior to the role played by participants in clinical trials, researchers, community workers, business groups, civil societies, and political agents also play a role in this testing process. For example, they may identify the therapeutic significance of the traditional knowledge of a particular community, such as the medicinal properties of the Neem tree which was known to many Bangladeshi and Indian communities. Even patients who have suffered from the H1N1 virus or Ebola virus can have important roles in the development of a new drug for that disease. Schroeder argues that the derived advantage or profit should be shared among stakeholders who have contributed to the process of drug development. It seems to me that this notion of benefit sharing is based on both principles of compensation and of reciprocity. On this model of benefit-sharing, participants are compensated for their sufferings and are provided with some other benefits (access to new drugs, diagnostic technologies etc.) for their involvements, and the host nation benefits as a result of their contribution.

However, critics may argue that post-trial benefit sharing is problematic as post-study benefits such as successful interventions often take a long time to become apparent and may be of uncertain value. As a result, some critics argue for the provision of some other type of benefits to the research participants of the host country other than access to interventions. For example, considering the disadvantaged conditions of research participants in LMIC, Ballantyne (2010) argues for levying an infrastructure charge as a threshold benefit in the form of a global tax on research conducted internationally (p. 31). However, if we accept the above definition of benefit sharing, it is not possible to

distribute benefits/profits justly without having a reasonable idea of the value of post study results. In this regard, I agree with the spirit of Schroeder's conception of 'benefit sharing' and thus recommend her definition of benefit sharing as a basis of justice if 'benefit sharing' is to be implemented. However, she based her definition of benefit sharing on sharing resources of a material kind. I would like to extend the scope of the definition to include detailed sphere of international clinical trials/research. In an international collaborative setting, a clinical trial can provide a reliable drug or technology for future use that is sometimes developed with the assistance of participants' contribution which may include bio resources or intellectual contribution. In this process, the host nation provides material resources and makes financial contributions as well. These unique contributions of developing nations deserve moral consideration because of the way in which they add value to the original product or process. A new drug or technology is developed following the prescribed process as I mentioned above. Later, it is patented in host nations' patent office. Then drugs are manufactured and sold in the market for profit.

The developed nation's pharmaceutical company contributes by purchasing patent rights from the researcher. This is undoubtedly a large monetary contribution of the pharmaceutical company. Then they hire clinical trial doctors and nurses, and technicians to form the team. They also contact their foreign office and overseas counterpart. On the other hand, the developing nations also contribute providing doctors, nurses, and other experts beside money for physical facilities. At this stage, the developing nation's resource persons may make intellectual contributions to the process

of developing a successful intervention. For example, along with the American doctors involved in Cholera research in Bangladesh, local doctors also made intellectual contributions to this research. Dr. James Taylor asked a local investigator, Dr. Rafiqul Islam, to write a short protocol for oral therapy when treating cholera patients, and this has come to be known as the Chittagong protocol. Dr. David Nalin was assigned to supervise Dr. Islam's protocol. The result of the Chittagong protocol was also analysed by Dr. Nalin who reported that "he realized precisely what went wrong with the Chittagong study and understood that if the dosage of the therapy corresponded to intake and output measurements then it would be "a sure success" (quoted in Ruxin, 1994, p. 382). Subsequently, Dr. Nalin developed the second protocol which was successful in treating cholera and diarrheal diseases. Initially, Dr. Islam and his local colleagues were disregarded as co-authors of Nalin's Protocol, though this was later rectified (Ruxin, 1994, P.382). In this regard, "benefit sharing" involved sharing IP rights with all intellectual contributors to the development process of a drug/intervention. Although, the research team acknowledged the intellectual contribution of Bangladesh team but sharing patent rights as recognition of the intellectual contribution of participants in the process of innovation remained a possibility. The aims of IB research could be achieved if there were a condition that Bangladesh will have right to claim IP, then Bangladesh could secure continued benefits from such valuable contribution.

In IB research, benefit sharing is agreed by most bioethicists to be an ethical obligation of sponsoring nations or pharmaceutical companies, and this is acknowledged in different international frameworks (e.g., CIOMS, 2002, revised in 2016). However, this

moral obligation has typically been undermined or neglected by most pharmaceutical companies and sponsors of the research for decades both at local and global levels. Pharmaceutical companies often try to close the chapter by providing one-off payments to developing nations' researchers or research participants during the clinical trial in order to meet what they take to be their international obligations. One of the reasons for adopting the one-off payments approach to benefit sharing is that people have rights to freely bargain and fix the benefit amount without waiting for future benefits. As was mentioned above, however, critical examination is required to identify the consequences of accepting a salary package deal when there is unequal bargaining power. Critics may argue that in contemporary research settings intellectual property is typically disregarded by researchers in preference for a salary package for their contribution. Nevertheless, researchers are often allowed to also claim a share of IP rights along with salary package. Furthermore, there are cases where equal bargaining potential of host nations may exist. In such cases, the idea of sharing IP may seem to involve forced IP sharing which could be regarded by some as morally unacceptable. I just want to note here that IP sharing is a morally reasonable way of sharing benefits of IB research as this benefit sharing is based on contribution rather than needs. However, the host country of research can freely decide what or how the IP rights will be used once they receive it. It is merely a possibility that there might ever exist equal bargaining potential within developed nations and among the LMIC, where the LMIC would be able to get fair share through bargaining, unless the world community stands beside the LMIC for their social structure improvement and capacity development.

For benefit sharing, considering the role of developing nations in IB research and their capacity for meeting their health needs, a concerned community of researchers is developed at international level based on reciprocity and compensation overriding national boundary. For example, nation A accepts a package offer as recognition of its contribution to developing drug X from nation E. X is a very important drug for developed nation E. On the other hand, A also needs drug X. So, nation A can buy the IP (patent rights) by paying a royalty to E for X. This is a reciprocal relationship of compensation that is applied mostly in social transactions. My question is whether such arrangements have enough potential for ensuring global justice?

Rather, in this chapter, I discuss in further detail the limitations of some of the benefit sharing approaches which have been recommended by international ethical guidelines. In addition, I argue that recognition of the contributions of local participants through conferral of intellectual property rights is a necessary condition for these approaches to be able to ensure the just distribution of the benefits of international biomedical research. Next, I explore the concept of reciprocity as a principle for achieving justice which has been recommended for benefit sharing.

4.3 The Reciprocity Principle Approach to Benefit Sharing

According to reciprocity-based notions of justice, if anyone contributes something novel for the community or nation then they at least deserve some form of recognition for their

contribution in return (Dauda and Dierickx, 2013, p.4; Zong, 2008). Post-trial benefit sharing based on the principle of reciprocity is proposed in various international ethical guidelines as a means of ensuring the just distribution of the benefits and burdens of international biomedical (IB) research. For example, in 2002, CIOMS adopted the reasonable availability (RA) requirement⁶¹ in accord with the principle of reciprocity to address justice-based concerns. To understand how the principle of reciprocity operates in meeting post-trial benefit sharing obligations, I briefly outline the background of IB research conducted in developing nations below.

Most IB research carried out in low or middle-income countries is funded by developed nations or by the multinational pharmaceutical companies of developed nations. Petryna (2007) claims that 40% of the 50,000 international clinical trials undertaken worldwide were conducted in low or middle-income countries. According to Lavery (2008), it is common for researchers from developed nations to collaborate with researchers from developing nations, but the fruits of the research are enjoyed mostly by the developed

⁶¹ The idea of reasonable availability attracted serious criticisms (London, 2005, p.25). Therefore, in 2016 CIOMS updated their framework and revised guidelines removing reasonable availability. They have rewritten the guideline in the following way:

“As part of their obligation, sponsors, and researchers must also: make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity. In some cases, in order to ensure an overall fair distribution of the benefits and burdens of the research, additional benefits such as investments in the local health infrastructure should be provided to the population or community; and f consult with and engage communities in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders.”

They have adopted best parts of other approaches to make it more acceptable framework of IB research. Alex London, an advocate of Human Development approach joined in the CIOMS team and played a role to remove reasonable availability requirement. However, it seems to me such change has no value unless it is mandatory as compulsory the TRIPS. I have discussed the RA as this has played a key role in the past 25 years.

nations (p. 698). In addition, Glickman et al. (2009) found that from 1995 to 2005, the USA sponsored 509 clinical trials, with one-third of them conducted in low or middle-income countries, even though none of these trials were designed to address diseases that predominantly affect the health of these less developed countries. This has raised concerns among moral philosophers over the exploitation of host populations. Some of these studies are referred to as “parachute”, or briefcase or helicopter⁶² research by these moral philosophers as the studies do not usually contribute much value to the countries hosting such research (Emanuel, 2008, p. 719; Lavery, 2008, p. 699).

Moreover, there is a general complaint in the bioethics literature that researchers from developed nations exploit both research participants and host countries researchers (Macklin, 2004; Sova, 2007). I agree that it is unjust that most of the burdens of such research is borne by the research participants from low or middle-income countries. From this perspective, exploitation can be avoided by providing research participants with access to successful interventions after the completion of clinical trials as a means of acknowledging the contributions of the host country (Annas and Grodin, 1998). The advocates of the reasonable availability requirement argue that one way of ensuring fairness in the clinical trial process is by following standard ethical guidelines - e.g., providing participants with access to the successful interventions has been regarded as an appropriate way of providing benefits to research participants and communities of the host country. The following sections deal further with the notion of reciprocity

⁶² The main focus of such research is to conduct research for obtaining data without any concerns for sharing benefits of such research with the research participants or research community (Emanuel, 2008 p. 719).

applied in the reasonable availability approach and acknowledged in various international ethical guidelines for conducting research in low or middle-income communities or countries, as reciprocity, in my opinion, is a very influential justice principle and has been used to develop social structure.

In 1993, the reasonable availability requirement appeared in the commentary to guideline 8 and was emphasised again in the commentary to guideline 15 in the CIOMS guidelines for the ethical conduct research involving human participants. In the commentary it states,

“If the knowledge gained from the research in a such a country is used primarily for the benefit of populations that can afford the tested product, the research may rightly be characterized as exploitative and, therefore, unethical...In general, if there is good reason to believe that a product developed or knowledge generated by research is unlikely to be reasonably available to, or applied to the benefit of, the population of a proposed host country or community after the conclusion of the research, it is unethical to conduct the research in that country or community(CIOMS, 1993).”

In 2002, this commentary was included as a guideline. According to the 2002 revision of the CIOMS guideline 10,

Before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that...any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community.

In 2016, the CIOMS revised their guidelines. In these guidelines the CIOMS has argued that IB research must be responsive to host nations health needs following the spirit of human development approach. For example, in 2016 Guideline 2 CIOMS states,

Before instituting a plan to undertake research in a population or community in low-resource settings, the sponsor, researchers, and relevant public health authority must ensure that the research is responsive to the health needs or priorities of the communities or populations where the research will be conducted.

The CIOMS Guidelines 2 further states,

“As part of their obligation, sponsors, and researchers must also: make every effort, in cooperation with government and other relevant stakeholders, to make available as soon as possible any intervention or product developed, and knowledge generated, for the population or community in which the research is carried out, and to assist in building local research capacity. In some cases, in order to ensure an overall fair distribution of the benefits and burdens of the research, additional benefits such as investments in the local health infrastructure should be provided to the population or community; and consult[ation] with and engage communities in making plans for any intervention or product developed available, including the responsibilities of all relevant stakeholders (CIOMS, 2016, p.3).”

The UNAIDS⁶³ document on *Ethical Considerations in HIV Preventive Vaccine research* adopts similar guidelines to CIOMS’ reasonably available requirement as a basic requirement:

Any HIV preventive vaccine demonstrated to be safe and effective, as well as other knowledge and benefits resulting from HIV vaccine research, should be made available as soon as possible to all participants in the trials in which it was tested, as well as to other populations at high risk of HIV infection (UNAIDS, 2000).

In addition, the reasonable availability requirement is also supported by the Nuffield Council on Bioethics (Nuffield Council) of the United Kingdom. The Nuffield Council acknowledged post-trial benefit sharing as an obligation and also suggests that research participants should have access to beneficial treatments continually after the conclusion of a trial. The Nuffield Council also recommends that before conducting research, the authorities, associate researchers and sponsors should identify potential harmful outcomes of the research. Further, if research is carried out in an underdeveloped or developing country, both parties should agree upon the monitoring of unforeseen harmful outcomes for a period of time after the completion of trial.

⁶³ Joint United nations Programme on HIV/AIDS (UNAIDS), *Ethical Considerations in HIV Preventive Vaccine research*, Geneva, Switzerland, UNAIDS, 2000.

The United States' National Bioethics Advisory Commission's (NBAC) Executive Director stated that,

if the intervention being tested is not likely to be affordable in the host country or if the health care infrastructure cannot support its proper distribution and use, it is unethical to ask persons in that country to participate in research, since they will not enjoy any of its potential benefits (Shapiro and Meslin⁶⁴, 2001).

Moreover, both the Nuffield Council on Bioethics and the National Bioethics Advisory Commission (NBAC) require justification for the arrangement of availability of successful research outcomes to the host country. That is an explanation of how the successful outcomes of the research will be made available is required in the research proposal submitted for ethics approval to both authorities. However, a justification is also required, if the research outcome will not be made available to the research participants or host communities after the conclusion of the research.

Similarly, in 2000, the World Medical Association (WMA) embraced post-trial benefit sharing obligations in the Declaration of Helsinki. According to paragraph 30 of the Declaration,

At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study" (WMA, 2001, p.374, also cited in Lavery, 2008 p. 698).

The 2008 revisions of the Helsinki Declaration states that,

"At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits" (WMA, 2008, Section, 33).

⁶⁴ Shapiro H.T, Meslin E.M.2001. Ethical issues in the design and conduct of clinical trials in developing countries, *New England Journal of Medicine*, 345: 139-42.

Furthermore, in 2013 revisions of the Declaration of Helsinki declare that,

In advance of a clinical trial, sponsors, researchers, and host country governments should make provisions for post-trial access for all the participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process (WMA, 2013, section 34).

The Declaration of Helsinki has gone through more revisions of these requirements, and there has been numerous criticisms of each of these. However, the obligation of post-trial benefit sharing with host countries has been retained in successive versions of the Declaration. The Declaration takes the view that achieving justice requires fulfilling the post-trial benefit sharing agreed to by sponsors, researchers along with the host nation's governments of IB research.

Thus, we can see that the reasonable availability requirement has been taken as a *necessary* condition for avoiding exploitation to conduct research in the developing countries. Also, the reasonable availability approach recognises that research participants and the host country of clinical trials deserve to be acknowledged in the distribution of benefits for their valuable contribution, as they are partners in the drug development process.

Post-trial benefits sharing is taken to be a moral obligation on sponsors of the research. However, fulfilment of the reasonable availability requirement in various ethical guidelines at international levels is not obligatory/mandatory for sponsors conducting ethical research. Therefore, the reasonable availability requirement as ethical guidance,

at least as it currently stands does not guarantee benefits for the host country. Therefore, it can be said that the reasonable availability requirement seems to be an insufficient solution for a moral claim and fails to acknowledge that countries may reasonably differ on what they regard as a just distribution of benefits. In order to address exploitation claims, the reasonable availability requirement is also now supported by most ethical guidelines for conducting biomedical research in international settings. Whether such frameworks can ensure justice effectively in benefit sharing of IB research is a critical question. The next section investigates the reasonable availability requirement further.

4.4 Can Reasonable Availability Address Justice Adequately?

The reasonable availability requirement has attracted some serious criticisms for not sufficiently avoiding exploitation by ensuring the just distribution of the benefits and burdens of clinical trials (London, 2005). For example, Emanuel (2008) argues that the reasonable availability requirement implies that the host country be provided with a successful intervention from every single clinical trial, yet it is not certain that a product will be developed from every single trial (see also Hawking and Emanuel, 2008, p.10). To develop a drug or intervention usually requires several trials as a successful drug may require further research to assess the reliability of trial results. Thus, how the fruits of the trial should be distributed to the participants of the research in a single trial is not clear. Therefore, the reasonable availability requirement seems problematic for implementation as this framework of benefit sharing is unable to capture the complex

nature of biomedical research. Besides, Phase I and II trials have more often than not been unable to produce any successful intervention that can later be made available to the participants' community. As reasonable availability offers only successful drugs or other interventions for benefit sharing, it fails to consider how other benefits accrue from such research. If a trial X generates Y benefits, how should they be distributed among Z (a,b,c,..., a, b, c are stakeholders and participants of the trial X)? There is no suggestion anywhere for that. Further, not every research participant may even need the successful intervention at the end of a trial. Hence, the reasonable availability requirement seems to adopt an overly narrow conception of benefits when considering distributing the fruits of such research. Therefore, For Emanuel, this approach is inadequate for achieving justice in IB research (Emanuel, 2008).

I agree with this criticism and argue further that there must be a requirement to consult with host nation governments, communities and participants to understand what is beneficial for them and whether their concept of benefit is relevant and is feasible to deliver. Accordingly, a framework should be developed to distribute such benefits. As justice in IB research also implies that providing information about burdens and benefits to all involved parties is necessary for developing protocols for a collaborative research.

At this point, critics may argue that there is evidence that when such consultations are organised, in many cases the research participants do not join in or may not join in the discussion. In this regard, I would like to argue that all participants should have the

opportunity to join the consultation meetings. Although many participants might not end up joining in the consultation, at least those who are interested may join in and could thereby contribute to the process of benefit sharing protocol development. That ultimately helps to achieve a distribution of benefits and enhances the transparency of decision-making processes, as a shared decision legitimises the final arrangements and protocols. Failing to implement such consultation process contributes to building mistrust between parties, as was the case with Indonesian Avian Influenza virus sharing. When or how the Australian private vaccine development company CSL gained access to the H1N1 virus specimens was a surprise for Indonesian researchers and government authorities. Prior discussion or permission was not sought from Indonesia, and CSL was not part of the network of WHO Reference Laboratories for virus sharing information. I discuss the Indonesian Avian Influenza virus sharing case in more detail in the following chapter.

To overcome the problem raised by Emanuel, I suggest that participants should be recognised at each stage of clinical trial for their contributions, whether or not a particular host individual group says that this matters to them. Finally, when a successful drug is derived, recognising all participants' contribution through sharing IP rights can help to ensure justice.

Secondly, the wording of the guideline 2 of the CIOMS is vague. For example, it offers to share the proven effective intervention or product and knowledge generated from

such research. However, this wording is not specific about whether the knowledge sharing means publishing data or translating data to local languages, or to giving access to data for participating nations (CIOMS, 2016). The word “or” in Section 33 allows the research sponsor community to be flexible in sharing benefits (WMA, 2008). If a research sponsor wants to share knowledge but a host community does not have sufficient infrastructure and resources to make use of such knowledge, such benefit sharing can mean very little for the host community. Consequently, such benefit sharing may pose more risks to the host communities.

Furthermore, the CIOMS framework, which is also known as a reasonable availability approach, includes the entire community or population of the host country as recipients of benefits, which seems to be a wide group when considering the sharing of benefits (CIOMS, 2002, 2016, HUGOEC, 2000). Given that not all of the members of such wide groups would have made any direct contribution to the research, and so did not bear any of the burden during clinical trial, it might be wondered how we can justify their stake in benefit sharing? The CIOMS framework, according to which the whole country or population should receive the benefits while a particular community took the burden of the research is often taken to be justified on the ground that the allocation of host nations’ resources come from one common budget. I also elsewhere argued that governments of a nation are responsible for access to essential medicine as part of their duty to respect global health rights. Therefore, the whole nation could be thought to be a part of an IB research benefit-sharing scheme.

I disagree with the above view because the sponsoring country or population of research can access the drug or intervention in various social systems. In most developed nations, the price of a new intervention is controlled by the governments through cap pricing (i.e. the TGA in Australia) and it is incorporated into the public health care system for the use of wider community (Zong, 2008, Lexchin, 2006). Further, Greenwood claims that except for some expensive interventions, most new beneficial interventions would be provided to all for free in case the new ones are not introduced in the healthcare system (Quoted in Zong, 2008, P. 188). Subsequently, people of developed nations can enjoy the benefit of clinical research. If people in the research sponsor's country can access the product, then the host countries people should also get access to the product. However, such price control systems are generally absent in developing nations and so a system should be developed to ensure availability of the drug at a subsidised rate or free access to the product for direct participant community. Usually, states act to protect their citizens from potential harm and set up institutions and programmes that are designed to assist citizens to flourish by meeting basic needs, offering educational and job opportunities, and so on. Citizens also have some responsibilities to share some forms of benefit with the state as reciprocity operates between state and individual. Furthermore, Zong (2008) argues that most research participants in developing nations lack knowledge of science in general and clinical research more specifically. This means that potential research participants generally do not have the ability to engage effectively when negotiating post-trial benefits such as access to successful interventions (p. 188).

Justice requires that the benefits of clinical research should be distributed among involved parties equitably. Therefore, let us imagine roughly what each involved party (sponsor & host) will receive from a successful research outcome. Sponsors receive patent rights if new drugs, devices, or diagnostics are being tested, and these rights extend for 20 years as well as data protection exclusivity for 5 years in the United States of America (USA) and 10 years for the European Union (EU) to prevent generic producers from exploiting the originators' data during these periods. Sponsors receive profit from selling the drug for 20 years which will help them to recoup the research and development cost and revenue for future research, though only if the intervention proves safe and effective and is successfully marketed. Further, sponsors sell licenses to others, with originators recognised for their contribution globally. On the other hand, the host nation of clinical trials, who are partners in the research collaboration often receive a nominal one-off payment or access to the intervention as discussed above. As this shows, sponsors receive the lion's share of research outcome, but, as I have argued, this should not be considered as just benefit sharing.

Some may argue that research participants receive ongoing health care during trials, which is a great benefit to them. But health care or other services received during trial is a type of benefit for research participants, it is not a benefit derived benefit from the research outcomes. As such, health care services provided during trials are part of the conduct of a research, and so should be considered as running costs of the research for the sponsor. Moreover, the host nation is deprived of international recognition if IP rights are not shared with them (although IP sharing might not always be the only way to

achieve recognition). However, the reasonable availability requirement extends the benefits not only to research participants but also includes communities and the population (Lavery, 2008 p. 698). Once the outcomes of research are known, the subsequent benefits should be distributed among involved parties who have helped during the process on the basis of each party's contribution.

In 2008, more than 300 bioethics scholars from Caribbean and Latin American countries met in Cordoba, Argentina for a Latin American and Caribbean Bioethics Network of UNESCO meeting. The Declaration of Cordoba - *About Ethics in Research involving Human Beings* - resulted from the meeting. From the intense discussion of the 2008 version of the Declaration of Helsinki bioethics scholars at that meeting acknowledged that the absence of firm post-study obligations for benefit sharing does not meet the requirements of justice stated in the Declaration. Subsequently, the Declaration of Cordoba stated that the absence of post-study obligations for those conducting or sponsoring research also disrespects research participants' integrity. The lack of firm post-study commitments intensifies social inequality and creates further concerns about the rights and wellbeing of participants in clinical trials (Garrafa, Solbakk, Vidal and Lorenzo, 2010). According to Garrafa et al. (2010), "it seems appropriate to say that today's international research ethics runs the risk of making research participants and populations in poor and low-income countries victims of alterable forms of vulnerability" (p. 502).

Moreover, the CIOMS guideline does not allow any early phase trials to be conducted in developing countries. Yet, the representatives of developing nations argue that CIOMS should not apply such limitations and restrictions (Emanuel, 2008). I agree with the representatives of developing nations that such restrictions on early phase trials will eventually encourage research communities in developed nations not to conduct research on neglected diseases. Because the limited samples and disease conditions in developed nations make it difficult to conduct research on such diseases. For instance, dengue fever or malaria or cholera can be examples of such research.

However, the CIOMS guideline of 2002 and 2016 is an achievement of the biomedical research ethics community. Once it was just a statement. The CIOMS admits that providing drugs/interventions which have resulted from the research being evaluated to the research participants and research community of the host country is an obligation of research sponsor. The CIOMS guideline also recognises the importance of avoiding exploitation in IB research through transferring benefits to collaborative host countries of research. I agree that if knowledge acquired from research is not going to address the host communities' people health needs, they will be deprived of the benefits of the research even though they carried the burden of the research.

I consider the cost of conducting trials as a running cost for the sponsor and after the completion of the trial, what they achieve should be considered as benefit. Thus, the post-trial products or knowledge should be considered as benefits for sharing.

Nevertheless, the limitations of the reasonable availability requirement have lead researchers to search for a more comprehensive and plausible approach for ensuring justice. Following this guideline, justice is based on the proportionate distribution of benefits that have been developed through IB research. Accordingly, the proportional notion of justice proposes that benefits should not be limited to the successful intervention only, but that a range of benefits should be included for just benefit sharing. Consequently, as a response to the limitations of the reasonable availability requirement, in 2001, a group of bioethicists attending a conference in Malawi on 'Ethical Aspects of Research in Developing Country' collectively known as 'the participants' proposed the fair benefits framework approach (2004). The following sections will examine the fair benefit framework critically, and will consider whether or not this framework has the potential to ensure more just distribution of the benefits of clinical research than a reasonable availability approach.

4.5 Fair Benefits Approach (FB)

I have discussed the strengths and limitations of the reasonable availability approach for the distribution of benefits in the previous sections of this chapter. In this section, I explore the fair benefit approach and I demonstrate how the idea of sharing IP can contribute to good governance (World Bank, 2002) in international biomedical research, as well as to ensuring more equitable access to post-study benefits for the host nations.

The proponents of the FB framework argue that the reasonable availability requirement cannot alone meet all requirements for distributing benefits and burdens justly. Their (FB) argument is based on a conception of benefit that is much broader than the reasonable availability approach accepts. In various ethical guidelines including CIOMS frameworks, avoiding exploitation, respecting the autonomous decisions of research participants, and sharing successful interventions reasonably were key aspects for promoting justice in international biomedical research protocols. The FB approach, on the other hand, urges the proportionate recognition of the contributions of the involved parties and emphasises the distribution of benefits accordingly. Proponents of this approach argue that benefit should be given based on the ratio of risks and burdens borne by the involved parties and their participating members. For ensuring justice in the distribution, proponents argued, if the risks and burdens are higher, then participants are entitled to claim and to receive higher benefits from the fruit/s of the research. These benefits may include new investment in collaborative health research, additional funding to increase the health-care capacities of host nations, or investment in healthcare infrastructure development and the development of healthcare facilities for future research opportunities that may contribute to sponsors satisfaction and expected future gains. In these ways, advocates of the FB approach have drawn attention to the different types of benefits [(Benefits to the Participants during the research, benefits to the Population during the research and benefits to the Population after the research) (Participants, 2002, p.2134)] that should be considered in the distribution of benefits and burdens. The kind of benefits that should be prioritised in such contexts is a crucial

issue that needs further elaboration and discussion. Then it might be wondered why I am advocating in this thesis for IP sharing in particular? I would like to mention here that the FB approach to benefit-sharing implicitly acknowledged the importance of IP sharing in their tenth (10) recommendation (see the table on page 157). This gives me a further opportunity to explore the sharing of IP. I will discuss this in later chapters.

Indeed, the FB approach has included, amongst the kinds of potential post-study benefits, the sharing of IP rights with participants or host communities of clinical trials. This would enable the host country of clinical trials to receive financial rewards from royalty sharing. However, the FB approach has not at all addressed *why* IP rights in particular should be shared with the host nation. My research in this thesis is designed to address this gap. But without a clear definition of the term 'benefit sharing' endeavours to redesign justice frameworks in IB research may yield injustices in different forms (see Schroeder, 2007).

Source 1: Principles and Benchmarks of the Fair Benefits Framework From (Emanuel J.E., 2008, in Emanuel, J. E, (eds.) p.725)

Principles	Benchmarks for determining whether the principle is Honored
Fair benefits	<ul style="list-style-type: none"> • Benefits to participants during the research <ol style="list-style-type: none"> 1. Health improvement: Health services that are essential to the conduct of the research that improve the health of the participants 2. Ancillary health services: Health services beyond those essential to the conduct of the research that are provided to the participants • Benefits to participants and population during research <ol style="list-style-type: none"> 1. Ancillary health services: Health services provided to the population 2. Public health measures: Additional public health measures provided to the population 3. Employment and economic activity: The provision of jobs for the local population that stimulate local economic activity • Benefits to population after the research <ol style="list-style-type: none"> 1. Availability of the intervention: Provision of the intervention if it is proved safe and defective 2. Capacity development: Improvements in the health-care infrastructure, training of health care and research personnel, and training of research personnel in research ethics 3. Public health measures: Additional public health measures provided to the population 4. Long -term collaboration: Development of additional research projects with the population 5. Financial rewards: Sharing of the financial rewards or intellectual property rights related to the intervention being evaluated
Collaborative Partnership	<ul style="list-style-type: none"> • Free, uncoerced decision making: The population is capable of making a free and uncoerced decision; it can refuse participation in the research • Population support: When it has understood the nature of the research trial, the risks and benefits to individual participants, and the benefits to the population, the population decides that it wants the research to proceed.
Transparency	<ul style="list-style-type: none"> • Central repository of benefits agreements: An independent body creates a publicly accessible repository of all formal and informal benefits agreements. • Community consultation: Forums with populations may be invited to participate in research, informing them about previous benefits agreements.

IB research is undoubtedly beneficial for the low or middle-income countries where access to medical services are poor and limited. During the research, receiving free health check-ups and experimental drugs, or being paid for their time or inconvenience as compensation for research participation may be perceived by the research sponsors, participant, and host community as sufficient sharing of benefits. I argue against this presumption, as while these do seem to be of some benefit to participants, these should be treated primarily as a part of the costs to sponsors of undertaking research or as falling short of what justice arguably requires to be provided – to participants/their governments.

It is only on completion of the research that its potential value becomes clearer, and so at this time what level and kind of post-study benefit-sharing is appropriate. In this regard, sharing IP rights can potentially achieve justice by allowing the host community to receive sustainable financial rewards longer-term. Then the host community can allocate such funds to fulfil their prioritised needs accordingly for the development of their health without fear of being treated in an undignified way. As the funds were gained from health research, it would be prudent to spend it for the improvement of health conditions or social determinant of health sector such as, education for awareness of maintaining better health.

The fair benefit framework and the reasonable availability approaches both seek to achieve justice in IB research through benefit sharing. While the reasonable availability

approach emphasises that the proven intervention is to be shared (changed in 2016 guidelines and asked for other forms of benefit sharing), the fair benefit approach extends to other forms of benefits that it argues also should be shared between research partners. In this regard, providing a proven intervention may be one way of transferring benefit to the host community, but this should not be the only way of transferring benefit in the research host community.

Proponents of the fair benefit approach realise that there is no guarantee that a proven intervention will result from every single trial. Therefore, the FB approach argues that the research collaborative partners (research sponsors, research community) should decide through negotiation what the appropriate level of benefit is for them. The idea of collaborative partnerships, as recommended by fair benefit approaches, promotes opportunities for discussion between involved parties. In contrast to the fair benefit approach, the reasonable availability requirement approach has no option for involving host communities of research in a discussion about benefit sharing. Therefore, it can be argued that the fair benefit approach, by involving host communities in such discussions better acknowledges the distribution of proportionate benefits towards achieving justice in international biomedical research (Dauda & Dierickx, 2013, p.4).

On the fair benefits approach to obtain the best possible benefit sharing protocols, each party needs to bargain. Bargaining situations provide an opportunity for listening to each other's' reasons for claiming benefits. This allows a process of negotiation between

involved parties. The host (usually a developing country) of the research is generally less powerful than the sponsor, which raises the risk that host countries would agree to an unfair deal as they may be unaware of the true value of the potential commercialisation of the research outcomes (Millum, 2012). To achieve fair proportionate benefits through negotiation needs reasonable (if not strong) negotiation capacities.

In this regard, any knowledge gaps of the involved parties, along with other disparities should be considered. Without provision of claim rights (i.e. IP rights), typically, negotiating parties tend to lack reasonable bargaining positions. Through the sharing of IP rights, the host nations can access these claim rights. Also, unless the negotiation capabilities of host nations are developed, a lack of meaningful autonomous decision making by the host country negotiators increases the chances of an unfair deal being agreed to. So, in general, deals worked out between countries based on preconceived notions of exactly what deal would be fair should not be regarded as morally acceptable. Countries should be allowed some scope to discuss their own deals. Failure to achieve meaningful autonomous decision promotes injustice and fails to duly respect persons. I discuss the implications of negotiation capacities and the importance of developing such skills in the following chapter 6. The next section of the present chapter briefly discusses the FB approach further.

According to Emanuel (2008), the fair benefits framework aims to ensure that benefits either from the research or from the fruits of the research accrue to the people who bear the risks or burdens of the research, and so is essential for the just distribution of these. These people may be participants or community members who bear the burdens and risks of the conduct of the research. The fair benefits framework also suggests that recipients of benefits may extend beyond those immediately involved in the study in question to include the relevant population who might be at risk of exploitation.

The fair benefits framework incorporates key considerations from existing human research ethics guidance: social or scientific value; scientific validity; fair selection of participants; favourable risks-benefits ratio; review approval or modification of the research proposal by an independent ethics review committee; respecting research participants by ensuring the protection of their well-being and privacy; and obtaining participant's informed and voluntary consent (Emanuel, Wendler & Grady, 2000). So, such a framework takes there to be many necessary conditions for justice in such research. No single condition is supposed to secure justice all by itself. In addition to these above seven conditions, the FB approach includes three more principles to ensure fair benefits for the people who bear the risks and burdens of the research. These three principles are: fair benefits, collaborative partnership and transparency. In the following section, I discuss and evaluate these three principles to assess whether they have potential to support my overall argument.

4.5. a. First Principle: Fair benefits

The fair benefits principle maintains that a fair level of benefits, which can be broader than just post-trial access to a successfully tested drug (and can include, for example, capacity building), is the key for ensuring the just distribution of the benefits and burdens of the research for research participants and host communities. Broadly speaking this principle takes into account three types of benefits. The first type is direct health benefits for research participant, such as, health check-ups and access to experimental drugs during the research, which may improve the wellbeing of participant.

The second type of benefits that may flow from the research are employment opportunities to the host community. For example, the sponsor of the research team may need some local personnel to assist with the research, which can be beneficial for the development of the local community.

The third type are outcome- related benefits, which accrue after the completion of the research. These include benefits such as the availability of the tested intervention to the host community, and potentially sharing of the intellectual property right with host nation (the Participants, 2004, Sova, 2007, Emanuel, 2008).

However, the fair benefits approach does not demand that *all* of these types of benefits are required to ensure a fair level of benefit sharing. These benefits can be for the participants or the host communities, or for both participants and the host communities. And the FB approach recommends that host community decide which of these is to apply in a particular case. Subsequently, the fair benefits approach emphasises the ratio of potential benefits and harms. That is, this approach holds that if the burdens imposed on research participants' increase, the benefits should increase proportionately, and if the benefits to sponsors' communities increase, the level of benefits for the host communities should also correspondingly increase (Emanuel, 2008). Linking sponsor and host community benefits in this way is helpful for determining how much of a share of IP should be given to the host nation.

In this regard, a question may arise as to why participants' communities, or others who are not participating directly in the trial, should receive such as IP benefits of a clinical trial, as the contributions are made only by participants. But I argue later, a clinical research is conducted with the assistance of the government, concerned health professionals, and the host community. They are part of the greater community. Furthermore, the state is responsible for access to medicines for its citizens. Since the host nation governments facilitate the clinical research, then a portion of the benefits can be distributed among the non-participants who may indirectly bear the burden: such as when a trial participant is injured or harmed, or dies due to the participation in a trial, his/or her family usually face the enormous psychological, social or financial burden of losing an earning member (and indeed, perhaps the only earning member) of the

family, which likely affects them greatly as a family, to the extent that they may lose the opportunity to flourish properly. At the same time, a state loses their human resource because a citizen of the state (no matter what their job) is still contributing to the economic development of the state. Similarly, trial participants are contributing to the economic and medical development of their nations. This is because from the successful testing in the clinical trial, the company is earning revenue, and from that revenue the nation earns tax. With that tax the nation is able to develop the community of the trial participants to develop the human resources of the nation. This is applicable to LMICs, as, when compared with more affluent countries, human resources in LMICs are not as developed and are less knowledgeable about the impact of social determinants of health on the capacity for human development. Companies and governments should walk hand in hand in developing the community of the participants, with the government acting as a watchdog to eliminate the chance of exploitation from direct development by the company."

There is evidence that in practice, the promise of such fair benefits to host communities sometimes remains a hollow commitment (Page, 2013, p.63)⁶⁵. Furthermore, FB advocates argue that negotiation depends on many factors. The FB approach argues for benefit sharing with the community. But according to Page (2013) this is also problematic as the term community implies the local community. For Page, there are cases where IB research is conducted in a refugee camp involving people who do not

⁶⁵ In 2000, several allegations were published in the *Washington Post* concerning post-trial benefits sought by Thailand to VaxGen. The VaxGen refused to admit their responsibility of doing harm as they committed to provide standard care. The VaxGen also committed to share benefits to the community. However, the VaxGen did not make available the vaccine. Thailand proposed that the drug can be made in a cheaper price if it is manufactured and packed in Thailand. However, the VaxGen rejected the proposal. So, the research in question failed to address the health needs of the host country.

belong to any existing local community at the time of clinical trial. For example, recently Muslim and Hindu people from Rakhine state of Myanmar have been living in Bangladesh in a refugee camp. If they are the participants in a clinical trial, then who should receive the benefits of the clinical research is a critical question to be answered. These limitations of FB approaches can be overcome if details of the participants are recorded properly to confer IP rights as benefit-sharing for the relevant parties, including those in a refugee camp, where applicable. Although they are standing in the border of Bangladesh-Myanmar, they are now part of the Bangladesh community and all supports for conducting research are provided by Bangladesh government. So, the benefit-sharing issue can be resolved accordingly because the Bangladeshi government would need to become involved in the process of conducting collaborative research. These are special cases to be treated in a different way from normal situations. Furthermore, the FB approach, like other present models of benefit-sharing, is non-binding and leaves the door open for research sponsors to refuse to share post-trial benefits. The IP sharing approach that I argue for in this thesis is morally superior to the FB approach, as the former has more potential to avoid exploitation of research participants/host communities and to ensure a more binding responsibility for sponsoring nations, compared with the FB approach.

