# Intellectual Property Rights

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# Indian pharma: Pricey patented drugs do not seem the norm

Jaideep Mishra, Economic Times

5 July, 2012: There seems considerable policy action in the Indian pharmaceutical scene. There is the reported move to boost supply of essential drugs in government hospitals, the attempt to vet cross-border investments here and the first compulsory licence has been granted to locally manufacture the low-cost version of a patented anti-cancer drug, and that has since led to a still-lower-priced generic version by a third party.

A recent policy research working paper is on the price behaviour of patented drugs in India, following the domestic product patent regime for drugs beginning in January 2005. What has been the impact of the stronger intellectual property rights (IPRs) on prices and supply of drugs?

The study involves a single therapeutic category, albeit a large one. The finding in the paper is that the introduction of product patent did not generate any significant withdrawal of generic drug products containing the relevant molecule.

One possible explanation cited is the likelihood of licence deals or joint ventures between the innovator and one or more local generic firms.

Overall, what's revealed is that as per the study, product patents appear to have a 'positive and significant effect' on the drug price, upping it on an average by 12%. Also, ample therapeutic substitutes seem to be available for most new patented drugs.

Of the 160 molecules tracked in the particular therapeutic category, only nine were under price controls - the government currently controls the price of 74 drugs, representing about 8% of the market - and only one such molecule was subjected to a product patent. So, the effect of price controls on curbing patent-induced price rise seems negligible, it is averred.

Now, prior to 1970, Indian pharma was dominated by western MNCs that controlled over 75% of the market, mostly through imported drugs. The situation changed with the Patents Act of 1970, which mandated only process patents for drugs. The law allowed generic drug producers to basically reverse-engineer a product by tweaking the production process.

Back then, the reasoning was that a weak IPR regime might allow domestic firms to imitate foreign technology so as to boost access and keep drug prices low in the bargain. Later, it was felt that continuing with such a policy regime would reduce incentives for research and development on drugs that could differentially benefit the requirements of tropical countries in the South.

Big pharma may have lobbied hard as well. Hence the change in world trade rules, in 1995, which called for a system of product patents and legal protection to all Trade-Related Intellectual Property Rights (TRIPS) that included pharmaceuticals but with safeguards like provision for compulsory licensing.

And since 2005, the patent regime in India - and China and Brazil from 2002 and 1997, respectively - has allowed patenting of drug products.

Now, on the one hand, it is entirely possible that patent enforcement would lead to higher drug prices, which then might lower utilisation and adversely affect public health.

The mavens have indeed been pressing for a change in the rewards system that would boost least-cost manufacture and appropriate pricing of innovative drugs, and provide direct grants, prizes and other rewards for the innovators.

On the other hand, it is hoped that prices of research-intensive patented drugs may not increase much provided there are generic substitutes available. Besides, it may well be that the patent holder is somewhat more efficient than generic imitators and so would strive to economise on overall costs and prices.

The paper is on the effects of introducing product patents for the central nervous system (CNS) therapeutic segment of the Indian pharma market.

In terms of retail sales, the CNS category is the second-largest globally, and one of the fastest growing in India. The study uses proprietary data on pharma sales from 2003 to 2008, to correlate the figures when product patents were granted by the patent authority.

What is calculated is average price per dose in each quarter for each product. For simplicity, only single-ingredient products, those with only one active molecule, are tracked. It narrows down the search to some 1,700 drug products involving 160 new molecules. There were no CNS product patent granted in 2005; by the end of 2008, they added up to 24% (39 out of the 160).

Further, 90% of the patent filings in the segment turned out not to claim the active ingredient, in what remains a price-sensitive market.

Most were secondary patent filings - for a new formulation, dosage or derivative of an existing molecule. The authors plan to extend the research to other therapeutic segments to study the effects of patenting on drug prices.

*(Pharmaceutical Patents and Prices: A Preliminary Empirical Assessment Using Data from India,* ***Mark Duggan*** *and Aparajita Goyal,* ***World Bank*** *working paper, May 2012)*

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# India, Brazil & China defend generic drugs at WTO

Amiti Sen, Economic Times

New Delhi, June 25, 2012: India, Brazil and China have defended the right of poor countries to access cheap generic medicines at the World Trade Organisation, resisting attempts by the US, Japan and some other developed countries to club counterfeits or copies of patented drugs with fake or spurious ones.

