POLICY BRIEF

ACCESS TO MEDICINES IN THE ERA OF PATENTS

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SUMMARY

Health is a fundamental right and all persons are equitably entitled to universal access to healthcare. International Human Rights instruments to which India is a signatory make it incumbent to bring about legislative reform and changes in policies to provide for the highest attainable standard of health and health care to all persons. Trade treaties and agreements, like the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) have a significant impact on the domestic law and on access to medicines and healthcare. Patents on pharmaceuticals have a big impact on the accessibility and affordability of patented medicines, making it difficult for developing countries to realize and secure the right to health for all.

The obligation of the State to protect the right to health also includes the availability of reliable, quality, safe and efficacious medicines, including new medicines, through a regulated system of quality testing, research and development of drugs to treat and cure various diseases endemic in the country. This policy brief examines the cycle of drug development and the impact on accessibility and affordability of drugs when product patents are granted on the drugs, the conflicts between public health and the commercial interests of multinational pharmaceutical companies, and the importance of implementing and using the law to make medicines accessible.

INTRODUCTION

The fundamental right to life and health has been in constant conflict with the commercial privilege to patents on pharmaceutical products. The conflict emerged starkly after the World Trade Organization formulated a new treaty,

the TRIPS agreement that required member nations to provide product patents on pharmaceutical products for a period of 20 years. India, being a developing country, had to change its laws by 2005, from only process patents providing protection for about 7 years to 20 years of protection for product and process patents on pharmaceuticals. Product patents give patent holders a legal right to control the market to the exclusion of others, i.e. in the manufacture and supply of that medicine (patented product) in the country. This monopoly prevents competition from generic production and reverse engineering by other manufactures. It also makes access to patented medicines a challenge, much to the detriment of health and well-being of people.

The primary reasons for inaccessibility of patented medicines are:

a) hiking up prices of patented medicines by the patent holder (as a monopoly is created through patents);

b) lack of new technology and resources to produce the medicines in developing countries;

c) less resources available with public institutes, domestic industry to invest in research and development and conduct clinical trials for new medicines;

d) low incentives for domestic industries to challenge the patents granted on pharmaceuticals in courts, due to high litigation costs;

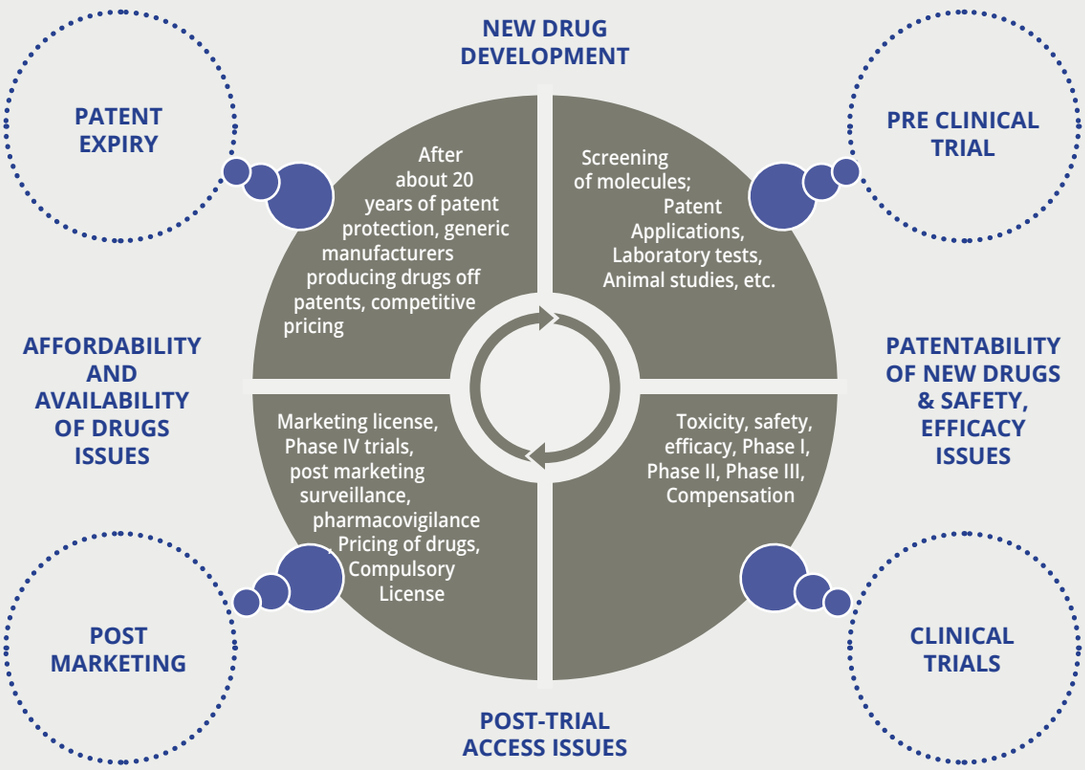
e) patented medicines do not come under the Drug Price Control Order that places a cap on the prices of essential medicines; and

