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Landmark Pharma Patent Jurisprudence in India

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In a short span of less than 10 years after the new WTO/TRIPS based product patent regime came into effect, there have been many landmark judgments from Indian Courts on interpretation of various provisions of the exhaustive (Indian) Patents Act, 1970, as amended. Even though very large number of product patents have been granted during this period, patent challenges and infringement suits are limited to a few blockbuster molecules. Currently, litigations are in progress, including those in appeals as well as on matters remanded back to patent office. The landmark cases, in recent times, are dealt with, herein. Additional areas which may require judicial intervention arising out of the ambiguities in the Act and Rules are also briefly dealt with.

Keywords: Gleevec, Section 3(d), Supreme Court order, IPAB, Erlotinib, Sitagliptin, Sorafenib, Dasatinib, Sunitinib, date of patent

Dating back from the recent *KSR* v Teleflex[1] decision of the US Supreme Court to the earliest landmark Indian judgment of *Bishwanath Prasad Radhey Shyam* v *Hindustan Metal Industries*[2], the obviousness test has travelled a long distance from 'mere workshop improvement'[2] to TSM test[3] to 'obvious to try'[1] conclusions. Indian Patent office has been extensively applying the obviousness test through mosaicing of prior arts and application of Section 2(1)(ja). Even though a large number of patent applications have been rejected in India due to lack of inventive step (obviousness) and many pre-grant as well as post grant oppositions have succeeded on this ground, the obviousness test has substantially been overshadowed by 'What is not patentable/ Inventions not patentable' as in Section 3 of Patents Act, 1970. More particularly, Section 3(d) has gained considerable global attention from Indian jurisprudence. The most famous Indian case on Section 3(d) has been Gleevec.[4] The sequence of litigations on Section 3(d) in Gleevec has been covered in an earlier article.[5]

Even though India has one of the most exhaustive Patent Act/Rules, there are many grey areas which need to be resolved through jurisprudence. While it is admitted that US Patent regulations[6] substantially emerge through 'judge made laws', the exhaustive style and status of Indian Patent Act was expected to be resolving every issue, finding answers to all questions within itself. However, within the short span of less than 10 years from the adoption of product patent regime many substantive issues have cropped up before the judiciary. A few of the landmark Indian patent related judgments, more particularly relating to pharmaceuticals, which have resolved many outstanding issues, are dealt with in this article. A few potentially contentious provisions of the Patents Act, 1970 are also discussed herein.

The (Indian) Patents Act, 1970 underwent three major amendments, in the years 1999, 2002 and 2005. Each of these three amendments had its own significance to enable India, in phases, to fulfil the obligations under the World Trade Organization (WTO) and to make the Indian Patents Act, 1970 TRIPS[7] compliant. Out of the three amendments, the major amendment in the Patents Act 1970 was the 2005 amendment which came into effect retrospectively from 1st January 2005 (the 2005 amendment Act was passed in March 2005). Prior to the amendment, the erstwhile provisions of the Patents Act only permitted the grant of 'process patents' in India. The 2005 amendment extended protection to 'product patents' in the areas of drugs, pharmaceuticals and agriculture, reversing the 1970 amendment. The 2005 amendment was in consonance with Article 27(1) of TRIPS which stated that 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. As required

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under Article 70(8) of TRIPS, a mailbox facility[8] was already provided under transition arrangements. The Exclusive Marketing Rights (EMR) provision got exhausted in 2005 having been replaced with a full-fledged product patent regime effective since 1 January 2005.

Even though the Indian Judiciary is familiarising itself with respect to patents, the Judicial Pronouncements from Indian Courts, in recent times, are worth a mention for having far reaching consequences. In fact, patent litigation in India is currently receiving considerable international attention. It was post 2005 that India began to witness large number of litigations with respect to 'product' patents. The Gleevec case, one may also call it the 'Mother of all product patent litigations in India', caused a stir, almost in the form of a 'tsunami', among intellectual property practitioners, both nationally and internationally.