"The cases of seizure of high quality generic or off-patent drugs by third countries that hold patents for these could gain legitimacy if counterfeits are confused with fakes," an Indian official told ET. "We cannot allow this as it could seriously hinder access to cheap drugs by the poor."

In a recent meeting of the WTO's Trips Council, developed countries such as Canada, Switzerland and the EU said they considered counterfeiting to be one of the most serious problems to be discussed by the council. These countries said counterfeit medicines not only cause economy loss but also put the lives of patients at risk as they could be "dangerously sub-standard".

India, Brazil and China, however, argued that infringing intellectual property rights should not be confused with sub-standard products.

Intellectual property violation in medicines should not be mixed with sub-standard products and the issue of fake drugs should be discussed at other forums and not the World Trade Organisation, the three countries said at the meeting in Geneva.

"It is an attempt by developed countries to paint all generic medicines produced by developing countries with a dark brush and create doubts on the quality of such drugs," said Abhijit Das, head of the Centre for WTO Studies at Delhi-based Indian Institute of Foreign Trade.

India should resist such attempts as developed nations are trying to make the intellectual property regime more stringent through WTO as their attempts to do it through the ACTA, the proposed anti-counterfeit agreement between some countries, failed because of opposition by the European people, Das added.

Interestingly, many developed countries, led by the US and the EU, had earlier tried to convince WHO to include fake drugs in the definition of counterfeits.

India, with the support of countries like Thailand and Indonesia, managed to convince the WHO that merging of definitions was not only unwarranted but could also be counterproductive in terms of supply of cheap medicines to the poor.

Counterfeits are copies of patented drugs that may have infringed intellectual property rights of patent holding companies. However, a product that is considered a counterfeit in one country may not

necessarily be so in another as it may be off-patent there. Therefore, if counterfeits are considered as fake, countries that hold patents to particular drugs could destroy consignment of copycat version of those drugs that pass through their ports on health grounds without fear of retribution.

"In most cases the generic or off-patent drugs that are produced in developing countries are of very high quality," another Delhi-based WTO expert said. "Just because they would be considered counterfeits in countries where patents to these still exist does not automatically mean that they are also spurious drugs. These are two entirely different issues and should be dealt separately."

Last year there were several cases of seizures of Indian generic medicines on way to South America and Africa at European airports following complaints from patent holders of those medicines in Europe.

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# US ups the ante on Nexavar Generic, threatens to take India to WTO

Divya Rajagopal, Economic Times

Mumbai, 5 July,2012: The US House of Representatives and the US Patent and Trademark Office (USPTO) have threatened to drag India to the World Trade Organisation's dispute panel for issuing the first ever compulsory licence to a domestic company to manufacture generic version of Bayer's cancer drug Nexavar, saying the move violates international trade laws.

"As opposed to criminal activity, these international patent trade problems in the civil laws space seem to be driven directly by the foreign government to benefit their domestic industry," said Bob Goodlatte, a Republican Party member and member of the House sub-committee on intellectual property.

"It seems that they are getting a free pass as they devalue the patented innovation of the American companies. A WTO case can be brought on this dispute if the appeal doesn't work," he added.

Compulsory licence (CL) is a provision under Trade Related Intellectual Property law (TRIPS), which empowers the government to allow someone else to produce the patented product or process without the patent owner's consent.

In March this year, the Indian patent office issued compulsory licence to Hyderabad-based Natco Pharma on grounds that the patented version of Nexavar was too expensive for Indian patients, and by merely importing the drug to India, Bayer doesn't necessarily get a working patent in the country.

The compulsory licence order reduced the price of Nexavar from Rs 2 lakh to Rs 8,800. Bayer has appealed against the order, but the hearing is yet to begin. USPTO, in a testimony to the House of Representatives, has said by granting licence, India has not compiled with the international standards of patent laws.

"I was quite dismayed and surprised when India decided to grant CL... I think it didn't meet international standards and it was also not due to national crisis," said Teresa Stanek Rea, deputy director of the US Patent and Trademark Office.

"We have someone on the ground in the embassy in Delhi who constantly engages with all the respective officers in India to discuss with them the importance of not granting CL in a situation where it is not wanted," she explained.

However, legal experts back home have completely rubbished the claim that India's compulsory licence violates any international law, arguing Indian laws have such provisions which are permissible under TRIPS.

"Whoever is saying that CL issued by India should be a subject matter of dispute in the TRIPS dispute

panel needs to read the law properly," said Anand Grover, senior advocate, Lawyers' Collective.

