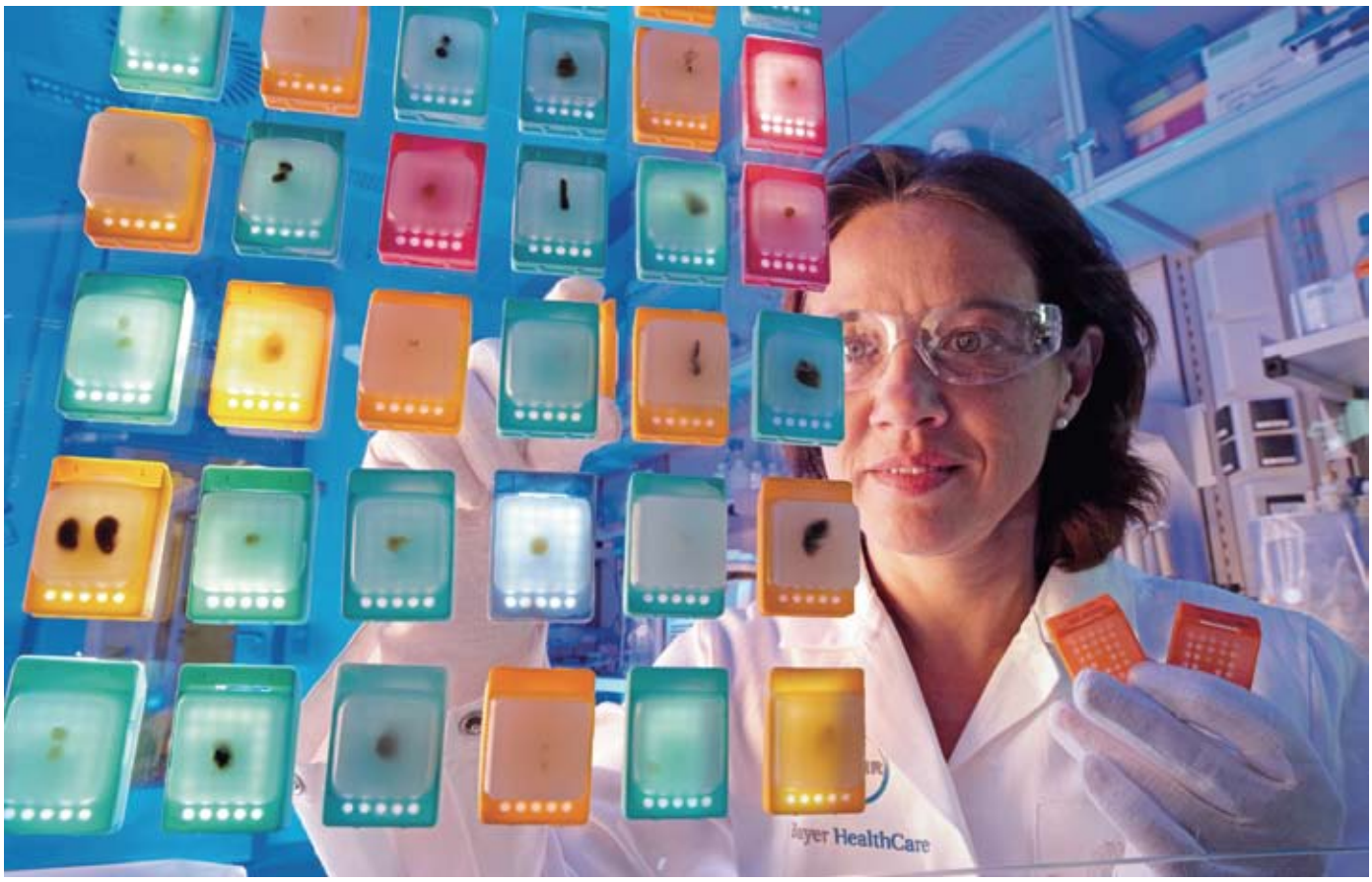

Sharing the medicine

Bitter pill for big pharma as India issues its first compulsory licence since the overhaul of its patent regime in 2005

Rebecca Abraham reports

In September 2007, Natco Pharma, one of India's smaller generic drugs manufacturers, filed applications at the Delhi patent office for compulsory licences for two anti-cancer drugs, Suninat and Tarceva, patented in India by Pfizer and Roche respectively.

