Whither to Public Interest-The Curious Case of Compulsory Drug Licensing in Indian Pharmaceutical Industry

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Abstract

Countries like India which are grappling with providing healthcare to heterogeneous and varied base of stakeholders including those at the bottom of pyramid have their own share of availability and affordability concerns in the healthcare sector for providing access of life saving drugs to the vast segment of Indian population and move towards the achievement of the Sustainable Developmental Goals (SDGs); in process addressing not only adequate availability of the primary health care but achieving the competition framework *vis- a- vis* patent control as the Original Patents which intend to protect innovation tangentially run across the consequential price determination power by monopolistic patented drug companies. Compulsory licensing of Patents provisions are used by the Governments as a means to correct anti-competitive practices to promote public interest or public health and in cases of emergency avoiding monopolies at the hands of patent holders to deter anti-competitive violations by engaging in unfair competition or abuse of dominant position in the market which aspect is so crucial to provide outreach of cheaper and quality drugs in common good.

Keywords: *Health Care Sector, Anti- competitive violations, Patent Holders, Compulsory Licensing.*

Introduction

The explosion of population and emergence of drug resistant communicable diseases like Tuberculosis and others like Malaria, HIV/AIDS epidemic, Cancer, Hepatitis C has made the task of providing cheaper health care in Indian market a frustrating experience despite increase in the domestic capacities of drug production, increased Government spending towards health care sector and alike. One has to take into account the learning outcomes out of the recent regulatory framework, wherein the epidemic diseases which have since resulted in the mutational form of the very disease itself; perhaps in majority of cases is the first (patented)version of the drugs being applied for curing such diseases is being provided whereas such diseases are being attempted to be controlled through second generation/further generic versions of the drugs in other developed countries under Compulsory Licensing; with the difference being the Patented version costing a significantly higher markup than those manufactured under Compulsory Licensing. Article 5 A(2) of the Paris Convention of 1883 provides that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work"[(1)]. Largely seen as an interventionist measure, it seeks to calibrate rights of the patent holder with Governments obligation to ensure working of patents, ensuring availability at a reasonable price, protection of public health and nutrition and simultaneously encouraging technological invention.

Compulsory Licensing has emerged as one of the effective tools to prevent the monopolistic situations at the hands of patent holders and cause supply of generic drugs at affordable price addressing health care *viz-a viz* intellectual property and has found favor in developed nations such as European Union, Germany, Italy, United Kingdom, France, Norway and Russia to name a few. Compulsory Licensing of Patents has facilitated low priced pharmaceuticals and in process encouraging the local generic drug industry Developing countries like

India face the issue of delivery of healthcare technology, and challenge for policy makers has been to ensure acceptability and affordability on an equitable basis which could theoretically accrue through Compulsory Licensing and said aspect has been highlighted by the United Nations Human Rights Commission Report, 2001 as well[2]. The National Bureau of Economic Research (NBER) Working Paper indicates that compulsory licensing has a strong and persistent positive effect on domestic invention [3]. Even without any effects on innovation, compulsory licensing may create significant positive welfare effects on consumers in developing countries as a mechanism to maintain product variety. One needs to examine the relevance of compulsory license framework in Indian scenario more particularly the will of the regulatory architecture coupled with the response of the pharmaceutical industry to make use of the flexibilities available in context of the two domains namely patented production versus the manufacturing under Compulsory Licensing; having varying mandate; the State working with the social objective and the private sector having a business mandate .

A study indicates 65% of the Indian population still lacks access to essential medicines[4]. Share of drugs in OPD expenses were estimated at 63 per cent by NSSO 60th Round (January 2004)[5]. NSSO in their Report on 61st Round indicated this expenditure having increased to 82 per cent [6]. As per National Health Accounts, medicines accounted for 50-60 per cent of inpatient expenditure in rural and urban areas[7].As per the Report of National Health Accounts Estimates for India (2016-17), for the year 2016-17, total health expenditure for India is estimated at Rs 581023 crores (3.8% of the GDP and Rs. 4381 per capita)[8]. These reinforce the issues raised by the Parliamentary Committee for the need to increase the availability and accessibility of drugs to the poor in the country[9]. The National Pharmaceutical Policy 2002 recognizes the need to 'ensure abundant availability at reasonable prices of good quality essential pharmaceuticals of mass consumption'[10]. The National Pharmaceutical Policy 2006 while acknowledging the explosive growth in this sector between 1990 and 2010, and the accompanying low cost of medicines notes, that concerns regarding the accessibility and affordability of medicines remain[11]. The National Pharmaceutical Policy 2017 has aimed to realign the 'price control' orientation now to 'monitoring of price'[12].

