

Access to Medicines as a Right to Health, and the conflict between Innovators and Generics: with a focus on India as the ‘*pharmacy of the developing world*’

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ABSTRACT (226 words)

Approximately one-third of the world's population does not have access to essential medicines needed to live a healthy and dignified life. As humans we are guaranteed certain human rights, one of which is the right to health. The provision of medicines for all, without discrimination for race, gender, age, geographic location, or socioeconomic status, is a means by which the right to health can be extended to all people. It is the objective of this research paper to research if there are international laws that make access to medicines a condition for the right to the highest attainable standard of health. It is also the goal of this paper to demonstrate that pharmaceutical companies in their development of essential medicines for society, have the responsibility to take the reasonable actions to make these medicines available internationally based on need and not a person's wealth. I hope to analyze the role of India as the 'pharmacy of the developing world', the relationship between its domestic law and international legal obligations (specifically in regards to patents), and how the country as an emerging economy and major player in access to medicines relates to the interests of multinational pharmaceutical companies. Lastly, I would like to conclude with a summary of these findings and my recommendations for how to improve access to medicines for the 2 billion people worldwide without access at this time.

Keywords

Access to medicines; right to health; human rights; essential medicines; pharmaceuticals; social responsibility; pharmaceutical patents; generics; international patent law; Indian patent law

INTRODUCTION

The World Health Organization (WHO) defines drugs and vaccines that must be part of a basic health care system as essential medicines.¹ Essential medicines are used to treat infectious diseases as well as non-communicable diseases. The problem which is known as the access gap or access to medicines, refers to the fact that: one third of the world's population or 2 billion people do not have access to these medicines, and 10 million deaths occur annually from diseases that are treatable by existing medicines.²

The pharmaceutical industry is responsible for the research and development of essential life-saving and/or life-improving medicines. These medicines can be defined as any of the following: active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals, and other related health technologies.³

The current business model of the pharmaceutical industry is based on patent-driven revenue that is designed to help companies recoup the high cost and risk of manufacturing a medicine. Patents are protections that are applied to intellectual property, which gives the innovator exclusive rights and ownership⁴. Estimates for the cost of bringing a new drug to market range from US\$802 million⁴ to US\$1.7 billion⁵, and it is this large investment that a patent generated monopoly is intended cover. As a business, the pharmaceutical industry's modus operandi is not different from other private companies⁵. However, there are noted concerns with this model when it comes to access to medicines.

Firstly, traditional research and development pipelines for medicines have been heavily invested for treatments of the non-communicable diseases of high-income countries (Type I Diseases such as cancer, diabetes, cardiovascular disease).⁶ This focus has led to a shortage of innovative products to address the disease burden in the developing world where neglected diseases are most prominent, accounting for 1 million deaths annually.⁷ Most of these neglected diseases are 100% treatable with medicines that may exist, but are not produced in adequate supply or are not made for appropriate administration in geographical settings different from the developed world. Neglected diseases are defined as diseases that disproportionately affect the poor in rural/low-income countries, and include: leishmaniasis (kal-azar), onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis (bilharzias), lymphatic filariasis, African trypanosomiasis (sleeping sickness) and dengue.³ Human Immunodeficiency Virus/Autoimmune Deficiency Syndrome (HIV/AIDS), Tuberculosis (TB), and malaria have sometimes been classified as neglected diseases, based on the definition, and irrespective of the focus they have garnered.³ The second issue with the pharmaceutical model is that high cost^{4,5} of novel drugs means that patent monopolies, making them unaffordable to populations in low- and middle-income countries.⁵ Thirdly, when medicines are produced which have potential therapeutic benefits in the developing world; they are not properly adapted for these populations.⁸

The current research and development model for medicines plays a large role in why one-third of the world's population, primarily in low- and middle-income countries, have an access to medicines issue.⁸ In addition to this, international trade agreements, such as the World Trade Organization's (WTO) Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS), that are having a profound impact on access to medicines by standardizing minimum intellectual property rights for medicines internationally.^{9,10,11}

India is one of the world's emerging economies, along with Brazil, Russia, China, collectively referred to as BRIC economies.¹² In regards to access to medicines, India has emerged as the leader among the BRIC economies, often being referred to as the 'pharmacy of the developing world'.¹³ India owes its success in regards to access to medicines to a strong generic manufacturing industry that ships two-thirds of their generic drugs to the developing world.¹³ Generic drugs play a significant part in the access to medicines problem, as they are cheaper and bioequivalent replacements to innovator medicines, and are much more affordable for governments and non-governmental organizations to treat populations of the developing world. Generic manufacturing is cheaper than its innovation counterpart, because it is the replication of an existing product and hence does not require the same degree of risky and costly investment into research and development.^{4,5}

It is one of the objectives of this paper to review how India's generic manufacturing capacity is being impacted by international laws such as TRIPS, and if these international laws recognize access to medicines in a right to health framework. In addition, this paper will analyze further the access to medicines issue from the perspective of research-based pharmaceutical companies or 'innovators' and their relationship with India's generic manufacturing industry.

THEORETICAL FRAMEWORK

The Right to Health

The right to health is an international human rights law. This fundamental right has been laid out in several international and domestic instruments over the years. Perhaps the most common statement of the right to health comes from Article 12 of the International Covenant on Economic, Social and Cultural Rights, which states: “*the right of everyone to the enjoyment of the **highest attainable standard** of physical and mental health...*”¹⁴ The right to health can be found incorporated into several other declarations as follows:¹⁵

International Instruments

- WHO Constitution
- Article 25.1 of the Universal Declaration of Human Rights
- Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination (1965)
- Articles 11 and 12 of the Convention on the Elimination of All Forms of Discrimination against Women (1979)
- Article 24 of the Convention on the Rights of the Child (1989)
- Articles 12.1/12.2 of the International Covenant on Economic, Social and Cultural Rights (1966)
- The 1989/11 resolution to the Commission on Human Rights
- The Vienna Declaration
- The International Bill of Rights

Regional Instruments

- Article 11 (revised) of the European Social Charter of 1961
- Article 16 of the African Charter on Human and Peoples’ Rights (1981)
- Article 10 (additional protocol) of American Convention on Human Rights: Economic, Social and Cultural Rights (1988)

International Covenant on Economic, Social and Cultural Rights

For the purpose of the ‘access to medicines’ issue, the International Covenant on Economic, Social and Cultural Rights (ICESCR),¹⁴ perhaps provides the most comprehensive coverage. One hundred & thirty-two States as of 1995, including Canada, India, Switzerland, Brazil, Russia, and the United States of America, have ratified the Covenant. Article 12.1 of the Covenant defines the right to health from an *availability* and *accessibility* framework. In regards to ‘availability’, the Covenant lays out the responsibility of the State to provide essential drugs as defined by the WHO Model Lists of Essential Medicines. Also, a State has the international obligation to “...facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary aid when required”. The ‘affordability’ or economic accessibility section of the Covenant stresses that health services, whether privately or publicly owned, be made affordable for all including disadvantaged populations. Therefore, it is the State’s obligation to ensure that their population has the financial means to access such goods as medicines.

