PHARMACEUTICAL PATENTING IN INDIA: PROBLEM OF PUBLIC ACCESS TO HEALTH

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ABSTRACT

In India, a large part of the population living below the poverty line, with expenses towards healthcare out of pocket; have been living in a significant health crisis with the inability towards accessibility, affordability and availability of the medicine.

Today, IPR Laws are getting more and more popular. They provide relief to the innovative minds ensuring their inventions, ideas, and discoveries remain theirs. Amongst these laws, patent laws have assumed maximum importance. However, where medicines are concerned, these patent laws act as a blockage to the access of these essential commodities. India has become a pioneer in the developing world with attempts towards adapting pharmaceutical patent law, taking account of the domestic health needs of its citizens thereby facilitating its national development.

The issue of access to medicines has assumed global dimensions since several decades ever since India became a part of the Doha Declaration on the TRIPS Agreement and Public Health, 2001. The recent patent law decisions including that of the Supreme Court in the *Novartis case*[i] have indicated that India has continued to put a premium on public health in relation to pharmaceutical patent law decisions. This article deals with the meaning of pharmaceutical drugs, the process of its patenting in India, and the problems that and the problems it follows, thereby disabling and making difficult the public access to health.

CONCERNS OF AVAILABILITY, AFFORDABILITY AND ACCESSIBILITY OF PHARMACEUTICAL DRUGS

In 1994, India had signed the TRIPS agreement as had been negotiated in the Uruguay round of the General Agreement on Tariffs and Trade (GATT) treaty post which India was required to introduce patents on products by January 2005.[ii] The same seemed to have affected the developing and third world countries in two ways:

a) By the direct undercutting of the supply of affordable medicines and;

b) By indirectly removing the generic competition that India had been long thriving on through the supply of copies of the patented medicines cheaply throughout the world's poor regions.

The availability and affordability of curative pharmaceutical products medicines are problems encountered by a majority of developing countries.[iii] It must also be kept in mind that grant of patent protection is not the only problem endangering the health of the people in the third world or developing countries. The life-threatening diseases which the people of the developing and third world countries suffer are much less investigated.

The problems related to affordability, accessibility and availability arose because:

a) The innovators were to be granted patent protection this indirectly led to monopoly pricing powers being given to the innovators for considerable lengths of time and the common man is unable to afford medicines that are still under patent protection.

b) The medicines were priced way beyond the affordability power of the common man in the developing and the third world countries most of whom are poor, this has affected the accessibility of medicines.

c) The kind of drugs needed for the curability of diseases suffered by the poor are never developed thereby affecting the availability of such medicines.

Despite of the same, one can note a brighter side which benefitted the developing countries after signing the TRIPS agreement they were:

a) The signing of the TRIPS agreement had the potential of awakening the interest of the pharmaceutical companies in developing pharmaceutical drugs for type 3 diseases[iv] which would enable the needs of the minority.

b) Once the term of the patent protection is over, these pharmaceutical drugs would be able to reach the third world countries which are in dire need of medicines for the poor.

INDIAN DEPENDENCE ON THE PHARMACEUTICAL DRUG INDUSTRY

The pharmaceutical drug industry in India has developed a strong generic base with almost thousands of generic brands in the market which was fostered by the then legal structure regarding patent. The domestic pharmaceutical industry has evolved in a manner that it has contributed to India's success.

