



Intellectual Property Attorneys

INDIA IP UPDATE

Quarterly Newsletter from K&S Partners
For private circulation only

Vol. XIII, Issue 1
January – March, 2016

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LEGISLATIVE UPDATE

Enactment of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015

The recently enacted Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Acts, 2015 ("the Act"), provides for the creation of Commercial Divisions in Indian High Courts having original jurisdiction and Commercial Courts at the district level, for trying all suits which are in respect of "Commercial Disputes" as defined under the Act. The Act assumes relevance for the IP sector since Section 2(1)(c) of the Act defines a "commercial dispute" to include inter alia, disputes arising from intellectual property rights relating to registered and unregistered trademarks, copyright, patent, design, domain names, geographical indications and semiconductor integrated circuits. Some of the salient features of this Act are as follows:

- **Jurisdiction and constitution:** The Act mandates

setting up of Commercial Divisions in those High Courts exercising ordinary original jurisdiction, namely, Himachal Pradesh, Delhi, Bombay, Calcutta and Chennai, to adjudicate all suits and applications relating to commercial disputes. In states where High Courts do not have ordinary original civil jurisdiction, the Act mandates setting up of the Commercial Courts at the District level. The Act further provides for constituting Commercial Appellate Divisions in each High Court having one or more Division Benches for the purpose of exercising appellate jurisdiction.

- **Pecuniary jurisdiction:** The Commercial Courts and Commercial Divisions will have jurisdiction to try all suits and applications relating to commercial disputes of a "Specified Value", set currently at INR 1,00,00,000 (approximately USD 146,000) or higher.
- **Transfer of suits and counterclaims:** All suits and applications relating to commercial disputes of the Specified Value pending in any civil court and a High Court will be transferred respectively to the newly constituted Commercial Court and the Commercial Division of the High Court. Further, if any counterclaims filed in a suit before a civil court relating to a commercial dispute is of the Specified Value, such suit shall also be transferred to the relevant Commercial Division or Commercial Court, as the case may be.
- **Timelines and case management procedures:** Commercial Divisions or Commercial Courts are required to hold 'Case Management Hearings' aimed at setting timelines for a speedy disposal of the cases. The Case Management hearings cannot be adjourned by the Courts only on the ground that the advocate appearing on behalf of a party is not present.

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- **Amendments to the Indian Code of Civil Procedure, 1908 ("CPC"):** The Act mandates that the provisions of the CPC shall, in their application to any suit in respect of a commercial dispute of a Specified Value, stand amended as provided in the Schedule to the Act.

Indian Patent Office (IPO) proposes fresh amendments to Patent Rules

The IPO has since published the draft amendments to the Patent Rules, 2015 aimed at expediting and further streamlining the patent process. It is likely that the final amended Rules would be rolled out in the next couple of weeks. Some of the key proposals are as follows:

- Timeline for placing the patent application ready for grant to be reduced from 12 to 4 months with possible extension of only 2 months;
- Controller to dispose of applications within 6 months of final reply or final deadline for placing the application in order for grant. In older cases, this time line would be 2 years from the implementation of the new Rules;
- Examination of divisional application would be along with the parent application, if the latter is pending;
- New expedited examination process introduced, subject to conditions and on payment of additional fees; existing requests can also be converted to expedited requests;
- Fast tracking of decisions in opposition matters;
- Adjourment request hearings to be discouraged;
- A new form for working statement proposed, seeking more comprehensive details from patentee and licensee regarding working of the patent;
- Withdrawal of application and Request for Examination (RQ) possible; possibility of fee refund in both cases;
- Cap on sequence listing page fee;
- Electronic submission of original documents to be made possible;
- Power of Attorney to be submitted within 3 months of filing or else no further processing of the file.