Section 12.2 provides guidance on the specific actions that States are obligated to take on.

Specifically, Article 12.2 (d), *the right to health facilities, goods and services*, states “The creation of conditions which would assure to all medical service and medical attention in the event of sickness”. Article 12 also includes information on a State’s obligation to provide equal health care and services; a denial of which could be considered non-overt discrimination based on wealth. Therefore, the state should not favour expensive health services that benefit a few privileged, over reasonably priced medicines and preventative medicine that improves public health broadly.

The obligations on a state to provide their people with the right to health falls into three categories: respect, protect, and fulfill. The obligation to *respect* means that a State should not interfere with a person’s enjoyment of their right to health, including the denial of health services to marginalized populations (i.e. prisoners, illegal immigrants, minorities), the marketing of unsafe medicines, or the restricting of contraceptive practices. The obligation to *protect* has strong implications to the access to medicines issue, as it outlines that a State must protect the guarantees made under article 12 by preventing third party interference. A state has the responsibility to oversee and keep in check the marketing practices of medicines by third parties, such as the pharmaceutical industry. The obligation to *fulfill* holds the State responsible for implementing legislature and policies that allow their population to realize the right to health.

In regards to ensuring access to medicines, a State can be found in violation to the above obligations, if:

- *Respect*—ignorance of State laws when entering bilateral or multilateral agreements with other parties (States, international organizations, multinational corporations),
- *Protect*—fail to regulate the actions of other parties who may infringe on the right to health of their population (i.e. “failure to protect consumers and workers from practices detrimental to health...e.g. manufactures of medicines”)
- *Fulfill*—failure to implement national policies that ensure the right to health for all, particularly marginalized populations

Constitution of the World Health Organization

The 1946 Constitution¹⁶ of the World Health Organization (WHO) defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition”. The Constitution also makes some important statements for the access to medicines issue, including: “The achievement of any State in the promotion and protection of health is of value to all...Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures”.

India’s Constitutional Law

The Indian Constitution (1950) declares that: “The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties...”. In stating this, Part IV article 47 of Indian constitutional law solidifies the responsibility of the Indian Government to prioritize population health.¹⁷

As Grover and Citro (2011) state “The right to health is a fundamental right in India,

judicially recognised under article 21 of the Constitution”.¹⁸ Article 21 of the Indian Constitution, ‘Protection of life and personal liberty’ states: “No person shall be deprived of his life or personal liberty except according to procedure established by law.”¹⁷

Universal Declaration of Human Rights

The Universal Declaration of Human Rights established in 1948, discusses health in only one of its sections. Article 25 is as follows¹⁹:

- (1) 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.
- (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Along with the other human rights provisions outlined by the Declaration, the guarantees of the right to health dictated in Article 25 are expected to be observed by all 193 United Nations Member States.

LITERATURE REVIEW

Following the initiation of the literature search in the UBC library database, the number of hits returned was 30,364. The articles were ordered sequentially based on relevance to the search term. Upon reviewing the first 20 articles, it was evident that there was a wealth of information on the topic. For the sake of time, the first 20 most relevant articles were reviewed for inclusion in this review. Article’s reference lists were reviewed to identify additional resources pertinent to the area of interest. In total, 15 pieces of literature were included in this review (14 primary sources and 1 secondary source). The identified literature has been categorized based on the titles found below.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration

The World Trade Organization (WTO) established the Trade Related Intellectual Property Rights (TRIPS) agreement in 1994 (enforced starting in 1995) to establish minimum standards for all WTO Member State Intellectual Property regulations. These minimum standards are flexible in that it is within the State’s discretion to enhance intellectual property if they see fit. Today the TRIPS Agreement is the most comprehensive multilateral agreement on intellectual property.^{20,21}

The TRIPS have large implications for the pharmaceutical industry and access to medicines, stemming particularly from Articles 27-38, which have provisions for patent protection. Article 27.1 perhaps being the most applicable for access to medicines: “The TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal

tests of novelty, inventiveness and industrial applicability. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced”.²¹

Before TRIPS, approximately 40 countries had no patent protection for pharmaceutical products. Some of the major changes that TRIPS enforces are a minimum of 20-year patent protection on innovations such as pharmaceutical products or processes to develop these products. This 20 year minimum patent is a drastic change from the 5-7 year patents that were common ground in many developing countries, but not vastly different from the 15-17 year patents in developed countries.²¹ In addition, TRIPS extends patent protection for inventions that include products and the processes for the invention of products; before TRIPS many countries, including India, provided patents only for products and not processes.²¹ The difference in patent protection is a matter of development, as developed countries and inventors traditionally favour end-product patents, while developing countries are more likely to enforce process patents. The legislations providing process patents only, allowed these developed countries to reverse engineer medicines and identify cheaper methods to manufacture generic versions of patented medicines. “Thus, India’s former patent regime favored domestic generic manufacturers who had been able to produce drugs for a fraction of the prices in the United States and Europe”.²² To provide developing companies with sufficient time to adjust their intellectual property regulations, the WTO provided transitional periods to the year 2000.²²

Another provision TRIPS instilled was data exclusivity, whereby a pharmaceutical company could prohibit the test data (safety, quality and efficacy) they had submitted for regulatory approval to be shared with others, including other states. Data exclusivity has a large impact on public health as it delays the efficiency by which affordable generic products can be brought to the market. Before TRIPS, generic manufacturers only had to prove their product was bioequivalent to the innovator’s product, and could then use the innovator’s test data to seek approval to market the generic product.²¹

The WTO has noted that while TRIPS has been implemented to standardize intellectual property rights worldwide and protect the property of pharmaceutical research and development, it has the ability to have negative effects on the accessibility to medicines. The Doha Ministerial Declaration on Public Health (henceforth referred to as the ‘Doha Declaration’) sought to minimize the ability of patents to reduce access to medicines. The Doha Declaration provides ‘TRIPS flexibilities’ that allow countries to uphold minimum standards of the TRIPS and take precautionary measures to ensure public health is protected. Some of these flexibilities include the ability²³:

- to oppose or revoke patents on medicines (e.g. medicines that do not demonstrate innovation or significantly increased efficacy),
- to apply for compulsory licensing (allows a developing country government to manufacture medicines that are currently on patent without the permission of the patent holder, paying the innovator royalties, and ensuring the generic products are sold to UN declared least-developed countries and others with per capita incomes below US\$745 per year),
- and for certain developing countries, to receive an extended transition period of 5 years beyond 2005 to implement TRIPS intellectual property rights domestically.

