Legal & Intellectual Property Dimension of Health & Access to Medicines in India

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Abstract

Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, 1995 established synergy with human rights laws in realization of right to health, access to medicine and sustainable development. The Doha Declaration on Public Health, 2001; Sustainable Development Goals, 2015-2030 and United Nations Secretary-General’s High-Level Panel on Access to Medicines Report, 2016 promote innovation of health technologies in developing countries. It is estimated that 75 per cent of the world’s population is health deficient and medicine starved due to patenting requirement of pharmaceutical industries. India passed Patents (Amendment) Act, 2005 dealing with exclusive marketing right, product patent and process patent to protect the interest of the generic drugs in compliance of TRIPS Agreement, 1995 under public interest. In post Patents (Amendment) Act, 2005 phase India faced formidable challenge of the Swiss drug maker Novartis’ patent application for Gleevec in Madras High Court, 2006; Intellectual Property Appellate Board (IPAB) in 2009 and Supreme Court in 2013. The judicial exuberance struck a balance between patent right, health right and access to medicine in Indian socio-economic context. It is followed by spelling out of the National Intellectual Property Right (IPR) Policy, 2016 focused on enhancing access to healthcare as human right.

Key Words: TRIPS Agreement, Public Health, Access to Medicines, Pharmaceutical Industries, Exclusive Marketing Right, Novartis Judgment, IPR& Health Policy.

Introduction

Globally innovations in health technologies and access to medicine has dramatically improved and brought commendable health improvements but the majority of patients in developing countries constituting around 75 per cent of the world’s population are denied access to medicines due to patent by the pharmaceutical industry. The investment in research and development (R&D) of health technologies is ill-equipped to respond to diseases, such as Ebola and Zika, neglected tropical diseases (DTNs) and Antiretroviral (ARV) drugs related to HIV/AIDS. The World Health Organization Statistic, 2016 documented that prevention and treatment of AIDS, tuberculosis, malaria hepatitis, communicable diseases and neglected tropical diseases have not received the adequate attention. The legal and intellectual property dimension of health and access to medicines in India is governed by the TRIPS Agreement, 1995 and the Patents (Amendment) Act, 1970, Patents (Amendment) Act, 1999, Patents (Amendment) Act, 2002 and Patents (Amendment) Act, 2005. The innovation of health technologies in post TRIPS Agreement, 1995 and Indian slew of reform desiderates human rights to health and its links with intellectual property rights. The TRIPS Agreement, 1995 flexibilities under the Doha Declaration on Public Health, 2001 addressed meaningfully to access to medicines as public health. This is supplemented by United Nations Sustainable Development Goals 2015-2030 which ensures healthy lives and well-being of all people of all ages. The United Nations Secretary-General’s High-Level Panel On

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Access To Medicines: Promoting Innovation & Access To Health Technologies Which Review And Assess The Situations of Health Technologies Report, 2016 reveals ground realities asserting the millions of people lack of access to health technologies. Thus the legal and intellectual property dimensions needs a serious engagement to foster realization of access to medicine and human right to health in India.

Material & Method

The material and methods applied for the study include analytical method of legal research by undertaking the legislative survey and scrutiny of health and intellectual property laws at international and national levels. The comparative law methods applied for the statutory interpretation of Universal Declaration on Human Rights, 1948, International Covenant on Economic, Social and Cultural Rights, 1966 TRIPS Agreement, 1995, Doha Declaration on Public Health, 2001 and United Nations Panel On Access To Medicines and Access To Health Technologies Report, 2016. The Indian Patents Act, 1970, Patents (Amendment) Act, 1999, Patents (Amendment) Act, 2002 and Patents (Amendment) Act, 2005 is examined for harmonious construction of health and intellectual property legal framework. This study has analyzed the corpus of legal materials on international and national health and IP laws in the framework of Maxwell’s qualitative research design.7

Findings

The Universal Declaration on Human Rights, 1948 which mandates that everyone has the right to standard of living adequate for the health, medical care and wellbeing. This is buttressed by International Covenant on Economic, Social and Cultural Rights, 1966 by conferring enjoyment of the highest attainable standard of physical and mental health.8 The Inter-Ministerial Conference of the WTO adopted Doha Declaration on Public Health, 2001 on access to medicines in the context of the TRIPS Agreement, 1995.

