3. JUDICIAL REVIEW

Important case laws on the contentious issues relating to patenting of pharmaceuticals were reviewed. Summary of theses case laws are presented below.

3.1 Patentability of polymorphs/ new forms

3.1.1 Novartis AG vs. Union of India

Appellant : Novartis AG
Respondents : Union of India & others
Case decided by : The Supreme Court, India
Case decided on : April 01, 2013

In 1998, Novartis filed a patent application 1602/MAS/98 in the Chennai Patent office for the β-crystalline form (polymorph) of imatinib mesylate (Glivec/ Gleevec). Glivec is a revolutionary first-line therapy for chronic myelogenous leukaemia (blood cancer). In 2002, Novartis started marketing Glivec in India and also applied for an Exclusive Marketing Right (EMR) in India. Novartis was selling Glivec in India at the price of Rs. 1.2 lakh per month, whereas generic companies were selling the generic versions of Glivec at the price of Rs. 8,000 - Rs. 10,000 month.

In November 2003, the Controller granted first Exclusive Marketing Right (EMR) to Novartis for Glivec for a period of 5 years on the basis of its patent for Glivec in Australia. The EMR gave Novartis the right to exclusively sell and distribute the drug in India.

In 2005, the patent act in India was amended and Novartis application for β-crystalline form was taken for examination. In 2005, an NGO, the Cancer
Patients Aid Association (CPAA) and some generic companies (Natco Pharma, Cipla, Ranbaxy and Hetero Drugs) filed a pre-grant opposition against the above patent application of Novartis. The opposition was filed on the grounds of lack of novelty; lack of obviousness; and non-patentable under Section 3(d). The opponents CPAA and the generic companies argued that Novartis was granted a patent on the drug imatinib in 1993 in many foreign countries; and that the 1993 patent disclosed both the free base imatinib and its salt imatinib mesylate. The opponents further contended that the present application only concerned with a specific crystalline form i.e. β-crystalline form of the imatinib mesylate salt. The opponents argued that the β-crystalline form of the drug imatinib mesylate has the same efficacy as that of the drug itself, and thus the claimed form must be considered as the same substance under Section 3(d) of the India Patents Act.

In January 2006, the Controller of Patents, refused to grant Novartis a patent for β-crystalline form of imatinib mesylate, agreeing with the contentions of the CPAA and generic companies that the claimed form lacked novelty, was non-obvious and non-patentable under Section 3(d).

Novartis then filed two writ petitions in the Chennai High Court in May 2006; one writ petition challenging the validity of Section 3(d) and its non-compliance with Article 27 of TRIPS, and the second writ petition against the order of the Patent Office rejecting the application. The high court transferred the second petition to the Intellectual Property Appellate Board (IPAB). In August 2007, the court dismissed the first petition to eliminate Section 3(d) on the ground of unconstitutionality. With respect to the question of TRIPS compliance, the court concluded that it was beyond the jurisdiction of the court and the proper venue for this issue would be WTO. In June 2009, IPAB upheld the controller’s decision and rejected Novartis’ appeal of granting product patent to Glivec. IPAB stated that although the claimed β-
crystalline form satisfied the tests of novelty and non-obviousness, however it was non patentable under Section 3(d).

Novartis subsequently appealed with a Special Leave Petition to the Supreme Court of India on the ground of urgency, as the patent if granted by the Supreme Court would expire by 2018. The Supreme Court in its decision clarified that the meaning of the term “efficacy” in Section 3(d) is “therapeutic efficacy”. On comparing the “new form” i.e. β-crystalline form with the “known substance” i.e. imatinib mesylate, the court found that although the new form had better flow properties, better stability and lower hygroscopicity, but these properties cannot be linked with the therapeutic efficacy of the drug. The court further noted that the bio-availability of a drug in itself cannot be used to prove the efficacy of the drug. The court finally rejected Novartis appeal on the grounds that the β-crystalline form of imatinib mesylate did not comply with the requirements of invention [Section 2(1)(j)] and patentability [Section 2(1)(ja)], and Section 3(d) of the Patents Act. The Court also noted that Section 3(d) prevents “evergreening”, yet keeps the thumbs up for well merit incremental inventions.