India was provided with an extended transition period until 1 January 2005 to bring its intellectual property rights in line with TRIPS. “India took advantage of such a transition period in order to develop an intellectual property law that facilitates robust competition amongst drug manufacturers. This is particularly significant as India has been and continues to be a leading provider of generic medicines to the developing world.”²³ The Patents (Amendment) Act 2005 (henceforth referred to as ‘Amendment Act 2005’), while making India TRIPS compliant sought to safeguard public health with certain provisions. Section 3(d) of the Amendment Act 2005 states: “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant”.²⁴

Section 3(d) is an attempt by the Indian government to protect public health in the face of patent holder attempts to ‘evergreen’ or extend patent protection on products based on minor alterations to the product that does not significantly increase efficacy.²² Using this mechanism, the Indian Government has been involved in several cases of litigation from the pharmaceutical companies seeking patents. In addition, “The governments of developed nations, under pressure from multinational drug companies, are employing new ways to thwart competition from generic drugs. The European Union and India free-trade agreement seeks to introduce TRIPS-plus¹² and other measures, such as patent term-extensions, data exclusivity, increased border and enforcement measures, and investment- protection agreements, all of which would impede generic competition.”¹⁸

Resolution 2002/32: Access to medication in the context of pandemics such as HIV/AIDS

The Commission on Human Rights resolution was generated in 2002²⁵, following news from UNAIDS that the HIV/AIDS pandemic killed 3 million people in 2001, and at the end of this year the number of infected was 40 million. The resolution recognized the need to promote treatment and access to medication for opportunistic infections of TB and malaria, and welcomed the work of the Secretary-General and other UN agencies to expand HIV/AIDS drug access in developing countries. However, the resolution stated that more needs to be done in regards to access to medicines, and welcomed the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria, as a public-private partnership capable of supporting programs for prevention, treatment, care and support internationally.

The resolution emphasized that within the context of a pandemic (as is the case with HIV/AIDS) to *progressively achieve the full realization* of the right of everyone to the enjoyment of the highest attainable standard of health, access to medicines *is* a fundamental element.

The resolution also stated that to ensure universal respect for human rights and fundamental freedoms States must follow relevant international law and agreements to:

1. Attain sufficient pharmaceutical supplies to treat pandemics and associated diseases;
2. Make available to at an affordable price, these pharmaceuticals, to vulnerable populations, who may be socially disadvantaged;
3. Avoid limiting equal access to treatment for all;

4. Adopt additional measures, in accordance with applicable international precedents, that “safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties”;
5. Strengthen their health care system to provide appropriate care for their populations;

The resolution called upon international States to:

1. Assist other countries access essential treatments to treat pandemics and associated diseases;
2. Ensure actions “take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies”.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health, which was implemented in 2001, and signed by all WTO member states, was welcomed by the resolution. The resolution re-emphasized the need for WTO members to adhere to the TRIPS Agreement and to:

- Understand that public health issues for developing countries are unique and severe in relation to HIV/AIDS, TB, malaria and other epidemics;
- Use TRIPS to address these public health problems;
- Recognize the importance of intellectual property (IP) for pharmaceutical companies to develop new and effective drugs, but also the effects of IP on drug pricing;
- “Agree that the TRIPS Agreement does not and should not prevent World Trade Organization members from taking measures to protect public health; accordingly, while reiterating their commitment to the TRIPS Agreement, they affirmed that the Agreement can and should be interpreted and implemented in a manner supportive of members’ right to protect public health and, in particular, to promote access to medicines for all; in this connection, they reaffirmed the right of members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

Special Rapporteur on the Right to the Health

Since 2002, the Human Rights Council from the UN Office of the High Commissioner for Human Rights has appointed two Special Rapporteurs on the right to the highest attainable standard of health. Mr. Paul Hunt (New Zealand) served as the Special Rapporteur from August 2002-July 2008. Mr. Anand Grover (India) has been the Special Rapporteur since August 2008. The mandate of the Special Rapporteur on the right to health was established by the Commission on Human Rights in April 2002 by resolution 2002/31, and was endorsed and extended by the Human Rights Council on December 14, 2007 in resolution 6/29.²⁷

The Human Rights Council sought the appointment of a Special Rapporteur to investigate the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as outlined by the following²⁷:

- Article 25 (1) of the Universal Declaration of Human Rights (UDHR) ;

- Article 12 of the the International Covenant on Economic, Social and Cultural Rights (ICESCR) ;
- Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination (ICERD)
- Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW); and
- Article 24 of the Convention on the Rights of the Child (CRC).

The mandate of the Special Rapporteur is:^{26,27}

1. Identify relevant right to health information from various sources;
2. Engage in dialogue and identify potential partnerships with relevant stakeholders including Government, UN bodies, specialized agencies, especially the WHO, the Joint United Nations Programme on HIV/AIDS, non-governmental organizations (NGOs), and international financial institutions;
3. Report on the progress of right to health projects worldwide (laws, policies, good practices, barriers);
4. Provide recommendations to improve and protect the right to health

Resolution 6/29 of the Human Rights Council states that the Council recognizes “...the need for States, in cooperation with international organizations and civil society, including non-governmental organizations and the private sector, to create favourable conditions at the national, regional and international levels to ensure the full and effective enjoyment of the right of everyone to the highest attainable standard of physical and mental health”.²⁸ Pursuant to resolution 6/29 the Human Rights Council requests that the Special Rapporteur also pay particular attention to: analyzing the issue of neglected diseases and diseases disproportionately affecting developing countries, the importance of gender perspective and the needs of children and other vulnerable and marginalized populations throughout her/his work.²⁸

Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines

Paul Hunt is a human rights lawyer and Professor of Law the University of Essex, United Kingdom. From 1999-2002, Prof. Hunt was assigned as the UN Special Rapporteur on the right to the highest attainable standard of health. His mandate was established by resolution 2002/31 of the Human Rights Council, which is outlined prior.²⁶