4.5. b. Second Principle: Collaborative Partnership

The fair benefits framework assumes that host communities are best placed to determine which benefits are most appropriate for their circumstances. Collaborative

partnership between researchers and host communities can enhance mutual respect and can provide a basis for ensuring better health outcomes for all involved.

The fair benefits approach also insists that potential host populations should be free of any obligation to participate in research in the first place, in much the same way that individuals' involvement in clinical trials must not be unduly induced or forced, and must always include the option of withdrawing. However, the fair benefits approach admits that it can be difficult to identify representatives who can legitimately speak on behalf of the community. This is a problem not only for the fair benefits approach, though, as it is a common concern for community-based consultations in general. Nonetheless, this can complicate the process of determining a fair level of benefits for host communities. Generally, lay people agree or disagree about fairness based on their intuitions about such matters. This means that as Pogge (2002) points out, there are no universally agreed among lay people criteria for fairness given that individuals usually disagree about what a reasonable benefit might be.

4.5. c. Third Principle: Transparency

Transparency is very important because the benefits and burdens associated with a clinical trial should not be kept secret. Research projects that are 'semi-colonial' in nature, i.e., may not be transparent where the results of the research are focused, and other important issues are left overlooked, such as ownership of research (Costello & Zumla, 2000). The business groups may try to take advantage of such conditions and

conduct clinical trials in developing nations which may in such cases be a source of injustice.

Furthermore, to assess fair levels of benefits requires full information about the potential benefits and harms of a research trial, as well as the likely value to be derived from research outcomes. The fair benefits approach also suggests establishing an independent repository of benefits agreements operated by the World Health Organisation (WHO) in order to improve transparency and to act as a resource for host communities when negotiating agreements. However, while this seems like a worthwhile initiative this (WHO's proposal) may be criticised as modelling international clinical research on an ideal market situation, where all information is available and perfect competition exists among business organizations, to assess the fair level of benefits. Nevertheless, I believe that the importance of access to information is undeniable as has been acknowledged by the World Bank and good governance scholars (World bank, 2016, <http://www.worldbank.org/en/access-to-information/9/06/2018>). The governments of developing nations either intentionally conclude a protocol or their lack of understanding may lead to them concluding a research protocol that distributes benefits and harms unfairly. For example, a government of a developing nation may consider that remaining in power, even though elected by vote rigging, and complying with the demands of powerful nations like the USA, to be more important than the interests of the people. However, if there is a repository of benefits agreements, developing nations have an opportunity to negotiate

for a level of benefits comparable to the other similar agreements, which would contribute to the development of a standard of fairness internationally.

I would like to add to this requirement that if there is no independent body such as the WHO to host such a repository, conflicts of interest may not be resolved properly. Because the research sponsor is likely to be in a much stronger negotiating position than the potential host community, if any conflict of interest arises the weaker party may be vulnerable to exploitation if there is no mediator who is neutral. The neutral party may consider both parties' interests and may assess an equilibrium point for resolving the conflict. The existence of a neutral party may be helpful in reducing the chance of further exploitation of the weaker party. The following sections will evaluate the fair benefits approach further.

4.6 Critique of Fair Benefits Approach

The FB approach has generated some criticisms. According to London, "the FB approach accepts the status quo in the host community as the appropriate "normative baseline" against which proposed research initiatives are evaluated (London, 2005, p.27)." As all parties are not equal in their bargaining power, if the status quo is considered as a baseline for assessing research benefits, then both parties will try to secure net benefits for them. There is a better chance for strong parties to extract a share of benefits that is more favourable to them to weaker parties. In that case, weaker

parties are much more likely to bear the risks of a clinical trial without adequate compensation, while developing nations remain vulnerable to future exploitation. Researchers from developed countries can even explore their alternative plans to secure more benefits. If suitable benefits cannot be extracted, then the developed nation may shift the research venue elsewhere, or may plan to suspend the research for a particular period. The distribution of benefits in such cases would be disproportionate for the parties involved.

In addition, the fair benefits approach makes community consultation a requirement for determining the fairness of the distribution of benefits. The idea of engaging communities in the decision-making process is consistent with recent political discourses, and is viewed as an appropriate way of ensuring fairness in governance of the international biomedical research. Nonetheless, what would happen if a community decides that reasonable access to the proven effective intervention after the completion of research is by itself sufficient compensation? Would the reasonable availability of the proven intervention here be fair? These are reasonable questions to explore further. At this point we can conclude that community consultation is necessary and may enhance moral ground of a decision, but it alone cannot serve justice in IB research because developing nations lack knowledge and skills for negotiation (discussed in chapter 6).

Moreover, I do not agree with the Participants and advocates of community consultation that justice, according to fair benefit approach, will be achieved at all times through

community engagement. Community involvement offer a means of eliminating or reducing existing knowledge gaps and enhancing the quality of decisions, but community involvement alone, being only one principle among many in research ethics frameworks, will not remove the potential for exploitation or ensure justice in the IB research process. There are, therefore, further steps that need to be taken besides community engagement. For example, an expert person is needed to explain research protocols to the community, as in most cases they are written in a scientific or foreign language. We must also not forget that protocols are designed in diplomatic language and commonly keep many things implicit. Such vagueness may create further complications in developing nations. Furthermore, let us consider the following scenario for comprehensive understanding of how a community may contribute to the development of various capabilities:

In a paternalistic society of developing nations, especially in the Indian subcontinent, the poor, girls, children, women, the sick and aged are not treated equally. Such societies are governed by masculine values; generally, boys are offered the best meals depriving the girls of these societies. A similar condition has been portrayed by Nussbaum in her *Creating Capabilities*. Nussbaum has shown how women are treated in Indian society portraying the case of Vasanti (Nussbaum, 2011). In such a patriarchal society, people customarily do not allow women to join in the work force or do not permit them be educated for various reasons, including religious regulations. Most women are pleased with little care if they are given access to education or work. In return, women are willing to accept all other conditions. In such societies, when a girl starts her own family, she

often accepts all conditions in exchange of her basic liberty. Imagine that a husband and wife both work to earn for the family. When both return home, the husband may take a rest, read a newspaper, or watch TV while the wife does all household work, such as cooking, cleaning, and preparing everything for next day. Additionally, if they have children, mostly the wife alone must do everything for the children. In terms of workload, there is enormous pressure on women, but they typically accept the situation and do not demand equal household workload sharing. Why? If they demand equality in workload, the husband may insist that the wife should stay at home to look after and raise children, and run the family smoothly. If going out for work hinders family life, the husband may insist that his wife should not seek employment. If the woman protests, and seeks justice from the community, in most cases the community will approve the husband's demand. However, isn't it just for women if both spouses are equal in dignity and rights? So, for mutual benefits, women accept all the workload at home so that they can enjoy their liberty. There is a long way to go for achieving justice for women. Nevertheless, even though the community may itself be unjust in some respects (as described above), it still has an important role in negotiating a fair benefits agreement to ensure a just distribution of research benefits. However, the community should not be abandoned, as human beings cannot live without community and community takes the burden in many ways when any individual is in need, e.g., incapacitate due to partaking in the research.

4.7 Conclusion

In the above discussion, it has been argued that traditional benefit-sharing models mostly appeal to two popular notions of justice: reciprocity and equality. These conceptions of justice have been used by the bioethics community as the base of benefit-sharing frameworks in IB research. The concept of reciprocity is used to achieve justice in the sense of giving host communities and research participants something in return for their participation. This approach has some potential for dispensing benefits in order to fulfil the commitments of developed nations to act in accordance with global health rights. However, these frameworks of benefit-sharing have several serious limitations. As I discussed above, one of the important limitations of these models is that they fail to recognise some important and unique contributions of host nations to clinical trials. These models have considered host nations' contribution of different types of material resources that they allocate for conducting a clinical trial. However, they did not notice the distinctive value conferred by participants' contributions (e.g., their labour) in the field of innovation, which, as I have already argued, can be similar comparable to the fundamental role played by sponsors and researchers from developed nations in the process of drug or technology development. The role of the researcher is regarded as valuable and so is standardly seen as affirming IP rights. They are offered IP rights and benefit packages as well. However, they (bioethics researcher, sponsor) do not take into account the difference between post-trial IP and pre-trial IP. They have regarded both as the same, whereas pre-trial IP is merely a hypothesis while post-trial IP is a confirmed hypothesis-a direct, and a proven product for marketing.

People of developing nations suffer from various diseases which may appear initially unimportant. However, the information gained about diseases from these populations, and the biological specimens collected by bio-prospectors are highly valuable. These valuable contributions have enormous potential to help the development of people treatments for regardless of their national boundaries. The Indonesian Avian influenza virus sharing is an example of this. These resources can be used to develop vaccine, diagnostics, and therapeutic or other health-related technologies. I have argued that such contributions cannot justly be compensated for by one-off payments that offer compensation for the inconvenience or harm caused by participation in the research.

The pharmaceutical industry in developed nations is able to access such resources free to develop health-related technologies and patent them. Subsequently, these can be traded in the world market regardless of the purchasing power of developing nations, which may have shared their resources earlier on as part of the development process.

Developing nations have to buy patented products from developed nations to meet their health needs. However, due to high prices, most patented products are out of reach for developing nations. Further, developing nations are unable to produce generic versions of the same technology due to sanctions imposed by the TRIPS Agreement. Therefore, health research brings significant economic benefits to sponsors from developed countries but fail to bring comparable economic benefits to the host country of clinical

trials in developing nations (Schroeder and Pogge, 2009, p. 274). Consequently, the health of populations in developing nations face more challenges to fulfil their health needs, and as a result they remain vulnerable to significantly higher levels of morbidity and mortality. This disparity will continue unless the contributions of both parties are valued properly. If this continues, health disparities between developed and developing nations will not be reduced or eliminated, but rather will be increased further. In this regard, a question might be asked about why I am considering IP reform instead of arguing for unrestricted access to essential drugs in the market at an affordable price? Such a question may ask us to propose, along with Pogge for a Health Impact Fund and similar approaches. If access to lifesaving medicines is the key concern, then such approaches are indeed useful. However, the main objective of my research is to bring greater fairness to the distribution of international biomedical research, as this also has the potential to address access to essential medicines to save the lives of millions of people. Access to IP rights will increase the income of the LMIC as well as their bargaining power. Under the TRIPS agreement, LMICs have very limited power to bargain and influence the price of essential medicines. The nature of contributions in IB research are different to other collaborative international businesses. My research focuses on clinical trials of various types of drugs in developing countries, whether or not those drugs are life-saving. And so, I am arguing that participants' equal contribution to developing drug A and Drug B count equally for the participants' IP claims on those drugs, even if drug A is a life-saving drug and drug B is not a life-saving drug.

The available models subscribe to another notion of justice: justice as equality. This is demonstrated in the “solidarity-based approach to justice” to international biomedical research to include all human for ensuring justice. This is one of the broadest concepts of justice that has been articulated. For example, the UNESCO Declaration on Human Genome and Human Rights states that “benefits from advances in biology, genetics and medicines, concerning the human genome shall be made available to all” (UNESCO, 1997, 2000, p.5). This approach recognises that humans as a species share 99.9% of their genome, and that their genes should be considered as a common for humankind. Therefore, according to this approach all the benefits derived from using human genetic resources should be made available to all. The equality as justice principle for benefit sharing was proposed by the Ethics committee on Human Genome Organisation in 2000 (HUGOEC, 2000).

However, this approach does not acknowledge the existing asymmetries of power and unequal economic conditions in the world (Pham, 2004). Although equality and solidarity as ethical principles play an important role in theories of justice, by themselves they fail to capture the reality and practical consequences of the asymmetries of power and economic inequalities between developed and developing nations (Pham, 2004)⁶⁶. Therefore, it is impossible to achieve justice by ignoring these existing asymmetries.

⁶⁶ Developing countries will almost always find themselves at a political bargaining disadvantage relative to developed countries because they often rely on developed countries for aid, military assistance, or technological transfers. A developing country also has a less important impact on a developed country's economy than vice versa, since bilateral trade is more likely to be a greater percentage of the developing country's gross domestic product (“GDP”) than of the developed country's GDP. A neutral adversarial dispute settlement system helps limit the scope of the debate to the legal merits, and thus offers increased judicial protection to a developing country against more powerful developed countries.

John Rawls' theory of justice, and Sen's and Nussbaum's capability approach can be mentioned in this regard. As Rawls first principle of justice was adopted based on equality, he realised that he needed another principle to ensure the fair distribution of social goods in order to meet basic human needs. This led him to develop his second principle which addresses existing asymmetries in arguing that advantages should be given to those who are, or would be, most disadvantaged.

In the next chapter, I explore another alternative approach to justice for the ethical conduct of IB research developed by Alex London (2005) which he refers to as the human development approach. Regarding the distribution of benefits and burdens in IB research, the human development approach to justice basically advocates for giving advantages to those who are marginalized and disadvantaged as part of human development. However, my critical analysis of this approach will demonstrate that giving IP can be more morally preferable approach than any of these approaches (discussed above) to justice in IB research.

Chapter Five

Exploring a Human Development Approach to Justice in International Biomedical Research

5.1 Introduction

A recent trend in international justice debates involves using Amartya Sen and Martha Nussbaum's capability approach to analyse, evaluate, and justify existing frameworks of justice, and to develop new models of benefit sharing that critically consider asymmetric power relations and socio-economic inequalities between developed and developing nations. Alex London is among those who have attempted to apply this approach to justice in international biomedical (IB) research, as a critic of the adequacy of a fair benefits (FB) approach to justice in IB research. London argues that conventional theories of justice primarily focus on reciprocity and a narrow notion of mutual advantage when considering the development of global ethical frameworks for the distribution of research benefits and burdens that result from collaborative endeavours (London, 2005). He has termed this the "minimalist view" and argues that it ultimately fails to capture the reality of developing nations. The minimalist view, London argues, reduces concerns about justice to considerations of non-maleficence, beneficence, and autonomy without disturbing the underlying social and political structure of the status quo, when what's required is a broader view of social justice⁶⁷. In contrast to the work of

⁶⁷ Social justice is concerned with social inequalities and equitable distribution of social wealth.

Thomas Pogge, the minimalist view sets aside questions as to why an unjust situation prevails in poor developing nations, and why developed nations choose these low-income nations as the venues for their collaborative biomedical research projects.

For London, broader issues of social justice are centrally linked to the health needs of a particular community. Failure to understand the multiple dimensions of these health needs leads to a narrow view of justice in IB research. In contrast to the minimalist view of justice, London proposed the human development (HD) approach to the ethics of IB research, which provides a broader view of justice capable of incorporating these multi-dimensional health needs. In this chapter, I discuss the HD approach in some detail and identify the resources and the valuable insight that the human development approach provides for resolving key distributional controversies and issues in IB research.

One of the key features of the human development approach is that it recommends reform of the basic social structures of low-income countries to ensure various types of freedom for all citizens (London, 2005). The main reason this reform is needed is that the social structures of low-income countries are neither well developed nor very responsive to the social needs of the population. As a result, the existing governance systems of these countries pave the way to injustice in every sphere of life (London, 2005). Inadequate social structures mean that the people of low-income countries lack various capabilities, for example they lack the ability to access to food, sanitation, and medicine. This lack of capability negatively affects freedom of choice and prevents people “being & functioning (Sen, 1999)” well in everyday life. Lack of access to

information is another crucial factor that leads to the suffering of people in low and middle-income countries (LMIC) and stops them from “being and functioning” well. The human development approach to justice in IB research emphasises the importance of developing basic social structures and governance system for the protection of global health rights and to ensure fair access to medicine for LMIC.

However, I will argue in this chapter that there are also some limitations of the human development approach to justice in IB research. For example, the human development approach fails to address IP issues in IB research and fails to understand the importance of the improvement of negotiation capabilities for LMIC in international negotiations (I discuss this topic in chapter 6). Despite these limitations, some aspects of the human development can still serve as elements of justice in IB research. Therefore, in this chapter I will discuss the human development approach in more detail, and I will show how it supports my thesis that conferral of IP rights on participating host nation governments can ensure justice in IB research, which would result in people being included in the development process and respected, so that they are more likely to flourish and live a dignified life. This discussion will also provide the basis for my reply to criticisms of my thesis to be address in subsequent chapters.

5.2 Background to the Human Development Approach

The human development approach to justice in international biomedical research is in various respects based on Amartya Sen's idea of justice. Reflecting on the economic and social conditions of LMIC, and what the persistence of these conditions mean for development and the struggle for emancipation from poverty, Sen (1999) established a relationship between development and freedom. For Sen, development signifies meaningful human development- a prerequisite for economic development or social development. Linking development, freedom and justice, Sen proposes that the goal of development should be to create and promote the various capabilities that the citizens of low-income countries need for "being & functioning" well. Sen, I believe, based his approach on Rawls (1971) principles of justice, although the two approaches differ significantly in the ways that they "measure justice" and injustice (Brighouse & Robeyns, 2010). Furthermore, Rawls was mainly concerned with political justice at a national level, while Sen and Nussbaum were focused on "extending the reach of justice" (Sen, 2006, p.232) to a global level (Venkatapuram, 2011, p.24). This aspect of Sen and Nussbaum's work has attracted advocates of human development to explore the approach as an ethical framework for research in the international setting. Therefore, in this chapter, I investigate the HD approach to justice to understand how far it can capture the reality of IB research.

The HD⁶⁸ approach is generally known as the capability- (or capabilities) approach (CA) to development, and these two terms are used interchangeably in the literature. Nussbaum (2011) is credited for further developing Sen's idea of justice into the capability approach to human development aimed at achieving a flourishing human life, i.e., being and functioning well. Sen and Nussbaum integrated what they described as the Western notion of freedom (in the sense of individual autonomy) with the Eastern notion of justice as living with dignity under the rubric of human development. For Sen and Nussbaum, the distribution of benefits and burdens should be guided by the goal of ensuring a decent quality of life. For this reason, people should have freedom of choice. Without having this capability, human beings cannot live a dignified life⁶⁹.

Nussbaum identified 10 human capabilities⁷⁰ which she argues are necessary for a dignified life. These capabilities are linked to some important human rights, e.g., a right to choose, to education, health, nutrition, shelter, etc. Sen and Nussbaum have argued that a flourishing life requires the fulfilment of various basic interrelated needs. Furthermore, they believe that the quality of people's life depends on several elements,

⁶⁸ This framework is also known as the maximin approach to justice in IB research because it uses benefit sharing as a broader concept for ensuring global distributive justice (Dauda and Dierickx, 2013).

⁶⁹ Autonomy, quality of life and dignity are interrelated. Dignity involves freedom. Access to information creates opportunity for quality of life and ensure various types of freedom. And when freedom is realized people can make choice and live a dignified life. For example, a woman known as mother of Falani works as a house cleaner in the city of Dhaka. She is sick and cannot work for few days. Her husband is a daily labourer got ill health. So, he has no regularly income to support family. She has no access to medicine as she has no saving. She has a daughter. Her daughter also suffers from malnutrition. Her daughter Falani has no access to education. She lives in a slam where access to fresh drinking water is not guaranteed. She has limited knowledge and do not wash her hand after toilet. Her economic conditions force her to live an undignified life. Her ignorance of health and hygiene prevent her living a better life and cause enormous sufferings.

⁷⁰ Nussbaum's ten central human capabilities are: Life, bodily health, bodily integrity, sense, imagination, and thought, emotions, practical reason, affiliation, other species, play and control over one's environment, (a) political, (b) Material. (See for details: Nussbaum, 2011, pp.33-34).

and that those elements cannot be reduced to single element as they are each distinctive in nature. Therefore, irreducibility and plurality are central to the Capability Approach. These aspects of Sen and Nussbaum's theory of human development for flourishing live carried over when it was interpreted by London (2005) as the foundation for a framework of international justice. For example, health and education play a crucial role in people's life. But while education is necessary to maintaining a healthy life, attaining education may not be possible for an individual because of malnutrition. So, we can see how the basic needs of health, education, and nutrition, while irreducible to each other, are fundamentally interrelated.

Proponents of the human development approach to justice in IB research argue that many people of low and middle-income countries lack the capabilities necessary to set up a basic social structure which is responsive to their health needs. The absence of a basic social structure affects these lack of capabilities and the lack of these capabilities is a root cause of various types of injustice, and thus from a development point of view this lack of capabilities needs immediate attention (London, 2008). However, this gives rise to the questions: what is meant by a "capability" and which of these capabilities are required by justice. The human development approach in this matter refers to Sen and Nussbaum works on justice. For Sen and Nussbaum, capability means having freedom of choice or a right to choose freely, i.e., capability is a person's ability to perform valuable acts and reach valuable states of being. Sen's example of the difference between fasting and starving explains how the notion of freedom of choice is inbuilt into the notion of capability: that is, a person can freely decide to fast only when she has

food available, which is significantly different from the person who starves due to circumstances beyond her control (Nussbaum, 2011). Fasting is an act that is valuable to the person when freely chosen, whereas starvation is a state that has negative value because it is involuntary. Similarly, a person may be unable to meet her health needs for several reasons. She may lack purchasing power, lack the physical ability to obtain medicine, or someone may obstruct her access to medicine. The poor of developing nations lack access to medicine because of their weak purchasing power, ill health, or disability. Woman, as well as the poor, lack choices even though they might have the physical capability to access healthcare. For example, a woman of a conservative family may need permission to visit a doctor or need family support to reach health facilities. In this regard, the reform of social structures creates enabling conditions for the poor and women. These aspects of social justice are now a prime concern for human development thinkers, and the goals of international biomedical researchers should be developed based on such observations.

A framework of justice cannot achieve fairness in distribution without answering these questions. I agree with Sen (1999) that freedom of choice is a core element of justice that needs to be addressed to improve the socio-economic conditions of developing nations. In many developing countries there are social and economic institutions that perpetuate injustices. It is only through the removal or reform of these institutions that freedom of choice can flourish, and in turn improve health conditions and access to education.

In addition, for Nussbaum,

“the CA or HD approach is concerned with entrenched social injustice and inequality, especially capability failures that are the result of discrimination or marginalization. It ascribes an urgent task to government and public policy—namely to improve the quality of life for all people, as defined by their capabilities (2011, p.19)”.

This creates the ground for IB research in that all governments should ensure that the benefits of this research are directed towards the fulfilment of health needs and respecting rights to health - in other words, that IB research should contribute to the fulfilment of health needs at a global level. Such an endeavour should underpin “a decent quality of life” for all. In this way, the capabilities approach to justice links human freedom with justice and health rights.

According to Nussbaum, a policy to promote health is different from a policy which promotes health capabilities because the latter relates to a person’s freedom to choose a lifestyle, not just to health as functioning (2011, p.26). Similarly, London (2005) argues that a health policy may affect the development of health capabilities of a particular society. For example, 90 percent of the health research budget globally is spent on meeting the health needs of 10 percent of the world’s population, which is known as the 10/90 research gap in the health literature (London, 2005, p.24, Pogge, Rimmer and Rubenstein, 2010, p.4). This ten percent mostly reside in developed nations. The research gap does little to help the 90 percent who mostly reside in developing nations, and to their access to effective medicines. The capability approach

as a perspective of addressing inequality can be used to reduce this gap and pave the way to justice in IB research.

In developing nations, poverty and social deprivation lead to both extreme health needs and a lack of access to effective medicines, and this creates a pressing incentive for individuals to participate in IB research in order to gain access to medicines and treatments that are the standard of care⁷¹ in wealthier parts of the world. Often the fruits of IB research are enjoyed by developed nations while the burdens of such research are borne by poor research participants in developing nations (London, 2005, Page, 2003, p.1). Acknowledgement of these existing asymmetries of power and economic conditions of developed and developing nations is required for the development of a

⁷¹ 'Standard of care' is a debated term in bioethics. The debate is about whether clinical research participants should receive the best treatment that is available *locally*, or the best treatment that is available *globally*, for the disease conditions being investigated in a developing nation by an organization from a developed nation. During the clinical trials, research participants are grouped in different arms. The participants are allocated into groups randomly to avoid biases and thus to achieve generalizable comparisons. In most cases, no-one other than principal investigator of the research protocols (and possibly a few others) is aware which members of which arms are receiving the active ingredient or who is receiving sham drug/intervention (Hawkins, 2008). For example, let us imagine that a HIV drug is tested by US pharmaceutical company in Thailand. A group of participants received the placebo during the study. Some moral philosophers argued that the study team acted wrongly in the above case, as the Helsinki Declaration suggests that the best proven care be provided (Should participants suffer adverse events from participating in the trial?). On the other hand, London (2000, pp. 379-397) claimed that the meaning of "the best therapeutic method" in the Helsinki Declaration is not clear that is, it is unclear whether this means "the best proven care available in the country" where the clinical research is conducted, or it is equivalent to the care that is available in the sponsoring country or available in the world during the trial time. The debate is no doubt very important for us. This certainly related to the distribution of benefit and burdens and matter of justice in international biomedical research. My view is that *at least* sponsoring nation should try to meet the global standard known to them unless it is beyond their capacity to provide to the participants. Also, the sponsoring nation must consider whether such treatment is acceptable in their own community. If the sponsoring nation agrees to share post-trial benefits, as I am proposing in my contribution model, then both nations should try to provide the best available care in their reach. The idea of Kant's good will should also be taken into consideration during the process of negotiation. For example, both parties should avoid any kind of deception in the determination of research protocol.

justice framework for benefit sharing in IB research. The HD framework takes into account the existing asymmetries of power and economic conditions between developed and developing nations, and recommends meaningful public participation and the development of basic social structures (I discuss this at more length later). London (2005) states that basic social justice issues can be addressed through sharing the benefits of IB research for the improvement of quality of life⁷², and this is something that has also been argued by Sen and Nussbaum.

Venkatapuram argues that, “human functioning, its biochemistry, is determined by the interaction of biology, behaviour and external physical environment and social conditions. And any constraints in human functioning, including the ultimate constraint of death, are also caused by the interactions of these four factors” (Venkatapuram, 2011, p.4). For example, if a person’s life conditions are affected by a natural cause

⁷² For Sen (1993) quality of life is connected with “doing and living”. This also depend on capabilities to achieve valuable functioning (adequately nourished, being in good health, achieving self-respect, or being socially integrated). For Nussbaum (1995, 2000, 2006, 2013) quality of life is connected with human dignity and achieving capabilities, at least 10 capabilities, for a flourishing human life. This is a kind of freedom to do something and freedom from something (free from barriers/lack of access to livelihood, access to information, access to medicine, access to justice, participating in policy-making etc.). Nussbaum’s list of capabilities are:

- Being able to live to the end of a human life of normal length.
- Being able to have good health, adequate nutrition, adequate shelter, opportunities for sexual satisfaction and choice in reproduction, and mobility.
- Being able to avoid unnecessary and non-beneficial pain and to have pleasurable experiences.
- Being able to use the senses, imagine, think, and reason; and to have the educational opportunities necessary to realize these capacities.
- Being able to have attachments to things and persons outside ourselves.
- Being able to form a conception of the good and to engage in critical reflection about the planning of one's own life.
- Being able to live for and to others, to recognize and show concern for other human beings.
- Being able to live with concern for and in relation to animals and the world of nature.
- Being able to laugh, to play, to enjoy recreational activities.
- Being able to live one's own life and no one else's; enjoying freedom of association and freedom from unwarranted search and seizure.

such as being born with a physical or intellectual disability, and if a person's normal functioning is a result of a freely chosen game of high risk for their own pleasure, these are particularly different from a justice point of view to a person dying or suffering due to social arrangement. Social structures can remain underdeveloped due to social injustice. For instance, if there is no school, it is not possible to obtain an education, and if there is no education, people have fewer options when it comes to participation and negotiation in the workplace. As a result, people in these circumstances live in poverty, which prevents the overall development of their human capacities as well as their meaningful political participation. This lack of meaningful political participation then means that the society fails to formulate effective health policies to support overall human development. As a result, social actions are required to prevent premature deaths and preventable impairments.

Devastating health disparities in developing nations need urgent attention. Health outcomes and socio-economic status (i.e. income, education and occupation) are correlated, as has been confirmed by the Whitehall studies which were started in 1967 and ran for 20 years (Brock, 2000). Sen and Nussbaum argue that due to poverty and poor socio-economic conditions, most people in developing countries live undignified lives and are unable to choose their livelihood freely (Sen, 1999, Nussbaum, 2011). Malnutrition makes their immune systems feeble, which makes it more difficult to prevent the spread of communicable diseases. Subsequently, they bear the heaviest burden of diseases morbidity and mortality.

As a citizen of a developing nation, I have personally witnessed the relationship between socio-economic status and health. In Bangladesh, the poor and disadvantaged live in slums where they lack clean water for drinking, cooking and bathing, and lack access to healthy living spaces, fresh air and sanitation. They cannot buy detergent to wash their clothes and do not have space to hang out their clothes to dry. Disease-bearing insects infest these living places, causing diarrhoea, malaria and dengue fever. People live many to a room, with children, pregnant women, and aged people sharing small rooms. The poor and disadvantaged also lack a means of transport to the hospital in emergencies, so they remain sick and die for lack of treatment. Even access to information is difficult for the poor and disadvantaged in developing nations, particularly information on health and hygiene which is necessary to live a healthy life.

One of the fundamental goals of collaborative international biomedical research should be to address the health needs of the developing world. Collaborative research has the potential to address the developing world's health needs, but it can pose significant risks and burdens for the population as well. The question is how research can be done justly and without imposing further burdens on already disadvantaged people. This why London links the social determinants of health with medical research as a means of facilitating human development (London, 2005).

According to London (2005), the fundamental problems of justice are captured by the minimalist view:

1. The needs and vulnerabilities of the host population and
2. The capacity of research to benefit and to burden.

Proponents of the minimalist view, such as Emanuel rely on three principles for ensuring justice. The first of these is non-maleficence, in the sense that researchers should ensure that research participants and host communities should not be worse off due to their involvement in research. The second value is beneficence, meaning that researchers should ensure that a fair distribution of the benefits derived from research should flow to the host community of IB research. Thirdly, the minimalist view emphasises respect for host communities' autonomous decisions. Autonomy is important for ensuring fair terms of cooperation. From the perspective of the minimalist view, then, just research is that which adheres to the duties of non-maleficence and beneficence and respects the autonomy of research participants and the host community.

One of the positive elements of the minimalist view is the stipulation that research should benefit not only researchers' communities, but also host communities as they bear the heaviest burden of the research.

In order to secure mutually advantageous benefits, each party should freely agree to conduct collaborative research that is not likely to leave the host community worse off, and will contribute some benefits to the community, and lastly that will respect the autonomy of participants and host community (London, 2005, p. 26).

The human development approach, on the other hand, does not agree with the view that just benefit sharing will necessarily result from negotiation between sponsors and host communities. London (2005) has considered how inequalities in bargaining power may unfairly influence the distribution of the benefits and burdens of research. For London,

“human development” is understood in this view as the project of establishing and fostering basic social structures that guarantee to community members the fair value of their most basic human capacities” (p. 32).

Hence, the human development approach regards just collaborative research as that which secures the right to basic social structures that support the development and expression of basic human capacities. The human development approach focuses on the overall improvement of social structures for host communities of IB research, whether these create opportunities for education, health care, employment or the political processes that allow individuals to participate in their own governance. It is therefore assumed that under the right conditions, social structures can be managed sustainably, and that this is more important than mere economic wealth, or access to resources alone.

London used the much-cited short course AZT trials to show how the reasonable availability requirement and fair benefit approaches fail to ensure a just distribution of the benefits and burdens of research. The short course AZT trials were conducted more than a decade ago in Thailand and Uganda under the patronage of National Institute of Health (NIH) and Centres for Disease Control (CDC). The experimental drug AZT was administered to participants orally for the last four weeks of pregnancy, as well as

during labor, in order to assess its efficacy in preventing Mother to Child Transmission (MTCT) prevention. The trial was successful. A critical examination of the process indicates that the trials met the minimal view's three principles of ethics outlined above; however, these trials were still controversial. Critics of these trials argued that they were unethical and exploitative (Lurie & Wolfe, 1997, see also Pavone, 2016). Lurie & Wolfe (1997, p.855), for example, argued that if the AZT trials were accepted as ethical, then

“[r]esearchers might inject live malaria parasites into HIV-positive subjects in China in order to study the effect on the progression of HIV infection, even though the study protocol had been rejected in the United States and Mexico. Or researchers might randomly assign malnourished San (bushmen) to receive vitamin-fortified or standard bread. One might also justify trials of HIV vaccines in which the subjects were not provided with condoms or state-of-the-art counselling about safe sex by arguing that they are not customarily provided in the developing countries in question.”

However, advocates of the AZT trials did not agree that the trials had failed to meet ethical standards. The trials' advocates argued that while the AIDS Clinical Trials Group's (ACTG) 076 regimen of AZT was recommended as standard of care in developed countries for reducing mother- to- child HIV transmission, due to the high expense of the drug, it was unaffordable to people in developing countries and therefore could not be considered to be the standard of care in HIV pandemic affected Africa. It was for this reason that the WHO asked multinational pharmaceuticals companies to develop a more affordable intervention in the first place. In response to this request, several trials for a short course of AZT (which is less expensive than the longer regimen of the drug standard in western countries) were conducted in various locations of Africa and Asia by the NIH and CDC. It was judged the FB advocates that these placebo-

controlled trials met the ethical standards set by the three principles of the minimal view (Varmus & Satcher, 1997, pp. 1003-1005). Firstly, the condition of non-maleficence was met as participants from the host countries, were not made worse off by their participation in the trials even participants who received the placebo treatment did not miss out on the standard treatment, it was argued, as a standard treatment for the condition *in these countries* did not exist. Secondly, the principle of beneficence was met as additional burdens were not imposed on the communities by these trials, the communities involved in this research benefited to some extent from hosting the research, and furthermore the research was carried out for the benefits of future patients (Benedtti, 2015). And lastly, research participants' decisions were respected as they were not being coerced to participate in the trials.

Given that the conditions of non-maleficence, beneficence and respect for autonomy were met, were the trials nonetheless unjust? Drawing on the HD approach, London argues that these trials were unjust because disadvantageous social structures drove host communities to participate in the research. If those participants were not poor and vulnerable, and they had the freedom to choose between participating in a research trial and receiving an experimental intervention, on the one hand, or on the other hand, receiving the proven effective intervention that was available to people in more wealthy countries, undoubtedly they would have chosen the proven effective intervention. The AZT trials met the ethical standards of the minimal view only because the social structures of the host countries were unable to provide opportunities for the development of basic human capacities, and this is why the AZT trials were unjust. According to the HD approach, IB research should include a focus on the development

of the social structures of the host country. As London argues, it is important “to expand the capacity of the basic social structures of that community to better serve the fundamental interests of that community’s members” (London. 2005. p. 33)

Health-related organisations can contribute to meeting the health needs of human development. A community cannot develop properly if the members of that community are not in good health. Thus, addressing a disadvantaged community’s “rudimentary health problems” assists it to function adequately. Clinical trials can address the gap between basic social structures and important health needs when research trials are designed based on specific scientific and statistical methods to address the health needs of the host community.

The HD approach mandates that as duty of rectification developed nations should work for developing nations as a way of fulfilling developed countries’ moral obligations. The duty of rectification requires the engagement of one’s own capacities and resources for the development of less well-off human beings. Adopting this sense of the duty of rectification supports the use of IB collaborative research to transfer significant wealth to developing nations from developed nations. Like Pogge (2002), London believes that the duty of rectification applies to all citizens of democratic developed nations because he points to the government policies of developed nations benefiting the citizens of those nations but cause various problems for citizens of developing nations. For example, many apparel industries are located in Bangladesh. These industries are polluting the environment of Bangladesh, causing much suffering disease, and deaths.

Furthermore, Ruger (2006) argues that a duty should be applied to the governments of developed nations specifically to address global health inequalities. Thomas Pogge (2002, 2008) and Norman Daniels (2008) have likewise argued that Western developed democratic nations are largely responsible for poverty⁷³ and unjust health inequalities in developing nations, since developed nations apply and support “international resource privilege (Hereafter IRP)”⁷⁴ policies funding development projects in the developing world.

The IRP right is a kind of global recognition of a government of low income or middle-income countries. While this might not sound terribly bad, one of the key features of developing nations’ governments is that they often come into power not by a fair election but by using illegal arms, military force, corruption, suppression, and the exploitation of poverty. Unjust governments of developing nations are nonetheless recognized by the international community, developed nations’ governments and their business groups. In return, those unjust governments of developing nations give advantages to their international supporters. The governments and corporations of developed countries gain access to natural resources such as oil and ore by signing an agreement that includes international recognition of the transactions and in turn, international recognition of the unjust government. By granting the governments of developing nations free reign to sell resources, the IRP allows corrupt regimes to fund their military, their collaborators, and other elements of their regimes so that they can

⁷³ For example, in the then India, the East India Company forced the then Indian farmers to cultivate indigo for UK textile industry.

⁷⁴ According to Pogge, international resource privilege policies allow the parties that succeeded wresting control of the national government “to borrow in the name of its people and to confer legal ownership rights for the countries resources (2008, p.119)” and consolidation of power for the privileged few.

maintain their control of the country. It also allows them to freely transfer resources and money out of the country to offshore bank accounts and havens. If a fair election is subsequently held and a democratic government comes into power in the developing nation, the democratic government is still required to respect the internationally-recognised contracts signed by the previous regime, whether or not these contracts represented the will of the country's citizens when they were signed.

As beneficiaries of such policies, Pogge argues that all citizens of developed nations indirectly bear the duty to aid the developing nations where such policies exist (Pogge, 2008, Rahman, 1972⁷⁵). According to Pogge, “the social starting positions of poor and of the affluent have emerged from a single historical process that was pervaded by massive, grievous wrongs. The present circumstances of the global poor are significantly shaped by dramatic period of conquest and colonization, with severe oppression, enslavement, even genocide, through which the native institutions and culture were destroyed or severely traumatized (Pogge, 2008, p.67).” Pogge (2008, 2011⁷⁶) argued that there is a relationship between world poverty and human rights. For him, every human being has right to a good life, good health, and well-being. However, affluent western countries for their economic order and prosperity played a dominating role and established colonies in different parts of the world. This has caused enormous harm to the citizens of those countries, who now make up the global poor.