"The criticism of the US Representative is completely misplaced and ignorance can no longer be an excuse for making such remarks," he added.

Grover says since the patent order is quasi-judicial in nature, and not a government order, the issue cannot be termed as a bilateral dispute. However, the US patent office has gone on record saying they are lobbying with Indian drug regulators and the patent office to revoke the licence decision.

"We are trying to continue our discussion with India's equivalent of USFDA and with regulatory authorities , engaging in discussions with them. Outside the US patent office context, we are doing everything we can to respect the rights of US innovators," said Stanek Rea.

But DG Shah of the Indian Pharmaceutical Alliance says these 'threats' are mere pressure tactics by the US. "China, Thailand and Argentina have issued CLs taking a cue from India, and such public statements are the only option left with the US to impose its protectionist measures," he says.

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# No WTO violation by issuing licence for Nexavar: Sharma

Press Trust of India

June 14, 2012, Sao Paulo**:** Commerce and Industry Minister Anand Sharma today said India has not violated any provision of multi-lateral trade agreement by issuing compulsory licence (CL) for patented anti-cancer drug — Nexavar — to be produced and sold at a much cheaper cost in the country.

"We have not violated of any WTO agreement...This (invoking CL) is very much in conformity with the international agreement under the WTO," Sharma said here while addressing industry leaders of pharmaceutical sectors.

Sharma is leading a Ficci business delegation, mainly consisting of players from pharmaceuticals industry, to Brazil.

In March, Hyderabad-based Natco Pharma was allowed to manufacture and sell cancer-treatment drug Nexavar at a price over 30 times lower than charged by patent-holder Bayer Corporation, under compulsory licensing (CL).

The German firm has already filed an appeal against the Indian Patents Office's order with the Intellectual Property Appellate Board.

As per the WTO agreement, a CL can be invoked by a government, allowing someone else to produce a patented product or process without the consent of the patent owner in public interest.

India's intellectual property rights regime is fully TRIPS-compliant, the minister said, adding that the developed nations have invoked CL more than developing economies.

"In case of India, this was the process of adjudication. It was not an executive invocation," he added.

He said around the same time when India had issued the CL for anti-cancer drug, the US government, through an executive order, placed an order with Indian company for anti-cancer drug.

Natco was allowed to sell the drug at a price not exceeding Rs 8,880 for a pack of 120 tablets required for a month's treatment compared to a whopping Rs 2.80 lakh a month charged by Bayer for its patented Nexavar drug.

Seeking greater cooperation in pharmaceutical sector, the minister informed the industry leaders that India is the third largest medicines producer in the world and produces 20% of world's generic drugs.

According to sources, the minister took up several problems of Indian pharmaceutical sector during his meeting with Brazilian Minister of Development, Industry and Foreign Trade Fernando Pimentel.

"The minister raised the issue of requirement of multiple testing despite having approvals from agencies like USFDA, delayed registration of products in Brazil, delay in port clearances and fast tracking of issuing of import licenses," sources said.

On the occasion, industry leaders too raised their problems and concerns which they are facing here.

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# A mission to defend traditional knowledge

Sidhartha, TNN

June 5, 2012: In a few weeks, negotiators from the group of like-minded countries such as India, Columbia, Peru, and New Zealand will converge on Bali to decide on what "traditional knowledge" is. For over a decade now, the like-minded countries have been trying to do just that but have so far been unable to narrow down their differences and agree to a common definition.

In private, negotiators would tell you that in large part, the developed-countries gang, led by the US, has done its bit to scuttle an agreement. After all, US patent attorneys stand to lose business if countries agree to protect traditional knowledge, genetic resources and traditional cultural expression.

Once an agreement is thrashed out, patenting the healing effects of turmeric or ayurveda, yoga and dance forms such as Bharatnatyam would not be easy. In 1995, the patent of turmeric by non-resident Indians in the US woke the world to the negative impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights or Trips.

Although the patent was subsequently declared null and void, since then countries such as India have been trying to get protection. Since 1999, the issue has been under negotiation at international forums such as the World Trade Organisation (WTO) and the World Intellectual Property Organization (WIPO). But a breakthrough is yet to be reached.

Definition apart, who gets to share the royalty or fee that accrues to a company due to the use of traditional knowledge, genetic resources or traditional cultural expression is the other issue that must be decided. While the Peruvians and the Columbians want the resources to flow to the local communities, those like India are seeking that sovereign governments get the funds. "After all, we don't know who developed ayurvedic techniques," says a negotiator.