One of Prof. Hunt’s major works was the drafting of the ‘*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*’²⁹ (henceforth referred to as the *Guidelines*). The 47 guidelines are based on Universal Declaration of Human Rights, and with the help of extensive research and consultation with pharmaceutical companies.³⁰ Access to essential medicines is failing approximately 2 billion people, leading to the deaths of 10 million people each year (4 million from Africa and South-East Asia). Goal 8 of the Millennium Development Goals (MDG) is “in cooperation with pharmaceutical companies, (to) provide access to affordable essential drugs in developing countries”.³¹ Prof. Hunt states that medical care and access to medicines are in fact essential components of the right to the highest attainable standard of health. The crux of his report, is that while States have human rights responsibilities, “Pharmaceutical companies, including innovator, generic and biotechnology companies, have

human rights responsibilities in relation to access to medicines”. While Prof. Hunt emphasizes the most important role of a pharmaceutical company from a social responsibility perspective is the enhancement of access to their medicines internationally to those who need them most.²⁹

In regards to management, monitoring and evaluation, Prof. Hunt suggests that companies develop a detailed policy on access to medicines; one of which should be made available, a report on performance published, and monitoring to be held accountable. In addition, the Guidelines discuss the importance of developing medicines and the importance of pharmaceutical companies being committed to engaging in research and development for neglected diseases that disproportionately infect the poorest of the poor.²⁹

However, Professor Hunt concedes: “Pharmaceutical companies also have other responsibilities, for example, a responsibility to enhance shareholder value.” He goes on to state “companies also have a human rights responsibility to extend access to medicines for all, including disadvantaged individuals, communities, and populations”. A pharmaceutical company has methods at their disposal to allow access to medicines and business interests to be maintained. Prof. Hunt provides right to health considerations and guidelines for pharmaceutical companies when it comes to licenses, and patents, and pricing options:²⁹

- Respect a State’s right to fulfill the provisions of the TRIPS and the flexibilities designed within the Doha Declaration on the TRIPS Agreement and Public Health (2001/2003) that allow a State to protect public health through the promotion of access to medicines
- Pharmaceutical companies should waive test data exclusivity for all low-income countries and for middle-income countries in the case of this forces these countries to run their own clinical trials before manufacturing a medicine, a feat that is often impossible due to the countries capacity, and if it is possible delays the availability of essential medicines.
- Companies should not apply for patents of trivial or insignificant alterations to existing medicines, in developing countries.
- Companies should develop policy that makes their medicines accessible to individuals irrespective of wealth and social status, by using tiered pricing between and within countries, voluntary licenses (for commercial sale and for use by not-for-profit organizations), donations, and Public Private Partnerships.

Are drug companies adhering to their human rights responsibilities?

In a perspective paper written by Hunt and Khosla (2010),³⁰ the authors assess if pharmaceutical companies are living up to their right to health responsibilities as outlined in Prof. Hunt’s *Guidelines*²⁹ discussed prior. The article reiterates Prof. Hunt’s *Guidelines* and explicitly states “the right-to-health responsibility is to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need, within a viable business model...If the patent is worked without these steps being taken, the patent holder is in breach of its right-to-health responsibilities”³⁰. The article finds that many pharmaceutical companies are making efforts to improve access to their medicines. The Access to Medicine Index, which ranks the access to medicines efforts (public policy influence and advocacy, pricing, patents and licensing and donation programs) of the top 20 pharmaceutical companies, demonstrates that

certain companies are making efforts to improve their access to medicines policies³². Table 1 indicates the overall ranking of companies in 2008, 2010, and 2012.

Table 1. The ranking of the top pharmaceutical companies in regards to access to medicine efforts in 2008, 2010, 2012 (adapted from Access to Medicine Index 2012)³²

| Pharmaceutical Company | Overall Access to Medicine Index Ranking | | |
|-------------------------------|--|-----------------------|-----------------------|
| | 2008 | 2010 | 2012 |
| GSK | 1 | 1 | 1 |
| Novo Nordisk | 2 | 8 | 6 |
| Merck & Co. | 3 | 2 | 4 |
| Novartis AG | 4 | 3 | 7 |
| Sanofi | 5 | 5 | 3 |
| Astrazeneca | 6 | 7 | 16 |
| Roche Holdings Ltd. | 7 | 6 | 10 |
| Johnson & Johnson | 8 | 9 | 2 |
| Bayer AG | 9 | 14 | 9 |
| Eli Lilly & Co. | 10 | 13 | 14 |
| Bristol-Myers Squibb | 11 | 15 | 12 |
| Abbott Laboratories Inc. | 12 | 10 | 13 |
| Merck KGaA | 13 | 17 | 8 |
| Cipla Limited | 14 | <i>Fell out of 20</i> | <i>Fell out of 20</i> |
| Gilead Sciences Inc. | 15 | 4 | 5 |
| Ranbaxy Laboratories Ltd. | 16 | <i>Fell out of 20</i> | <i>Fell out of 20</i> |
| Pfizer Inc. | 17 | 11 | 11 |
| Wyeth | 18 | <i>Fell out of 20</i> | <i>Fell out of 20</i> |
| Teva Pharmaceutical Ind. Ltd. | 19 | <i>Fell out of 20</i> | <i>Fell out of 20</i> |
| Schering-Plough Corp. | 20 | <i>Fell out of 20</i> | <i>Fell out of 20</i> |
| Boehringer-Ingelheim | <i>Not in top 20</i> | 12 | 17 |
| Eisai Co. Ltd. | <i>Not in top 20</i> | 16 | 15 |
| Takeda Pharmaceutical Co. | <i>Not in top 20</i> | 18 | 18 |
| Astellas Pharma Inc. | <i>Not in top 20</i> | 19 | 20 |
| Daiichi Sankyo Co. Ltd. | <i>Not in top 20</i> | 20 | 19 |

As the Access to Medicines Index reports from 2008, 2010, and 2012 indicate, GSK is at the top. However, the reports show that the margin between the number one spot and those behind GSK is shrinking over the 3 years that the report was conducted. The 2012 report states that pharmaceutical industry as a whole is improving progressively, and “is doing more to improve access to medicine than it was doing in 2010”³². In 2012 compared to 2010, 17 of 20 pharmaceutical companies had their score increase. Some of the major advances noted by the 2012 report include the development of HIV and malaria diagnostics that are simpler and more affordable. Laboratory based diagnostic technology for TB has been dramatically improved. Increases in innovative research and partnerships with other organizations (biotechnology companies, academia, etc.), have lead to the adaptation of medicines for specific populations, such as: child formulation for Chagas disease, a new meningitis vaccine designed for a specific strain that affects Africa, and a fixed-dose combination malaria drug. In addition, the report found that up to 20% of the drug development pipeline for some companies is devoted to diseases of the developing world, meaning that there is an increasing effort to produce medicines for these populations.³²

The Access to Medicines Index 2012 also looks at the issue from the context of the pharmaceutical industry. Two circumstances had major implications for the pharmaceutical

industry in 2012: (1) an unstable economic environment, (2) the expiration of patents on key products was prominent this year (fewer patents mean reduced monopoly-driven revenue). Some of the challenges outlined by the 2012 report that have been obstacles for the pharmaceutical industry include:³²

- Developing innovative drugs in a market that has become increasingly competitive
- Changes to regulatory, pricing and government reimbursement policies
- The emergence of generic manufacturers as innovators and not simply replicators, and the threat this poses on commercial return

In light of these challenges, the pharmaceutical industry has looked at different business models to remain competitive.

