

Pharmaceutical news round-up for India

The First Compulsory Licence Application

Natco becomes the first Indian generic company to apply to the Controller of Patents for a compulsory licence under section 84 of the Indian Patents Act. It is seeking a licence for Bayer's Nexavar drug used for the treatment of liver and kidney cancer. Natco sells the generic version – sorafenil tosylate. The principle ground for the application is that Nexavar is not available at “a reasonably affordable price” in India. Natco claims that it will be able to sell the drug for Rs 8,900 (about \$198) for a one month course compared to the Rs 285,000 (2.5 lakhs) (about \$5600) charged by Bayer. The informal application for compulsory licence was rejected by Bayer.

Under section 84, three years after the grant of a patent in India, any interested person (including a charitable organisation) can apply for a compulsory licence on the grounds that:

- the reasonable requirements of the public with respect to the patented invention have not been satisfied or
- the patented invention is not available to the public at a reasonably affordable price or
- the patented invention is not worked in India.

The applicant has to provide a statement in the application setting out the nature of its interest with such particulars as may be prescribed and the facts upon which the application is based. Under the provisions of section 92, the Controller is required to allow the patentee to respond to and make submissions.

In considering whether a licence should be granted, the Controller will need to be satisfied on:

- the nature of the invention and the steps taken by the patentee to make full use of the invention
- the ability of the applicant to work the invention for the advantage of the public
- the capacity of the applicant to undertake the risk in providing capital and working the invention
- the efforts made by the applicant to obtain the licence from the patentee.

Prima facie, given the alleged price difference and the fact that Natco is manufacturing sorafenil tosylate (Bayer has commenced an action for patent infringement), and it approached Bayer for a licence, potentially work in favour of Natco.

Whether the Controller of Patents is capable of determining on the basis of “reasonable affordable price” remains to be seen. What benchmark/data will he apply? Given the range and scale of poverty and affordability, for a worker earning Rs 500 a day, even the Rs 8900 may not be “reasonably affordable”. The issue also is whether it is viable for the Controller of Patents to grant licences on the basis of “fair price” and “public policy”. Surely it would be beyond the scope of his expertise (which essentially is technical), if not authority. The provisions of The Essential Commodities Act (“ECA”) (under which drugs are an essential commodity) extensively cover the control of production, distribution and price control of drugs. Under that Act the authority lies with the Central (and perhaps the State Government) who can control the distribution and price of the drugs and reduce it to an affordable level. How can that power be devolved to Controller of Patents (who incidentally cannot further delegate this power).

Ironically, the ECA is being diluted on the basis that the Indian economy is liberalised and fair competition should be facilitated and encouraged. The approach to patent protection and enforcement is just the opposite.

It is rumoured that if Natco is successful, it may open flood gates of similar applications. That should not be so as the principle of compulsory licensing was included in the TRIPs agreement to enable the governments to legislate in order to prevent abuse of monopoly and not create compulsory pricing system. It should not create unfair prejudice to the patentee and should be granted in emergencies or in exceptional circumstances. The Controller hopefully will approach the matter with careful deliberation as legislatively there is no power intended to the Controller or the government to grant licences.

The Act refers to “patented inventions”. The Indian authorities should dwell on the fact that inventions as patented are quite often not commercialised. Patents are negative rights enabling the owner to stop third parties from using the patented rights and not a right that enables the owner to use them or forces it to use them.

Whatever the outcome, it is unlikely that the matter will conclude at the Controller stage. Ultimately it is likely to be adjudicated by the Courts.

The optimum solution may be for the parties to negotiate a licence between themselves. This may enable Bayer to retain control over the extent and scope of use, and the market segment. It would also retain control over the quality of the drugs produced and sold.

Novartis/Gleevec in SC

The hearing of the appeal by Novartis in relation to the rejection of its application for the beta crystalline form of imatinib mesylate (the "Invention") has commenced in the Supreme Court of India ("SC"). Its progress depends upon whether there is a judge who will not be coerced into "recusing" himself by the public interest lobby. A few days ago Justice Bhandari recused himself apparently because he spoke at a conference about educating people on IPrights.

The main ground of rejection by the Intellectual Property Appellate Board ("IPAB") was that although the Invention was novel, involved an inventive step and was non-obvious, it did not satisfy the requirements of "enhanced efficacy" under section 3(d) of the Indian Patents Act which states that *"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substanceis not an invention"*.

The current position is that it is limited to "therapeutic efficacy". The Madras High Court construed this as *"healing a disease/ having a good effect on the body"*. The IPAB in its decision construed it as only *"curative effect"*.

The SC has to decide whether under section 3(d) a patent for new forms or compounds be granted only if they clearly demonstrate enhanced therapeutic efficacy that too "curative" or, whether it extends to advantageous technical effect/solution to a problem akin to the approach in the EPO/ USA. Given that 3(d) is not limited to just drugs and extends to chemical compositions, medical devices and other mechanical inventions (which is acknowledged by the Madras High Court and the IPAB) it is hard to see how the SC can interpret section 3(d) narrowly without creating ambiguity. Even in relation to drugs and in the context of cancer and HIV

drugs can it ignore palliative care or reduction in side effects with no cure, which are essential in management of these diseases.

