VOLUME 11 ISSN 2456-9704

PATENT RIGHTS V. PATIENT RIGHTS

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ABSTRACT

Patents are a tribute to human ingenuity. Patent ecosystem has led to remarkable innovations in field of medicines. The availability of patents does result in more inventions of drugs; we do not wish to question this fact – but this positive effect may well be cancelled out by the limitation of the use of patented drugs. The patent system allows the price of patented items to be kept artificially high which makes the patented drugs inaccessible for common public.

Atfirst, when I chose up the topic, after a superficial reading I felt that Right to health is supreme and patient's rights would over shadow patent rights, thus opting for a human rights based recourse. But after a thorough research and understanding of the equally important aspect of patent rights, the dilemma surfaced.

The article deals with justification of both the rights followed by overview of drug pricing policy in various countries then critical analysis of Indian scenario and the suggestions to strike a balance between both.

1. MONOPOLY AS A PRACTICE: ETHICAL JUSTIFICATION

Ithasbeen several times claimed that IP has its root in natural law. Lockean's labor desert theory [1] was popularly the first justification for IP. Other IP rights thus are quite easily justified but patents are different. They face an uphill battle which other rights do not.

The main cause behind dealing with this issue of Patent rights v. patient rights is due to the monopoly granted to the owner of the patent rights. Now, the question arises that as a policy should monopoly be practiced? Attempts to construct a moral justification of the patent system have been based on three grounds: (1) natural rights; (2) distributive justice; and (3) utilitarian (economic) arguments.[2]

Natural rights

Some people believe that man has a natural right to his ideas and consequently that society is obliged to enforce that right. Thus, the use of ideas without the authorization of the owner must be considered as theft. Natural property rights take precedence over social institutions and should be respected whatever the consequences.

Discussions on the natural rights argument generally refer to John Locke's 'labor theory of property'. Although Locke seems to identify property with land, various commentators have applied his theory to

[1] According to Locke, the appropriation of a thing occurs by man applying his labor to it, by 'mixing' the thingwithhis labor. By adding something of his own to the thing, he excludes others from having a right to it.

[2] Sigrid Streckx, *Patents and Access to Drugs in Developing Countries: An Ethical Analysis*, 4, Dev. WorldBioeth, 58, 62 (2004).

other types of goods, including 'intangible' objects.

Distributive justice

According to the distributive justice argument, fairness requires that inventors be rewarded because they render a service to society. It would be unfair to allow people a 'free ride' at the expense of others who apply themselves to the act of inventing.

Free riders – people who did not invest time or money in the development of an invention – should not be allowed to compete with the inventor under normal market conditions. Therefore, society should grant exclusive rights to inventors.

A utilitarian justification

The utilitarian justification, which is considered by many as the most convincing, is essentially based on the following two arguments.

(a) The so-called 'incentive-to-invent-and-innovate' argument: in the absence of patents, inventions can be copied by competitors. Consequently, the price must be reduced and the investor does not have the opportunity to regain his investments, let alone make a profit. Thus, the incentive to invent and innovate is eroded. A 'special' incentive is required so that enough people should be prepared to invest in R&D. According to this argument, the patent system provides the necessary encouragement.

(b) The so-called 'incentive-to-disclose' argument: the patent system encourages inventors to disclose their inventions instead of keeping them secret. One of the patentability requirements is that the applicant must disclose the invention in sufficient detail in the application forms. Thanks to the patent system, it is said, technological information is spread – making technological progress possible, which in turn induces economic growth. Several commentators claim that both these arguments are nowhere more valid than in the pharmaceutical sector, as this is the most research-intensive sector.

The theories are not black and white as it seems so. Each of these attempts involves many problems. For Example, If we look at the implications of this theory for the justification of drug patents, the main question seems to be: how much 'labor' is really involved in the research anddevelopment (R&D) of drugs? The greater part of pharmaceutical R&D budgets is spent on 'me-too' drugs – the slightly altered versions of successful products manufactured by the competition.

