Journal of Advances and Scholarly Researches in Allied Education
Vol. 16, Issue No. 6, May-2019, ISSN 2230-7540

Challenges to Patent Laws Related to Pharmaceutical Innovations at International Level

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Abstract – Patents are the legal protection for inventions, including new medicines discovered by research-based pharmaceutical companies. In return for such protection, a patent-holder discloses to the world patented research and science underlying the invention. Pharmaceutical products are currently not granted patent protection under Indian law. India had a product patent regime for all inventions under the Patents and Designs Act 1911."Thus, under our existing Patent laws, molecules, which are products of chemical reactions, are as such non-patentable in India. The term of an innovation patent is eight years from its effective filing date (Section 68, Patents Act). Annual renewal fees are payable from the fourth anniversary of the filing date for a standard patent and from the second anniversary for an innovation patent. Pharmaceutical companies have the ability to develop new drugs that can prolong life and provide cures to diseases that affect people worldwide. Patents are especially important to these drug companies because they can guarantee profit and make all the time and cost put into developing their new drug worthwhile. In the United States, the Patent Protection process as it relates to the drug industry has been distorted by the political system, intense lobbying and large campaign contributions. The result has been pricing contrary to the greater good of the nation. Millions of people mostly in developing countries lack access to life-saving drugs. Patents can put a dramatic impact on access to medicines when they are used to prevent competition. Thus a patent is a monopoly right granted to a person who has invented a new and useful article or a new process of making an article. In this Article the researcher has probed the limitations and expectations of Patent Laws at International level as it is now a worldwide issue especially in case of life saving drugs.

Key Words – Intellectual Property Rights, Copyrights, TRIPS, Patent Laws, Pharmaceutical Innovations, Compulsory Licensing, Advance Market Commitment, R&D, HIF (Health Impact Fund), QALYs or DALYs (Disability-Adjusted-Life Years), Ethical Problems

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INTRODUCTION

Patent is one of the major forms of Intellectual Property Rights (IPRs) used in the Pharmaceutical industry. Trade mark, Industrial design, Geographical indication and Copyright are other forms of IPRs available in India. Grant of Patent in India is governed under the Patents Act, 1970. Significant changes like provision of product patents and increase in the term of patent to 20 years were introduced in the Indian Patent law, after India signed TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement in 1995. A brief overview of development of Patent laws in India shows that it is an outcome of TRIPS agreement. Criteria of patentability and different types of pharmaceutical patents currently being granted in India are described by many researchers with the aim to provide the fundamental knowledge of pharmaceutical patenting to the others. Patents are granted for protection of the inventions. Patent is an exclusive right granted by the government to the applicant for an invention. A patent can be applied by the inventor or any other person/ company assigned by the inventor. It is the right to exclude others from unauthorized making, using, offering to sale, selling or importing the invention. Patent is a negative right that means patent is not a right to make, use or sell the invention, rather it is a right that empowers the patentee (patent owner) to prevent or stop the use of his/ her invention by third parties without his/ her permission. Patent includes right to license others for the purpose of making, using or selling the patented invention. A patent is a contract between an applicant/ inventor and the government wherein the government provides right