While Europe and the US were once the major sites for research, manufacturing and sales of medicines, the pharmaceutical industry has begun to shift these tasks to Asia and South America, where emerging markets are keen to invest. They have also set their sights on “the so-called ‘pharmerging’ markets - e.g. Brazil, Russia, India, China, Russia, Mexico and Turkey - are also major new sources of sales revenue, with a fore-casted growth of approximately 14% by 2014, which compares with an estimated growth of less than 10% over the same period for the global pharmaceutical market.”³²

There has been a refocus on the development of medicines for rare diseases, as the pharmaceutical industry feels the need to innovate and branch out the types of medicines they produce. The success of many pharmaceutical companies was once based on the focused development of ‘blockbuster drugs’, which were drugs that generated more than US\$1 billion in revenue globally each year.³³ With a shrinking number of viable drug candidates in the pharmaceutical industry pipeline, a shift to rare diseases with few drugs, old and ineffective drugs, or no treatments at all, is a logical next step.³²

Patient ‘crowdsourcing’ refers to companies efforts to involve patient groups in their decision making process. These efforts have benefits for the pharmaceutical company as it provides insights into how diseases effect people, how treatments can improve symptoms, and how treatments can be adapted into formulations that are more easily administered.

Pharmaceutical companies have also begun to increase their business partnerships and reduce ownership. Some examples of these collaborative efforts are: Public-Private Partnerships such as those between pharmaceutical companies and academia, and Private-Private Partnerships such as those between pharmaceutical companies and biotechnology firms or other pharmaceutical companies. These collaborations allow the pharmaceutical industry to broaden their scope, in regards to emerging biological research, and access to new drug candidates without directly investing in research and development themselves.

The pharmaceutical industry has also looked at reorganizing the way they conduct research and development, by operating more like biotechnology firms. Some companies have implemented programs where teams of researchers are formed to focus on a specific project, and then these teams submit business proposals to compete for limited funding.

Pharmaceutical companies are also looking at emerging business markets, and beginning to purchase generic manufacturers in these regions. Companies are also implementing access to medicine strategies into their operating procedures.³²

The Access to Medicine Report provides compelling evidence that the pharmaceutical industry is changing. The new modes of operation, business partnerships, and the emerging markets provide great opportunities for the industry to increase their commercial revenue in the face of shaky U.S. and European economies.

GSK Report

In Prof. Hunt's role as the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of health he visited with senior management of GlaxoSmithKline (GSK).³⁴ GSK is a British research-based pharmaceutical company with a market cap of US\$137.7 billion as of 31 December 2011.³² Prof. Hunt created a report based on his meetings with GSK (henceforth referred to as the *GSK Report*),³⁴ in which he discussed the right to health responsibilities of patent-holding or big pharmaceutical companies (*henceforth referred to as innovators*).

A member of the senior management of an innovator pharmaceutical company recently remarked to the Special Rapporteur that the company's patents were "its crown jewels". The image was revealing. In one sense, the image is legitimate - patents are immensely valuable. In another sense, the image reflects a profound misunderstanding of the role of a company that develops a life-saving medicine. As discussed in chapter II, such a company has performed a critically important social, medical, public health and right-to-health function. While the company's "reward" is the grant of a limited monopoly over the medicine, enabling it to enhance shareholder value and invest in further research and development, the company also has a right-to-health responsibility to take all reasonable steps to make the life-saving medicine as accessible as possible, as soon as possible, to all those in need. For a limited period, the company holds the patent for society - but the patent must be worked, so far as possible, for the benefit of all those who need it.

The status of innovator companies would be immeasurably enhanced if they did not see, and treat, patents as their "crown jewels". Companies must grasp, and publicly recognize, their critically important social function and right-to-health responsibilities. They must demonstrably do everything possible, within a viable business model, to fulfill their social function and human rights responsibilities. Presently, this is not happening. If it were to happen, it would not only greatly enhance companies' status but also pressurize States, generic manufacturers and others to provide the environment that companies need if they are to enter into arrangements, such as commercial voluntary licences, that enhance access to medicines for all."³⁴

The *GSK Report* discussed that pharmaceutical companies are not adversaries but are partners in the progressive reality of the right to health. The report noted that GSK is committed to adhering to the Universal Declaration of Human Rights, as outlined by the following company statement: "As a marketer of pharmaceutical products with life saving and enhancing properties, we will strive to make them as widely available as possible while running our business in a sustainable way".³⁴ The *GSK Report* applauded GSK's recognition as a contributor to the attainment of the highest standard of health, however it noted gross shortcomings with regard to accountability and oversight of its right to health functions. The report stresses the importance and lack of external validation of the company's Corporate Responsibility Reports, a process that other patent-holding pharmaceutical companies should follow. It also recommended that oversight of innovator's access to medicines and right to health mandates be standardized. The report suggested that GSK work with similar companies to develop an accountability mechanism that oversees the industry, such as an independent Ombudsman.³⁴

Consultation on access to medicines and the right to health

Under resolution 12/24 adopted by the Human Rights Council, Mr. Anand Grover, Special Rapporteur on the right to health conducted expert consultation with Governments, pharmaceutical companies, and international civil society organizations, “for an exchange of views on human rights considerations relating to the realization of access to medicines as one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”³⁵. The last of the consultations were due in October 2012, and Mr. Grover is tasked with summarizing the findings for presentation at the 23rd session of the Human Rights Council in June 2013.³⁵

METHODOLOGY

The literature review was conducted in a systematic manner with a specific focus in mind. The search phrase: “access to medicines and right to health” was entered into UBC Library Database to generate hits of relevant articles. The articles were automatically ordered by the system based on relevance. Due to time constraints the first 20 articles were reviewed for relevance to the specific objectives of this paper, which were international law considerations for access to medicines as a right to health, and the identification of the interplay between the right to health, multinational pharmaceutical company practice, and access to medicines. The reference lists of selected article were reviewed in detail to find additional articles and background information on international and domestic laws and secondary sources of information.