Like traditional knowledge, even cultural expressions or folklore is on a similar stage of negotiations.

Everything from the definition to beneficiaries, the extent of protection and its length and penalties are to be decided.

"Unlike patents these do not provide negative rights. What we are seeking is that companies that use these techniques and genetic resources should clearly say that they have been legally accessed. But quite obviously the developed countries would not like things to be settled," says Biswajit Dhar, director general of research and information systems for developing countries. He has for long championed the cause of protection for genetic rights.

From all accounts protection is not coming any time soon. Luckily, through steps such as the Traditional Knowledge Digital Library, which can be accessed by patent offices in several countries, the government has sought to prevent companies from walking away with protection for products such as neem and turmeric that are based on resources development in India centuries ago.

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# HR issues hold up trademark dispute cases

Nayanima Basu, Business Standard

New Delhi May 13, 2012: As many as 126,102 trademark dispute cases are lying with the government due to shortage of manpower in the trade marks registry offices. That's not all. As many as 8,183 applications are missing.

The maximum number of pending cases is lying in the Delhi office, followed by Mumbai, Chennai, Ahmedabad and Kolkata. Most cases pertain to domain name dispute and intellectual property rights. Since 2001-2002 the number of dispute applications filed has increased by 100 per cent. The Trade Marks Registry of India is suffering from severe manpower shortage. Of the 122 sanctioned posts, 71 are lying vacant and all pertain to the post of examiners and above, according to the ministry of commerce and industry. The government has asked recruitment agencies to urgently fill up the vacant posts.

“There is not enough manpower to look after cases which are complex and require expertise. We are concerned and looking into the matter,” an official from the Office of the Registrar of Trade Marks told Business Standard on condition of anonymity. Emailed questions to Chaitanya Prasad, Controller-General of Patents, Designs & Trade Marks, went answered.

To mitigate problems and streamline the process of trademarks registration, the ministry of commerce and industry is also planning to introduce free search facilities and digitisation of records.

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# Copyright Bill cleared; artistes entitled to lifelong royalty

The Hindu

*"Poor artistes had been left in the lurch, as producers cornered all royalties"*

23 May, 2012: Song writers, artistes and performers can now claim royalty for their works, as Parliament on Tuesday approved amendments to the Copyright Act that entitles artistes to lifelong royalty.

The Copyright Act (Amendment) Bill, 2012 was passed by the Lok Sabha unanimously, with members from all parties supporting the measure for creative artistes, whose benefits are cornered by producers under the existing law.

The Bill, passed by the Rajya Sabha last week, declares authors owners of the copyright, which cannot be assigned to producers, as was the practice till now.

Introducing the Bill, Human Resource Development Minister Kapil Sibal said poor artistes had been left in the lurch, as producers cornered all royalties, but the new law would help them live a good life even in old age, as they would continue to get their dues for their work.

Citing the examples of *shehnai* exponent Bismillah Khan and music composer Ravi, to press home the point that the condition of such excellent artistes was pitiable, as they weren't able to pay even house rent and hospital charges, Mr. Sibal said the Bill made it mandatory for broadcasters — both radio and television — to pay royalty to the owners of the copyright each time a work of art was broadcast.

It bans persons from bringing out cover versions of any literary, dramatic or musical work for five years from the first recording of the original creation.

The Bill received overwhelming support, including from the Opposition, which appreciated the government for such a step, though there was still resistance when the Bill was introduced in the winter session, and the Minister had to withdraw it in the Rajya Sabha.

Leader of the Opposition Sushma Swaraj pointed out that eminent artistes, ranging from Pandit Ravishankar to A.R. Rahman, had pleaded for the changes in the Copyright Act.

The Bill provides for exemption from copyright for any work prepared for the physically challenged in special formats such as Braille. It also permits compulsory licence to be granted for a certain number of copies in non-special formats to non-profit organisations working to help disabled persons.

The Minister said the amendment would allow authors to negotiate with music companies for royalty to be paid to them for their creations. The Bill also exempted students from the copyright laws for using

such material for research purposes. It sought to impose a fine and two years' imprisonment for persons indulging in piracy.

Noted lyricist and Rajya Sabha member Javed Akhtar, who has been spearheading the campaign for such a measure, was in the Lok Sabha gallery, as was Ms Swaraj, who said she was supporting the Bill despite her being told that film producers would be unhappy with her if she did so.

