International Journal of Research
Available at https://edupediapublications.org/journals
e-ISSN: 2348-6848
p-ISSN: 2348-795X
Volume 05 Issue 01
January 2018

"Intellectual Property Rights and Human Right to Health"

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Abstract: Intellectual Property Rights raise a number of concerns with regard to their impacts on the realization of an important aspect of sustainable developmental law i.e. the realisation of the human rights. Human rights include cultural heritage, traditional knowledge, and right to health, science and technology and access to knowledge. Intellectual property law and human rights law have largely evolved independently. However, with the broadening scope of patents in areas related to basic needs such as health, and recent developments in the health sector itself, the links between the two fields are becoming increasingly obvious and direct, necessitating further consideration of the relationship between the right to health and patents on medicines, in particular in the case of developing countries. With regard to the human right to health there is a direct link between patents, the price of drugs, and access to drugs.

This paper analyzes the direct and indirect relationships between human rights and intellectual property rights. It also briefly examines the existing laws and the realization of human rights specifically the rights to health relating to medical patents and access to medicines.

HUMAN RIGHTS AND INTELLECTUAL PROPERTY RIGHTS:

These are two distinct fields that have evolved independently. On the one side, IPRs are statutorily protected rights which provide incentives for the involvement of the private sector in certain fields and requires to contribute to technological development. Intellectual property rights specially patents are near monopolistic right. On the other hand, human rights are fundamental rights, which are recognized by the state but are inherent rights linked to human dignity. Their relationship needs to be re-examined for sustainable under existing intellectual property rights

regimes.[1] Patent laws recognize that there is a socioeconomic dimension to the rights granted and that a balance must be struck between the interests of the patent holder and the broader interests of society. The intellectual property rights are considered to be diametrically opposite to the human rights, concerned only with the economic returns without any social perspective.

The main justification which is given in support of patent is stated to be that those incentives and rewards to inventors and the results in the benefits for the society

References to the links between the two fields seem to have surfaced mainly in two distinct periods, namely at the time of the drafting of the ESCR Covenant and the Universal Declaration of Human Rights[2], and more recently following the adoption of TRIPS and the growing importance of intellectual property rights in the realization of some human rights. In treaty law, the core human rights provision dealing with intellectual property is found in The International Covenant on Economic, Social and Cultural Rights (ESCR) Covenant. The Universal Declaration of Human Rights in Article 27 state that:

(1) Everyone has the right to voluntarily participate in the cultural life of the community and to enjoy the arts, to share in scientific advancement and its benefits.

(2) Everyone has the right for the protection of moral and material interests emanating from any scientific, literary and artistic production of which he is the author".

The relationship between human rights and intellectual property contributions was an issue of debate while drafting of the Covenant. Later on, it was in the limelight again as a result of problems faced by developing countries in implementation of the TRIPS Agreement. In the past decade, there has been increasing interest for these questions and different bodies have addressed certain aspects of the issue. The Sub Commission on Human Rights has, for instance, come to the conclusion that since the implementation of the TRIPS Agreement does not adequately reject the fundamental nature and specialty of human rights including the right of everyone to enjoy the fruits of scientific progress and applications. Regarding the right to health, the right to food and

[1] Philippe Cullet Human Rights Quarterly 29 (2007) 403_ © 2007 by The Johns Hopkins University Press
[2] Universal Declaration of Human Rights, 10 Dec. 1948, UN General Assembly Resolution 217 (III) A, Official Records of the Third Session of the General Assembly , Part 1, 21 Sept.-12 Dec. 1948, Resolutions.

the right to self-determination, there are visible conflicts between the IPRs regime contained in the TRIPS Agreement and human rights.[3]