of protection of the invention for a limited period of time after the full disclosure of the invention by the applicant/ inventor. Thus, patenting provides a strategy for protecting inventions without keeping the invention secret. Patent offers technical solution to a technical problem. Patent is granted only to those inventions which satisfies certain conditions known as criteria of patentability. Patents have limited term of 20 years counted from the date of filing the patent application. Patent is a territorial rights thus it can be enforced only in the country where it is granted. Therefore, any legal action against the infringement or violation of the patent rights can be sought only in that country only. For getting patent protection in different countries patent has to be applied in each of the countries. Patent Cooperation Treaty (PCT) provides a route to file an international patent application through with patent can be filed in a large number of countries through a single patent application. However, after filing the PCT application grant of patent remains under the discretion of the individual patent office only. The principal law for patenting system in India is the Patents Act, 1970. Initially, according to the provisions of this law no product patent but only process patents could be granted for inventions relating to food, drugs and chemicals. However, since 2005 product patenting is allowed in India. India being a member country of World Trade Organization (WTO) signed TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995. TRIPS prescribed the minimum standards of IP laws to be followed by each of its member countries. India being a signatory of the TRIPS agreement was under a contractual obligation to amend its Patents law to make it compliant with the provisions of the agreement. The first amendment in this series was in the form of the Patents (Amendment) Act, 1999 to give a pipeline protection till the country starts giving product patents. It laid down the provisions for filing of applications for product patents in the field of drugs and agrochemicals with effect from 1st January 1995 as mailbox applications and introduced the grant of Exclusive Marketing Rights (EMRs) on those patents. To comply with the second set of TRIPS obligations India further amended the Patents Act, 1970 by the Patents (Amendment) Act, 2002. Through this amendment provision of 20 years uniform term of patent for all categories of invention was introduced. This amendment also made other changes in the principal Act like definition of the term “invention” was made consistent with TRIPS agreement and provision for reversal of burden of proof in case of infringement suit on process patent was added in the Act. The third set of amendments in the patent law was introduced as the Patents (Amendment) Act, 2005. Through this amendment product patent regime was introduced in India. Mere discovery of new form, new property or new use of a known substance was made patentable under certain conditions, provisions related to pre grant and post grant oppositions were modified and provision for the grant of compulsory license for export of patented pharmaceutical products in certain conditions was introduced. The basic requirements for any invention to be patentable are Newness, Inventive steps and industrial applicability. There are different categories for Pharmaceutical Patents or drug Patent in India which are as follows: Drug Compound Patent, Formulation or Composition Patent, Synergistic combinations Patent, Technology Patent, Polymorph Patent, Biotechnology Patent and Process Patent. These rights can be transferred by Assignments or Licenses. The Patent law of India is an exemplary piece of Patent legislation as it is aimed to balance the interests of both the common man and the inventors. After the introduction of product patent regime a wide range of pharmaceutical products can be patented in India. Before applying for the patent the researchers shall carefully take into consideration the criteria of patentability and advice of a patent expert is highly desirable in this respect. Once acquired patent rights can be transferred through assignment or licensing to other persons or companies. Organizations such as academic institutions and universities not having sufficient manufacturing or marketing capacities can use patents as an effective tool for the technology transfer. These organizations can outsource their patented products/ processes to third parties and in return they can earn revenues to recoup the investments made in the development of such products/ processes. Compulsory license provide an opportunity to market the patented products under certain conditions. In the International literature it has been argued that IPR’s as implemented in the TRIPs agreement has been faced with large number of ethical problems that need to be considered. Many cases have been sighted in the past literature that points at the need to consider these ethical problems objectively. The cases like the patent for Viagra need us to consider the patent issues internationally for the pharmaceutical companies. Viagra patent was a veritable gold mine, enabling Pfizer to bring in more than 2 billion a year but obtaining the patent was full of practical hurdles. The English, Canadian, Columbians, Venezuelans, South Koreans and Chinese court struck down the patent for Viagra. As for India, there was no patent issued, as the Indian regime prohibits second medical use patents and methods of medical treatment. The Viagra patent centered around Silderanfil Citrate, a chemical substance that works by inhibiting an enzyme (PDE enzyme) that retards the relaxation of the penile muscle. Silderanfil Citrate was a potential cure for cardiovascular diseases and was mentioned in the Pfizer documents. This made it difficult to grant this a second patent for the cure of Male Erectile Dysfunction (MED). The English court first ruled against the patent and then later granted it a patent after the renowned publication by authors including Nobel laureate published on the positive effects of Silderanfil Citrate on MED. The Regents of University of California Vs. Union of India, 2nd March 2017 is another case to consider.