When examined in the context of distributive justification of drug patents, this argument, too, seems problematic. First, the question arises whether fairness does not also require an equal access to drugs, which is prevented by the working of the patent system.[3] Another question at issue here is: does justice require that inventors be rewarded with patents, allowing them to decide who may legally use the invention? Thirdly: what about the fairness of granting private property rights to the results of R&D, which is, in great part, publicly funded? Whether it is fair to grant inventors rewards that are excessive? Many

[3]In a utilitarian framework, as discussed above, the unequal access is said to be justified by the incentive-to invent it creates. However, in a framework of distributive justice such an argument cannot be decisive.

manufacturers of brand-name pharmaceuticals relentlessly try to obtain extensions of the protection term of their patents, and they often succeed. This phenomenon, known as 'patent evergreening', hinders producers of generic drugs (products equivalent to brand drugs, which can be put on the market after the patent expires).

Well, to some extent these arguments are negated when we talk about India specifically as Indian patent laws are stringent and neither do they allow evergreening of patents nor would they ever confer patent rights for frivolous inventions. Of course, the availability of patents does result in more inventions of drugs; we do not wish to question this fact – but this positive effect may well be cancelled out by the limitation of the use of patented drugs. The patent system allows the price of patented items to be kept artificially high. The introduction in developing countries – mandated by TRIPs – of product patents in the field of pharmaceuticals will almost certainly lead to a price increase of 200–300%. [4] Moreover, as we noted earlier, pharmaceutical companies frequently take legal action to postpone the introduction of generic alternatives. This hinders the access to drugs even more. So, should we look into the alternatives? There exist a few non-patent methods that support innovation. Such as, fees, awards, acknowledgements, gratitude, praise, security, power, status, and public financial support. [5] Also, research grants and contracts; tax policies; innovative finance mechanisms including research mandates; and innovation inducement prizes are few other alternatives, analyzing them is beyond the scope of researcher and I personally feel patent as the best available option.

Patents are a tribute to human ingenuity. Patent ecosystem has led to remarkable innovations in field of medicines.Theadvocatesofstrongdrugpatents claimthattheimplementationoftheWTO-TRIPs Agreement will offer the following advantages:

(1)the encouragement of local drug research, through which new drugs would become available catering to the country's specific needs (e.g. drugs for tropical diseases);

(2)industrialized countries making important new drugs available in developing countries;

(3)the attraction of foreign investments in the pharmaceutical sector.

Each of these arguments is again susceptible to criticism. Argument in relation with hindrancetoaccessofdrugs,thatisnotcountered yetgivesrisetoourissueof***Patentrights v. Patient Rights.***

2. PATENT RIGHTS INTERFACE WITH PUBLIC'S RIGHT TO HEALTH

Drug patents, particularly the strong kind of drug patents granted today, are hard to

[4] Watal. 2000. *Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement hinder it? (Science, Technology and Innovation Discussion Paper No. 8).* Cambridge, MA. Center for International Development, Harvard University: 5.

[5] E. Hettinger. Justifying Intellectual Property. *Philosophy & Public Affairs*1989; 18: 41.

justify on natural rights, fairness or utilitarian grounds. Many drugs are of vital importance for very large groups of people. This vital importance should be reflected in the debate about the justification of drug patents.

Clearly, fighting not only human rights, but also *Doctors without borders* and Nelson Mandela against a backdrop of dying children to defend a 'trade related' right is difficult public relations battle, one which should never have been waged.[6]

Various claims based on right to health, and right to development demanding access to quality health and medicines, the battle with AIDS, etc. has left scars on pharmaceutical companies
.
Major concern in the interface of patent rights and right to health is the exclusionary affect that may result in difficulty to access medicines. Here we are talking about the right of patent owner to prevent third parties from acts of making, using, offering for sale, selling, or importing the product for these purposes conferred by Article 28.1(a) of Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[7]

The link between medical patents and the human right to health subjects as a central concern at the international level. Article 25 of United Nations' Universal Declaration of Human Rights 1948 states that "Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing and medical care and necessary social services."[8]Human rights law, in particular through Covenant on Economic, Social and Cultural Rights, has made a contribution to the codification of the human right to health and our understanding of its scope.[9]

When we talk about the Right to health in the National aspect, India has been a well-known example of State adopting domestic legislation that fully incorporates safeguards and flexibilities that ensure access to medicines. Article 21 enshrines the right to life. Although not providing explicitly for the right to health, the Indian Supreme Court has consistently interpreted enjoyment of the right to life u/a 21 as including within its scope right to health and access to means by which to achieve health.[10]

The Supreme Court has also made it clear that the Indian govt. has a constitutional obligation to provide health facilities.[11]
Also, part IV of the constitution, Article 47 and various other Directive Principles of State Policy makes improvement of public health a primary duty of State.

