

# amicus

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## Second Anniversary Issue

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## Article

### Working of patents in India

By Siddharth Sharma & Ranjan Matthew

#### *Why the need? – A rational perspective*

Primarily, in order to understand the reasoning behind why a patentee or a licensee thereof is required to furnish information regarding the working of patents in India, it may be pertinent to study the statutory provisions envisioned under Section 83 of the Patents Act, 1970, hereafter referred to as the Act.

Section 83, under Chapter XVI, which is titled “Working of patents, compulsory licences, and revocation”, teaches us the general principles applicable to the working of patented inventions. *Inter alia*, this Section lays down the reasoning or legislative scheme behind the granting of patents, including that patents are granted to encourage inventions and to secure the *working* of the patented article in the country [Section 83 (a)]. Furthermore, from the broader perspective of the Act, the patenting system ensures that a *quid pro quo* is maintained. In return for the monopoly granted by the government over the patented article, the patentee and the licensee are expected to disseminate this inventive knowledge to the public (for example through the publishing of the patent), as well as work the patented invention, and provide the patented invention to the public at a reasonable cost. Even though Section 83 provides only guiding principles and not rules by mandate, it is helpful in understanding the requirement of working patented inventions in India.

Furthermore, the statement of working provided by patentees and licensees can also provide useful insight into the effectiveness of the patenting

system for various industries and companies that utilize the patented inventions in their course of business.

#### *Working of patents in India – Legal overview*

According to Section 146 read with Rule 131, a patentee or a licensee, exclusive or otherwise, of a granted patent, is required to submit a statement regarding the working of the patented invention on a commercial scale in India in the prescribed manner (Form 27).

Furthermore, the Controller of Patents may issue a notice in writing, requiring the patentee or a licensee to furnish such information related to working in Form 27 within a period of two months from the date of issue of such notice [Section 146 (1)]. Form 27, amongst other details, requires the patentee or the licensee to furnish the following relevant information:

- 1) Whether the invention has been worked;
  - a) if not worked, the reasons for not working the invention, and the steps being taken to work the invention;
  - b) if worked, quantum and value (in rupees) of the patented product:
    - i) manufactured in India,
    - ii) imported from other countries, giving details of the countries concerned;
- 2) Licences and sub-licences granted during the year;
- 3) Whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

As per Rule 131, this information should be filed every calendar year, within three months of the end of each year. Thus, the latest that a patentee or licensee can file such information for a given calendar year is March 31st of the following year.

### *Failure to oblige*

Failure to furnish such information creates a presumption of non-working, and may assist the process of grant of compulsory licences. It is also a punishable offence and may incur a fine which may extend to rupees ten lakh (i.e., INR one million or USD sixteen thousand). Additionally, intentional furnishing of false information is an offence punishable with imprisonment for up to six months, or a fine, or both (S. 122).

### *Recent developments in India – The system works!*

In a recent unprecedented move, the Indian Patent Office (IPO) made all the working statements filed by patentees during the year 2012 publically available. Section 146 (3) clearly provides this power to the Controller to publish the information received by him under Sections 146 (1) and (2).

The publishing of such a vast quantum of working statements by the IPO provides a host of valuable information regarding the effectiveness of the patenting system in India and can be utilized by various forums, such as academicians, potential licensees, and law makers to improve or amend the law of patents in the country as well as to value the patents covered under these published working statements.

### *Compulsory licensing, revocation, and the working of patents*

The legal provisions relating to compulsory licences are closely interwoven with the provisions relating to the working of patents. Section 84 states

that an interested person may, after the expiration of three years after the grant of a patent, apply to the Controller for a compulsory licence on the patent on grounds that, *inter alia*, the patented invention is not worked in India [S. 84 (1)(a)]. Occasionally, the Controller may also adjourn the application for a compulsory licence, specifically to allow sufficient time for working in certain conditions (S. 86). This includes a decision, by the Controller, whether the patentee has taken adequate steps to at least begin working the invention on a commercial scale in India.

