pISSN: 2454-7107, eISSN: 2455-4189

Indian Journal of Law and Human Behavior
Volume 3 Number 2, July - December 2017
DOI: http://dx.doi.org/10.21088/ijlhb.2454.7107.3217.5

Review Article

Right to Access to Essential Medicine: A Study under Indian Legal Framework

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Received on 15.11.2017
Accepted on 24.11.2017

Abstract

Right to health is one of the most important human rights in the world. Since health is wealth and disease is a common phenomenon, right to access to medicine is an important human rights. The UN Working Group on Access to Medicines identified six barriers to access to medicines in resource-poor countries 1 which include inadequate national commitment; inadequate human resources; failure of the international community to keep its promises of assistance to developing countries; lack of coordination of international aid; obstacles placed by the Trades Related Intellectual Property Rights (TRIPS); and the current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries.

Keywords: Medicine; Vaccines; Right to Health; Access to Medicines; Essential Medicines etc.

Introduction

Access to essential medicines has gradually come to be recognized as part of the human right to health, enforceable under both international and national laws [1,2,3]. The right to health first emerged as a social right in various international covenants details the progressive realization of the right to health through concrete steps, including access to health facilities, goods and services [4]. Arguably one of the most significant developments in the battle for universal access was the 1978 Alma Ata Declaration [5] on the same. "Essential Medicines", according to the World Health Organization (WHO), "are those that satisfy the priority health needs of the population" and, "are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at prices the individual and the community can afford [6]. The UN Working Group on Access to Medicines identified six barriers to access to medicines in resource-poor countries [7] which include inadequate national commitment; inadequate human resources; failure of the international community to keep its promises of assistance to developing countries; lack of coordination of international aid; obstacles placed by the Trade Related Intellectual Property Rights (TRIPS); and the current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries.

Concept of Essential Medicines and It's Development

'*Essential medicines*', according to the World Health Organization (WHO), are those that "satisfy the

priority health care needs of the population" and "are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford [8]."

The United Nations Development Group defines '*access*' in this context as "having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour's walk from the homes of the population [9]." Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in international law.

But unfortunately, about 2 billion people lack access to essential medicines [10]. This deprivation causes immense and avoidable suffering [11]. Besides deprivation, gross inequity in access to medicines remains the overriding feature of the world pharmaceutical situation [12] and save many lives across the globe [13]. Now, let's have an overview on the emergence and chronological development of the concept of right to access to essential medicines internationally.

- The World Health Organization (WHO) Constitution (1946);
- The Universal Declaration of Human Rights (1948);
- The International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966 [14].
- The General Comment 14 (2000) on the WHO Action Programme on Essential Drugs".
- Strategic Objective 11, the WHO Medium Term Strategic Plan for 2008-2013.

Millennium Development Goal & Right to Access to Medicine: The MDG Gap Task Force addressed the relation between the MDG issue of access to medicines and the right to health by noting that:

"…Health is a fundamental human right recognized in at least 135 national constitutions. Access to health care, including access to essential medicines, is a prerequisite for realizing that right. However, only five countries specifically recognize access to essential medicines and technologies as part of the fulfilment of the right to health [15]."

The Working Group on Access to Essential Medicines of the United Nations: The Group gave priority consideration to improving access to medicines in resource-poor settings and promoting research on new medicines for diseases of poverty. It identified six barriers to access the medicines which are as under-

- Inadequate national commitment,
- Inadequate human resources,
- Failure of the international community to keep its promises to developing countries,
- Lack of coordination of international aid,
- Obstacles created by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, and
- The current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries

Factors Contribute to Making Essential Medicines Available: -

Numerous factors contribute to making essential medicines available in poor countries [16]-

- Affordable prices;
- Government commitment through a well-conceived and implemented national medicines policy (NMP);
- Adequate, sustainable and equitable public sector financing;
- Generic substitution;
- Transparent and widely disseminated consumer information;
- Efficient distribution;
- Control of taxes, duties and other mark-ups; and
- Careful selection and monitoring.

R& D vis-à-vis Essential Medicines

As a component of the right to health, the right to essential medicines depends not only on the production, distribution, and pricing of medicines, but also on the incentives for research and development of drugs needed to treat diseases in developing countries, functioning health systems so that drugs are part of a rational system of quality treatment and care, as well as on infrastructure [17]. There are a good number of impediments in existence to the realization of the right to essential medicines e.g. the *protection of intellectual property; the international trade regime*. The global IPR system is increasingly being questioned with regard to both its implications on access to medicines as well as its effectiveness in stimulating research and development (R&D), notably for diseases that are mostly prevalent in developing countries [18].