The other grounds that may be:

- **Mandatory disclosure of prior art in the specification at the date of Application.** The IPAB held that unlike the EPO, under section 10(4) of the Indian Act it is not compulsory or mandatory to do so. But if the Applicant wants to avoid opposition or litigation it should. It implies compulsion by saying that *"unless the relevant prior art including the closest prior art is disclosed the patent applicant cannot be said to have discharged its duty and obligations"* and *"We are of the view that the closest relevant prior art is also necessary to be disclosed in the patent specification."* The SC could clarify this.
- **Disclosure of Efficacy data in the specification at the date of the Application.** Originally Novartis had not claimed improved bioavailability and only claimed it when the examiner raised objections under section 3(d). It then conducted further experiments/ study and submitted the new data. The IPAB held that Novartis could not amend its application to introduce this new data. It should be included at the time of the application. This may be correct but given that the application was "mail box" prior to 2005, it is not equitable. Moreover, the reasoning that *"a patent is granted on the basis of its full disclosure of the invention in the specification furnished on the priority date of the application. Even an amendment is not allowed in the specification which in substance is not disclosed therein. The Patent law debars an applicant a grant of patent for belated discovery of a new form..... The Applicant is not entitled*

to make out a case for patent in its favour by importing a new matter in the specification which was later discovered/ established" whilst correct, on the facts may be unreasonable and unduly onerous. There is nothing in section 10 that expressly requires data disclosure at the application stage. It may not even be relevant until the application is examined and the 3(d) objection is raised. Second, the practice manual advises that the specification only succinctly explains how the prior art is overcome and the problem solved. Third, IPAB's approach does not commensurate with the patent rules for PCT applications. It is different if the examiner asked for the data and the applicant fails to do so. There is also the issue of confidentiality of the data.

- **Reliability of witnesses.** The IPAB agreed that the evidence of the expert who has not himself carried out the experiments but has supervised the technical team that conducts such experiments is credible and sufficient. On the other hand, it deemed that the evidence of the employees is partial and not neutral and therefore could be ignored. That may not be correct given that in majority of the cases the factual evidence can only be adduced from the employees.
- **Possible high price of drug could lead to unrest and public disorder.** The IPAB held that: *"We are fully conscious of the Appellant's benevolent GIPAP program for free distribution of GLEEVEC to certain cancer patients. But when the Appellant was holding the right as EMR on GLEEVEC it used to charge Rs. 1,20,000/- per month for a required dose of the drug..... which in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous*

effect on the society as well. 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.” This has to be the most unreasonable ground for rejecting an application.

The aim of section 3(d), to prevent patent “ever greening” or discourage “patent trolls”, is sensible and laudable. However, the manner in which this section and the patent law generally has been interpreted thus far by the Indian patent offices and the Courts is that almost all incremental inventions are rejected. The SC has a golden opportunity to bring order to the chaos.

In the meantime the advice is that when applying for a new form of known chemical compound specially a drug :

- adduce clear incontrovertible efficacy data
- include prior art and efficacy data in the application to the extent possible
- produce that data to the examiner when requested
- keep him informed of all equivalent applications worldwide including their progress to the extent practical

You need permission to use Indian Biological Resources

A company that is not incorporated in India or registered there cannot obtain a “biological resource” from India without the approval of the National Biodiversity Authority (“NBA”). This is under the provisions of the Biological Diversity Act 2002.

A biological resource is defined as plants, animals, microorganisms or parts thereof, their genetic material and by-products with actual or potential use or value but does not include human genetic material. It includes

any knowledge associated to the resource for research or commercial utilisation or for bio-survey and bio-utilisation (together “Resource”). Bio-survey and bio-utilisation includes any survey or collection of species, sub species, genes, components and extracts of biological surveys and extends to characterisation, invention and bio-assays.

Therefore if a foreign company intends to do the following or commission a third party, it needs prior written approval of the NBA. An Indian company needs only to inform them.

- obtain the Resource
- obtain any knowledge relating to a Resource for research or commercialisation
- transfer the results of any research relating to a Resource for monetary consideration or otherwise
- apply for a patent or other intellectual property right relating to a Resource, either in India or anywhere else in the World.

The above excludes any collaborative research which involves transfer or exchange of Resources between jurisdictions provided that the research confirms to or is approved by the Central Government of India. An application for approval has to be made in a prescribed form and with a prescribed fee.

In granting an approval the BDA may impose, certain conditions, benefit sharing fee, royalty and/or sharing of financial benefits arising from commercialisation of the Resources (the “Benefits”). The approval is not transferable. Any transfer requires further formal approval. The NBA cannot reject an approval without giving the applicant an opportunity of a formal hearing.

The Benefits are to be shared between the applicants, local concerned bodies and benefit claimers and can include:

- a joint ownership of IP rights with the NBA and/or the benefit claimers (meaning conserves of the Resources and by-products, creations or holders of knowledge and information relating to the Resources, their practices or applications).
- transfer of technology to the benefit claimers
- setting up a VC fund for the benefit claimers
- repayment of monetary or other compensation to benefit claimers

As part of obtaining approval, if it appears, that there may be a benefit claimer, it may be advisable to make a proposal to the NBA. The contravention of the above provisions is a criminal offence with up to 5 years of imprisonment or a fine of up to RS ten lakhs plus damages. In the case of a company, its directors are liable.



Rajita Sharma
Partner, IP and Media
T: +44 (0)20 7344 5552
E: rajita.sharma@fsilaw.com

About the author

Rajita Sharma specialises in all areas of intellectual property law, including patents, trademarks, copyright, design rights, databases and related competition law both commercial and litigation. She represents a range of clients, in the life sciences, pharmaceuticals, consumer and luxury goods, and the shipping sectors. She is qualified to practice in England and Wales and India.



Finers Stephens Innocent LLP

179 Great Portland St, London, W1W 5LS, T: +44 (0)20 7323 4000, www.fsilaw.com

 @FSILAW   Finers Stephens Innocent LLP