Furthermore, two years after the grant of the first compulsory licence, anyone may apply to the Controller to revoke the patent, if, *inter alia*, the patented invention has not been worked in India. The onus lies on the applicant of the compulsory licence to furnish the facts upon which such revocation is sought and the nature of the applicant's interest. Such an application must ordinarily be decided within one year of its presentation to the Controller (Section 85).

### *Industrial benefits*

Besides encouraging development in the field of science and technology, the publishing of working statements has other numerous advantages related to business and trade. For instance, a working statement pertaining to a patent can help in estimating the worth/value of a patent and thus may help a potential licensee to negotiate the fee for obtaining a licence based on the value of the patent. On the other hand, working statements may prove to be of significant importance from a business merger or a business takeover perspective, as patents can form a significant part of the intangible assets of a company, and a good patent portfolio along with the information about its working may help companies in negotiations.

Furthermore, small scale industries may customize resources spent in research and development (R&D) according to the prospering technology pertaining to their field, based on information gathered from available working statements. Thus, data about working of inventions,

*inter-alia*, gives an idea about the effectiveness and commercial viability of inventions, for valuation of patent portfolios and compulsory licensing.

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## Ratio Decidendi

### Enhanced stability and moisture absorption do not constitute “enhancement of known efficacy”

The IPAB has revoked Indian Patent IN221171 on Quinazoline Ditosylate Salt Compounds on obviousness. The Board, relying on the recent Supreme Court Order in the case of *Novartis*, held that qualities of superior moisture absorption properties and enhanced stability, over the prior art, are physicochemical in nature and not related to therapeutic efficacy.

It was held that the complete specifications of the patent disclosed that problems existed with the hydrochloride salts and also provided the motivation to a person skilled in the art to look for a compound which would overcome the above limitations. The IPAB admitted that salt selection is an arduous task but held that the prior art not only mentioned the tosylate salt but also provided the person skilled in the art the reason to select the same.

However, in another case, revocation to Indian Patent IN221017, relating to Bicyclic heteroaromatic compounds, was rejected. IPAB noted that too many randomly made right choices cannot be called a matter of obviousness and that there was no clear teaching in the prior arts in this case. Observing that the applicant did not tell why the persons skilled in the art would select

those examples in Exhibit-1 containing a furan ring as the starting point at every stage and why the same person would choose from Exhibit-2 a furan ring substitution on the quinazoline ring out of the 39 examples, it was held that there was no obviousness, more so as the applicant wanted to pick and choose from multiple options not just from one prior art but more than one exhibit.

The Appellate Board, rejecting the objections under Section 3(d) in the case pertaining to rejection of revocation, observed that the plea that because the exhibits were admitted prior arts, the invention is only a new form of those compounds, was not enough and was vague. It was noted that the challenger has to show that the claimed substance is a new form of a known substance and has same therapeutic efficacy and then the patentee has to establish either that it is not a new form or derivative of a known substance or that even if it is, there is enhanced therapeutic efficacy. The IPAB also noted that there were no such pleadings in the present case.

Objections under Section 8 were also rejected by the IPAB in both the cases, stating that a bald statement that the patentee had not complied with the requirements of Section 8(1) and (2) will not suffice. The IPAB noting the Ayyangar Committee Report, held that applicant seeking revocation has to state, at the time of filing application, the

specific foreign office actions which ought to have been filed but were not filed with the office by the patentee. [*Fresenius Kabi Oncology Limited v. Glaxo Group Limited* – IPAB Orders dated 27-7-2013 in ORA/17/2012/PT/KOL and ORA/22/2011/PT/KOL]

### Combination of two popular drugs – Patent revoked on ground of obviousness

Intellectual Property Appellate Board has revoked patent pertaining to combination of two eye drugs on the ground of obviousness. IPAB in this regard noted that the history of the state of the art showed that two drugs were popular; two drugs were combined serially, and the serial administration showed advantages over single therapy, and composition of two drugs in one bottle was known. Further, in respect to objections under Section 8 of the Patents Act, it was held that said section has to be complied and the fact that there are search engines from which information can be culled out is no answer. It was held that patentee having given an undertaking in Form-3 which is a pre-requisite for consideration of the application, cannot avoid the solemn obligation by stating that the information is available in the internet or the website. Noting that Rule 12(3) clearly says that the applicant must furnish information relating to patentability objections raised in other countries, IPAB observed that patentee had information of adverse action by both EPO and US PTO which was not disclosed.