f) pressure from developed countries on developing countries not to make use of TRIPS flexibilities that could make medicines accessible and affordable to the people, such as the issuance of compulsory licenses.

NEW DRUG DEVELOPMENT

Research and development (R&D) of new drugs requires capital investment, scientists, infrastructure, and technology. Developing countries have limited resources and their expenditure on R&D is negligible compared to that of developed countries.Patent applications are filed as soon as a molecule or compound is found. The laboratory test, animal studies and human studies are done later in a phased manner. It is only when the drug is found to be safe and efficacious in humans, it is given approval to enter the market for consumption. During this time period, if a patent is granted on the application filed for patent, then issues of pricing of the drug, post-trial access, affordability and availability of drugs arise, as a patent would prevent others from manufacturing or selling the drug, till the expiry of the patent.

The diagram below is a depiction of the stages and the issues raised with regard to new drug development and patents on the drug:



IN THE NAME OF R & D – MEDICINES ARE OUT OF REACH

It takes about 800 million to a few billion USD to produce a new drug over a development period of about 16 years.[1] A miniscule number of chemical compounds tested in the pre-clinical phase warrant trials in humans and a small number of those are tried on humans reach the market.[2] Once the drug hits the market, pharmaceutical companies tend to recover the costs of development rather quickly, making profits of about 1 billion USD per year for a successful drug.[3] Pharmaceutical companies spend only about 15% of their revenues on R&D, whereas they spend much more on advertising and marketing of the drugs.[4] Yet, high investment in R&D is generally used as an argument to justify the high prices of the medicines.

[1] Giaccotto, C., Santerre, R. E., & Vernon, J. A. (2005). Drug prices and research and development investment behavior in the pharmaceutical industry. *The Journal of Law and Economics*, *48*(1), 195-214. (citing DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. *Journal of health economics*, *22*(2), 151-185.)

[2] Singham, S. A. (2000). Competition policy and the stimulation of innovation: TRIPS and the interface between competition and patent protection in the pharmaceutical industry. *Brook. J. Int'l L.*, *26*, 363. (citing Fisch, A. M. (1993). Compulsory licensing of pharmaceutical patents: an unreasonable solution to an unfortunate problem. *Jurimetrics J.*, *34*, 295.)

[3] Citizen, P. (2001). Rx R&D Myths: The Case Against the Drug Industry's R&D 'Scare Card'.

[4] *Supra note 2* ShankerSingham

A patent on medicines allows pharmaceutical companies to fix the prices way beyond the production costs. High prices lead to fewer units of the drug being sold. The value of the drug[5] would be the effectiveness of the drug in reducing the morbidity and mortality and cost to the patients. The demand for new drugs is thus affected not just by the price of the drug, but also other factors such as insurance coverage, availability of drugs freely or at a subsidized rate through the public health sector, capacity of the patient to purchase the drug,alternative affordable therapies, and such other factors. However, when the prices of the drugs are about INR 1,00,000 to more than INR 3,00,000 per month of dosage, as is seen in a lot of the new cancer drugs, the demand is reduced substantially, even though there is disease prevalence. It was seen that from 2011 to 2016, the prices of newer cancer medicines shot up by almost 88%, with an increase from 54,000 USD to 1,20,000 USD per year of treatment in the Unites States of America,[6] and likewise in other places of the world too. High prices of patented medicines are seen not just in cancer but for other diseases too, that necessarily threaten the very survival and sustainability of health care systems in any country. Governments and people have to spend a lot more on health care and well-being. Widespread poverty and low health insurance coverage make it almost impossible for countries like India to provide the latest and quality healthcare to its people.

