

India's Options for Improving Affordable Access to Lifesaving Patented Medicines

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On the lines of the cautionary observation made by the Hon'ble Supreme Court in Para 156 of the Lordships' order on Gleevec¹, the ongoing patent litigations in India seem to be equalling or crossing the cost estimates of US patent litigations. Doha Declaration has not made affordable access to lifesaving medicines on expected lines. Exemptions and legal provisions enshrined in the Patents Act, 1970 (such as compulsory licence and regulatory exemptions) are also being denied and delayed through protracted litigations burdening the Indian pharma SME sector. Provisions of Section 107A(a) of the Patents Act, 1970 are also being ignored by the Indian judiciary. It is, therefore, desirable to look at and evaluate options available to India for improving and facilitating affordable access to lifesaving medicines within the Indian patent legal system. Such options are discussed in this paper.

Keywords: Compulsory licence, Dasatinib, protracted litigations, affordable access to lifesaving patented medicines, Competition Act, government use, licence of right, obligatory licence

Are affordable access options for lifesaving medicines running out for India? Has the 'spirit' of 'Doha Declaration' been diluted and wasted? If the current trends of endlessly protracted, alleged and perceived pharma patent litigations are to be analysed and evaluated, it becomes clear that developing countries like India with its own domestic pharmaceutical manufacturing capabilities, will need to look for alternate options for improving affordable access to lifesaving medicines. India may need to have a relook at the flexibilities available under TRIPS and 'Doha' to wriggle out of the stranglehold of endless adjournments without 'cause of action' and irrationally claimed injunctions against imaginary infringements and validly granted compulsory licences (CL). Such an analysis is possible by starting to look at available options under the Patents Act, 1970, as amended to date, which are dealt with in this article.

TRIPS compliance in the amended post 2005 Patents Act, 1970 is evident from the provisions of Section 83(c), (d) & (f) which is verbatim reproduction of Article 7 and 8 (1) & (2) of TRIPS.² The objectives and principles linked to specific exemption and flexibility with regard to healthcare in adopting the intellectual property provision in general and patents in particular have been enshrined in the

TRIPS document which is the final result of Uruguay Round³ negotiations and Dunkel draft.⁴ Article 2 of TRIPS binds itself to the Paris Convention & provisions thereof to prevent abuse of intellectual property rights. However, it was in the Doha Round of World Trade Organisation (WTO) on 14 November 2001 the Declaration on the TRIPS Agreement and Public Health⁵ was adopted. This declaration recognized the need for flexibility in dealing with public health problems in developing and least developed countries while implementing intellectual property/patent regime. Need for wider national and international actions to address this problem were also recognized. It was explicitly agreed that member countries should not be prevented from taking measures to protect public health through TRIPS provisions. The need to promote access to medicines for all was appreciated. Consequently, the declaration in Para 5 were incorporated by India into the provisions of CL under Chapter XVI and Sections 83 to 92 of the Patents Act, 1970. Para 6 of Doha Declaration was implemented by India through Section 92 A of the Patents Act, 1970. The compulsory licensing provisions in the amended Patents Act, 1970 is, therefore, to be understood as specifically relating to affordable access to essential and lifesaving medicines. It was also decided that pending adoption of final recommendations, 'non

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violation' complaints will not be entertained based on loss of an expected benefit caused by another member's actions. On 30 August 2003, the agreement was reached to allow member countries to export. It was also decided that all member countries are eligible to import, out of which 23 developed countries were afraid that the decision might be abused and therefore voluntarily announced that they will not use the system. Trying to provide comfort to them the General Council Chairperson stated 'the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives and that issues such as preventing the medicines getting into the wrong hands are important'.⁶ Some member countries announced that they will use the system only in emergencies and extreme urgent situations. The decision protects, product patents and process patents in pharmaceutical sector and is framed in such a way so as to address the public health problems recognized in Para 1 of Doha Declaration on TRIPS and Public Health, in which it is mentioned that WTO ministers 'recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'.⁷ It is to be noted that a decision was taken to provide an interim waiver which allows countries producing generic copies of patented products under compulsory licences to export the products to eligible importing countries. The waiver would last until the WTO's intellectual property agreement is amended. In the meantime, on 30 August 2003 a general guideline for implementations of Para 6 of Doha Declaration was arrived at the General Council of TRIPS. This decision, including the waivers granted in it, shall terminate for each member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.⁵ However, the procedures prescribed in the said notification are very cumbersome and difficult to implement in a time bound manner.