The Curious Case of Gleevec®

India amended the Patent law in 1970 by introducing a new Section (Section 5) declaring food, drugs, and agro-chemicals as being not eligible for grant of product patents. Consequent to India ratifying the WTO & TRIPS agreements in 1.1.1995 and in compliance to Article 70.8 of TRIPS, India was obliged to introduce a mailbox transition system. One such application which was filed as a convention 'Mailbox application' was Indian patent application No. 1602/MAS/1998 for the invention titled 'crystal modification of a N- phenyl-2-pyrimidineamine derivative, processes for its manufacture and its use'. The patent application primarily sought to claim 20 years monopoly over beta crystalline form of Imatinib Mesylate (Gleevec).

However, since India was not obliged to recognize/ receive product patent applications prior to 1.1.1995, any disclosure/claim made anywhere for a pharmaceutical product prior to 1.1.1995 was considered automatically ineligible for grant of a product patent in India. The beta crystalline form of Imatinib Mesylate (Gleevec) was a typical case where Imatinib base, its salts as well as process of making the salts were clearly disclaimed prior to 1995.

The case of Gleevec® began in 1997, when Novartis AG, a pharmaceutical company based in Switzerland, filed a patent application in the Chennai (Madras) Patent Office for the beta-crystalline of Imatinib Mesylate on 17th July 1998. The patent application no. 1602/MAS/1998(ref.9) sought patent protection for beta crystalline salt form of the free base, Imatinib, which was covered by an earlier pre-1995 patent no. 5,521,184A,10 popularly known as the 'Zimmerman Patent'. In the 'Zimmerman Patent' many obvious options of salts were discussed and disclaimed. Since the Indian patent application no. 1602/MAS/1998 was filed during the transitional phase, it was kept in the mail-box and not opened for examination until 2005.

In the meantime, on 10th November 2003, Novartis obtained EMR for marketing Gleevec® in India. In order to enforce the EMR, Novartis obtained injunction order from the Hon'ble Madras High Court to restrain the Indian generic manufacturers from manufacturing, selling and distributing the generic versions of Gleevec®. Once the generic manufacturers stopped producing Gleevec®, the price of Gleevec® increased from approximately Rs10,000 to around Rs1,20,000 for a month's treatment. (The generic version of the drug was costing about Rs 90 per 100 mg capsule, while after Novartis was granted an injunction order, the price of Gleevec® rose to Rs1,000 per 100 mg capsule).[11] However, in a parallel litigation, the Hon'ble Bombay High Court[12] refused to grant an injunction, unlike Chennai High Court.[13]An important amendment in 2005, (made on the floor of the House) was the introduction of an explanation to Section 3(d), introducing the concept of 'efficacy'. Taking cognisance of emerging patent practices for extension of patent terms, more particularly in pharmaceuticals in developed countries, the Indian Parliament introduced a significant and important provision to prevent 'evergreening', by blocking grant of frivolous patents by way of Section 3(d) and explanation thereof. After the 2005 amendment to the Indian patent law, various generic companies (Opponents) [14] and an NGO filed pre-grant oppositions against Novartis' patent application. The Opponents averred, among other grounds, that the alleged 'invention' was not novel and did not involve an 'inventive step'. Further, it was argued that the alleged invention was merely a 'new form' of a 'known substance' that did not result in the enhancement of efficacy. It was argued that the alleged invention did not meet the patentability criteria and it was also not patentable under Section 3(d). These arguments were based on the fact that Novartis had already been granted a US patent in 1993 for the free base, Imatinib, including disclaimer