The literature review does not provide a significant amount of information on India’s role in access to medicines, as my intention was to first identify the degree to which access to medicines was recognized as a right to health internationally and within India. Following the elucidation of this, I planned to analyze the relationship between the multinational pharmaceutical industry and Indian generic manufacturing, and to comment on whether or not certain practices violate the right to health from a human rights perspective.

DISCUSSION

The concept of the universal right to the highest attainable standard of health is a topic that society will be engaged in for the remainder of our existence. As long as there is disease and ill-health, society will question if the powers that be are taking adequate measures to allow us to experience the full attainment of health. However, there are nuances in the human right to health that is afforded to us through the international instruments, some of which were discussed in previously in the Theoretical Framework. It is worth briefly revisiting here. Article 12 of the International Covenant on Economic, Social and Cultural Rights obligates State’s to ‘respect, protect, and fulfill’ the right to health of their populations, including making available, accessible and of acceptable quality the services and goods necessary to achieve this health.¹⁴

Firstly, the right to health does not mean ‘the right to be healthy’. This is not to say that Article 12 does not acknowledge that we as humans have a right to health care and conditions that provide us with tools to live healthy lives; in fact “the entitlements include the right to a

system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health".¹⁴⁻¹⁵ Article 12 simply states that there are limitations on the attainment of health that "cannot be addressed solely within the relationship between States and individuals...genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health"¹⁴. The second nuance deals with the notion of progressive realization for the right to health. Progressive realization, means that a State's obligation to provide conditions that allow for the highest attainable standard of health is an ongoing process, and that States have an "obligation to move as expeditiously and effectively as possible towards the full realization of article 12".¹⁴⁻¹⁵ Now, the question remains can access to medicines be considered a right to health?

It is my belief that one can reasonably conclude that access to essential medicines is an issue that all members of society are entitled to under Article 12. If one questions whether access to medicines is a right to health topic, they do not need to look much further than (to name just a few) the Human Rights Council's resolutions on access to medicines and the right to health, the appointment of Prof. Hunt and Mr. Grover as Special Rapporteur on the right to health and the extensive reports and consultations they have engaged in, the Doha Declaration, and the countless non-governmental agencies that have been devoted to this specific issue. The question is not of whether access to medicines is a right to health issue internationally, but rather what needs to be done internationally to remove the barriers impeding the poorest and sickest people from accessing the medicines that will provide them with dignity and the ability to live, even if this is not the highest standard of physical and mental health.

I believe, that a major step to achieving the right to health for all begins by looking at the access to medicines issue in India. Between 1972 and 2005, India's was provided to the freedom to manufacture generic drugs without the patent protection that is increasingly demanded for by innovator companies today. Unlike most other low to middle income countries, this freedom has allowed India to provide first-line antiretroviral therapy at no cost to the 340,000 HIV positive people within the country.¹⁸ India's commitment to access to medicines for the right to health does not end domestically. India has been called the 'pharmacy of the developing world' because of its essential role in providing accessibility to life-saving medications to those in the developing world who would otherwise go untreated and likely die. India manufactures and sells more than half of all HIV patients in developing countries, at a price that is 5% of what is charged by the innovator pharmaceutical companies of the U.S. and Europe.³⁶ Donor funded programs in the developing world purchase 89% of their adult antiretroviral medications from India. Generally speaking, two-thirds of India's generic medicines are exported at an affordable cost for use in the developing world.³⁷

Given India's strong history of providing life saving medications to the developing world, today one third of the world or a staggering 2 billion people do not have access to essential medicines.¹⁸⁻²³⁻²⁹⁻³² Imagine the situation, if India's ability to supply these essential medicines to the developing world is inhibited? India's ability to continue its role as the pharmacy of the developing world has been threatened by multinational pharmaceutical companies, and in certain bilateral and multilateral agreements between States.

In *Novartis AG v. Union of India* (2007)³⁸ the Swiss pharmaceutical company Novartis challenged the Indian government's decision to reject their patent application for the cancer drug Glivec. India denied Novartis' patent application on the grounds outlined in Section 3(d) of their 2005 Patent Amendment Act, stating that the drug was not significantly more efficacious than its predecessor. The case was heard by the High Court of Madras, and was the first high profile case by a pharmaceutical company challenging India's new patent laws following their alignment with TRIPS.²²

In 2006, India provided their first patent under TRIPS regulations to Roche Holdings Ltd. for pegylated interferon alfa2a; a treatment for chronic Hepatitis C Viral (HCV) infection. The six-month course of treatment costs approximately US\$8,752. In a country where, 34.7% earn less than US\$1 per day, and 77% of the population working in a sector with an average salary of \$0.5 per day, the ability to purchase this medicine for the 10-12 million HCV positive patients in India would likely be impossible.³⁹ The patent was initially challenged by a patient group in 2009 and turned down, before the Intellectual Property Appellate Board (IPAB) decided to revoke this patent in November of 2012. This was a landmark case as it set the precedent allowing patient groups to challenge the validity of patents. During the appeal, Roche challenged the patient group, stating that they had no interest in the case. Special Rapporteur Mr. Grover hailed this victory: "We are happy that the IPAB has recognised the element of public interest in setting aside undeserving patents and held that patients' groups, who are directly impacted by patents on medicines, can challenge granted patents. This will be of import as concerned patients' groups will now have better clarity in challenging patents on medicines for HIV, cancer and other diseases."⁴⁰

Similar appeals for patent protection have been filed and rejected by India since the installment of TRIPS regulations and the Patent Amendment Act. Boehringer-Ingelheim's plea in 2008 for a patent on a syrup based form of the existing drug nevirapine (a pediatric HIV medicine) which was discovered in 1989, was rejected on the grounds of section 3(d).⁴¹ AstraZeneca challenged the IPAB's rejection of their patent on the lung cancer drug Iressa in 2007. The IPAB dismissed this challenge in November of 2012 "because the drug had 'known prior use' and could not be considered an invention."⁴²

Since the implementation of TRIPS in India, several actions on the part of other States have also threatened India's ability to use the flexibilities guaranteed by the Doha Declaration to protect public health. In the 4 years preceding 2011 four of India's major pharmaceutical manufacturers were purchased by foreign State multinational pharmaceutical companies⁴³. According to Grover et al. (2012) "Pharmaceutical companies have lobbied governments directly and through the promotion of bilateral and multilateral trade agreements in order to restrict the use of TRIPS-flexibilities and to enact TRIPS-plus measures. TRIPS-plus measures raise intellectual property protections beyond the floor established by TRIPS, increasing the price of medicines".²³ These 'TRIPS-plus' movements include: European Union and India free-trade agreement, the Anti-Counterfeiting Trade Agreement (ACTA), and more recently the Trans-Pacific Partnership lead by the U.S. These negotiations have been rejected by many international non-governmental organizations—such as Médecins Sans Frontières, Universities Allied for Essential Medicines, Health Action International, Oxfam, Amnesty International—who express

their concern that these actions only recede progress that has been made to provide access to medicines and the right to health for all.