It is relevant and interesting to note that the TRIPS Council decided to extend the deadline for complying with TRIPS provisions for Least Developed Countries (LDCs) to 2016 and recently further extended it to 2021(ref. 8). Relevant statements of this recent TRIPS decision are as follows:

This transition period has been extended twice for all LDC members in response to a specific request by the LDC Group. In its decision of 29 November 2005,

the TRIPS Council extended the period until 1 July 2013, and on 11 June 2013, it extended this further until 1 July 2021 — or when a particular country ceases to be in the least developed category if that happens before 2021.

Members recognized the progress LDCs had already made towards implementing TRIPS and the LDCs expressed their determination to preserve and continue this progress. The 2013 decision does not affect LDCs' right to fully use flexibilities in the TRIPS Agreement and to seek further extensions of the transition period.

WTO has also acknowledged the need/willingness to extend this deadline further.

Consequently, countries like India with large pharma manufacturing capabilities will be able to export to LDCs to meet their healthcare needs. However, the illustrative models prescribed by WTO/TRIPS Council for notifying under Para 6 system are too cumbersome and impracticable. Model- 1 (Importing Member's General Notification of Intent to use) [on Government letterhead]⁹ Model- 2 (Importing Member's Specific Notification) [on Government letterhead]¹⁰ Model- 3 (Exporting Member's notification) [on Government letterhead]¹¹ are not only extremely bureaucratic and time consuming, but also intended to defeat the very cause of affordable access.

It is surprising that countries like India, Brazil and South Africa have agreed to such impossible and impracticable procedural hurdles for implementing the Doha Para 6 proposal. It is indeed a matter of dismay and disappointment that in a country like India with high disease burden and strong manufacturing capabilities, the Indian pharmaceutical manufacturing companies have not adequately attempted to make use of the compulsory licensing provisions both under Section 84, Section 92 as well as Section 92 A of the Patents Act. In spite of the need for providing affordable access, where other provisions are being frustrated, the Government has, hitherto, not made use of the 'Government use' provisions of Section 100 & Section 101 of the Patents Act, 1970.

Compulsory Licence in India

The first attempt to obtain a CL was made by Natco by filing an application u/s 92 A of the Patents Act, 1970. Natco produced an order from Nepal to manufacture and export Roche's anti cancer drug,

Tarceva (Erlotinib). However, this CL application was rejected by the Delhi Patent Office for want of proper documentary support especially, Government endorsement or CL for importation into Nepal.

However, Natco succeeded in the second attempt for a CL for Sorafenib (Nexavar) of Bayer which was protected by Patent no. 215758 granted on 3 March 2008. Natco approached Bayer for voluntary licence to manufacture and sell its patented drug which did not materialize. Therefore, Natco filed an application for CL under Section 84 (1) of the Patents Act, 1970.

The Controller General passed a detailed and well reasoned order¹² which was delivered on 9 March 2012.

A brief history of CL is mentioned in the Order. CL under the patents system is described as an involuntary contract between willing buyer and an unwilling seller imposed and enforced by the State. As per WTO, CL is when a Government allows someone else to produce the patented product or process without the consent of the patent owner. The order justified the grant of CL under all the three counts under Section 84 (1) being (a) reasonable requirement of the public not satisfied, (b) patented invention not available to the public at a reasonable price or (c) patented invention is not worked in the territory of India. CL was granted to Natco subject to various conditions,¹² fixing a price of Rs 8880 (as against Rs 2,80,000) for a pack of 120 tablets and a royalty of 6% on the net sales of the drug on a quarterly basis.