Discussions

The 2001 Doha Declaration brought in a silver lining for Developing and Least Developed Countries as Declaration of the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)and Public Health reiterated the flexibility of the member states to avail of the compulsory license to manufacture cheaper version of the patented drugs. Article 6 (b) of the said Declaration further highlighted the right of each Member State to grant Compulsory License and determination of grounds when such licenses are to be granted[13,14]. The Indian Patent Act 1970 (as amended in 2005) has been made fully compliant to incorporate these flexibilities[15].

The compulsory licensing as per Article 30 and 31 of TRIPS is very much WTO compliant for effecting in India. Article 31, while listing out 12 conditions/ circumstances highlights public non commercial use as one of the criteria's. Article 31(k) permits the grant of Compulsory licences to remedy anti-competitive practices. The DIPP paper of 2010 -made a reference to National Pharmaceutical Policy wherein the Drug Regulatory System has a National List of 354 essential drugs subjected to effective price control and limiting trade margins; that apart 74 drugs being under regulation has seen instances of regulatory contraventions[16]. Infact the developed countries with regard the Doha declaration having instituted two loop-holes as exceptions to the TRIPs agreement; one of them being parallel importing, where a "country may import patented drugs from another country where the patent-holding manufacturer sells them for less," and compulsory licensing. Developed countries and big pharmaceuticals are definitely against use of CL provisions[12]. No CLs have been issued in India under the amended Patents Act*(supra)*. In September 2007, three applications under section 92A of the Patents Act, 1970 were received for grant of compulsory licence for the manufacture and export of patented drugs to countries which reportedly did not have manufacturing capacity nor had insufficient capacity. The process envisaged under the Act was initiated. However, the applicant subsequently withdrew his applications

The Indian Patent Act deals with the issue of Compulsory Licensing through Section 84 (General CLs to be issued by Controller on application), Section 91 (Issue of CL by the Controller for the related Patent on application), Section 92 (issue of the CL by the Controller upon a Notification for National emergency/

extreme emergency or in case of Public Non Commercial Use) and Section 92 (A) (When insufficient or no manufacturing capacity is there to address pubic health problems).

Given the varied and a larger landscape under which Compulsory licenses provisions could be invoked, definitely there is a need to put in regulation justifying the elements of Section 92 of the Indian Patents Act i.e. national Emergency/extreme emergency/public non commercial use circumstances, which would mean further elaboration of provision of Section 92 (C) as per Para 43 of the Discussion Paper and the Guidelines should be made available both in case of Category 1 (production at lowest prices) and Category 2 (production at affordable prices) to ensure considerations of quality and availability, which would address the distribution aspects of the medicine to the desiring section of the society (*supra).* One also needs to examine the effective alternative to compulsory licensing wherein the patents could be opposed and more importantly questioning the drugmakers of "ever-green" provisions where pharmaceutical companies make subtle variations to the existing medicines to extend their patent monopolies for a larger duration

A cursory look at the provisions involved in the Indian Patent Act viz. Section 84, 89, 90, 92, 92A reveal that while CL provisions are yet to be tested; it may have technical administrative difficulties in view of the clear cut regulations not in place. (unlike section 84 which stresses for expiration of a 3 year period before a compulsory licensing application can be made, section 92A is silent on this. MoreoverSection 92A conditions are left to be decided by the controller; further the 3year lock-in period under Section 84 may prove to be deterrent given any unknown epidemic to occur. Moreover post 2005; many of the drugs may fall under the patent regime). This is an area which is subject to international pressures, political considerations and varied role of civil society including NGOs and the implementation may not be an easy task. The circumstances as stated in Section 92 (Para 40 & 41) are different from those sated in Section 100 (50 & 51). Section 100 provisions appear to vest in more authority with the Central Government or its constituents for using an invention for the purpose of Government. Given the societal context and the social and public interest that the Government of India concentrates upon the provisions of Section 92 and 100 while being complimentary; albeit Section 100 would cover extreme situations under Section 92 provisions.

