



Intellectual Property Attorneys

I N D I A

IP UPDATE

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We are proud to inform our readers that India IP Update completes 10 years with the current issue! Also, please check out our brand new website at www.knspartners.com!

IP news at a glance!

- India joins Madrid Protocol
- Supreme Court on Glivec patent
- IPAB upholds grant of compulsory license
- Renewal notice a must for removal of registered mark
- Privacy of dacoit not breached by film on his life: Madras High Court
- Online publication of FER not communication
- Amul v. Imul

INSIGHT



Glivec: Incremental invention or an attempt at 'evergreening'?

The judgement of the Supreme Court of India in the Glivec case issued on April 1, 2013, is by far the most important Indian patent case, with wide implications for domestic and overseas pharmaceutical businesses. While the judgement has been hailed by many domestic generic pharma companies and NGOs as a victory for affordable and accessible public health, it has received flak from multinational pharma companies, questioning India's commitment to fostering a patent regime that encourages innovation.

Facts

The controversy revolved around the patentability of the anti-cancer drug sold under the name Gleevec/Glivec, whose main constituent was β -crystalline form of Imatinib Mesylate. Imatinib, a derivative of N-phenyl-2-pyrimidine-amine, was originally developed in the United States in the late 1990s and is believed to have

SPECIAL UPDATE

India joins the Madrid Protocol

On April 8, 2013, India deposited its instrument of accession to the Madrid Protocol for the International Registration of Marks at the World Intellectual Property Organization (WIPO), bringing the total number of members of the WIPO administered international trademark system to 90. Effective July 8, 2013, the Protocol will enter into force in India.

anti-tumour properties. N-phenyl-2-pyrimidine-amine derivatives including Imatinib are patented in the United States (“the Zimmerman Patent”). Further research on Imatinib led to Imatinib Mesylate, which was more stable and suitable to be administered as an effective drug for the treatment of chronic myeloid leukaemia (CML). Nearly 40 patents have been granted for this drug

in countries such as USA, China, Russia and Taiwan. However, in 2006, the Indian Patent Office rejected a 1998 patent application filed by Novartis, triggering a legal marathon spanning seven long years through the hierarchy of the Indian legal system culminating in the final judgment passed by the Supreme Court of India on April 1, 2013.

Chronology of events	
The late 1990s	Imatinib developed by Nicholas Lydon and Brian Druker
April 28, 1994	Application filed in the US for Imatinib (The Zimmermann Patent) by Jurg Zimmermann, later assigned to Novartis.
July 18, 1997	Novartis files Swiss application for β -crystal form of Imatinib Mesylate
July 17, 1998	Novartis files Indian application for β -crystalline form of Imatinib Mesylate by claiming priority from the Swiss application.
January 18, 2000	US Application for β -crystalline form of Imatinib Mesylate filed
May 10, 2001	USFDA approval for Gleevec to treat CML.
November 14, 2001	The Doha Declaration affirms that TRIPs should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and promote access to medicines for all.
November 10, 2003	Exclusive Marketing Rights (EMR) granted and Glivec launched in India
April 5, 2005	Indian patent laws amended to introduce provisions, inter alia, to prevent "ever-greening" of patents
May 17, 2005	US patent granted for β -crystalline form of Imatinib Mesylate.
January 25, 2006	Indian Patent office rejects the Glivec application pursuant to 5 pre-grant oppositions (4 by Indian generic manufacturers and one by Cancer Patients Aid Association)
May 2006	Novartis appeals the rejection before the Intellectual Property Appellate Board (“the IPAB”). Simultaneously, Novartis files a constitutional writ against the Indian government and four other companies in the Madras High Court challenging Section 3(d)
August 6, 2007	The Madras High Court rejects Novartis’ writ
June 2009	The IPAB rejects Novartis’ appeal against the Patent Office rejection order
August 2009	Novartis approaches the Supreme Court of India
April 1, 2013	Supreme Court rejects Novartis’ plea for patent

Issues before the Supreme Court

The main issue before the Supreme Court was the true import of Section 3(d) of the Indian Patents Act, 1970 (‘the Act’):

3. *What are not inventions. - The following are not inventions within the meaning of this Act,*