Intellectual property law and human rights law have largely evolved

[6] CHRISTOPHE GEIGER,RESEARCH HANDBOOKONHUMANRIGHTSANDINTELLECTUALPROPERTY,96,(Edward Elgar Publishing Inc. 2015)
[7] Article 28, TRIPS Agreement:

[8] Universal Declaration of Human Rights, United Nations, 1948.
[9] International Covenant on Economic, Social and Cultural Rights, New York, 16 Dec. 1966.
[10] *Bandhua Mukti Morcha* v. *UOI,* AIR 1984 SC 802.
[11] *State of Punjab* v. *Mohinder Singh Chawla* 1997 2 SCC 83.

independently. However, with the broadening scope of patents into basic needs such as health, and recent developments in the health sector the links between the two fields are becoming increasingly obvious necessitating further consideration of the relationship between health and patents on medicines, in particular in the case of developing countries like India

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Patents generally constitute an incentive for the development of the private sector in areas where they are granted. In the pharmaceutical sector, the private sector health industry finds them indispensable. Industry representatives argue that the pharmaceutical industry spends more than any other industry on R&D and that, while the development of new drugs is a costly process, it is relatively easy to copy an existing drug. The patent system thus allows firms to charge prices that are higher than the marginal price of production and distribution for the first generations of patients, who are expected to absorb the cost of developing the drug. It is only after the patent protection for the product expires that competition among generic versions can bring the price closer to the marginal cost.

This is in part attributable to the fact that there is a significant tension between the pharmaceutical industry's aim to recoup its investments and governments' interest in containing the costs of healthcare. The issue of patent protection in the health sector has proved increasingly divisive.

Surveys by Taylor and Silberston (1973) of industry participants about the impact of patents on R&D incentives have found the pharmaceutical industry to be critically – and almost uniquely – dependent on patent protection. Other such surveys include Mansfield (1981), and more recently, Levin et al (1987) and Cohen et al (2000) and the various Community Innovation Surveys conducted in EU member states since the early 1990s. In these surveys, pharmaceutical companies show a very high propensity to patent, and research managers typically report that patents are very important to securing competitive advantage, or would reduce R&D by a very large fraction (>50 per cent) if patent protection for pharmaceutical products were removed.

Till now it must be felt that Right to health and patent rights are in conflict with each other but it is not so. Patent rights, in one way or the other increase access and availability of medicines. Let us understand how. Even from a health perspective, TRIPS is justified because, while it protects the interests of the private sector pharmaceutical industry, it also promotes increased R&D in the health sector, which in turn increases the availability of medicines and thus also accessibility. For a detail understanding of the aforesaid concept, the determinants of availability, accessibility and affordability should be known.

Determinants of Availability[12]

[12] WHO report of the Commission on Intellectual Property Rights, Innovation and Public Health: *Public health, innovation and intellectual property rights*, 112 (2006).

Innovation is an important determinant of availability at the level of product development but also at that of local communities. For products where a commercial market exists, delivery is not the end of the story. Rather, the experience with the product in real life situations by large numbers of patients provides new information on responses, side-effects and other characteristics, which may form the basis for further incremental, or even more fundamental, innovation. In a commercial setting it is this feedback from the market-place that contributes to a process of continuous improvement and innovation. Although the experience in the developing country setting may reveal significant deficiencies in the existing treatment regime, the incentive for innovation to improve the regime is lacking. For instance, no new TB drugs have been discovered for about 40 years and the current treatment regime is very lengthy (six months or more), making compliance a big problem, and fuelling the spread of drug-resistant strains. Only in the past few years, as a result of the work of groups such as the TB Alliance, has there been a systematic programme to develop new drugs in combinations which will shorten treatment, improve compliance and combat resistant strains.