At the heart of all of these efforts by innovator pharmaceutical companies and foreign States, is the motivation to impede generic competition, and expand their market reach. “Competition from generic companies is the key to affordable drugs”¹⁸ as evidenced by India’s access to medicines successes between 1972 and 2005. It is extremely disappointing to witness these companies and State actors so blatantly chose to ignore the right to health responsibilities that have been ratified in such international agreements as the Doha Declaration, The International Covenant on Economic, Social and Cultural Rights, The Universal Declaration of Human Rights, WHO Constitution, and the recommendations by the former Special Rapporteur ‘*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicine*’.

Under Indian domestic laws (The Indian Constitution and The Patents (Amendment) Act 2005) and the auspices of established international law, the Indian government is acting well within its powers when taking measures to protect the right to health of citizens and the people of the developing world. It is unwarranted and a violation of social corporate responsibility and more importantly international law, when multinational companies and foreign States chose to challenge Indian patent law that is attempting to provide affordable medicines to those of the developing world. These companies and States must recognize that they have obligations to humanity, and realize that their actions while profit-driven and beneficial to shareholders; can have a dramatic impact on the health and security of populations who are already struggling to survive at the margins of our society.

CONCLUSION

The realization of the right to health may be pursued through numerous, complementary approaches, such as the formulation of health policies, or the implementation of health programmes developed by the World Health Organization (WHO), or the adoption of specific legal instruments. This paper has provided evidence to demonstrate that the right to health is in fact a human right in India and internationally. Access to essential medicines for the billions who lack life-saving treatments today, is a vital role that society must take on. Multinational pharmaceutical companies and Governments are in positions of power and have the obligation to make decisions that allow for the progressive reality of the right to the highest attainable standard of health. While the Access to Medicines Index (2012) shows that many companies are taking this role more seriously today than ever before,³² their actions against India’s efforts to protect global health fall contrary to this report.

As Prof. Hunt, the former United Nations Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, outlined, pharmaceutical companies are providing a great service to society when developing medicines, and in doing so are awarded by society with protection for their discovery for a period of time that allows them to raise profit. It is understandable that the cost and risk of research and development of medicines is high, however it is the patent protection agreed upon through international agreements, which allows these companies to recoup their investment and often more. Patent

protection does not exempt these companies from adhering to their human rights obligations to the global community, and it is not enough to state their support of these measures in a Corporate Responsibility Report.

It is my recommendations in concert with those outlined by Prof. Hunt's Guidelines²⁹ that pharmaceutical companies be held accountable for their obligations to provide equitable access to medicines, and allow internationally agreed upon methods for States to enhance the availability and affordability of these medicines. I agree, that the development of an Ombudsman to oversee company's right to health responsibilities in regards to access to medicines, would provide a degree of accountability for these companies to act transparently and effectively towards these goals.

I also believe that reforms to the way in which research and development is done in the pharmaceutical industry must be considered. It is promising to see that the a *Consultative Expert Working Group on Research and Development: Financing and Coordination* has been established to work with WHO Member States towards novel methods of providing incentive for research and development that extends beyond patents. It is my opinion that the establishment of 'a binding global instrument for R&D and innovation for health'⁴⁴, would provide guaranteed funds to develop medicines for the developing world, while allowing developing countries to receive assistance in building capacity to engage in their own research and development. With the appropriate infrastructure, training and funding mechanisms, the least developed countries can be given an opportunity to produce essential medicines in a self-sufficient manner; similar to successes seen in India and the other 'BRICS' nations.

APPENDICES

Appendix 1. Mr. Joseph Jeune of Haiti. March 2003: On the left prior to treatment for HIV/AIDS/TB co-infection. September 2003: Following access to medicines.⁴⁵



REFERENCES

- ¹ World Health Organization. *WHO Model Lists of Essential Medicines*, online: <http://www.who.int/medicines/publications/essentialmedicines/en/>. [accessed on: 2 December 2012]
- ² Habiyambere V. Progress of WHO Member States in developing national drug policies and in revising essential drugs lists (WHO/DAP/98.7). World Health Organization: Geneva, 1998.
- ³ UN General Assembly (11 August 2008) The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt. U.N. General Assembly, 63rd Session, Agenda Item 67(b). U.N. Doc. A/63/263. Available: http://www.essex.ac.uk/human_rights_centre/research/rth/index.aspx. [accessed 2 December 2012]
- ⁴ DiMasi, Hansen, Grabowski (2003) “The price of innovation: new estimates of drug development costs,” *Journal of Health Economics*; Vol 22, pp. 151-185.
- ⁵ Collier R (2009). Drug development cost estimates hard to swallow. *CMAJ*; 180(3): 279–280.
- ⁶ World Health Organization. Public health, innovation, intellectual property and trade: Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). Available: http://www.who.int/phi/news/cewg_2011/en/. Accessed Nov 2, 2012.
- ⁷ Hotez PJ, Fenwick A, Savioli L, et al. Rescuing the bottom billion through control of neglected tropical diseases. *Lancet* 2009;373:1570.
- ⁸ Médecins Sans Frontières/Doctors Without Borders (MSF). How a Global R&D Convention could fill the gaps left by today’s medical innovation system. Available: http://www.msfacecess.org/sites/default/files/MSF_assets/Innovation/Docs/MedInno_Briefing_GlobalConventionRD_ENG_2012Update.pdf. Accessed Nov 1, 2012.
- ⁹ Office of the United Nations High Commissioner for Human Rights. The Right to Health. (GE.08-41061–June 2008–13,600) 4 November 2012.
- ¹⁰ The Pharmaceutical Industry in Figures, European Federation of Pharmaceutical Industries and Associations (2008), p. 5, <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=4883>.
- ¹¹ Médecins Sans Frontières/Doctors Without Borders (MSF). How a Global R&D Convention could fill the gaps left by today’s medical innovation system. Available: http://www.msfacecess.org/sites/default/files/MSF_assets/Innovation/Docs/MedInno_Briefing_GlobalConventionRD_ENG_2012Update.pdf. Accessed July 19, 2012.
- ¹² Bird RC and Cahoy DR (2007). The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement. *Northwestern Journal of Technology and Intellectual Property*. 5(3):400-425.
- ¹³ Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495
- ¹⁴ UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3, available at: <http://www.unhcr.org/refworld/docid/3ae6b36c0.html> [accessed 6 December 2012]
- ¹⁵ UN Office of the High Commissioner for Human Rights, *Fact Sheet No. 31, The Right to Health*, June 2008, No. 31, available at: <http://www.unhcr.org/refworld/docid/48625a742.html> [accessed 6 December 2012]
- ¹⁶ UN General Assembly, *Entry into force of the constitution of the World Health Organization*, 17 November 1947, A/RES/131, available at: <http://www.unhcr.org/refworld/docid/3b00f09554.html> [accessed 6 December 2012]