Seeking to do a balancing act, she said she had done for film producers what nobody else did. She said she was the one who declared film-making an industry within three months of her becoming Information and Broadcasting Minister during the NDA rule. [Back to Top]

# AP seeks royalty for Brahma bull

U. Sudhakar Reddy, The Asian Age

15 May 2012: The Andhra Pradesh biodiversity board wants to claim royalty for the Brahma or Brahman bull, a species taken from Ongole and bred widely in Brazil, the United States and Australia for over 100 years.

The bull, scientifically known as Bos indicus, is in great demand as it is known to be resistant to foot and mouth disease and for its flavourful meat. Biodiversity board chairman R. Hampaiah, back recently from a biodiversity conference in Brazil, said steps are being taken to form breeders' associations of countries using the Ongole or Brahma bull so that the benefits could be shared. Farmers from Andhra and some other parts of India are, ironically, going to the World Brahma Bull Congress in Panama in July to buy Brahma bulls bred overseas. Dr Hampaiah said a Hyderabad-based NGO, Ankush, had recently approached the board seeking to buy these foreign-bred Brahma bulls and seeking the animal husbandry department's permission to import the cattle.

Said Dr Hampaiah: "We have to apply for the geographical indicator (a WTO requirement to prove ethnicity) for the Ongole bull." Ongole bulls are found in the area between the Gundlakamma and Alluru rivers in Ongole and Kandukur mandals of Andhra Pradesh. The board will also seek a geographical indicator for Red Sanders and KPV (Krishnapuram vulli) onions grown near Mydukur in the state.

"The Brahma cow gives 45 litres of milk a day. There are several restaurants with Brahma bull beef on the menu in Brazil and the US. They may have improved the breed genetically. But under the AP Biodiversity Act, we have the right to claim royalty," said Dr Hampaiah.

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**Bayer challenges India cancer drug ruling**
AFP

6 April: NEW DELHI — German pharmaceutical giant Bayer AG has challenged a ground-breaking Indian ruling that allowed a local firm to produce a vastly cheaper copy of its patented drug for kidney and liver cancer.

India's patents chief ruled in March the price Bayer charged for the drug, Nexavar, was "exorbitant" and ordered the firm to give a so-called "compulsory licence" to make the medicine to Indian company Natco Pharma.

"We will rigorously continue to defend our intellectual property rights which are a prerequisite for bringing innovative medicines to patients," Bayer spokesman Aloke Pradhan told AFP in an emailed statement on Saturday.

The patent controller's order "damages the international patent system and endangers pharmaceutical research", Pradhan said.

It was not immediately known when the appeal, filed with the country's Intellectual Property Appellate Board on Friday, would be heard.

Drug firms insist they need patent protection for medicines to recoup costs of long years of research and development.

Under the World Trade Organization's TRIPS Agreement, which governs trade and intellectual property rules, compulsory licences are a legally recognised means to overcome barriers in accessing affordable medicines.

The Indian ruling in March marked the first time a so-called "compulsory licence" for production of a patented drug had been granted in the country of 1.2 billion, known as a global generics drug powerhouse.
India has long been a key provider of cheap generic medicines to the developing world as it did not issue drug patents until 2005, when it was obliged to adhere to WTO intellectual property regulations.
But after a new patent law was introduced in 2005, newer medicines are increasingly being patented in India, keeping prices high.

Under the ruling, Natco will pay Bayer a six percent royalty on sales of the drug and sell the medicine for 8,800 rupees ($165) a month -- compared to the 280,000 rupees ($5,320) the company charges, which is more than 30 times as much.

Patent controller P.H. Kurian granted the right to Natco to produce the drug after concluding Bayer's pricing made it "out of reach" of most Indian patients.

Experts have said the Indian ruling could pave the way for a rush of other "compulsory licence" applications in India and in other poor nations, allowing access to patented life-saving drugs at a fraction of the cost.

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# India protests US's move to put it on IP rights watch list

Asit Ranjan Mishra & Vidya Krishnan, Mint

May 8, New Delhi: The government strongly objected to the US placing India on a priority watch list in its latest trade representative's report, which raises concerns over the country's enforcement of intellectual property rights.

In a letter to the US trade representative Ron Kirk, commerce minister Anand Sharma termed the move "unilateral, unfortunate and unjustified".

India has a stable intellectual property regime fully compliant with trade-related intellectual property rights (TRIPS) and a strong enforcement mechanism, Sharma wrote in the letter, which *Mint* has reviewed.