Delivery is also about the ability to make existing products available, for which a capacity for efficient local production as well as a capacity to import are important. The adequacy of national health systems – basic infrastructure, adequate human resources with the requisite skills, functioning primary and secondary health-care delivery systems, among many others – are central to making existing treatments available. Investments in health delivery systems are necessarily hampered by a lack of resources. But the diverse experience of countries and regions at different levels of income shows what can be done if there is a political commitment to improved health—success story of Cuba and Kerela.

Cuba is an example of a lower middle income country that has achieved considerable success in ensuring good health for its people. Life-expectancy at birth in Cuba, 76 years, is closer to that in the United States and United Kingdom, 76 and 77 years respectively. Despite its economic challenges, Cuba's public health picture resembles that of far wealthier nations. Cuba's public health achievements are derived in large part from its focus on education and on its health-care system. Cuba remains committed to providing free, universal, and mandatory education up to the 12th grade. Cuba's public health system was also designed to limit disparity, and focus on the principles of universality and accessibility. The strong primary health care system, with doctors and nurses living in neighbourhood clinics, was able to provide comprehensive care for the community. Moreover, the integration of primary, secondary and tertiary services, despite economic strain and limited infrastructure, has led to the strong performance of the public health system in Cuba.

> Kerala's per capita income is only about a hundredth of that in wealthy countries.

Its annual expenditure on health (US$ 28 per person) is much less than that of the United States (US$ 3925 per person), and

yet its performance with regard to standard health indicators is remarkably similar. Life expectancy at birth in Kerala, 76 years for women and 70 years for men, is close to that in the United States, 80 years for women and 74 years for men. In contrast, life expectancy at birth in India as a whole is 63 years for women and 62 years for men.

A number of different factors have facilitated the public health success that Kerala has achieved. Primary among them are the government's focus on education, on access to primary health care, and strong political and financial commitment towards ensuring public health. Also, a large allocation of funds for Education purposes has resulted in its overall development. Moreover, more than 97% of Kerala's population has access to health care, facilitated both by the state's strong focus on primary health care facilities and the substantial work of faith-based organizations in the state. Much like Cuba, Kerala has been able to protect and ensure the health of its people despite facing strong economic challenges.

***Determinants of Accessibilty*[13]**

There are many determinants of accessibility (and indeed availability) which, in particular circumstances, may override economic and other considerations. Policies can be influenced by legal, political, cultural and religious factors. However, the determinants of accessibility on which we will concentrate are principally economic. We have described above, at some length, how availability is dependent on the state of health-care infrastructure and resources provided by governments. The focus here includes factors affecting the price at which products, whether existing or prospective, can be supplied and the funds available to purchase these products (by patients or by others on behalf of patients) or to subsidize further their price. Together these determine economic accessibility. The price of medicines and other health products, even when "at cost" in the poorest settings, and the ability to pay for them, are the critical factors in enhancing or hindering access. The price of the product involved (such as an antibiotic for TB) may not be directly related to the overall cost of treatment. For instance, a new TB antibiotic may itself cost significantly more than its predecessors but the overall cost of treatment may be much lower because the treatment time is shorter, compliance better and the overall call on ancillary services less. Assessing the cost-effectiveness of different interventions requires taking a long-term view of cost, and not simply counting the dollars required up-front for the purchase of a product. In the case of the Brazilian AIDS programme, although the cost of the drugs and administration is high, substantial savings have been estimated, which are likely to exceed the costs of the programme. Apart from direct health benefits (extended life of better quality), direct cost savings include avoided hospitalization. (such as TB).[14]

[13] Ibid.

[14] Baracarolo J, Teixeira P, Vittoria MA. Antiretroviral treatment in resource-poor settings: the Brazilian experience. *AIDS*, 2004, 18(3):S5–S7.

Thus products which are more expensive than their possible substitutes can make economic and financial sense as well as improve health, provided the price remains affordable.

By reading the determinants in detail, we get to know that there are various market short comings that contribute to reduced access and availability of medicines and the reasons for unaffordability due to high price can be because of costly production and low demand other than IP issues.
Nevertheless, the pricing of the product itself is extremely important in developing countries because most medicines are purchased directly by patients, rather than the State or insurers.
A number of approaches may be adopted to ensuring that the prices of drugs and other products are as affordable as possible. There are global policies such as differential pricing, or global funding mechanisms to provide subsidized or free drugs or vaccines. For which we are going to study in brief the pricing policies in a few countries—US & UK (2 most developed super power nations), Germany (European Union country), and China (BRICS nation).