Meanwhile, the role of public sector investments in medical R & D is probably not always appreciated sufficiently, in spite of several instances where publicly funded R & D has contributed enormously to the advancement of medical knowledge. The Human Genome project is a prominent example. Thus, interest to develop alternative or complementary models to stimulate R & D is growing; this is, among others, illustrated by the relatively recent creation of several public–private partnerships [19]. Now let's have a look on the conflicting issues pertaining to this area-

- Protection from unauthorised Exploitation of Patents: Patent, protects the inventor from using the idea without license, and allow the inventor to set the price. Countries that fail to protect patents are now brought before the dispute settlement body of the WTO. As a result, in part due to the outcry over drug pricing in countries confronted by the HIV/AIDS pandemic, the least-developed countries, who were originally supposed to comply by 2006, now have until 1 January 2016 to implement TRIPS.
- Production of Drugs for Non- Medical Needs: Unfortunately, new drugs developed in recent years are useful to combat lifestyle diseasesi.e. aiming a market that can pay, while too few drugs are being developed for major public health problems prevalent in developing countries such as malaria, tuberculosis and helminthiasis. The challenge for developing countries is to put in place legislation that allows access to such products, without dampening the incentives for innovation. High price of medicines is driven by patent monopolies, limit access to medicines. In addition, the search for "blockbuster drugs" skews drug development in favour of new drugs for which there are buyers who are willing and able to pay high prices.
- Royalty and Pricing of Medicines: There is no international authoritative guideline for determining royalty rates, and hence, extensive flexibility is available in how to compute these rates [20]. Further, when a non-voluntary license is issued, the most contentious element in the discussion is about the computation of the royalty rate to compensate the patent holder. The TRIPS text provides some major ground rules for computation. Canada and Japan have developed national guidelines for determining royalty rates. There have also been proposals for a "tiered royalty rate" with a rational relationship between amount of royalty and the ability to pay [21].

The Doha Declaration, the deliberations of IGWG (*Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*) etc. events played an important role in minimising the tension between the claim of IPRs and the right to access essential medicines keeping in mind the idea that the scope of the later is much broader than a claim against the negative impact of IPRs.

Rights to Access to Medicines: A Global Approach

In a conflictbetween the claim of IPRs and the right to access essential medicines keeping in mind the idea that the scope of the later is much broader than a claim against the negative impact of IPRs. A good number of international instruments addressed this issue. Let's have a discussion on the same-

ICESCR (International Covenant on Economic, Social and Cultural Rights, 1966): The ICESCR interalia speaks about the followings having linkage with the right to medicines-

- Access to essential medicines can be affirmed as a human right on the basis, not only of the right to health as discussed under Article 12;
- The rights "to the protection of the moral and material interests resulting from any scientific, literary or artistic production" (Article 15(1)(c)) and
- "To share in scientific advancement and its benefits" (Article 15(1)(b)).

Article 15(1)(c) seems to protect the 'right' of pharmaceutical companies to earn a profit from the drugs they develop, by setting prices that render medicines inaccessible to the destitute sick, while Article 15(1)(b) seems to protect the 'right' of those destitute sick to benefit from the development of new drugs. The way out of this dilemma is to distinguish intellectual property rights from human rights and consider them a temporary monopoly established for the valid social purpose of encouraging scientific invention and artistic creation. In other words, an IPR is a legally protected interest of a lower order than a human right, which implies a superior moral and legal claim. This distinction should not be interpreted to imply that IPRs do not have social value for, indeed, they have a very high value, justifying limiting Article 15 rights reasonably to promote innovation and creativity.

Commission on Human Rights

The *Commission on Human Rights* adopted a resolution in 2001, in which it recognized "that

access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

WHO: The World Health Organisation (WHO) stated, "to refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them [22]."

TRIPs Agreement

The TRIPs Agreementon the matter of pharma products stated "to ensure that their actions as members of international organizations take due account of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and that the application of international agreements is supportive of public health policies which promote broad access to safe, effective and affordable preventive, curative or palliative pharmaceuticals and medical technologies [23]. Further, Parallel importing of pharmaceuticals reduces price of pharmaceuticals by introducing competition; TRIPS agreement in **Article 6** states that this practice cannot be challenged under the WTO dispute settlement system and so is effectively a matter of national discretion.

Doha Ministerial Meeting of the WTO

The right to essential medicines was discussed broadly in the Doha Ministerial meeting of the WTO which resulted into the Doha Declaration on the TRIPS Agreement and Public Health, 2001. The meeting declared: "*The TRIPS agreement does not and should not prevent members from taking measures to protect public health … in particular to promote access to medicines for all [24].*" It further reaffirmed *the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose*," meaning parallel importing and compulsory licensing [25]. The next paragraph instructed the Council for TRIPS to find an expeditious solution to the problem of compulsory licensing for countries "with insufficient or no manufacturing capacities in the pharmaceutical sector," which was done in August, 2003. The Doha Declaration also extended the deadline to 1 January 2016 for the least-developed countries to apply provisions on pharmaceutical patents.