In the US trade representative's Special 301 report published last week, it urged India to continue to work to streamline its patent opposition proceedings. "The US will closely monitor developments concerning compulsory licensing of patents in India following the broad interpretation of Indian law in a recent decision by the Controller General of Patents, while also bearing in mind the Doha Declaration on TRIPS and Public Health," it said.

Trade between India and the US has soured in the recent times with both the countries taking each other to the World Trade Organization (WTO) to fight out differences in policies.

The US approached the WTO seeking a consultation with India after the country in March banned imports of the US poultry. India followed this with seeking a consultation with the US over import duties levied on Indian steel products. India also said it will take the US to WTO against what it calls a discriminatory visa fee regime against Indian information technology firms. Consultations at the WTO is the first step towards resolving a disagreement before entering into a full-fledged legal dispute. Both sides have already postponed twice the crucial eighth round of US-India trade policy forum talks.

In March, India's Controller General of Patents passed an order allowing Hyderabad-based Natco Pharma Ltd to manufacture and market a copy of Bayer AG's liver and kidney cancer drug Nexavar—the first time an Indian firm was granted a so-called compulsory licence, which permits a generic drug producer to make and sell its version of a patented drug without the consent of the patent holder. The US raised concerns over the development holding that this may weaken the global patent regime under TRIPs.

"The world is eagerly watching India and if we give in now it will only lead to recolonization. The Indian government is favouring Indian drug makers, but if we succumb to US pressures, we will go back to the 1970s—when we had to depend on other countries for life-saving drugs," said Chinu Srinivasan, public health activist and managing trustee of the non-governmental organisation Low Cost Standard Therapeutics.

“This is a battle between Indian companies and global giants. In any case, it is disheartening to note that people or public health does not figure in this debate and (the focus) remains purely on trade,” he added.
Sharma said India was found to be compliant with all WTO regulations in a recent review of the country’s trade policy at WTO. India’s intellectual property regime has seen many steps in the recent times to improve efficiency and transparency and measures have been taken to accede to the Madrid Protocol, he added.

The Madrid Protocol is an international treaty adopted in 1989 enabling owners of trademark applications and registrations to extend their rights to dozens of other member countries. Also, “legal developments in the copyright field are at an advanced stage and are awaiting the required parliamentary approvals,” Sharma said.

A US report in December identified Nehru Place in New Delhi as among the 30 most notorious IT markets of the world dealing in goods and services that infringe intellectual property rights.
Sharma assured the US trade representative that the intellectual property regime in India will continue to be responsive to the country’s needs, especially on public health issues, within the parameters of flexibilities available under TRIPS.

“The application of law will be equal across residents of all countries including India,” he said.

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# Natco gets India’s first compulsory licence

C.H. Unnikrishnan , Livemint

Mar 13, 2012,Mumbai: In a landmark decision, India’s intellectual property office on Monday allowed Hyderabad-based Natco Pharma Ltd to make and sell a copycat version of German drug maker Bayer AG’s patented cancer treatment Nexavar. It’s the first time that an Indian company has been granted the so-called compulsory licence to market a generic version of a patented drug.

The drug, patented by Bayer in India in 2008, is used in the treatment of liver and kidney cancer, and costs Rs. 2.8 lakh for a month’s dosage. After Bayer rejected Natco’s request for a commercial licence to manufacture Nexavar, the Indian company in September applied for a compulsory licence to make a copy of the drug, claiming the patent holder had failed to meet the needs of the local market.

A compulsory licence allows a generic drug producer to make and sell its version of a patented drug without the consent of the patent holder.

According to the World Health Organization, India has an estimated 29,000 patients with liver and kidney cancer.

In a 62-page order, the Controller General of Patents, which completed hearing both companies in February, said a compulsory licence under Section 84 of the Patents Act has been granted to Natco to make the drug.

The patent office stipulated that Natco price the drug at Rs. 8,880 for a pack of 120 tablets (a month’s dosage) and pay 6% of net sales as royalty to Bayer.

“We will stick to the terms on pricing and drug accessibility to patients,” said a spokesperson for Natco. The company’s stock gained 6.17% on BSE to close at Rs. 314.95 on Monday; the benchmark Sensex rose 0.48%.

Section 84 lays down that three years after the grant of a patent, any entity may apply to the patents office for a licence to sell a generic version of the drug on grounds that the patented version has not worked in India, that the requirements of the public haven’t been met or that it isn’t available to users at a reasonable price.