Indian Patent Office rejected the University's patent application for Xtandi drug (drug used for treating prostate cancer). University claims to have invented this drug and to have secured patents in 50 jurisdictions since 2007. In India the drug was sold by Japan's Astella Company. Despite this the patent application was rejected in India on the grounds that it lacked inventive step and was hit by section 3(d) and 3 (e) of the patent act. Writ pretention as a way to appeal against the judgment was filled in Supreme Court where it was argued that the IPO decision was *"contrary to public interest"*, and failed to assess the full scientific and legal evidence presented, as well as ignored precedent on the matter. This petition is yet to be concluded.

The turmeric battle is also worth mentioning in these discussions where in October 1996 Council for Scientific and Industrial Research (CSIR), filed a re-examination claim with USPTO for the invalidation of the patent granted to two researchers affiliated with the University of Mississippi, Medical Centre. The inventors claimed that certain amount of turmeric administered orally or locally to wound would enhance the wound healing process.

The granting of the patent was contested by on the grounds of lack of novelty and 'prior art' categorization. Turmeric has been used in Indian traditional medicines for healing wound since long time. An array of evidences like citing of ancient Sanskrit, Urdu and Hindi literature and paper published by Indian Medical Association in 1953 were presented as the support document for the case. In final order USPTO, taking into consideration the evidence presented the patent was invalidated on the grounds of 'prior art'.

This level of uncertainty in global patent protection, amplifies the need to question the efficiency of patent system as an inducement to pump in more money into R&D for innovation in pharmaceutical products. After a long, lengthy, time consuming and expensive research and development of new drug than undergoing equally long and lengthy approval to go through. This limits the pharmaceutical industries to go through rigorous R&D for new drugs as cost for bearing the whole process and time taken is very long.[1] Long process of IPR increases the cost for the patentee but as soon as the drug is in the market the cost of replicating the same drug for other company is lot cheaper and it decreases the benefits for the patentee. The failure to recoup the R&D cost leads to market failure for the pharmaceutical innovations.

For establishing monopoly and ensuring the return of the investment IPR are the key tool. The long process involved although reduces its effectiveness. This problem is more prominent in underdeveloped and developing countries. Pharmaceutical companies have little incentive in developing drugs for common ailments in these countries.[2]

There is a two standard solution to the above mention access problem in pharmaceuticals field. One of the solutions is the differential pricing in different geographical areas for the same drug. In developed countries the same drug is sold at a higher price than in the underdeveloped and developing countries. This is presumed to be good for investors to get good price for their product and enable low income population to use the drug. However, this solution is problematic as it does no justification for the lifesaving drugs all around the world.

The second standard solution is providing the rights to government to provide 'Compulsory Licensing' for the production of the lifesaving drugs to deal with public emergencies.[3] However, both these solutions are problematic.[4] One such problem is differential pricing that can lead to seepage of the cheap drugs in the developing countries thus, opening up a parallel smuggling channel.[5] Another problem is unequal treatment as high income people of developing countries will have access to drugs in low cost and low income people in developed countries will pay a higher price. So, the marking of geographical location doesn't ensure fair usage by the people who are actually in need.

Compulsory licensing has also its own set of problems. Originally WTO has allowed the national governments to issue the compulsory license in emergency to only generic manufacturers.[6] However, this did not solve the problem of the low income countries that still lacked the capability to develop their own domestic generic drug manufacturing capacity. Later WTO revised this in 2003 in WTO General Counsel Decision as countries except Brazil, India and China all low income countries lacked in this capacity. Decision was thus revised by WTO allowing all countries with the capacity to have drug manufacturing limit to be issued with the compulsory licensing to meet the national emergencies. This revision however, fails to be effective as it involves a complex licensing process and have lots of hurdles and red tapes.[7] This argument is strengthened by a study on HIV/AIDS medicine under WTO, 2003 revised decision for issuing compulsory licensing for Canadian generic drug manufacturers, Apotex. This study has concluded that WTO, 2003 decision is flawed and fails to provide a speedy and cost efficient delivering of the essential medicines. Social cost of the compulsory licensing is also high because of the following reasons[8]:

1. Compulsory licensing will lead to diminished direct investments as the owners of IP products will prepare to work in more business-friendly legal environments.