NEED TO USE THE LAW TO MAKE MEDICINES AVAILABLE AND AFFORDABLE

Patents are supposed to be granted on products that are novel, inventive, contain an inventive step and have industrial application. The TRIPS agreement, though has brought about product patents on pharmaceuticals, it does allow individual countries to make provisions within their law for protection of public health, promotion of competition, curbing monopolistic potential of patent rights and encouragement of technology transfer and dissemination of knowledge. Even though such provisions could make medicines affordable and accessible, these provisions are hardly used by the developing countries.

India has a fairly good Patent law that does not allow patents for drugs that are not truly inventive. The law has provisions that do not allow patents on known compounds, derivatives or forms of those compounds, for use of the drugs, for combination of known compounds, etc. The law also has provisions for pre-grant and post-grant oppositions and revocation of patent applications, wherein a person interested can file an opposition providing reasons or evidence showing that the compound was known, has been used earlier or

[5] Campbel, J.D., & Mocanu, J. (2017, October 10). Measuring the Value of a Drug. Retrieved September 14, 2018, from http://health.oliverwyman.com/maximize-value/2017/10/measuring_a_valueof.html

[6] Bernal, I. and Iráizoz, E. (April,2018). Cancer Drugs: High Prices and Inequity. NO ES SANO Campaign. Retreived from:http://noessano.org/es/wp-content/uploads/2018/06/Cancerdrugs_report_2018.pdf, last accessed on 27.8.2018

is obvious and therefore the drug claimed to be new, novel or inventive does not deserve to be patented. The opposition system in the Indian law provides a kind of check on the patent office and also supplements the inquisitorial role of the patent office by providing material and grounds for why the patent (application) ought to be rejected. Unfortunately, the opposition provisions are not used much by individuals or generic pharmaceutical companies.

Pharmaceutical companies also try to get extensions on the 20 year patent period by applying for multiple patents for various forms of the patented product. Unfortunately, more than 72% of patents granted by the Indian patent office are for pharmaceutical products that are not novel or inventive.[7] The granted patents on pharmaceutical products are largely for slight increments, derivatives, forms, combinations, etc., of known compounds which are per se not patentable in India. This displays a weak system of scrutiny that has allowed patents on pharmaceutical products that do not deserve patents. The impact of this makes medicines unavailable, inaccessible and unaffordable for a long period of time. Patent revocation proceedings are less explored and are difficult to pursue in resource poor settings. Nevertheless, revocation of patents that have been wrongly granted is an option that governments can use to make access to medicines a reality in India.

The Doha Declaration of the TRIPS agreement and Public Health, 2001, made explicit provisions for the use of Compulsory Licenses (CL) to prevent anti-competitive behavior, encourage transfer of technology and knowledge, and address the issues of excessive pricing of medicines.

Brazil and Thailand have used provisions under the TRIPS agreement and have negotiated reduction in prices with pharmaceutical companies[8] that hold patents on the medicines, and have issued CLs to make medicines accessible.[9]It has been documented that CLs issued for HIV medicines have reduced the prices of drugs by 27% to over 50% and the number of patients using the medicines almost tripled[10]. Once a CL was issued and prices fell. India too has issued a CL for an anti-cancer medicine. However, even though India has a huge generic pharmaceutical industry, issuance of only one CL in 13 years of the product patent regime displays a lack of will and gumption on the part of the government to make medicines accessible to its people. By not implementing the provisions of the law, India appears to bow down to the pressure imposed by the multinational companies and developed countries.

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[7] Dr Feroz Ali et al. (April 2018). Pharmaceutical Patent Grants in India How our safeguards against evergreening have failed, and why the system must be reformed. White Paper Published by AccessIBSA and the Shuttleworth Foundation. Available at https://www.accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf. Accessed on 14/09/2018

[8] Greco, D. B., & Simao, M. (2007). Brazilian policy of universal access to AIDS treatment: sustainability challenges and perspectives. *Aids*, *21*, S37-S45.

[9] El Said, M., & Kapczynski, A. (2012). Access to Medicines: the role of intellectual property law and policy. Retrieved from:https://hivlawcommission.org/wp-content/uploads/2017/06/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY.pdf

[10] Ibid.