The Committee on Economic, Social and Cultural Rights, 2001:

TheCommittee included among the facilities, goods and services which must be available in sufficient quantity within the state "essential drugs, as defined by the WHO Action Programme on Essential Drugs". As a part of the obligation to protect, the committeestrongly suggested that the states should intervene where marketing of drugs by pharmaceutical companies is detrimental to the right to health. Further, the General Comment 17, adopted in 2006, the Committee affirmed, "In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. The Committee further stated, that the states parties should "… ensure that their intellectual property regimes constitute no impediment of their ability to comply with their core obligations in relation to the right to health … States thus have a duty to prevent that unreasonably high license fees or royalties for access to essential medicines … undermine the right … of large segments of the population to health.. [26"

Existing Legal Mechanisms Supporting the Ideas of Right to Access to Medicines

As a matter of solution, the global community has started to find out the ways how this issue may be sorted out. Presently, in addition to the delayed compliance until 2016, developing countries may avail themselves of 'flexibilities' to avoid patent protections through parallel importing (importing cheaper versions of drugs from countries where pharmaceuticals are not patented or where their term of protection has expired) and Compulsory licensing.

- *Parallel Import:* An *import of parallel product* is a non-counterfeitproduct imported from another country without the permission of the intellectual property owner. Parallel imports are often referred to as *grey product*, and are implicated in issues of international trade, and intellectual property. Parallel importing is based on concept of exhaustion of intellectual property rights: According to this concept, when the product is first launched on the market in a particular jurisdiction, parallel importation is authorized to all residents in the state in question. Some countries allow this, others do not. In this connection, we may refer to the following approaches-

EU (*European Union*): The European Union (and European Economic Area) requires the doctrine of international exhaustion to exist between member

states (contracting states) but EU legislation for trademarks, design rights and copyright prohibits its application to goods put on the market outside the EU/EEA.

USA: The USA allows the parallel products.

INDIA: In India, the issue of parallel import is addressed as follows-

The approach under the Trade Marks Act, 1999

Section 27(1) suggests that no person shall be entitled to institute any proceeding to prevent, or to recover damages for the infringement of an unregistered trade mark.

Section 30(3) provides that: [w]here the goods bearing a registered trade mark are lawfully acquired by a person, the sale of the goods in the market or otherwise dealing in those goods by that person or by a person claiming under or through him is not infringement of a trade by reason only of- (a) … or (b) the goods having been put on the market under the registered trade mark by the proprietor or with his consent.

Views of the Ministry of Commerce

The Ministry of Commerce views parallel trade as benefitting the consumer and as a 'mechanism for price control'. In a communication to the WTO on investor's obligations the Ministry of Commerce described restraints on parallel imports as 'anti-competitive practices.

A Division Bench of the Delhi HC in *Kapil Wadwav. Samsung [27]* held that India follows an international exhaustion regime which legalizes parallel imports of trademarked goods. Further, in *Philip Morris Products S.A &Anrv.. Sameer &Ors [28]* considering the arguments, the court first established that India follows an international exhaustion regime for trademarked goods as per Kapil Wadwa v Samsung (2012), interpreting S. 29 and S. 30(3)&(4) of the Act and stated that the burden of proving that the initial purchase of the trademarked good was legal on the importer: "*The importer/defendant has to prove that the impugned goods, bearing a particular trademark, were placed in any market worldwide by the registered proprietor of the said trademark or with its consent and thereafter, the defendant lawfully acquired them therefrom.*" Therefore, once goods have been lawfully purchased i.e. purchased in accordance with the laws of the country of purchase, the sale of such goods in India would not infringe the registered trademark in India. However, it was on the importer to prove that the goods had been lawfully acquired.

Development of Generic Drugs: Patents are granted with the understanding that they will be accompanied by "full disclosure" about the contents of the patent. Full disclosure usually means providing enough detail for a "person skilled in the same area of technology to construct and operate" the patented object. Some observers have, however, noted a tendency to disguise or omit important details in patent documents; this undermines the concept of full disclosure, and is a matter of concern for the scientific community. Domestic industries outside the developed countries have been able to develop in places where strong protection for product patents did not exist. India is representative of such a situation; the Indian Patents Act of 1970 allowed Indian companies to develop and market generic versions of patented drugs. Similar strategies were used by developed countries when they were in the early stages of their industrial development [29]. In *F. Hoffmann-La Roche Ltd. And Anr. v. Cipla Limited [30]*, Roche, a Swiss multinational corporation owns a patent over an anticancer drug, Tarceva in India. It sues Cipla for introducing a generic version of this drug and requests the Delhi High court for an interim injunction against Cipla. The court decides in favour of Cipla on grounds of "public interest" i.e. Cipla was selling a cheaper and more affordable version of Tarceva. Interestingly, while delivering the judgment observed, as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life- saving drug, the balance has to be tilted in favour of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendants product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.