The order is globally significant because India hadn’t previously invoked the compulsory licensing provision although several developing countries, including Brazil and Thailand, have used the provision to increase citizens’ access to expensive, life-saving drugs.

“The order will have a global impact as developing as well as developed countries were eagerly following this case to see how the world’s largest democratic country uses these patent laws,” said Gopakumar Nair, a patent expert and intellectual property consultant. “The order paves the path for using the flexibilities provided by trade-related intellectual property rights against the abuse of patent rights.”

Bayer is currently fighting a patent infringement case with another local drug maker, Cipla Ltd, on the drug, and is awaiting a verdict in the case from the Delhi high court.

The order by the patents office said Natco was being permitted to produce a generic version of Nexavar because it had established that the drug wasn't affordable in the local market. The patentee continued importing the drug, but was able to provide it to only a small fraction of patients.

"We are disappointed by the decision of the patent controller in India to grant a compulsory licence for Nexavar," Bayer India's spokesperson Alok Pradhan said in an email response. "We will evaluate our options to further defend our intellectual property rights in India."

The foreign drug makers' lobby, the Organisation of Pharmaceutical Producers of India, echoed its disappointment.

"Today's announcement to issue a compulsory licence is disappointing, as such measures cannot be the permanent solution of improving access to innovative medicines in India, while creating an appropriate ecosystem to foster innovation in the country," said Tapan Ray, director general of the group.

*Mint* had in February reported that Bayer, during hearings on the matter, had been asked to justify the high price of the drug. Natco claimed in its application that the patentee could supply Nexavar only to a fraction of the patient population in the local market because the majority couldn't afford it.

Bayer argued that it will be difficult for the company to reduce the price because it had incurred a substantial cost in developing the drug, while saying that it supplied the drug at a discount to the needy through its patient access programme.

The patents office's order showed that the company had failed to furnish data specific to the drug to establish its claims.

"During the hearing, the patentee submitted that the cost of making the invention and developing a new medical entity like the drug in the case works out to be about €1.8 billion (around Rs. 11,775 crore today)," controller general P.H. Kurian said in the order.

"However, the figure arrived was for the cost of R&D (research and development) for five years preceding 2010... In the absence of any definite figure on the cost of developing the drug and making it available to the market, including the patenting, etc.... I am unable to arrive at the actual cost...," the order said.

Natco's lawyer Rajeshwari H. had in the hearing stated that since Nexavar (generically known as sorafenib) was developed as an orphan drug, which typically receives grants from governments and other agencies as such a product is meant for meeting the needs of a tiny patient segment that is otherwise ignored by commercial entities, the cost may not have been substantial.

The US Food and Drug Administration has on its website identified sorafenib as an orphan drug.
"This decision heralds the start of a new era in the history of pharmaceutical patents and public health," said Shamnad Basheer, a professor of intellectual property law at the National University of Juridical Sciences, Kolkata. "It will effectively spur other generic manufacturers to apply for compulsory licences

and we'll soon see the start of a phase where prices of patented pharma drugs drop significantly, at least in developed countries, where the threat of a compulsory licence looms large."

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# India opposes pharma piracy pact by 10 nations

Amiti Sen, ET Bureau

Mar 3, 2012, NEW DELHI: India has strongly opposed an anti-counterfeiting trade agreement by a small group of countries including the US, Switzerland, Canada and Japan recently, which it feels will be used to stop the country's generic drug exports.

New Delhi has said the agreement is at the behest of the multinational companies that fear competition from cheaper drugs produced in India. China, Brazil, Bangladesh, Thailand and Equador, too, backed India's concern that the anti-counterfeiting trade agreement, or ACTA, goes beyond TRIPS - the multilateral agreement on intellectual property.

The ACTA was signed by ten WTO countries including Australia, Canada, Korea, Mexico, New Zealand, Japan, Morocco, Singapore, the US and Switzerland in October last year to check global trade of counterfeit goods and pirated copyright protected works through stricter enforcement laws.
The EU, and its 22 member states, signed the plurilateral pact in January this year, but key countries including Germany, Poland and the Netherlands have refused to join the treaty on the ground that it breached freedom of speech and privacy.

The EU can ratify the agreement only when all its constituent states are on board. The agreement, which intends to improve "the enforcement of intellectual property rights" in participating countries by setting international standards over how copyright infringements are dealt with has also been criticised for providing for 'criminal' enforcement and seizures.