for salts and processes thereof. The Opponents further averred that the US 1993 'Zimmerman' patent effectively disclosed both the free base, Imatinib,[15] and the acid-addition salt, Imatinib Mesylate. It was also averred that different crystalline forms of Imatinib Mesylate did not differ in properties with respect to efficacy. Thus, various forms of Imatinib Mesylate must be considered the 'same substance' under Section 3(d) and explanation thereof. During the proceedings, the technical expert representing Novartis produced affidavits wherein beta crystalline salt was compared with the insoluble Imatinib base. The expert further stated in the affidavit that the 30% increase in bioavailability is to be expected since the beta crystalline salt is soluble while the insoluble Imatinib base will not get absorbed in the bloodstream readily. It was argued by the opponents that the comparison for enhanced efficacy should have been done between the alpha crystalline salt and beta crystalline salt of Imatinib and not between the Imatinib base and beta crystalline salt.

Pursuant to the pre-grant oppositions, on 25th January 2006, the Patent Controller in Chennai refused to grant a patent to Novartis. Accordingly, the EMR got extinguished.

In response to the order of the Patent Controller rejecting the grant of an Indian patent to Novartis, Novartis filed Writ Petitions[16] against the Government of India and the opponents before the Hon'ble Madras High Court. These Writ Petitions challenged the Patent Controller's decision as well as the Constitutional validity of Section 3(d). In the Writ Petition challenging the Constitutional validity of Section 3(d), Novartis averred that the term 'efficacy' in Section 3(d) was vague and ambiguous. Therefore, it violated the Equity provision provided in Article 14 of the Indian Constitution. Novartis also averred that Section 3(d) was not TRIPS compliant. Over a period of time and after many adjournments and arguments, the writ petitions challenging the decision of the Patent Controller were converted into statutory appeals. The first appeal challenging the Constitutional validity of Section 3(d) was heard by the Hon'ble High Court of Madras. The Constitutional validity of Section 3(d) was upheld and the appeal was rejected.

On 6 August 2007, the Hon'ble Madras High Court issued an order on Writ Petition that challenged the constitutional validity of Section 3(d). Dismissing Novartis' writ petition and pronouncing Section 3(d) as constitutionally valid, the Hon'ble Madras High Court stated that,

> 'We state that in this case we have already found, analysing the alleged offending provision, that it is not in violation of Article 14 of the Constitution of India. We have borne in mind the object which the Amending Act wanted to achieve namely, to prevent ever-greening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.'

Further, the Hon'ble High Court defined the term 'efficacy' as 'therapeutic effect in healing a disease or having a good effect on the body'. However, the Hon'ble High Court refused to examine whether Section 3(d) was TRIPS compliant or not, leaving it to be contested at the WTO's Dispute Settlement Body/Forum (DSB).

The second appeal relating to the rejection of the patent application for beta crystalline salt was transferred to the Intellectual Property Appellate Board (IPAB) after Government of India notified the IPAB to hear appeals relating to patents.[17]

A spate of litigations ensued thereafter with regard to the competence of the Technical Member of IPAB to hear the appeal, and alternate remedies and options. The issues were contested both before the High Court and also before the Supreme Court repeatedly.

On 29 June 2009, the Hon'ble IPAB reversed the order of the Controller in part and held that the beta-crystalline form of Imatinib Mesylate was novel and involved an inventive step. However, the Hon'ble IPAB[18] held that Novartis's alleged invention did not satisfy the test of Section 3(d) since, Novartis could not show any actual enhancement of known efficacy for its beta crystalline form of Imatinib Mesylate. Concluding, the Hon'ble IPAB observed as follows:

> 'Considering all the circumstances of the appeals before us, we observe that the Appellant's alleged invention won't be worthy of a reward of any product patent on the basis of its impugned application for not only satisfying the requirement of Section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of Section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things.'

In response to the Hon'ble IPAB's order, Novartis filed a Special Leave Petition before the Hon'ble Supreme Court challenging the IPAB's interpretation and application of Section 3(d). Appeals were also filed by generic companies including Cipla and an NGO, against the order of the IPAB which held the Novartis' invention to be novel and inventive.