Compulsory Licensing: Compulsory licensing (manufacturing generic versions of patented medicines without patent holder's authorization under certain conditions). Most agree that the patent system is necessary and beneficial to promote innovation in the pharmaceutical industry, but there are various barriers to developing countries taking full advantage of the flexibilities, and hundreds of free trade agreements impose greater restrictions than TRIPS. The idea of compulsory licencing has been addressed under Section 84(1) of the Patent Act, 1970

[31]. The Patents (Amendment) Act, 1999 added a full chapter for the grant of compulsory licenses and the revocation of licenses. After the 1999 amendment, the grounds on which a compulsory license could be grantedwere: a) *Reasonable requirements of the public with respect to the patented invention have not been satisfied*; or, b) *The patented invention is not available to the public at a reasonably affordable price;* or, c) *The patented invention is not worked (i.e. not used or performed) in the territory of India*. The Amendment of 2005 added an Explanation to Section 84 (6), which states that the Controller, while examining the application for the grant of compulsory license, "shall take into consideration that the Applicant has made efforts to obtain a license from the patentee… and such efforts have not been successful within a reasonable period of time." The Explanation states that "reasonable period" shall be construed as a period not ordinarily exceeding six months. The Explanation also added under what conditions "reasonable requirements of the public shall not be deemed to have been satisfied". In addition, Section 90 (1) (vii) was added to the Act, which states that in settling the terms and conditions of the compulsory license as required under Section 84 of the Act, the Controller shall "secure that the license is granted with the primary purpose of supply in the Indian market, and the licensee may also export the patented product, if need be". Another significant insertion to the Act by the 2005 Amendment was the inclusion of Section 92A, which states that "Compulsory license shall be available for the manufacture and export of patented pharmaceutical products to any country having insufficient or manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided such a country permits importation of pharmaceutical products from India."

In Natco Pharma Ltd v Bayer Corporation Case [32], the Indian Patent Office granted compulsory license to Indian generic major, NATCO for the drug Nexavar, used for treating kidney and liver cancer in March, 2012. Nexavar was manufactured and sold by the Germany-based pharmaceutical company, Bayer, which had received regulatory approval for importing and manufacturing the drug in India. In July 2011, the applicant, NATCO had filed for a compulsory license, after a voluntary license request was rejected by Bayer. NATCO proposed to sell the drug at Rs. 8800/- for a month's treatment, as compared to Rs. 2, 40, 425 charged by Bayer. The Patent Office granted compulsory license to NATCO for selling the generic version of Nexavar in India, on condition that NATCO shall pay royalty to Bayer at rate of 6% for selling generic versions of Nexavar. On appeal before the IPAB, the Board increased the royalty rate from 6% to 7%. On appeal to the Supreme Court, the decision of the IPAB was upheld. One of the grounds for granting of compulsory license is that requirements of the public should be satisfied. The decision reflected that the needs of the public were the driving force for the Supreme Court's decision. The Supreme Court decision implied the desire of the Court to make the anti-cancer drug easily accessible and affordable to the patients.

Conclusion

Humans Rights is at the core of our society, therefore the approach should be incorporated in all national health and medicines policies and programmes. The NGOs should be empowered to put pressure on governments to fulfil their commitments and obligations under the international and national human rights instruments they have signed and ratified.The human right to essential medicines is a derivative right from the rights to health and to life. The right to health includes the right to emergency treatment and the right to health facilities, goods and services [33]. The right to health facilities, goods and services specifically includes the provision of essential medicines as defined by WHO. State Parties are under obligation to guarantee that the right to health will be exercised without discrimination, and to take deliberate and concrete steps towards its full realization with emphasis on vulnerable and marginal groups [34]. The human right to essential medicines has advanced in terms of its normative content and its legal recognition. However, it remains a daunting challenge to find accommodation with the international trade regime, bridge the gaps in political will, find incentives for innovation and affordable pricing and create the availability of adequate human and financial resources to ensure distribution networks.All these need to be achieved for the right to essential medicines to become a reality for over two billion people who have no access to essential drugs. In this connection, the different pharmaceutical policies in India have addressed the issue [35].

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