Natco, an oncology-focused company, intended to use the compulsory licences – applied for under section 92A of the Patents Act, 1970 – to manufacture and export the drugs to Nepal.

Section 92A provides for a compulsory licence for the export of patented pharmaceutical products in certain exceptional circumstances.

However, nothing came of the application as it was subsequently withdrawn. And while Natco appeared to have accepted defeat, skirmishes continued between the multinational pharmaceutical companies and Natco and other Indian generic drugs manufacturers, with infringement actions and suits for revocation of patents being filed in courts across the country.

A second try

Then, on 28 July 2011, Natco applied for a compulsory licence – under section 84 of the Patents Act – to manufacture and sell another patented drug: Bayer's sorafenib tosylate, which is marketed as Nexavar and costs ₹280,000 (US$5,500) for a course of 120 tablets. The drug is used for the treatment of kidney and liver cancer.

This time Natco had set its sights on the domestic market where – according to a November 2011 report submitted to the Planning Commission – in March 2011 alone the consumption of medicines was worth ₹560 billion.

When last month India's patent office granted Natco India's first compulsory licence since the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), it appeared that the multinational pharmaceutical companies had been outmanoeuvred.

Natco has the licence until 2021 and will sell the drug for ₹8,880 for a course of 120 tablets. Bayer had asked for

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> Richard Baddeley
> Principal
> Watermark

a 15% royalty, but will receive only 6%. Natco will supply the drug free of cost to 600 deserving and needy patients each year.

Cause for concern

The order, which was made public on 12 March, has set alarm bells ringing across the patent-owning community.

Describing the compulsory licence as "a terrible thing from the owner's perspective", Pravin Anand, managing partner of Anand and Anand and a stalwart of many patent battles, says it has "shaken the confidence of our pharmaceutical and other patent clients".

Overseas patent holders are particularly concerned. In a statement to *India Business Law Journal*, Bayer said it was "very disappointed with the order" and would appeal it "to defend our intellectual property rights, which are a prerequisite for bringing innovative medicines to patients".

But Richard Baddeley, a Perth-based principal at Watermark, an Australian IP firm, remarks: "It's not unexpected in some ways that a compulsory licence would be granted sooner or later."

"It is consistent with India's position on that type of patent in the pharma field," adds Baddeley, who has had a long involvement with the Indian IP regime and has been following the compulsory licence case closely.

Persuasive case

Natco's application for the compulsory licence made the case that Nexavar "is exorbitantly priced and limited in availability in India". Section 84 of the Patents Act provides that a person can apply for a compulsory licence on the basis of any of three grounds: the reasonable requirements of the public for the patented invention have not been satisfied; the patented invention is not available to the public at a reasonably affordable price; or the patented invention is not worked in the territory of India.

Natco, which was represented by Rajeshwari of Gurgaon-based Rajeshwari & Associates, persuaded the patent office and its then-head, PH Kurian, the controller general of patents, designs and trademarks, that a compulsory licence was warranted on all three grounds.

The order was published on the last day of Kurian's tenure as controller general.

Using patient data from GLOBOCAN 2008, a publication of the Globocan project of the World Health Organization, Natco submitted that Bayer's product "reaches less than 1% of patients and almost 99% of patients who are unable to afford the drug are left to die each year".

Disputing Natco's figures, Bayer argued that the reasonable requirements of the public were being fulfilled. In a written statement opposing the application, Bayer pointed out that a cheaper version of the drug made by Cipla, another generic drugs manufacturer, was also available in the market – a fact that it said Natco had suppressed.