CASE LAW UPDATE

Roche wins the Erlotinib patent infringement battle against Cipla

After a seven year long battle, F. Hoffmann La Roche ("Roche") finally had a sweet victory over Cipla before the Division Bench of the Delhi High Court, which held that Roche's patent IN196774 ('suit patent') was valid and was infringed by Cipla's ERLOCIP. Roche's infringement proceedings against Cipla regarding the anticancer drug Erlotinib began back in 2008. Marketed respectively by Roche and Cipla as TARCEVA and ERLOCIP, both products consisted of Polymorph B of Erlotinib hydrochloride.

In 2012, though a Single Judge of the Delhi High Court held the suit patent as valid, he found that Roche had failed to furnish evidence of Cipla's ERLOCIP infringing TARCEVA. Both the parties appealed the said order before the Division Bench, which finally ruled in favor of Roche on December 8, 2015, holding that the patent was valid and infringed by Cipla. The Bench refrained from granting an injunction since the patent was due to expire in March 2016 and Cipla had been manufacturing the infringing product since 2007-2008. However, Cipla was directed to render accounts concerning manufacture and sale of Erlotinib along with costs amounting to INR 500,000 (~US\$ 7500). The Court also directed that the evidence regarding profits made by Cipla should be reported to the Joint Registrar whose report will be further adjudicated upon by the Court.

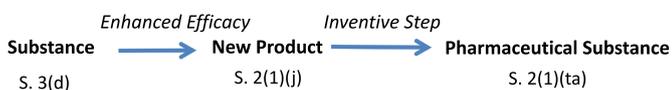
Some of the key findings of the Court in this matter are discussed below:

The product vs. substance dichotomy in the Act

Cipla contended that the inventions are product specific and thus, its product should be compared with 'the product' that is patented. It was thus asserted by Cipla that, while the patent sought to be enforced is for Polymorphs A+B, the respective products under manufacture (i.e., Polymorph B) by both Roche and Cipla are not covered by the suit patent. Since the patented product is Polymorph A+B, manufacturing polymorph B alone does not infringe the patent. It was further argued by Cipla that the infringement was relatable to 'that product' which is patented (by the suit patent) and not to any 'substance' (as read under section 3(d)). It is pertinent to note here that Roche's later patent application for Polymorph B of Erlotinib Hydrochloride was allowed in the US but rejected in India on grounds of being a mere new use of known substance (section 3(d)).

To clarify this ambiguity, the Court distinguished the terms 'substance', 'new product' and 'pharmaceutical substance' and held that:

- The essence of Section 3(d) is that a polymorph shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy
- A new form is neither the same substance nor the same product. If the new form does not show enhanced efficacy, it will be considered to be the same substance, but this form is not that product for the purposes of Section 48 which provides for the rights of patentee.
- If a new form of a known substance exhibited enhanced efficacy, it would qualify for assessment under section 2(1)(j) as if it was a new product involving inventive step.
- Section 2(1)(ta) which defines pharmaceutical substance provides a bridge between section 3 and 2(1)(j). Specifically it says, "if the substance has an added layer of enhanced efficacy then it would be treated as a 'new product' and would be eligible for assessment under section 2(1)(j) to ascertain whether its formation involved an inventive step. If the new product involved one or more inventive steps, then it would qualify as a pharmaceutical substance".



- Section 3(d) is a positive provision recognizing incremental innovations. However, if the incremental innovation is very less, the resultant product would be same as that of the original. In such a case, the inherent assumption would be that the infringement of the resultant product would be an infringement of the original. Thus, since Polymorph B of Erlotinib hydrochloride did not qualify as 'new product' for the purposes of section 2(1)(j), it should be regarded as the old product itself, i.e., Polymorphs A+B (as covered in suit patent).
- Relying on expert evidence, the Court noted that polymorphism is an 'inter'-molecular concept whereas the chemical structure of Erlotinib as protected by suit patent is an 'intra'-molecular concept. Thus, irrespective of any polymorphic form, the chemical structure of Erlotinib remains the same and is protected by the suit patent.
- Further, inside the body, the polymorphs behaved in the same way therapeutically and

that the polymorphic forms were only improving the storage and manufacturing capabilities.