⁷⁵ Similarly, the father of the nation Bangladesh, Sheikh Mujibur Rahman (1972) claimed that developed nations (i.e. Great Britain) exploited and extracted resources from developing nations (i.e. Bangladesh) for more than hundred years, in an interview in a Press conference in London when he was returning to independent Bangladesh from the Pakistan prison. As Bangladesh contributed so much in Great Britain's economy and well-being of its' citizens that Great Britain should help Bangladesh and its' people for alleviation of poverty in there. <https://www.youtube.com/watch?v=WLo1wfrM0Og>

⁷⁶ Pogge, Thomas. 2011. Are We Violating the Human Rights of the World's Poor, *Yale Human Rights and Development Journal*, Vol.14, Issue 2.

Pogge argues that if any action of yours causes any sort of harm to others, then this action is a violation of human rights. For the maintenance of the western economic order, we (western people) have harmed the people in developing nations and have violated their human rights. Western nations have done health research in developing nations for their own benefit. As a result, low income countries have suffered enormous burdens, while contributing to the economies of developed nation. For this reason, Pogge argues that Western nations have a negative duty towards the global poor in developing nations. Additionally, western nations have a duty to compensate for this injustice by contributing to research that addresses the health needs of the global poor. Pogge (2008) has proposed a health impact fund (HIF) to support international medical research as a way of ameliorating the suffering of the global poor. As a result of this research, poor people will have access to medicine and treatment, and this in turn will have a positive effect on global development as health is a prerequisite for human development.

Pogge (2008) explained how the economies of developed nations contribute to global poverty, listing eight causes of injustice to low income countries. In the past these include tariffs on the exports of developing nations, subsidies for agriculture in developed nations, resource and borrowing privileges, an arms race, illicit transfer of money out of developing nations, unrestricted pollution etc. The TRIPS Agreement is the latest instance of hegemonic domination by developed nations. Implementation of the TRIPS Agreement by the WTO imposed further restrictions on citizens of developing

nations accessing effective medicines. The USA and the EU strongly advocated implementing robust protection of patent rights for pharmaceutical companies (London, 2005, p. 30). Stronger patent protection policies may restrict production or importation of affordable medicine, which in turn may restrict access to antiviral medication and increase mortality rates amongst AIDS or HIV patients in a low and middle-income countries (Dauda & Dierickx, 2012).

IB researchers and their sponsors are directly engaged and linked with policy developments like those described above. But as a means of carrying out the duty to aid, clinical trials can be used to redistribute some resources from affluent countries to low income countries, which can be helpful in developing basic social structures (p.34). Thus, London (2005) argues that,

“the human development approach holds that research initiatives are permissible only if they expand the capacity of the host community’s basic social structures to meet the community’s health priorities” (p. 33).

As a result, in international setting, research should be approved only if the study is going to address the host community’s health needs and assist in the development of basic social structures⁷⁷.

⁷⁷ The “Canada and Mexico Battling Childhood Obesity” (CAMBIO) project is a current joint effort between research teams based primarily at the university of Guadalajara (Mexico) and Queen’s University (Canada) as well as other research institutions such as National Institute of Public Health (Mexico) and the Children’s Hospital of eastern Ontario (Canada). It is a capacity-building project funded by the International Development Research Centre of Canada.

Thus, the HD approach takes the development of the basic social structure in the relevant society as a necessary condition of IB research. Furthermore, the HD approach emphasizes sharing the fruits of any other ancillary benefits of the research that may result from the research with the host community. The imperative for the HD approach is to develop host nations' basic social structure so that knowledge resulting from the research can be translated into sustainable benefits for the communities where the research was conducted. If the host community does not have the basic social structures necessary to translate the knowledge into tangible benefits, the HD approach holds that the proposed research should be relocated to a community with similar health needs and adequate basic social structures, where the community will be able to translate knowledge resulting from the research into sustainable benefits.

5.3 Limitations of the Human Development Approach to Justice

The HD approach to justice in IB research has generated many criticisms. However, there are some elements in HD approach which is helpful to develop a much fairer framework of justice in the distribution of benefits and burdens of IB research. Therefore, some of these are discussed below.

According to Emanuel (2008), to eliminate or reduce exploitation, the RA and FB approaches to justice in IB research focus on the question of how much and what benefits should be distributed. These approaches aim to ensure justice in the distribution of the benefits and burdens of a particular research outcome. By contrast, the HD approach encourages researchers to address the “rudimentary health problems”

of the host communities as these problems may hinder the community's normal functioning, meaning that researchers should be responsive to host nations' health needs. Addressing "rudimentary health problems", that is identified by advocates of the HD approach, is related mainly to the selection of research questions, thus the HD approach is concerned more with the research agenda than with the question of how much or what benefits should be distributed from the derived benefits of the research. Therefore, Emanuel argues, the HD approach misunderstands the problem of exploitation in IB research. However, I think Emanuel himself misunderstands what the human development approach advocates. The HD approach argues that reform of governance, the basic social structure of a nation, is a prerequisite to addressing the nation's health needs. This is because host nations are or were mostly colonies of western nations and/or have no effective health care system at all. Without a responsive governance structure, or the existence of an institutional framework supportive of the health needs of the community, the demand for justice in IB research cannot be met (see below).

Another criticism of the HD approach is that it fails to provide guidelines about how much benefit the sponsors or researchers of a specific study are obliged to contribute to various sectors of the host nation, for example how to divide their contribution between economic development, the health sector and the education sector (Emanuel, 2008, p.727).

I agree with Emanuel that addressing “rudimentary health problem” refers to which health concerns should be studied. This is a question about which problems should be addressed when considering what might be helpful for establishing or restoring the host communities normal functioning. Both the RA and FB approaches seek justice from specific transactions and do not deny the relevance of the health needs of the host country. Research should be carried out on one of the health problems of the host community otherwise, how can research participants feasibly be recruited from that community (unless it requires healthy volunteers for Phase I study)?

In addition, the HD approach includes a stipulation that “research initiatives are permissible only if they expand the capacity of the host community’s basic social structures to meet the community’s health priorities” (London, 2005, p.33). According to Emanuel, the requirement to develop the basic social structures of the host community “is too demanding, too undemanding, or too abstract and vague to be action-guiding” (2008, p.727). For him, fulfilling this requirement would require researchers or sponsors of IB research to contribute more than what they are morally required to for a particular study. How can someone from outside of any particular community expand such capacities via social structures? As a result, Emanuel argues that the HD approach can be too lavish.

One way for the HD approach to address this would be, instead of demanding more benefits from the researcher or just giving more benefits, it could include a clause

directed at the host community to ensure that due benefits derived from the research should be dedicated to the development of the basic social structure of that community. This may include developing understanding that each person has dignity and equal opportunity. Host communities must acknowledge that everyone has the rights necessary for a flourishing life. The people of developing nations lack access to information. Therefore, their (developing nations) principles of justice, cognizance of freedom, and fairness, etc. (or how the principles of justice apply there) require elucidation. According to London (2008), “the basic political, legal, and economic institutions of a community have a profound impact on the health status of community members. Because they determine the distribution of basic rights and liberties within a society.” As it is unrealistic to expect people from outside a society to construct or expand social structures appropriate to that society, the HD approach could stipulate that people within the society direct (some of) the benefits of the research toward doing so.

An interesting fact about international biomedical research is that most clinical trials are carried out in those nations that have social structures designed by colonial rules. The basic social structure of colonies is designed using western values and notion of justice which ultimately serve to extract benefits from the colonized population without any struggle. The basic structures, such as social and political institutions, of developing nations were created intentionally by western nations to exploit the poor and ensure domination (Pogge, 2002). These systems exclude the voices of many and undermine the rights of the common people. As a result, the “most pressing health needs” of

developing nations remain unmet. According to London (2005, p.32), “justice is properly about the basic social structure”. If the basic social structure of the society of the host nation is constructed by their meaningful participation, then this structure will “guarantee members of the community opportunities for education, access to productive employment, control over their person and their personal environment, access to the political process, and the protection of their basic human rights (London, 2005, p.32).”

Emanuel argues that the HD approach lacks sufficient detail to guide the research team precisely and leave them in an ambiguous situation. The benefits provided by IB research, such as providing training to members of host communities, conducting information sessions for creating awareness, and establishing hospitals for conducting specific research by the researchers or sponsors, should be considered as ways of developing a host community’s basic capacities. If any research team is willing to provide such benefits, then this would be seen as justified by the HD approach. But would that research then be fair? In this explanation, the HD approach does not seem too demanding.

I agree with Emanuel that the HD approach does not provide clear enough guidance to direct researchers’ actions. In IB research, Phase I trials require small groups of participants who face high risks of harm, while Phase III trials require large groups of participants and lower risks of harm. The just distribution of benefits and burdens may require accounting for these factors, i.e., risk associated with harm, but the HD

approach does not even specify how benefit-sharing should be determined based on these factors.

Nevertheless, the HD approach demands that IB research should focus on building capacities and providing training or information sessions or building research facilities necessary to conduct proposed research would facilitate in capacity building. Thus, any research sponsors willing to provide such benefit would be viewed as justified by the HD approach. But I would like to point out that these above-mentioned costs are necessary to conduct the research, so these costs should be part of running costs for the researcher and should not be included as derived benefits from the research. In contrast, the reasonable availability requirement and fair benefit approaches are not limited to running costs, as they also focus on the outcome of the research. From this point of view, the HD approach views benefit sharing in an overly narrow sense.

Emanuel (2008) argues that justice in IB research requires considering the fair distribution of the benefits and burdens of each study. The derived outcome should be distributed justly to achieve fairness in IB research whatever the prior needs of the host community are, apart from the concerned research health problem. The HD approach aims to address background inequalities in host communities that have resulted from global injustices and the disproportionate distribution of global resources. However, Emanuel argues that if the host nation is already very corrupt, it is difficult to imagine how research could contribute to the development of the basic social structures. However, it seems to me that this criticism relies on a misinterpretation of the human

development approach. The human development approach recognises problems of corruption in developing nations, and advocates of the HD approach therefore argue for governance reform, i.e., developing responsive and responsible basic social structures, to ameliorate corruptions (Cheema & Maguire, 2004, p.20, Kohler et al., 2014).

The United Nations is one of the international organizations which is an outspoken supporter of the human development approach. For example, the UN development experts Cheema & Maguire⁷⁸ (2004) argue that,

When governance is democratic—that is, infused with the principles of participation, rule of law, transparency and accountability, among others—it goes a long way toward improving the quality of life and the human development of all citizens (p.2).

On the other hand, Kohler et al.⁷⁹ (2014) argue that corruption in the health sector can hurt health outcome, and the promotion of global health rights. Good governance, i.e., making health-related policies through meaningful public participation, can improve the integrity of the system and can facilitate both local and international investment opportunities to improve health outcomes. One of the key features of developing nations' governance is that they tend to lack accountability, transparency, and public participation. For example, while a good amount of essential pharmaceutical products may be available as aid for poor people living in low income countries in response to their global health rights, lack of basic social structures and good governance may mean that such benefits are wasted by corrupt governments. Therefore, the

⁷⁸ Cheema, S.G. and Maguire, L.2004.*Democracy, Governance and Development: A Conceptual Framework*, United Nations Development Programme, New York.

⁷⁹ Kohler,J.C, Tim Ken Macker & Ovtcharenko,N .2014. "Why the MDGs need good governance in pharmaceutical systems to promote global health", *BMC Public Health*,14(63).

development of basic social structures to prevent corruption and to fairly identify and prioritise the demands of the public is a prerequisite to the distribution of benefits among the target population.

In the case of IB research, the HD approach expands the moral obligations for the researchers and sponsors of the research compared to the reasonability approach and the fair benefit approach. They are usually the citizens of democratic developed nations whose policies directly or indirectly influence and sometimes cause problems in developing nations. As the beneficiaries of IB research, developed nations' researchers and employees of privileged entities or sponsors have a duty to aid the poor in the host nations and so should contribute more benefits to host nations as part of a duty of rectification. However, there are other industries beside pharmaceutical industries which also exploit developing nations' resources, such as garments industries, sweat factories, etc. These industries pollute the environment and create poor health conditions for employees and nearby residents. Whether it is plausible only to ascribe a duty of rectification only to IB researchers and sponsors and to not include these other industries requires more research which is beyond the scope of this project. In any case, from this perspective, justice on the HD approach seems too demanding.

Another criticism levelled at the HD approach is that it suffers from an internal inconsistency. According to Emanuel (2008, p.727), the HD approach maintains that "claims of justice cannot be limited to the boundaries of the contemporary nation-state" (London, 2005, p.32). Therefore, the HD approach recommends that researchers have

an obligation to ensure that the host communities receive sustainable benefits by supporting the expansion of basic social structures. However, the HD approach insists that if a potential host community does not have sufficient basic social structures to support the translation of research results into benefits of its members, researchers should relocate their research to locations where similar health needs exists but with more appropriate social structures. This means that researchers do not have a strict obligation to address the *rudimentary health needs* of developing nations, i.e., generally advocated, and that the neediest communities-those that lack basic social structures-would on this approach be likely to miss out on the benefits of IB research.

In this respect, the HD approach is similar to the reasonable availability requirement which also claims that it is unethical to recruit research participants from resource poor settings, where the health care infrastructures are not developed enough to benefit from research results. Thus, it can be argued that the human development approach fails in a similar way to the reasonable availability requirement (Emanuel, 2008).

I agree with Emanuel here about these shortcomings of the HD and RA approaches, and I would further argue that by suggesting the proposal that research sites should be relocated to better equipped communities when they fall below a given standard, the HD approach would discourage research from being conducted in the poorest communities, and so overlooks the dire needs of those who do not even have access to basic social structures.

The lack of appropriate social structures for supporting the translation of research results may have resulted from global injustices in the first place, and so further marginalisation of these communities may impose even greater disease burdens on those poor communities. If the HD approach is to maintain that “claims of justice cannot be limited to the boundaries of the contemporary nation-state”, IB researchers will have a moral duty to aid those suffering from global injustice, including communities that are not capable of meeting their health needs and lack basic social structures. The prime and necessary condition for such a duty to aid should be dedicated to development of basic social structures, not to meeting the desperate health needs for fulfilling duty to aid (Emanuel, 2008). It seems to me as an observer and citizen of a low-income country, that fulfilling existing health needs can ameliorate current problems for the time being. However, the problem of the non-existence of a responsive basic social structure will remain, yielding unjust distribution, oppression, and deprivation and will contribute to widening existing gaps among nations. As a result, meeting global health rights one of the main objectives of IB research may remain untenable.

Although there are many criticisms of the HD approach, broader social justice issues such as the freedom to choose, meaningful participation, and a decent quality of life are important when developing a justice framework. These ethical values should receive due consideration when international justice is debated. The conditions of developing nations are also important barriers for ensuring fairness in the distribution of social goods and burdens. Without such enabling conditions and changes in social structures,

locating biomedical research in developing nations remains a moral problem. In this regard, my idea of sharing benefits through intellectual property rights seems promising. Once these proposed ethical considerations are incorporated into benefit-sharing models, we can design an equitable benefit-sharing protocol.

The HD approach in part answers the question of why a benefit-sharing model that doesn't include the conferral of IP rights is problematic. I agree with the human development approach that there is a connection between broader social justice issues and IB research. Asymmetrical power relationships, the disadvantaged conditions of developing nations, including their socio-economic institutions, ultimately undermine the freedom of IB research participants at a fundamental level. The recognition of IP rights will help to empower participants and their communities to negotiate a better distributional framework in IB research. In developed nations, those who accept a salary package or negotiate a benefit package enjoy an extraordinary level of freedom and choice. On the other hand, host communities and research participants lack such freedom. For this reason, I propose ascribing IP rights to host nations for their contributions to IB research, so that the host nations and communities would be in a position to negotiate better and share of benefits fairly from the collaborative partnership projects in the near future.

In theory, justice in IB research means equity, recognition, and participation. In practice, however, justice is related to the basic needs and functioning of individuals and

communities. The human development approach places a fundamental emphasis on the enabling of human capabilities and functioning. Applying the capabilities approach to justice in IB research means considering a range of basic needs, social recognition, economic and political rights. This implies that justice is a plural concept that encompasses creating and functioning various human capabilities via the fulfilments of basic human needs (Schlosberg, 2013, p.40). I argue that this notion of justice can be regarded as the basis of justice in IB research.

In the above discussion, it has been observed that there is evidence that the existing disadvantages conditions of low and middle-income countries are the product of colonial legacies. I partially agree with Pogge and London about the influence of these colonial legacies. This is one of the contributing factors in creating disadvantageous conditions, but I would suggest that in the case of IB research, acknowledging the contributions of developing nations by conferring IP rights based on their contributions would be a more ethically justifiable way of “creating capabilities” in poor nations.

I have argued that participants from developing countries bear most of the burdens and risks of IB research, and that their contributions enable innovation, develop new interventions, and confirm new medical knowledge. Consequently, participants and communities from developing countries earn the right to be eligible for benefit sharing on the basis of their contributions. Therefore, it is the duty and responsibility of developed nations to transfer some benefits to the host nations of IB research.

Successful interventions developed through research should be given back to the study population in various ways. However, without a claim right, how can developing nation achieve a fair share of the benefits? This led me conclude that the conferral of IP rights to host nations will pave the way for justice in international biomedical research, and will allow the promotion of global health rights to overcome the limitations of traditional frameworks.

In international biomedical research, IP (patent) ownership is considered as capital by developed nations. On the other hand, developing nations, through their participation in clinical trials or by providing materials such as samples of diseases, make valuable contributions in the field of knowledge and innovation or provide opportunity for innovation. These intrinsic contributions cannot be compensated by a one-off payment, and to do so is exploitative. Kant (1787, p.93) said that percept without concept is blind and concept without percept is empty, and a similar situation exist in IB research. The clinical trial, through the contributions of the participants and communities of the host country, provides percept for the concept. Without the contribution of host nations and participants the potential new intervention would remain an empty concept, with the same status as an unwarranted assertion.

Generally, IP rights are preserved by developed nations and used by them to sustain their global political power and economic prosperity (Pham, 2004). Global IP rights are secured by developed nations through the WTO to extend their trading power as well.

My view is that as both parties contribute to health research, and IP (patent) rights are used as capital by developed nations to rule developing nations. I argue that, rather than depriving developing nations by providing them with only one-off lump sum payments, IP rights should be shared among the contributors to IB research. If the claim rights of developing nation are not included in the distribution of IP, the prevalence and severity of injustice and exploitation in IB research will remain. If fairness in distribution is a matter of justice in exchange, it cannot be achieved if both parties are not equally capable of bargaining and negotiating a distribution framework. Many researchers have identified developing nations lack of negotiation capacities and have argued for the creation such capabilities (Pogge, 2008, Nussbaum, 2011, discussed in chapter 6). I agree with them, and believe that negotiation power is crucial for benefit sharing and achieving justice in exchange. In the next chapter, I discuss the place of international negotiation in IB research and how this can contribute to fairness in the distribution of benefits and burdens in IB research.

Chapter Six

Increasing the Negotiation Capabilities of host nations to improve fair distribution of benefits of research outcomes through sharing patent rights.

6.1 Introduction

In the preceding chapter, I discussed the concept of benefit sharing in international biomedical (IB) research and I examined different models of benefit sharing proposed and used to achieve global justice in health. Capability approaches propose that securing capabilities for the citizens of poor developing nations is necessary to achieve global justice and to promote the human dignity of the citizens of those nations. For example, Martha Nussbaum (2011) claims that 10 types of capabilities are central to humans for flourishing and living a dignified life and so every government should enable their citizens to develop these capabilities. However, due to poverty⁸⁰ in developing nations, the governments of developing nations are often failing to create an environment where their people can achieve these capabilities (Pogge⁸¹, 2008, p.118),

⁸⁰ According to Benatar (2002, p. 1132) Poverty (defined as lack of economic resources, lack of education, lack of access to basic life resources such as food water and sanitation, and lack of control over the reproductive process) directly accounts for almost one-third of the global burden of disease.

⁸¹ In WP&HR Pogge (2002, pp.19-20) claims that the appalling trajectory of world poverty and global inequality since the end of Cold War as a shocking indictment of one particular, especially brutal path of economic globalization which our government choose to impose....The details of this order [globalization of economy] are fixed in international negotiations in which our governments enjoy a crushing advantage in bargaining power and expertise. And our representatives in international negotiations do not consider the interests of the global poor as part of their mandate...Our new global economic order is so harsh on the global poor, then, because it is shaped in negotiations where our representatives ruthlessly exploit their vastly superior bargaining power and expertise, as well as any weakness, ignorance, or corruptibility they may find in their counterpart negotiators, to shape each agreement for our greatest benefit. In such

and thus, many people in these nations cannot enjoy good health and a dignified life. In this chapter, I will argue that in addition to the capabilities highlighted by Nussbaum for people generally, including those in developing nations, the ability to negotiate a fair distribution of the benefits of international biomedical research is a key capability for the representative of developing nations achieving global justice in health and living a dignified life (Millum⁸², 2010).

6.2 Why is Negotiation Important?

Reasoning and reflection on the critical conditions of health of developing nations led me, in the first place, to explore the capacities of poor nations in the negotiations through which international collaborative clinical research is conducted. The people employing this negotiating capability may include research trial participants, local researchers, or higher-level officials as representatives for negotiation, but for simplicity I will refer to it in general terms as a developing nations' negotiation capacities. I also explain the contexts of negotiations in which both developed and developing nations' negotiations take place. On international negotiation, there are very limited literature in bioethics. Thus, I will discuss on international negotiation drawing from international relations literature. The capability of poor nations to negotiate fair access to health needs and rights is another crucial issue in this discussion as this capability is vital for

negotiations, the affluent states will make reciprocal concessions to one another, but rarely to the weak (pp.19-20).

⁸² Millum, J. (2010, p.25) has also emphasized for negotiating "benefit-sharing agreements with local community."

poor nations to claim their global health rights. Good negotiation skills also help with demonstrating how my contribution model can be applied to the realities of international research practice and the political negotiations involved.

The situation of developing nations' representatives negotiating with international health authorities and pharmaceutical companies to secure access to meeting health needs and rights for their citizens is in certain important respects similar to that of poor and vulnerable patients in those nations deciding whether to participate in IB research. On the one hand, the developing nations negotiators commonly face the challenge of calculating the value of the research and its relevance to the health needs of their population, often with little experience or understanding of the research. On the other hand, the research trial participants face dire needs and/or limited access to health care due to structural issues in their nations' of health system and the widespread poverty in developing nations. In both cases, a person faces many challenges due to poverty to fulfil various basic needs, and the temptation for negotiators is to try to solve the problem by whatever means might be immediately available at that time, without sufficiently considering the long-term consequences of the decision.

When dealing with wealthy nations, the negotiators of developing nations generally keep in mind the dire needs of the public in their nations. If a particular deal is not struck, then further socioeconomic or political unrest may result, and this may create extra pressure for the ruling government (Pogge, 2002, pp. 22-3). A developing nation

may even decide to compromise the ethical review of a research protocol simply because of the opportunity to collaborate with powerful sponsors from wealthy countries (Chuan and Schaefer, 2016). In the IB research context, sponsors/pharmaceutical companies from wealthy nations are usually very influential. They typically employ powerful negotiators and lobbyists to secure their benefits as they desire (Ballantyne, 2006, p.223). The capacity of developed nations negotiators as mentioned above is discussed in Pogge (2002, 2008). Pogge argues that, “our representatives (developed nations’ negotiators) ruthlessly exploit their vastly superior bargaining power and expertise, as well as any weakness, ignorance, or corruptibility they may find in their counterpart negotiators, to shape each agreement for our (developed nations) greatest benefit. In such negotiations, the affluent states will make reciprocal concessions to one another, but rarely to the weak (2002, p.20)”. Pogge’s statement strongly indicates that the developing nations, i.e., the hosts of IB research that I am considering here always have considerable limitations in power and resources which affect their bargaining power (Nuffield, 2002, pp.52-53, Aellah et al, 2016, p. 172). Furthermore, Pogge’s claim suggests that the moral character of rich nations’ negotiators can be questionable, and this deserves serious consideration. These deficiencies help to provide moral grounds for and emphasise the importance of capacity building of negotiators of developing nations.

Researchers and ethical guidelines for conducting research with human in developing nations have recognized an “asymmetric power relationship” that exists between developed and developing nations, and the lack of various “capabilities” of developing

nations - especially negotiation capability as (1) a barrier to achieving justice in international biomedical research, and in turn (2) a barrier to achieving fair access to health rights globally (Aellah et al, 2016, p. 172). Global access to health rights is something that should be a key goal of IB research. For example, according to the Commission on Health for Development Report 1990, global partnership in health research can play a significant role in achieving equitable access to health and moving forward with health needs in developing nations (also quoted in Pratt & Loff, 2011, Benatar, 2003, p.69, Aellah et al, 2016, p. 171).

Furthermore, the eradication of neglected tropical diseases by 2020 has been at the forefront of the World Health Organization's (WHO) roadmap, resulting in the 2012 London Declaration on Neglected Tropical Diseases. Consequently, the importance of finding new treatments and interventions through advanced research and development for neglected tropical diseases has been acknowledged in the London Declaration (Chuan and Schaefer, 2016). However, representatives of the developing nations in the World Trade Organization (hereafter WTO) and researchers also expressed concerns that the absence of binding treaties obligating developed nations to provide benefits (i.e. vaccines, drugs) in exchange for accessing bio-resources (such as virus samples), and traditional knowledge (Fidler, 2010, p. 2), provides opportunities for developed nations to evade their responsibilities and to take advantage of the unequal power relationship to benefit unjustly from their dealings with developing nations (Pogge, 2008, p.120, Page, 2002). For example, in 2001, representatives from Malawi produced a paper for

the WTO General Council (for the 4th Session of the Ministerial Conference). The paper claimed that

“the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement contains shortcomings unfavourable to least developed countries['] interests. These include, non-recognition of the rights of local communities to their traditional and indigenous knowledge which may lead to unjustified patenting of their knowledge and of biological resources by foreign corporations” (in Page, 2002, Appendix 2).

An example mentioned by Millum (2010) that a developed nations' pharmaceutical corporation unjustly taking advantage of the shortcomings of the TRIPS Agreement came in 1995, when the Council for Scientific and Industrial Research (CSIR) of South Africa applied for a patent (P57 patent) for the active appetite suppressing ingredients isolated from the Hoodia plant. The San communities of South Africa have been using the Hoodia plant as appetite suppressant for hundreds of years (Lucas and Schroeder and et al. 2013, p.81). The CSIR subsequently made a licensing agreement with a British company Phytopharm in 1997 to investigate development and commercialization of the P57 patent for a product derived from Hoodia. In 1998, the US pharma giant Pfizer was given the right of the P57 patent by Phytopharm through sublicensing, to market the Hoodia product as a weight loss aid in developed countries, without the knowledge of San people (cited in Millum, 2010, p. 24). Due to this agreement, the San people have not seen any benefit and further their access to the Hoodia plant has been restricted. In addition, Sedyaningish et al.⁸³ (2008, p. 486) also expressed a similar

⁸³ For them, “Developing countries provide information and share biological specimens/virus with the WHO system; then pharmaceutical industries of developed countries obtain free access to this information and specimens, produce and patent the products (diagnostics, vaccines, therapeutics or other technologies), and sell them back to the developing countries at unaffordable prices. Although it is general knowledge that this practice has been going on for a long time for other major communicable

concern regarding the Indonesian H5N1 virus sharing with the WHO, which I will discuss in chapter 7.

Different international covenants, declarations, protocols, and treaties have bestowed the responsibility of providing basic healthcare upon the governments of the nation/s in question (Singer & Schroeder, 2009, p.16). For example, “human rights to health have been enshrined in the Universal Declaration of Human Rights (ibid. 21).” Buchanan (1984) also argues that providing a minimum level of health care is the responsibility of each nation’s government. Unfortunately, many developing nations still lack the capabilities necessary for implementing such a responsibility. Furthermore, they have mostly failed in negotiations to establish their rights for increasing access to medicines and treatment technologies for the poor, for example in the Uruguay round of the WTO’s TRIPS Agreement (Drahos, 2001)⁸⁴. The WTO is a platform where every nation has equal moral standing in some sense – for example, basic equality has given equal veto rights and responsibilities to its members (WTO, 2016). However, the WTO did not allow a secret vote on the TRIPS Agreement. Secret voting allows a member to vote without being a sense of fear of coercion. So, there was no scope to exercise the equality of power distributed to member nations. The TRIPS Agreement has been reached by consensus through a series of negotiations (WTO, 2016). Nevertheless, an examination of the TRIPS Agreement and the process of negotiation demonstrate a

diseases-not just for avian influenza-the fear of potential pandemic influenza has magnified this gap. Moreover, in Indonesia’s opinion, what has been emphasised by the current global system is merely the responsibilities of developing countries, leaving a big hole in the right of these nations (Sedyaningish et al. 2008, p.486)”.

⁸⁴ In this context, moral philosophers such as Peter Singer and Doris Schroeder (2008, 2009) have argued for TRIPS reform. This requires negotiation capabilities of developing nations- i.e., fair access to information (knowledge power) and decision (political power).

crucial gap between affirmations of voting power and actual voting practice. However, I would argue that negotiators of developing nations have had no opportunity to properly deliberate on the principles of the TRIPS, or to walkout from the meeting or to refuse to sign the agreement if they believed that the proposed terms of the Agreement treated their country unjustly. Indeed, it seems to me that developing nations signed the agreement under some duress⁸⁵ as they lack various capabilities to negotiate effectively with their rich counterparts.

Negotiation processes generally, in the first place, involve fair inclusion of the parties into the decision-making process. However, merely being included in a decision means little if the participants in the negotiation lack fair access to information⁸⁶. Secondly, having the ability and opportunity to systematically analyse relevant information and to promptly share it within the interdisciplinary working parties is an integral part of the capability to articulate the position of a nation. International negotiation researchers have pointed out crippling limitations in developing nations' access to information and their incapability to claim redress and remedy for past injustices in IB research (Drahos, 2001, 2003, 2007). As Pogge persuasively argues in his book *World Poverty and Human Rights*, "the starting positions of the worse-off and better-off have emerged from a history of social injustices" (2002, pp. 16-24). Furthermore, Selgelid also explains how developed nations are responsible for creating an unequal world and he goes on to

⁸⁵ This reminds us two things. Firstly, J.L.Austin's distinction between "my hand goes up" and "I raise my hand" and secondly, Sen's distinction between fasting and hunger. In the WTO, member states supported the TRIPS Agreement as if they are bound to do so. If my hand (hand of developing nations representative in the WTO) goes up does not mean that I voluntarily raised my hand in a particular circumstance. Rather, "my hand goes up" also implies that I may raise my hand under compulsion. Similarly, fasting is voluntary but hunger implies both voluntary and involuntary actions.

⁸⁶ Access to decision, information and legal systems is considered as elements of justice in Aarhus Convention 1998.

explain why developed nations should be motivated to assist developing nations for improving health in developing nations as a part of redressing and remedying past injustice that developed nations have inflicted upon developing nations. For Selgelid,

“the current wealth enjoyed by those of us living in developed countries is partly a result of the long-term exploitation of developing nations’ human and natural resources” (Selgelid, 2008, p.120).

In the context of IB research, building the capacities⁸⁷ of developing nations’ is viewed by many bioethics researchers as an integral part of the moral obligation of developed nations to avoid exploitation and achieve justice (Lansang et al. 2004, Aellah et al, 2016).

The extensive work of Drahos (2001, 2003, 2007) has shown that the international negotiating team members of developing nations in the context of international multilateral treaty (i.e., TRIPS negotiation), and bilateral agreements (i.e., Free Trade Agreements (FTAs) negotiation) commonly lack a sufficient level of specific and/or relevant training and/or expertise, along with intuitive acumen when compared with negotiators from developed nations. UN special rapporteur Anand Grover highlighted how negotiations on international multilateral treaties and bilateral agreements vividly affect the health of the populations of developing nations. He argues that,

“Nearly 2 billion people lack access to essential medicines. Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia. The inability of populations to access medicines is partly due to high costs.... TRIPS [Agreement on Trade-Related Aspects of Intellectual Property

⁸⁷ Lansang et al. point out, “capacity building as the ongoing process of empowering individuals, institutions, organizations, and nations to define and prioritize problems systematically, develop and scientifically evaluate appropriate solutions, and share and apply the knowledge generated” (WHO, 2004, p.764-5).

Rights] and FTAs [free trade agreements] have had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health (Grover 2009).”

The negotiators of developed nations are well trained and are usually backed up by enough data and research before commencing negotiations. The negotiators of developed nations typically collect data, categorize collected data, and have proceeded to analyse the collected data. They also usually imagine possible scenarios and devise tactics to deal with these imagined conditions. On the other hand, the negotiators of developing nations are often selected by corrupt politicians who choose people loyal to the regime, and instruct their negotiators to preserve vested interests (Bonilla, 2004).

In many cases, the representatives of developing nations are reminded by their top management leaders of the policies of the government without being granted much flexibility, and mostly decisions come from the top government officials. For example, the Bangladesh textile sector receives significant benefits from the US governments. Thus, in any IB research negotiation, Bangladeshi negotiators must weigh these benefits against the benefits derived from IB research in circumstances where these might come into conflict – e.g., the textile benefits may be jeopardised if Bangladesh exercise the nation’s patent rights in IB negotiations. For example, they (i.e., developed nations) may raise some unintentional/incidental violations of labour laws and this might result in an embargo on imports from Bangladesh.

The unequal position of developing nations led me to ask the question: how should the negotiation capabilities of developing nations be enhanced so that fair agreements, treaties and protocols can be developed and the benefits of IB research can be distributed equitably? In this chapter, I explore the concerns of negotiation, its importance and influence in IB research, and whether more effort should be made to create and enhance the negotiation capabilities of developing countries. For the purposes of this discussion, I will be placing emphasis on the exploitation of international research participants as I assume that lack of fairness in IB research protocol design, and lack of negotiation capability of developing nations, are directly related to the capacity of participants to provide informed consent and to the quality of consent of the negotiators. In both cases – that is, the negotiation process and obtaining consent from the participants, there are scopes for developed nations to exploit various types of vulnerabilities of the developing nations.

Implementing the benefit sharing principle that I argued for in the previous chapters involves negotiation by the parties involved. Thus, a clear understanding of good negotiation process is required. Revisiting negotiations, I address the ethical requirements of fair negotiation and argue that fundamental principles of justice as *equal opportunity* should play a crucial role in negotiation for fairness. Bioethics researchers have argued that the existence of an asymmetric power relationship is a barrier to fairness in negotiation, and therefore in IB research. This has been identified in the TRIPS negotiation. The WTO recognised equal status and the members hold dignity for their states, but the crucial question is why the parties sign an unjust treaty?

Thus, I also investigate what I call the capillaries of justice in negotiation, so that access to medicine can be fairer for all and global health rights can be protected.

The aim of this chapter is therefore to demonstrate how some of the principles of justice examined in the previous chapter can be utilised in the practice of IB research to eliminate or reduce the scope for injustice and/or exploitation through the implementation of a fair benefit sharing framework. This framework will serve to empower host communities by removing barriers to fair access to information, decision-making and justice, the key sources of injustice (Lansang et al. 2004, p. 766, Costello and Zumla, 2000, Edejer, 1999). I will demonstrate how the lack of various capabilities of host nations can be addressed through benefits sharing, and respecting participants' contributions.

6.3 Revisiting Capillaries of Justice in Negotiation

International declarations such as (WMA's Declaration of Helsinki) and international institutions (CIOMS guidelines) state that justice can be achieved by developing ethical frameworks for the protection of human participants' rights and welfare in IB research. They also argue for ethical training for developing nation's administrators so that exploitation of participants can be addressed and fairness in negotiation can be elevated.

Another view points out that the pharmaceutical industry of developed nations uses poor nations to test drugs or technologies that benefit the people of developed nations, rather than the people on whom the research is conducted (London, 2005, Schulz-Baldes, Vayena and Biller-Andorno, 2007). Developed nations invest less in research on diseases that mostly affect the citizens of the developing nations, such as Malaria. Rather they conduct clinical trials for drugs to treat diseases such as hypertension and diabetes where the primary market for the drugs would be developed world (Lo, 2009, p.194). Hence, to improve the conditions of developing nations, bioethics researchers propose capacity building (i.e. Ballantyne, 2006, Schulz-Baldes, Vayena and Biller-Andorno, 2007, Lansang et al. 2004, Costello and Zumla, 2000, Edejer, 1999) of poor nations to redress and remedy this type of injustice. Enhancing the negotiation skills of developing nations would mean that if any research proposal is not responsive to the host community's health needs, or is not based on an acceptable moral principle of justice, or is exploitative, then the host community could reject the proposal or alternatively, could negotiate an appropriate level of compensation for any harm that occurs because of their participation in the research.

Developed nations currently provide aid to health and multidisciplinary study areas in developing countries by providing scholarships, research and training, and opportunities for skills development, mentoring, workshops and to gain practical experience (Lau et al., 2015, p.3, Pratt and Loff, 2013, Lansang et al., 2004). For example, the National Institutes of Health (NIH) through the Fogarty International Center provides education and research training for developing ethics expertise in low and middle income

countries, so that expertise in ethics also can complement other areas of research and training in global health. However, for capacity building in developing nations, developed nations' research and philanthropic institutes have dedicated less than 1% from their health research fund (Lansang et al., 2004, p.768).

I want to acknowledge that the International Centre for Diarrhoeal Diseases Research of Bangladesh (hereafter ICDDRDB) was established by international communities, and offers space and facilities for Bangladeshi researchers to work with international scholars and to treat various types of diseases in innovative ways. This is a rare opportunity for international community to work for global health rights and address health needs of the poor developing nations.

However, these collaborative practices are not the result of binding agreements for developed nations. There are no agreements that developed nations should provide similar support to all of those nations that host IB research where such support is needed, in the way the TRIPS Agreement binds developing nations to observe its spirit and to implement the TRIPS commitments at a national level for the protection of IP. Why does such a gap exist between developed and developing nations' achievements in negotiation, and in the distribution of the benefits and responsibilities of IB research?

The developed nation sponsors of IB are not currently seen by them as bound to acknowledge the contributions of host nations usually by sharing resulting IP, to

address health problems of developing nations and in turn to share benefits equitably. I argue that the problem is that the developed nations often take the opportunity to innovate ideas and technologies in collaboration with international research participants, and then patent those ideas and technologies without sufficiently acknowledging the host nations' contributions or sharing the benefits of this research. By contrast, under the TRIPS Agreement it is mandatory for the governments of developing nations to acknowledge pharmaceutical companies responsible for the violation of IP rights. The TRIPS Agreement is made to protect developed nations' business interests and patent rights, with no consideration for the level of access to medicine in poor nations, and in turn global health rights (Fidler, 2010, p.2). The majority people of developing nations are therefore left destitute and suffer further because of these unjust negotiations.