Indeed, according to data provided by Bayer, Cipla sold almost eight times as much of the drug as Bayer in the Indian market in 2011. Bayer had filed an infringement action in April 2010 against Cipla.

However, the patent office was unmoved by Bayer's stand. In a 62-page order granting the compulsory licence, Kurian said: "I am not inclined to accept the argument of the patentee that the sales of patentee combined with that of M/S Cipla satisfy the reasonable requirements of the public."

Noting that Bayer was in the midst of suing Cipla, the order added that the "patentee appears to be indulging in two-facedness by adopting one stand before this tribunal and another stance before the Hon'ble High Court of Delhi, in order to defend the indefensible".

Bayer was represented by a senior advocate, Sudhir Chandra Aggarwal, and three advocates: Sanjay Kumar, managing partner of Perfexio Legal; Arpita Sawhney, a partner at the same firm; and Rahul Kumar. Sanjay Kumar declined to respond to queries from *India Business Law Journal* citing "confidentiality re strategy etc. of our client, Bayer".

Out of pocket

Responding to Natco's allegation that Nexavar was exorbitantly priced, Bayer pointed out that about 75% of its total research and development (R&D) costs go towards funding failed projects.

Bayer also told the patent office that Nexavar had been granted "orphan drug" status in the US and Europe as it had a limited market. Natco's lawyers said that based on this, clinical trials conducted between 2002 and 2005

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> Partner
> Luthra & Luthra

were funded or sponsored by the National Institutes of Health, which is a US government organization.

"The early role of the public sector was most important for phase II trials, where 70% of the trials involving half of the enrolled patients were in trials that had no industry funding," says Rajeshwari.

Bayer argued that the reasonably affordable price for Nexavar has to be construed with reference to the patentee as well as the public – for it is the patentee, "being the innovator and having invested resources in developing/marketing the innovation-based product," which would decide what would constitute a "reasonably affordable price".

Once again the patent office was unmoved as it concluded that "reasonably affordable price has to be construed predominantly with reference to the public" and that "the drug was not bought by the public due to only one reason, i.e. its price is not reasonably affordable to them".

Refusal to put down roots

Natco submitted that even three years after the patent was granted, Bayer had "not taken adequate steps to manufacture in India and make full use of the invention". Although Bayer makes some of its drugs in India, it imported Nexavar from its manufacturing facilities in Germany.

Bayer argued that imposing local manufacturing requirements on patents granted in India "would be beyond the scope of the Patents Act". Bayer also said that the quantities required in India do not economically justify setting up a manufacturing unit in India.

This argument too did not pass muster with the patent office. Drawing on the provisions of the Paris Convention for the Protection of Industrial Property, the TRIPS agreement and the Patents Act, the controller held that a patent granted in India must contribute to the promotion of technological innovation and to the transfer and dissemination of

A mixed reaction

NS Gopalakrishnan speaks with Rebecca Abraham about the compulsory licence order and what he makes of it

I believe that the order is a good start. It sends a message to the owners of patents that if they register a patent in India, they should manufacture in India. It will discourage patent owners who want to occupy a niche market and try and exploit it, without any attempt to make it benefit large sections of society.

Any country will get maximum benefit from granting a patent when the patented product is actually manufactured and sold in the country and made as affordable as possible to a large section of consumers. Philosophically and theoretically, that is why a patent is granted.

Bayer provides a classic example of how an owner of a patent can take maximum advantage by registering a patent. In this case, there is no manufacture in India, it is imported and sold at a very high price. If the objective of the patent law is to ensure that benefit of a granted patent reaches society, this is a fit case for government to issue a compulsory licence because the purpose of granting a patent has been completely lost.

Issues like economies of scale are problems patent owners have to deal with. The problem of the country that grants a patent is to ensure that it gets the maximum benefit out of the grant of patent. There is a quid pro quo in the grant of a patent – the owner gets some monopolistic rights while the country gets the benefits.