3. PRICING POLICY FRAMEWORK OF PATENTED PHARMACEUTICALS IN DIFFERENT COUNTRIES

United States of America

The US has one of the most efficient patent systems in place. Though, it is world's largest pharma industry, it has excluded pricing system for medicines. There is almost no involvement of government and prices are set by the manufacturers according to the market forces of demand and supply. Emphasis has been laid on clinical and economic data to support reimbursement decisions, the reason being the high penetration of coverage of health insurance products through private sector and public sector products like Medicaid and Medicare. [15] Such kind of highly capitalistic approach is not suitable for country like India.

United Kingdom

UK has one of the best health policies in the World. The National Institute for Health and Care Excellence (NICE) is an executive non- departmental public body of the Department of Health inthe United Kingdom.[16] It serves the English National Health Service (NHS) which is the world's largest public funded healthcare service. It has Pharmaceuticals Price Regulation Scheme valid till 2019. This is a scheme of holistic UK pricing agreement which ensure Value Based Pricing (VBP) through retaining pricing freedom for innovative products. There is Patient Access Schemes on NICE's value assessment.

Germany

Germany has a well defined pricing mechanism. It has an institute of Quality & Efficacy in healthcare which assesses

[15] CIPRA, NlSIU, Bangalore: Conference report on *Affordability, availability, accessibility of Medicines and IPR*, (2016).

[16] Great Britain: Parliament: House of Commons: Health Committee (2013). *National Institute for Health and Clinical Excellence*: Eighth Report of Session 2012-13, Vol. 1: Report.

products and Federal Joint Committee, which decides for additional Health benefits. Prices are determined by negotiations and until the agreement is reached, maybe on the basis of arbitration or cost benefit analysis, the companies can decide whatever prices they want to quote. Thus, Germany has one of the highest medicine prices amongst EU. But still 90% of the population is covered by Statutory Health Insurance which reduces out-of-pocket expenditures.

China

China has high proportion of health expenditure. It used to work on price mark-up system. But with the current reform from June 2015, aiming at Universal Health Coverage, the government has attempted to replace its direct control over the prices of reimbursable drugs with indirect, incentive-driven influence. Although the exact implementation of the reform remains unclear at the moment, the changes introduced so far and the pilot project designs indicate that China is considering adaptation of some form of internal and external reference pricing policies, commonly used in the OECD countries.[17] China also gives high importance to the National Formulary to ensure affordability of new approved drugs.

4. DRUG PRICING MECHANISM IN INDIA

In India, responsibility of price fixation of medicines, revision, etc. lies with the National Pharmaceutical Pricing Authority (NPPA). The Authority is primarily mandated to oversee the implementation of Drugs (Prices Control) Order (DPCO).

The DPCO 2013, notified under the Essential Commodities Act, 1955 adopts the National list of Essential Medicines (NLEM) 2011 for the purpose of determining prices of scheduled drugs.[18] The NLEM drugs are listed in the First Schedule of the DPCO 2013, as scheduled formulations. Those not specified in the schedule are non- scheduled formulations. The NLEM 2011 comprises of 680 scheduled formulations. The DPCO 2013 adopts market based pricing instead of *the cost based pricing of DPCO 1995 i.e.R.P. = [M.C.+C.C.+P.M.+P.C.] × [1+MAPE/100] + E.D.*

Where, RP: Retail price stands for - RP, MC: Material cost, CC: Conversion cost, PM: Packaging material cost, PC: Packaging charges, MAPE: Maximum allowable post-manufacturing expenses, and ED: Excise duty stands for ED.

Market-based pricing is defined as a process of setting prices of goods/services based on the current market conditions, and prices are set according to mutual decision between sellers and buyers.

The prices of scheduled drugs are regulated by fixing the ceiling prices on the basis of simple average pricing of all brands of formulation that have a market share of 1% and above.

[17] http://www.jmahp.net/index.php/jmahp/article/view/30458last viewed on 15th September 2018.