WTO &TRIPS Agreement, 1995: The adoption of the WTO and TRIPS Agreement, 1995 ushered intellectual property norms and enforcement. Article 7 strikes the balance between the intellectual property rights holders and broader social interests and common good. Article 8 adopts measures to protect public health and nutrition, as well as to promote the public interest in sectors of vital importance to socio-economic and technological development.9 Article 27.2 restrict the patentability of inventions to save human life and health without prejudice to environment.10 Article 30 permits states to limit the exclusive privilege granted through patent rights in the interest of third parties, such as people suffering from HIV/AIDS diseases. It is further supplemented by Article 31, which sets out a regulatory framework for compulsory licensing with number of conditions. One of the strategies which have been debated in recent times is based on the implicit provision in the TRIPS Agreement, 1995 on the issue of parallel imports or the principle of exhaustion of rights of the patent holder under Articles 6 as a means of reduced prices and increased basket of access. However, negotiators included safeguards and flexibilities within the TRIPS Agreement, 1995 that could be used by signatories to tailor national intellectual property regimes so that countries could fulfill their human rights and public health obligations.11

Doha Declaration & Access to Medicines: The Doha Declaration, 2001 recognizes that the patent rights in health sector to protect the public health as obligations of WTO members to interpret the TRIPS Agreement, 1995 in public interest of medicinal access and drugs. It recommended exporting patented products and utilizing their compulsory licenses to needed drugs at affordable costs. It further enunciates that public health issues will supersede private interests in view of life threatening diseases such as tuberculosis, malaria and HIV/AIDS be issued under Article 31 of TRIPS Agreement, 1995.12 The Doha Declaration on Public Health, 2001 reaffirmed Article 31 of TRIPS Agreement, 1995 by empowering WTO members to utilize flexibilities available for the right to health and public health. However on the ground we find that the Median availability of essential generic medicines in developing countries generally reveals that only countries 37.7% in public sector whereas the inPrivate sector 70% found to be disturbingly very high.13 Despite these pronouncements, the sovereign right to issue compulsory licenses provided for by TRIPS Agreement, 1995 has been often stymied by threats of retaliation from governments and corporations.14

United Nations Health Technologies Report, 2016: The UN Secretary-General convened a High-Level panel to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies in 2015. The Panel called for proposals that promote research, development, innovation and
increased access to medicines, vaccines, diagnostics and related health technologies to improve the health, wellbeing and sustainable development. The United Nations Health Technologies Report, 2016 penultimately replicated WHO Model List of Essential Medicines as a tool to advocate for access to priority medicines in all countries. It also calls for more transparency about the patent status of essential medicines and build domestic capacity to procure generic copies and develop Medicines Patent Pool to all disease.\(^{15}\)

**Health & Sustainable Development (SDG) Goal 2015-2030:** The SDG Agenda demonstrates unprecedented scope and ambition in the context of the current intellectual property system has created situations where new treatments are launched at increasingly high prices. The SDG Agenda creates affordability and sustainability issues for health systems even in high-income countries. The third SDG Agenda enunciates to ensure healthy lives and promote well-being for all at all ages in its own right. It institutionalizes the fact that the health significantly contributes to environment and sustainable development goals as reliable indicator.\(^{16}\) To usher these objectives the SDG Agenda enjoins WHO to play a strategic role public health, innovation and intellectual property.\(^{17}\) It also mandates to build capacities by providing an appropriate balance between affordability and maintaining incentives for investment in R&D. These endeavor’s will result in downsizing of rising burden of chronic non-communicable diseases (NCDs) and removal of barriers to access to medicines deficits.\(^{18}\)

**Discussion**

India’s obligation to faithfully comply with its commitments under international treaties and resulted to the status of the pharmacy of the world. It protects the interest of the generic manufacturers who have been manufacturing certain drugs patented elsewhere by providing the compulsory licensing regime. This mechanism encourages innovations as well as inventions in India to secure the effective working on a commercial scale. The combined impact of these attempts enlarged the ambit and scope of the public policy in health sector in the existing legal and intellectual property framework.