These unjust conditions led me to ask: is there any way that processes of negotiation could be improved to result in a morally binding treaty, protocol, or agreement for justice in IB research? Could there be an agreement that would prevent developed nations negotiating unjust protocols that exploit developing nations? Why is it that developing nations fail to argue for their rights and shoulder disproportionate burdens in IB research? Are they not capable of bargaining? Do they simply lack knowledge of the principles of justice on which they could base their negotiations? To answer these questions, the following sections explore negotiation, the skills that are required for such negotiation and the necessity for principles of justice in these sorts of negotiations. These are the foundations necessary for the negotiation of any declaration, protocol, or agreement for the fair distribution of the benefits of IB research.

To investigate the negotiation capabilities of developed and developing nations I have selected two well-known cases for further examination: the WTO's TRIPS Agreement (which resulted in protecting the developed nations' strong interest in global IP protection for pharmaceuticals), and the Indonesian H5N1 virus material sharing agreement with the WHO. The latter will be discussed in chapter 7, which (by contrast with my focus in the present chapter) is focused on demonstrating the demands of developing nations in the process for drug development, such as Indonesia's demand for recognition in the IP distribution of their material sharing. These historical cases are useful to demonstrate how an unfair agreement can be arrived at through unequal negotiations, and how this poses another level of threat to the health rights of developing nations. An investigation of these case studies will serve to demonstrate how the lack of various capabilities by the negotiators of developing nations, as explained by Nussbaum (2011), contributes to the negotiation of an unfair agreement. This injustice is exacerbated by the existence of asymmetric power relationships at a global level, (even though the WTO gives formally equal status to every member of the organisation), and the absence of an appropriate justice principle for fairness in distribution.

Nussbaum has developed a general theoretical framework of capabilities. This framework can be applied for creating capabilities for achieving fairness in international negotiations of treaties, and in IB research protocols. For Nussbaum, the creation of

capabilities is a principle of justice, and is required if respect for human dignity, the first principle of Universal Human Rights Declarations, is truly a global concern. I agree with Nussbaum and will use her principle of justice to argue for bringing fairness into the international negotiation of health rights by the creation of various capabilities that developing countries often lack, and which are essential for fairness in negotiation.

6.4 Investigating the TRIPS Agreement Negotiation

The TRIPS Agreement has recently created the most debated issue in the current international law and bioethics literature. In this case, developed nations used their strong bargaining power, negotiation strategies, and communication skills, and lobbied on a popular notion of justice as “equality” to secure the product and process patent for pharmaceuticals in the TRIPS Agreement. In these negotiations, developed nations’ military power and the possibility of economic sanctions were perceived as background threats by developing nations negotiators (Drahos, 2003, Pogge, 2002, pp. 22-3). The developing nations were in a position such that they did not have any option but to sign the agreement. In this regard, the US role can be mentioned which is similar to their role in negotiating a free trade agreement (FTA) with Singapore and Chile. The US signed the free trade deal with Chile upon the condition that Chile will support Iraq war (Crump, 2011, p.198). However, this FTA proposal was suspended for five to six years by the US governments, as the US Congress did not grant approval to the then president Bill Clinton.

When the TRIPS Agreement was being developed, the powerful nations involved only considered the national interests and patent rights of their pharmaceutical companies and biomedical research organisations. The Agreement thus was intended to siphon benefits unilaterally to the pharmaceutical companies of developed nations (Draho, 2003). The representatives of developed nations at the WTO negotiation knew that compliance with the TRIPS Agreement would have devastating consequences for access to medicines for the poor in the developing nations, as the latter nations will lose the opportunity to produce generic versions of drugs and medical technologies, or to import cheap generics from other countries. In addition, TRIPS has given developed nations the ability to take legal action for a violation of the agreement by any member⁸⁸.

Draho (2007, p.100) claims that “TRIPS were the product of politically powerful and linked networks deploying a regulatory pyramid with the threat of trade sanctions at its apex⁸⁹.” Thus, TRIPS Agreement allows sponsoring nations to capitalise on the results of IB research without recognising the substantial contributions of host nations or giving

⁸⁸ For example, article 61 says that “Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines enough to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale” (WTO, 1994).

⁸⁹ Quote from Draho (2007, p.100) “10+10 (and the variants thereof such as 5+5, 3+3). The US and the European Community were always part of any such group if the issue was important. Other active members were Japan, Nordics, Canada, Argentina, Australia, Brazil, Hong Kong, India, Malaysia, Switzerland, and Thailand.)”

them any share of the profits resulting from the products developed through that research.

For Drahos, developed nations ensure that TRIPS negotiations were in their own interests, by following a strategy that

“[i]n the actual negotiations developing countries were not part of the informal groupings where much of the real negotiating was done and where the consensus and agreement that matter was obtained (Drahos, 2007, p.100).”

This view has been strongly supported by Pogge’s research. For example, he has argued that developing nations signed WTO’s TRIPS Agreement “under duress”. Rege has expressed a similar concern and has noted that the WTO negotiations of the TRIPS Agreement were kept utterly secret to prevent lobbying by member states in advance (Rege, 1999, p. 49).

Keeping aspect of an international negotiation secret, is tantamount to a kind of deception, and is morally unjustifiable since most of the members involved in the TRIPS negotiations are poor and lack negotiation capabilities. This means that developing nations had no awareness specifically of IP protection for pharmaceuticals in the content of the negotiation agenda, or of the supporting documents prior to the negotiation. In this case, participating developing nations were somewhat shocked to discover that patents on pharmaceuticals were included in the TRIPS Agreement, and that developing countries must follow the fixed rules and procedures of the WTO, and would have to unconditionally accept the consequences of these negotiations. The WTO officials thus violated the good governance principle of transparency, something

which is also a principle of justice, as access to information is a core element of justice. If developing nations were aware of their right to information and could thus have argued in that forum against the withholding of such an important right, then a morally sound TRIPS Agreement could perhaps have been reached. The unconditional acceptance of the unjust procedures by developing nations is further evidence of their lack of knowledge and skill in international negotiation.

Page (2002) argued that developing nations' negotiators were not supported by their own government during the negotiations. For Page, "many developing countries also suffered from a lack of back up from their government (Page, 2002, p.20)." This also implies that representatives of developing nations were under undue pressure during the negotiation process. Without knowing more information about the positions of the parties involved in the negotiation and without any external support from own governments, they negotiated the TRIPS⁹⁰ deal. The governments and people of developing nations accepted the outcome of this negotiation without having an opportunity to give enough consideration of whether it might be beneficial for their nations (Page, 2002, p.21).

⁹⁰ Moreover, TRIPS waiver has given to all low and middle-income countries. As recipient of waiver, member states of the WTO were given due dates must to modify/ update their domestic regulations for compliance with the IP standards of the TRIPS Agreement. Middle income countries do not have to follow the pharmaceutical IP by 2005, and least developed countries (LDCs) until 2016 initially. However, LDCs were not able to fully absorb with the changes specifically with addressing the pharmaceuticals IP, thus further extension until 2033 has given to them. For example, as a LDCs listed country, Bangladesh must comply with the pharmaceutical IP standard by 2033.

I believe that just as developing nations signed the TRIPS Agreement, with devastating consequences under such disadvantageous conditions that they were under pressure for various reasons as mentioned above (i.e., lack of access to information, backup support etc.), there is a significant risk that developing nations will sign IB research protocols under similar pressure, and without considering the morality and implications of such unjust agreements.

Otherwise, nations that do not comply with the IP requirements - for example compliance with the TRIPS principles granting permit to produce generic essential drugs, enforcing laws to protect IPs of foreign nationals, developing laws and regulations by maintaining international standards of biomedical research, of the TRIPS Agreement - must face the dispute resolution process of the WTO. According to Drahos (2001, 2007), dealing with the dispute resolution process involves a high level of sophisticated legal expertise and resources. He acknowledges that unluckily the developing nations are substantially lacking in such expertise. Having legal expertise without domestic manufacturing capacity is expensive and thus burdensome to the developing nations (Land, 2014, p.150)⁹¹. Under the TRIPS Agreement, if industries of developing nations, such as India or Brazil wish to produce and export drugs, then they must pay royalties to the patent holders. If any patent holder declines to authorise the

⁹¹ For instance, Land argued, "WTO dispute resolution is expensive, and these costs are, in relative terms, "much higher for developing than developed countries."45 Legalised adjudication "demands increasingly sophisticated legal talent" thereby "driv[ing] up the cost of formal dispute settlement, which is disproportionately burdensome to developing countries."46 Developing nations also tend to possess less domestic legal expertise in the area of intellectual property and have access to fewer resources necessary to initiate or defend against suits (Land, 2014, p.150).

production of any drug, either for political reasons or due to an inadequate amount of royalties on offer, then how can developing nations meet their health needs?

6.5 Paving the Way to Justice in Doha Declaration – a Result of Robust

Negotiation/Increased Bargaining Potential:

Generally, having the skills and capacity for convincing different parties to harmonise their interests is considered crucial for successfully negotiating a fair outcome (Zartman et al 1996, p.80). Consequently, developing strong negotiation skills in general and specifically, building a coalition for poor nations are crucial when negotiations take place with developed nations due to the asymmetry in the power relationships between them (Drahos, 2003). If the problems of benefit distribution and global health justice are to be addressed, then adequate negotiation skills for poor nations are necessary. In this regard, the role of international Non-Governmental Organizations (Hereafter NGOs) are also emphasised (Matthew, 2014, p.12) as NGOs such as Oxfam and Medicines Sans Frontiers (MSF) played a robust role in securing further benefits for public health measures over access to medicine at the WTO' Ministerial Conference in Doha in 2001. The Doha Declaration has resulted in the provisions of the TRIPS Agreement. The

TRIPS Agreement is being relaxed somewhat and so are adding opportunities⁹² for developing nations.

The Doha Declaration Paragraph 4 urges the [WTO] Council for the TRIPS Agreement, that “the Agreement can and should be interpreted and implemented in a manner

⁹² The Doha Declaration states: “4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

supportive of WTO members' right to protect health and, in particular, to promote access to medicines for all". The Doha Declaration also states that, "5(b) Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted".

That is to protect public health, the Doha Declaration allows states to override the rights of patent holders and produce generic versions of patented drugs, when necessary, but certain conditions must be followed (Drahos, 2007, p. 98). For example, the state must have adequate manufacturing capacity to obtain compulsory licensing⁹³ provision when the TRIPS Agreement was adopted. And under the Article of 31 of the TRIPS Agreement, a nation must use compulsory licensing principally to produce generic medicines for domestic supply.

The limitation of compulsory licensing to the production of drugs for domestic supply raised a problem for those WTO members that did not have sufficient pharmaceutical

⁹³Compulsory Licensing is an international legal measure for global public health laid out in the Article 31 of the TRIPS Agreement. Compulsory License can be obtained by any state with domestic manufacturing capacities with minimum royalties. Then a state has the power to authorize an experienced government generic producer to produce generic copies of a patented drug as an emergency response to a pandemic in the state. In this situation, patent owner is forced to lose rights for taking action against copying, which means it is not an option that pharmaceutical companies are willingly sharing with the developing nations to address problems of access to medicines for the global poor. This is completely different from sharing benefits of international collaborative research. Compulsory license can be obtained by any nation whether they have contributed in the drug development process or not (Ballantyne, 2006, Schroeder and Singer, 2009, Drahos, 2007). However, some scholars have argued for such provision, as Schuklenk and Ashcroft (2002) believe that it is morally and pragmatically better solution over drug donation or price cut option.

In this regard, I would like to point out that there are two issues: one is access to health care for the global poor and another is international clinical research benefit sharing. As this research is focusing on the international clinical research benefit sharing, compulsory license cannot be a solution to the problem of benefit sharing rather it is more relevant to the problem of access to global health care.

manufacturing capacity in place, and were therefore required to import essential medicines. Access to essential generic drugs for these states remained obstructed, as other nations were not permitted to produce generic drugs for export (Draho, 2001, Schroeder and Singer, 2009).

But since 30 August 2003, an instruction of the Doha Declaration was adopted as the solution to increase access to essential medicine in low and middle income countries in the WTO General Council, in “the form of waivers of the obligations in Article 31”, which means that compulsory licensing also can be used by low and middle income countries for export from India and Brazil to African nations. For example, perhaps now Bangladesh could apply for a compulsory license to produce generic HIV drugs while the drugs are under patent, and Bangladesh could do this because it has local manufacturing capacity and could then export these drugs to Malawi. The relaxation of the TRIPS Agreement benefits has occurred because of successful negotiation and a strong campaign by international civil society, NGOs and a coalition of developing nations at the Doha. However, researchers are sceptical about using compulsory licensing for exporting purposes (Schroeder and Singer, 2009, p.11). For example, Johnston and Wasunna (2007, S18) express concerns that using compulsory licenses for export is excessively complex and extremely bureaucratic, so that it is virtually impossible and unworkable in practice.

It might be argued that the Doha Declaration 2001 at least enabled licences to be issued for access to medicines in emergency situations, and relaxed other conditions of

the TRIPS Agreement. However, applicants for such a waiver had to apply, satisfy and justify in various ways that they deserve such consideration, and this process requires a high level of negotiation and technical skills (although preparing an application for compulsory license is not demanding as participating effectively in international trade negotiation).

Generally, the TRIPS Agreement is considered a win for developed nations, and the Doha Declaration is considered as a win for the developing nations (Draho, 2007). However, in international law, an agreement and a declaration do not have similar status and legal enforceability. But the evaluation of the legal status of a declaration and an agreement is not the intended topic of my research here. This violation of global health rights, resulting from the introduction and observance of the TRIPS Agreement in the first place highlights the lack of negotiation capabilities of developing nations, and provides a strong argument that this capability should be enhanced.

However, that the TRIPS Agreement ⁹⁴(“data exclusivity” and “market exclusivity”) is a binding agreement and the Doha Declaration is just an affirmation. And questions remain about whether building/increasing negotiation capacity for developing nations and creating ethical guidelines are sufficient to achieve procedural fairness in IB research? And whether it is possible to secure a similar “binding provision[s]” for developed nations, as developing nations pursuing “equitable access” to medicine, for

⁹⁴ Reichman, H.J.2009. Rethinking the role of clinical trial data in international intellectual property law: The case for a public goods approach, *Marquette Intellectual Prop Law Rev.* 13(1): 1–68.

the protection of global health rights (Fidler, 2010, p.2). Such a question arises in our mind because there remain more avenues for developed nations to unfairly extract further benefits from such declarations. According to Drahos, beside acquiring the negotiation skills necessary to achieve a binding treaty for global public health, developing nations must also build a coalition for effective negotiation for fair access to medicine and treatment technologies (Malawi, 2001 in Page 2002, Drahos, 2001, 2007).

Currently, the USA is negotiating a bilateral free trade agreement (FTA) with different nations for stronger IP protection. For example, during the FTA negotiations between Australia and the USA in 2004, the US government asked the Australian government to reform the pharmaceutical benefit scheme (PBS) of Australia. Consequently, in 2007, the Australian PBS has been reformed and has been broken into two formularies. One is known as F1 which is essentially for patented medicines and the other one is F2 which is essentially for generic medicines. As a result of this reforming, average prices have risen by 35% for patented medicines in F1 between 2005-06 and 2009-10. The Australian public has been paying this increased cost (Drahos, 2011). Paying the increased prices that result from FTAs may not be a severe problem for developed nations like Australia, but high prices are a significant barrier to accessibility⁹⁵ of medicines in the developing nations (Selgelid and Sepers, 2006, p. 153, Schuklenk, 2003, p.64).

⁹⁵ Accessibility of medicines problem arises when the poor cannot afford a drug due to high price.

The USA led FTAs are used to restrict access to medicine in developing nations (Drahos 2001, Grover, 2009 in Singer, 2009). For example, the Committee on Government Reform in the United States House of Representatives examined a number of these FTAs and concluded in the report that

“US trade negotiators have repeatedly used the trade agreements to restrict[s] the ability of developing nations to acquire medicines at affordable prices” (Drahos, 2007 in Crump and Maswood, 2007, p.99).

The lack of recognition of developing nations’ significant contributions in IB research and the lack of equitable distribution of patent rights provide moral grounds for developing nations to argue against the TRIPS, in order to ensure fair access to health needs and to distribute IB research outcome equitably. These unjust acts of developed nations justify efforts towards “creating capabilities”, as discussed by Nussbaum (2011).

6.6 The Idea and Skill for Effective Negotiation

Fisher and Ury (1981, p.xi), define negotiation as “back-and-forth communication designed to reach an agreement when you and the other side have some interests that are shared and others that are opposed.” Negotiation is used in national and international settings for reaching an agreement or making a decision on any conflicting issue. During the negotiation process involved parties consider each other’s’ interests, their ideas about the issue, and discuss how to reach a conclusion for declaration, agreement and signing a protocol. Therefore, negotiation is a process of decision

making which requires each party to understand the strategic consequences of different outcomes, and to communicate effectively to reach an agreement. In this section, I explore the negotiation capability of most developing nations with reference to the TRIPS Agreement, as this agreement has a profound impact on the issues of access to medicine for the global poor, the promotion of global health rights, and the protection of the rights of poor developing nations.

The outcome of a negotiation depends on several factors. Some important factors are the agents' current knowledge of the issues of negotiation, their interpersonal skills, and their ability to present an argument in a persuasive way, something which heavily relies on the communication skills of negotiators. Fisher and Ury, (1983: p.xi, 33) agree that "without communication there is no negotiation". Further, Stein (1988, p. 222) expressed a similar view that communication is at the heart of international negotiation.

Effective communication requires that the issues are presented in a coherent and businesslike fashion. The capacity of each party to understand strategically different options and their possible outcomes is also essential for effective negotiation. Other vital skills for negotiation include the ability to liaise with others, and past experience in negotiation. Prior to negotiation, parties should carry out research on the interests of their domestic and international counterpart's. Information should be accurately obtained, collected, updated, and analysed before proceeding to any negotiation. In summary, negotiators use various types of power and strategies, ability, and knowledge to make their case in negotiation.

Negotiators require access to relevant information reasonably in order to make competent decision. In addition, each involved party should be able to choose freely which option they regard as fair/best, and they should not be under duress in any circumstances. They should not be required to gamble on an uncertain outcome just to fulfil their basic needs. These issues require more attention in research and development. However, developing nations often do not have enough budget for health, education and business research. In consequence, they are usually behind developed nations in innovation (Bonilla, 2004, p.32). Thus, negotiators from developing nations in many cases attend and participate in the process of negotiation unprepared and do not have sufficient data to back up their position. For example, in 2015-16, the Bangladesh government allocated 4.3% of their budget for health care, whereas the Australian government allocated 26.6% in their budget for health⁹⁶. These negotiators from developing nations find themselves in a position of disadvantage in their training, their research, and their need to attract resources from developed nations.

Some scholars argue that concepts such as fairness and justice actually do play a crucial role in international negotiation between governments/states. These scholars suggest that, for example, if we explore the processes or outcomes of a negotiation, then we will find that in practice these have been conducted and achieved based on a principle of justice. Zartman et al (1996) claim that

⁹⁶ The budget allocation for health in Bangladesh is for 162.9 million people, whereas the Australian government's allocated budget is for 24.3 million people. (Source: United Nations Department of Economic and Social Affairs: Population Division, Australian Bureau of Statistics, countrymeters.info/en/Bangladesh, accessed on 13.1.2017).

“negotiated outcomes are achieved by the combined and competing efforts of parties holding initially conflicting positions. But they are not merely the results of a contest of countervailing wills and power nor of a confrontation of skills and tactics. Rather the range of potential agreements and the shape of the final outcome are determined in large part by underlying notions of fairness or justice (p.79)”.

By contrast, Nash (1950) also notes that at a certain period in the history of negotiation, negotiation was simply a process of harmonisation of competing claims of contending parties and principles of justice did not have any role to play in the process. However, some scholars argue that this practice has been changed over time and that the importance of justice principles in negotiation is subsequently apparent. For example, Zartman et al. argued that justice and fairness are fundamental values that we do apply to resolve conflicts more generally, and that negotiation is not the only example of this. Furthermore, Druckman & Wagner (2016, p.392) state that, “[j]ustice principles may also serve as heuristics”. In international negotiations many justice issues can be discussed in detail by the involved parties. Some of these issues may be very critical and cannot be reached on consensus immediately. Rather these issues require extended deliberation. These issues in some cases prolong decision making process and obstruct access to available benefits and may ultimately violate human health rights. In such cases, negotiation teams require a solution quickly. The negotiators in which case had to consider whether, if the negotiation is prolonged, this will increase sufferings of the patients. For example, in different parts of the globe cancer or HIV patients are suffering enormous pain. Lack of access to HIV virus sample may cause delay in research and drug development to address epidemic outbreak. Or prolonged negotiation may hinder access to technologies for further development. In such cases, if

there is scope for utilizing very broad principle of justice, for example “both parties will receive benefit and contribute to humanity”, then such a principle can act as heuristic in an international negotiation.

Druckman & Wagner (2016, p.392) argued that “[t]he role of justice principles in negotiation implies that neither any simple harmonisation of claims or interests, nor any power imposition will provide the framework for an agreement, but rather that an applicable principle of justice with a set of conditions may serve as foundation of negotiation.” Nevertheless, in theory, concepts of justice and fairness should play a role in the decision-making process of parties in negotiation, but especially, in cases where an asymmetric power relationship exists, justice and fairness may not be exercised.

A comprehensive bioethics literature review indicates that strongly asymmetric power relationships do exist between the parties in IB research negotiations (NBAC, 2001, p.60, Nuffield, 2002, pp 52-53). This raises an important question: how can a principle of justice, which will assist in the fair distribution of international collaborative research benefits and burdens, in practice play a role in the process of IB research negotiation? Therefore, in the next section of the thesis, I explore the role of including a justice principle for IB research negotiations.

6.7 A Principle of Justice in Negotiation

Justice principles play a crucial role for fairness in distribution of benefits and burdens of IB research negotiation. The value of having a justice principle in negotiation is

empirically tested and recognised by researchers (See e.g. Druckman & Wagner, 2016). Zartman (2002) argued that various principles of justice play a role in international negotiation between corporation and/or governments, and deliver a kind of justice to poor communities of developing nations even though an asymmetric power relationship exists (Zartman and Rubin, 2001)⁹⁷. However, Zartman expressed concern that power symmetry, a justice principle used in the TRIPS negotiation, in most cases may prolong bargaining and fail to dispense any benefit on time (ibid, p.1). Does it follow from this that all IB research is based on a morally justifiable justice principle? Does it mean that the TRIPS Agreement, which poses a threat to global health rights, is also based on a justice principle that should be acceptable to all? To avoid prolonged discussions many things were kept secret, and this secrecy is a violation of the transparency principle of justice, but this lack of transparency could perhaps be justified if it facilitated the actual negotiation process, avoiding any delay in justice. Does it follow that these principles of justice are not sufficient conditions to bring fairness in distribution of IB research? If these are not sufficient, then it becomes necessary for us to explore further a principle of justice for fairness both in the procedural and substantive aspects of distributive justice in negotiation.

One answer to this problem might be to apply another principle, i.e., the principle of contribution that I developed in chapters two and three in addition to these principles of justice, creating an ethical guide for conducting IB research and developing negotiation skills to overcome barriers to global health rights and to achieve fairness in IB research.

⁹⁷ https://www.press.umich.edu/16897/power_and_negotiation

In order to respect global health rights, I have argued that the principle of contribution should be applied to govern IB research for the distribution of benefits and burdens of IB research equitably. This principle should be considered as a necessary but not sufficient condition to bring fairness in international negotiation, to increase access to medicine and medical technologies for the global poor. There are other factors which are intricately intertwined with the global health rights, such as lack of education and limited access to information for addressing and resolving issues with access to basic health care and essential medicines. In addition, a lack of civil rights to participate into decision making is critical in developing nations.

As I mentioned above, some abstract principles of justice should always play a crucial role in the background of negotiation. These justice principles provide a moral justification of the agreement reached by the negotiating parties. This implies that no negotiation would become successful unless both parties agree on a minimal principle of justice. However, according to Simm (2007, p.496),

“the moral concerns [principle of distribution] that surround benefit sharing are important, but their relative weight in justifying specific benefit-sharing arrangements might well differ depending on the situation”.

For Simm (2007 p. 496), “the moral justifications for benefit sharing can reasonably be contradictory.” For example, one party can approach benefit sharing based on solidarity-based arguments” while another party “may produce a different benefit sharing rationale than one that is formed around compensatory justice.” Cloninger et. al (2014) also identified such difficulties in health care policy making. For them, one party

might argue for universalism and another group can stand for relativism. One party can argue for person centred health care system for global health rights. In contrast, libertarians can argue for individual's liberty and selfish approach. And through negotiation, these two parties can arrive at a compromise solution, and can adopt a different justice principle from the one on which they based their initial claims. Therefore, the negotiation process can be complicated and requires a clear understanding of different justice principles as well as a high level of negotiation skills. As the adoption of different principles of justice may result in different outcomes. If representatives of developing nations are for any reason incapable of discerning sometimes the subtle differences that can exist between different justice principles, then they may reach an agreement (as they did in the case of TRIPS) that may hinder the equitable distribution of benefits and burdens of IB research. Such an agreement would hinder fair access to health rights of the global poor.

Access to relevant information is important for fairness in negotiation as this paves the way to choosing a mutually acceptable principle of justice and thus to enhancing a negotiator's capability to articulate rights in negotiation process. Access to such information is also a prerequisite for informed consent in IB research as this access brings fairness in the process of research and enhances the quality of resulting decision. Ethical guidelines and researchers emphasise the importance of obtaining informed and voluntary consent during international clinical trials, to avoid exploitation and ensure justice in the distribution of benefits and burdens (Macklin, 2004). All parties involved in IB research should give their consent autonomously, and their consent should be given equal worth in the process of benefit sharing.

If the parties to an agreement voluntarily consent to it and agree upon a principle of justice, then justice requires that the agreed parties should respect and obey the agreement. But in the case of IB research negotiations, it is necessary to explore whether developing nations' negotiators and participants face any constraints on their giving autonomous consent - for example whether they have the necessary skills and understanding of negotiation like their counterparts from developed nations have. In the next section, I will investigate whether clinical trial participants and protocol negotiators from developing nations commonly face any barriers to making autonomous decisions, or whether we can assume that the developed nation's party and the developing nations party have a qualitatively similar capability to consent or agree upon any protocol or agreement. Thus, the next section explores informed consent and the capability to choose.

6.8 Informed Consent, Capability to Choose, and Access to Information

Fair access to information is unequivocally regarded as a core element of justice. When providing informed consent to clinical research, designing protocols for clinical research, and negotiating agreements like the TRIPS Agreement, access to relevant information is also fundamentally important. However, it has been revealed in the previous chapters that international clinical research participants from developing nations typically lack the capability to choose different treatment options: as they mostly rely on clinical research

for access to health care, they remain in a vulnerable situation. The vulnerable situation of these research participants means that they lack the capability to choose freely, thus, their ability to provide informed consent⁹⁸ to IB research is an issue of justice. And research participants lack not only autonomy here, they also lack the capability to choose the right strategy in a vulnerable situation; thus, their ability to provide informed consent to IB research remains an issue of justice.

Ballantyne (2006, p.80-84) makes a crucial distinction between 'invalid consent' and 'limited choice'. She uses this distinction in defining exploitation. For her, invalid consent is *not* a requirement of exploitation - that is, Ballantyne argues that it is still possible for someone to be exploited in a transaction even where they have given their informed consent to the transaction. However, Ballantyne rightly argues that limited choice, i.e. a critical situation when a vulnerable patient has no alternatives but to participate in a clinical trial in order to receive treatment, *is* a necessary condition of exploitation. In this case, the research participants are under duress due to their unfortunate and difficult circumstances. The participant has little alternative but to consent to the exploitative transaction. The situation may be such that the research participant will die or would become disabled if he/she does not comply with participation in the trial. However,

⁹⁸ Whether such an association of informed consent with vulnerability and bargaining potential is justifiable or not and whether is tantamount to exploitation is not the topic of my discussion. Instead, I would prefer to focus on whether benefits and burdens are shared proportionately by the parties involved. Because imperfect informed consent, both in TRIPS Agreement negotiation and collaborative research protocol negotiation, may produce a better outcome that benefits the research participants as against their sufferings. For example, the participants may receive a fair share of the profit although the participants were not properly informed. Furthermore, informed consent related injustice, far from constituting outcome related injustice, is process related exploitation. This chapter is not concerned with this form of exploitation although I recognize the seriousness of this and other forms of exploitation in clinical trials in developing countries.

facing limited options when making a transaction is not sufficient for that transaction to be exploitative. Indeed, this situation can also occur at times in developed world - for example, terminally ill cancer patients may enrol in a trial to receive an experimental drug which is their only hope of a cure. But there is a morally significant difference between a situation where the experimental treatment offered by a clinical trial that offers the only possibility of a cure and a situation where a trial offers access to basic care that would otherwise be unavailable due to a participant's circumstances. Circumstances such as lacking access to basic health care and also having inadequate access to medicines necessary to treat the health of clinical research participants, have profound implications for the decision-making process in negotiations, and are critically linked with global health rights and justice in IB research. Such a situation poses enormous morally important challenges to/for negotiators' capability to choose an option for their nation, or to make that option available for a research participant. This is another important dimension of negotiation which is beyond the scope of this research. In such situations only a rule of thumb may serve as principle of justice (Smart, 1973).

According to Ballantyne (2006), clinical researcher groups are at present facing a scarcity of prospective research participants in such a disadvantageous situation, and are taking unfair advantage of them. Researchers are exploiting participants' vulnerability and incapacity to reject their offer, while not necessarily violating the requirements of informed consent (London, 2005, see also Ballantyne, 2006, p. 84). This type of scenario results in the 'pure exploitation' of the research subject, who is forced to gamble with their wellbeing in order to obtain their basic health needs. Such

exploitation is considered a gross violation of human rights. However, research participants in such circumstances may still end up receiving a fair share of the benefits of research, regardless of the invalidity of their informed consent. Consequently, invalid consent does not necessarily lead to the form of exploitation that involves a lack of fairness in distribution.

To define exploitation, researchers often use fairness as the criterion for judging an action, i.e., a transaction is free from exploitation if and only if it appears as fair in that given circumstance. An action may be fair in one situation and not in another: for example, according to the people of host nations it is unfair of researchers, who are involved in clinical trials in developing nations, if they do not tell the public what research they are doing and what results they have found from that research. Similarly, the host nation has the right to know what they are doing, how they are selecting participants and how long they will continue the research. But, from the researchers' perspective, releasing this information may affect their future business success as their competitors may get an indication to adopt suitable strategy for the business. So, researchers feel that they cannot disclose all information for the sake of their business sponsor and for their own sake.

Similarly, a participant has the right to know what benefits and burdens are associated with this research and who gets what and when. Access to such information in this regard is essential for fairness. However, fairness does not require the release of all

information associated with the study: for example, fairness does not require the release of all information to a visiting foreigner as to what clinical research a scientist is doing in the field of cancer drug development. The foreigner may be a scientist in the field who may bypass the research outcomes and patent the new drug in their country or another country which would represent a great loss for the nation. In this case, disclosure of information is unfair to local scientists.

The Participants of the conference (2004) argued that “universal agreement” regarding the fair distribution of benefits in international research would be “a naïve and unrealistic goal (Participants, 2004, p. 26).” However, the moral response to exploitation relies on the intuition that it is unacceptable to take advantage of the weakness or vulnerability of another by denying them a just share of the benefits of the transactions to which they are fairly entitled. It seems premature to conclude why universal agreement on fairness in the distribution of benefits and burdens would be a naïve and unrealistic goal. And further, what participants of the conference meant by the term ‘universal’ requires further explanation.

The idea of capacity building has come through the development literature based on Sen’s capability approach to development. Sen (2001) argues that poor people of developing nations lack several different types of freedom. This situation has led development thinkers to propose a model for capacity building. Ballantyne (2006) applies this idea under what she calls the infrastructure charge which means imposing a global tax on research conducted internationally for providing as a threshold guaranteed

benefit to host countries of IB research. Ballantyne claims that where a power imbalance exists between the parties to an IB research agreement, including an infrastructure charge would be an effective method of benefit sharing to develop human capabilities. This infrastructure charge would provide some benefits to the host communities, and may facilitate further opportunities for meeting the health needs of poor communities. For example, the ICDDR, B has facilitated such opportunities for people in Bangladesh. The ICDDR, B was established in 1970 and successfully developed drugs, providing benefits to Bangladesh in various ways and so, . Ballantyne argues that this method of benefit sharing satisfies her three criteria: *feasibility, internal and fairness*.

I agree that such infrastructure charges may deliver a form of fairness, and that a certain amount of benefits could be transferred to communities in developing nations. Such a transfer of resources may help to reduce future exploitation and may increase the bargaining potential for negotiation of developing nations, so that in the future poor people would not need to gamble with basic goods. However, it would be inappropriate to claim that such fairness is all that is ethically required here. Infrastructure charges may guarantee some benefits, but if we rely only on Locke's property rights theory then it is unjust if intending participants receive any benefits, before they make any contribution to the research. Such a system also fails to recognise that benefits are a moral claim against contributions. Ballantyne's suggestions are helpful for addressing global disparity and may be useful for the improvement of the health of the global community. However, it seems to me that Ballantyne is highly motivated by global

poverty campaigns and is dedicated to enlarging the range of choices available to the participants of developing nations so that the conditions of their consent can be fairer. She attempts to employ John Rawls (1992) 'principle of difference' through the proposal of an infrastructure charge. However, she did not notice that contributions of research participants and their nations are enormous and in contrast to this a successful trial yield guaranteed benefits continuously for about twenty years as this has been protected by the TRIPS. It appears to be unjust to deny participants their deserved benefits earned through contributions and to propose upfront benefits, instead.

To understand the nature of exploitation as the disproportionate distribution of benefits and burdens researchers must consider the somewhat subtle distinction between the contributions of drug manufacturing workers and the significant role that trial participants play in this process. The nature of the burden borne by a worker for drug development and the nature of contribution made by test participants are qualitatively different. Upfront fair pay can reward the first type of contribution. However, the contributions of the participants of the drug trials deserve different types of management.

If negotiators and research participants from developing nations are under duress, and have no option but to accept whatever offer or opportunities are available to gain access to medicines, then there is the possibility that mutually advantageous exploitation could occur. For example, the economic conditions of poor nations are crucial in negotiation. To save the millions of people from hunger and diseases, a poor nation can gamble and

accept a clinical trial - for example suppose X government accepted HIV trial using placebo control as they were benefiting in many ways from Y (sponsoring) nation's economic cooperation. The government of X might compare possible deaths caused by a placebo control clinical trial and millions of deaths caused by hunger and diseases, and decide to accept an offer of clinical trial on the grounds that the trial may be likely to result in fewer deaths to the citizens of that country. There are millions of refugees staying in many parts of the world. For example, Bangladesh, a developing nation, is hosting one million refugees from its neighboring country Myanmar. These refugees are suffering various diseases due to lack of access to essential medicine. There might be cancer patients as well. A developed nation may propose to the Bangladesh government to give access to refugees for conducting clinical trials. The Bangladesh government is struggling for economic development. The government is in trouble because according to critics the elections held in 2014 and 2018 were not participatory, as less voters were present in the polling centers on the days of elections, compare to the previous election held in 1991, 1996, 2001 and 2009. Prior to this the World Bank cancelled the 4 billion dollar Padma Bridge project as did Japan and the Asian Development Bank. This has put enormous challenges in internal politics for the ruling government. In this case, to avoid international pressure the Bangladesh government might decide to accept a clinical trial on refugees. Is mutually advantageous exploitative IB research a morally justifiable way to achieve justice, or there is something morally wrong with mutually advantageous exploitation? In the next section, I briefly explore mutually advantageous exploitation.

6.9 Is mutually advantageous exploitation a morally acceptable way of achieving justice, when is there a possibility for mutually advantageous exploitation to occur?

In many cases, negotiated exploitative decisions are labelled mutually advantageous. I disagree that such a decision is morally acceptable. Alan Wertheimer (1996) gives an account of such “mutually advantageous exploitation”. According to Wertheimer, exploitation occurs when both parties are competent to make a rational decision to engage in voluntary and informed transactions, but one party gains unfair advantages from the transaction. For me, Wertheimer’s account of exploitation is a much more useful account of exploitation for IB research ethics. I will use the idea of exploitation introduced by Wertheimer (“mutually advantageous exploitation”) a notion further developed by Resnik (2001) and Ballantyne (2006). Mutually advantageous exploitation is unfair not because it is deception, coercion or anything else. It is unjust because within such transactions the distribution of risk and benefit is *disproportionate*⁹⁹ If, within a transaction, the distribution of risk and benefit is not fair, then the transaction becomes unjust and an example of exploitation.

As part of developing negotiation skills, participants in developing nations need to be able to identify injustice or exploitation in IB research. According to Alan Wertheimer, exploitation can occur through mutually advantageous transaction where both parties

⁹⁹ It can be happened in consensual or non- consensual form. Exploitation may found with other types of moral offence, such as deception, coercion, manipulation.

benefit, if there is unequal bargaining power. The mutually advantageous exploitation occurs when one party receives the lion's share of benefits, and the other party receives only a minimal amount. Thus, mutually advantageous collaborative research may produce unjust distributions and unequal outcome, even if they were freely agreed to by all parties.

6.10 Reinventing Capability Approach to Justice in Negotiation

The capabilities approach to justice in general argues that the people of developing nations lack freedom of choice either due to an asymmetric power relationship or through the lack of various capacities such as access to education, livelihood, and decision-making processes (Sen, 2001, Nussbaum, 2011). This lack of freedom places the people of developing nations in an unequal bargaining position relative to the people of developed nations. Thus, they suffer and are deprived of the benefits that they need for survival and flourishing. The situation of developing nations has led development thinkers to design a model for capacity building in international negotiation so that they can articulate their needs and rights in the discussion forum. For example, Malawi emphasises the necessity for capacity building to reduce poverty and to address the lack of negotiation skills of developing nations. They asked for urgent assistance to strengthen their capacity building and negotiation skills, as these are vital to be effective in the current multilateral trading system (Malawi in Page, 2002, p.77).