This order was challenged in the IPAB by Bayer. IPAB dismissed Bayer's appeal.¹³ However, IPAB increased the royalty fixed by the Controller by one percent to 7%. It was held by IPAB that the grant of CL is not to favour the licensee, but to make the medicine reasonably affordable and accessible to the public. It upheld the Controller's decision that drugs should be made affordable and available to the public. IPAB found that Bayer had clearly failed the tests of Section 84(1); on all counts, even though IPAB observed that 'working' may not be interpreted solely as manufacturing in the country in all cases. IPAB interpreted that importation may also be treated as working if the full and complete (or atleast reasonable) requirements of the public are being met at a reasonably affordable price, in India.

While reading the decision in an open court on 4 March 2013, Justice Prabha Sridevan, Chairman of IPAB, said that drugs used for treating kidney and liver cancer should be made available at an affordable

price to all needy patients. Bayer had not taken any effort to revise the marketing strategy and cut the price of the product in the preceding three years after the grant of the patent from the date of filing the CL application by Natco. Reportedly, Bayer was importing the drug only for philanthropic activities in India, in relatively small quantities and at unreasonably high prices, as per IPAB. The IPAB upheld the order of the Controller General of Patents, granting the CL to Natco. The royalty rate was, however, enhanced by IPAB to 7% as stated earlier.

Bayer challenged the IPAB order through a Writ Petition before the Bombay High Court which was heard on 11 October 2013 and has since then been repeatedly adjourned and is pending to be heard, as on date.

It is clear from the trend of the legal proceedings following the CL order, that grant of CL u/s 84 of the Patents Act, 1970 could also lead to protracted legal proceedings. In spite of the provisions for grant of CL u/s 84, 92, 92 A and use for purpose of Government permission u/s 100 & 101, most Indian companies are reluctant to come forward to file application for CL in view of apprehension of protracted litigations. M/S BDR Pharmaceuticals International Pvt Ltd on 16 November 2006 filed an application u/s 84 of the Patents Act, 1970 for grant of CL for Dasatinib 'Sprycel' of Bristol Myers and Squibb which was granted an Indian Patent no. 203937 titled 'A compound 2-amino-thiazole-5-carboxamide'. Dasatinib is used mainly in the treatment of patients suffering from chronic myeloid leukemia.

However, the Controller General of Patents issued a show cause notice which was followed by a hearing. The CL application was thereafter rejected¹⁴ by an order of the Controller General of Patents stating that BDR has failed to make a *prima facie* case. In the meantime, it has become clear that the strategy of not rejecting a voluntary licence application and continued correspondence without leading to any closure of the negotiations¹⁵ is being adopted by the attorneys on behalf of international overseas patentees.

While continued communications are in progress for voluntary licence negotiations, the information being sought and made available are being used in the ongoing patent infringement litigations filed by international patentees. These patent infringement suits are filed in most cases purely based on application for regulatory approvals, either to the Drugs Controller General of India (DCGI) at the

Central Drugs Standard Control Organization (CDSCO) or to the State Food and Drug Administration. In view of this the uncertainties linked to the new strategies, grant of CLs in India u/s 84 of the Patents Act, 1970 appears to be bleak. In the meantime the Government of India, Ministry of Health had put forth a proposal for granting CL u/s 92 for three molecules, including Dasatinib an anti-cancer drug. As per latest report¹⁶, this proposal also appears to have been shelved. Another molecule which was under consideration of CL is Trastuzumab (Herceptin). The patentee, Roche has, in the meantime, decided to abandon¹⁷ and therefore not renew the Patent no. IN 205534 for Trastuzumab, without paying the renewal fees. Consequently, biosimilar version of Trastuzumab has been introduced by Biocon and Mylan. An infringement suit has been filed by Roche against Biocon and Mylan even though the patent has been abandoned, apparently for copyright violation. A hearing on this suit is presently in progress. It is, therefore, not surprising that no further compulsory licensing applications are being filed in spite of the very high price and very poor quantum of imports of anti-cancer drugs as seen from the filing of Form-27 with regard to working of patents, relating to patented anti-cancer drugs. A few larger Indian pharma companies have entered into voluntary licence- based marketing in India. In a few cases, joint venture companies have been formed to import and sell in India while in other cases local manufacturing under voluntary licence have been undertaken. The larger Indian companies, being natural allies for joint venture and voluntary licenses have opted not to apply for compulsory licences. The responsibility of applying for compulsory licences, in public interest, have come to settle on the medium level Indian pharma companies whose voluntary licence applications are being rejected or perennially denied through protracted cross communications, by design. In spite of such established defensive practices, medium sized pharma companies could have initiated the compulsory licence route, at least as an option to offer the lifesaving patented medicines at substantially lower prices, by utilizing the existing development and manufacturing capabilities. However, the reasons for such reluctance to venture into compulsory licensing are worth analysing. Threat of protracted litigations appears to be a dampener with dissuading effect on potential CL applicants.