However, with regard to objections under Section 3(d), the IPAB held that combination mentioned in the explanation to Section 3(d) can only mean a combination of two or more of the derivatives mentioned in the said explanation, or combination of one or more of the derivatives with the known substance which may result in a

significant difference with regard to the efficacy. It was held that a combination of two active drugs like Brimonidine and Timolol cannot be considered derivatives of each other and hence cannot be considered as a form of a known substance. [*Ajantha Pharma Limited v. Allergan Inc.* – IPAB Order dated 8-8-2013 in ORA/21/2011/PT/KOL].

### Combining sample with prior art – Applicability of obviousness

Dismissing the appeal against invalidation of patent of the defendant, the UK Court of Appeals upheld the claimant's argument that it was permissible to combine a commercial sample and teaching of earlier patent [US patent 5,047,517 (“the 517 patent”)] in arriving at the (allegedly infringing) product. In the instant case, the defendant held a patent for beta polymorph of calcium laked azo pigment (PY 191), which it had developed by varying its method of production, introducing a new solvent conditioning process. The claimant questioned the validity of the patent arguing that the said beta polymorph was contained in an intermediate product, a filtered suspension of PY 191 (known as wet cake). On drying at particular temperature, the alpha polymorph would crystallise to the beta polymorph.

The patentee argued that the claimant too had to make several trials before he arrived at the product and it was not obvious from the teachings of the 517 patent. The court did not accept the argument that several iterations and trials to determine the right mix to make a product similar to an existing commercial product, made it non-obvious.

The Court also held in favour of the claimant on the issue of ‘groundless threat’ wherein the patentee had written a letter to the claimant about serious penalties which could ensue to them and

customers. The court was of the view that if a company has applied for and secured the grant of a patent and then seeks to enforce it, the controlling mind of the company must include at least the mind of the properly informed patent attorney or, put another way, the minds of the patent attorney and the inventor. Hence, even though the original inventor was no longer with the company, the fact that the company had his records showing

that 'vacuum dried wet cake produced by the process of the 517 patent contained 100% of the beta polymorph', it had enough reason to believe that its patent was invalid. [*Sudarshan Chemical Industries Ltd. v. Clariant Produkte (Deutschland) GmbH*, Judgment dated 30-7-2013 of the Court of Appeal (Civil Division) on appeal from the High Court of Justice, Chancery Division (Patents Court), London]

## News Nuggets

### Parallel submissions as amicus curiae

The International Trademark Association has sought to file submission as *amicus curiae* in the case of *Samsung v. Kapil Wadhwa & Ors.* Earlier the larger bench of Delhi High court had upheld international exhaustion of trademarks. The INTA petition urges that trade mark owner 'cannot and should not be deprived of its right of territorial commercialization of its trade marks unless it is proven that it has expressly consented to such sale in a particular country'. On price advantage ensuing to consumer when goods are imported from lower-priced markets, INTA argues that prices reflect research and development costs, brand study,

local marketing costs etc., and parallel imports tend to skew the pricing model which is unfair to the trademark owner. It submits that provision 30(4) of the Trademarks Act, which deals with 'legitimate reasons' to oppose further dealing in goods should be broad enough to include non-confirmation with packaging and labelling laws. Goods intended for sale in a particular jurisdiction may not be in conformity with such laws of another. Adopting international exhaustion, a proprietor will run the risk of being found guilty of non-compliance with such laws. It also states that there is no consensus on standard of national or international exhaustion.

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