The epic battle of Section 3(d) which commenced in 2004/2005 finally culminated on 1 April 2013 at Supreme Court of India. The Hon'ble Supreme Court held[19]

> 'that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of Section 2(1) and Section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost.'

Reports have been abuzz that Novartis was contemplating filing a review petition against the order of the Hon'ble Supreme Court. Till date it appears that Novartis has not filed a review petition, the deadline of which expired on 1 May 2013. However, an investigation has been initiated by ITC (International Trade Commission) on Trade, Investment, and Industrial Policies in India: Effects on the US Economy. This investigation no. 332-543 (ref.20) by ITC *inter alia* appears to cover Section 3(d) of the Patents Act, 1970 also among 'IP intensiveness' in India.

The Hon'ble Supreme Court judgement on Gleevec also set at rest the allegations that India does not allow incremental innovations. The transitional status and the impact of prior patenting as well as that of Section 3(d) in the Gleevec case was unjustifiably interpreted to allege that India does not allow patenting of incremental innovations. With regard to incremental innovation, the order stated

> '191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that Section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of Section 5 from the Parent Act. That is not said in this judgment.'

Further, the Supreme Court observed in Para 156 of the judgment[4] that the trend of excessive patent litigation should not be introduced in India,

> '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'.

Novartis had also filed a divisional patent application for the alpha crystalline form of Imatinib which was rejected by the Patent Office through pre- grant oppositions which was neither appealed nor challenged by Novartis.

Erlotinib Case

Examination of product patent applications filed in India between 1.1.1995 and 31.12.2004 commenced post 1.1.2005. Many patents for post 1995 molecules and NCEs were granted in India after examination. One such molecule which was developed by Roche was Erlotinib. In the meantime, Cipla leading generic Pharma manufacturer began manufacturing and marketing the generic version of Erlotinib in India. On grant of the Erlotinib Patent no. 196774, Roche initiated infringement proceedings against Cipla specifically seeking injunction against Cipla. On the other hand, while the patent no. 196744 for the Erlotinib base was granted, a product patent application for the polymorph B of Erlotinib was rejected under Section 3(d) among other grounds. Since, the product marketed by Roche and later by Cipla was distinctively identifiable as the polymorph B of Erlotinib, Cipla had proceeded to launch the product in the anticipation of non-infringement. While the litigation against Cipla on Erlotinib is at the appeal stage in the High Court of Delhi, a few more generic manufacturers are being sued by Roche, parallelly.

During the *Roche* v *Cipla* litigation, the two interesting legal aspects were brought through the orders of the Delhi High. These orders are discussed below in Part I, II and III.

Erlotinib Part I

Third Party (Public) Interest and ad-interim Injunctions

F Hoffmann-La Roche Ltd & Anr v *Cipla Ltd*[21]

The present case dealt with the Roche's application, before the Single Bench presided by Hon'ble Justice S Ravindra Bhat, for ad-interim injunction to restrain Cipla from manufacturing, offering for sale, selling and exporting the generic version of the drug Erlotinib (Tarceva®), for which Roche was granted Indian patent no. 196774.

This judgment was hailed by NGOs and the public alike who referred to this order as 'judge-made compulsory licence.' It is well-known that the scales of justice tilt in the direction of either the plaintiff or the defendants. However, in this landmark order special consideration was given to Public (third party interest), which would be deprived of the generic product and thus shortening of lives of several unknown persons. Hon'ble Justice S Ravindra Bhat held this damage which cannot be restituted in monetary terms, is not only uncompensatable, but it is irreparable.

Hon'ble Justice S Ravindra Bhat, while rejecting the ad-interim application filed by Roche, held that

> 'the Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable. Another way of viewing it is that if the injunction in the case of a lifesaving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erloticip are concerned.'