[18] Nishith Desai, *The Indian Pharmaceutical Industry* Business, Legal & Tax Issues, (July 2014) http://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/The_Indian_Pharmaceutical_Industry.pdf

While, prices of non scheduled formulations are not regulated by the govt. but it monitors the MRP of all drugs including the non scheduled ones and ensure that no manufacturer increases the MRP of the drug more than 10% of maximum retail price during the preceding 12 months.

Unfortunately Market based pricing has bearing with cost of medicine, directly it has no relation with cost of medicine; it is simply based on the competitors price prevailing in that therapeutic category.

The following (**Table 1**) further proves my point that how the current market based pricing mechanism is making the drugs costly.

Drug	**Disease**	**Market based pricing (weighted average) (in Rupees)**	**Market based pricing (Simple average) (in Rupees)**	**Cost based pricing (in Rupees)**
Metformin	Diabetes	33	45	14
Atorvastatin	Highbloodcholesterol	142	127	17
Atenolol	High Bloodpressure	51	38.5	8

(Source: Jan SwasthayaAbhiyaan (JSA))

The MBP strategy is certainly not working in favour of common masses-there is strong demand that essential drugs should be sold under generic name- a strategy which India's neighbouring country is pursuing since last 3 decades and as per 2011 statistics the NMR (Neonatal Mortality rate, per thousand live birth) of India and Bangladesh is 34 and 30 respectively; even the U5MR (Under five mortality rate, per thousand live births) of India and Bangladesh is 64 and 52 respectively.

Hence, in my opinion, Indian government should review the drug policy and should consider with a strong base to consider that pricing strategy which the society at large and makes healthcare accessible and affordable to the citizens.

In the whole DPCO, patented drugs are referred to only once in the case of non-application of provisions of the order under para 32 wherein the patented drugs are exempted from price control for a period of 5 years from the date of commencement of commercial production.

ANALYSIS

This price control exemption clause acts as the only reward and motivating factor for the innovators. The fallacious arguments of curbing this period of 5 years is not appreciated at all because at least this much incentive is needed for keeping alive the innovations in Pharma Industry as it allows the inventor to recoup the time and capital invested in the invention. Also, as diseases now a days are gradually becoming resistant to all kinds of prevailing treatments, this calls for newer innovations on a regular basis. Availability and

accessibility can only be attained if innovations are promoted in this manner. In India, presently, according to the IP annual report of 2014-15; no. of drug patent applications filed in 2014 was 2640 and 389 were granted. This figure again proves that India has a strong IP regime with stringent patent laws and higher standard of patentability. If we look at the 389 drug patents granted in the year 2014-15, though the exclusive rights would exist for 20 years from the date of filing the patent application as per Indian Patents Act, but after 5 years i.e. by 2019-20, the number of drugs that fall into the category of scheduled formulations would have their maximum prices ceiled and those falling into the category of non scheduled formulations would have rate of increase of MRP's monitored as per the Drugs price control order 2013. In such case the question of affordability arises only for the first 5 years of price control exemption. This short term trade off is necessary for long term welfare gain that would be achieved once the patent expires. Now, when we understand that this period is very crucial for the development and growth of the patentee group along with the whole Pharma Industry and that right to health cannot be granted at the cost of Innovation. What can be the possible resorts that lie with the government so that the patient group does not have to suffer?

As per my understanding government can resort to following measures:-

For instant relief

- The first thing that comes to my mind is subsidizing the price of patented drugs for which the total public expenditure for 5 years and its feasibility according to fiscal year's budget has to be evaluated and granting of subsidies are economically unadvisable to the government. In such a scenario, if taxes and tariffs on those patented drugs are eliminated and the existing concept of tax holiday or tax exemption is more easily granted, that would somewhat reduce the cost of the drug thereby reducing the out of pocket expenditures.

- Another thing that can be done is bringing in the role of NGO's and non-profit organizations who would work like Robinhood for the patient group by buying medicines from the large funds donated to them by the philanthropic group of the society and providing it to the needy. In recognition of NGOs' value, even the Millennium Declaration recommends that greater opportunities be given to NGOs to contribute towards global health goals. NGOs play a critical role in campaigning for increased and better-coordinated resources for healthcare and promoting sustainable health systems, notably for chronic disease treatment. However, their attention has to be shifted from specific diseases like HIV/AIDS towards other high impact diseases as well and thereby attempting overall health improvement.