Protracted Indian Pharma Patent Litigations

The Hon'ble Supreme Court in para 156 of their judgment¹ on Gleevec in *Novartis v Cipla & Ors* observed as follows: 'we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the coverage and the disclosure under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its claims by skilful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent'.

Similarly, in *Roche v Cipla*¹⁴ case, the Delhi High Court had categorically ruled out that Pharmaceutical Patent Regulatory Linkage which was upheld by the Division bench as well as the Supreme Court. Section 107 A(a) of the Indian Patents Act states as follows: 'any act of making, constructing [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India or in a country other than India, that regulates the manufacture, construction [use, sale or import] of any product.' The Section 107A(a) of the (Indian) Patents Act, 1970 is substantially similar to the Hatch Waxman Act of USA and the European directive no. 2004/27/EC and 2004/28/EC exempting clinical trials from patent infringements. Countries like USA have specific provisions similar to Section 107A(a), such provisions have been made much more liberal and broad through the *Merck v Intergra*¹⁸ case decided by the Supreme Court of USA, wherein, the Apex Court had observed that any research on patented molecules has a potential to lead to regulatory submissions for approval and hence, should be exempted from patent infringement. Unfortunately, the Indian judiciary is either not appreciating this provision or has not been adequately appraised.

There are extensive and protracted litigations in progress in Indian courts, wherein the 'cause of action' is either applying for a regulatory approval or obtaining a product manufacturing licence from the FDA. Consequently, the international practice of filing infringement suits purely on regulatory initiatives is being extended to India, even though

India does not have any data/marketing exclusivity, as in the developed countries. However, what distinguishes the Indian patent litigation from the litigations in the developed countries is the practice of protracted adjournments and procedural delays. In a recent case of *Bayer Corporation v Union of India and Ors*¹⁹, Natco raised the legal availability of the provisions of Section 107 A(a) of the Patents Act, 1970 with the Delhi High Court. In spite of which, the court has granted an injunction order against Natco. The legal status of export for regulatory approvals under Section 107 A(a) of the Patents Act, 1970 will hopefully be resolved in this case which is due for further hearing. The case laws described hereinafter would exemplify the current status and the need for legitimising the research exemptions available under Section 107 A(a) of Patents Act, 1970.

Dasatinib 1

Bristol Myers Squibb Company & Ors v Mr J D Joshi & Anr CS(OS) No. 2303/2009

There were around 31 hearings that took place in this case during the last five years since its filing in December 2009. The major issues are mentioned below:

The present case dealt with the application made by Bristol Myers Squibb (BMS) in Delhi High Court, for ad-interim *ex-parte* injunction to restrain defendants from manufacturing, offering for sale, selling and exporting the generic version of the drug Dasatinib (Sprycel), for which BMS was granted Indian Patent No. 203937. It was also averred that the defendant no.2 (BDR) is in the process of seeking marketing approval from the Drug Controller General of India for the drug. Balance of convenience was found to be in favour of plaintiff. Therefore, order was passed restraining the defendants from manufacturing, selling, distributing, advertising directly or indirectly any product which infringes the plaintiff's registered patent, till the next date of hearing.