Following what became a highly public controversy concerning access to drugs, medical patents and the right to health in the context of the price of HIV/AIDS drugs in sub-Saharan African countries most affected by the epidemics, the ESCR Committee decided to first adopt a statement on intellectual property rights and human rights in 2001 as a first step towards the adoption of a General Comment. The 2001 Statement was adopted in the wake of the collapse of the case filed by pharmaceutical companies against the South African government for attempting to limit their patent rights and the Doha Health Declaration adopted by the 2001 Ministerial Conference of the WTO.[4] In this Statement, the ESCR Committee specifically argued that the protection of the moral and material interests of authors must be balanced with the right to take part in cultural life also introduced at Article 15. It argued that intellectual property protection must serve the objective of human well-being which is primarily given legal expression through human rights. In other words, intellectual property regimes should promote and protect all human rights. More specifically, the Committee stated that any intellectual property rights regime that would make it more difficult for a state to comply with its core obligations in relation to the right to health and food would be inconsistent with the legally binding obligations of the concerned state.[5] At the national level, there is a duty for governments to ensure that everyone has access to all technologies that contribute to the fulfilment of human rights. An additional duty of governments is to ensure, as required by Article 2(2), that the benefits of scientific progress and its applications are available to all without any discrimination. Article 15(1) b also has an important international dimension. The right to enjoy the benefits of scientific progress implies that everyone in all countries should be able to benefit from all scientific and technological advances. Given the highly skewed distribution of technology around the world, the realization of this right in most developing countries necessitates international assistance and

[3] Resolution 2000/7, Intellectual Property Rights and Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 17 August 2000, UN Doc. E/CN.4/Sub.2/2000/7
[4] Declaration on the TRIPS Agreement and Public Health, Ministerial Conference – Fourth Session, WTO Doc. WT/MIN(01)/DEC/2 (2001).
[5] Paragraph 5(ESCR), 2001 Statement.

co-operation. The realization of the right recognized at Article 15(1) (b) therefore necessitates significant technology transfers in favour of developing countries.

United Nations High Commission for Human Rights Sub-Commission on Human Rights Resolution at the Sixty-First World Health Assembly on 24 May 2008, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property attempts to balance the right to health with the right to own intellectual property by calling for more efforts to be made to implement States' obligations arising under applicable international human rights instruments with provisions relevant to health. [6]

Though the linkage between IPRs and human rights is tenuous, but IPRs cast strong impacts on human rights. On the one side, existing IPRs have the potential to impact the realization of human rights particularly the right to health. On the other hand, it is possible to understand existing science and technology provisions in human rights treaties, not as providing a link to existing intellectual property rights but as providing a basis for the recognition of the non-economic aspects of intellectual endeavor. It can be argued that this is in fact what was sought in the context of the adoption of the relevant clauses in the Universal Declaration and the ICESCR. In India, a decision was taken to provide for a balance between rights, which puts property below inherent rights such as the right to health or food.[7]

HEALTH CONCERNS IN THE IPRS SYSTEM:

The relation between medical patents and human right to health has arisen a major issue of concern at the international level, as seen in the discussions and debates in WTO ministerial conference in 2001. International attention to the issue has been pointed in HIV/AIDS crisis in Africa regarding the question of access to drugs and medicines for patients in developing countries.

[6] World Health Assembly (2008) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Sixth-First World Health Assembly, WHA61.21, 24 May 2008.
[7] M.P. JAIN, INDIAN CONSTITUTIONAL LAW (Nagpur: Wadhwa, 5th ed. 2003).

The issue of access to drugs is of general concern in most developing countries. Debates on access to drugs are now strongly linked to the questions of whether drugs can, and should, be patentable. The increasing scope of patentability in the health sector, codified in the Agreement on TRIPS constitutes one of the most significant changes in law for developing countries which are WTO members.

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 then competition among generic versions can bring the price closer to the marginal cost. Compared to products in other sectors, however, the marginal price of drugs tends to be higher due to the relative inelasticity of demand for medicines.