Generic pharmaceutical companies find it increasingly difficult to challenge patents and would rather enter into voluntary licenses with the multinational companies to acquire the technical knowhow and save costs of litigation. Voluntary licenses are private agreements that do not necessarily bring down the prices of the drugs as such agreements often contain clauses that not only would prevent the domestic industry from purchasing the active pharmaceutical ingredient at competitive prices, they would also include clauses restricting the geographical area where the medicines can be sold, among other obstacles. This does not give much scope for the prices to fall drastically, thereby allowing the prices of medicines to remain unaffordable.

The generic industry may use some of the provisions in the TRIPS agreement that provide an exception to the exclusive rights given by the patent, provided it does not unreasonably conflict with the rights of the patent holder. Post-grant exceptions (aka Bolar exceptions) allow research and experimental use of the patented product by the generic industry to prepare for regulatory approval, so that generic industries can launch the patented product in the market as soon as the patent expires. This can bring back the competition, even though the patent holder would have already established their brand in the market.

ACCESS TO MEDICINES – POST TRIAL ACCESS AND COMPULSORY LICENSE

Clinical trials conducted in India for drugs are regulated and many systems have been put in place to ensure that the trials are registered. Approvals are taken from the Drug Controller General of India and from Independent Ethics Committees prior to commencement of the trials. The process ensures that the research is scientifically and ethically sound and follows the requirements of the law and guidelines (both national and international) on ethical conduct of clinical trials on humans. Provisions of compensation have been formulated within the law in India for adverse and serious adverse events, if any, during the clinical trial. R&D in India needs to be encouraged so that the domestic pharmaceutical industry can match the quality and quantity of medicines required in the country, at low costs.

Certain diseases for which there are no standard treatment or cures, and for which clinical trials have been undertaken to test new medicines, provisions relating to post-trial access of the drugs should be made so that if the medicine being tested is found to be effective, patients do not suffer after the completion of the trial, and are able to continue their treatment (if required) even after the trial.

Once the drug has been approved for marketing, steps need to be taken to ensure that the medicine is made available to all who need it. The effect of the drug on a larger population at the post-marketing stage is conducted to ensure that only safe and effective drugs enter and remain in the Indian market.

If the drug that has been approved for marketing also has a product patent, then the Patent Controllers need to be vigilant if the patent granted is working in India or not. The Controller also needs to know if the drug is available at affordable rates to the people, is meeting the needs of the people in the country, and does not impede protection of public health. If the patent holder does not make the patented drug available at affordable rates within three years of the grant of the patent, then a CL on the drug should be issued so that it is accessible to patients requiring the medicine at affordable prices.

Developing countries represent a small share of the global pharmaceutical market. Even though India is labeled as the pharmacy of the third world, India accounts for a very small percentage of the global pharma market.[11]Therefore, issuance of CLs on pharmaceutical products to make medicines accessible to the people in India should not pose a threat to the multinational pharmaceutical companies, as it may not really result in any major reduction in their market or profitability.

CONCLUSION

India needs to make public health a priority and in the conflict between the fundamental right to health and legal right to patents, the right to health should prevail, allowing steps to be taken to make medicines and health care accessible and affordable.

RECOMMENDATIONS

Nations should get together to re-visit the TRIPS agreement to include provisions that would ensure prices of patented drugs are kept low and affordable to all;

The Patent Controllers should be sensitized on issues relating to public health, right to life and health of people and the importance of not granting patents where the pharmaceutical product is not truly novel or inventive;

India should implement and use the flexibilities in the TRIPS agreement and take measures to protect public health;

India should issue more compulsory licenses for pharmaceutical products and not fear the backlash from developed countries or multinational pharma companies;

India should ensure that post-trial access of drugs is provided to participants of trials and provisions relating to compensation are implemented well;

[11] Friedman, M. A., den Besten, H., & Attaran, A. (2003). Out-licensing: a practical approach for improvement of access to medicines in poor countries. *The Lancet*, *361*(9354), 341-344.

Generic industry should be encouraged to invest in R&D and to produce drugs at low costs to make medicines accessible to all;

Government should take steps to bring patented medicines under price control and to make patented medicines available free or at subsidized rates through the public healthcare sector;

Government should take steps to revoke patents that have been wrongly granted and ensure that patent holders make the patent product (medicines) available in the country at affordable prices;

Ensure equitable access to medicines to all in need of healthcare and medication.

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