AIRO JOURNALS
Free / Unpaid
Peer Reviewed
Multidisciplinary
International
ISSN: 2320-3714
Volume:4 Issue:2
November 2021
Impact Factor:6.7
Subject:Law

Access to essential medicines is a part of Right to health

[1]K. JAMEELA, [2]Dr. SANJAYA CHOUDHURY
[1]Research Scholar, Deptt. of Law, Bhagwant University, Sikar Road, Ajmer, Rajasthan
[2]Professor of Law, Bhagwant University, Ajmer, Rajasthan

Abstract: The objective of this paper is to analyze and trace the development of the patent law system in India and its development in response to pressures from globally influential intellectual property frameworks, such as TRIPS and developed countries, the US and Europe, so that cash-rich pharmaceuticals can grow in India. Allowed to expand its market opening and Companies have been made to sell their medicines and get patent protection in India. An overview of legislative actions and judicial responses has revealed that it aims to promote the generic drug industry through a protected interpretation of Section 3(d) and at the same time protect the health care needs of the poor as the supreme authority of Parliament and the judiciary. Both the levels have to be very careful. According to the Patents Act, 1970, it has been intended to critically analyze the legislative reforms and judicial interpretations of patent law in the light of the socio-economic needs of the country.

Keywords: TRIPS, US, India, Economics, Section, Country etc.

Introduction

Activists fear that major changes to drug pricing policy could result in more expensive drugs in India. A government committee formed about a month ago is considering changes in the prices of medicines. "We are working with the objective of 'ease of doing business' and 'Make in India'," the committee's principal health secretary CK Mishra said. The new price policy of medicines will be in line with this. These discussions within the government have upset health workers working on drug pricing. Malini Aisola of All India Drug Action Network said, "It is clear that the policy change is meant to give a unilateral boost to the industry." "All gains made in previous years in reducing drug prices will be reversed."[1]

It is an established law that the right to health is included in the right to life guaranteed by Article 21 of our Constitution. It is undeniable that the availability of essential medicines to combat

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serious diseases is a component of the right to health. If a person cannot access essential medicines due to poverty or economic incapacitation, the brutal reality is that the person is likely to fall victim to a fatal disease and the right to life will be violated.[2]

A Supreme Court bench comprising Justices GS Singhvi and SJ Mukhopadhyay recently directed the central government to give details of the steps taken by the Center to check the prices of 348 drugs on the National List of Essential Medicines (NLEM). The PIL petitioner's contention before the Court was that though there were 348 drugs in NLEM, the prices of only 37 drugs were controlled by the National Pharmaceutical Pricing Authority. Over the past two years, the Court had repeatedly asked the government to put in place a mechanism under the price control regime, essential medicines that are used by poor patients to fight diseases, but to no avail. In this context, the Bench asked the secretaries of the Ministry of Health and the Ministry of Chemicals and Fertilizers to file affidavits stating whether the central government wanted to bring essential drugs under price control.[2]

The alleged impediment due to Intellectual Property Rights (IPRs) for access to essential medicines by the poor in developing countries has been the subject of fierce controversy since the finalization of the Agreement on Trade-related Aspects at the World Trade Organization (WTO). Intellectual Property Rights (TRIPS) in April 1994. The purpose of this chapter is to examine whether it is a fact that the provisions of TRIPS hinder access to essential medicines.[3]

Right to Health

Exemption on patented drugs under NPP is a violation of the right to life under the Constitution of India. Recognizing that the fundamental right to life in Article 21 of the Constitution emphasizes the value of human dignity, the Supreme Court began to address the importance of health as a fundamental right for Indian citizens. Apart from Article 47, the origin of the Right to Health is also in Articles 3836, 39(E), 4138 and 48A of the Directive Principles. In 2001, Jorge Odir Miranda Cortez v. Director of the Salvadoran Institute of Social Security, the Supreme Court of El Salvador held that the El Savadorian government should provide ARV therapy and other drugs that prevent death and improve the quality of life of individuals[4]. The State shall endeavor to promote the welfare of the people by promoting the welfare of the people.- (1) The

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State shall endeavor to promote the welfare of the people by securing and preserving a social order which shall have justice, social, economic and political shall inform all the institutions of national life. (2) The State shall, in particular, endeavor to reduce inequalities in income, and inequalities in status, facilities and opportunities not only among individuals but also between groups of people residing in different regions or engaged in different occupations. Will try to remove Certain principles of policy to be followed by the state:- The state shall, in particular, direct its policy towards securing it. (e) that the health and strength of workers, men and women and the tender age of children are not abused and that citizens are not compelled by economic necessity to enter occupations inappropriate of their age or strength.[5]

Right to work, education and public assistance in certain cases - The State shall, within the limits of its economic capacity and development, make effective provision for the right to work, to education and to public assistance in cases of unemployment. In case of old age, sickness and disablement, and in other cases unwanted deprivation

Article 48A: Protection and improvement of the environment and protection of forests and wild life - The State shall endeavor to protect and improve the environment and to protect the forests and wildlife of the country[6].