In recent years there have been wide-ranging debates concerning the potential contribution of the introduction of patents in developing countries to the development of drugs related to specific tropical diseases. One of the perceived advantages is that it should give incentives to the private sector pharmaceutical industry to undertake more R&D in finding cures for diseases common in developing countries.[8]

ACCESS TO DRUGS AND MEDICAL PATENTS:

Access to drugs is one of the fundamental components of the human right to health.[9] It is of specific importance in the context of the introduction of patents on drugs, because patents have

[8] Pradeep Agrawal and P. Saibaba TRIPS and India's pharmaceuticals industry', Economic and Political Weekly 36, 2001, p. 3787.
[9] Commission on Human Rights, Resolution 2001/33, `Access to medication in the context of pandemics such as HIV/AIDS', in Report on the 57th Session, 19 March-27 April 2001.

the potential both to improve access, by providing incentives for the development of new drugs, and to restrict access, because of the comparatively higher prices of patented drugs. Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them. This implies a strong link between lack of access to drugs and poverty. About one-third of the world's population does not have access to basic drugs, a proportion which rises above one-half in the most affected regions of Africa and Asia. Furthermore, a large proportion of people in developing countries does not have access to medical insurance and more often than not pay for drugs themselves. Since price is a major issue in access, it is significant that patented drugs are more expensive than generics.[10] However, patents are not the only factor influencing access since even cheap generic drugs may not be affordable for people below the poverty line. In these situations access can be ensured only through further measures such as public subsidies or price control measures.

The links among patents, the price of medicines and access to drugs have been taken into consideration by various countries in developing their legal and policy framework in the health sector. India is particularly noteworthy in this respect. India adopted patent legislation which prohibited products patents related to drugs and medicines and this resulted in one of the major incentives for the growth of a strong pharmaceutical industry.[11]

INDIAN SCENERIO:

The Constitution of India confers fundamental liberties to every citizen including the right to life and personal liberty. The Supreme Court of India has been a pioneer in expanding the scope of this right ever since.[12] Through various decisions the Supreme Court observed that Right to life includes right to health and access to medical treatment has become a part of Article 21 of the Constitution. It is the prime duty of the state to provide cheap medicines and drugs, better

[10] World Health Organization and World Trade Organization Secretariats, Report of the workshop on differential pricing and financing of essential drugs, Hosbjor, Norway, 8-11 April 2001
[11] Jean O. Lanjouw, The introduction of pharmaceutical product patents in India: O Heartless exploitation of the poor and suffering, NBER Working Paper no. 6366, 1999.
[12] Dr.L.M. Singhvi, Jagdish Swarup Constitution of India, Vol-1, 2nd Ed, 2006, Modern Law Publications at pg 1100.

equipped hospitals with modernized medical technological facilities and these things have to be done by the state in accordance with the international declarations, mandate of the constitution and the judicial observations. Thus, access to medicines is protected by its international human rights obligations and through law made by judicial activism. Therefore, any legislation made has to keep itself with in the canons of law developed.

India is a signatory to the ICCR, ICESCR and TRIPS. It has been arguably, one of the front runners in raising issues related to TRIPS and developing countries. Nevertheless, there is a high international pressure from developed countries on India to provide efficient, effective and strong intellectual property protection for patents, which are owned by multinational corporations in the developed countries. India, certainly agrees that a strong IP would attract strong foreign investment which will lead to India's development; it also understands the price it has to pay. Recently, India amended its Patents Acts 1970 and introduced Pharmaceutical product patents.

However, the new amendment will have repercussions on access to medicines to many who cannot afford them. The Amendment Act extended product patents to products from all sectors including pharmaceuticals. It also set the term of patent protection to 20 years. This further closed the option of reverse engineering that largely contributed to the growth of Indian pharmaceutical industry. It will not be possible to produce the patented product by adopting a different process.[13] Under TRIPS there are various flexibilities afforded to developing countries. However, India not only failed to use the flexibilities provided there under but also the ones clarified and confirmed under the Doha agreement. India did not protect product patents on medicines in the last 35 years, since it enacted the first Patents Act in 1970. With the introduction of the product patent system on medicines, the world's supply of new affordable generic medicines wills essentially disappear.