3.1.1.1 Criticism of the Supreme Court’s decision
Regarding the Supreme Court’s interpretation of the term “efficacy” as “therapeutic efficacy”, it has been argued that it is a very restrictive interpretation of the term “efficacy”. Since, in many cases when the already known drug substance is toxic or producing side effects, increasing its therapeutic efficacy may not be the prime goal of the researchers. In such cases, the researchers would endeavour to develop a new form of that substance which is less toxic or produces lesser side effects. It has been further argued that interpreting the meaning of “efficacy” merely to “therapeutic efficacy” unduly limits the application of the Section 3(d) to drugs only. Whereas, a plain reading of this Section clearly indicates that this section is
intended not only for drugs but also for other chemicals like agro-chemicals and fertilizers for which it is not even possible to test the therapeutic efficacy. It is therefore suggested that the meaning of the term “efficacy” may be defined in the Patents Act in a broader way to encompass other relevant aspects such as decreased toxicity or side effects, increased bio-availability or improved physicochemical properties.

3.1.1.2 Whether Section 3(d) is TRIPS compliant?

During the case proceedings in Supreme Court, Indian government argued against Novartis’ contention that Section 3(d) violates Article 27 of TRIPS agreement. Counsels of Indian government asserted that Article 27 the TRIPS Agreement obliges member countries to grant patents for products as well as processes in all fields of technology based on the criteria of newness, inventive step and industrial applicability. However, TRIPS has not defined newness, inventive step and industrial applicability, and thus member countries are allowed to define the scope of these criteria in a manner that suits their national interests. The counsels further stated that the Doha Declaration on the TRIPS and Public Health (paragraphs 4, 5 and 6) enables the member countries to control the patent rights in a manner to protect the public health and to promote access to medicines for all. Therefore, TRIPS agreement coupled with the Doha Declaration permits the member countries to set higher standards of patent protection for pharmaceutical and health related products.

Based on the argument presented by Indian government in the Novartis case, it can be concluded that Section 3(d) of the Indian Patents Act is fully TRIPS compliant.
3.1.2 Pfizer vs. Apotex

Plaintiff - Appellee : Pfizer Inc.
Defendant - Appellant : Apotex Inc. (formerly known as TorPharm, Inc.)
Case decided by : United States Court of Appeals, Federal Circuit, USA
Case decided on : March 22, 2007

Apotex filed an Abbreviated New Drug Application (ANDA) with USFDA for seeking marketing approval of generic version of Pfizer’s antihypertensive drug amlodipine besylate, before the expiration of Pfizer’s U.S. Patent No. 4,879,303 (‘303 patent). In July 2003, Pfizer filed a law suit against Apotex in the United States District Court for the Northern District of Illinois, alleging that Apotex’s generic amlodipine besylate infringes its ‘303 patent. Apotex denied Pfizer’s charges of infringement and counterclaimed that the ‘303 patent is invalid on the grounds of lack of novelty and obviousness. In January 2006, the district court dismissed Apotex’s contention of ‘303 patent being invalid and declared the “303 patent” infringed by Apotex’s generic amlodipine besylate.

Apotex appealed at the Federal Circuit court against the district court’s ruling. The Federal Circuit court after carrying out a de novo assessment found the ‘303 patent invalid on the ground of obviousness and reversed the district court’s judgement227. The Federal Circuit court observed that Pfizer developed the besylate salt of amlodipine to overcome the drawbacks viz. chemical instability and stickiness of the tablet associated with the prior art form amlodipine maleate. To assess the validity of the ‘303 patent, the court carried out a three pronged test of (i) motivation to combine prior art references, (ii) reasonable expectation of success, and (iii) obvious to try. Considering all the evidences, the court opined that to solve the problem of stickiness of the tablet a person skilled in the art would have been motivated with a reasonable expectation of success to substitute the besylate salt for the earlier maleate
salt. Thus it was obvious to try by Pfizer for the new form i.e. besylate salt of the drug amlodipine. The court asserted that development of besylate salt of amlodipine by Pfizer involved “routine experimentation” only, and therefore it was merely a work of skilled person, and not of an inventor. The court further noted that although evidence of any unexpected results can be used to rebut a prima facie case of obviousness however, Pfizer failed to demonstrate any such unexpected or superior results of the claimed besylate salt over the prior art maleate salt. Based on all of the above grounds the Federal Circuit court invalidated Pfizer’s “303 patent”.228