If economies of scale cannot be achieved, the patent owner need not manufacture the product – they can license someone else to do so in India. This generates valuable follow-on inventions. In addition, the act does not say that the invention must be manufactured in India. It may be possible to import the product provided it is made available to large sections at an affordable cost and it satisfies the reasonable requirements of the public. This is the balance built into the act on working arrangement.

I see this case as emblematic of a wider problem of the attitude of some owners of patents who look at a patent as a market monopoly for exploiting a niche market.

The order has also prompted me to ask the question: is compulsory licensing the solution for affordability of drugs as has been made out so far? My answer is that it is not a complete solution, but rather a partial solution. Even though the price has come down from ₹280,428 to ₹8,880 we have to see whether this is affordable to all the needy in a country like India.

Using statistics provided by the controller general in the order, I would like to infer that more than 50% of the cancer patients cannot afford Nexavar even at Natco's prices. The drug has been made affordable to some more sections of the population, but not all.

So the belief that compulsory licensing is the flexibility built into the TRIPS agreement to take care of health care needs is not completely true. And if people project compulsory licensing as a solution, then this case shows that it is not.

As for the order in particular, I am disappointed that there is no discussion as to the sanctity of this ₹8,800 [Natco's price for the drug]. Is this the right figure? That should have been answered. I believe it would have made the order more rational.

I believe the controller has a duty – as mandated in the Patents Act – to find out if what has been stated by Natco is a reasonable amount.

This order should serve as an eye-opener for the government on the limitations of compulsory licensing as a tool for achieving affordable drugs to all sections of society.

NS Gopalakrishnan is the Ministry of Human Resource Development chair professor of IPR at the Inter University Centre for Intellectual Property Rights Studies at Cochin University of Science and Technology.

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> Partner
> Ranjan Narula Associates

technology. More importantly, the controller found that working a patent could not imply importation and it must mean manufactured in India to a reasonable extent.

Flaws in the order?

It is this aspect of the compulsory licence that is causing the greatest anxiety among patent holders. While acknowledging that this is the first time the patent office has had to grapple with such complex legal questions, some lawyers say that the order is wrong in requiring that a patent has to be worked locally to avoid a compulsory licence.

Citing a Delhi High Court judgment (*Telemecanique and Controls Ltd v Schneider Electric Industries Ltd*), Anand says that there is precedent to show that a patent can be worked through importation. He also points out that Form 27, which is a crucial statement on the working of the patent that patent holders need to submit each year, refers to working by importation.

In addition, Anand says a patentee and a licensee cannot be held to the same standard. He believes that the controller incorrectly held that if, under section 90(2), a licensee cannot import the patented product for working the invention under licence, the same logic must apply with respect to the patentee.

Anand says this is clearly in violation of the rights of a patentee to import a patented product under section 48 of the Patents Act.

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> Inter University Centre for Intellectual Property Rights Studies
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> Managing Partner
> Rajeshwari & Associates

Lacking in rigour

Gayatri Roy, a Delhi-based partner at Luthra & Luthra, suggests the evidence provided could have been more rigorous, given the importance of the case.

"If at the outset the controller had required Natco to get better evidence, this entire case may have taken a different turn," says Roy.

Roy adds that the order suggests that the controller was unhappy with relying only on statistics from Globocan, which was used for evidence of incidence of cancer, but did not ask either Natco or Bayer to produce anything better.

"I don't think a compulsory licensing proceeding is such that additional information could not have been called for," remarks Roy.

Similarly, both Natco and Bayer made potentially significant claims – Natco submitted that "the product is often out of stock … in common pharmacies in metro cities" and Bayer said there are "alternate remedies available to the patient" – but neither was asked to provide evidence to back up the claims.

Leaps of logic

Another problematic area was the manner in which the controller concluded that the demand for Nexavar was not being met.