Further, the plaintiffs filed a second suit against the defendant BDR Lifesciences Pvt Ltd alleging that they have applied for a compulsory licence and that they have suppressed the fact that they have obtained a manufacturing licence for Dasatinib in bulk from the Food and Drug Control Administration, Gujarat. Apart from seeking initiation of contempt proceedings on the ground of suppression on the part of the defendants, the plaintiff has also sought a direction to the defendants to enquire about the oath of the manufacturing licence. The High Court rightly held that this was not a case of contempt and directed the

defendants to disclose the oath whether any such licence has been obtained and if obtained, produce the same before the Court. The contempt petition was disposed off, thereafter. CS(OS) 2303/2009 will be heard along with the fresh suit of CS(OS) 679/2013 on 7 May 2014. The details of this case are available in an earlier article by present authors titled 'Landmark Pharma Patent Jurisprudence in India'.²⁰

Dasatinib 2

Bristol Myers Squibb Company & Ors v Mr D Shah & Anr CS(OS) No. 679/2013

It is pertinent to note that the second suit against the same defendants has been filed with alleged cause of action being filing of a CL application.

Bristol Myers Squibb (BMS) filed a suit against Mr D Shah & Anr for infringement of its patented drug Dasatinib in April 2013. Court mentioned that the admitted position on 12 April 2013 is that the defendants are not manufacturing or selling the medicine in question i.e. Dasatinib. The Counsel for plaintiff stated before the court on 12 April 2013 that though defendants are not manufacturing or selling Dasatinib, however it appears as a 'finish formulations' on the website. Counsel for defendant replied that the website shows their capability to produce the drug and is not an offer for sale. Appropriate notification to that effect was provided on the website. On 3 October 2013, senior counsel for the defendants, stated that till 9 January 2014 when I.A. Nos. 5910/2013 and 11286/2013 are listed for hearing, the defendants shall not produce the drug in question. This case will hopefully be heard jointly with the 2009 case, on 7 May 2014.

Dasatinib 3

Bristol Myers Squibb Company & Anr v Mr VC Bhutada & Ors CS(OS) No. 2801/2012

Bristol Myers Squibb Co (plaintiff no. 1) and Bristol Myers Squibb Pvt Ltd (plaintiff no. 2) filed a suit against Mr V C Bhutada and the Managing Director of Shilpa Medicare Ltd (defendant no. 1 & 2 respectively) both located at Raichur, Karnataka and Natco Pharma Ltd (defendant no. 3) having its office in Hyderabad and also operating from D-70, Okhla Industrial Area, Okhla Phase-I, New Delhi, asking for permanent injunction relating to infringement of its patented drug Dasatinib protected under patent no. 203937. Plaintiff no. 1 has its principal place of business in New York, USA. Plaintiff no. 2 has its registered office in Mumbai and it also carries on business from its office in Barakhamba Road, New

Delhi. Plaintiff no. 2 is a subsidiary of Plaintiff no.1 and it markets pharmaceutical products in domestic market. Defendant no. 3 in its written statement stated that it had no relationship with defendant no.1 and 2 and alleged that the suit was filed to multiply the litigations against it. The validity of jurisdiction and 'cause of action' were challenged by the defendants. Whether the court has territorial jurisdiction to entertain the suit, one will have to wait till the trial is completed as the court held that this is a mixed question of law and fact.

Dasatinib 4

Bristol Myers Squibb Company & Anr v Mr M Adinarayana and Anr CS(OS) No. 2279/2009

A similar suit no.CS(OS) 2279/2009 has been filed in 2009 against Natco, the hearings for which are also in progress. In this case the issues are being consolidated and framed. This case is due for hearing later in 2014.

Dasatinib 5

Bristol Myers Squibb Company & Anr v Dr BPS Reddy & Ors CS(OS) No. 2680/2008

This suit no. CS(OS) 2680/2008 filed in 2008, continues to be heard through adjournments and procedural issues. BMS appears to be impleading additional defendant for which the matter is adjourned to 8 May 2014. The large number of adjournments on procedural issues extending over 4 to 5 years, without any substantive hearing, leads to the conclusion that these are protracted litigations to tire out the generic companies and prevent them in future from applying for regulatory approvals under Section 107A(a) during the validity of pharma patents.