3.1.3 Schering Corp. vs. Geneva Pharmaceuticals

Plaintiff - Appellant : Schering Corporation
Defendants - Appellees : Geneva Pharmaceuticals, Inc. & others
Case decided by : United States Court of Appeals, Federal Circuit, USA
Case decided on : August 1, 2003

Schering held two U.S. Patents viz. 4,282,233 (’233 patent) and 4,659,716 (’716 patent). ’233 patent claimed loratadine, an antihistamine drug, whereas ’716 patent claimed an active metabolite of loratadine called as descarboethoxyloratadine (DCL). Schering marketed loratadine under the brand name “Claritin”. After the expiry of ’233 patent Geneva Pharmaceuticals and a number of other pharmaceutical companies filed an Abbreviated New Drug Application (ANDA) with USFDA for seeking marketing approval of generic version of “Claritin”. Since Schering also listed ’716 patent in the Orange Book to protect “Claritin”, Schering initiated an infringement law suit against Geneva and other ANDA filer companies in the United States District Court for the District of New Jersey. In the counterclaim, the defendant companies asserted ’716 patent invalid, for being anticipated (lack of novelty) by the ’233 patent.
The district court noted that although DCL was not explicitly disclosed in the ’233 patent, however scientific data proved that DCL was necessarily produced as a metabolite by carrying out the method of administering loratadine as disclosed in the ’233 patent. Hence the district court concluded that ’716 patent lacked novelty and was invalid.

Schering appealed to the Federal Circuit court against the decision of the district court. The Federal Circuit court affirmed the district court decision stating that the DCL form was inherently present in the prior art i.e. loratidine, so it was already in the public domain, therefore not patentable\(^\text{229}\).

The doctrine of “inherent anticipation” used by the U.S. courts in the above case could be applied to the cases of other new forms like new salts or polymorphs as well\(^\text{230}\).

### 3.1.4 Warner-Lambert vs. Teva

Appellant : Warner-Lambert Company LLC  
Respondent : Teva Pharmaceutical Industries Ltd.  
Case decided by : Boards of Appeal of the European Patent Office, Europe  
Case decided on : May 24, 2011  
European patent No. 1148049 granted to Warner-Lambert Company, claimed forms II and IV of crystalline atorvastatin hydrate, corresponding pharmaceutical compositions and uses. Teva filed opposition at EPO for revocation of the patent on the grounds of lack of novelty and inventive step. EPO opposition division after holding the oral proceedings revoked the patent on the ground of lack of inventive step.

The patentee lodged an appeal (case number: T 777/08) at the Boards of Appeal of the EPO against the decision of the opposition division. The Board examined inventiveness of the claimed polymorphic form of atorvastatin and
held the polymorphic form non-patentable\textsuperscript{231}. During the proceedings in front of the Board, the patentee asserted that claimed polymorph presented an effective technical solution in the form of improved filterability and drying as compared to the closest prior art i.e. the amorphous form of atorvastatin. The board was satisfied that the technical problem was solved, however the board noted that to be inventive the proposed solution must not be obvious to a person skilled in the art based on the common general knowledge at the priority date. The board held that the claimed polymorph provided only the obvious advantages of a crystalline material over the amorphous form viz. improved filterability and drying. The board finally ruled that in the absence of any technical prejudice and in the absence of any unexpected property, merely providing a crystalline form of a known drug compound cannot be considered as involving an inventive step\textsuperscript{232}.