The success of the ICDDRDB notwithstanding, there is evidence that negotiators in Bangladesh lack the bargaining capability and negotiation skills and resources necessary to negotiate a fair level of benefit from IB research. The Human Development¹⁰⁰ approach admits that the people of developing nations often do not have adequate freedom of choice, as they lack various capabilities. This lack of capabilities results from global injustice, something that raises social justice issues. The unjust social circumstances in developing nations means that they are usually unable to negotiate a fair level of benefit from participation in IB research, as they are under duress to participate in such research. Before it will be possible for these nations to negotiate for fair benefits from IB research, their social structures need to be developed so that they can foster basic human capabilities. The human development approach has outlined the basic reasons why people in developing nations do not have the same bargaining power as the people of developed nations.

Poverty directly contributes to disease and poor health, and results in more than two billion people in developing nations living an undignified life (Benatar, 2002, p. 1132, Pogge, 2008, p.118). In this context, the powerful organisations of developed nations often exploit the vulnerability of developing nations in various ways. As I explained earlier in this chapter, the TRIPS Agreement, for example, creates the potential for developed nations to exploit the vulnerability of developing nations. The TRIPS Agreement does certainly marginalise the poorest of the poor by imposing sanctions

¹⁰⁰ The Human development approach is such that it is able to foster basic social structures which secure fair value of members' basic human capacities. Then social structures can create opportunity for education, health care, employment and political process so that individuals can participate and ensure their health. Members of the society will create the right conditions and guide to sustain the social structure which is more important than mere economic wealth or resources (London, 2005, p. 26).

against unrestricted access to health needs such as food, medicines, and educational materials (Drahos, 2003).

Justice in IB research can be promoted for developing nations by developing a principle of justice based on what I have called the 'contribution model', and by assisting developing nations to build their capacity for negotiation, which would allow these nations to argue more effectively in practice for justice based on such a principle. The reasonable availability, fair benefit and human development approaches, as discussed previously, acknowledged how the poverty of developing nations and the vulnerable conditions of their research participants play crucial roles in the mutually advantageous form of exploitation. Portraying the host nations' socio-economic and political conditions, they demonstrated how the participants in research were harmed or open to risks of potential harm because of their participation in research studies. Given this background, advocates of these three models of benefits sharing have proposed different mechanisms of benefit sharing to achieve justice. Much attention was given in the bioethics literature to discussions of the health and wealth disparities between sponsors and hosts to overcome exploitation. The question of whether it is ethically justifiable to confer conventional patent rights only to sponsors is yet to be considered.

This is because previous researchers in bioethics either overlooked or undervalued the value added by the participants of host nations by providing local expertise, personnel,

and material support, for the research. Sharing patent rights is a way of achieving justice for the developing nation.

Further, bioethics researchers such as Ballantyne and London have also raised concern about the existence of unequal power relationships between developed and developing nations. Why do these frameworks propose to share benefits with the host nations? As discussed in previous chapters, they have given several reasons in answer to this question. However, I argue that any benefit sharing framework that does not take into consideration whether the host country is entitled to the proceeds of patent rights has overlooked some important aspects of IB research. Patent rights, or the benefits thereof, should be shared equitably with host nations according to their contributions in the innovation process. Considering the host nation's socio-economic background, if research sponsors want to share further benefits along with sharing patent rights to alleviate the global health disparity, i.e., by donating drugs to host nations, then this should be considered as an act of generosity by the sponsors.

The reasonable availability (RA) approach argues that taking advantage of someone's vulnerability is a moral wrong, as that does an injustice to those vulnerable people. This approach demonstrates the moral imperative to address the lack of access to health needs in developing countries as well as increasing fairness in IB research, and to thereby reduce the negative impacts of the TRIPS. However, proponent of RA approach

failed to observe that most IB research protocols are signed while developing nations have a dire need for access to basic health care, and to essential drugs for their people.

Another factor which has been suggested as contributing to the representatives of developing nations' inadequate capabilities to negotiate a fair agreement is their seemingly inadequate capacity to argue effectively, and to articulate what is fair and unfair when negotiating a distribution of benefits (see e.g., Fidler, 2010, p.2). Thus, both IB research protocols and TRIPS have to some extent become tools of exploitation, and injustice. International institutions such as the WTO have become instruments to protect the interests of the developed countries (Pogge, 2002, p. 24, Ingram, 2009, p. 207). The reasonable availability approach holds that there should be reasonable availability of drugs and other medical facilities that have resulted from such research to meet the health needs of people globally. But the actual scenario is different. Proponents of RA and others benefit sharing models never considered fairness in distribution as they do not regard this as binding for them in the way that the TRIPS Agreement is a binding agreement for poor nations.

The fair benefit (FB) approach, on the other hand, accepts that IB research should be governed by, among other things, achieving health justice and non-exploitation. To avoid exploitation, this approach proposes three core principles: fair-benefits, collaborative partnership and transparency. As I explained in chapter four using these three principles allows the host community or country to negotiate a level of benefits

appropriate to the risks involved in participating in a research project. This would help to prevent the sponsors of the research taking unfair advantage of people's vulnerability.

The reasonable availability, fair-benefit and human development approaches all acknowledge one common concern: bargaining inequalities. This is because there is a strong correspondence between a person's capability for negotiation and their ability to obtain fair benefits in a free market environment. The decision of a person will likely be significantly different when that person has the privilege to explore their full potential capabilities, as opposed to a situation where under duress by unjust circumstances they gamble for fulfilment of their basic human needs. If we treat the quality of agents' decisions equally without considering those agents' background conditions, further injustice will be inflicted on people who are already under duress to gamble to fulfil their basic needs. The struggle to fulfil basic human needs often undermines a person's capacity to make an autonomous choice, as well as their ability to negotiate benefit in a transaction.

There is a view that a respectful global relationship can be developed between poor and rich nations' research communities, allowing them to work together towards achieving the global goal of better public health. For example, Lau et. al (2014, p.1) argue that "collaborative research partnerships provide mutual advantages by sharing knowledge and resources to address locally and globally relevant scientific and public health questions." This view proposes developing health facilities and infrastructure as part of

collaborative research centres, and signing agreements for the training of doctors, nurses, technicians as part of collaborative research projects. Proponents of this point of view argue that maximum health benefits are gained from collaborative biomedical research when each party freely decides to participate, and negotiates that participation by applying their bargaining power. Research projects resulting from negotiation of this type are considered effective for efficiently producing mutually advantageous benefits for the global poor.

Furthermore, such collaborative research will not leave the poor host community worse off, instead it will provide some benefit to the host communities. In addition, the decisions of all parties will be respected in the process to some extent, and in consequence this type of research project would be fair. However, while international collaborative research projects theoretically have the potential to reduce global health inequality, a bleak picture is revealed in practice (Aellah, et al, 2016, p.172). For example, Limaye et. al (2015) conclude that,

[d]espite an increase in clinical trial activities, there is a clear gap between the number of trials conducted and market availability of these new drugs in India and South Africa. Drug regulatory authorities, investigators, institutional review boards and patient groups should direct their efforts to ensuring availability of new drugs in the market that have been tested and researched on their population.

The above statement would suggest more generally that the developing nations are failing to effectively negotiate and establish their rights in the distribution of collaborative research benefits.

Drahos claims that the negotiation power of a party depends on various factors, and that one pivotal factor is what he calls a party's "commercial intelligence networks" (Drahos, 2001). The commercial intelligence networks of developed nations regularly carry out extensive rigorous research to analyse the potential costs and benefits of conducting clinical trial in a developing nation, and to articulate their position before proceeding to a negotiation or reaching an agreement. Developed nations have established strong networks around shared business interests, which serve to build coalitions for an agreement. For instance, the Quad countries¹⁰¹ shared a similar interest in including intellectual property rights issues with multilateral trade which resulted in the TRIPS Agreement in the WTO in 1994.

While developed nations benefit from strong commercial intelligence network, in this regard, developing nations are seriously lacking in the ability to establish a similar system. They typically arrive at negotiations insufficiently prepared, depart early, and are often unable to cope with the ongoing series of meetings due to their lack of capability. This "negotiation fatigue" results from numerous factors which may include lack of knowledge, understanding, and also language barriers (Alkoby, 2012 in Foreman & Kohler, 2012, p. 56, Drahos, 2003). In 2001, Drahos interviewed many negotiators from developing nations responsible for many different areas i.e., in business, and based on these interviews he claims that,

"expert tracking of so many areas is not, as the interviewees readily conceded, a realistic possibility. Instead many negotiators stumble from one meeting to

¹⁰¹ This coalition is between four countries and these are European Community, Canada, the United States and Japan (Drahos, 2003, p. 79).

another with little evidence-based understanding of what they are dealing with, largely repeating what they have picked up in conversation or read in a summary briefing paper that has found its way onto their desk (Drahos in Crump and Maswood, 2007, p.109).”

As Drahos points out the representatives of developing nations often severely lack understanding, knowledge and language (scientific and legal) which may affect their effective communication skills. If negotiations are held in such a situation, then it can be argued that most policies are imposed on the developing nations in a structural way as well as interpersonally. These will further restrict equal opportunities for developing the other capabilities of the poor people.

Bonilla (2004) claims that the process of selection of representatives of negotiations lacks transparency. An Ex-Bangladesh Bank (BB) Governor¹⁰² who is a prominent economist also expresses a similar view (2016) that it is common for the appointment of permanent representatives in different international organisations to be politicised. In many cases, these appointees lack business acumen, any background knowledge of the relevant area and of international negotiation in general. In many cases, representatives of developing nations evidently treated such negotiation meeting as foreign holidays for shopping and sight-seeing (Bonilla, 2004).

In addition, the Ex BB Governor mentioned another crucial factor, which is that the majority of the international negotiations are carried out by bureaucrats who lack

¹⁰² Personal communication on 12 September 2016.

capacity¹⁰³ in their role for a specific ministry, for example the ministry of health, as international negotiators. For example, if a particular bureaucrat is in the health ministry, she may have to deal with negotiations on health issues and build on her experience on health negotiations, but if she is transferred to a cultural ministry or railway ministry position within two or three years, then her expertise remains unutilized. Consequently, the knowledge acquired by serving in the health ministry mostly become useless to serve in the cultural or railway ministry negotiation due to the differences in the work of these ministries. Further, in some cases, if these bureaucrats hold a different political ideology or fail to act according to the appointed political authoritative figure, they are placed as an Officers on special duty (OSD) for an indefinite period of time (meaning no desk or regular work). So, there is not much value built on expertise and experiences of such international negotiations to address health issues, and thus these bureaucrats are less accountable for their decisions. Consequently, without having any background knowledge in international negotiations, representatives are often expected to participate in the negotiation process of the health department.

These cases highlight that human resources development is a fundamental need for any country. This is because the creation of opportunities for the personnel of institutions within a country, and investments towards these opportunities, are required for the effective functioning of the countries' organisations and institutions. However,

¹⁰³ Currently, Mr Syed Monjurul Islam who is the Secretary for Ministry of Health and Family Welfare, Bangladesh, is serving as a Board Trustee member for icddr,b as a government representative. His brief biography as presented in the icddr,b website reveals the issue of incapacity of service. The person has no background of working with health professionals or academic training at any stage of his career. However, as an ex-officio he is serving at icddr,b and may deal international negotiation related to health matters. The biodata can be found at: <http://www.icddr.org/about-us/leadership/board-of-trustees>

such practices are absent in most cases, and are unavailable and not valued in the least developing nations. The Ex BB Governor (2016) raised some important problems for promoting negotiation capacities in Bangladesh, including a lack of interest among the top bureaucrats who make up most of the nation's negotiators in engaging or supporting research. For example, he created a fund aiming to support human resource development in the Bangladesh Bank during his tenure. This support was seen as necessary because the banks employees come from a range of different academic backgrounds. As a result of this fund, the employees of the BB can engage in training and research in local and international financing systems. Then the BB can provide better service for the banking and investment sectors, and can adopt or develop policies to negotiate more effectively with International Monetary Fund (IMF) and the World Bank (WB) effectively. Prior to the establishment of this fund, no system of human resource development of BB employees was in place. And once the governor finished his tenure, the following BB Governor argued that the fund was a waste of money, and froze the human development program. Placing such a low priority on human resources development results in the negotiators of the developing nations typically lacking skills and knowledge, and thus as likely to fail in negotiation in most cases.

The politics of the governing party may also hinder a developing nation's chances of negotiating a fair deal. For example, there are two major political parties in Bangladesh. These are the Bangladesh Awami League (AL) and the Bangladesh Nationalist Party (BNP). The AL is allied with India while the BNP is allied with Pakistan. So, negotiators are expected to consider the external relationships of the ruling party when engaging in

international negotiations with these countries. Similarly, Japan, Saudi Arabia and the USA are key development partners of Bangladesh. The governments of Bangladesh have seen it as necessary to take these relationships into account when negotiating a deal in an international forum. Thus, as well as often lacking skills and capabilities, negotiators of poor nations typically lack much freedom, as they are constrained by their domestic and international context. By contrast, the negotiators of developed nations' rarely encounter such contextual constraints and usually enjoy high level of autonomy in negotiations though presumably they often are inclined/feel it necessary to take into account their external relationships with other countries to some extent. Their knowledge and skills add value in successful negotiation.

The concept of benefit is also important in the process of negotiation. According to Simm (2007, p. 496),

Benefit sharing concerns what, if anything, is owed to individuals, communities or even populations that participate in research. However, the concept of 'owing something' is vague, and the essence of any justice-related idea is infamously difficult to pin down.

Given this vagueness, if poor nations' representatives lack the understanding or ability to define what benefit means to their community, then any agreement they participate in may result in a deal that is unfair to them. For Simm (2007, p.496),

“The existence of various arguments behind benefit sharing is not necessarily problematic in itself, but awareness of the complexities involved, of the distinct historical and conceptual roots, might help to ease the negotiations that precede benefit-sharing agreements between local populations and researchers.

Once a mutually advantageous agreement is fairly negotiated between a developed nation and a developing one, then all parties should be legally obliged to respect the agreement regardless of what the principle of justice might otherwise say is fair. Furthermore, once the involved parties have given their voluntary consent (which is questioned below) to reach an agreement for mutual benefit, then they also have a *pro tanto* moral obligation to respect the agreement. Thus, the negotiators must have clear understanding of what constitutes benefit to their communities and what principle can be pursued to distribute the outcomes of IB research equitably.

If the perceived notion of justice is defective, then it may produce a morally unacceptable decision. Since developing nations are often unable to articulate what specific benefits they have a justified claim to, therefore, they often eventually fail to claim what is just for them.

I will describe an example to demonstrate such a limitation. The TRIPS Agreement in question was signed by all members of the WTO voluntarily but, as questioned by many researchers this agreement was based on a defective notion of justice. The agreement has created a legal and perhaps a *pro tanto* moral obligation for both the developed and the developing nations to comply with this. If the agreement is not respected and implemented - i.e., if the TRIPS based rights of patent holders are not protected then (according to this defective notion of justice) justice will not be achieved, regardless of the outcome of such non-compliance. Apparently, it is regarded as fair by the TRIPS Agreement proponent that the rights of patent holders are respected to serve justice.

However, Pogge (2010) rightly argues (as discussed above) that the developing nations were “under duress” to sign the TRIPS Agreement as members of the WTO. Thus, from a moral point of view the agreement became an unjustified deal for developing countries. In consequence, the TRIPS Agreement has become something of a nightmare for developing nations in relation to access to medicine. Peter Singer and Doris Schroeder (2009) critically scrutinize the TRIPS Agreement. For them,

“intellectual property right systems have to be designed to secure human well-being and flourishing in mind. They are not mandated to secure natural rights of inventors to have their mind creations protected. In fact, there are no such natural, universal valid rights to IPRs. Any benefits to inventors need to be weighed up against benefits to humankind (Singer and Schroeder, 2009, p.21).”

The above criticism by Singer and Schroeder is quite different from my critique. I argued against the TRIPS regime by acknowledging Locke’s property right as a basis of justice. In contrast, Singer and Schroeder stand against the TRIPS system of IP from a utilitarian principle of justice perspective considering global people’s common interest, i.e., global health rights.

The scope of the concept of ‘creators’ to whom IP rights are granted in the TRIPS Agreement is in my view usually understood too narrowly, and so results in the application of a narrow view of justice that unjustifiably excludes patent rights of poor nations as participants in IB research. The historical background of IB research provides a concrete rationale for introducing the key claim that I have argued for in this thesis, that the poor nations who participate in the research also deserve equity in the patent resulting from it. However, it might be suggested, in response to my argument, that poor nations’ contributions could be compensated for in other ways, or that pharmaceutical companies could purchase their rights. Recognition is indeed an element of justice and

should be properly acknowledged. However, the TRIPS Agreement at no stage acknowledges the various contributions of developing nations to IB research. Thus, the complaint that poor nations are deprived of their rights remains unanswered, and this historical injustice against the poor deserves redress and remedy.

Someone may object that the WTO Secretariats offer developing nations help with legal expertise. However, the WTO secretariats must remain neutral and therefore, it is almost impossible for them to advocate for developing nations.

The existence of asymmetries of power, i.e., skill, ability, wealth, or military power between the parties to a negotiation raises the question of which concept of justice could play a role in the negotiation process between these parties. What is the role of power in the context of negotiation in the international setting, where all parties seek to maximise the benefit for their own nation? According to Zartman (2002) power can be structural (such as military strength) or un-structural (such as technical skill in persuading the other party to agree to the desired outcome). In this chapter, I argue that steps need to be taken to address the asymmetry in un-structural power, i.e., knowledge and skill, as doing so will enable developing nations to establish their health rights at global forums like the WTO, WHO and UN.

Plato argued in his *Republic* that power equality promotes fairness and justice whereas power asymmetry prevents the achievement of justice (Albin, 1999, p.32). Cecilia Albin (1999) agrees with him and claims that

“it is a consensus view that power equality facilitates the negotiation of just and fair agreements, and that such agreements are more likely to be implemented and durable. They create a state of equilibrium in which every party feels that it received its “fair share” and that likewise the other parties got neither more nor less than that (Albin, 1999, p.259, Albin, 2001).”

However, the TRIPS Agreement was consented to even though all members formally had equal status. This indicates that not only political power but also arguing power is necessary for success in such negotiations. If this is the case, then the negotiation skills of all parties should be taken into consideration when assessing the fairness of an agreement. My first question here is: are the parties' negotiation skills qualitatively similar or are they different? If one party is not skilled enough, then they will likely be compelled to comply with the agreement regardless of the outcome. The bargaining power of this party needs to be enhanced if we want to achieve justice in international negotiation. All parties should be adequately informed and should have a clear understanding of the consequences of the agreement. Further, both parties should have other options, so it will not be the case that one party can walk away freely without signing the agreement while other party is under duress to sign or comply with it.

The implementation of the TRIPS Agreement suggests that the developed nations are pushing to implement a liberal notion of justice whereas in practice it may be that other notions of justice - such as, a Kantian notion of Justice - are better for social cohesion and harmony. There is an important division among philosophers who hold a liberal view of justice, between Mill's universal utilitarianism and Kant's universalism. Kant's universalism suggests the adoption of a justice principle that promotes his universalism, where we should act from duty and each person has equal moral worth. The person-centered health care approach takes into account Kant's egalitarian moral philosophy.

Although, more than two hundred years ago, Kant argued for equal moral worth for everyone and intrinsic dignity (Cloninger et. al, 2014).

Therefore, in the interest of achieving justice in the IB research, I will now explore this remaining concern. I will argue that the unjust practices of research sponsors should be considered a kind of exploitation that violates fundamental human rights. The rights violated include the right to health, as has been mentioned by Nussbaum in *Creating Capabilities*, as this exploitation jeopardises, and may even endanger the right to health which every human being can justifiably claim.

6.11 Negotiation for Fair Benefits and Inequality of Bargaining Potential

The TRIPS is a global treaty that affects the health rights of individuals, communities and states. The TRIPS also affects the social, economic, and cultural rights of people across the globe. One of the objectives of this thesis is to address the critical conditions of health rights of LMICs, and therefore, in this section of the thesis, I focus my attention on the negotiation capabilities of participants, communities and nations regarding IB research. And I am arguing for creating and supporting the capabilities of participants, communities, and nations to devise morally justifiable research protocols, and for a global treaty recognizing the IP rights of the participants through the respective state governments to facilitate IB research.

As I discussed above, the inequality of bargaining potential creates scope for the negotiation of unjust treaties and research protocols at a global level. In such ways, this inequality of bargaining potential creates vulnerability at individual and community levels too. The more vulnerable a person, the more unequal bargaining potential he or she must face. But unequal bargaining potential also leads to further vulnerability - it is like a vicious cycle. I agree with Ballantyne (2006) and Wertheimer (1996) that inequality of bargaining potential is the basis of an unfair distribution of benefits and burdens in the context of IB research. I also agree that the greater the inequality of bargaining potential between two parties, the greater the likely degree of exploitation of the party with lesser bargaining potential by the party with greater bargaining potential. As citizens of a poor nation, often participants in clinical trials are put in a position where they have little choice but to accept many things that we do not anticipate or deserve in our life.

According to Leonard et al. (1998, p.39), poverty is one of the main factors which account for why people agree to participate in clinical trials as experimental subjects. Further, Schuklenk (2000, p.89) claims that,

“If patients are given the option of choosing between joining a clinical trial (in which their survival interests do not always have priority over research interests) or simply buying and using the drugs in which they are interested, many potential trial participants would choose this latter option”.

The poverty of a person or a nation places them in an unequal bargaining position: “[t]his inequality [certainly]¹⁰⁴ reflects the unequal starting positions of the parties and affects the process of negotiation’ (Ballantyne, 2006, p.116).”

However, some researchers disagree that an inequality of bargaining potential inevitably leads to the exploitation of research participants. The Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries (cited in Ballantyne: 2006, p.117) states that “[s]ince exploitation involves the distribution of benefits and burdens; vulnerability is neither necessary nor sufficient for its occurrence. The status of the parties is irrelevant in determining whether exploitation has occurred.” However, Ballantyne disagrees with this. She argues that maybe vulnerability is not a *sufficient* condition of exploitation, but that it is a *necessary* condition of exploitation. For Ballantyne, “An inequality of bargaining potential is a necessary condition for exploitation.... In all cases of exploitation one party is vulnerable in some respect to the other party (2006, p.117).” I would like to qualify this statement and argue that in *almost* all cases of exploitation, and especially in the case of the participants in IB research in developing nations, test subjects are vulnerable, and in several different ways. The researchers of developed nations exploit these participants’ vulnerabilities to gain access to knowledge about the nature of disease and to test hypotheses for the improvement of their drugs and theories. If we investigate this at a deeper level, it may appear rational in some sense for vulnerable participants to comply with unfair agreements and I will now investigate to demonstrate this.

¹⁰⁴ I am using this term not in its absolute sense.

To some extent, I differ from Ballantyne in her claim that an unequal bargaining potential is always caused by poverty. My view is that unequal bargaining potential can be caused by factors other than poverty. Obviously, it is fallacious if anyone argue that unequal bargaining potential is always caused by poverty. And it would be dogmatic to claim that there is a necessary connection between inequality and vulnerability and yet to completely deny that poverty is a cause of vulnerability. For example, in developing nations, there are many wealthy people who have the ability to bargain to escape their undesirable situation. This bargaining potential is based on their wealth. They can go abroad for treatment and buy drugs. Those who feel that developing nations' participants must accept an unfair offer from overseas researchers because poverty is a function of economic inequality. But the Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries did not recognise that economic poverty is a kind of vulnerability.

Another way that the bargaining potential of developing nations can be undermined is when international research projects are proposed as part of a larger development project. It is no secret that developing nations have to export their products, import necessary drugs, medical and educational equipment, and train doctors and officials. To facilitate these necessary activities, often vulnerable countries believe that they need to allow industry-sponsored clinical trials. In this respect, the government and the participants of developing nations have considerable limitations when it comes to

negotiating with the sponsors of IB research. Their undesirable and sometime unalterable circumstances constrain their free choices, in addition to their poverty.

For example, the government of Bangladesh has felt compelled to allow access to research subjects for international researchers under different agreements. Cholera and diarrhoea epidemics take the lives of many people every year in Bangladesh, and many lives are also lost to malaria. If the government of Bangladesh does not allow international researchers to carry out their investigations, then there will be fewer hospitals and research facilities and less research will be carried out on these endemic diseases. This will ultimately lead to the people of Bangladesh living in deeper poverty. When overseas nations respond to requests for help from the Bangladeshi government, their offers of assistance often come on the condition of a program of governance reform by the Bangladeshi government (Leach et al 2005).

6.12 Creating/Increasing Negotiation Capabilities as Justice to the Poor Nations

Fairness in distribution implies “equal opportunity¹⁰⁵” for both parties, in our case developed and developing nation and equal capacity in negotiation. To enhance negotiation capabilities and avoid systematic injustice, generally people should have

¹⁰⁵ “Equal opportunity” as the principle of justice advanced by John Rawls at domestic levels further expanded at international sphere by Norman Daniel, Thomas Pogge, Micheal J Selgelid, and Peter Singer.

their claim rights recognised. Research participants of developing nations are placed in a position where they are led to see themselves only as a recipient of *generosity*, (somewhat analogous to those in Plato's "allegory of cave"¹⁰⁶) such that if they do not agree with the protocol, then they will lose the potential benefits. In such a situation, a claim right is morally important. Participants in the host country, who are neglected and poor, often believe that it is a privilege for them to be selected for research participation when there are other communities with similar health needs. The host community often then feels that it has no other option but to show its gratitude to the sponsors of the research. To avoid this undesirable situation (though presumably such feelings of gratitude could still sometimes justifiably exist), research participants should be led to understand that research is collaborative activity and that the researcher-participant relationship is reciprocal, and that both parties have equal moral standing and need each other to achieve a successful outcome.

Rather than international biomedical research participants being portrayed simply as grateful recipients of generosity, it should be understood that they are collaborating in research that is essential for global health security, as diseases respect no national boundaries and do not afflict just any specific community. The contributions of IB research participants should be valued and recognised as contributions to humanity. There should not be a double standard regarding the contributions of research/sponsors and those of participants, as these contributions are all necessary elements for the

¹⁰⁶ In Plato's allegory of the cave, people are conditioned to see their shadows, an unreal thing, as real. Similarly, people of developing nations are conditioned and convinced to see themselves as recipient of gratis.

success of this research. That one party to a successful research project will receive a “red carpet reception” i.e., developed nation, while the other will not even be recognised is further injustice.

Everyone who contributes to a research project does so according to their capacities to contribute to this endeavour. But scientists’ capacities may stem from their having a background of privilege, which enabled them to explore their capabilities, whereas the capacity of a sample collector - i.e., working for the scientist/ project or provider - may stem from their simply not having these opportunities. But if you consider a world where everyone is equally privileged, there would still need to be people in the role of sample provider or collector, otherwise it would not be possible to achieve the desired progress. For example, H5N1 or AIDS/HIV sample collectors often endanger their health in order to facilitate research into these diseases.

Early history provides evidence that people worked collectively towards the common goal of survival and created governments to safeguard their tribe/group, rather than to create disparity. However, in the present day, it is a matter of regret that people are often treated differently according to their birth place or colour or their race or religion. Governments invade other countries, or under colonialization people were treated in an inhumane way. Morally, every person deserves to live a dignified life.

However, there is scepticism about this process of empowerment and critics argue that the idea of empowering the host countries' various capabilities is "naïve". They further argue that in the developed world, well-educated and well-resourced people, well-funded non-government agencies (NGO) and well-equipped trade unions have all been unsuccessful in negotiating fair deals or benefits from multinational corporations- specifically from the monopolies or duopolies of pharmaceutical industry (Schuklenk and Ashcroft, 2010). For example, Medecins Sans Frontieres (MSF) was negotiating for price reduction of pneumonia vaccines with GSK and Pfizer for five years without any success (Cone, 2016¹⁰⁷). Given this circumstance, Schuklenk argues that,

"[t]he idea that severely impoverished, frequently undereducated, communities could readily be empowered to the point that they would be able to extract fair benefits from developed-world for-profit trial sponsors is unrealistic" (Schuklenk, 2010)."

There is an argument that the ability of a research participant to consent to IB research depends on their level of vulnerability. Particularly, the participants of developing nations are more vulnerable¹⁰⁸ because of their limited access to health care and their disadvantaged economic circumstances. Therefore, the consent of participants from developing nations is typically distinctive and different compared with what developed nation provides in terms of such participants' understanding and the voluntariness or otherwise of such participants to decide to (or not to) participate in such research,

¹⁰⁷https://medium.com/@MSF_access/there-is-no-such-thing-as-free-vaccines-why-we-re.../2/12/2016.

¹⁰⁸ According to Deborah Zion; L, Gillam; B, Loff (2000) vulnerable people are those in developed nations', who are incapable of making their autonomous decision regarding their own benefits by some reason their reason may be impaired, such as prisoner; children, Mental patient (see also NHMRC: 1999). In contrast, in developing nations' vulnerable population are those who are not only incapable of making their autonomous decision but also those who are illiterate, ignorant, malnourish, and their poverty, socio-political condition and corruption, always driving them wacky and make them vulnerable and unstable to think and make considerable beneficial decision. They do not have access to basic rights and goods. (Also quoted by Leonard, H, George, J. A, Miichael A. Grodin and Wendy K. Mariner (1998) in "Research in Developing Countries: Taking "Benefit" Seriously", *Hasting Center Report*, p.39.)

compared to the consent of research participants in developed nations. Assuming this, informed consent must be examined in the light of the concepts of unequal bargaining conditions and gambling with basic goods. Participants may be fully aware of the consequences of their participation but may decide to bargain for more than minimal benefits because they consider that “something is better than nothing” (Annas and Grodin, 1998, p.562).

A similar conclusion can be drawn about the representatives of developing nations taking part in the WTO negotiations on the TRIPS Agreement. These representatives signed this agreement in the same way that they agreed to host collaborative international biomedical research previously - that is, under both internal and external pressure. Internal pressure can be built by the research sponsor using an aggressive media campaign. The claim right that is recognition of contribution in the patent rights, and equal opportunity in negotiation I have argued here, not only contributes to refining the TRIPS and IB research practice but can also play a significant role in building the capabilities of developing nations. The acknowledgement of such a claim right in the WTO/WHO agenda will necessarily make such negotiation processes fairer.

Chapter Seven

Lacks of Negotiation Capabilities of Developing Nations – Two Case Studies: Indonesian Avian Influenza (H5N1) Epidemic and the TRIPS Agreement

7.1 Introduction

Power¹⁰⁹ and trust have profound implications in international negotiation and thence for justice in International Biomedical (IB) research (Ballantyne, 2006, Cheng, 2009). According to Malhotra, “all negotiations involve risk. That is why establishing trust at the bargaining table is crucial (Malhotra, 2010).” In order to understand and explain the role of power and trust in negotiation, I have chosen two case studies: the Indonesian Avian Influenza (H5N1) epidemic and the TRIPS Agreement. Through a close examination of these two cases, I will investigate and demonstrate how trust and asymmetric power¹¹⁰ relationships between developed and developing nations pose a threat to global health rights and contribute to the disproportionate distribution of the burdens and benefits of IB research. These two case studies demonstrate how a lack of capacities and power (as access to information, resources) for developing nations influence international

¹⁰⁹ For Dhal, power implies “A has power over B to the extent that he can get B to do something B would not otherwise do”. Zartman and Rubin, in studying power in negotiation, define it as “the *perceived* capacity of one side to produce an intended effect on another through a move that may involve the use of resources.”

¹¹⁰In *Power and Trust in Negotiation and Decision-Making: A Critical Evaluation*, *Harvard Negotiation Law Review*, Yan Ki Bonnie Cheng argue, “power is said to pervade all facets of negotiation. Indeed, the very idea of negotiation intuitively conjures images of power contests and tough bargaining.”
(<http://www.hnlr.org/2009/09/power-and-trust-in-negotiation-and-decision-making-a-critical-evaluation/>).

negotiation an unequal and polarised world, divided into developed and developing nations. These two case studies are helpful for understanding the barriers to justice in IB research.

Trust¹¹¹ is considered as key element of negotiation. For example, Brian Gunia, Jeanne Brett and Amit Nandkeolyar(2012)¹¹² claims,

It's no secret that negotiations are more fruitful when parties freely share information about their interests and goals. But that requires trust, which may be in short supply at the bargaining table. This appears to be true especially in Asian countries, including India and Japan, and in negotiations involving parties from different cultures.

In the first place, I will examine the Indonesian Avian Influenza H5N1 case study to discern the role of trust in IB research. On the other hand, I will consider the case of the TRIPS Agreement to understand existence of asymmetric power relationships at a global level as these are connected with global health rights and procedural fairness in the distribution of the benefits and burdens of IB research.

The importance of creating negotiation capabilities for developing nations can be elaborated in the light of the Indonesian case of Avian Influenza Virus Sharing. Secondly, this case will reaffirm developing nations' claim right to IP sharing, highlighting the developing nations' demand for fair-benefit sharing. The suspension of

¹¹¹ "an expression of confidence in another person...that you will not be put at risk, harmed or injured by [his/her] actions." Cheng (2009).

¹¹² Gunia,B., Jeanne Brett,J., & Nandkeolyar.A.2012. Cross-cultural management In Global Negotiations, It's All About Trust, *Harvard Business Review* (<https://hbr.org/2012/12/in-global-negotiations-its-all-about-trust>)

Indonesian Avian Influenza H5N1 virus sharing with the World Health Organization (WHO) posed a challenge to an established system that was more than 50 years old. Finally, an analysis of this case will help us to show right, responsibility, level of contribution and equity issues of benefit sharing between rich and poor nations. In addition, the case study demonstrates further that developing nations are bound to obey international law in relation to TRIPS Agreement. However, no such binding agreements exist for benefit sharing by developed nations with developing nations, while developing nations are important contributors to the protecting and promoting of global health rights, economy and progress.

7.3 Case Study-1: Indonesian case of Avian Influenza (H5N1) Virus Sharing with the World Health Organization (WHO):

In December 2003, Avian Influenza (H5N1) was identified among poultry in Indonesia. According to the Indonesian Ministry of Agriculture (quoted as unpublished data in Sedyaningish et al., 2008), between December 2003 and December 2007, Avian Influenza illness and culling resulted in the deaths of 16 million poultry (quoted in Sedyaningish et al., 2008). Measures were taken by the Indonesian government to diminish H5N1 in the poultry sector. Nevertheless, in July 2005 the first human avian influenza (H5N1) case was reported in Indonesia. By December 2007, Indonesia was reporting the highest number cases of human avian influenza (H5N1) in the world. Indonesia was also reporting an unusually high mortality rate (81%) from the disease.

18% of Indonesian patients suffering from avian influenza had no history of contact with dead or sick fowls. A gradual increase in the number of Indonesian avian influenza patients per month in each year was observed: 4 per month in 2005, 9 per month in 2006 and then 12 per month in 2007 (Sedyaningish et al., 2008). From the suffering and dead patients, clinical specimens¹¹³ were collected for testing¹¹⁴.

Initially, Indonesia's National Institute of Health Research and Development, and/or in the Ministry of Health had no capacity for further risk assessment and diagnostic confirmation. Therefore, for the purpose of risk assessment and diagnostic confirmation, clinical specimens were sent to international laboratories of the global influenza surveillance network (GISN), part of World Health Organization (WHO). However, within a reasonably short period of time the capacity for risk assessment and diagnostic confirmation was established in Indonesia with the help of WHO and international aid from various developed countries.

7.4 What has happened in Indonesia and how has Indonesia contributed to the GISN of WHO?

According to the International Health Regulations (IHR) 2005 which is another International binding legal agreement to obey by 196 countries, every nation is required

¹¹³ Clinical specimens include dead patients' lung biopsies, nasal and throat swabs, washes from intubated patients and if available, endotracheal aspirates of patients.

¹¹⁴ According to Sedyaningish et al. (2008), "Testing included detection of H5-specific viral RNA by conventional and real-time reverse-transcriptase polymerase chain reaction (RT-PCR), and detection of H5N1 antibody in sera by a modified horse red blood cell hemagglutination inhibition (H1) assay."

to notify the WHO of events that may pose a risk of global health crisis, and to share completed and precise public health information about these events to avoid spread of disease internationally. This is so that a public health emergency of international concern (PHEIC) can be declared, prevented and addressed. There are two possible interpretations of the scope of this mandatory reporting about the public health information sharing. One is that sharing public health information includes sharing of relevant biological samples, as it is not possible to address a PHEIC in a “timely and consistent” manner without testing samples for aetiological agents (Sedyaningish et al., 2008). In May 2006 and May 2007, the World Health Assembly resolution adopted this interpretation, and requested Indonesia to send all positive avian influenza (H5N1) specimens to the GISN. The Indonesian Ministry of Health complied with this request. Through the Naval Medical Research Unit 2 in Jakarta, some specimens were sent to the US CDC Atlanta, a WHO Collaborating Center, and some were sent to the WHO H5 Reference Laboratory at the Hong Kong University (HKU) (cited in Sedyaningish et al., 2008).

However, another interpretation of the IHR is that these regulations do not specifically require the sharing of biological samples. This interpretation considers public health information and biological samples independently, with the former being defined only as facts and knowledge. Under this interpretation states have sovereign control over biological samples of resources found within their states or territories, as stated in the Convention on Biological Diversity (CBD). The question of whether or not a country has

the right and authority to decide whether to share their specimens with the WHO is dependent on the interpretation of the IHR.

7.5 Why did Indonesia decide to withhold sharing Avian Influenza (H5N1) virus Specimens with WHO?

In March 2005, to avoid human influenza pandemics, WHO has developed and released guidance about the timely sharing of influenza viruses /specimens. According to the WHO (2005) guidelines of influenza viruses sharing,

“the designated WHO Reference Laboratories will seek permission from the originating country/laboratory to co-author and/or publish results obtained from the analyses of relevant virus/samples” and “There will be no further distribution of viruses/specimens outside the network of WHO Reference Laboratories without permission from the originating country/laboratory.” (Sedyaningish et al., 2008, p. 485, Lucas et al., 2013 p. 117)

It would be a clear violation of this guideline if ‘the designated WHO Reference Laboratories’ failed to obtain the permission of the Indonesian authorities or Indonesian scientists prior to the publication of results from the analyses of H5N1 virus/sample obtained under mandatory sharing regulations. Nonetheless, Indonesia has claimed that without prior approval from or notification of the Indonesian authorities or scientists, the results of laboratory analyses of H5N1 virus were presented by international scientists in several international meetings. Furthermore, the Indonesian authorities and scientists were not notified about this presentation in enough time for them to deliberate about

whether to provide their informed consent for this information to be presented at these meetings, as notification was given to Indonesian authorities and scientists just a few hours before the presentations (Sedyaningish et al., 2008).