(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

Following an extensive discussion of the legislative history and Parliamentary debates leading up to the amendments introduced by the 2005 amendments to the Act, the Supreme Court held that the amendment introduced by Section 3(d) created two separate concepts, one dealing with “invention” and the other dealing with “patentability”. In its view, Section 3(d) set up a second tier of qualifying standards for chemical substances/ pharmaceutical products so as to leave the door open for true and genuine inventions while at the same time checking any attempt at repetitive patenting or extension of the patent term on spurious grounds. Consequently, the Supreme Court was confronted with the following two-fold challenge:

- i. Whether the product qualified as an invention under Section 2(1)(j) of the Act?
- ii. Whether it was barred from patentability under Section 3(d) of the Act?

Test for ‘Invention’

Section 2(1)(j) stipulates that to qualify as an ‘invention’, it must be ‘new’, is non-obvious to a person skilled in the art, is capable of industrial use and represents a technical advance over existing knowledge or has an economic significance. After an extensive review of the materials and arguments advanced on behalf of the respective parties, the Supreme Court firmly rejected Novartis’ case that Imatinib Mesylate was a new product and the outcome of an invention beyond the Zimmerman Patent. The Court went on to say that not only was Imatinib Mesylate known as a substance in the Zimmerman Patent but its pharmacological properties had also been known in the Zimmerman Patent.

In reaching the above conclusion, the Court went a step further and drew a distinction between ‘disclosure’ and ‘coverage’ under a patent and decried the practice, *‘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 skillful 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’.

Known efficacy

Having held that Imatinib Mesylate did not qualify the test of invention under Section 2(1)(j) and 2(1)(ja) of the Act, the Court proceeded to examine whether the β -Crystal form of Imatinib Mesylate could be accepted as a new pharmaceutical substance in the sense that it was not known from the Zimmerman Patent. This involved the applicability of the exclusion under Section 3(d) of the Act. Section 3(d) requires an applicant to show enhancement of known efficacy. The Court noted that “efficacy” meant ‘the ability to produce a desired or intended result’ and that the test of efficacy in the context of Section 3(d) would depend upon the function, utility or the purpose of the product under consideration. It held that *“in the case of a medicine that claims to cure a disease, the test of efficacy can only be “therapeutic efficacy” and that such therapeutic efficacy must be judged strictly and narrowly, taking account of the genesis of Section 3(d) and the circumstances in which it was amended”*. Applying the test of efficacy in the sense interpreted, the Court held that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, might be otherwise beneficial but these properties could not muster the test of therapeutic efficacy under section 3(d). In other words, under the test of therapeutic efficacy laid down by the Court, the physical attributes such as solubility, thermostability, hygroscopy etc., would not pass the threshold of therapeutic efficacy. On the question of other factors such as reduced toxicity as contributors to increased therapeutic efficacy, the Court left this question open for discussion.

It is important to note that this judgement categorically holds that incremental pharmaceutical inventions are protectable under Indian law provided therapeutic efficacy is established and any attempt at repetitive patenting or extension of the patent term on spurious grounds would be frowned upon.

CASE LAW UPDATE

Madras High Court allows release of film on the life of Veerappan, the forest brigand!



There would be very few Indians who would be unfamiliar with Veerappan, a name synonymous with sandalwood smuggling, elephant poaching, illegal ivory trade, kidnapping, murder and dacoity. He was gunned down by the State in 2004, putting an end to the reign of terror spanning over two decades across the jungles of Southern India.

Veerappan's life story came alive once again recently when his widow sued a production house that sought to release a movie in two local languages, portraying the life events of the late brigand and his widow (*V. Muthulakshmi, w/o Late Veerappan vs. Gemini Industries & imaging Pvt. Ltd.*). The question before the High Court of Madras was: if the undisputed life incidents of a deceased dacoit were part of public records, would his legal heirs be entitled to claim the 'right to privacy' if a film merely dramatized these life incidents?

Seeking an injunction against the release of the films, the plaintiff alleged that the producers had made the films without verifying the facts and that there was no basis for the characterization of her late husband in bad taste. She asserted that the 'right to privacy' of her late husband continued even after his death.