- Since Roche itself had admitted in the subsequent US application for the polymorphic form that Polymorph B was not covered in the suit patent, the cardinal principle of claim construction that the claim must be interpreted on its own language and if it is clear, subsequent admissions or documents cannot narrow down its scope must be applied.
- The issue to be decided is not whether Roche and Cipla's products are identical but whether the Cipla's product is covered under the claims of Roche's patent. The compound may exist in various polymorphic forms and all such forms will be subsumed within the suit patent. Cipla's product Erlcip being one polymorphic form (Polymorph B) would clearly infringe the suit patent.

Whether the suit patent was obvious

The Court also rejected Cipla's attack on the inventive step of the compound in the suit patent and noted that the following inquiries are required for assessment of inventive step.

- **Step 1:** To identify an ordinary person skilled in the art (POSA).
- **Step 2:** To identify the inventive concept.
- **Step 3:** To ensure that the POSA is given all prior art that existed before the priority date.
- **Step 4:** To identify the differences between the prior art and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications.
- **Step 5:** To decide whether those differences would have been obvious to a person skilled in the art.

The Bench further held that mere structural similarity cannot be a ground for presumption of non-patentability, there must also be similarity in properties between the prior art and the patent in question. Obviousness is a question of law and the burden of proof to make out a prima facie case of invalidity was on Cipla, which it did not meet.

Violation of Section 8

In its counter-claim, Cipla asserted that during the prosecution of the suit patent, as required under section 8, Roche did not file the information relating

to the US application for Polymorph B. Court, however, held that Roche's omission in providing this information was due to its bona fide belief that the two were completely different inventions and the US application was not the same or substantially the same as the suit patent. The Court held that the section 64(1)(m) providing the ground for revoking the patent for non-compliance of Section 8, is not directory and that there was no need to revoke the patent.

Lack of title

Cipla further claimed that the exact status of Roche's patent and its ownership was neither known nor fully established and that no documents which vest any right in Roche of ownership or Right to Sue have been placed on record. As per the Patents Act, any assignments or changes in entitlement in a patent must be recorded at the Patent Office. The Court rejected Cipla's plea stating that lack of title was not a ground for revocation under section 64 of the Act and that there was no merit in Cipla's contention seeking dismissal of the suit on the ground of lack of title.

This well reasoned decision will pave way for further jurisprudence in the area of pharmaceutical patent enforcement in India as it sets straight a number of issues hitherto vague. However, with regard to account of profit, as per the latest order of the Supreme Court, the proceedings before the Joint Registrar shall continue and no final orders shall be passed without the leave of the Supreme Court.

Delhi HC upholds jurisdiction of Competition Commission of India (CCI) in SEP related matters

On March 30, 2016, the Delhi High Court issued a common order in two writ petitions filed by Ericsson against the orders of CCI, in complaints filed by Micromax and Intex. The common order in these two writ petitions was passed in view of similar issues and more or less overlapping facts. This is a part of the infringement proceedings instituted by Ericsson against its Standard Essential Patents (SEP) which were reported previously in our India IP Update (Issue Vol. XIII, Issue 2 April - June, 2015; Vol. XIII, Issue 4 October - December, 2015).

The main issue to be decided in this case was whether CCI had the jurisdiction to commence inquiries under Section 26(1) of the Competition Act

in relation to a claim of royalty by a proprietor of an SEP in a complaint regarding abuse of dominant position. The Court affirmed CCI's position as a watchdog for abuse of dominance in such matters.

On the issue of maintainability of the complaint before the CCI, Ericsson had argued that Micromax and Intex were unwilling licensees and that they could not maintain a complaint for abuse of dominance since they had challenged the validity of Ericsson's patents claimed in the infringement suits. The High Court rejected this argument and held that a potential licensee could not be precluded from challenging the validity of the patent in issue. It further held that it would not be necessary for Micromax and Intex to waive their right to challenge the patent for instituting a complaint which was based on the premise that Ericsson's patents were valid.