[13]Viviana Munoz Tellez, Patent Reform in India: The Campaign to Protect Public Health, available at http://www.ipngos.org

The Act will have serious repercussion on the Indian pharmaceutical sector as well as on those millions who are not in a position to afford expensive medicines. Basheer observes, Insofar as new drugs are concerned, the costs are likely to increase and in the absence of a nationwide healthcare insurance system, the common man may have to bear the brunt of the new regime.[14]

At this stage there are two available options either the government amends the law or the judiciary plays its role by upholding the constitutional values, striking down the unconstitutional provisions of the law or interpret the law with a positive approach to human rights and thereby play the balancing part. The most controversial provision under the new Amendment Act is Section 3 (d). The Act permits generic manufacturers to continue producing generic version of new drugs in the mailbox. Though, this practice applies, where the generic product developer has made major investments. But it is provided that they were producing and marketing the generic version before the 1st Jan 2005. Otherwise such generic producers and manufacturers will have to back from the market. Moreover, the Act demands the generic companies to pay the, patent holders a reasonable royalty. Again, it could be argued that the term reasonable is ambiguous and gives the patents holder an upper hand to claim more percentage of royalty. This clearly shows the amount of pressure levied on India which had finally changed its laws to fit the TRIPS frame. Strong IP rights are said to bring more foreign investment while such ambiguous laws leave more room for the patent holders to manipulate in the market. Thus, it leaves major burden on the common man without proper access to medicines which is a violations of the basic right to health enshrined under Article 21 of the constitution. Indian judiciary as mentioned above has been actively involved in expanding the scope of human rights. It can protect the human rights of individuals through its interpretation of the new Patents Amendment Act, 2005. It should interpret the controversial provisions such as section 3(d) in such a way that they leave behind the meaning that the law is meant is to advance technology through inventions but at the same time safeguard human rights. Not only the judiciary but also the adjudicating authorities at WIPO should also approach a human rights test to the TRIPS provisions and should read them in harmony with human rights.

[14] Shamnad Basheer, India's Tryst With TRIPS: The Patents (Amendment) Act, 2005, 1 Indian J. Law and Technology, 15-46 (2005)

A number of recent developments at the international level indicate that developing countries can explore different possible interpretations of the TRIPS provisions or decide to act on the margin of TRIPS. The Doha Declaration restates and increases the mechanisms that states can use within the TRIPS context to foster public health goals. The declaration confirms, for instance, that member states can interpret their TRIPS obligations in such a way that they contribute to and do not work against their health policies.[15] Recent debates have focused mostly on the extent to which developing countries should be able to adapt the intellectual property rights system in situations where major problems have arisen. This does not address the question of whether the introduction of process and product patents in all WTO member states is generally reconcilable with the measures that states must take to foster the realization of the right to health. The declaration also fails to provide answers to more practical questions, such as the prohibition on a country such as India compulsorily licensing a drug mainly to export it to other countries that do not have a manufacturing base of their own. If exports are not permitted in this context, most Sub-Saharan African countries will not be able to take advantage of alternative sources of medicines.[16]

This problem points to one of the major challenges that all developing countries will face in the future. If existing manufacturing capacity in countries like India were to be substantially reduced, this would have an impact not only on India but also on a number of other countries which do not have the capacity to manufacture drugs themselves and would therefore become totally dependent on supplies from developed country manufacturers. Since the Doha meeting, there seems to be an international consensus that countries trying to deal with health emergencies will not be questioned in terms of their obligations under TRIPS. This, however, leaves completely open a number of other issues.

From the perspective of the right to health and access to drugs, the TRIPS Agreement needs to be revised to include principles in favour of access to drugs in the main provisions of the agreement

[15] Para 4 of the Doha Health Declaration.
[16] CIPR Report, p. 35

rather than as exceptions.[17] However, an amendment to article 27 of TRIPS that would compulsorily reduce the scope of patentability is not very likely in the near future, while a strengthening of TRIPS in the context of forthcoming WTO negotiations is possible. There is, therefore, a need to analyse TRIPS in its present form and examine the extent to which states can fully implement their TRIPS obligations together with their human rights commitments.

More generally, the central concern that should guide the implementation of all international treaties concerning health directly or indirectly is the promotion of better health care. From the point of view of human rights, the link between the two fields was considered in the drafting of human rights treaties, when, as noted above, it was concluded that the interests of the community at large should generally prevail over those of individual authors.