It is a fact that drugs patented before 2005 Indian Patent Amendment are "off" patent items; that apart after the new patent regime for India in 2005 there have been instances of highly prices patented drugs in India and therefore there is a need that price control of patented medicine should not only be brought under the mandate of NPPA which presently caters to control the price of scheduled drugs and monitors the prices of non-scheduled drugs but also the patented drugs (*supra).*

Sections 84 to 94 of the Patents Act, 1970 deals with issue of compulsory licences i.e. circumstances under which compulsory licence should be issued, procedure for dealing with applications for compulsory licences, powers of the Controller to grant compulsory licence and terms and conditions of licence (*supra)*. But the time frame within which such compulsory licence should be given, once application for licence has been submitted has not been mentioned under the Act including time frame for Controller to dispose of general applications for compulsory licences, time frame to serve copy of application on the Patentee/patentee to oppose the application, time frame to grant/revoke licence on submission of opposition statement by the patentee,time frame for issue of compulsory licence under Sec.92A for export of patented pharmaceutical products in certain exceptional circumstances and time frame for information to be given to patentee under Section 92, where compulsory licence is issued on notification by Central Government in case of national emergency, extreme urgency or public non-commercial use. Further, the meaning of national emergency, extreme urgency and public non-commercial use should be clearly defined in the Patents Act. The circumstances under which these terms can be used should also be given in detail. Under Section 84(6) (ii) and (iii), the Controller is required to satisfy himself about the ability of the applicant to work the invention to the public advantage as well as the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted.

Article 27(1) of TRIPS interalia states "… patents shall be available and patent rights enjoyable without discrimination as to ...whether products are imported or locally produced" implying that so long as the patented product is available in the market at an affordable cost, the use of the patent cannot be differentiated on the basis of its sourcing – whether it was manufactured within the country or imported from without (*supra)*. The bone of contention has been that the exceptions provided

in Articles 30 and 31 of TRIPS override the general stipulations in Article 27 with Articles 7 and 8 of TRIPS which recognizing transfer of technology to support provisions for local sourcing making local working stipulations valid and enforceable.

Findings: What is needed in India is robust regulations to allow for compulsory licensing at standard royalty rates so that the essential medicine are priced competitively. After the Doha Declaration over 50 countries have issued CLs prominent being USA, UK, Canada, Italy and amongst developing ones; Brazil(2007 for an anti AIDS drug); Thailand(2006 and 2007 for anti AIDS drugs), Malaysia (2003 for Anti AIDS drugs), South Africa (Anti Aids Drug) Kenya (voluntary licenses issued in 2004 after threat of CL), and most recently Ecuador (April 2010 for an anti AIDS drug) (*supra)*.It also remains a fact that in Thailand, use of CL provisions while being totally compliance with the TRIP Law was criticized by the pharmaceutical companies and the Governments of developed countries and it showed the clout of the pharmaceutical industry in their displeasure against the use of CLs. It is gathered that with such successful intervention the pricing of ARVs could be reduced by 40%. A study highlights that CLs are waning away much to detriment of bringing serenity in drug pricing and improved health governance.

While Section 84(1) of the Indian Patent Act provides that at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence; lack of an objective framework for the issue and maintenance of compulsory licences has not made permeation of the likely benefits of Compulsory Licensing in India (*supra)*. Manufactured in India for working of a patent would foster domestic pharmaceutical industry aiding employment of chemists, physiologists, pharmacists, doctors thus effectively contributing to national economy by producing medication that is compatible with the average local income, because the cost of labour would be commensurate with the average income. It would be important to examine the price or availability of a drug becoming perilous through an anti competitive agreement or a combination which has an adverse effect on competition; or the abuse of dominant position and take appropriate regulatory intervention. For affirmative action to take place on SDG-3 relating Good Health and Well being; there is inherent need to revive discussions on Compulsorily License Framework to address issues of equity and reach while maintaining balance between Patent Rights and Competition framework[17].

Conflict of Interest: Nil

Source of Funding: Self Funding

Ethical Clearance: I declare that the article written is my ownliterary and multidisciplinary creation and there is no plagiarism involved. All reference material used for the article has been acknowledged.

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