However, the Court was not oblivious to the interests of Roche. While allowing Cipla to manufacture and sell the generic version of Tarceva®, that is Erlocip®, the Court directed Cipla to furnish the following,

(i) an undertaking to pay damages in the event of the suit being decreed,

(ii) maintain faithful accounts of its sale of the product Erlocip and file quarterly accounts in this court,

(iii) File an annual statement of the sales figures, of Erlocip.

Third Party (Public) Interest upheld by Division Bench of Delhi High Court

F Hoffmann-La Roche Ltd & Anr v *Cipla Ltd*[22]

The present appeal was filed before the Division Bench of Hon'ble the Chief Justice and Hon'ble Dr Justice S Muralidhar against the order of the Hon'ble Single Judge, Justice S Ravindra Bhat, who dismissed the Roche's application for ad-interim injunction in public interest.

The Hon'ble Division Bench while upholding the order of the Single Bench and dismissing the appeal with costs at Rs 5 Lakhs to be paid by Roche to Cipla, made several observations such as,

1 That Roche failed to inform the Controller of a second patent application filed by Roche for Polypmorph B form of the Erlotinib during the prosecution of patent application for Erlotinib Polymorphs A and B (IN196774). This was inconsistent with the requirement of a full disclosure.

2 Change in the stand of Roche that the earlier patent US5747498 (equivalent to 196774 - in respect of a mixture of polymorphs A and B) did not disclose Polymorph B free of Polymorph A, however, that it covered all known and unknown forms of Erlotinib.

3 That Roche has to make an unequivocal disclosure that the patent they hold covers the drug in question and that whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent and the effect of such applications on the suit patent. That Roche will have to disclose to Court the x-ray diffraction data of the product, particularly if it is a pharmaceutical drug in polymorphic form.

4 Since Cipla has raised a serious doubt on whether Roche held a patent for the product sold in the tablet form as Tarceva, Roche must be held not to have been able to show that they have a *prima facie* case in their favour for grant of an order restraining the Cipla from marketing Erlocip.

5 Assuming that Roche held a patent for Tarceva, it would not *ipso facto* entitle Roche to an interim injunction, since Cipla had raised a credible challenge to the validity of the patent by raising a serious triable and substantial question by way of counter-claim for revocation.

6 That general public access in India to lifesaving drugs assumes great significance and the public interest in greater public access to a lifesaving drug will have to outweigh the public interest in granting an injunction to Roche.
7 That Cipla was *prima facie* able to demonstrate that Roche did not hold a patent yet for the drug Tarceva, a polymorph B form of Erlotinib, product patent application for which was rejected.

Pursuant to the order of the Hon'ble Division Bench, Roche filed a Special Leave Petition[23] before the Hon'ble Supreme Court of India. However, since the Civil Suit was pending before the Hon'ble Delhi High Court, the Supreme Court was not inclined to interfere with the impugned judgment with respect to the interim order. The Hon'ble Supreme Court while dismissing the Special Leave Petition directed the Single Judge dealing with the Civil Suit to conclude the trial as expeditiously as possible without being influenced by any observation made by the Division Bench in the judgment.

Erlotinib Part II

Patent Valid - not Infringed

When the Erlotinib[24] infringement suit filed by Roche and the counter claim for revocation by Cipla came up before Single Judge, Hon'ble Mr Justice Manmohan Singh, Section 3(d) was put to test from both sides. While the Judge rejected the impact of Section 3(d) on patentability of Erlotinib in Patent no. IN196774 and upheld its validity, the impact of Section 3(d) on another patent application no. IN' 507 (IN/PCT/2002/00507/DEL) of Roche which was rejected by the Patent Office being a polymorph of the basic molecule in Patent No.IN196774 led to the conclusion by the Judge that the patent is not infringed though valid. This conclusion emerged from the fact that Tarceva the Erlotinib brand of Roche as well as Erlocip the Erlotinib brand of Cipla both were the stable form of polymorph B, the patent for which was rejected in IN' 507. While the patent no. IN196774 was held valid for polymorph A or for the basic molecule.