3.2 Compulsory licensing

3.2.1 Natco vs. Bayer

Petitioner : Bayer Corporation
Respondents : Union of India & others
Case decided by : The Supreme Court, India
Case decided on : December 12, 2014

On March 9, 2012, the Controller of Patents issued the first compulsory license for patents in India. The compulsory license was issued to Natco Pharma Ltd. in patent number 215758 granted to M/s Bayer Corporation\textsuperscript{233}. This patent relates to drug Sorafenib tosylate or “Nexavar” sold by Bayer. Nexavar is indicated in Renal Cell Carcinoma (kidney cancer) and Hepatocellular Carcinoma (liver cancer). The Controller granted the compulsory license to Natco to manufacture and sell a generic version of Nexavar and pay Bayer a royalty of at the rate of 6% of its net sales. Further,
Natco cannot charge more than Rs. 8800/- for a monthly dose of 120 tablets of the drug.

The decision of the Controller was based on the grounds for the grant of compulsory license mentioned u/s 84 of the Patents Act, 1970. The Controller found that the reasonable requirements of the public with respect to the patented invention had not been satisfied, since only 2% of the total kidney and liver cancer patients were able to access the Bayer’s drug. The Controller determined that the patented invention was not available to the public at a reasonably affordable price, because Bayer was charging about Rs. 2.8 lakhs for a therapy of one month of the drug. The Controller also found that the patented invention was not worked in the territory of India since Bayer was not manufacturing the product in India rather it was importing it from outside India.

Bayer appealed to the Intellectual Property Appellate Board (IPAB). In March 2013, IPAB upheld the Controller’s decision but increased the royalty payable to Natco from 6% to 7%. On the issue of working a patent in India, IPAB took a contrary view stating that the requirement of working of a patent could be satisfied by importing the patented product if the patentee could satisfy that the patented product could not be manufactured in India. Therefore, manufacture in India was not an absolute necessity to satisfy the working requirements. Bayer then filed a writ petition in the Bombay High Court, challenging the IPAB order. In July 2014, The Bombay High court dismissed the writ petition upholding the order of the Controller and the IPAB. Subsequently Bayer filed a Special Leave Petition (SLP) in the Supreme Court against the Bombay High Court’s decision. However, in December 2014, the Supreme Court dismissed Bayer’s SLP upholding the compulsory license issued to Natco and concluded the legal proceedings on the case.
3.2.2 Other cases of compulsory license in India

Following the Natco vs. Bayer case, two more applications were filed in India for the issue of compulsory licenses. However, both the applications were rejected by the Controller of Patents. Brief details of these applications are outlined below.

3.2.2.1 BDR vs. Bristol-Myers Squibb

Applicant : BDR Pharmaceuticals international Pvt. Ltd.
Respondent : Bristol-Myers Squibb
Case decided by : The Controller of Patents, Patent Office, Mumbai, India
Case decided on : October 29, 2013

In March 2013, BDR Pharmaceuticals filed an application for compulsory licence to make generic version of anti-cancer drug Dasatinib patented by Bristol-Myers Squibb in India. The Controller rejected BDR’s application stating that before making the application for compulsory licence the applicant didn’t make reasonable efforts to convince the patentee for grant of a voluntary license and therefore applicant failed to make out a prima facie case for the issue of a compulsory license under the Patents Act.

3.2.2.2 Lee Pharma vs. AstraZeneca

Applicant : Lee Pharma Ltd.
Respondent : AstraZeneca AB
Case decided by : The Controller of Patents, Patent Office, Mumbai, India
Case decided on : January 19, 2016

In June 2015, Lee Pharma filed an application for seeking the grant of a compulsory licence for manufacturing and selling the drug Saxagliptin used in the treatment of type-II diabetes mellitus. Saxagliptin is patented by Bristol Myers Squibb and marketed by AstraZeneca in India. The Controller rejected
the application mentioning that applicant failed to satisfy regarding any of the
grounds as specified in the Section 84(1) of the Act\textsuperscript{237}.