A further, complaint made by Indonesia is that international scientists who had access to the specimens of the Avian Influenza (H5N1) viruses/samples provided by Indonesia to the WHO Reference Laboratories, asked the Indonesian government officials or scientists to be co-authors of written papers publications about the findings and analysis of H5N1 viruses at a very late stage of writing manuscripts (Sedyaningish et al., 2008). The Indonesian government was disappointed by the unethical practices of these international scientists in general and claimed that the WHO guidance was violated on several occasions. Nevertheless, Indonesia continued sharing viruses/samples of confirmed Avian Influenza (H5N1) cases with the WHO system for further risk assessment until the beginning of 2007.

Things came to a head for the Indonesian government at the end of 2006, when a journalist called the Indonesian Ministry of Health to confirm that an Australian vaccine company was planning to develop a vaccine against the H5N1 influenza virus. Indonesian virus samples provided to the WHO would be used by the Australian vaccine company for the development of this vaccine. This incident gave Indonesia the impetus to make the harsh decision to withhold further H5N1 viruses/samples from the WHO system from January 2007.

At this point, we are faced with the question of how an Australian vaccine company gained access to the Indonesian avian influenza H5N1 virus specimens. Indonesia had not shared specimens outside the network of WHO Reference Laboratories, and the WHO guidelines on influenza virus sharing clearly stated that permission will be obtained from the country and laboratory in which the viruses originated in the case of further distribution outside these laboratories.

Is it possible that the Australian company was part of the network of WHO Reference Laboratories? At that time there were no specific explanations regarding the network of WHO Reference Laboratories. However, “the network of WHO Reference Laboratories” was known and was referred generally to the four WHO H5 Reference Laboratories and four WHO Collaborating Centres, none of which belonged to the vaccine company in question. Other laboratories were added to the list at a later date, all of which were claimed to be necessary for the avian influenza H5N1 vaccine development. However, a clear, formal explanation of the functions and roles of each laboratory included were not given. All of these laboratories were located in developed nations. In addition, the terminology by which these laboratories were referred to changed quite a few times over this time period. For instance, “global research laboratories” was changed to “essential, non-commercial research laboratories” which once again was changed to “essential regulatory laboratories”.

7.6 Case Study-2: History of the TRIPS Negotiation and the Outcome:

In this section of the thesis, I discuss the TRIPS Agreement, an international agreement that has caused enormous suffering by imposing sanctions against poor nations. The TRIPS not only restricts access to medicine and confers rights to patent holders without considering the roles of clinical trial participants, but also distributes the burdens of IB research disproportionately and unjustly onto the poor (Malhotra,2010). The TRIPS Agreement grew out of the World Intellectual Property Organization (WIPO) which was established and located in Geneva in 1967. This organization was tasked with addressing world Intellectual Property Rights issues but seemed unable to stop “piracy” to meet the expectations of the IP rights leaders. Furthermore, advocates of the TRIPS Agreement alleged that the WIPO disproportionately looks after the interests of developing countries. Consequently, the TRIPS Agreement negotiations in the Uruguay Round in 1994 was driven by American corporate interests. Now the TRIPS Agreement is accepted as a legal tool for the world trade negotiations for exploitation.

It is important to consider the historical background to the TRIPS Agreement. During 1980s, Pfizer CEO, Edmund Pratt and IBM Chair, John Opel played central role in changing the vision of the USA government in relation to intellectual Property (IP). At that time, they were serving as member of the US President’s Advisory Committee on Trade Negotiation (ACTN). Later, they also established the Intellectual Property

Committee (IPC) in 1986 to actively persuade their colleagues in Europe and Japan to include IP rights in multilateral trade policies.

In 1985, the US private sector was asked by the United States Trade Representative (USTR) to express IP related concerns. The former Economist of the ACTN, Jacques Gorlin prepared a report in 1985 for the private sector titled “A Trade- Based Approach for the International Copyright Protection for Computer Software”. This report subsequently became the USTR blueprint policy. The USTR, the Japan Federation of Economic Organizations (Keidanren) and the Union of Industrial and Employers’ Confederations of Europe (UNICE) all pushed for the inclusion of IP rights as multilateral trade negotiation issues on the Uruguay Round agenda.

In September 1986, to prevent the production of counterfeit goods, IP rights were included within the Uruguay Round for trade negotiation. The Uruguay Round was sponsored by the General Agreement on Tariffs and Trade (GATT), and consequently the talks were dominated by intellectual property rights issues raised by the United States of America (USA), Japan, Canada and the European Community (EU). The TRIPS Agreement was ratified and the World Trade Organization (WTO) was established to oversee the agreement.

In the WTO forum, equality was accepted as a principle of justice to deal with multilateral trade issues meaning that all countries should receive equal rights and

responsibilities regardless of their developmental differences. Thus, the playing field is meant to be levelled for each member state creating the provision that no state will be treated differently in the relevant respect – i.e. Intellectual property rights. Including IP rights with the WTO means no consideration will be given in negotiations to the different developmental stages of nations.

7.7 Justice and TRIPS Perspectives

The main objective of TRIPS Agreement is stated in article 7:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

The TRIPS Agreement is examined in the discussion that follows from different perspectives. The WHO and Indonesian government documents explain some reasons for advancing the TRIPS Agreement in the WTO forum. For example, Karin Timmermans and Togi Hutadjulu (2000) write that in the process of TRIPS Agreement negotiation, “industrialized countries argued, as part of stakeholder group, that patent protection in all fields of technology, as stated now in TRIPS Agreement Article 27, would have three main effects in developing countries:

- there would be more foreign direct investment (FDI),

- it would promote the transfer of technology,
- patent protection would promote local R&D (Timmermans & Hutadjulu, 2000, p.11)

However, a totally different opinion was expressed in the following statement by the United Nations Development Programme (UNDP). The UNDP states that:

The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed -in every country- of the economic and social consequences of the TRIPS Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents (UNDP Human Development Report, 1999).

Another critical view is noted by Yu (2009), that the TRIPS Agreement:

ignore their local needs, national interests, technological capabilities, institutional capacities, and public health conditions¹¹⁵.

Another effect of the TRIPS Agreement is to create a further imbalance in negotiation. For example, a firm of a nation might agree to pay the price demanded by a patent holder to license their technology. However, the patent holder can still impose “onerous conditions that makes [it] impossible or extremely difficult for the technology to be used by the firm,” (Correra, 2005).

Advances in technology and knowledge are crucial for the development of a country. These not only contribute to the country’s economy but also help them to address social

¹¹⁵ Yu, Peter K.2009. The objectives and principles of the TRIPS Agreement, *Houston Law Review*, 46.

justice issues. Therefore, developed nations spend a lot on research and development projects. The private sectors of developed nations fund investment in research and development as a lucrative business enterprise. To this end they formed multinational corporations and invested their capital in poor developing nations. This investment has led to the multinational corporations of developed nations being the right holders of most or the world's patents. According to Timmermans and Hutadjulu (2000, p.11),

innovation -the development of NCEs- was almost exclusively undertaken in industrialized countries. At that time, 96% of worldwide R&D expenditures took place in developed countries and only 4%, in all areas of science and technology, in developing countries. This is perhaps the most dramatic asymmetry in contemporary North-South relations, since it relates to the ability to create and apply new scientific and technologic knowledge.

The inclusion of IP rights in the WTO in practice means that a country at its early stage of development is unable to produce any technology necessary for its development without paying royalties and licensing fees to patent holders. This has a significant impact on global health and the economies of poor countries. If poor nations have to pay royalties for the medical technologies that they need, then the prices of drugs and medical technologies will go up. This will in turn limit access to health needs and ultimately pose challenge to the global health agenda, i.e., health for all for a decent life and livelihood. It seems morally wrong to do profitable business by capitalizing on vulnerability caused by disease.

The morality of the TRIPS Agreement is further called into question when we consider that the countries we think of as developed nations reached that states before the

TRIPS Agreement in 1994, and thus were largely able to access the technology they needed for their development free of charge. That is, had an agreement like the TRIPS Agreement been in place at the time, the development of these countries may have been slower and more difficult. Developed country used technology to become developed free of charge in the first place. The protection of IP rights through the TRIPS Agreement, facilitates further economic progress for a few technologically and industrially advanced countries, who themselves benefited from the absence of such measures, at the expense of developing nations (Drahos, 2003, Maskus, 2000, p. 503, World Bank 2017, p.133).

To illustrate this, consider for example, a country in the process of developing manufacturing capacities for their economic development. Under the TRIPS Agreement, they must pay royalties and licensing fees before they start production. Thus, an extra cost is imposed by the WTO on emerging countries. Subsequently, it becomes more difficult for the least developed countries to develop further. Those countries that have no pharmaceutical industry to provide medicine to the poor will find it harder to develop one. Developing nations such as India and Brazil, which have industries for drug manufacturing, find that they cannot sell their products to other poor nations due to the TRIPS Agreement. These concerns have been expressed openly by developing countries since the adoption of the TRIPs in 1994. For example, in October 1996, the Secretary of the Commerce Ministry of Bangladesh, expressed concerns at the board session of the United Nations Conference on Trade and Development (UNCTAD), on behalf of the Less Developed Countries (LDCS) Group. According to him,

“LDCS are not yet well placed to take advantage of the Uruguay’s Round opportunities. Instead, the challenges arising from it are most immediate: erosion of preferences, limited number of exportable items resulting in their inability to participate effectively in global trade; higher prices for import of food, pharmaceuticals and essential capital goods; and increased administrative cost of compliance with the Uruguay Round obligations” (Khor, 2001, p. 73).

Initially, for about three years developing nations refused to sign the TRIPS Agreement. Developing nations such as India, Brazil, Mexico, and Egypt and developed nations such as Spain, were reluctant to include patent protection on pharmaceutical and delayed agreeing to patent protection for pharmaceutical products as stated in the TRIPS article 27. Article 27 states that patents should be granted in all fields of technology without exclusion (Timmermans and Hutadjulu, 2000). If this was so problematic for these nations, then why did they agree to the TRIPS Agreement in the Uruguay Round in the first place? Did they not realise that this would restrict access to medicine and pose a challenge to global health rights? Why did they not negotiate this point in the Uruguay Round, or apply their veto power against such an unfair agreement? Did they consider any other benefits of signing such an unfair deal? A definite answer to these questions would require extensive interviews with the participants in the TRIPS Agreement negotiations, which is beyond the scope of thesis research. Pogge has hypothesised that developing nations signed the agreement under duress though such a claim is not clearly substantiated by Pogge (2010, p.6). Another possible answer is that it was difficult for developing nations to negotiate a suitable deal in the Uruguay Round because of political, economic and knowledge power gaps between developed and developing nations.

However, developing countries were unhappy about the TRIPS Agreement's extension of patent right protection to pharmaceuticals. They felt that this would have significant detrimental impacts their economy and health conditions. The developed nations countered these concerns by offering benefits in other sectors of trade such as, textile exports. For example, the USA offered the generalized system of preferences (GSP¹¹⁶) to Bangladesh in textile exports. So, it was a package deal between developed nations and developing nations based on a utilitarian maxim. As to whether such a package deal is morally justified according to the notion of justice, I argue in this thesis that the answer is no (I discuss this at greater length below). The additional funds available from other sectors, for example, GSP in Textile Exports, may be used to develop social structures as argued by development thinkers Sen and Nussbaum. But unfortunately, the USA government has recently cancelled the GSP. So why not pay the benefits that are morally justifiable? The cancelation of GSP proved that package deals like the TRIPS, as many critics have argued, are not only morally wrong but also risky for developing countries.

Overall, then, there are good grounds for holding that the TRIPS Agreement is morally wrong, as it has been made binding on developing nations without considering what I have argued are their rightful claims on a share of patents from the fruits of the IB research that they have participated in. Developing nations were not given detailed

¹¹⁶ GSP is a system of tariff exemption based on general rules of the General Agreement on Tariffs and Trade (GATT).

information about the nature and outcome of the TRIPS Agreement, though many hollow promises were made in the process of negotiation. The developing nations also expected that when the TRIPS Agreement was signed by the USA, the USA would rescind the “Special” section of Trade Act 301, which allows the US to use force to retaliate against any foreign nation for non-compliance with IP rights. However, this was another mistake made by developing nations- Section 301 remained in place following the signing of the TRIPS Agreement.

Indeed, as Drahos (2005) has argued the TRIPS Agreement negotiation process lacks legitimacy. For him a democratic negotiation first ensures that “all relevant interests have been represented by all parties in the negotiation process” (p.163). Secondly, “all those involved in the negotiations must have full information about the consequences of various possible outcomes”. Thirdly, “one party must not coerce the others.” However, these three conditions, the condition of representation, the condition of full information, and the condition of non-domination, of fair negotiation were not met in the process of the TRIPS negotiation (Drahos, 2005, p. 770). As discussed in previous chapters, for example the USA dominated the whole process, only India and Brazil sent their representatives, and “Green Room” dirty politics were played by developed nations.

Drahos (2003) mentioned that the numerical superiority of weak states in the negotiations did not allow them to achieve strong bargaining power in the negotiation.

The WTO provided some institutional support for the weaker states, such as setting up some rules so that strong parties did not exercise their power during the negotiation and communicated within the set of rules dictated by the WTO. But this did not mean that developed nations could not use their advanced knowledge, tactics, and other negotiation capabilities to influence the weaker parties to get a desired outcome or an agreement. In the background of the negotiation, the stronger parties used their bilateral relationships to reach the TRIPS Agreement.

Increasing demand for globalization gives impetus for building relationships between nations for trade. In this process of globalization negotiations play a crucial role. In the negotiations, the negotiators are key factors. For success in the process of negotiation the negotiators need to be aware of how different negotiation principles can result in different outcomes. For example, negotiators must be able to discern how a proposed benefit is morally weak, how it might distribute benefits and burdens disproportionately. The TRIPS Agreement negotiations not only demonstrate the effect of asymmetric power relationships, they also provide strong grounds for believing that there are gaps in negotiation capability between developed and developing nations. The above case studies, on the one hand, show that developing nations lack significant levels of tactics, strategies, and information and on the other hand, show how developed nations intelligently applied their expertise, tactics, and strategies to legitimize their proposal. Therefore, it is important to develop the negotiation capabilities of the developing nations so that they can play a competent role during negotiation in any setting.

7.8 Trust and Respectful Global Relationship in IB research

Within the global research community, the presence of respectful global relationships is crucial for successful collaborative research. Respectful global relationships are also necessary to secure optimal benefits from IB research for the involved parties. Recognition, trust, transparency, and procedural fairness are prerequisites for these relationships. According to Cloninger et al., “Social systems cannot function optimally unless there is mutual respect and trust for one another (2014, p.84).” Similarly, at global level, mutual respect and trust are important for the operation of a distributive justice system to deliver optimal global health care. The two case studies examined in this chapter suggest there is significant imbalances in the distribution of benefits and burdens in IB research. There is also a lack of trust, transparency, and procedural fairness in the process of negotiation. Such conditions along with disproportionate distributions of benefits and burdens, prevents the fulfilment of global health rights and reaping the benefits of global cooperation.

An extensive bioethics literature emphasizes the building of respectful relationships between sponsors and hosts of IB research. For example, the fair-benefit framework proposes sharing benefits fairly, developing collaborative partnership, and ensuring transparency as core principles and emphasises the development of such relationships within the research communities of developed and developing nations (Emanuel, 2008). Transparency in this regard promotes trust. Building collaborative partnerships and

relationships is almost impossible without trust. The Indonesia case further reminds us importance of trust.

In medical relationships, trust is an important element. Thus, some researchers in bioethics argue that using sham ineffective substitute as placebo instead of real medicine can have damaging effect on patients' trust. To highlight the importance of trust and consequences of rupturing trust in medical relationship, Sissela Bok (1978, p. 63) claims that

“the giving of placebo is a waste of a very precious good: the trust on which so much in the medical relationship depends. The trust of those patients who find out they have been duped is lost, sometimes irretrievably. They may lose confidence in physicians and even in bona fide medication which they may need in future. They may obtain for themselves more harmful drugs or attach themselves to fad cures.”

To avoid detrimental effect on patient trust in medical relationship, researchers such as Allen (2015) argues that patients should be told when placebo is used, and why it is necessary, and their therapeutic needs are compromised with placebo.

Resnik (2010) argues that even though public trust is not clearly mentioned as a necessary part of the promotion of public good in biomedical research, the various ethical guidelines or policies that have been developed to protect human research participants show how essential public trust is to biomedical research. He argues that without public trust it would be difficult to recruit enough research participants for drug

development research. Furthermore, without research participants from developing nations in drug development research simply would not move forward. Government funding and institutional involvement also depend on public trust (Vol. 10, No 6, p. 16). As Shavers et al. (2000) mentioned, African Americans are often unwilling to take part in medical research due to broken trust stemming from episodes like the Tuskegee Syphilis Study. Therefore, I agree with Resnik that in international biomedical research, public trust should remain as an important policy objective. I argue that it should be mentioned explicitly in the ethics policies, guidelines, agreements, and declarations governing international biomedical research.

The case study above outlined how in particular Indonesia was not able to trust the existing GISN of the WHO. A lack of transparency in H5N1 virus sharing through the WHO system raises the question of its 50 year old established role and the fairness of the global system. Indonesia claims that the WHO was unable to fulfil its role justly. This kind of practice deprives one party who is weak in power and negotiation capabilities and benefits others who are strong. As a result of such practices, developing countries fail to obtain benefits equitably- and Indonesia is an example of this. A similar view was expressed by Sedyaningish et al. (2008) who further claimed that:

“Countries that are hardest hit by a disease must also bear the burden of the cost for vaccine, therapeutics and other products, while the monetary and non-monetary benefits of these products go to the manufacturers that are mostly in the industrialised countries. Poor countries have no bargaining position because their participation in the production of these products are not valued as they [seen as] are just natural resources (clinical specimens, viruses, and other microbes); on the other hand, the industrialised countries’ contributions are highly valued because they are human invented technology.”

Once again, above statement by Sedyaningish et al. (2008) reconfirms our research findings that there are inequities and unfairness in the distribution of the benefits and burdens of international biomedical research. For Sedyaningish “What has been emphasised by the current global system is merely the responsibilities of developing countries, leaving a big hole in the rights of these nations (p.486)”.

The world community is urged to work collaboratively and increase equitable benefit sharing with the developing world to achieve global health justice (Sedyaningish et al., 2008, Fidler, 2010, Krinshamurthy, 2013). Consequently, properly recognizing the contributions of all involved parties and the creation of negotiation capabilities of developing nations can strengthen the relationships among developed and developing nations and can help to pave the way for global health justice. The two case studies discussed above show that when creating congenial conditions for IB research, it is the responsibility of developed nations to avoid exploitation, and to respect the contributions of host nations properly.

Chapter Eight

Addressing Possible Criticisms and Implications of Proposed Benefits of Sharing Patent Rights

8.1 Introduction

In this chapter, I am answering criticisms against my thesis statement of giving due return to the host nations, i.e., that conferral of IP rights to host nations is morally justifiable in IB research. Addressing criticisms will help me to reinforce the arguments presented in the previous chapters. Second, I would argue that, apart from my approaches to reducing disparity for the protection and enjoyment of global health rights, there are more windows of opportunity thought by moral philosophers in concurrence with my thesis statement to be included in IB research benefit sharing framework. For example, Rawls followers advocated and provided us with important reasons for addressing global health rights. I would like to acknowledge their contributions and compare and contrast my thesis with them, to emphasis how moral philosophers overlooked/undermined role of contribution of developing nations in global health rights protection. They explored a principle of justice while tolerating too much inequality in access to global resources. Addressing critics' concerns about my thesis statement will enhance the plausibility of my arguments by clarifying the contributions of participants in international clinical trials.

The global poor act to improve global health conditions by participating in international biomedical (IB) research. They contribute to the process of drug development and donate their biological samples and other resources to health research for the advancement of knowledge. According to the Novo Nordisk Annual Report (2008), 40% of medicines are tested on the global poor prior to going to market, while medicines are marketed primarily in developed nations.

Full global implementation of the Trade Related Intellectual Property Rights (TRIPS) Agreement on pharmaceuticals (i.e. patent rights) by the WTO would have a serious effect on the health rights of citizens of the poor developing nations (Dreyfuss, 2010, p.36, Pogge, 2008, p.121). Implementation of the TRIPS Agreement would definitely cause the price of patented medicine to rise, (for example in Australia drug prices rose by 35% between 2005 and 2010) and would likely exclude generic drugs from the market for a longer period (usually for 20 years) than at present (Drahos, 2011, p.350, Dreyfuss, 2010, p.36, Malhotra, 2010, p.183). Finger and Schuler¹¹⁷ (2001, quoted in Malhotra¹¹⁸, 2010, pp.179-181) estimated that following implementation phase of the TRIPS Agreement in poor countries would have to spend an extra US\$150 million each on healthcare, two thirds of which would have to be spent on access to medicines. If any developing nation faces a national emergency, then it will be permitted to use

¹¹⁷ Finger, J.M and Schuler, P. 1999. *Implementation of Uruguay Round Commitments: The Development Challenge*, Washington DC: World Bank.

¹¹⁸ Malhotra, P. 2010. *Impact of TRIPS in India- An Access to Medicines Perspective*, Great Britain: Palgrave-Macmillan.

compulsory licensing arrangements to access medicines developed through clinical trials in developing nations. Compulsory licensing means that patent holders will be obliged to accept a lump sum remuneration from the country in need, a sum that is based on the developing nation's capacity to pay. But why should the poor have to pay a royalty to access the medicines that are a result of their contributions?

To improve the existing global health conditions, many researchers (such as Norman Daniels¹¹⁹, Alex London, Thomas Pogge, Angela Ballantyne) have argued that John Rawls' principles of justice in *A Theory of Justice* can be applied to address global health rights obligations. Further, they argue, the global poor¹²⁰ should receive also assistance on compassionate grounds to remedy the disadvantageous conditions caused by the TRIPS implementation. A possible global justice principle considering health rights is explored by Peter Singer and others. They tried to apply universal utilitarianism to reform the TRIPS Agreement. However, Rawls himself denies that his principles of justice from *A Theory of Justice* are applicable at a global level (Cited in Martin and Reidy, 2006 by Miller, 2006, p. 192, and Martin, 2006, p. 228, John Rawls, *Law of the Peoples*, 1999, pp. 82-83, 106-107, 113-120). And Thomas Nagel, in his article "The Problem of Global Justice" (2005) also rejects the possibility of global justice. So, one might wonder why the above mentioned researchers are still inclined to employ Rawls' principles of justice for global health rights, instead of considering further the significant contributions of developing nations in IB research?

¹¹⁹ Cited in Selgelid & Pogge (2008, p.244).

¹²⁰ Burdened societies according to Rawls (2003, p.106)

Amartya Sen in *The Idea of Justice* tried to answer the question of the applicability of Rawls' two principles of justice at a global level (Sen, 2009, pp.379-387). The problem is that applying Rawls, fairness principle and difference principle globally, extending the sphere of justice from a national level to an international level, would seem to inevitably entail levying a global tax on the citizens of rich nations in order to improve the conditions of citizens in poor nations. The collection of this tax is viewed as problematic by Rawls would curtail the autonomy of the citizens of rich nations and impose sanctions on their property rights.

For Pogge (1999) such a tax is to be collected as General Resource Dividend (GRD) for a certain period, in order to "raise the disadvantaged conditions of world's poor until they are either free and equal citizens of a reasonably liberal society or members of a decent hierarchical society" (Pogge, cited in Rawls, 2003, p.119). Rawls argues against such a global taxation system by examining analogous examples. For example, two nations may have similar ecologies, economies, and cultures. But one nation may be more frugal in the use of their resources and so may save a lot of resources. On the other hand, the second nation may not save anything. For Rawls, it is unacceptable if the more frugal nation is taxed to help second nation who did not save resources. Nevertheless, in some respects, I agree with Daniels and intend to apply the egalitarian principle to address global health rights.

The global application of the egalitarian principle is necessary because, as Benatar argues, “modern international economic policies have resulted in the [continued] extraction of vast quantities of material and human resources from poor developing countries to rich industrialized nations” (1998, p.296). This process has created various health, wealth, and human rights disparities between developed and developing nations. Because these disparities are so massive and deep-rooted, and the extraction of resources was carried out in such a unilateral and unjust way, this is a situation that demands rectification. These unequal conditions between developed and developing nations necessitate a positive role for developed nations towards developing countries. Therefore, I also agree with Pogge (2008, p.262), and others that developed nations should address the global disparity. Developed nations must assist disadvantaged people to redress historical injustice and to address the conditions of hardship of the global poor to allow them to live flourishing human lives.

While I agree with Pogge and others on the need for developed nations to address global inequality, my reasons for believing this are different to those of the researchers mentioned so far¹²¹. My view is that the global poor have contributed to the economies of the rich in various ways. This includes the global poor’s participation in the process of successfully developing certain drugs, and in turn improving the security, international harmony, and health conditions of developed nations. In addition, citizens of poor nations also contribute directly to the health sectors of developed nations. According to

¹²¹ Prior to learning about the Rawls principles of justice, I discovered similar basic principles from my common-sense beliefs. Later, I came to know that Rawls uses these principles for his Republic. Why Rawls unjustifiably restricted global application of his theory of justice is beyond the scope of this thesis.

Pogge, Rimmer and Rubenstein, for example, “in the year 2000, some 65, 000 physicians and 70, 000 nurses born-and mostly also trained-in Africa were working in developed or rich nations, leaving behind huge gaps in their home countries’ healthcare coverage as well as in their educational budgets” (2010, p. 6). These above mentioned reasons are sufficient for developed nations’ governments to impose tax burdens on their citizens, as they are the beneficiaries of this clinical research and this contribution to their health sectors.

Another example of the contribution of developing nations to global health is the Oral Re-Hydration Solution (ORS), developed in Bangladesh by US and Bangladeshi researchers (Ruxin, 1994). This solution was later patented in the USA. The ORS was used by US military personnel during the Gulf war, to prevent dehydration in the desert environment (see also chapter 4). The American company that manufactured ORS earned huge profits from selling this product in the international and local markets. This product is marketed globally, and enormous benefits are enjoyed by the global community. I argue that the Bangladeshi contribution to this global benefit provides a moral basis for the people of Bangladesh to claim a share of the post-trial benefits of ORS to address their health needs. Other host nations likewise have a claim to a share of the benefits of trials carried out in their countries as these benefits will help them to meet the health needs of their people.

While sharing the benefits of IB research is an important way to address global injustices and thus help to realise global health rights, I believe it is not the only way. The benefits of any other transactional interactions between developed and developing nations should also be distributed proportionately according to the contributions of the developing nation, in order to support global health rights and to ensure fair access to medicine and technologies. However, I disagree with the claim that this distribution of benefits should be based entirely on the disadvantageous conditions of the developing countries, as this would overlook or undervalue their contribution to the venture. And furthermore, given that the grave disadvantageous conditions were largely created by the developed nations' thrust for wealth accumulation, I believe that Rawls critique of international redistribution does not apply here. Because once again, the enormous success of developed nations in health research and wealth accumulation, was achieved with substantial contribution from the global poor and so developing nations deserve fair treatment.

If Rawls is correct that his principles of justice should not be applied at global level, then this might be thought to imply that there is no moral ground for host nations to demand justice, and consequently that no obligation applies to the nations who conduct clinical trials at a global level. This may also be thought to imply that despite being valuable contributors to realising global health rights through a negotiated structure of interaction, developing nations have no claim to post trial benefits from products patented in developed nations. In this regard, I argue that there is a moral ground if a relationship between, which Rawls' *relationism* argues for justice within a state, is necessary for

claiming rights. The people of the globe are related in various ways and their various interests and rights are interconnected. For example, people share a common humanity and they are now related through various global and international institutions, such as, the UNs, IMF, World Bank, WHO (Risse, 2012). In the case of IB research, there exists a very specific unique relationship between the people of host nations and the people/pharmaceutical companies of sponsoring nations, I believe this relationship is sufficient to provide a moral ground for justice as it is a substantive productive relationship and is in no way inferior to the relationship among citizens within a state, or between citizens and the state itself.

A defining feature of the relationship between nations in IB research is the shared interest of the nation's citizens in health. Health is important for any person, and I agree with Daniels (1985) that health care is special because it allows a person to function normally to improve quality of life, and not simply due to a mere preference to be happy. Commonly, in IB research, host nations take the burden to address the health needs of developed nations. For example, from 1 January 2005 to 30 June 2012, 2644 research participants died during clinical research in India. During this period in India, 475 new drug trials were conducted on human research participants, but only 17 of these drugs were approved for the local market (i.e. India) according to the Supreme court of India (Times of India, 25 April 2013). These past burdens cannot now be outweighed, and this relationship is stronger than other international relationships. Relationships like this are based on mutual trust and are intended to overcome the disadvantaged conditions of both parties. The developed nations are disadvantaged by insufficient numbers of

suitable research subjects, whereas developing nations are disadvantaged by a lack of access to medical treatment. Clinical research creates opportunities to access medicines for global people. The pharmaceutical industries utilise the outcomes of international clinical trials to contribute to the global economy and to improve the health conditions of sponsoring nations exponentially.

The principles of justice designed by Rawls in his *A Theory of Justice* are clearly applicable to a domestic setting. By virtue of his notion of justice, a citizen of a developed nation is protected and also entitled to claim subsidised fulfilment of their health needs from the state and from the pharmaceutical companies of that nation. If membership of a nation is essential to be eligible to receive benefits, and if the obligation of the state to its citizenship emerges from the relationship between the state and its citizens, then why should participant in collaborative clinical research not have a right to claim future benefits, and why are sponsoring nations usually thought to have no obligations to address the health needs of participating nations? Considering this circumstance, Risse (2012) argued that since people of developing nations are members of global institutions such as UN, WHO, WTO, WB, IMF, they should be recipients of justice within the scope of global justice.

Furthermore, common ownership of earth is another reason for there to be obligations to developing nations basic health needs (Risse, 2012). In this context, I proposed accounting further and re-fixing the meaning of contribution provided by Locke for the distribution of benefits and burdens of IB research to pave the way to address global health rights in a just manner. I also argued that the initial acquisitions were unjust, and

that rectification is essential for justice. However, there are some possible criticisms of my proposal and in the remainder of this chapter I will address key criticisms of my proposal.

In the following sections of this chapter, I try to answer some of these possible criticisms. I have found that various contributions of poor nations to IB research are not recognized properly, and that poor nations are therefore denied their fair share of benefits derived from IB research. Instead of sharing IP rights with the host nations of research in recognition of their contributions, sponsors provide host nations with only some ancillary one-off benefits. Thus, in this thesis, I argued for the sharing of IP rights (patents) with host nations of IB research as the pro tanto obligation of research sponsors, in recognition of host nation's contributions to the progress and promotion of global public health.

In response to my argument above, a critic may argue that it is not feasible to grant to thousands of IB research participants/entire nations IP rights that are given to individuals for their contribution in IB research. How is it possible to give IP rights to all the thousands of participants of IB research? Furthermore, one may argue that the claim for IP rights for the research participants is overly demanding. It might also be claimed that such a demand is also based on an overestimation of the participants' contributions to IB research. I recognise that giving royalty rights to research participants faces some challenging practical obstacles. In an international clinical trial,

there are many participants, and it is very difficult to measure each participant's contribution to a particular study. If IP is granted to each contributor, this distribution process might also be thought to involve excessive cost, which may make the process a less effective means of ensuring patent rights. However, practical problems like this should not prevent international pharmaceutical companies from meeting their ethical requirements. The problem of patent rights management is a practical problem. Drug companies, like other business organisations, already have mechanisms for distributing benefits to large numbers of share-holders, in order to meet their obligations to these people. So, I would like to propose a manageable process that is similar to shareholder management for distributing the benefits of IB research.

To overcome the possible distribution problems, I would like to consider the two parties in international biomedical research. One is the sponsoring/researchers' group. The other one is the host /participants' group. Collaborative clinical research can be viewed as in some ways analogous to creating a state where members of both states are members of his new state. The relationships are more than a relationship between an employer and a labourer. It is not like (P and not P) where if we admit P then not-P is impossible. IP and Patent are two different side of one coin. Patent IP is divisible and can be distributed just like shares of a business can. Thus, I argue that to reduce the cost of management it is pragmatic that management of IP rights shall be conferred to the host country. Addressing injustice and avoiding exploitation is no doubt an integral requirement in IB research. Consequently, any objection based on the unfeasibility of distribution of IP rights to IB research participants fails.

A critic may further object that IP sharing may pose a further threat to global health rights because pharmaceutical companies of developed nations may think that the sharing of IP rights with the host country of research is problematic. Registration of patents in host countries might be one of the problems. However, if host nations of IB research are allowed to register the patent in their country alongside the sponsoring nations or multinational pharmaceutical companies, this will also create scope for licensing the drug in the host nations' market. As a result, the pharmaceutical industry would likely flourish, and citizens of the nation would benefit in several ways such as through job opportunities and by receiving revenues from licensing.

8.2 Is requiring IP rights to be provided to the host nation for research participants' contribution an unjustifiably paternalistic restriction of the autonomy of research participants in developing countries?

My proposal that the host nation of IB research be given IP rights may raise concerns that this conferral of patent is unjustifiably paternalistic and so is a violation of the personal autonomy of prospective research participants in developing countries. Critics of my proposal may argue that participants have rights to sell their labour, or the fruits of that labour, without claiming IP rights should those participants choose. If participants are automatically given patent rights, then they would lack freedom to choose from

available other options as the state would thereby take control of the patent rights, thus denying their freedom to do as they wish. If we propose giving IP rights to the host nation to avoid such limitations, then we require justified reasons for the state acting as representative of the participants. If the state is given the rights to negotiate a fair level of benefits with the sponsor, then the autonomy of the participants is further restricted than it already is.

There is no doubt that the autonomy of a person is a key political value and must be respected by every society. Locke and Rousseau in the enlightenment, and Rawls and Nozick in the recent past have argued for human freedom as a fundamental basis of liberal social structure (Rawls, 1993). If autonomy is the highest value to be respected, then the participants of a clinical trial should have the power of speech to determine a framework for the distribution of the benefits and burdens of the trial. And recipient of benefit should be the people who contribute to the clinical trial in question. But there is no international law which allows an individual participant of a clinical trial to negotiate the specific terms of their participation. Rather, international forums, for example, the International Court of Justice allows only nations to conduct negotiations like this. There is no way that a foreign pharmaceutical company can be held legally responsible for any misdeeds by an individual participant. If there is such system as discussed above, then a lack of information and negotiation power may jeopardize their autonomy. There are concerns that governments of developing nations are corrupt. For example, developing country governments often sign deals with International Monetary Fund (IMF) and/or the World Bank for their nation to borrow money for development projects. However, they

ultimately misuse the money drawn in the name of public welfare. So, it is reasonable to believe that conferral of IP rights to the government of developing nation may not be an effective way to achieve justice and ensure global health rights. In this regard, I argued for involving civil society at local and global level in addition to the governments.

On the other hand, global human rights frameworks, for example the Universal Declarations of Human Rights 1948 Article 25, and the Millennium Developmental Goals (MDG) confer global health rights on state actors (Selgelid, 2008, pp.243-253, Singer & Schroeder, 2009). This further justifies that it should be host nations that should be the recipient of IP rights instead of individual participants of IB research.

Civil society (e.g. NGOs) at an international level has succeeded in influencing international biomedical research in the past. For example, I can mention the Doha Declaration on compulsory licensing of the TRIPS Agreement. Another example is the UN, organizations have urged pharmaceutical companies to address global health rights issues in the past. More recently, the UN Special Rapporteur in 2008 released a report after visiting pharmaceutical companies. The report clearly stated the duties and responsibilities of pharmaceutical companies regarding access to medicines. Some developed nations took this request seriously and created scope for international pharmaceutical companies to conduct IB research with the developing nations. For example, the Japan Pharmaceutical Manufacturing Association (JPMA) claims that they are taking efforts to improve the health of the poor by investing and conducting research on neglected disease and breaking the vicious circle that binds poverty and

communicable diseases (JPMA, 2018). For example, they have engaged in development of HIV treatment, are working towards eliminating tuberculosis, and are helping to develop medicine for dengue fever, and treatment of malaria (JPMA, 2018). Also GSK has opened a research lab for external researchers so that discoveries can be made for neglected diseases (www.gsk.com/en-gb/partnerships/neglected-tropical-diseases/25/05/2018).

According to Pogge (2008, p.264) by imposing a global institutional order, such as the WTO's TRIPS Agreement, governments of affluent nations are participating in "the largest human rights violation in history." Therefore, Pogge (2008) urges developed nations to explore global health research opportunities, including globally neglected diseases, in the IB research agenda for the realisation of global health rights and to reduce the global burdens of diseases. The prospect of such global health research raises crucial questions of how the benefits of an internationally developed drug be distributed and who should be rewarded for such noble work. This inspired me to explore IB research and to conclude that IP should be distributed among host nations governments.

8.3 Why should IP rights (Patent rights) be shared with the host nation instead of with the individual participants in the research?

Critics of my thesis may argue that it is unreasonable to share IP with host nations when it is the individual participants themselves who contribute to the clinical trials. In my

view, the state level actors are responsible for instituting legal frameworks for the protection of global health rights as well as for IP rights. In this regard, I would recommend some levels of participation of the research participants at a national level in negotiation. However, it would be naïve to recommend participation of each research subject at the WTO negotiation and other international law-making institutions. Rather, someone can represent for them, for example, a member of civil society, who has knowledge about and respect for their choices.

8.4 Reasons for considering IP of IB research as collective rights:

In previous chapters, I have argued that global health rights undeniably exist, and that respecting such rights requires ensuring fair access by all to medicine and medical technologies. To achieve this, I argued that conferring on a host nation a share of the IP rights of a collaborative clinical trial is one way of bringing fairness in distribution, promoting global health rights, and widening the scope of access to medicine and technologies fairly.