The Erlotinib order has been appealed by both Roche and Cipla and is now pending before the Division Bench of the Delhi High Court.[25] No substantive arguments have yet commenced on the appeal before the Division Bench of the Delhi High Court.

Erlotinib Part III

A series of law suits have been filed in India by Roche against Glenmark Pharma, Reddy's Lab, Natco pharma, Innova pharma, Cipla, Aureate Healthcare Pvt Ltd, BDR Pharma, Oncare Lifesciences, Accura care Pharmaceuticals for enforcing Erlotinib Patent IN 196774. In spite of the conclusive Judgment on Erlotinib in *Roche* v *Cipla*, the multiple Erlotinib suits continue without any final order, yet. Awaiting final judgement on *Roche* v *Cipla* on Erlotinib, the plethora of suits on Erlotinib are being adjourned regularly and perennially.

In the meantime, infringement actions initiated by Roche against Matrix[26] , Intas[27] in Madras High Court have been dismissed for lack of jurisdiction.

Sitagliptin Case

The recent case of *Merck Sharp and Dohme Corporation and Anr* v *Glenmark* on Sitagliptin[28] came up with a judgment which is very similar to that of Erlotinib case in *Roche* v *Cipla*. The parent Sitagliptin patent was granted to Merck under patent no. IN209816 and Merck had licensed the product for marketing in India to Sun Pharma. However, Merck has also filed an application for phosphate salt of Sitagliptin which did not find favour with the Patent Office on patentability criteria and was hence, rejected by the Patent Office. Consequently, Merck abandoned its patent application for the phosphate salt in India. Having considered the vulnerability of Merck with regard to Sitagliptin (Januvia®), Glenmark came up with a patent challenge by launching Zita and Zitamet, the branded generics of Sitagliptin. Glenmark argued for the 'safe harbour' of marketing the phosphate salt of Sitagliptin which is same as Januvia (also a phosphate salt of Merck/Sun Pharma). Eventhough, Merck has been a granted Indian patent no. IN209816, since, the patent for phosphate salt was abandoned by Merck in India, the Hon'ble Single Judge of the High Court of Delhi while not going into the merits of the suit patent held that *prima facie* there was no infringement as the marketed product is a phosphate salt, the patent application for which was abandoned by Merck in India.

The order of the Single Bench[29] is under appeal before the Division Bench[30] of the Delhi High Court. Judgement of the Division Bench was reserved for 10th January 2014. However, no final order has yet been pronounced by the Court, eventhough the hearing is over and the order has been reserved.

The Glenmark Case however needs to be distinguished from the Aprica Pharma case. In the case of *Merck* v *Aprica pharma*[31] it was contended by Merck who holds patent for Sitagliptin under patent no. IN209816 that Aprica Pharma is planning to launch the medicine with content which is an identical salt for which Merck holds patent. In this case the balance of convenience was found to be in favour of Merck. Hence, Hon'ble Delhi High Court passed ex-parte injunction restraining Aprica from launching its product. The *ex-parte* injunction continues against Aprica and not against Glenmark.

Sorafenib Case

Sorafenib (Nexavar) has created major ripples emanating from India. While patent infringement litigations are in progress against many Indian generic manufacturers, Cipla is marketing a generic version and, a compulsory licence (CL) has been granted to Natco on 9 February 2012. Along with the now famous 3(d) judgement from the Supreme Court of India, the Nexavar CL issue has caused heartburn to the United States Trade Representative (USTR) and United States International Trade Commission (USITC) who threatened sanctions against India. In the meantime, the CEO of Bayer has made a statement that 'Bayer has not invented Nexavar for the poor people of India, but for Western patients who can afford it'.[32] Strong reactions to this statement has emanated all across the globe. It may however be noted that Sorafenib (Nexavar) was invented jointly with Onyx, with whom Bayer had a civil suit for breach of agreement which was settled in 2011.