In 40 consumer education and research centers and others v. Union of India, (1995) 3 SCC 42, The Supreme Court held that the right to health and medical aid is a fundamental right to protect health and that health implies more than the absence of disease. The Supreme Court, in another case, State of Punjab and Ors. Vs Mohinder Singh Chawla, (1997) 2 SCC 83,7 reiterated that the right to health is an integral part of the right to life and it is the constitutional obligation of the government to provide healthcare. Amenities. Living with HIV/AIDS.[8] The court based its decision on the importance of the rights to life and health. In addition, a Colombian appellate court recently held that the health ministry violated the right to health by Abbott not complying with Kaletra's reference value. As a result, the ministry implemented this requirement and the price of Kaletra was reduced by 70 percent. Therefore, this policy of the government is violating the right to health and life of people living with HIV/AIDS by not bringing affordable patent drugs under the price control policy of the government, which is being implemented with the main objective of providing access and for affordable lifesaving drugs.[9]

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Also in the ongoing Supreme Court litigation, in All India Drug Action Network (AIDAN) v Union of India, the Supreme Court of India, during a hearing in July 2012, held that the government should do everything possible to provide access to life saving needed. Therefore, the patent exemption should be reconsidered for 5 years before the actual notification of the price drug order takes place and the patent drugs should be brought within the price control policy of the government.[10]

Problem in accessing essential medicines

Expenditure on medicines can represent up to 66% of total health spending in developing countries and can be a major cause of household impoverishment, as 50–90% of such spending is out-of-pocket. Today, more than a third of the world's population and more than half of the poorest people in Asia and Africa still do not have access to essential medicines. According to WHO, such access should include medical, physical and financial aspects i.e. cover primary health problems, be available within easy physical reach and be affordable to all.[11]

Availability and affordability of essential medicines are both major problems for the poor in developing countries. Some fear that with the introduction of stronger product patents for medicines through the worldwide uniform standards of the WTO TRIPS agreement, the prices of essential medicines will be even higher and, therefore, less affordable for the poor. This is because such patents give their owner the right to exclude everyone else from unauthorized making, using, selling or distributing the product, thus giving a 'legal monopoly' right. However, others say that some drugs listed as essential by the WHO are currently covered by patents.[12] This is almost by definition, as affordability is one of the criteria used in the selection of these drugs.[13] Lack of sufficient purchasing power and necessary infrastructure will result in poor access to drugs even in the absence of patents.

The case of HIV/AIDS in developing countries has focused on patents and prices. An estimated 95% of people with the disease live in developing countries where the disease shows no signs of reduction. More than half of such individuals are in the most productive age under 25, the disease posing serious social and economic consequences. Being a relatively new disease, many drugs are still under 'live' patent protection, with expiration dates of a decade or more.

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Before TRIPS, most developing countries and some developed countries excluded drugs from being patented even if they met the criteria for being new and inventive. Today, almost all of these countries are members of the WTO and enforce TRIPS, thus requiring the filing of patents for new pharmaceutical inventions and granting product patents or similar exclusive marketing rights on them since at least 1995 permitted, where eligible.

It should be noted that even under the TRIPS regime, patents are to be granted only on applications received since 1995 for new, patentable pharmaceutical inventions. Thus, the prices of existing drugs already in the market, or even those covered by patent applications before 1994 anywhere in the world, should not be affected by TRIPS, as these markets remain as competitive as before. The required patent period is 20 years from the date of application. Patent owners typically file for patents only in critical markets or where they are particularly susceptible to theft. Therefore, even when a patent is available, a patent cannot be requested in every developing country.

In addition, the patent owner's ability to price the product above its marginal cost is largely governed by the availability of close substitutes: the greater the number of effective substitutes, the less the patentee's ability to raise the price without losing revenue and profit. . It is rare to find a disease condition that can only be treated with a patented drug. Often a successful patented drug gives rise to "me-to" products that invent around it.

Estimation of price difference of drugs due to patents

There are few reliable estimates of differences in drug prices in developing countries due to patents alone. A simple and attractive method often used is intra-country comparison of drugs of similar composition and presentation. However, such a comparison is clearly flawed, because without more information, one cannot attribute the differences to the presence or absence of patents alone. Even comparing prices between countries with similar levels of economic development only gives a partial picture.[17]

A more meaningful study would be the effects of generic entry on patented drugs, for which, of course, data is not yet available in these countries. Several studies using data on the US market show that there is a significant and rapid price decline with generic entry upon patent expiration.

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For example, one study shows an average generic/branded price ratio of 0.59 after patent expiration with only one generic manufacturer and 0.17 with twenty such manufacturers. This is partly because, perversely, the price of the LEED brand, which has lost patent protection, is actually increased to protect the total revenue.[14] A more recent report suggests that the average retail prescription price for innovative drugs from a single source can be up to 300% higher than prescription generic drugs.[15] A simulation study by this author for the Indian pharmaceutical market, controlling for substitutes, shows similar price differences. Under some estimates the price increase due to product patents alone could be as much as 250%.[16]

Conclusion

It is imperative for the government to reconsider the exemption clause for patented drugs under the NPP, 2012 allowing exemption from price control of patented drugs for a much shorter period, and put in place a robust mechanism by which prices can be reduced. These drugs could be made accessible to save the lives of many people living with HIV/AIDS. The TRIPS agreement includes flexible mechanisms to balance access to remedies with protection of intellectual property rights, such as compulsory licensing, parallel imports and patent conflict procedures. This change will almost certainly lead to higher prices for patented drugs by about 200-300%, including critical diseases such as HIV/AIDS, in countries where such patents are valid. Policy instruments available under TRIPS such as compulsory licenses or government use, parallel imports and price controls can mitigate such adverse effects on affordable access to drugs considered essential. None of these tools is without some disadvantages and should be used with caution. Finally, despite pressures from some sectors, developing countries need not go beyond the need for TRIPS. However, these tools will inherently be limited in increasing access to treatment as the successful implementation of each depends on a number of legal, administrative and political factors. Litigation and unsuccessful patent conflicts with Novartis5051 are just a few examples of limitations that further delay or deny access to affordable lifesaving drugs. , The Government of India should reconsider this and consider whether the best interests of the country allow an inclusive price control policy or conflict with other restrictive or limited provisions available. TRIPS has virtually required the availability of

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product and process patents for pharmaceuticals since 1995, dramatically changing patent laws in developing countries that previously allowed such exclusions.

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