Yet another issue before the High Court was that of the interplay between the Patents Act and Competition Act. The Court held that the Patents Act was a special Act, and that the remedies under the two Acts were different though not mutually exclusive. The Court observed that there was no irreconcilable repugnancy or conflict between the two enactments and hence, CCI could entertain complaints for abuse of dominance in respect of SEP rights.

The Court also observed that the position of a proprietor of an SEP could not be equated with the proprietor of a patent, which was not essential to an industrial standard. Accordingly, if in certain cases, the conduct of the SEP owner was directed towards pressurizing an implementer of SEP to accept non-FRAND terms, it would amount to an abuse of dominance.

Taking serious note of Ericsson's apprehension regarding breach of confidentiality in relation to the sensitive and confidential information provided to CCI during the investigations, the Court directed that the Director General (DG) of CCI and employees of CCI were obliged to maintain confidentiality and secrecy of the confidential information provided by Ericsson. The Court has gone to the extent to state that DG/CCI may not, in a given case, be immune from a claim of loss or damages in case of failure to maintain the confidentiality/ secrecy of the sensitive information provided to them.

As we bring this news to you, there are reports that Ericsson has obtained a stay of two weeks on this order.

No Compulsory License for Saxagliptin after all

The IPO finally rejected Lee Pharma's Compulsory License ("CL") application for the anti-diabetes drug Saxagliptin on January 19, 2016. India IP Update had reported the filing of this CL application in Vol. XIII, Issue 3. The Controller had earlier issued a notice to Lee Pharma that no prima facie case was made for the issuance of a CL. After a hearing, the IPO finally rejected all grounds raised in the application as provided under Section 84(1) of the Patents Act, 1970.

Rejecting Lee Pharma's claim "that the reasonable requirements of the public with respect to the patented invention have not been satisfied", the IPO held that the data provided by Lee Pharma in that regard was not sufficient. The Controller General held that it was doubtful whether all 60.1 million diabetic patients required saxagliptin. Secondly, if there were other Dipeptidyl peptidase-4 (DPP 4) inhibitors in the market, it was unclear what proportion of the patients would be prescribed saxagliptin. Finally, the IPO found it difficult to accept the argument that saxagliptin was the best option over other DPP 4 inhibitors for type II diabetes without authentic evidence to that effect through a study or doctors' evidence.

With regard to the ground that "the patented invention is not available to the public at a reasonably affordable price", the IPO concluded that the pricing of saxagliptin as compared with the pricing quoted by Lee Pharma could not be considered as excessively priced or as a barrier to afford the medicine.

The IPO also dismissed the third ground that "the patented invention is not worked in the territory of India" as the same was hindered by importation from abroad. Quoting the Bombay High Court in Bayer v. Natco, the IPO held that manufacture in India was not a precondition to working the patent in India. Further, Lee Pharma had failed to provide the exact quantitative requirement of saxagliptin without which it was difficult to conclude whether the drug was in shortage or whether it was necessary to manufacture the same in India.

This is the third CL in a row to be rejected by the IPO

after the first Indian CL granted to Natco Pharma for Bayer's anti-cancer drug Nexavar. This indicates that the IPO is not granting CLs to anyone applying for it and that all the grounds relied upon under Section 84(1) are tested against substantive data and evidence before even making out a prima facie case. This is certainly a promising trend for the patentees and most of all for a maturing patent regime in India.

No trade mark rights in the name of holy texts: Supreme Court

Ramayana, the Indian epic, is a holy text of the Hindus. The issue before the Supreme Court of India in Lal Babu Priyadarshi v. Amritpal Singh, concerned the registration of the name RAMAYANA in respect of incense sticks and perfumes. The appeal before the Supreme Court arose from an order passed by the IPAB which had set aside the order of the Assistant Registrar of Trade Marks holding that RAMAYAN could be registered as a trade mark since it also had the device of a crown along with the word "RAMAYAN". IPAB, in addition to finding the mark to be not distinctive of the goods claimed thereof, also found that there was extensive use of the mark by numerous other entities which rendered the same publici juris and common to the trade.