Bayer was granted patent on 3 March 2008 for the drug 'Sorafenib Toslate' under patent no. 215758. Bayer sold Sorafenib under the name 'Nexavar'. All other statutory approvals were also obtained by Bayer in India by January 2008. Sorafenib Tosylate is a palliative drug for patients suffering from Renal Cell Carcinoma (RCC) and Hepato-Cellular Carcinoma (HCC) at stage IV.

Bayer filed a suit for infringement[33] against Natco for infringement of its Sorafenib patent. It had earlier filed suit for infringement[34] against Cipla Ltd for infringement for the same. Both these cases are pending before the Hon'ble Delhi High Court. A suit is also pending in High Court of Bombay against BDR Pharma Intl Ltd.

In compliance with the statutory requirement under Section 87(1), Natco addressed a letter on 6 December 2010 approaching Bayer for grant of licence (voluntary licence). In response, Bayer refused to grant a voluntary licence to Natco. Natco's efforts to obtain a voluntary licence from Bayer on reasonable terms and conditions had not been successful. Therefore, the Controller proceeded with Natco's application for CL of Bayer's drug 'Nexavar' under Section 84(1) of the Patents Act, 1970 on 28 July 2011.

Three substantive issues were raised and justified by Natco, which have been decided in this case as under:

1 Section 84(1)(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
   It was held that drug was accessible to only 2% of patients
2 Section 84(1)(b) that the patented invention is not available to the public at reasonably affordable price, or
   It was held that the costs of the drug was Rs 2,80,428 per month
3 Section 84(1)(c) that the patented invention is not worked in the territory of India.
   It was held that mere importation of the drug into India amounted to 'not worked in the territory of India'.

Having been satisfied with the pleadings and submissions put forth by Natco, by way of order[35] dated 9 March 2012, Shri P H Kurian, the Controller General of Patent and Designs granted a CL to Natco on thirteen terms and conditions.

In response, Bayer Corporation filed an appeal on six grounds against the order of the Controller General of Patent and Designs before the Hon'ble IPAB. However, Hon'ble IPAB dismissed[36] Bayer's appeal. IPAB while confirming the order of the Controller General of Patent and Designs, the Hon'ble IPAB modified the order only to the extent of rate of royalty to be paid to the patentee.

Disposing the appeal filed by Bayer, Hon'ble IPAB held that compulsory licence proceedings are in public interest; they are neither against the inventor, nor in favour of the compulsory licensee.

Bayer has appealed against the Hon'ble IPAB's decision on the CL before the High Court of Bombay. This appeal remains pending without interim relief.

In the meantime, Bayer has initiated infringement actions against other Indian generic companies which are in progress.

Dasatinib Case

Dasatinib litigation which commenced around 2008 is still in progress in various courts. Natco[37], Hetero[38] and BDR[39] have been sued by BMS from 2008 onwards. Fresh cases have been filed in 2013. However, these cases have not yet reached substantive hearing, which may happen in 2014. Initially, the litigation commenced on the ground of patent regulatory linkage. Currently the proceedings are related to injunctions, drug approvals and potential infringement of patent.

A CL application for Dasatinib which was filed by BDR was rejected *prima facie* by the Controller General of Patents on 5th May 2013. BMS filed a second infringement suit[40] on Dasatinib against BDR on the cause of action that a CL application had been filed. The two suits are currently pending for hearing. In other matters, injunction orders have been passed against V C Bhutada[41] and others on Dasatinib.

Litigations reported herein have been protracted and lengthy. In the typical case of BMS's suit for infringement on Dasatinib with specific reference to the alleged infringement of Indian patent no. IN203937 (wherein regulatory approval or CL have been sought), several suits have been filed for the cases CS(OS) 2303/2009 and CS(OS) 679/2013 and are in the process with no substantive arguments or hearings yet.

In the meantime, the Ministry of Health jointly with the Department of Industrial Policy and Promotion (DIPP) under the Ministry of Commerce are exploring the possibility for grant of a CL for Dasatinib u/s 92 of the Patents Act, 1970.