Contesting the suit, the producers argued that the films were based on information gathered from public records, including registered complaints from police and court records. However, the plaintiff contended that while charges in some of these cases were dropped, in other cases her late husband was acquitted and, therefore, such an argument was devoid of factual basis. As such, she argued that these films, if released, would not only invade the right to privacy of her late husband, but would also interfere with the life of his surviving family.

Citing the ratio of the Supreme Court ruling in *R. Rajagopal and Another vs. State of Tamil Nadu & Others*, the Court reiterated that when scenes are based on public records, including court records, the right to privacy no longer subsists and it becomes a legitimate subject for comment by press and media, among others. Permitting the release of the films subject to minor deletions, the Court further pointed out that since the public records in question remained undisputed by the late brigand during his lifetime, it was not open for his widow or children to claim 'right to privacy' after his death.

IPAB upholds the grant of the first compulsory license in India

In Volume X Issue 2 of India IP Update, we had reported that on March 9, 2012, the Controller of Patents in India had granted India's first compulsory license under the new post-TRIPs patent regime in India. In an expected move, the Indian Intellectual Property Appellate Board ("IPAB"), in a decision passed on March 4, 2013, confirmed the grant of the compulsory license in favour of the Hyderabad based NatcoPharma Limited ("NATCO"). The compulsory license related to an anti-cancer drug, Sorafenib Tosylate, used for palliative treatment of liver and renal cancer for which a patent is owned by Bayer Corporation ("Bayer") in India. The drug has been sold in India since 2008 by Bayer under the brand name 'Nexavar'. To reiterate, the key considerations for grant of compulsory license under the Indian Patents Act are set out in Section 84 and are to the following effect:

- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) the patented invention is not available to the public at a reasonably affordable price, or
- (c) the patented invention is not worked in the territory of India.

The IPAB essentially reaffirmed the conclusions arrived at by the Controller General as reported by India IP Update earlier. It held that all three conditions for grant of a compulsory license under the Act were satisfied. While most of the conditions laid down by the Controller General in his March 2012 order were retained in the IPAB's decision, the royalty rate payable to the patentee

was increased from 6% to 7% of the net sales of the drug. Also, the IPAB differed with the Controller of Patents in his decision not to count importation of a drug as working of the patent. IPAB clarified in its order that the word ‘worked’ must be decided on a case to case basis and that it may be proved in a given case, that ‘working’ can be done only by way of import. However, in such a case, the patentee must show with adequate evidence as to why the drug could not be locally manufactured. A mere statement to that effect would not be sufficient.

It was further found by the IPAB that if there was any issue of non-compliance of any requirements under the license by NATCO, Bayer had the option to approach the Controller for appropriate relief as permitted by law.

Finally, the IPAB noted that the grant of compulsory licenses was to be considered on a case to case basis. IPAB also maintained throughout the decision that compulsory license proceedings must be viewed only from the perspective of public interest and not as a proceeding against the innovator or in favour of a compulsory license applicant.

Removal of registered mark without renewal notice wrongful: High Court of Delhi

This appeal (*Union of India vs. Malhotra Book Depot*) arose from an order of a Single Judge of the High Court of Delhi in a constitutional writ which directed the restoration and renewal of the trademark of the respondent in the appeal. The writ petition sought a writ of mandamus for restoration and renewal of the trade mark of the respondent. While the writ petition was filed in 2010, the registration had fallen for renewal in 1984 and was eventually notified as removed from the Register in the Trade Marks Journal in 1990 for non-payment of renewal fees. The respondent became aware of the removal only in the year 2010, when in response to an application for a certificate for use in legal proceedings, the respondent was informed that there were no records of the mark in the Register. When the respondent’s application for renewal and restoration was not accepted by the IPAB, it challenged the said order by way of a constitutional writ.