**Access To Medicines In India:** The Patents (Amendment) Act, 1970, Patents (Amendment) Act, 1999, Patents (Amendment) Act, 2002 and Patents (Amendment) Act, 2005 are to be seen in continuum of TRIPS Agreement, 1995 and Doha Declaration on Public Health, 2001 and the most progressive patent laws in terms of diagnostic, surgical and therapeutic methods of treatments. India extracted benefit of TRIPS Agreement, 1995 and introduced product protection on pharmaceuticals by Patents (Amendment) Act, 2005. By product patent protection India created supply of low-cost active pharmaceutical ingredients and investment in R&D. The shift in public policy dimensions under legal and intellectual property framework is evidenced an exponential growth in pharmaceutical R&D in post Patents (Amendment) Act, 2005 phase.\(^{19}\) Indian pharmaceutical companies increased the share of its revenues by focusing on building on their strengths by launching generic versions of big-selling drugs in the from the developed world. In 2003, India was granted 72 pharmaceutical patents in the United States. Although this is a small proportion of the total, it makes India the eleventh largest foreign source of United States patents in that category.\(^{20}\) Thus the new patent regime not only enabled better access to medicines at more affordable prices but foster the pharmaceutical industry R&D an upswing trend.

**Health & Public Policy:** The National IPR Policy, 2016 provides strong and effective IPR laws, which balance the interests of rights owners with larger public interest. The policy take away is a vibrant Intellectual Property ecosystem imbied in public welfare of health care within the framework of the Doha Declaration on Public Health,2001.\(^{21}\) The mission statement of the policy is to stimulate a balanced intellectual property system in India to foster innovation entrepreneurship and enhance access to healthcare as sectors of vital importance.\(^{22}\) a perusal of seven broad objectives of policy reveals the desire and direction of the legislative space and flexibilities available in international treaties to engage constructively in the negotiation of human right healthcare, access to medicine and drug as an inalienable entitlement. The National Health Policy, 2017 also expresses a firm commitment to Intellectual Property protection establishing a direct correlation between IPR and healthcare access. It has been observed that economies with the strongest IP protections are 60 percent more likely to provide environments conducive to innovation. And economies with IP protection in life sciences see an average of 13 times more biomedical investment than those lacking IP protection.\(^{23}\) The target of universal healthcare can sustain in a cohesive scientific, economic and policy ecosystem of medical
innovation.

**Novartis Judgment:** The impact of legal and intellectual property policies reached to culmination in Novartis Judgment when the patent application for Gleevec was rejected by the Indian Patent Office in 2006. It appealed to IPAB in June 2009 and Madras High Court challenging the denial of patent under Section 3(d) of the Patent Act, 1970. The Madras High Court rejected these appeals on the ground that ‘the domestic courts could not be asked to give an opinion regarding international treaties and obligations and that Novartis should take its complaint to the disputes settlement mechanism in the WTO.’

Novartis further appealed to Supreme Court through special leave petition in 2012. The Supreme Court merged three petitions in one popularly known as Novartis AG and observed that:

The Court was urged to strike a balance between the need to promote research and development in science and technology and to keep private monopoly (called an ‘aberration’ under our Constitutional scheme) at the minimum. The Court was reminded of its duty to uphold the rights granted by the statute, and the Court was also reminded that an error of judgment by it will put life-saving drugs beyond the reach of the multitude of ailing humanity not only in this country but in many developing and under-developed countries, dependent on generic drugs from India.

The Novartis judgment fortified the right to health and access to medicine in public interest than that of commercial interest. The Indian courts played seminal role in enforcing the right to life encompassing health access and affordability of medicine in to national interest.

**Conclusion**

With the adoption of TRIPS Agreement, 1995 and the introduction of pharmaceutical patents in developing countries to the development of Anti retroviral (ARV) drugs related to HIV/AIDS and other tropical diseases have become matters of great concern and posing continuous challenge. The intellectual property rights and human rights auditing demands that access to affordable drugs for realizing agenda of sustainable development goals. The TRIPS Agreement, 1995 flexibilities as approved by Doha Declaration on Public Health, 2001 and TRIPS Agreement, 1995- plus should foster public funded research prioritizing public health objectives among the pharmaceutical companies. The regime which denies product patentability in the field of health naturally leads to reduced access to drugs and derogation of human right norms. This is illustrated by the fact that one-third of the world’s population does not have access to basic drugs and pharmaceutical patents are hitting hard to disadvantaged people. It calls for human rights to place over intellectual property laws and all countries must freely be able to use flexibilities granted under TRIPS Agreement, 1995 to access affordable medicines. There is need to create cohesive legislative and policy framework for access to medicine and health care system.

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