Back in the1950s, India used to be an import dependent industry. In today's date, the pharmaceutical sector in India has reached the levels of global recognition as a low-cost producer of high-quality pharmaceutical products and according to reports, has a turnover of approximately $1.5 billion through its exports. This can also be credited to a no product patent system for drugs and pharmaceuticals in India before.[v]

RAMIFICATION OF THE TRIPS AGREEMENT ON PHARMACEUTICAL INVENTIONS IN INDIA

The TRIPS Agreement gives member states some slack ensuring that the protection of intellectual property rights (IPRs) does not invade public health interests within states.[vi] Patent protection acts as the mainspring of a healthy research environment in any country as patents protect new inventions from exploitation, and process patents act as the protectors of the method of production of a product.[vii] India's assent to the World Trade Organization (WTO) and its obligation to enforce the TRIPS Agreement has indeed resulted in drastic change in Indian pharmaceutical industry.[viii]

RIGHT TO HEALTH V. RIGHT TO PATENT

Right to health has been recognized as a fundamental right not only in India but also in the rest of the world. The TRIPS Agreement also asserts that its member countries may exclude from patentability; certain inventions, the exploitation of which could be necessary for the protection of public order and morality in order to prevent a serious prejudice to the environment.[ix] Therefore, one can say that the right to health care or access to health care at affordable prices has become a universally recognized human right. A country like India, with a variety of socio economic settings, needs to design on priority, national health programs with enough flexibility to permit the state public health administration to craft its own programs according to the present needs.

IMPACT OF COMPULSORY LICENSING ON PHARMACEUTICAL DRUGS

The WTO countries may provide for different forms of compulsory licenses in respect of patents that are explicitly authorized by the TRIPS Agreement.[x] Compulsory licenses as set out in the TRIPS Agreement are intended a strike a balance between public interests and the legitimate interests of the owners of the patents.

Compulsory licensing will enhance the public interest while still maintaining the incentive to develop new inventions, it is important to keep in mind that compulsory licensing be allowed only where it is necessary to promote public interest, not significantly reducing the incentive to develop a new drug.[xi]

CONCLUSION

The TRIPS Agreement by its flexible mechanisms such as compulsory licensing, parallel importation, and opposition of patent has tried to balance the access to medicines or treatment along with preserving the intellectual property rights. The “flexibilities” under TRIPS provide sufficient room for developing countries to secure their interest.

After analyzing the status of India's pharmaceutical industry and the scope of the generic drugs in India as well as outside India and the various legal instruments and legislations regarding health, compulsory licensing has an important place in the patent system as the compulsory license acts as an important tool to balance out the interest of various IP and public health stakeholders. The government should step in to take pro-active measures to ensure accessible healthcare for all, insurance schemes where health coverage extends to the poorest of the poor, its only then can we translate mere good health on papers to practice.

ENDNOTES

[i] *Novartis AG v. Union of India* (2013) 6 SCC 1: (2013) SCC (Civ) 227: (2013) SCC OnLine SC271 decided on April 1, 2013. A division bench of Aftab Alam and Ranjana P. Desai, JJ.
[ii] Peter Singer and Doris Schroeder, "Ethical Reasons for Intellectual Property Rights Reform: A Report (D1.3) for Innova-P2", available at: http://healthimpactfund.org/wpcontent/uploads/2012/11/DP7_Singer_and_Schroeder.pdf (last visited on July 16, 2021).
[iii] T G Agitha, "Global Governance for facilitating Access to medicines: Role of World Health organisation" 18 Journal of Intellectual Property Rights 589 (Nov. 2013).
[iv] Diseases that occur exclusively or overwhelmingly in poor countries.
[v] Nidhi Joshi, "Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India" 1 Delhi law review 104 (2005).
[vi] Emmanuel KolawoleOke, "Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes" available at: http://www.hhrjournal.org/2013/12/06/incorporating-a-right-to-health-perspective-intothe-resolution-of-patent-law-disputes/html (last visited on July 16, 2021).
[vii] National working group on patent laws and public interest legal support and research centre, Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970, available at: http://www.who.int/intellectualproperty/documents/Report4thCommission.pdf (last visited on July 16, 2021).
[viii] *Ibid.*
[ix] Art. 27(2) TRIPS Agreement, 1995
[x] Art. 31 TRIPS Agreement.
[xi] Surabhi Shekhawat, "Compulsory Licensing of Pharmaceutical Patents, 5 Madras Law Journal 36 (2014).