Continual measures:-

- Making Renegotiation of prices in periodic intervals integral part of negotiation process. By using threat of compulsory licensing, the government gets a better bargain position. Though, use of compulsory licensing is not advisable at all

because it highly disincentivizes innovation and CL would make India's image as a weak IP regime and abate domestic R&D. It would rather seem fairer to place the burden of proof on the side of the patent holder– in other words, to force the patent holder to prove that granting a compulsory license is not necessary which would prevent the patent holder from abusing his monopoly.

- It should be checked that prices of patented drugs that do not provide a significant breakthrough in treating diseases should not be higher than maximum prices of the other drugs that treat the same disease.

- Developing advance purchases chemist to contribute to the development of vaccines, medicines and diagnostics and improve financing of the purchase of medicines and vaccines and investing appropriately in health delivery infrastructure would lead to greater accessibility and availability.

- Also, encouraging the creation of patent pools would facilitate product development as well as reduced costs.

- Analyzing the health needs of the nation, especially the poor segment and promoting health research that is in line with public health needs and driving research towards priority diseases should be the exact required approach

- A new trend has been observed where Companies tend to spend more on marketing than R&D, this should be discouraged. (see pg19).

- A global R&D treaty could encompass a number of measures that would improve the existing system. For example, countries could commit on making sustainable contributions to an international R&D fund. This fund, analogous in some ways to the US National Institutes of Health, could pay the full costs of R&D so that there would be no need to recoup investments and medicines could be sold at cost, making treatments much more affordable and health systems more sustainable.

Long term approaches

- Academic institutions should be research oriented. A lot of funds are allotted to the institutions for this purpose. Hence, Mandate should be passed that all the Medical universities, bio-tech institutions should come up with substantial research every year, failing to which strict actions would be taken. Academicians should assume the role of researchers. In a Malyalam movie named Ohm Shanti Oshana; wherein the doctor lives with thought that what is the use of being a doctor when he cannot invent a new efficient drug, such mentality should be inculcated which would promote research and development significantly.
- Building efficient domestic R&D and increasing funding for research projects run by public–private partnerships and making that funding more sustainable would enhance affordability.
- Ideally, India's business environment should incentivise innovators to conduct an increasing portion of their R&D and drug manufacturing in low cost hubs within India, thereby decreasing the

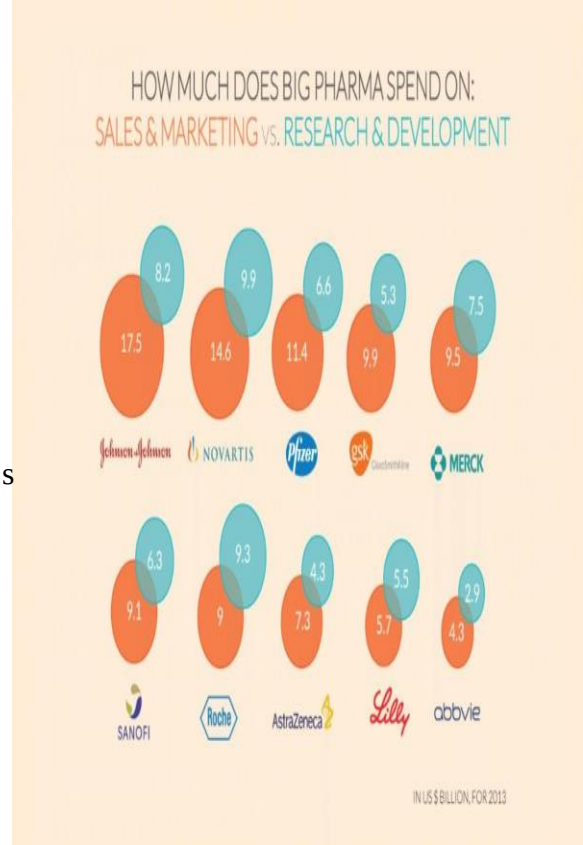
overall cost of drug discovery and development to the benefit of consumers worldwide. A regulatory framework conducive to such a scenario requires serious attention from Indian policy makers.