"The question whether all the patients had a demand for the drug is also something that was not gone into," says Roy.

Similarly there was little discussion on the companies' pricing of the drug.

"The controller accepted the price given by Natco, but who is to decide if that is suitable for the Indian market?" asks Rachna Bakhru, a Gurgaon-based partner at Ranjan Narula Associates.

> Keep the potential licensee of a compulsory licence engaged without a clear outright rejection
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> Managing Partner
> Anand and Anand

NS Gopalakrishnan, professor of IPR at the Inter University Centre for Intellectual Property Rights Studies at Cochin University of Science and Technology, is equally sceptical. Using statistics provided in the order, he infers that more than 50% of cancer patients cannot afford Nexavar even at Natco's prices.

"The drug has been made affordable to some more sections of the population, but not all," says Gopalakrishnan.

Roy believes the problem is that the controller failed to determine a notional price that was reasonably affordable. As she points out, section 90 of the act, which provides guidelines for settling the terms and conditions of a compulsory licence, requires that patented articles are made available to the public at reasonably affordable prices. A controller who finds for an applicant under section 84(1)(b), which gives the lack of a reasonable affordable price as a ground for applying for a compulsory licence, may have to identify the notional price or price band that is reasonable and affordable when section 84(1)(b) is read with section 90.

Anand suggests that the controller also erred in holding that the demand for the patented invention has to be satisfied by the patentee or its licensee and not by a third party, such as an infringer. He points out that a patented drug does not cease to be a patented drug if manufactured by an infringer or another third party.

Other actions

As it stands, Cipla produces around 85% of the sorafenib tosylate consumed in India and it is hard to understand how this could be ignored as it challenges Bayer's hold on the market for the drug.

In addition to pushing for a compulsory licence, Natco has also challenged the validity of Bayer's patent in Delhi High Court, through a counterclaim to an injunction suit filed by Bayer against Natco in May 2011.

"Challenging the validity of the patent and asking for a compulsory licence are two separate rights that are available under the law … we have exercised both the rights," explains Rajeshwari, Natco's lawyer. Rajeshwari did not comment on whether Natco will pursue its challenge of the patent. The next hearing in Delhi High Court is set for 30 May.

Some observers suggest that the patent office should not have granted a compulsory licence on a patent that is under attack. The controller should have waited for the courts to resolve the infringement and other actions before deciding on Natco's compulsory licence application.

Better safe than sorry

Now that the genie has been let out of the bottle, patent owners are scrambling to ring-fence their assets.

Bakhru at Ranjan Narula Associates suggests that asset owners in the pharmaceutical sector consider licensing their patent to generic drugs manufacturers well in advance of the three-year period after which a compulsory licence application can be made.

"This way at least their interests are being met and on their terms and conditions rather than the terms and conditions of the generic manufacturers or the government," she says.

Anand says patent holders should not dismiss any request for a voluntary licence, like Bayer did.

"Keep the voluntary licence talks on," he advises. "Keep the potential licensee of a compulsory licence engaged without a clear outright rejection".

Other suggestions are: try to have the application adjourned using section 86, which entitles patent owners to seek time in order to work the patent in India; and if it is possible to reduce the price, do it before rather than during the hearing for a compulsory licence.

Anand also believes that although the controller rejected working a patent through importation, it "appears likely that this part of the judgment would be rejected in appeal". Therefore he suggests that patent owners should use it as a defence.

Bayer's coming appeal will no doubt generate great interest for, as Bakhru says: "When the law is not very tight, you have to look to the courts for a correct interpretation".

Coming soon: more choice

Meanwhile, according to P Bhaskara Narayana, director and chief financial officer at Natco, the drug will be available in the Indian market "very soon".

Natco's version of Nexavar will be called Sorafenat. ■

Medicine for the masses: Natco's case for a compulsory licence was based on the argument that Nexavar is expensive and hard to obtain in India.