¹⁷ *Constitution (consolidated up to 2007)* [India], 26 January 1950, available at: <http://www.unhcr.org/refworld/docid/3ae6b5e20.html> [accessed 6 December 2012]

¹⁸ Grover A and Citro B (2011). India: access to affordable drugs and the right to health DOI:10.1016/S0140-6736(10)62042-9

¹⁹ UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III), available at: <http://www.unhcr.org/refworld/docid/3ae6b3712c.html> [accessed 6 December 2012]

²⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994)

²¹ World Health Organization. *WTO and the TRIPS Agreement*, online: WHO medicines: <http://www.who.int/medicines/areas/policy/wto_trips/en/index.html>

²² Linda L. Lee, Trials and TRIPS-ulations: Indian Patent Law and *Novartis AG v. Union of India*, [23:281] Berkeley Technology Law Journal (2008)

²³ 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. *J Law Med Ethics* 40(2):234-50.

²⁴ The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005

²⁵ UN Commission on Human Rights, *Commission on Human Rights Resolution 2002/32: Access to Medication in the Context of Pandemics Such as HIV/AIDS*, 22 April 2002, E/2002/23- E/CN.4/2002/200, see chap. X., available at: ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-32.doc [accessed 6 December 2012]

²⁶ UN Commission on Human Rights, *Commission on Human Rights Resolution 2002/31: The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 22 April 2002, E/2002/23- E/2002/23- E/CN.4/2002/200, see chap. X., available at: ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2002-31.doc [accessed 6 December 2012]

²⁷ Office of the High Commissioner for Human Rights. *Overview of the mandate*, online: UN Human Rights: <<http://www.ohchr.org/EN/Issues/Health/Pages/OverviewMandate.aspx>>

²⁸ UN Human Rights Council, *Human Rights Council on Resolution 6/29: Right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 14 December 2007, available at: http://ap.ohchr.org/documents/E/HRC/resolutions/A_HRC_RES_6_29.pdf [accessed 6 December 2012]

²⁹ UN General Assembly (11 August 2008) The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur, Paul Hunt. U.N. General Assembly, 63rd Session, Agenda Item 67(b). U.N. Doc. A/63/263. Available: http://www.essex.ac.uk/human_rights_centre/research/rth/index.aspx. [accessed 2 December 2012]

³⁰ Hunt P, Khosla R (2010) Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008). *PLoS Med* 7(9): e1000330. doi:10.1371/journal.pmed.1000330

³¹ United Nations, *Millennium Development Goal 8: Strengthening the Global Partnership for Development in a Time of Crisis. MDG Gap Task Force Report 2009*, 2009, available at: <http://www.unhcr.org/refworld/docid/4ab38ba52.html> [accessed 7 December 2012]

-
- ³² Access to Medicines Index. *The Access to Medicines Index 2012*, online: <<http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/2012-access-to-medicine-index-full-report-clickable.pdf>>
- ³³ European Commission, Pharmaceutical Sector Inquiry, Preliminary Report (DG Competition Staff Working Paper), 28 November 2008, page 17.
- ³⁴ UN Human Rights Council, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt : annex : mission to GlaxoSmithKline*, 18 May 2009, A/HRC/11/12/Add.2, available at: <http://www.unhcr.org/refworld/docid/4a1d0af22.html> [accessed 6 December 2012]
- ³⁵ UN Human Rights Council, Promotion And Protection Of All Human Rights, Civil, Political, Economic, Social And Cultural Rights, Including The Right To Development, *Resolution adopted by the Human Rights Council 12/24. Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 12 October 2009, A/HRC/RES/12/24, available at: <http://www2.ohchr.org/english/bodies/hrcouncil/12session/resdec.htm> [accessed 6 December 2012]
- ³⁶ Vijay Yalamanchili, State of India's TRIPS-Compliant Patent Regime, 26 *Biotechnology Law Report* 211 (2007)
- ³⁷ Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 *U. Pitt. L. Rev.* 491, 495.
- ³⁸ *Novartis AG v. Union of India*, (2007) 4 *Madras L.J.* 1153.
- ³⁹ Kotwani A (2010). Will generic drug stores improve access to essential medicines for the poor in India? *Journal of Public Health Policy*; 31:178–184.
- ⁴⁰ Lawyers Collective, *Hope for hep-c patients: Patients succeed in overturning first ever product patent on medicine in India*, online: <http://www.lawyerscollective.org/updates/hope-hep-c-patients-patients-succeed-overturning-product-patent-medicine-india.html> [accessed on: 6 December 2012].
- ⁴¹ Rupali Mukherjee. *India rejects Boehringer's AIDS drug patent plea*. The Times of India, online: <http://timesofindia.indiatimes.com/business/india-business/India-rejects-Boehringers-AIDS-drug-patent-plea/articleshow/3146786.cms?> [accessed on: 6 December 2012].
- ⁴² FirstWord. *Indian board dismisses AstraZeneca's appeal on Iressa patent*. Online: http://www.firstwordplus.com/Fws.do?articleid=E01233AA2FE947ACB013F977BC53BBB2&src=corp_site [accessed on: 5 December 2012].
- ⁴³ Indian Department of Industrial Policy and Promotion. *Discussion paper. Subject: compulsory licensing*, Online: http://www.dipp.nic.in/ipr-feedback/FeedBack_JyotiMirdha_MP_28September2010.pdf [accessed on: 30 Nov 2010].
- ⁴⁴ World Health Organization. *Public health, innovation, intellectual property and trade: Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG)*, online: http://www.who.int/phi/news/cewg_2011/en/. [accessed on 2 November 2012].
- ⁴⁵ The Three by Five Initiative. *Treatment Works*, WHO, online: http://www.who.int/phi/news/cewg_2011/en/. [accessed on 6 December 2012].