2. Company that obtains compulsory licensing can shadow the original higher price of the IP protected drugs.

3. Compulsory licensing also endangers to bring down the need, incentive in the pharmaceutical sector for new research and innovation.[9]

4. Trade sanctions by the Government of various countries can also impact the distribution and storage of the products manufactured by the national issues compulsory licensing and thus can severely impact their economy.[10]

Various suggestions have been made internationally to deal with these issues and to stimulate the R&D of pharmaceutical products. Some of the suggestions are as follows:

The Medical Innovation Prize Fund Act (H.R. 417),[11] encourages using monetary rewards for motivating R&D of pharmaceutical products. Variations have been suggested in this scheme. Monetary prize for the pharmaceutical companies which first develops the drug meeting all the requirements with respect to the medical profile determined by an independent Committee of experts in the field.[12] Example of this includes Prize 4Life (aimed at advancing the research on Amyotrophic lateral sclerosis) and Archon X (advancing research for the low-cost gene sequencing technique).[13] In exchange of the prize the winner under this scheme forbears the IPR to innovation and the product is placed under the public domain.

The limitation of this scheme is that it undervalues the efforts of the companies doing R&D on the specific product and the scheme only acknowledges the winner who declares the product first. In such cases the expanses to the basic research and clinical trials will be wasted thus making companies reluctant to enter this field.

Another drawback of this scheme is the demand and supply may not match. The time when award is announced for developing a drug for a disease and company actually coming out with the product for the market, the market conditions might have changed. Due to unforeseen or tertiary reasons the demand has diminished then the cost for producing those drugs might be recovered. Hence, the market conditions also play an important part in this process.[14] Last but not the least the prize scheme does not offer any incentive for the second-generation drugs. The prize is limited for the first entry drugs.[15]

Advanced Market Commitment (AMC), was first introduced by Michael Kermer in 2001. In June 2009, The World Bank, WHO, Global Alliance for Vaccines and Immunization (GAVI), UNICEF and many other donors has designed a pilot AMC to accelerate the development of effective pnemo vaccines to meet the demand of developing countries.[16]

The AMC presupposes three things as follows:

1. Drug meets the target drug profile

2. There is a demand for the drug

3. The pharmaceutical companies sign a guaranteed document and supply agreement to donors under AMC for long term tail price long after the funds of AMC are depleted.

On basis of these presuppositions AMC is formed by the donors (like UNICEF, WHO, GAVI etc. on number of such donors), make a legal commitment to heavily subsidize the future purchase of a fixed amount of medical drugs. AMC can use the drugs both in the first stage of development drugs (that require the scientific testing and clinical trials) or the final developmental stage drugs (those that are nearing the regulatory approvals and setting up of manufacturing units).[17]

Piloting AMC for malaria included donors to legally committing to pay UD $14 of the cost up to 200 million treatments. The developing country governments will contribute US $1 per treatment for the first 200 million treatments.[18] Technical specification of the drugs is enlisted and made ensure by an Independent Adjudication Committee (IAC). The members of this committee are the experts from their various fields. An important part of this scheme is that the second -generation drugs that are superior to their first-generation counterparts as verified by the IAC are also eligible to be the part of AMC. IAC also recognizes them and makes them eligible for the price guarantee.[19] This is a great motivator for the for-profit pharmaceutical companies. This helps to meet the huge mark up on the cost of production and development incurred by pharmaceutical companies.

The greatest objection to AMC is the role of IAC.

1. Development of the drug profile in advance by the IAC committee is questioned. It is challenging to know all the requirements and criteria of the drug to be developed in advance and IAC has to write down the exact specification of the drugs in order to legally make the agreement between the donors and for-profit pharmaceutical companies. That makes it logical that most of the eligible candidates for AMC are the drugs in their later stage of development.[20] The drugs whose side effects can only be known by stage III of clinical trials are thus not included to be

eligible for AMC. This makes AMC not a scheme eligible for all the R&D innovations.