The proprietor of the mark argued in the appeal before the Supreme Court that mark had been in use since 01.01.1987 and was therefore distinctive of its goods. The respondent on the other hand placed reliance on Section 9 of the Act providing absolute grounds of refusal and stipulating that a mark that contained any matter that was likely to hurt religious susceptibilities may not be registered.

The Supreme Court, after hearing rival contentions ruled that no one person can claim the name of a holy or religious book as a trade mark for his goods or services. In arriving at its conclusions, the Supreme Court placed reliance on the Eighth Report on the Trade Marks Bill, 1993 submitted by the Parliamentary Standing Committee, wherein in clause 13.3 the Committee expressed its opinion that any symbol relating to Gods, Goddesses or places of worship should not ordinarily be registered as a trade mark.

Mere use of a toxic chemical in an invention does not preclude patentability of the invention

In a recent decision in a pre-grant opposition

against Galatea Ltd., (hereinafter "the applicant"), the Indian Patent Office (IPO) rejected the opponent's allegation that Selenium used as a medium for immersing gemstones for determining the location of any inclusions, is prejudicial to human, animal or plant life or to health or to the environment. The opponent had also alleged that over exposure of Selenium, could cause harm to human, animal or plant life or to health or to the environment and therefore, the application should not be allowed u/s 3(b) of the Patents Act. Section 3(b) proscribes patenting of inventions contrary to public morality and causing serious prejudice to human and animal health and environment.

Relying on a document prepared by the Central Pollution Control Board (Ministry of Environment and Forests, Government of India) on "Compilation of MSDS for the 708 + Hazardous, Toxic and/or Flammable Chemicals", the applicant argued that materials such as Selenium did not cause prejudice to human, animal or plant life or health or to the environment, when used in accordance with their Material Safety Data Sheets (MSDS) which provides pertinent information as to the chemical identity of the product, hazardous ingredients present, physical characteristics, fire and explosion data, reactivity data, handling of recommendations and procedures, and personal protection recommendations.

The relevant portions relied upon from MSDS read as follows:

"... In order to act in a reasonable safe manner and handle all the chemicals with due respect it is essential to first obtain a comprehensive information on the hazards originating from them. Although the minimum relevant information on common hazards may be available from the product catalogue and labels of the containers etc., more detailed but essential information is often found on the Material Safety Data Sheets, commonly abbreviated MSDS. Material Safety Data Sheets come in many forms and present the information in different ways.

Regardless of the format, The Occupational Safety Health Administration (OSHA) requires that all individuals using or otherwise coming into contact with chemical materials have access to the Material Safety Data Sheet (MSDS) for those materials. The MSDS provides pertinent

information as to the chemical identity of the product, hazardous ingredients present, physical characteristics, fire and explosion data, reactivity data, handling recommendations and procedures, and personal protection recommendations...."

The applicant also indicated that in the case of the impugned invention, if used with known safety measures, there was no exposure of Selenium to either the person carrying out the method or to the environment. The applicant also presented a technical affidavit from one of the inventors stating the known precautions and safety measures to be taken while using Selenium. It was also submitted that such precautions and safety measures were within the general knowledge of a person using such materials and hence the use of Selenium in the impugned invention was safe. Satisfied with the arguments, technical evidence and amendments carried out to the claims, the IPO rejected the opposition and granted a patent on the application.

This case sets a precedent in assessing patentability of subject matter prima facie excluded under Section 3(b) of the Patents Act.