Other Pending Suits

Erlotinib has been subject matter for many infringement litigations, *Roche v Cipla* being the lead one. 'Patent valid, but not infringed'²¹ judgement was given by the Hon'ble Single Judge which had been challenged by Roche. The same is in appeal before the Division Bench. However, a large number of cases against other parties are in progress at Delhi High Court. Similarly, 'patent valid but not infringed' order has been delivered by the Hon'ble Single Judge, in the preliminary hearing on Sitagliptin²² in the case of *Merck/Sunpharma v Glenmark*, which has also gone to the Division Bench on Appeal. Many similar cases are pending such as relating to Sorafenib, Sunitinib, Ixabepilone, Cabazitaxel and many others.

Groundless Threats of Infringement Proceedings

Section 106 of the Patents Act, 1970 relates to groundless threats of infringement proceedings. Many infringement proceedings have been initiated in India inspite of statutory exemptions to Section 48 (rights of patentees), such as Section 47 (general exemptions) and Section 107A(a). The cause of action in many ongoing suits, as already stated earlier, are merely relating to applications for regulatory approval of a medicine, either to the DCGI at the Central Drugs Standard Control Organization or to the State Food and Drug Administration. In atleast one infringement suit, the cause of action is reported to be 'filing of a compulsory licence application'. Listing of a patented drug on the website with disclaimers of 'not for sale' has also been considered as a cause of action. While such exemptions are available, as stated earlier, under Hatch-Waxman Act in USA and EU Directive no. 2004/27/EC and 2004/28/EC, it is unfortunate that Indian pharma companies are being denied this validly available and eligible statutory exemption. Indian pharma companies lack financial strength and logistics as well as economically viable legal support to fight protracted litigations. Even if these costly litigations eventually exonerate the generic companies, they get financially exhausted by the time the suit is decided, dismissed, withdrawn or settled. It has, therefore, become imperative to look at various options for the generic companies to provide affordable access of lifesaving medicines to the needy patients for extending or saving their lives. A few options are discussed hereinafter.

Patents on Lifesaving Medicines

Admittedly one has to tread a middle-path and follow a fine balance while debating whether patents should be bypassed for public health. A patent which acts as a statutory support to researchers and inventors, is admittedly the only option for encouraging and rewarding innovative research leading to new drugs and treatments. However, the pricing of such new drugs should have some parity with the purchasing power of patients and the mode of funding treatments which vary from the developed countries, developing countries and least developed countries. In this context, the proposal from Indian drug price regulatory authorities to adopt a mode for fixing the prices of patented drugs may be worth referring to.

Price Negotiations for Patented Drugs by the Government

In early 2013, the Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers came out with the Reports of the Committee on price negotiations for patented drugs.²³ Different pricing models such as reference pricing, differential pricing, cost based pricing and negotiated pricing were considered by the Committee for pricing of patented drugs. The Committee also studied the pricing models in various countries such as Australia, Canada, China, France and others. The prices of patented drugs were compared with specific reference to the innovators price and their corresponding generic medicines marketed in the country by Indian pharmaceutical companies such as Cipla, Natco and others for medicines such as Erlotinib and Sunitinib. The Indian generic equivalents which were already marketed with or without CL were found to be in the range of close to 10- 12% as per detailed comparative data provided in tabular form. The Committee proposed to have reference pricing or negotiated pricing based on therapeutic category. The proposal for negotiated pricing based on a methodology as suggested by the Committee was subjected to comments, views and suggestions from the industry associations. The associations suggested that the pricing of patented drugs should be negotiated on the basis of purchasing power parity and per capita income of India compared to the countries of reference pricing instead of per capita gross national income with purchasing power parity. There are many proposals that have been considered in the past for fixing prices of patented drugs. NGOs have opposed fixing prices of patented drugs on the grounds that this will close the door on future grant of compulsory licences. However, the past and recent examples of compulsory licences clearly indicate both a strong reluctance on the part of the authorities for grant of CL application as well as extensive protracted litigation, even if CL applications are filed or granted. Hence, there has to be a practically viable and efficient mode for fixing prices of patented drugs, especially in India, since it has substantial research and manufacturing capabilities and process development potential.