2. The members of IAC also need to include members and experts outside the for-profit pharmaceutical sector for the fair guidelines and reducing the gambling possibilities.[21]

3. Another argument against AMC is in case if the second-generation drug comes before the granted agreement with the first-generation drug is over then the for-profit pharmaceutical company is bound to supply the second-generation drug but cannot secure any further purchase contracts to cover the R&D cost of second-generation drug. This again makes AMC ineffective scheme in light of such unforeseen circumstances.

The Health Imapct Fund (HIF) has been proposed by Thomas Poggel (2005[22], 2006[23]). This work has been published in a book, co-authored with Aidan Hollis, who in significant detail spells out how that plan works.[24] The strong point of HIF is that it leaves IPR based incentivizing scheme intact. The HIF is proposed as an amendment and gives a choice to innovators to choose a reward through IPR system or through HIF.

This reform plan consists of 3 components as follows:

1. The successful efforts in producing the new drug should be provided as a public good to all pharmaceutical companies for free of charge. This will enable all the companies to reproduce the drugs thus reducing the overall cost of the drugs in market and also eliminating the exclusion and access problems.

2. He inventor of the drug should be entitled to multiyear patent and should be rewarded through HIF in proportion to the impact of drug on the global disease burden.[25]

3. Strong economic incentives for pharmaceutical companies to develop the drugs for poor population of low-income developing countries.[26]

Another important feature of HIF according to Poggethat if two drugs are used as the alternative treatment for some disease then the reward corresponding to their aggregated impact must be allocated to the respective investor on the basis of the effectiveness of each drug[27]. This, reform plan will make it possible to create top-flight medical-research jobs in high-income, developed countries. It will enable these countries to respond more effectively to public-health emergencies and problems in the future. This will be achieved by enabling them to develop more rapidly increasing medical knowledge combined with a stronger and more diversified arsenal of medical interventions.[28]

The objections to HIF are as follows:

1. The reform requires involvement of international agencies to keep the track on the impact of drug on global disease burden. This increases the transaction coat and also the changes of corruption by such agencies.[29]

2. Developing the exact metric[30] with accurate information about impact of the drug on the global disease burden is also a problem. This involves both setting the metric for the measurement and doing actual field work to attain such information. For the fieldwork the visits must be made all over the world and on a continuous basis. The chances of misrepresenting causal efficacy, failing to report data, making wrong estimates and miscalculating data-input are high, and any error with respect to the reporting, filing and computation of empirical data results in an unjust distribution of rewards. Thus calculating the impact of the drug on the global disease burden is more theoretical than a practical concept.

3. Sonderholm[31] has raised worries about the prudential appeal of the HIF. The storage and distribution needs of the drug might also impact the widespread use of the drug. So if there are two alternative drugs for the same disease and one drug is more effective but needs specific temperature to be stored at and other one has no such requirement and is less effective than the first drug, the chances are the second drug will be used more in the low-income countries. Thus, not the effectiveness of the drug but the storage requirements of the drug will influence its market demand. This will impact the drugs impact on the global disease burden and the second drug will be eligible for the higher reward then the first drug. This makes HIF scheme as an unfair scheme. Pharmaceutical companies that are for-profit will realize that the economic prospects of developing high-tech essential drugs aimed at the medical needs of the populations in developing countries are meager.[32] They will therefore, reorient their research and development efforts towards low-tech drugs. There will also predictably be an emergence of new pharmaceutical companies that have as their only focus the development of low-tech essential drugs that address the

medical needs of the populations of developing countries.