Usually, the benefits of a patent from IB research are enjoyed by the sponsors or developed nation that own the IP rights. In effect, patents allow the transfer of wealth from developing nations to developed nations and later on that transferred wealth can be used to advance pharmacology (Dreyfuss, 2010, p.36). The view that this is a just distribution of benefits is typically based on John Locke's idea of ownership resulting

from the mixing of labour with something - in our case, the investment made by sponsoring nation's pharmaceutical companies in IB research. Locke assumed that the earth is a common property and that mixing labour with it provides us reason for private ownership of what is thereby produced. Nozick criticised this view of appropriation, arguing that someone who tips a can of juice in the sea does not necessarily take private ownership of the sea. I agree with Nozick that mixing a can of juice in the sea does not give any right to claim ownership of the sea by an individual. On the other hand, Risse (2012) has argued that global health rights are morally important and must be respected by treating the IP of essential drugs as common property even to non-contributors. Risse's argument draws on Grotius's view of property in relation to the discovery of sea routes that such a discovery does not necessarily give rise to private ownership of the sea routes, and thus no one can claim the sea route is his or her property. The sea is common for all; thus, the sea routes are common for all. The use of a sea route by people other than the discoverer does not obstruct the discoverer from getting benefits if they use it. Similarly, Risse argues that the use of an idea by others beside the inventor do not obstruct the discoverer getting at least some benefits from the idea though less benefits than the inventor would gain if they did not share the benefits with other contributors. So, Risse argues that the idea (in this case an essential drug) can be held in common.

I disagree with Risse's ontological assumption that ideas, especially ideas of medicine and medical technologies, should be common for all in the same way as Grotius proposed for sea routes. By contrast with discovering a new sea route, it is reasonable

to claim that medical discoveries are the products of rigorous scientific research of a researcher/group of researchers and clinical drug trial participants. I therefore have proposed a more restricted common type of ownership i.e., sharing IP with the host nation of the research. This takes into account the collective collaborative nature of IB research, and the management problems of IP rights. And the sponsor would be able to get more benefits from the idea this way than if it was held in common for everybody, in the way Risse proposes.

A concern might be raised here that the state may misappropriate the right or whole population of a country have not participated in the trial so, why should IP be conferred to a state rather than individuals? But my view is that global health rights frameworks place on the state the responsibility to ensure fair access to medicine. For example, Foreman & Kohler in *Access to Medicines as a Human Rights...* argue that “states continue to hold primary responsibility under international human rights law for realization of such rights, including the right to health (2012, p. 4).” So, the state should have or develop the resources for fulfilling such duties.

There are doubts about granting IP rights to governments in some poor developing nations, which may be corrupt. There is the possibility that such governments might abuse these rights against the interests of their people, much as developing country governments sometimes abuse the borrowing privileges that are intended to improve the national economy (Pogge, 2008). There are different approaches to combating

corruption in developing nations. One of the ways of combating corruption is by empowering civil society. In this case, civil society can be engaged to monitor IP and global health rights conditions in poor nations along with local and international stakeholders. When granting IP to a state there should be a clause stating that if the revenue accrued as a result of the contributions of a particular community or population, then that revenue should be spent for the development of that particular community.

Another criticism of my thesis might be that while it might be conceded that participants are morally entitled to receive some IP rights, this would not entail that participants are legally entitled to these rights. That is, according to this criticism, although it is morally justifiable that participants should receive IP recognition, this does not entail that the law must ensure that this happens. This leads us to the debates between theories of natural law and legal positivism. First, I should say that I consider legal positivism as a valid process of making law because this helps to protect the social fabric that binds us together. Also, I have already argued that it is the obligation of the state to provide primary goods such as health care facilities and essential medicines for the maintenance of good health of the members of the society. Then the state must have the authority to make policies and law that seems reasonable to the state. On the other hand, a natural law approach creates awareness and provides direct moral grounds for law making. In my view, both approaches are mutually supportive for law making.

The idea of IP rights, in our case to be acknowledged and conferred, is initially based on natural rights and it can be legalised in the spirit of legal positivism. I argue that non-recognition of IP rights in IB research is tantamount to the denial of the natural rights of the participants of IB research, on the grounds that such non-recognition creates barriers to accessing medicines and to the fulfilments of health needs. Furthermore, Risse (2012) proposes that members of the human race, and members of global institutions such as the UN, WHO, WTO, WB, everyone should have equal access to essential medicines even non-contributors to IB research, therefore IP of essential medicines should be treated as a common property. His recommendation would certainly have a beneficial impact on addressing the global disparity. But for me all participants in IB research deserve access to medicine and are entitled to IP rights as part of a benefits package of collaborative contribution. Therefore, denial of IP rights to host nations constitutes an injustice to the host nations of IB research, as it poses a threat to their citizens' access to medicine and global health rights. Therefore, there should be a legal apparatus or tool to address this injustice (see chapters 1,2, & 3).

I then argued that IB research participants should be empowered so that they can negotiate a fairer agreement. I have argued for their freedom of choice and for an obligation conferred on the host nations to expand options available to IB research participants. In the distribution of benefits and burdens, the conferral of IP rights on the host nations of research participants helps to negotiate a better outcome and continuous support for global health rights. Here I took an underlying natural law approach based on the idea that natural human rights must play a crucial role in

international law-making institutions. The actors in the WTO seem to deem that IP should be protected at the cost of global health rights. On the other hand, actors in the UN system decided that global health rights should be protected. If social solidarity and the global social fabrics are important, then we must consider that global health rights are more stringent than IP rights.

8.5 Should IP rights be given automatically to host nations of IB research? Or should the host nations negotiate IP rights sharing as a condition for their citizens' participation in the research?

Considering current global health and wealth disparity, if developed nations share IP rights with host nations of IB research, it will still be helpful to develop the host nation's capacity to realise their contribution and rights. As most people in developing nations are poor and receive various kinds of aid from developed nations, they might lack the courage to pursue or claim their right actively. Recipients of aid may tend to become accustomed to dependency and loyalty, which ultimately affects their ability to negotiate. They may feel bound to accept what is an unfair deal.

According to London, "pre-existing social structure put research sponsors in a much stronger bargaining position than members of the host community in the developing world (2005, p.31)." The sponsoring party is in an advantageous position to know about the potential commercial and scientific value of the research outcome, so it is

reasonable to call the sponsoring party a well-informed party. But the host community or country may not be aware of the potential value of the results of a research project - this knowledge gap is commonly acknowledged among host communities. Therefore, expecting developing nations or host nations to negotiate for a fair share of benefit from a stronger party may not be very pragmatic or feasible. However, as an ethical business practice the sponsor can bridge this power gap and level the playing field because they can promote respect and trust and provide a strong foundation for future collaborative partnership research. Furthermore, each party will be dignified in the eyes of the others. I therefore argue that sponsoring nations or companies should meet their moral responsibility of transferring fair benefits and include terms and conditions to share patent rights with the host nations.

Most developing nations' developmental projects depend on aid or loans from developed nations. Developing nations may fear losing access to this aid if they are inflexible about certain claims and requests from developed nations. During negotiations regarding the TRIPS Agreement, for example, developing nations signed the agreement due, in part, to tensions like this, without realising the severe consequences that would likely result for their people from compliance to the agreement. These kinds of tensions or hesitation should be avoided as they can pose a substantial threat to the negotiation capability of developing nations, and thus negotiators might be afraid or overly modest about asking for justice. Avoidance of unacceptable tensions like these is vital until developing nations develop basic social structures that are capable of promoting freedom of choice and develop reasonable capacities to negotiate for their own rights.

In our case, sponsoring IB research developed nations should be expected to carry out the responsibility to share IP rights (patent) with the host nations.

8.6 Might the provision of IP rights to research participants constitute undue inducements to participate in research?

Usually, participation in research should be altruistic. This means that participants take the risk or bear the burdens of research for the benefits and interests of others, without receiving some form of benefit in return (Scott and Seglow, 2007, p.1). Offering benefits to research participants may be thought to unduly influence their decisions to participate in the research, meaning that they may agree to participate against their better judgement. Thus, undue inducement is morally impermissible and must be avoided. In this case one might argue that if we give IP rights to host nations this may be an inducement or undue inducement to host nations. IP rights may be a tempting offer for a host country and could influence their judgment to conduct the trial in their country.

According to Arnason and Schroeder (2013, p.20, in Schroeder & Lucas, 2013), in developed nations biomedical research usually leads to the following benefits:

- “1. Ever increasing numbers of medical interventions to achieve and maintain health tailored to local health needs and, in principle, accessible to all.
2. Increased knowledge about human health made available to citizens through general education or health campaigns.

3. The availability of jobs in a high-tech industry (pharmaceutical research) and various related sectors (e. g. academia), and indirectly the very infrastructure and institutions that make such jobs possible.
4. Profits for commercially oriented research companies and the pharmaceutical production and retail industry (See also Schroeder and Gefenas 2011, p.4, in Schroeder & Lucas, 2013)".

Can the research participants of developing nations also gain access to similar long-term benefits when they take part in the IB research sponsored by a developed nation's pharmaceutical company? There is consensus in the bioethics literature that research participants in developing nations mostly are in dire need of access to health care. Therefore, research participants invest their time, health, and knowledge to obtain the benefit of this access. Most developing nations, however, lack well established and operated health care services system. Thus, in developing nations, most research participants and citizens are unable to enjoy above mentioned benefits delineated by Arnason and Schroeder on a long-term basis. The lack of an effective health care system constrains access to the benefits of scientific research by the host communities. Thus, in IB research the altruism model of research participation is inappropriate to apply to participants from developing nations (Arnason and Schroeder, 2013 in Schroeder & Lucas, 2013).

Whether or not the benefits offered by participation in a clinical trial constitute undue inducement to participate in a clinical trial really depends not on the nature of the benefits themselves, but rather on the circumstances of the participants. Access to medical treatment, for example will not be an undue inducement to someone who lives

in a society that provides ready access to medical care, but it may well be an undue inducement to someone who lives in a developing country where healthcare is scarce. Granting IP rights to research participants through their host nations will direct the benefits of IB research toward long-term capacity building projects, which will in turn improve the circumstances of people in developing nations and make them less dependent on medical trials to access the things they need to flourish. This in turn will mean that the benefits offered by future trials are less likely to constitute undue inducement, as participants will be in a better position to make free and informed decisions about their participation. By contrast, in the current system participants in IB research are offered only short-term benefits like temporary access to medical care and lump-sum payments. This serves to keep participants in circumstances where participating in future trials may be their only means of accessing the things they need to flourish, and they are therefore less able to make a free decision about their participation. Therefore, there is good reason to believe that granting IP rights to research participants will likely reduce the problem of undue inducement in IB research.

Furthermore, I argue that such a narrow conception of undue inducement, i.e., giving a share of IP of a collaborative clinical trial, ultimately contravenes the fair entitlement of the research participants and host nation. The question of whether the benefit is fair is more important than the question of whether it is an undue inducement.

8.7 Does justice require that IP rights are given to the Host nations of IB research?

One may question whether justice requires that IP rights should be given to the host nation in the first place. In developing nations, research participants are not usually made worse off by participating in a trial. I must acknowledge that the research participants are typically in a much better position than that of those who don't participate in clinical research. The sponsor of a trial will usually do nothing to worsen participants' pre-existing conditions. And because of the clinical trial some opportunities for accessing health care have been created. For example, the participants of developing nations have usually had no access to drugs or health check-ups, but they may be able to access these things because of the trial. So, it might be objected that host nations/participants are not owing any benefits other than the care they receive during the trial.

This argument highlights how research participants and host nations benefit from pharmaceutical companies and sponsoring nations in many ways. For example, the research sponsors provide infrastructure and drugs and care during the clinical research. My view is that access to health care facilities (like health check-ups) are part of the trial procedures and should not be regarded as a benefit from the trial, even though it is in one sense a type of benefit to research participants. These services are provided because they are essential to the conduct of the trial, and as such they should

be considered as an overhead cost of the research protocol (Ballantyne, 2006). Regardless of how they are viewed by the participants, these services should be considered part of the conduct of the research trial rather than being included among the benefits of the trial.

It seems to me unreasonable that developing nations are required to pay a royalty for access to drugs that were developed with their assistance. Since drug development is a collective activity, then all concerned parties deserve similar attention in benefit sharing. The relationship between the drug company and their users and the relationship between researchers and the participants are significantly different. An appeal to this distinction allows us to argue for the benefit sharing of IP rights to research participants.

8.8 How should benefits be provided to participants in unsuccessful IB research?

Whether IP should be shared with host nations for all clinical research trials and whether research participants should receive any benefits if a trial does not result in a successful product are also crucial questions. A trial may fail to produce a successful product, but such a failure may well contribute to knowledge in the bio-medical sciences, as biomedical research is always progressive in nature. There should often be benefits available for such trials. For example, from an unsuccessful trial the researcher may find a new virus or clue that benefits them in such a way that helps them to rethink and address future health needs by developing an effective intervention. The host nation

can also share post-trial burdens of unsuccessful clinical research proportionately. It is a moral duty of the researcher and sponsor to share some form of benefits with trial participants - for example money to compensate for their time and post-trial care if required. These benefits may not involve sharing IP, however some recompense should be provided to those research subjects who originally suffered and bore the burden of the research. However, the ideal situation is still that in each case IP should be distributed proportionately based on the amount of contributions and burdens shared by the involved parties. However, such policies may appear to be impractical. In this regard, the benefits of small scale (from economic point of view) clinical research may be distributed based on a consensus reached by both parties.

8.9 Demanding, overestimated and rigorous

My view is different from other ethical approaches to these issues, which have proposed solutions and have argued for fair distributions of benefits on the assumption that developed nations have an obligation to help underdeveloped nations to address their health needs. Proponents of this view think that the people of developing nations' need access to medicine and that developed nations can help to meet their needs without sacrificing anything of comparable moral significance. For example, Ballantyne (2006) argues that in providing infrastructure as guaranteed benefits to the host community the sponsor of the trial is not sacrificing anything morally comparable to the suffering of poor in developing nations. Further London (2005) argues that sponsors of IB research

should be helping to improve the social structures of the host communities as the sponsors have the power to prevent the suffering of poor people in the host nations. This is an expression of compassion based on “Principle of Sacrifice”. By contrast, I argue that it is not a matter of compassion but an obligation as an informed person to deliver benefits to those who have already earned those benefits.

Furthermore, the investment of the sponsoring company or nation, for example building infrastructure, is in no way greater than the investment of the participants and host country. If the research sponsor provides money for a building, then the host nation provides their land. Then it appears to be unfair that the participants receive benefits only once, while the pharmaceutical industry exploits the benefits for a potentially infinite period.

In this thesis, I am not proposing that the approach I have argued for is the *only* way of resolving disputes that arise in IB research in a just manner. I should mention that my conception of fairness is much far from the Marxist notion of fairness. Marxist notion of fairness suggests that injustice occur when someone is coerced by somebody to do or accept something to advance others’ interests or benefits other than pursuing their own interests or benefits. In IB research, as long as research sponsors do not coerce research participants to participate in the research that does not violate the ethical constraint against coercion (Hawking, 2008, p. 46). However, the research participants may be forced by their unjust circumstances to participate in the research.

8.10 Conclusion

In the above sections I have discussed potential criticisms and emphasised that for justice as fairness in IB research, we need to affirm that the contributions of both parties should be the basis of sharing the benefits of the research. The research participants are entitled to enjoy the benefits of the trials to which they have contributed. I recommended that developing nations morally deserve recognition of their contribution, have rights to claim the post-trial benefits, and consistently should receive a portion of the royalties for their contribution. The value of their contribution is not overstated, and the autonomy of the participants is not overlooked.

Chapter Nine

Conclusion: Towards Global Health Justice

Lack of access to medicine is one of the key impediments to global health rights. The aim of this research is to argue for global health rights to create “equal opportunities” for enjoying the gift of life. Moral philosophers urge taking of the positive steps to ensure fair access to medicine for those who are disadvantaged by ethnic, race, class, or sex barriers as an aspect of global health rights. These rights are also enshrined in various international human rights declarations and are based on the assertion that not taking any positive measures to promote, or alternatively obstructing access to or enjoyment of health rights is an injustice to humans. Therefore, I explored avenues of fair access to medicine globally and demonstrated how the TRIPS Agreement obstructs access to global health rights. I argued that access to medicine can be ensured globally provided that the TRIPS Agreement properly acknowledge the contributions of host nations by recognizing IP rights for them.

Bioethics researchers have proposed conducting more international biomedical (IB) research, especially into neglected diseases that afflict poor countries, as a way of ensuring fair access to medicine for low and middle-income countries. However, in the second chapter of the thesis, I argued that the notion of patent rights currently accepted as the norm in IB research poses a problem for the idea that IB research can promote fair access to medicine. At present, patent rights are ascribed to the pharmaceutical companies or nations that sponsor IB research, in a way that fails to recognize the

substantial contributions that participating host nations make to the conducting of clinical trials. Under this patent rights scheme the host nation of IB research receives only a one-off monetary payment for their contributions, while bearing the non-monetary overhead costs that are necessary for conducting clinical trials and participating in international clinical research. The sponsoring nation, on the other hand, invests to develop intellectual property (IP) or buys IP from biomedical researchers and thus bears the monetary costs of the clinical research, but in return they can deny any intellectual property rights to the participants of the host country despite the latter's valuable contributions. I argued that this is an injustice to host nations and to the community who bears the burdens of the clinical research and contributes to reducing the costs of clinical trials. In contrast, the sponsoring nation enjoys the ongoing benefits of the IP rights resulting from the research, which means that they can license or market the successful products of the research globally.

After completion of the trial there are chances of side effects that may impose enormous burdens onto the host nations. Under this system of international clinical research there is no way to hold responsible the sponsoring nations/pharmaceutical company even if something goes drastically wrong. If anything goes wrong in the host community or any clinical research subject suffers because of the participating in the clinical trial host nation has to bear such burdens without any compensation from sponsoring nation.

Another obstacle to global health rights is identified as the TRIPS Agreement. This international agreement allows global recognition of IP rights, specifically patent rights

on pharmaceuticals, and impose unequal burdens on the health of people in poor nations. Respecting global patent rights for pharmaceuticals, as poor nations are required to do under the terms of the TRIPS Agreement, means restricting their citizens' access to cheap generic drugs. These restrictions will limit the global poor's access to medicines essential to their health. Under the terms of the TRIPS Agreement the citizens and health care systems of signatory countries will have to pay for access to patented medicines, which are more expensive than their generic equivalents due in part to the royalties that must be paid under the compulsory licensing system. Patent protection means that global people must wait until the patent on drug expires-which will be usually 20 years before they can access affordable generic versions of the same drug. Lastly, implementation of the TRIPS Agreement imposes extra burdens on the least developed countries, as the global implementation of this agreement requires developing nations to expand their capacity for governance and to educate their human resources accordingly.

In order to critique these unjust intellectual property frameworks, in the second chapter of this thesis, I explored what is meant by IP rights. IP rights imply a positive right. A positive right gives the holder power to “urgently, peremptorily, or insistently” make a claim for his/her rights. This is a power, the holder of which can assert his or her claims authoritatively, confidently, unabashedly. This is something, as Feinberg argued, on which a person can *'stand'*. In addition, this is not a form of gift or favour that is motivated by love or pity and delivered or accepted with gratitude. In this case,

recognition of intellectual property rights respects dignity of both the holder of the right and the bearer of such a right. It gives due respect to contributors and places the bearer in a dignified position such that he or she is not exploited anyone.

Having laid out the general concept of IP rights, I next applied this specifically to the development of pharmaceuticals through IB research. Based on the prominent Lockean concept of property rights, I argued that there are two conditions for ascribing intellectual property rights to the people who participate in IB research: (a) whether the participants are contributing to development of the drug being researched, and (b) whether their contributions added value to the drug.

In chapter three of this thesis, I investigated the contributions of the host nations of clinical trials to see if the host nations' contributions satisfy these two criteria, and my findings established that the host nations improve the value of the investigational drug by adding their labour in various ways. Not only are the host nations contributing by adding labour, but they also contribute financially as they run clinical trials at a subsidized rate. In addition, the host countries contribute to sponsoring nations' clinical trials through material sharing for the improvement of global health. Such unique contributions deserve the highest appreciation as they promote and protect global health rights, peace and the global economy.

I argued that, as the contributions of host nations of IB research satisfy the Lockean requirements, host nations should be recognized as part owners of the resulting intellectual property. As a result, I proposed that host nations have rights to claim and enjoy the benefits that the property accrues. There is no disputing that the research participants bear many of the crucial burdens of research and improve the product or related research outcomes. Sometimes, the host country also provides biological samples (e.g. blood samples) which are necessary for current or future research. Consequently, I argued that they should be given property rights and be allowed to claim - authoritatively, confidently, unabashedly - their share of the benefits exacted from the drug.

In chapter four, I examined various existing models of benefit sharing as a just means of remedy and redress. I discussed how these models do not adequately answer claims of exploitation and injustice, and to ensure justice in IB research. The discussions of chapter one, two and three established that the contributions of host nations must be an integral consideration for the just distribution of IP resulting from IB research. However, the traditional benefit sharing models mostly appeal to two popular notions of justice, i.e., reciprocity and equality. These conceptions of justice have been used by bioethics community as the basis of benefit sharing frameworks in IB research, but I argue that they fail to take into account the unique contributions of host nations. The concept of reciprocity, in the context of international biomedical research and global health development, means giving participants something in return for their participation, in recognition of fairness. A benefit-sharing framework based on reciprocity has some

potential to dispense benefits and fulfil the commitments of developed nations to achieve global health rights. However, it also has several serious limitations. As I discussed, one of the important limitations of these models is that they fail to recognize some important unique contributions that host nations make in clinical trials. While these frameworks acknowledge that they have considered host nations contribution of different types of material resources that they allocate for conducting a clinical trial, they did fail to take account of the distinctive value conferred by the participants' contributions (e.g. through their labour) in the field of innovation. Participant' contributions in this field, I argue play a similar fundamental role to those of the discoverer and innovator in the process of drug or technology development in various morally significant respects. By comparison, distributive justice frameworks recognize the role of the researcher as valuable and thus as supplying grounds for IP rights. Researchers are offered IP rights and benefit packages as well. However, these frameworks do not address the difference between the post-trial IP and pre-trial IP - both are regarded as same IP. Distributive justice approaches should take this difference in the value of property before and after the trial, and the role of trial participants in making this difference, when they are developing benefit sharing models. I must emphasize the difference in value: the pre-trial IP is *merely* a hypothesis and the post-trial IP is a *confirmed* hypothesis – that is a proven product for marketing. The *substance* is added in the clinical trial, in no small part due to the labour of the participants.

In chapter 5, I argued for the development of basic social structures for ensuring public participation in, and fair access to, decision-making as part of creating capabilities for developing nations. This approach does not acknowledge the existing asymmetries of power and unequal economic conditions in the world (Pham, 2004). I argued that although equality and solidarity as ethical principles play an important role in the theory of justice, these notions as principles of justice fail to capture the reality and practicality of the asymmetries of power that exist between nations (Pham, 2004)¹²². Therefore, it is impossible to achieve justice while ignoring existing asymmetries.

John Rawls' theory of justice and Sen and Nussbaum's capability approach were mentioned in this regard. Rawls' first principle of justice was adopted based on equality, but he realized that he needed another principle to cover the distribution of social goods for fulfilling basic needs/primary needs/primary goods. This led him to develop his second principle to include and address the existing asymmetries in a society, where he argued that advantages should be given to the most disadvantaged people living in the society. There is evidence that such disadvantaged conditions in developing countries are often the legacy of colonialism. I partially agree with Rawls that justice requires that disadvantaged people must receive benefits to reduce the gaps, but prior to that I would suggest that, in the case of international biomedical research, acknowledging the

¹²² "Developing countries will almost always find themselves at a political bargaining disadvantage relative to developed countries because they often rely on developed countries for aid, military assistance, or technological transfers. A developing country also has a less important impact on a developed country's economy than vice versa, since bilateral trade is more likely to be a greater percentage of the developing country's gross domestic product ("GDP") than of the developed country's GDP. A neutral adversarial dispute settlement system helps limit the scope of the debate to the legal merits, and thus offers increased judicial protection to a developing country against more powerful developed countries."

contributions of developing nations and conferring of IP rights based on their level of contributions will be a much more logical and ethically justifiable way of “creating capabilities” for the poor nations.

In chapter 6, I argued that, lack of access to information is another barrier to fairness in negotiation around IB research. The WHO and WTO must shoulder the responsibility for addressing this lack of capability. I also argued that, as a moral agent, developed nations have some responsibilities to provide information and to increase the negotiation capabilities of developing nations. Another type of justice can be achieved through negotiation, i.e., justice in exchange (i.e. proposed in CBD). Justice in exchange mainly emphasizes “translating intrinsic value of something into monetary value of it to achieve fairness in transaction.” Based on this notion of justice several questions can be asked. For example, we can ask: is it possible to convert something’s intrinsic value to monetary value in reality? In terms of intrinsic worth of bearing the risk and burden for the research, is it fair if in exchange the monetary sum the hosting country receive for their contributions (Schroeder and Pogge, 2009, p. 274)? If the answer to the first question is yes and second question is no, then in exchange of intrinsic contributions made by host nations require sharing IP rights and accordingly paying royalties.

In international biomedical research, IP (patent) ownership is considered a right of developed nations. However, developing nations contribute to this research by

participating in clinical trials or by providing materials such as samples of diseases. These contributions add to knowledge and innovation and provide opportunities for further innovation. These value-adding contributions by developing nations cannot be rewarded or compensated by one-off payment. The compensation system as it stands lacks fairness as it keeps open the door of injustice and exploitation.

Kant (1787, p.93) said that percept without concepts are blind, and that concepts without percept are empty. This is one way of illustrating the value of developing nations, participation in international biomedical research: the participation of developing nations in clinical trials to prove the efficacy of an intervention adds a percept to the concept of the drug or technology. That is, without an efficacy approval gained via the involvement of participants in developing nations, a drug or technology would be merely an empty concept.

My view is that as both parties contribute to international biomedical research, IP (patent) rights should be shared among the contributors. This is because IP rights can be used as capital for typically 20 years by developed nations, and this is a benefit that goes further than the one-off lump sum- typically paid to developing nations under the current system. And if the IP rights reside solely with the developed nations then for the duration of these rights most people of developing nations will be prevented from accessing the benefits that result from the research they participated in - this is ensured by the agreements and systems put in place by the WTO. If the claim rights of

developing nations are not included in the distribution of IP, then the scope of injustice and exploitation remain open at global level.

If fairness in distribution is a matter of justice in exchange, then it cannot be achieved if both parties are not equally capable of bargaining and negotiating a distribution framework. Many researchers have identified developing nations' lack of negotiation capacities and argued for creating or improving their negotiation capabilities (Nussbaum, 2011). I agree with this and believe that negotiation power is crucial for benefit sharing and achieving justice in exchange. Therefore, in chapter 6, I discussed international negotiation in international biomedical research and how it contributes to fairness in distribution of benefits and burdens in IB research. From this discussion I concluded that an asymmetric power relationship is a key barrier to fairness in negotiation. The WTO conferred equal voting power but did not allow voting in the process of the TRIPS Agreement.

In chapter seven, I discussed two cases and revealed that the various diseases suffered by people of developing nations are usually considered as less valuable. However, the disease information and biological specimens are highly valuable to bio-prospectors. These valuable contributions have enormous potential to help people to treat disease, regardless of their national boundaries. The Indonesian Avian influenza virus sharing represents an example of international sharing of biomedical information. The developing nations share information, samples of the virus, and their biological specimens with the various international research collaborative centres run by the WHO

to protect and develop preventative and therapeutic interventions for public health. These resources can be used to develop vaccines, diagnostics, and therapeutic or other health related technologies. Such contributions cannot be fairly compensated simply by a one-off payment to cover the inconvenience or harm of participating in the research.

The injustice of this compensation is highlighted by the fact that pharmaceutical industries of developed nations are able to access such shared healthcare resources and are free to develop and patent health related technologies based on these resources. Subsequently, these technologies can be traded in the world market and charged at a set price, regardless of whether this price puts the technologies beyond the purchasing power of developing nations, which may have shared their resources earlier on.

In this thesis, I have argued that global health rights are undeniable, and that respecting such rights requires ensuring fair access to medicines and medical technologies. To this purpose, I argued that conferring IP rights to the host nations of collaborative clinical trials would help to bring fairness in distribution, promote global health rights, and assures fair access to medicine and technologies. Under the current convention, IP is given to the researcher and the patent IP is given to the investor. This view is typically based on John Locke's idea of mixing labour. Locke assumed that the earth is a common property and that mixing our labour provides us with a basis for private ownership. Nozick criticized this view of appropriation. For Nozick, if anyone mixes a

can of juice in the sea, this does not necessarily give rise to private ownership of the sea. I admit that mixing a can of juice in the sea does not give any right to a claim of ownership by an individual. On the other hand, Risse (2012) has argued that global health rights are morally important and must be respected by considering the IP of essential drugs as common property. Risse argues, based on Grotius's view of property in relation to sea routes that such a discovery does not necessarily give rise private ownership of the sea routes, and that no one can claim the sea route is his or her property. However, these routes are named in recognition of the discoverer's contribution to humanity. The sea is common for all; thus, the sea routes are common for all. The use of sea route by people other than the discoverer does not obstruct the discoverer from getting benefits from it. Similarly, the use of an idea by others beside the inventor need not obstruct the inventor getting benefits from it. So, an idea can be common property.

I disagree with Risse on this especially the idea that medicine and medical technology should be common for all in the way he proposes. It is reasonable to claim that these ideas are the products of rigorous scientific research by a researcher or group of researchers. I proposed a common type of ownership different from Risse, i.e., giving a share of the IP to host nations. This recognises the collective collaborative nature of IB research and also the pragmatic problems of IP rights management, such as keeping track of or calculating each participants' contribution to the final outcomes precisely. In an international clinical trial there are many participants, so it would be very difficult to

manage IP if each contributor is granted IP. Thus, it is pragmatic that the participants' IP shall be conferred to the host state.

Developing nations have to buy patented products from developed nations to meet their health needs. However, due to high prices, most patented products are out of reach for developing nations. Furthermore, developing nations are not permitted to produce generic versions of the same technology due to sanctions imposed by the TRIPS Agreement. Therefore, health research brings significant economic benefits to the sponsoring parties from developed countries but fails to bring such economic benefits to the developing nations that host clinical trials (Schroeder and Pogge, 2009, p. 274). Consequently, developing nations face more challenges to fulfil their health needs and their health conditions remain vulnerable. This disparity will continue unless the contributions of both parties to IB research are valued properly. Currently, the contributions of one party are valued highly and the contributions of other party are undervalued. If this continues then health disparities between developed and developing nations will not be reduced or eliminated, rather they are likely to increase further.

I have argued that participants from developing countries bear most of the burdens and risks of international biomedical research. Therefore, the contributions of these participants enable the advance of medical knowledge and the development of new medical interventions. Consequently, participants and communities from developing

countries have the rights to share in the benefit of the research that they have contributed to the IB research. Therefore, the developed nations who sponsor IB research should give some benefits in return not only to the participants but also to the governments of host nations. Therefore, it is a duty and an obligation for the developed nations to provide some benefits to the host nations of the research. Some ethical guidelines have proposed that a successful intervention developed through research should be given back to the study population in various ways. However, without a claim right to a share of the IP, how can developing nation achieve a fair share of the benefits? This led me to conclude that conferral of IP rights to host nations is a better way to overcome the limitations of traditional frameworks, to promote global health rights, and to pave the way to justice in international biomedical research.

Bibliography:

Aellah, G., Chantler.T., & Geiddler, W.P.2016. *Global Health Research in the Unequal World, Ethics case studies from Africa*, Welcome Trust.

Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), being Annex 1C of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations signed in Marrakesh, Morocco on 15 April 1994.available online. http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

Albin, Cecilia.1999. in Berton P., Kimura, H., & Zartman I.W.1999.eds. *International Negotiation: Actors, Structure/ Process, End Values*, New York: Palgrave Macmillan.

Albin, Cecilia. 2001.*Justice and Fairness in International Negotiation*, UK: Cambridge University Press.

Allen, A.2015. *Sweet Little Lies: The Ethics of Placebo use in clinical practice*, PhD. Thesis, Centre for Human Bioethics, Monash University, Australia.

Ang, S.2014. *The Moral Dimensions of Intellectual Property Rights*. Edward Elgar Publishing online at 04/22/2014 via The University of Melbourne.

Angell, M.2004. *The Truth About the Drug Companies, how they deceive us and what to do about it*, New York: Random House.

Annas G.L., & Grodin, M.A.1998. Human rights and maternal-fetal HIV transmission prevention trials in Africa. *American Journal of Public Health*, 88(4) pp.560-3.

Appiah-Poku, J., Newton, S., & Kass, N.2011. Participants' perceptions of research benefits in an African genetic epidemiology study, *Developing World Bioethics*, Vol. 11(3) pp. 128-135.

Australian Government.2003. *Pharmaceutical Patents Review*. IP Australia.
<http://www.ipaustralia.gov.au/understanding-intellectual-property/what-is>

Bader, M. R., & Meadowcroft, J. (Ed.).2011. *The Cambridge Companion to Nozick's Anarchy, State and Utopia*. UK: Cambridge University Press.

Ballantyne, J.A.2006. *Exploitation in HIV/AIDS International Clinical Research*, PhD Thesis, Monash University.

Ballantyne, J.A.2010. How to Do Research Fairly in an Unjust World, *The American Journal of Bioethics*, 10(6), pp. 26-35

Bandewar S.V.S., Kimani J., Lavery J.V .2010. The origins of a research community in the Majengo observational cohort study, Nairobi, Kenya, *BMC Public Health* 10 (630).<http://www.biomedcentral.com/1471-2458/10/630>

Beck, U.1992. *Risk Society: Towards a New Modernity*, CI, Newbury Park, Sage Publication.

Becker, L. C.1977. *Property Rights-Philosophic Foundations*, USA: Rutledge and Kegan Paul.

United States National Commission for the Protection of Human Subjects of Biomedical Behavioral Research. 1978. *The Belmont report : Ethical principles and guidelines for the protection of human subjects of research* (DHEW publication; no. (OS) 78-0012). Bethesda, Md.] : Washington: The Commission ; for sale by the Supt. of Docs., U.S. Govt. Print. Off.

Benatar, S. R.1998. Global Disparities in Health and Human Rights:A Critical

- Commentary, *American Journal of Public Health*, Vol. 88, pp. 295-300.
- Benatar, S. R.2000. Avoiding Exploitation in Clinical Research, *Cambridge Quarterly of Healthcare Ethics*, Vol. 9, pp. 562-565.
- Benatar, S. R.2002.Reflections and recommendations on research ethics in developing countries, *Social Science & Medicine*, Vol. 54, pp. 1131-1141.
- Benatar, S. R.2003. Improving global health: the need to think 'outside the box'!, *Monash Bioethics Review*, Vol.22 (2) pp. S69-S72.
- Benedetti, F.2015. *Placebo effects*, Oxford: Oxford University Press.
- Bhaumik, K. T.2006. *The WTO A Discordant Orchestra*, New Delhi: Sage Publications.
(M382.92B575W2006)
- Bok, S.1978. *Lying:Moral Choice in Public and Private Life*, New York: Pantheon Books.
- Bonilla, M.I.2004. *Understanding Developing Countries' Capacities to Negotiate Effective Trade Agreements: Colombia*, M.Sc. Thesis, Massachusetts Institute of Technology.
- Bottomley, A., & Aaronsons, N.K. 2007. International Perspective on Health-Related Quality-of-Life Research in Cancer Clinical Trials: The European Organisation for Research and Treatment of Cancer Experience, *Journal of Clinical Oncology*, Vol 25, No 32.
- Brighouse, H & Robeyns, I. ed. 2010. *Measuring Justice: Primary Goods and Capabilities*, Cambridge: Cambridge University Press.

Buchanan, A.E.1984. The Right to a Decent Minimum of Health Care, *Philosophy and Public affairs*, Vol 13, pp. 55-78.

Capell, Kerry.2004. Drug makers have a 'Perfect Storm', *Business Week*, October 4, available online.
http://www.businessweek.com/magazine/content/04_40/b3902082_PG2_mz0_54.htm

United Nations.1992. *Convention on Biological Diversity*,
<https://www.cbd.int/doc/legal/cbd-en.pdf/>

Chalmers, I.1995. What Do I Want From Health Research And Researchers? When I Am A Patient? *British Medical Journal*, Vol. 310 (6990) (May 20, 1995) pp. 1315-1318

Chuan,T.V., & Schaefer,O.G.2016. *Research in Resource-Poor Countries*
<http://www.thehastingscenter.org/briefingbook/multinational-research/>

Chudi, I. P.2010. Healthcare problems in developing countries, *Medical Practice and Reviews* Vol. 1(1), pp. 9-11.

Cloninger, C. Robert, MD, PhDa, Luis Salvador-Carulla, MD, PhDb, Laurence J. Kirmayer, MDc, Michael A. Schwartz, MDd, James Appleyard, MD, FRCPCHe, Nick Goodwin, PhDf, JoAnna Groves, MScg, Marc H. M. Hermans, MDh, Juan E. Mezzich, MD, PhDi, C. W. van Staden, MDj, and Salman Rawaf, MD, PhD, FRCP, FFPHk.2014. A Time for Action on Health Inequities: Foundations of the 2014 Geneva Declaration on Person- and People-centered Integrated Health Care for All, *Int J Pers Cent Med.* 4(2): 69–89

Cornwall, A., & Jewkes, R.1995. What is Participatory Research? *Journal of Social Science and Medicine*, Vol. 12 pp. 1667-1676.

Correa, Carlos.2005. "Can TRIPS Agreement foster technology transfer to developing countries? in Maskus,K.E.,& Reichman,J.H.(edited) *International Public Goods and Transfer of Technology: Under a Globalized Intellectual Property Regime*, Cambridge.

Costello, A. & Zumla, A.2000. Moving to research partnerships in developing countries, *British Medical Journal*, Vol. 321 pp. 827-829.

Council for International Organisations of Medical Sciences (CIOMS) (2002).