The Competition Act, 2002 to help Affordable Access to Patented Lifesaving Medicines

The Competition Act 2002, notified on 20 May 2009, is empowered to intervene in anti competitive abuse of dominant positions. Admittedly,

patents granted under Patents Act, 1970 enjoy monopoly under Section 48. However, such monopoly is subject to other laws of land, including other provisions of the Act such as exemptions thereof, compulsory licensing and Government use. Protracted abusive litigations with cause of action being exempted acts or applying for compulsory licensing or applying for regulatory approval could be challenged under the Competition Act, 2002. Competition Commission of India (CCI) has already intervened in pharma related complaint against AIOCD.²⁴ This landmark decision has resolved long pending problems in pharma distribution in India. Similarly, the CCI has also got involved in the Google²⁵ case and granted an extension order to its Director General in order to ensure a thorough and complete investigation. Another case in which the CCI intervened was that of *Intex v Ericsson*, in which Ericsson managed to obtain an order from the Delhi High Court restraining CCI from adjudicating the dispute.

In recent times, extensive non tariff barriers (NTBs) are being erected against Indian generic pharma both domestically and internationally. Intensive attacks on quality of Indian generics are being synthesized to tarnish and damage Indian pharma reputation in international market. In spite of USFDA vouching²⁶ for the quality, efficacy and safety of Indian pharma generics, vested interests consisting of leading MNC's appear to have initiated sponsored studies by doctors and academicians to malign the reputation for quality of Indian pharma generics. Combined with the frivolous and imaginary infringement litigations in India in pharma generic companies, such abuse of dominant position could be challenged through Competition Commission of India.

'Licence of Right' for Lifesaving Drugs

Affordable access to expensive and lifesaving drugs for serious medical conditions to be ensured through the re-instatement of the provision of 'Licence of right' under Section 92 of the Patents Act, 1970, may be one of the options. Those drugs which are covered by patents and which are expensively priced, but needed for extending the lifespan of patients suffering from life threatening diseases need to be made available for public access by invoking the provision of 'Licence of right' which was covered by Section 86 of the earlier (amended) Patents Act, 1970. This erstwhile Section 86 read as follows:

Section 86 : Endorsement of Patent with the Words ‘Licences of Right’

(1) At any time after the expiration of three years from the date of sealing of a patent, the Central Government may make an application to the Controller for an order that the patent may be endorsed with the words ‘Licences of right’ on the ground that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price.

(2) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, may make an order that the patent be endorsed with the words ‘Licences of right’.

(3) Where a patent of addition is in force, any application made under this section for an endorsement either of the original patent or of the patent of addition shall be treated as an application for the endorsement of both patents, and where a patent of addition is granted in respect of a patent which is already endorsed under this section, the patent of addition shall also be so endorsed.

(4) All endorsements of patents made under this section shall be entered in the register and published in the Official Gazette and in such other manner as the Controller thinks desirable for bringing the endorsement to the notice of manufacturers.

The provision for ‘Licence of right’ was omitted in the Amendments to the Patents Act, 1970, post TRIPS compliance, not taking into account the Doha Declaration. In view of the failure of implementation of Doha Declaration, the non review of TRIPS as mandated under Article 27(3)-(b) and in view of protracted, abusive, obstructive and exorbitantly costly litigations in progress including against valid grant of CL, it appears to be time for India to consider reintroduction of licence of right provision for patented lifesaving medicines, once again. However, this option will need amendment of the Patents Act, 1970.

Obligatory Licence

Dr Yusuf Hamied, Cipla has lately been propounding the concept of ‘obligatory licence’²⁷ for lifesaving patented medicines. This proposal appears to be a hybrid between CL and licence of right. This option will also, however, need amendments of the Patents Act, 1970.