4. Michael Selgelid has identified a problem of causal attribution for the reimbursement process essential to the HIF (2008:140). This objection is based on the problem to determine the extent to which the global disease burden has been reduced due to one intervention or the other. Selgelid illustrates the problem with an example: Imagine that someone who would have died from malaria ends up living because the person received a partially effective vaccine and gains access to a mosquito net. But it's hard to quantify how much percent of the drug and how much percentage of the mosquito net was responsible for her recovery and not deing. The causal attribution problem thus is a significant threat to the viability of health impact measurement by either QALYs or DALYs (Disability-Adjusted-Life Years), thus a threat to the successful implementation of HIF. This is so because the crucial reimbursement process of the HIF is exactly premised on the idea that pharmaceutical companies are rewarded in proportion to the effect that their products have on the size of the global disease burden.

CONCLUSION

The process of liberalization initiated in 1991 has helped develop policies that are focused on attracting capital from overseas and making India a global industrial base. The resultant inflows of foreign direct investment and technology transfers have created an environment for dynamic growth and increased competitiveness of Indian industry. India is now moving into global markets and competing with international quality standards and prices. Although R&D is an important factor to ensure a competitive edge in the International arena, the future of the Indian Pharmaceutical Industry hinges on Patent Protection. The above discussed schemes along with the schemes like wild-card patent extensions[33], patent buyouts[34] and priority review vouchers[35] are some of the mechanisms that are currently being discussed by academics, policy-makers and NGO sectors as changes/amendments to the TRIPS regime. However, no single mechanism is fault free and can be endorsed independently. Hence, their strengths and weaknesses need to be weighed against each other to make any conclusive decision. To have more access and protection to the drugs we need transparent Policies and agreements on innovations at International Level as well as at National Level for better R&D globally in Pharmaceutical Industries.

REFERENCE

1. Pogge, T. (2005). Human rights and global health: a research program. Metaphilosophy 36 (1 -2): pp. 182-209.

2. Sonderholm, J. (2010). Intellectual Property Rights and the TRIPS agreement. An overview of ethical problems and some proposed solutions. Policy Research Work Paper by the World Bank Development Research Group Trade and Integration Team and Human Development Network Development Dialogue on Values and Ethics, March, 2010.

3. The right of individual countries to issue compulsory licenses in cases of public emergences was clarified and emphasized in the 2001 Doha Declaration on the TRIPS agreement. The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights. See: http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html [Accessed September 20, 2009].

4. Ravvin, M. (2008). Incentivizing Access and Innovation for Essential Medicines: A Survey of the problem and Proposed Solutions. Public Health Ethics 1 (2).

5. Love, J., and T. Hubbard (2007). The big idea: prizes to stimulate R&D for new medicines. Chicago-Kent law review 82 (3): pp. 1519-1554.

6. Reichman, J. H. (2009). Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options. The Journal of Law, Medicine & Ethics 37 (2): pp. 247-263.

7. Johnston, J., and A. A. Wasunna (2007). Patents, biomedical research, and treatments: examining concerns, canvassing solutions. The Hastings Center report 37 (1): pp. 1-36.

8. Bird, R. C. (2009). Developing nations and the compulsory license: maximizing access to essential medicines while minimizing investment side effects. The Journal of law, medicine & ethics: a journal of the American Society of Law, Medicine & Ethics 37 (2): pp. 209.

9. Pogge, Thomas. 2009. The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices. INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO MEDICINES, Thomas

Pogge, Matthew Rimmer, and Kim Rubenstein, (eds.), Cambridge: Cambridge University Press, 2010.

10. Pogge, T. 2008. World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms. 2nd, expanded edition: Cambridge, MA: Polity Press.

11. It is worth noting that The Medical Innovation Prize Fund Act (H. R. 417), introduced to the US Congress in January 2005 by Senator Bernard Sanders, calls for the implementation of cash prizes to stimulate R&D of pharmaceutical products.

12. A commonly cited estimate of the cost of bringing a new drug to market puts the cost at US$800 million. See The Tufts Center for the Study of Drug Development: http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 [Accessed August 2, 2009].

13. Love, J. 2007. Would cash prizes promote cheap drugs? New Scientist Magazine, 12 November, 24-25.

14. Barder, O., M. Kremer, R. Levine, A. Albright, Development Center for Global, and Group Advance Market Commitment Working. 2005. Making Markets for Vaccines: From Ideas to Action: Center for Global Development.