International Ethical Guidelines for Biomedical Research Involving Human Subjects (Revised in 2002). Geneva: Council for International Organisations of Medical Services. Available on-line

http://www.cioms.ch/guidelines_nov_2002_blurb.htm

Crump,L & Maswood,S.J(edited).2007. *Developing Countries and Global Trade Negotiations*, U.K. Routledge.

Cullet, P.2003. Patents and Medicines: The Relationship between TRIPS and the

Human Rights to Health, In Selgelid, M.J., & Pogge,T. (edited) *Health Rights*,

The International Library of Essays on Rights, UK: Ashgate Publishing Ltd.

Cullet. P. 2003. Patents and Medicines: The Relationship between TRIPS

and the Human Right to Health' *International Affairs*, 79, pp. 139-60.

Council for International Organizations of Medical Sciences (CIOMS).2002.

International Ethical Guidelines for Biomedical Research Involving Human

Subjects (Revised in 2016). Geneva: Council for International

Organisations of Medical Services. Available on-line.

http://www.cioms.ch/guidelines_nov_2002_blurb.htm

Council for International Organizations of Medical Sciences (CIOMS).2016.

International Ethical Guidelines for Biomedical Research Involving Human

Subjects (Revised in 2016). Geneva: Council for International Organisations

of Medical Services.

Declaration of Cordoba.2008. *The Cordoba Declaration on the Right to Food and the Governance of the Global Food and Agricultural Systems*

Davies, M.2017.*Asking the Law Question*, Fourth Edition, Law Book Co,AU.

Daniels, N.2008. *Just Health: Meeting health needs fairly*, Cambridge, UK:
Cambridge University Press.

Daniels, N.1985. *Just Health Care*, Cambridge, UK:
Cambridge University Press.

Dauda, B. Dierickx, K.2012. Health, Human Right, and Health Inequalities:
Alternative Concepts in Placing Health Research as Justice for Global Health,
The American Journal of Bioethics, Vol.12(11), pp.42-44.

Dauda, B. Dierickx, K.2013. Benefit Sharing: an exploration on the contextual
discourse of a changing concept, *BMC Medical Ethics*, Vol. 14:36.

Drahos, P.2001. "BITS and BIPS: bilateralism in intellectual property", *Journal of World Intellectual Property*, 4:791

Drahos, P. 2003. "When the weak bargain with strong: negotiations in the World Trade Organization", *International Negotiation*, 8: pp.79-109

Drahos, P. 2007. "Making and keeping negotiation gains: lessons for the weak from the negotiations over intellectual property rights and access to medicines", in Crump,L., & Maswood,S.J. (edited).2007. *Developing Countries and Global Trade Negotiations*, U.K: Routledge.

Dareke,E., Malik,A., Xu,Y., Kotsioni,I.,Habashy,R., Misra,V.2002.*Good Governance and the World Bank*, Edited by Vivien Collingwood, Nuffield College, University of Oxford.

Dresser, R.2008. The role of patient advocates and public representatives in research, *The Oxford textbook of clinical research ethics*, New York: Oxford University Press.

Dresser, R.2009. First-in-Human Trial Participants: Not a Vulnerable Population, but Vulnerable Nonetheless, *Journal of Law, Medicine & Ethics*, Vo.37, No.1, pp.38-50.

Dresser, R.2012. Alive and Well: The Research Imperative, *Journal of Law, Medicine & Ethics*, Research Ethics, Vol. 40, No.4, pp. 915-21.

Dresser, R.2013. Subversive Subjects: Rule-Breaking and Deception in Clinical Trials, *Journal of Law, Medicine & Ethics*, Vol. 41(4): pp.829-40

Druckman, D. and Wagner, M. L.2016. Justice and Negotiation, *The Annual Review of Psychology*, Vol.67 pp. 387-413.

Edejer, T.T.T.1999. North-South research partnerships: the ethics of carrying out research in developing countries, *BJM*,319: pp.438-441.

- Emanuel, E.J.2008. Benefits to Host Countries, In Emanuel,E.J, Grady,C, Crouch,A,R, Lie,K,R, Miller,G.F, Wendler,D(eds.)*The Oxford Textbook of Clinical Research Ethics*, Oxford, New York, Oxford: University Press.
- Emanuel, E.J., Wendler D, and Grady C.2000. What Makes Clinical Research Ethical? *Journal of American Medical Association*, Vol 283: No 20, pp.2701-2711.
- Emanuel, E.J., Wendler D, Killen J, Grady C.2004. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *Journal of Infectious Diseases*, pp.189: pp.930-7.
- Feinberg, J.1980. *Rights, Justice, and the Bounds of Liberty Essays in Social Philosophy*. New Jersey, USA: Princeton University Press.
- Feinberg, J.1973. *Social Philosophy*, New Jersey: Prentice –Hall.
- Fidler, P. D.2010. Negotiating Equitable Access to Influenza Vaccines: Global Health Diplomacy and the Controversies Surrounding Avian Influenza H5N1, *PLoS Medicine*, Vol. 7(5) pp.1-4.
- Fisher, R. Ury L W. & Patton, B.1981. *Getting to Yes: Negotiating Agreement Without Giving In*, New York/Boston, Houghton Mifflin Company.
- Finniss, D. G., Kaptchuk, T. J., Miller, F., & Benedetti, F. 2010. Biological, clinical, and ethical advances of placebo effects. *Lancet (London, England)*, 375(9715), 686–695. doi:10.1016/S0140-6736(09)61706-2

Fried, B.1995. Wilf Chamberlain Revisited: Nozick's 'Justice in Transfer' and the Problem of Market-Based Distribution, *Philosophy and Public Affairs*, 24, pp.226-245.

Flaherty M. P, Nelson D, Stephens J.2000. The body hunters: overwhelming the watchdogs. *Washington Post*, 18 December. United States of America. A01.

Flaherty M. P, Struck, D.2000. Life by Luck of the Draw. *Washington Post* 22 December. United States of America. A01.

Foreman, L & Kohler, JC.2012. *Access to Medicines As A Human Rights- Implication for Phramacutical Industry Responsibility*, Toronto: University of Toronto Press.

Garrafa, V, Solbakk, H. J., Vidal, S. & Lorenzo, C. 2010. Between the needy and the greedy: the quest for a just and fair ethics of clinical research, *Journal of Medical Ethics*, Vol: 36, pp. 500-504.

Gerhart, P.M. 2000.Reflections: Beyond Compliance Theory-TRIPS as a Sustentative Issue, *Case W.Res. J. International Law*, vol.32, p.358.

Getz,K. 2013. PhRMA Conversations - Clinical Trials Data Sharing and Patient Privacy Balancing the Public Health Benefit of Clinical Trials Data Sharing with Patient Privacy and Continued Innovation 08.27.13 | By John Castellani - See more at: <http://www.phrma.org/catalyst/balancing-public-health-benefit-clinical-trial-data-sharing#sthash.YGsxEhHv.dpuf>

Gibson, J.2009. *Intellectual Property, Medicine and Health Current Debates*, UK:

Ashgate Publishing Ltd.

Glantz,LH, Annas,GJ, Grodin,MA, Mariner,WK.1998. . Research in Developing

Countries: Taking "Benefit" Seriously, *The Hastings Center Report*. 28(6):pp.38-42.

Glickman SW, McHutchison J, et al.2009. Ethical and scientific implications of the

globalization of clinical research, *New England Journal of Medicine*, Vol: 360, pp: 816-23.

Global Alliance for TB Drug Development.2001. Estimating Clinical Development

Costs, *Economics of TB Drug Development*, New York: The Global Alliance for

TB Drug Development. Available online

[http://66.216.124.114/pdf/Economics%20Report%20Full%\(final\).pdf](http://66.216.124.114/pdf/Economics%20Report%20Full%(final).pdf);56-57.

Goodin, E. R., Pettit, P. & Pogge, T. (Eds).2007. *A Companion to*

Contemporary Political Philosophy. Vol. II, Victoria-3053, Australia: Blackwell

Publishing Ltd.

Goodare, H., Savage, R.1995. The rights of patients in research: patients

must come first in research, *British Medical Journal*. 310:1277.

Goozner, M.2004. *The \$800 Million Pill, the truth behind the cost of new drugs*,

Berkley, LA: University of California Press.

Grover, A., Citro, B., Mankad, M. & Lander, F.2012. Pharmaceutical

companies and global lack of access to medicines: strengthening
accountability under the right to health, *Journal of Law, Medicine & Ethics*.

Grover, A.2009. *Promotion and Protection of Human Rights, Civil, Political,
Economic, Social and Cultural Rights, including the right to development: A
report of the Special Rapporteur on the right of everyone to the enjoyment of the
highest attainable standard of physical and mental health*. United Nations,
A/HRC/11/12.

Haddad, M. B.2003. Methods property rights, ecosystem management, and
John Locke's labor theory of ownership, *Ecological Economics* Vol. 46, pp. 19-
31.

Hawkins, J. and Emanuel J.E. (ed.) 2008. *Exploitation and Developing Countries: the
ethics of clinical research*, New Jersey: Princeton University Press.

Hermann, R., Heger-Mahn, D., Mahler, M., Seibert-Grafe, C., Klipping, C.,
Breithaupt-Grogler, K., May de, C.1997. Adverse events and discomfort in
studies on healthy subjects: the volunteer's perspective a survey conducted by
the German Association for Applied Human Pharmacology, *European Journal of
Clinical Pharmacology*, Vol. 53, nos. 3-4: pp. 207-214.

Hirtle, M and Weisbaum, K.2010. Benefit sharing in the field of biomedical

research, focusing on research carried out in countries with emerging or developing economies. Commissioned by the Council of Europe under Contract No DGIII/Bioethics/06/09.

Hollis, A., Pogge, T. 2008. The Health Impact Fund: Making new medicines accessible for all, *Incentives for Global Health*, New Haven.

Holt F, Gillam, S.J, Ngondi, J.M. 2012. Improving Access to Medicines for Neglected Tropical Diseases in Developing Countries: Lessons from Three Emerging Economies. *PLoS Negl Trop Dis* 6(2): e1390.
<https://doi.org/10.1371/journal.pntd.0001390>

Hughes, J. 1989. The Philosophy of Intellectual Property, In May, C. (Ed.). (2010). *The Political Economy of Intellectual Property Rights*. UK: Edward Elgar Publishing, Inc.

HUGO Ethics Committee. 2000. *Statement of Benefit-Sharing*, http://www.hugo-international.org/Resources/Documents/CELS_Statement-BenefitSharing_2000.pdf

Ingram, D. 2009. Of sweatshops and subsistence: Habermas on human rights, *Ethics and Global Politics*, Vol. 2, No. 3, pp. 193-217.

International Health Division. 2016. *Guidelines for International Collaboration/ Research Projects in Health Research*,
<http://icmr.nic.in/guide.htm/visited:29/12/2017>

Jansen, A. L.2009.The ethics of altruism in clinical research, *Hastings*

Center Report.

Jefferies, N.2012. Levelling the playing field? Sharing of Influenza viruses and

access to vaccines and other benefits, *Journal of Law and Medicine*, Vol. 59.

Joint United Nations Programme on HIV/AIDS(UNAIDS).(2000). *Ethical*

Considerations in HIV Preventive Vaccine Research, Geneva, Switzerland:

UNAIDS,[http://data.unaids.org/publications/irc-pub01/jc072-](http://data.unaids.org/publications/irc-pub01/jc072-ethicalcons_en.pdf)

[ethicalcons_en.pdf](http://data.unaids.org/publications/irc-pub01/jc072-ethicalcons_en.pdf)/24/12/2017.

Johnston, J. and Wasunna, A. A.2007. Patents Biomedical Research

and Treatments-Examining Concerns, Canvassing Solutions, *A Hastings Centre Special Report*, 37 (1) S1-S36.

Kamuya, D.M. et al.2014. "When they see us, it's like they have seen the benefits!"

experience of study benefits negotiations in community-based studies on the Kenyan Coast, *BMC Medical Ethics*, 15:90, pp. 1-16.

Khan, M. T.2013. TICFA, Political Economy Of US Bilateralism And Bangladesh,

Countercurrents.org. 27 November 2013. accessed on 23.11.2015.

Kant, I.1787. *A Critique of Pure Reason*, Translated by Friedrich Max Müller. The

Macmillian Company. 1881.

Khor, M.2001. *Rethinking globalization: Critical issues and policy choices* (Global

- issues series (Zed Books)). London; New York: Zed.
- Khor, M.2001. *Globalization Versus Development*. International Political Economy Series. Palgrave.
- Krishnamurthy, M.2013. Political Solidarity, Justice and Public Health, *Public Health Ethics*, Vol. 6, No. 2, pp.129-141.
- Land M.2014. Adjudicating TRIPS for development, in Ghidini, G, Peritz, J.R. Rudolph and Ricolfi, M ed. *TRIPS and Developing Countries Towards a New IP World Order?* Elgar Online at 01/10/2017 via Monash University.
- Lairumbi, D.M. et al.2017. Forms of benefit sharing in global health research undertaken in resource poor setting: a qualitative study of stakeholder's view in Kenya, *Philosophy, ethics, and Humanities in Medicine*, &:7, pp.1-8
- Lansang, A. M. and Dennis, R.2004. Building Capacity in health research in the developing world, *Bulletin of the World Health Organization*, Vol. 82 (10).
- Lau, Chuen-Yen, Wang, Crystal, Orsega, Susan, *Tramont*, Edmund C, Koita, Ousmane, Polis, Michael A, and Siddiqui, Sophia.2014. "International Collaborative Research Partnerships: Blending Science with Management and Diplomacy" *Journal of AIDS Clinical Research*, 2014 December; 5(12)

- Lavery, J.V.2008.The *Obligation to Ensure Access to Beneficial Treatments for Research Participants at the Conclusion of Clinical Trials*, in *The Oxford Text Book of Clinical Research Ethics*, Edited by Emanuel, EJ et al. pp. 697-708.
- Lawson, C. Hocking, B. A.2013. Accessing and benefit sharing avian influenza viruses through the World Health Organisation: a CBD and TRIPS compromise thanks to Indonesia's sovereignty claim? in Pogge, T., Rimmer, M., Rubenstein, K. 9 (Ed.), *Incentives for Global Public Health Patent Law and Access to Essential Medicines*, Cambridge University Press. (2013).
- Leach, B., Paluzzi, E.J, Munderi, P.2005. *Prescription for healthy development: increasing access to medicine*, London: Earthscan.
- Leonard, H, George, J. A, Michael A. Grodin and Wendy K. Mariner in "Research in Developing Countries: Taking "Benefit" Seriously", *Hasting Center Report*, p.39.
- Letterman, G.G.2001. *Basics of International Intellectual Property Law*, NY Transnational Publishers, Inc.
- Lexchin, J.2006. The pharmaceutical industry and the pursuit of profit in Cohen, J., Illingworth, P. and Schuklenk, U. (ed.). (2006) *The Power of Pills social, ethical and legal issues in drug development, marketing, and pricing*, London, Pluto Press.
- Limaye, Dnyanesh, Langer, Janka Marisa, Rühling, Tjorben, Fortwengel, Gerhard

.2015. A critical appraisal of clinical trials conducted and subsequent drug approvals in India and South Africa, *BMJ Open* 2015;5:e007304.
doi:10.1136/bmjopen-2014-007304.

Li, R.2013. PhRMA Conversations - Clinical Trials Data Sharing and Patient Privacy
Balancing the Public Health Benefit of Clinical Trials Data Sharing with Patient Privacy and Continued Innovation 08.27.13 | By John Castellani - See more at:
<http://www.phrma.org/catalyst/balancing-public-health-benefit-clinical-trial-data-sharing#sthash.YGsxEhHv.dpuf>

Lo, B.2009. Clinical Research in Resource Poor Countries, *Ethical Issues in Clinical Research: A practical Guide*,

Locke, J.1976. *Two Treatises of Government & A Letter Concerning Toleration*, ed.by Gough (1976), Oxford, England: Basil Blackwell.

London, J.A.2008. Responsiveness to Host Community Health Needs in Emanuel,J,E, Grady,C, Crouch,A,R, Lie,K,R, Miller,G.F, Wendler,D(eds.) *The Oxford Textbook of Clinical Research Ethics*, Oxford, New York: Oxford University Press.

London, J.A.2005. Justice and the Human Development Approach to International Research. *Hasting Center Report*, 35(1): pp.24-37.

London A.J, Zollman, K.J.S.2010. Research at the Auction Block: problems for the Fair Benefits Approach to International Research, *Hasting Center Report* ;40 (4) pp.34-45.

- Low, N & Gleeson, B.1998. *Justice, Society, and Nature- an exploration of political ecology*, London: Routledge.
- Lucie, Y. 2012. *New Drug Approvals FDA: Year in Review, Food and Drug Administration, USA.*
www.fda.gov/downloads/drugs/scienceresearch/researchareas/oncology/ucm314088.pdf
- Lyons, D.2006. Rights and Recognition, *Social Theory and Practice*, Vol. 32, pp. 1-15.
- Macklin, Ruth.2012. *Ethics in Global Health-Research, Policy and Practice*, U.K., Oxford University Press.
- Macklin, R.2004. *Double Standards in Medical Research in Developing Countries*, New York: Cambridge University Press.
- Martin, R.2013.Rights, *The International Encyclopedia of Ethics*, edited by Hugh LaFollette, Blackwell Publishing Ltd, pp. 4616-4631
- Martin, R., & Reidy, David A. 2006. *Rawls's Law of Peoples: A realistic utopia?* Malden, MA: Blackwell.
- Maskus, K.E.2000.*Intellectual property rights in the global economy*, Washington, D.C.: Institute for International Economics
- Matthew, D.2014. When framing meets law: using human rights as practical

- instrument to facilitate access to medicines in developing countries, in Ghidini, G., Peritz, Rudolph, J.R. & Ricolfi, M. (edited). 2014. *When framing meets law: using human rights as practical instrument to facilitate access to medicines in developing countries* Elgar Online at 01/10/2017 via Monash University
- May, C. (edited.). 2010. *The Political Economy of Intellectual Property Rights*. UK: Edward Elgar Publishing, Inc.
- May, C. 1998. Thinking, Buying, Selling: Intellectual Property Rights in Political Economy. *New Political Economy*, 3(1), pp.59-78.
- Malawi Government. 2002. [Appendix 2: WTO paper, Preparation for the 4th Session of the Ministerial Conference: Communication from Malawi: Issues and Proposals for the Fourth Session of the Ministerial Conference WTO Ministerial Conference: Communication from Malawi Government, Ministry of Commerce and Industry, in General Council October 3, 2001.].
- Malhotra, P. 2010. *Impact of TRIPS in India An Access to Medicines Perspective*, UK: Palgrave Macmillan,
- Mendes, P. 2002. Transfusion Medical Technology Transfer: *Traps to Avoid*, *Transfusion Medicine Reviews* – Vol 16, No 1, pp. 25-33.
- Miller, A., & Davis, M. 2000. *Intellectual Property: Patent, Trademarks and Copyright*. St. Paul, MN: West Publishing.
- Millum, J., & Grady, C. 2013. The ethics of placebo-controlled trials: methodological

- justifications. *Contemporary clinical trials*, 36(2), 510–514.
doi:10.1016/j.cct.2013.09.003
- Millum, J.2010. How should the benefits of Bioprospecting be Shared? *Hastings Center Report*, Vol.40 (1), pp. 24-33.
- Millum, Joseph.2012. Sharing the benefits of research fairly: two approaches, *Journal of Medical Ethics*, Vol. 38 pp. 219-223.
- Moore, D.A.2012. A Lockean Theory of Intellectual Property Revisited, *San Diego L. Rev.* 1069.
- Muula, S A.2007.What Drives Health Research in a Developing Country, *Croatian Medical Journal*, Vol.48 (2), pp. 261-7.
- Muzaka, V.2011. *The Politics of Intellectual Property Rights and Access to Medicines*, USA: Palgrave Macmillan.
- Nash, J.1950. The bargaining problem, *Econometrica*, XVIII (2):pp.155-162.
- National Bioethics Advisory Commission.2001. *Ethical and policy issues in International Research: Clinical Trials in Developing Countries*, Vol. 1, Bethesda, Maryland: National Bioethics Advisory Commission;60.
- Nicol, D.2003. Balancing access to pharmaceuticals with patent rights, *Monash Bioethics Review*, Vol.22 (2) pp. 50-62.
- Nighil, W. L. (Ed.).2009. *Research and Development in the Pharmaceutical*

Industry, New York: Nova Science Publishers Inc.

Nozick, R.1974. *Anarchy, State and Utopia*. Oxford: Blackwell.

Nussbaum, M.2011. *Creating capabilities, The Human Development Approach*,
Harvard University Press.

Page, A.K.2003. Prior Agreements in International Clinical Trials: Ensuring the
Benefits of Research to Developing Countries, *Yale Journal of Health Policy, Law
and Ethics*. 3, Iss.1.

Page, Sheila.2002. *Developing Countries in GATT/WTO Negotiations*, ODI, UK.

Participants of the 2001 Conference on Ethical Aspects of Research in Developing
Countries. 2004. Moral Standards for Research in Developing Countries: From
Reasonable Availability to Fair Benefits. *Hasting Center Report*, 34 (3), pp.17-28.

Participants in the 2001 Conference on Ethical Aspects of Research in Developing
Countries.2002. Fair Benefits for Research in Developing Countries,
Science, Vol. 298, Issue 5601, pp. 2133-2134

Pavone, R. I. 2016. Legal responses to placebo-controlled trials in
developing countries, *Global Bioethics*, 27:2-4, 76-90, DOI:
10.1080/11287462.2016.1192979

Pratt, B., & Loff, B.2011. Justice in the international clinical research, *Developing World
Bioethics*, Vol.11, No. 2, pp 75-81.

Pratt, B., & Loff, B.2013. Linking Research to Global Health Equity: The Contribution of

Product Development Partnerships to Access to Medicines and Research Capacity Building, Government, Law and Public Health Practice. *American Journal of Public Health*, Vol. 103 No. 11 pp. 1968-1978.

Petryna, A.2007. Clinical Trials Offshored: On Private Sector Science and Public Health, *Bio Societies*, Vol. 2, pp. 21-40.

Pham, H.T.2004. Developing Countries and the WTO: The need for more mediation in the DSU, *Harvard Negotiation Law Review*.

Pogge, T.W.2008. "Medicine for the World: Boosting Innovation without Obstructing Free Access", *SUR: Revista internacional de DIREITOS Humanos*, 8, pp.117-40.

Pogge, TW.2002. *World Poverty and Human Rights*, Cambridge, Polity Press.

Pogge, TW.2008. *World Poverty and Human Rights*, 2nd Edition, Cambridge: Polity Press.

Pogge, T., Rimmer, M., Rubenstein, K. 9 (Ed.).2013. *Incentives for Global Public Health Patent Law and Access to Essential Medicines*, Cambridge:Cambridge University Press.

Rahman, M. 1972. Press Conference of Sheik Mujibur Rahman in London,
<https://www.bing.com/videos/search?q=Sheik+Mujib+London+Press+Conference&mkt=en-au&httpsmsn=1&refig=98046f55e98f4504ee2a9c4acc7383b7&sp=-1&pq=sheik+mujib+london+press+conference&sc=0-35&q=s&sk=&cvid=98046f55e98f4504ee2a9c4acc7383b7&ru=%2fsearch%3fq>

%3dSheik%2bMujib%2bLondon%2bPress%2bConference%26form%3dIENTNB
%26mkt%3denau%26httpsmsn%3d1%26refig%3d98046f55e98f4504ee2a9c4ac
c7383b7%26sp%3d-
1%26pq%3dsheik%2bmujib%2blondon%2bpress%2bconference%26sc%3d0-
35%26qs%3dn%26sk%3d%26cvid%3d98046f55e98f4504ee2a9c4acc7383b7&vi
ew=detail&mmscn=vwrc&mid=37184284521590A9276137184284521590A9276
1&FORM=WRVORC

Rawls, J.1971,1992. *A Theory of Justice*, Oxford: Oxford University Press.

Rege, Vinod.1999. Developing Country Participation in Negotiations Leading to the
Adoption of the WTO Agreement on Customs Valuation and Pre-shipment
Inspection: A Public Choice Analysis, *World Competition*,22(1), pp.37-117

Resnik, B.D.2001. Symposium: Drugs for the Developing World Developing
drugs for the developing world: An Economic, Legal, Moral, and Political
Dilemma, *Developing World Bioethics*, Vol.1 (1)

Resnik, D.B.2001. Developing drugs for the developing world: An Economic,
Legal, Moral, and Political Dilemma, *Developing World Bioethics*, Vol.1 (1)

Resnik, D.B.2003. A Pluralistic Account of Intellectual Property, In May, C.2010.
(edited). *The Political Economy of Intellectual Property Rights*.

Resnik, D.2010. Genomic Research Data: Open vs. Restricted Access. *IRB: Ethics &
Human Research*, 32(1), 1-6.

Resnik, D. 2010. Public Trust as a Policy Goal for Research with Human Subjects. *The American Journal of Bioethics*, 10(6), 15-17.

Rai, S.2005. Drug companies cut cost with foreign clinical trials. *New York Times*. 24 February. United States of America.

Reeve, A.2007. Property, in Goodin, E. R., Pettit, P & Pogge, T (eds.) *A companion to Contemporary Political Philosophy*. Vol.II, Victoria: Blackwell Publishing.

Reichman, H. J.2009. Rethinking the role of clinical trial data in international intellectual property law: The case for a public goods approach, *Marquette Intellect Prop Law Rev*. 13(1): 1–68.

Risse, M. 2012. *On Global Justice*, Princeton University Press, US

Risse, M. 2012. *Global Political Philosophy*, Princeton University Press, US

Ruger, J. P.2006. Ethics and governance of global health inequalities, *Journal of Epidemiology and Community Health*, Vol 60, pp. 998-1003.

Ruxin, N Joshua.1994. Magic Bullet: The History of Oral Rehydration Therapy, *Medical History*, Vol.38: pp.363-397.

Schaefer, G. Owen, Emanuel, J. Ezekiel & Wertheimer, Alan.2009. The Obligation to Participate in Biomedical Research, *Journal of American Medical Association*, Vol. 302(1)

Schroeder, D & Lucas, J.C.2013. *Benefit Sharing, From Biodiversity to Human Genetics*

Netherland: Springer.

Schroeder, D.2007. Benefit sharing: it's time for a definition, *Journal of Medical*

Ethics, Vol. 33, pp. 205-209.

Schroeder,D & Diaz,C.L.2006.Sharing the Benefits of Genetic Resources: from

Biodiversity to Human genetics, *Developing World Bioethics*, Vol. 6, Issue, 3, pp.

135-143.

Schroeder, D. & Gefenas, E.2012. Realizing Benefit Sharing-The case of Post-study

Obligations, *Bioethics*, Vol. 26 No. 6, pp. 305-314.

Schroeder, D. Pogge, T.2009. Justice and the Convention on Biological Diversity,

Ethics and International Affairs, Carnegie Council for Ethics in International
Affairs.

Schroeder, D.2007. Benefit sharing: it's time for a definition, *Journal of Medical*

Ethics, Vol. 33, pp. 205-209.

Schroeder, D. and Singer, P.2009. *Prudential Reasons for IP Reform A Report*

(D1.3), for *Innova-P2 HIF*, CAPE, The University of Melbourne.

Schroeder, D. & Singer, P.2011. Symposium on Global Bioethics Access to Life-

Saving Medicines and Intellectual Property Rights: An Ethical Assessment,

Cambridge Quarterly of Healthcare Ethics (2011), 20, pp. 279–289.

- Schroeder, D. & Singer, P.2008. *Intellectual Property Rights Reform Plans A Report for Innova-P2 (D1.1)*, CAPE, The University of Melbourne.
- Schroeder, D., & Lasen,D.C. 2006.Sharing the benefits of genetic resources: from biodiversity to human genetics. *Developing World Bioethics*, Vol.6 issue3 pp.135-143.
- Schuklenk, U & Ashcroft, R.E.2010. Affordable Access to Essential medication in Developing Countries: Conflicts between Ethical and Economic Imperatives, In Selgelid,M.J & Pogge,T edited *Health Rights, The International Library of Essays on Rights*, UK,Ashgate Publishing Ltd.
- Schuklenk, U.2003. Intellectual property rights, compulsory licensing and the TRIPS agreement: Some ethical issues, *Monash Bioethics Review*, Vol.22 (2) pp. S63-S68.
- Schuklenk, U.2000. *Access to Experimental Drugs in Terminal Illness*, New York: Haworth Press.
- Schlosberg, D.2013. Theorising Environmental Justice: The Expanding Sphere of a Discourse, *Environmental Politics*, 22(1), pp. 37-55.
- Schmidtz, D.2011. Bader, M. R., & Meadowcroft, J. (eds.). 2011. *The Cambridge Companion to Nozick's Anarchy, State and Utopia*. UK: Cambridge University Press.
- Schulz-Baldes, A., Vayena, E., & Biller-Andorno, N.2007. Sharing benefits in

- international health research: Research-capacity building as an example of an indirect collective benefit. *EMBO Reports*, 8(1), 8-13
- Scotchmer, Suzanne.1991. Standing on the shoulders of Giants: Cumulative Research and the Patent Law, *The Journal of Economic Perspectives*, Vol 5 (1).
- Sedyaningish, R. E., Isfandari, S., Soendoro, T., and Supari, F. S.2008. Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia, *Annals Academy of Medicine, Singapore*, Vol. 37 (6) pp.482-488.
- Selgelid, M.J.2008. Improving Global Health: Counting Reasons Why, *Developing World Bioethics*, 8, pp. 115-125.
- Selgelid, M.J., & Sepers, M.E.2006. Patents, profits and price of pills: implication for access and availability, In Cohen,C.J., Illingworth,P., Schuklenk, U. (eds.). 2006. *The Power of Pills, Social, ethical and Legal Issues in Drug Development, Marketing and Pricing*,London,UK: Pluto Press.
- Selgelid, M.J.2006. *Ethics and Infectious Disease*, Co-edited with Margaret P. Battin, and Charles B. Smith. Oxford, UK: Blackwell.
- Selgelid, M.J.2006. The Ethics of Dangerous Discovery, *Cambridge Quarterly*

of Healthcare Ethics, Special Section on Bioethics and Armed Conflict Guidelines to Prevent Malevolent Use of Biomedical Research, Vol. 15, No. 4, Fall 2006, pp. 444- 447.

Selgelid, MJ & Pogge, TW .2010.edts. *Health Rights, The International Library of Essays on Rights*, UK:Ashgate Publishing Ltd.

https://medium.com/@MSF_access/there-is-no-such-thing-as-free-vaccines-why-we-re.../2/12/2016.

Sen A. 2006. What Do We Want from a Theory of Justice?. *Journal of Philosophy*. 2006;CIII (5) :Ma

Sen, A.1999,2001. *Development as Freedom*, Oxford: Oxford University Press.

Sen, A.1993. Capability and Well-Being, *The Quality of Life*,
<http://existencia.org/files/alt-eco/quality.pdf>

Shapiro, H.T., Meslin, E.M.2001. Ethical Issues in the Design and Conduct of Clinical Trials in Developing Countries, *New England Journal of Medicine*, 345, pp. 139-142.

Shashikant, S.2009. Intellectual Property Rights and Technology Transfer Issues in the context of climate change, *World Economy and Social Survey*.

Shavers, V., Lynch, C., & Burmeister, L.2000. Knowledge of the Tuskegee study and its impact on the willingness to participate in medical research studies. *Journal of the National Medical Association*, 92(12), 563-72.

Sheremeta L.2003. Population genetic studies: Is there an emerging legal obligation

- to share benefits? *Health Law Review*, Vol. 12 issue:1 pp.36-38
- Simm, K.2007. Benefit-sharing: a look at the history of an ethics concern, *Nature Review Genetics*, Vol 8 (7), P. 496.
- <http://www.nature.com/nrg/journal/v8/n7/full/nrg2145.html>
- Singer,P & Schroeder,D.2008. *Intellectual Property Rights Reform Plans, A Report for Innova P-2,(D 1.1)*, CAPE, The University of Melbourne.
- Singer, P. & Schroeder, D.2009. *Ethical Reasons for Intellectual Property Rights Reform A Report (D1.3)*, for Innova-P2 HIF, CAPE, The University of Melbourne.
- Steinbrook, R.2008. The Gelsinger Case in Emanuel,J,E, Grady,C, Crouch,A,R, Lie,K,R, Miller,G.F, Wendler,D(eds.) *The Oxford Textbook of Clinical Research Ethics*, Oxford, New York: Oxford University Press.
- Stephens J.2000. Where profits and lives hang in balance. *Washington Post* 17 December. United States of America. A01.
- Stuart Rennie, and Bavon Mupenda.2011. The Ethics of Globalizing Bioethics, *Ethics Biol Eng Med.*, Vol. 2(2): 147–156.
- doi:10.1615/EthicsBiologyEngMed.2012004265.
- Stein G. J.1988.International negotiation: A multidisciplinary perspective, *Negotiation Journal*, Volume 4, Issue 3.
- Timmermans,K., & Hutadjulu,T.2000. *The TRIPS Agreements and Pharmaceuticals*, Director General of Drug and Food Control and World Health organization, Indonesia.

The Nuffield Council on Bioethics.2002. *The ethics of research related to healthcare in developing countries*, London: The Nuffield Council on Bioethics Participants

Thompson, J.J.1990. *The Realm of Rights*, MA: Harvard University Press.

Turner, M. 2000. Universities's rift over Aids vaccine defused. *Financial Times*, 23 October.<http://www.aegis.com/news/ads/2000/AD001902.html>

United Nations.1948. *Universal Declaration of Human Rights*, New York: UN

United Nations Educational Scientific Cultural Organization.1997,2000. *The Declaration on Human Genome and Human Rights*,
<http://unesdoc.unesco.org/images/0012/001229/122990eo.pdf>

United Nations Development Programme.2003. Millennium Development Goals: A
Compact Among Nations to End Human Poverty, Human Development Report 2003.

United Nations Department of Economic and Social Affairs: Population Division,
Australian Bureau of Statistics, countrymeters.info/en/Bangladesh, accessed on 13.1.2017).

Venkatapuram, S.2011. *Health justice: An Argument from the Capabilities Approach*, Cambridge: Polity Press.

Varmus, Harold and Satcher, David.1997.Ethical Complexities of Conducting Research in Developing Countries,*New England Journal of Medicine*,Vol.

337, No. 14, pp. 1003-1005.

Waldron, J. 1976. Enough and As Good Left For Others, *Philosophical Quarterly*,
29 (117): pp. 319-328

Watal, J. & Taubman, A. 2015. *The Making of the TRIPS Agreement- personal insight
from Uruguay Round negotiations*, Geneva, World Trade Organization.

Wendler, D., Emanuel, E. J., & Lie, R. K. 2004. The standard of care debate: can
research in developing countries be both ethical and responsive to those
countries' health needs?. *American journal of public health*, 94(6), 923–928.
doi:10.2105/ajph.94.6.923

Wendler, Dave. 2000. Informed Consent, Exploitation and Whether it is Possible to
Conduct Human Subjects Research Without Either One, *Bioethics*, October
2000, Vol. 14 (4), pp. 310-339.

Wertheimer, A. 1996. *Exploitation*. Princeton. New Jersey: Princeton University
Press.

Wellman, C. 1995. *Real Rights*. New York: Oxford University press.

Wenar, L. 2015. Rights, *Stanford Encyclopedia of Philosophy*,
<https://plato.stanford.edu/entries/rights/12/05/2019/>

Wolf, J. 2006. *An Introduction to Political Philosophy*. New York: Oxford University
Press.

Wood, A.J.J., Darbyshire, J. 2006. Perspective, Injury to Research

Volunteers-The Clinical –Research Nightmare, *The New England Journal of Medicine*, Vol.354 (18), pp. 1869-1871.

Wood, E., Hogg, R.S., Montaner, J. S.2005. When to initiate antiretroviral therapy in HIV-1-infected adult: a review for clinicians and patients, *Lancet Infectious Diseases*, 5(7), pp. 407-414.

Wood, E., Hogg, R.S., Yip, B.,Harrigan, P.R., O'Shaughnessy, M.V., Montaner, J. S.2003. Is there a baseline CD4 cell count that precludes a survival response to modern antiretroviral therapy? *AIDS*, 17(5), pp.711-720.

Brepant,K.edited.2017. *WIPO-WTO Colloquium Papers Research papers from the WIPO-WTO Colloquium for Teachers of Intellectual Property Law 2015*, WTO-OMC.

The World Bank.2002. *Human Development*, Washington DC.

World Bank.2017. *What is Governance?*

<http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/MENAEXT/EXTMNAREGTOPGOVERNANCE/0,,contentMDK:20513159~menuPK:1163245~pagePK:34004173~piPK:34003707~theSitePK:497024,00.html>

World Health Organization.2005. *Revision of the International Health Regulation*,23 May. WHA58.3. World Health organization.

World Medical Association. 2013.*Declaration of Helsinki: Ethical principles for Medical*

Research Involving Human Subjects, Adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964, latest revision by the 59th WMA general Assembly, Seoul, South Korea, October/

World Trade Organization (WTO), TRIPS Agreements.

http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm

Yang, L.2012. Drug Development Overview, FDA Basic Research to Clinical Use

(<http://www.fda.gov/downloads/drugs/scienceresearch/researchareas/oncology/ucm314087.pdf> .Available on-line
<http://www.phrma.org/innovation/clinical-trials>

Zartman, I.W., Druckman, D., Jensen, L. Pruitt, G. D. & Peyton, Y.H.1996.

Negotiation as a Search for Justice, *International Negotiation*, 1 pp.79-98.

Zartman, W. I.2002. What I Want to Know about Negotiations, *International Negotiation*, vol. 7, pp. 5–15, Printed in the Netherlands: Kluwer Academic Publishers.

Zartman,W.I & Rubin,J.Z.2001. *Power of Negotiation*, Ann Arbor: University of Michigan. https://www.press.umich.edu/16897/power_and_negotiation

Zion,D., Lynn,G., & Loff,B.2000. The Declaration of Helsinki, CIOMS and the ethics of Research on Vulnerable populations, *Nature Medicine*, Vol. 6, pp. 615-617.

Zong, Z.2008. Should post- trial provision of beneficial experimental interventions be mandatory in developing countries? *Journal of Medical Ethics*, Vol. 34, pp. 188-192.