Government Use Option

Section 100 and Section 101 of the Patents Act, 1970 provide for Government use without prior permission of the patentee. With large number of Government and semi- Government hospitals including ESIS, Defence, Government owned cancer hospitals, Municipal hospitals, Rural healthcare centres and others, Government could invoke the provisions of Section 100 and Section 101 to make affordably priced or free lifesaving medicines which are otherwise only imported and exorbitantly priced, under patents. The recent proposal from the Ministry of Health for grant of CL for lifesaving cancer drugs has been rejected by the Department of Industrial Policy and Promotion (DIPP) under Section 92 of the Patents Act, 1970. The Health Ministry of India could make similar proposal for getting the essential patented medicines which do not meet the affordable drugs criteria, met by getting these drugs manufactured by generic pharma companies of international standards (GMP standards) as per provisions of Section 101 and make the same available for distribution through government channels by invoking the provisions of Section 100 of the Patents Act, 1970. In view of the protracted litigation preventing practical solutions to implement affordable access as unanimously admitted under Doha Declaration in 2001, invoking of Section 100 and 101 of Patents Act, 1970 appears to be the most workable solution in the current context.

Conclusion

The product patent related provisions have been newly incorporated in the Patents Act, 1970 post WTO-TRIPS amendments. Even though, the harmonised provisions are new to Indian pharma industry, patent litigations in Indian courts have increased, post 2005. While, the international provisions are being adopted liberally for granting injunctions and even *ex-parte* injunctions, in infringement suits filed, most often, for applying for regulatory approvals, the statutory research exemptions available under Section 107 A(a) of the Patents Act, 1970 are being substantially ignored. In view of the reluctance of Indian pharma companies for applying for compulsory licence or for availing the exemptions, there appears to be a need for evaluating alternate options to improve affordable access of patented medicines in India. Few such provisions need to be put to test in coming years especially in view of the failure to implement the Doha Declaration.

India, with the high disease burden and poor per capita income, needs to pursue options for improving affordable access to lifesaving patented medicines in view of the failure of Doha Declaration and legal impediments in invoking the flexibilities and provisions incorporated in the (Indian) Patents Act, 1970. One or more of the options as suggested herein may be considered for adoption, especially for patented lifesaving drugs to be made available to all the needy patients at affordably reasonable price.

References

- 1 *Novartis AG v Union Of India & Others*, Civil Appeal Nos. 2706-2716 of 2013 and Civil Appeal No. 2728 of 2013 and Civil Appeal Nos. 2717-2727 of 2013 Supreme Court of India order dated 1 April 2012, <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212> (5 September 2013).
- 2 Article 7 & 8 of TRIPS as well as Sec.83 (c)(d) and (f) of the Patents Act, 1970 reads as follows:
Article 7/ Sec.83 (c) reads: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.
Article 8(1)/Sec.83(d) reads: Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
Article 8(2)/Sec.83(f) reads: Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.
- 3 The Uruguay Round was the 8th round of multilateral trade negotiations (MTN) conducted within the framework of the General Agreement on Tariffs and Trade (GATT), spanning from 1986 to 1994 and embracing 123 countries as 'contracting parties' which concluded in Marrakesh on 15 April 1994.
- 4 Sir Arthur Dunkel was entrusted with the work of eliciting views from member nations and adopting a unanimously acceptable draft which eventually culminated in TRIPS.
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- 9 http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs1_e.htm (4 October 2013).
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- 11 http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs3_e.htm (3 October 2013).
- 12 *NatcoPharmavBayer, C.L.A.No.1/2011*, http://www.ipindia.nic.in/iponew/compulsory_License_12032012.pdf (12 October 2013).
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- 21 *F Hoffmann-La Roche Ltd & OSI Pharmaceuticals Inc v Cipla Ltd*, High Court of Delhi, CS (OS) No.89/2008, High Court of Delhi order dated 7 September 2012, <http://lobis.nic.in/dhc/MAN/judgement/10-09-2012/MAN07092012S892008.pdf> (25 September 2013).
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