One of the first steps in tackling the problems faced by the most disadvantaged sections of society would be to make sure that all essential medicines remain free from patent protection. This conceptual framework is what informed the 1970 Indian Patents Act, which rejected product patents on drugs, and, to a more limited degree, the Brazilian decree on compulsory licensing, which seeks to provide an extensive definition of the public interest.[18]

From a practical point of view, patents on medicines in developing countries are fraught with other difficulties. In a number of countries, most people pay for their own health care. Since a large part of the population does not have access to existing drugs today, any price rise tends to limit access for more people. In India millions of Indian people cannot afford drugs under a regime which denies product patents on pharmaceuticals. If prices are allowed to go even higher under TRIPS-mandated product patents, even fewer people in India will have access to drugs. From this perspective, there is a need not for patent rights that lead to price rises but for even lower prices to facilitate broader access to drugs. If compliance with TRIPS leads to reduced access to drugs, this might imply a substantive violation of the ESCR Covenant. Indeed, while

[17] As argued by the World Bank; see Global economic prospects 2002, p. 148.
[18] Indian Patents Act 1970 and Brazilian Presidential Decree on Compulsory Licensing, Decree no.3,201, 6 Oct. 1999.

article 2 of the covenant does not require immediate full implementation of the right to health, it requires states to take positive measures towards the fulfilment of that right.[19] The introduction of product patents could be construed as a `deliberately retrogressive' step if no measures are taken to limit the impacts of TRIPS compliance on access to medicines.

In case of conflict between the relationship of WTO treaties and human rights treaties, states should first refer to treaty law, which provides broad rules of interpretation and reviews the question of conflicts between different treaties. At a general level, states must attempt to the maximum extent possible to reconcile all their international obligations, or at least to minimize conflicts, to comply with their duty to implement all their obligations.[20]

CONCLUSION:

IPR laws recognize that there is a socioeconomic dimension to the rights granted and that a balance must be struck between the interests of the patent holder and the broader interests of society. However, with the broadening scope of patents in areas related to basic needs such as health, and recent developments in the health sector itself, the links between the two fields are becoming increasingly obvious and direct, necessitating further consideration of the relationship between the right to health and patents on medicines, in particular in the case of developing countries. The link between medical patents and the human right to health has become a subject of central concern at the international level. Debates on access to drugs are now strongly linked to the questions of whether drugs can, and should, be patentable. The increasing scope of patentability in the health sector, codified in the TRIPS, constitutes one of the most significant changes in law for developing countries that are WTO members and has provoked a significant outcry in a number of developing countries where access to medicines is already abysmally low. The justifications offered for the existence of patents as incentives to innovation often do not

[19] Committee on Economic Social and Cultural Rights, General Comment no. 3, `The nature of states parties obligations (art. 2,para. 1 of the covenant)', in Compilation of general comments and general recommendations adopted by human rights treaty bodies , UN Doc. HRI/GEN/1/Rev.4 (2000

[20] See article 26 of the Convention on the Law of Treaties, Vienna, 23 May 1969, in International Legal Materials 8, 1969, p. 679 [hereafter Vienna Convention 1969].

appear convincing to patients in developing countries, who see that hardly any R&D is being invested in diseases specific to those countries. In other cases, such as HIV/AIDS, where drugs to alleviate the condition exist, the prices of these-for all practical purposes, life-saving-drugs have been so high as to render them unaffordable for all but the wealthiest in developing countries.

The legal arguments concerning the relationship between human rights and intellectual property rights, and the practical debates concerning access to drugs in developing countries, both point towards the existence of potential conflicts between the introduction of patents on drugs in developing countries and the realization of the right to health. While states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPS directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health. This appears to be unacceptable under the ESCR Covenant and countries in this situation would be expected to give priority to their human rights obligations. Policy- makers should ensure that IPR systems including any required by WTO agreement promote and do not undermine fundamental human rights to self determination, food, health and development.