3.3 Duty to disclose information regarding foreign applications

3.3.1 Ajanta Pharma vs. Allergan

Opponent : Ajanta Pharma Limited
Respondents : Allergan Inc., Allergan India Pvt. Ltd., and the Controller of Patents and Designs, India
Case decided by : Intellectual Property Appellate Board (IPAB), India
Case decided on : August 08, 2013

Ajanta Pharma filed an application at the IPAB for revocation of patent no. 212695 entitled “Hypotensive lipid (prostaglandin derivatives) and Timolol composition and methods of using same” granted to Allergan Inc. Ajanta Pharma raised the grounds of obviousness and Section 8 violation. Section 8 of the Indian Patents Act mandates the patent applicant to submit to the Indian patent office detailed particulars of the patent applications filed outside India in respect of “same or substantially the same” invention. Failure to submit such information by the patent applicant is a ground of patent revocation u/s 64. Ajanta Pharma asserted that Allergan failed to provide the application numbers of the corresponding patent applications filed at Canada, Korea, China, New Zealand and Japan. Allergan also failed to provide the required information on the prosecution of the counterpart European and U.S. applications. Allergen contested the arguments of Ajanta Pharma by stating that information and documents necessary to comply with the Section 8 requirement were sent from time to time to their representing IP law firm in India, but it was due to the negligence of the law firm that such information was not submitted to the Indian patent office. IPAB held that it was immaterial that why the required information was not furnished, but the fact remained that there was violation of the Section 8 requirement. During the proceedings
IPAB also found the claimed invention obvious. So IPAB finally revoked Allergan’s patent on both the grounds of obviousness as well as violation of Section 8 requirements.\textsuperscript{238}

3.3.2 Roche vs. Cipla

Petitioners : F. Hoffmann-La Roche Ltd. & others

Respondent : Cipla Ltd.

Case decided by : The High Court of Delhi, India

Case decided on : November 27, 2015

Pfizer holds Indian patent number 196774 (IN ‘774) on an anticancer drug Erlotinib hydrochloride, which is marketed by Roche under the brand name “Tarceva”. Roche filed a suit of infringement of IN ‘774 patent against Cipla in the Delhi High court and demanded for permanent injunction on the sale of generic version of Erlotinib by Cipla. Cipla in its counter claim of infringement prayed for revocation of IN ‘774 patent u/s 64(1) on various grounds including lack of novelty, obviousness and violation of Section 8 requirements.

Regarding violation of Section 8 requirements Cipla argued that Roche failed to disclose before the patent office information about its U.S. patent no. 6900221 (US ‘221) which claims Polymorph B of Erlotinib hydrochloride, a form “same and substantially the same” as claimed in the IN ‘774 patent. Cipla further argued that Section 8 is a mandatory provision and its non-compliance shall result in the revocation of the concerned patent. Roche contested by stating that IN ‘774 patent claims the new chemical entity “Erlotinib hydrochloride” and discloses a combination of its Polymorph A & B, which was an invention different from the invention of Polymorph B as disclosed in US ’221, and therefore there was no requirement to disclose US ‘221 patent under Section 8. Roche further stated by referring to the case
Sukesh Behl vs. Koninklijke Phillips Electronics decided by Delhi High Court, that provision of revocation of a patent u/s 64(1) is discretionary in nature because of use of the word “may” in Section 64(1), and does not automatically mandates the revocation of a patent. In the Phillips case the court held that to prove violation of Section 8, it must be shown that the information was deliberately or wilfully suppressed, and the omitted was information was material to the grant of the patent in India.

In the present case, the High Court accepted the arguments submitted by Roche and noted that while assessing whether there was a violation of Section 8 it is necessary for the court to consider whether omission of the information was intentional by the applicant or it was a mere clerical/ bona-fide error. In conclusion the court held the IN ‘774 patent valid. The court also found the IN ‘774 patent infringed by the sale of generic Erlotinib by Cipla.

Above decision of the High Court was in sharp contrast with the opinion of IPAB in similar cases decided earlier, in which IPAB held that wilful suppression or materiality of the suppressed information was irrelevant while determining whether a patent can be revoked on the ground of non-compliance of the Section 8. This decision of High Court has therefore set guidelines for IPAB while adjudicating similar cases in future.