[The applicant was represented by K&S Partners]

Jurisdiction to rectify the Register lies exclusively with the IPAB: Full Bench of the Delhi High Court

The Full Bench of the Delhi High Court was called upon to interpret Section 124 of the Trade Marks Act in the case of Data Infosys Ltd. vs. Infosys Ltd. Section 124 essentially states that when in a suit for infringement of a trademark, the defendant pleads invalidity of the plaintiff's registration or the plaintiff pleads invalidity of the defendant's registration, the court would stay the suit if there is a rectification proceeding pending in relation to either party's mark before the Registrar of the IPAB. If no such proceedings are pending and if the court is satisfied by the prima facie tenability of the plea of invalidity, the court would adjourn the case for three months to enable either party to apply for rectification.

The Full Bench has since held that the right to seek rectification of a registered trademark is not dependent upon the determination of the prima facie tenability of the plea of invalidity of the trademark by a civil court, before which the registered mark is the subject matter of an

infringement suit.

In this case, IT giant, Infosys Ltd had filed a suit for passing off and infringement of its registered trademark INFOSYS against the defendant, Data Infosys Ltd, before the Delhi High Court. During the pendency of the suit, the defendant filed and secured registration of the trademark DATA INFOSYS, prompting the plaintiff to file a rectification against the mark DATA INFOSYS before the IPAB. Thereafter, the defendant filed an application before the Court under Section 124 seeking an order declaring the plaintiff's rectification as null and void, on the premise that the plaintiff had not satisfied the Court of the prima facie tenability of the plea of invalidity.

The Single Judge's finding that Section 124 did not envisage any permission from a civil court prior to initiating a rectification petition was challenged by the defendant before a Division Bench, which noted the conflicting views on the issue and referred it to a Full Bench, comprising of three judges. One such view (by the Madras High Court and the IPAB) was that seeking rectification of a registered mark under Sections 47 (non-use) and 57 (invalidity) of the Act was a statutory right, which could not be taken away by the provision of Section 124. The other view (by the Delhi and Gujarat High Courts) was that rectification proceedings could not be initiated without the civil court's prima facie satisfaction of the plea of invalidity of the trademark.

The Full Bench observed that Section 9 of the Civil Procedure Code provided that courts had jurisdiction to try all civil suits, except those, which had been expressly barred. Referring to several judgments of the Supreme Court and the scheme of the Trade Marks Act, the Full Bench concluded that the jurisdiction to adjudicate the plea of invalidity of a registered trademark was exclusively vested with the IPAB and that the jurisdiction of the civil court to try such an issue is barred.

The Full Bench further observed that Section 124 did not preclude the filing of a rectification petition and

opined that the view that rectification proceedings could not be initiated without the civil court's prima facie satisfaction of the plea of invalidity of the trademark would lead to anomalous situations. It noted that, on the one hand, the IPAB had the exclusive jurisdiction to adjudicate the validity of a trademark, and the civil court was obliged to stay the suit till such decision was passed by the IPAB [under Section 124(1)(i)]. On the other hand, if the applicant were to seek prior permission of a civil court and if such permission were to be rejected, then the applicant's right to approach IPAB would be curtailed.

The Full Bench thus unanimously overruled the view (by the Delhi and Gujarat High Courts) that rectification proceedings could not be initiated without the civil court's prima-facie satisfaction of the plea of invalidity of the trademark. It was further held that IPAB had the exclusive jurisdiction to adjudicate the plea of invalidity of a trademark, including in cases where the said mark was the subject matter of a suit. Even if the civil court were to prima facie hold that the plea of invalidity was not tenable, the applicant was not precluded from preferring a rectification petition before the IPAB.

Further, the Full Bench in its majority Judgment held that:

- (1) The only two situations where the civil suit would be stayed are – (a) if the rectification petition is filed prior to the filing of the civil suit [Section 124(1)(i)], and (b) where a civil suit is already pending, and the rectification petition is filed after the plea of invalidity is held to be *prima facie* tenable by the court [Section 124(1)(ii)]; and
- (2) Where the civil court holds that the invalidity plea is not tenable or where the court holds the plea to be *prima facie* tenable, but the applicant does not approach the IPAB within the specified time; then the defense of the invalidity of the trademark in the infringement suit is deemed to be abandoned.

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