- Incorporation of digital libraries of traditional medical knowledge into the patent offices' data to ensure that data contained in them are considered when patent applications are processed has proved to be a wise measure. Only need is to work on its development for a wider coverage and a better classification system for its worldwide easy access. The origin of Traditional Knowledge Digital Library (TKDL) goes back to the legal battle waged by Council of Scientific and Industrial Research (CSIR) from India for re-examination of patent No. US 5 401 504, which was granted for the wound healing properties of turmeric filed by two US based Indians. In a landmark decision, United States Patent and Trademark Office (US PTO) revoked this patent after ascertaining that there was no novelty, the innovation having been used in India for centuries. This was the first time that a patent based on the traditional knowledge of a developing country was challenged successfully and US PTO revoked the patent. The case of the revocation of the patent granted to W.R. Grace Company and US Department of Agriculture on Neem (EPO patent No. 436257) by European Patent Office, again on the same grounds of its use having been known in India, is another example.[19] TKDL will not only prevent frivolous patents but at the same time promote innovation as it acts as a bridge between modern science and traditional knowledge, and can be used for international advanced research based on TK for developing novel drugs.
- Fewer failures at the lab and development stage can drastically reduce the cost of a new drug. Such an approach is wholly welcome. In India, policymakers should be equipped to assess the real cost of a patented drug.
- And last but most important, India too like various other countries should aim Universal Health coverage. In the absence of effective health insurance system, out of pocket expenditures for purchase of health care and more so for drugs is ever increasing. Health insurance in India has just begun to emerge for select population. Nearly, 79% of the health expenditure is borne by the private individuals out of their pocket while only 21% is covered by govt. or insurance companies. Thus, strong and efficient health coverage and reimbursement policy is the need of the hour and has to be developed as soon as possible.

The scale and complexity of today's global health problems, calls for a joint action. While governments continue to hold the primary responsibility for ensuring access to health- care and essential medicines for all their citizens, pharmaceutical companies are expected to assume their share of responsibilities. Some companies like GSK and Dr. Reddy have understood this but others still remain ignorant. For instance, a new trend has been observed where Companies tend to spend more on marketing than R&D.

[19] V.K. Gupta, *TRADITIONAL KNOWLEDGE DIGITAL LIBRARY,* Asia-Pacific Database on Intangible
Cultural Heritage (ICH) by ACCU, 2005.

The biggest spender, Johnson&Johnson, shelled out $17.5 billionon sales and marketing in 2013, compared with $8.2 billion for R&D. In the top10, only Roche spent more on R&D than on sales and marketing. Most of this marketing money is directed at the physicians who do the prescribing, rather than consumers.[20]



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Source: Dadaviz

At the same time, Pharmaceutical firm Glaxo Smith Kline has already said it wants to make it easier for manufacturers in the world's poorest countries to copy its medicines. [21] And thus it would not file patents in some 50 countries while in lower middle income countries it will continue to file patents, but will grant licenses to generic manufacturers in exchange for a “small royalty”. It would continue to seek full patent protection in richer parts of the world.

The experience GSK has with the Medicines Patent Pool for Tivicay- their newest HIV medicine and one of our most commercially successful products-gives us confidence that increasing access, incentiveising innovation appropriately and achieving business success can go hand in hand.[22]This is a brave and positive step towards broadening the access to important new medicines in the developing world.

With the help of DRF (Dr.Reddy’s Research foundation) and an ever increasing production capacity, Dr. Reddy’s has been able to alleviate the financial burden many people face when trying to obtain lifesaving medication. Emphasizing the importance of access to medicine for everyone, many of the medicines Dr. Reddy’s launched in to the Indian market are so affordable that even a rickshaw driver in a remote village can afford them.[23]

[20] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/lastaccessedon24/01/2017.

[21] http://www.bbc.com/news/health-35933692accessedon16/01/2017

[22] Ibid.

[23] http://www.wipo.int/ipadvantage/en/details.jsp?id=2659accessedon27/12/2016

These examples should set precedent for the major pharmaceutical firms to follow as company's assuming of its share of responsibilities would help Indian Pharmaceutical Industry has to emerge in a way that both producers as well as customers reap the benefits. Now, more than ever, we must act. As academics, researchers and scientists it is our responsibility to generate and transmit knowledge. And we should think about striking a balance in accordance with the Government for better policies in the sector.

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