Sunitinib Case

The Sunitinib case is typical case of protracted litigations. Sunitinib imported into India and marketed by Pfizer under the brand name 'Sutent' had initially obtained grant of a patent which was revoked thereafter on challenge through post grant opposition by Cipla. However, there have been extensive protracted litigation thereafter which are in progress. In the meantime, Sugen/Pfizer has initiated infringement action against other Indian generic companies also.

The Sunitinib patent no. IN 209251 was granted to Sugen/Pfizer on 5 October 2007. However, the same was revoked[42] by the Controller of Patents pursuant to post-grant opposition by Cipla. This order was challenged initially in the Hon'ble High Court, Single Bench as well as Division Bench from where the appeals proceeded to the Supreme Court. The Supreme Court sent it back to the Patent Office for re-hearing after providing a copy of the 'Recommendation of the Opposition Board' to Sugen/Pfizer. After doing so and after rehearing, the Controller of Patents, once again revoked the patent. Thereafter, Sugen/Pfizer went on to file a Writ Petition to High Court who directed them to IPAB. Hon'ble IPAB referred the matter back to Patent Office and ordered that a new 'Opposition Board' be constituted, their recommendation be made available and the hearing be conducted by another Controller. Consequently, new Opposition Board was constituted to hear the matter *de novo*. The decision of the Controller of Patent and Design is currently awaited. In the meantime, Sugen filed two Writ Petitions, the first Writ[43] challenging the observations of the IPAB in order no. 107 of 2013 dated 17 May 2013 on Section 8 and the second Writ[44] in relation to the recommendations of the Opposition Board dated 26 July 2013. Concurrently, an infringement suit is pending against Cipla.[45]

Date of Grant of a Patent

An entire set of litigations were settled by the order of the Hon'ble Delhi High Court[46] clarifying the 'date of grant of a patent'. The present case was very crucial in clearing the air of ambiguity with respect to the date on which a patent was considered to be granted. The issue in this case was 'When can a patent be said to be granted under the Patents Act, 1970?' There was a need for judicial intervention for this clarification, since, the date of grant of patent is critical for determining the time within which a pre-grant opposition has to be filed in terms of Section 25(1) of the Act. The date of grant of patent was considered to be different in pre-grant opposition compared to date of grant of patent for purpose of post- grant opposition.

In pre-grant opposition under Section 25(1) -Where an application for a patent has been published but a patent has not been granted...

It has been decided by the Hon'ble Delhi High Court that the date of recording under Rule 55(6) that a patent has been granted and the opposition has been refused/rejected is date of grant. Any further office procedures including release for publication of grant are only procedural formalities. However the date of grant of patent for post-grant opposition under Section 25(2) which states

'At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent....'

The date of publication of grant of patent in the Official Patent office journal is the date of grant for the post-grant opposition. This has been decided in *Dr Snehlata C Gupte* v *Union of India* and seven others[47] (group of petitions). However, it may be noted that the date of patent under Section 45 for calculating the date of expiry of the patent and for filing of infringement suits is considered to be dated as the date on which the application for patent was filed.

Conclusion

Though, Indian patent litigations are in nascent stage, the case laws originating from India are drawing global attention. Innovator corporations owning patents for NCEs have been successful in obtaining injunctive relief in infringement suits, except when the Court extended the balance of convenience to third parties. In spite of having an exhaustive Patents Act, 1970 in the amended form, a few provisions and language issues are yet to be interpreted and clarified through judicial interventions. While extensive patent litigations are in progress in India, there have been mixed reactions from developed and developing countries and NGOs with regard to few of the world-class judgments from Supreme Court of India and the Controller General of Patents in India. The USTR through the USITC have initiated hearings against India and have also proposed sanctions against India. However, the Patents Act, 1970 of India and provisions thereof are being appreciated and adopted across the world.

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