15. Ibid

16. See http://www.vaccineamc.org/pneu_amc.html

17. Ibid

18. The pilot AMC launched by GAVI and partners sets the price per dose for an eligible vaccine at US$7. See: http://www.vaccineamc.org/files/AMC_FactSheet2009.pdf

19. CGD is eager to design an AMC scheme in which there are strong incentives to always buy the best available medicines. From the point of view of CGD, it is a sub-optimal outcome if the best available medicines are not the ones that are purchased (Barder et al. 2005:65)

20. Hollis, A. (2007). Drugs for Neglected Diseases: New Incentives for Innovation. In Pharmaceutical Innovation: Incentives, Competition, and Cost-Benefit Analysis in International Perspective, edited by F. A. Sloan. Cambridge: Cambridge University Press.

21. For more on this point, see (Hollis and Pogge 2008:107). Hollis, A., and T. Pogge. 2008. The Health Impact Fund: Making New Medicines Accessible to All: Incentives for Global Health.

22. Pogge, T. (2005). Human rights and global health: a research program. Metaphilosophy 36 (1-2): pp. 182-209

23. Pogge, T. (2006). Harnessing the Power of Pharmaceutical Innovation. In The Power of Pills: Social, Ethical and Legal Issues in Drug Development, Marketing and Pricing. London: Pluto Press.

24. Hollis, A., and T. Pogge (2008). The Health Impact Fund: Making New Medicines Accessible to All: Incentives for Global Health.

25. It is the feature of the HIF that innovators are rewarded with a monetary prize from a centralized fund that makes it reasonable to describe the HIF as a 'prize proposal'. It is an 'advanced' such proposal because prizes are not paid out to the first innovator that meets a particular medical target, but are paid out to innovators in proportion to the impact of their innovations on the global disease burden. This crucial distinction between two types of prize proposals is emphasized by (Love and Hubbard 2007:1520).

26. It is emphasized that pharmaceutical companies that wish to be rewarded under the HIF are required to sell their products worldwide within a price window ranging between the average and marginal cost of production as determined by the fund in charge of reimbursement (Hollis and Poggethat 2008:74)

27. Ibid

28. Ibid

29. It is true that there are transaction costs involved with the current system for incentivizing research and development of essential drugs. Most importantly, this system requires both patent offices and patent courts, but, as Rosenberg notes "a patent system's greater reliance on individuals to pursue their own interests directly, instead of through an intervening

government, is generally more effective than any alternative" (2004:84).

30. There is general agreement among the proponents of the HIF that the most promising metric candidate is the Quality-Adjusted-Life Year (QALY) system which currently is being used by national health systems in Australia, Canada, the UK and USA to measure the health impact of pharmaceuticals (Ravvin 2008:120; Hollis 2008:127-128; Selgelid 2008).

31. Sonderholm, J. (2009). A Reform Proposal in Need of Reform: A Critique of Thomas Pogge's Proposal for How to Incentivize Research and Development of Essential Drugs. Public Health Ethics:php017.

32. What is meant here by a 'high-tech drug' is a drug that requires clean drinking water, electricity and/or educated health personal in order to be effective. Conversely, a low-tech drug is a drug that requires neither of these things in order to be effective

33. Spellberg, B., L. G. Miller, M. N. Kuo, J. Bradley, W. M. Scheld, and J. E. Edwards (2007). Societal Costs Versus Savings from Wild-Card Patent Extension Legislation to Spur Critically Needed Antibiotic Development. Infection 35 (3): pp. 167-174

34. Kremer, M. (1998). Patent Buyouts: A Mechanism for Encouraging Innovation. Quarterly Journal of Economics 113 (4): pp. 1137-1167.

35. Ridley, D. B., H. G. Grabowski, and J. L. Moe (2006). Developing Drugs for Developing Countries. Health Affairs 25 (2): pp. 313-324.

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