The task before the Appellate Bench of the High Court was to interpret the relevant provisions of the old Trade & Merchandise Marks Act, 1958 and the Rules (which was applicable at the relevant time). Sub section (3)

of Section 25 of the old Act (dealing with ‘duration, renewal and restoration of registration’) stated that before the expiration of the last registration of a trade mark, the Registrar shall notify the date of expiration and other conditions for renewal thereof to the registered proprietor in the prescribed manner and if at the expiration of the prescribed time, those conditions have not been complied with, the Registrar may remove the trade mark from the Register. Rule 67 of the Trade & Merchandise Marks Rules, 1959, under Chapter III (titled ‘Renewal of Registration and Restoration’, relevant Rules being 66 to 70) prescribed that if no application for renewal of a registration was received from the registered proprietor, a notice shall be sent to such proprietor before removal of the mark from the Register. Rule 68 dealt with advertisement of removal of trade marks from the Register and prescribed that in the event renewal fee was not paid at the expiration of the registration, the Registrar may remove the trade mark from the Register and advertise the same in the journal.

It was the case of the respondent, inter alia, that the statutory notice (under Form O3 or the ‘O3 notice’) under Rule 67 was not sent by the Registrar to the respondent and as such, the Registrar could not deny restoration and renewal of the trade mark. Further, it was argued that if the removal of the mark was wrong, its restoration could not be denied; that Rule 68, while providing for removal of the mark for non-payment of fees uses the word ‘may’ and not ‘shall’; that it was for this reason only that the Registrar in spite of the validity of the mark having expired in the year 1984 did not remove it till the year 1990; that if the removal of the mark was wrongful, the limitation of one year in Section 25(4) of the old Act for applying for renewal did not apply.

In defense, the Registrar argued, inter alia, that the due process was followed in this case and that the respondent was taking advantage of the fact that the records going back to 26 years would not be available with the Registrar.

Having considered the matter, the Court found as follows:

- The IPAB’s reasoning that renewal, removal and restoration were distinct matters appeared to be contrary to the legislative intent because in the old

Act and the Rules thereunder, these aspects were clubbed together.

- The constitutional principles applicable to property barred a person from being deprived of his property except as in a manner prescribed by law and such principles were applicable equally to intangible intellectual property.
- Section 25 of the old Act imposed a duty on the Registrar to effect removal of the mark only after sending the notice and upon failure of the registered proprietor to comply therewith. As such, the argument of the appellant that the Registrar should not be held duty bound merely for the reason of unavailability of proof of dispatch or service of notice was fallacious.
- Sub section (4) of Section 25 of the old Act was held to be applicable to matters only where removal is simultaneous to the expiration of the trade mark and not where removal is effected much after the date of date of expiration. The finding was based on the analogy that though the right to restoration accrued on removal but the time prescribed to apply for restoration became available from the expiry of the registration.
- Where a trade mark was removed without issuing the O-3 notice, an application for its renewal and restoration could be made at any time. The Registrar may consider such an application after establishing that the applicant was the registered proprietor of the mark which had expired and/or was the successor of the said proprietor and taking into consideration whether an identical or similar mark had in the interregnum been registered by any third party.

While the order relates to the old Act, it would be equally relevant under the new Trade Marks Act, 1999 since the provision relating to renewal, removal and restoration have remained unchanged.

SNIPPETS



AMUL's well-known status upheld by IPAB

In a recent appeal filed before the IPAB, one of the largest Indian dairy products manufacturers, marketed under the famous "AMUL" brand, successfully prevented registration of the mark 'IMUL'. The appeal originated from an order of the Registrar of Trademarks who held that while the 'AMUL' brand was indeed well-known, the adoption of 'IMUL' was justified as it was an acronym of the applicant's trade name 'Ichhamati Co-operative Milk Products Union Limited' and that it was in use since the year 2001. On appeal, the IPAB overturned the Registrar's order by finding strong similarity between the marks. The fact that the applicant had failed to adduce cogent evidence in support of its user claim for 'IMUL' was also a determining factor in the appeal.

Does the mere publication of an examination report on the Trade Mark Registry's website amount to communication?

The High Court of Bombay recently had the occasion to decide whether the uploading of an examination report in respect of a trade mark application on the website of the Trade Marks Registry satisfied the requirement of communication as envisaged under the relevant provisions of the Trade Marks Rules, 2002. Upon review of the Trade Marks Act, 1999 and the Trade Mark Rules, 2002, the Court noted that there was no express provision therein that required the owners or proprietors of trademarks to inspect the website on a daily basis. Thus, it was held that the mere uploading of the examination report on the Trade Mark Registry's website would not amount to communication as contemplated under the Trade Marks Rules, 2002.

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