India said ACTA can undermine the TRIPS Agreement, which has safeguards to ensure that legitimate trade in generics between two countries cannot be hampered even if it passes through a third country that has stricter domestic intellectual property regime. Citing cases of seizures by customs at European ports of generic medicines being exported by India to other developing countries, India said the ACTA would
legitimise such acts.

"In the recent cases of seizures, the EU had to release the shipments and admit that it was in the wrong as the move violated TRIPS Agreement. But with ACTA in place, there would be a risk of legitimising such seizures," a government official told ET.

Brazil said one-size fits all was not advisable as each country had a different IPR situation. India said ACTA would inhibit South-South trade and added that there were also concerns about digital freedom and fundamental hostility towards consumers.

WTO members are already signatories to international patent regime TRIPS that has in place regulations to ensure patent protection. India moved from a process patent regime to a stricter product patent regime in 2006 in line with its commitment under TRIPS.

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# Patent rights?

T S Vishwanath, Business Standard

*WIPO must protect the developmental needs of countries with genetic resources as it pushes for inventions and innovation in industry*

Mar 01, 2012:The Geneva-based World Intellectual Property Organisation (WIPO) has moved forward on the creation of a single text for discussions in the area of genetic resources. The use of genetic resources and traditional knowledge for industrial application through patents has been an issue of debate for many years at the World Trade Organisation (WTO) and WIPO.
The new text was discussed at the 20th session of the WIPO Intergovernmental Committee on Genetic Resources, Traditional Knowledge, and Folklore (IGC) in February. The committee was set up over a decade ago to sort out the differences between countries that are rich in genetic resources and traditional knowledge and the developed world that uses these genetic resources for developing patents for industrial use.

One of the most contentious issues in creating this single legal text started with some of the developed countries seeking to change the term intellectual property rights (IPR) mentioned in the text to patents. However, countries like Bolivia that supported the use of IPR said the term needed to have boarder coverage since patents, as a term, had a narrow focus, while IPR also included geographical indications.

The new text provides different options that can be chosen by countries for defining some important terms. For example, for defining “genetic resources” the text provides two options. The first option provided for discussions stated that “genetic resources” are genetic material of actual or potential value, while the second option defines “genetic resources” as it is understood in the CBD (convention on bio diversity) and related instruments and the International Treaty on Plant Genetic Resources for Food and Agriculture.

The other area of concern for developing countries has been the need for patent seekers to state the source from where the genetic resources have been obtained and also provide details of any traditional knowledge that may be associated with these. Developed countries like the US and Japan are of the view that mandatory disclosure of such information will make the job of patent seekers very difficult. The US felt the need for carrying out studies to see the impact of such a move that did not find support from many countries like Egypt, South Africa and India. The African group was, reportedly, of the view that there are several studies that exist and they can be put together by WIPO for better understanding. India, reportedly, made a strong statement at the meeting that there are enough instances of how available genetic resources and traditional knowledge had been used freely by patent seekers without acknowledging the source of the genetic resource or the traditional knowledge attached to it.

A few countries tried to overcome this issue by stating that WIPO may put together a non-binding document that lists out the genetic resources and traditional knowledge available in different countries. However, many others who support the need to acknowledge the presence of genetic resources in patents were of the view that non-binding documents would not serve the purpose.

The debate on the use of genetic resources and traditional knowledge has been going on for a long time since developing countries fail to make profit because of the use of genetic resources by patent seekers that are later developed into business products by industry.

The IGC, which was set up with the aim of resolving the dispute, has certainly come a long way to look at issues on both sides of the table. However, it is important for countries to ensure that the rights of the owners of genetic resources and the traditional knowledge associated with it is acknowledged and rewarded. Patents are extremely important instruments to provide a push to inventions that galvanise industry into making better products.

However, any move that takes away the original rights of the people who own the resources would be unfair. The possible exclusion of the rights of people was evident when the indigenous people who attend the meeting of the IGC staged a walkout stating that they were not being heard in these meetings.

If WIPO has to be seen as a transparent and fair organisation that balances the developmental need of members with genetic resources with the need for providing a push to inventions and innovation in industry, then it will have to find the right mix of proposals in the final document on this contentious issue.

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# A European pill best avoided

S. Srinivasan, Business Line (The Hindu)

*The proposed India-EU FTA will compromise our generics segment and health security.*

January 3: Even as India's generic pharma industry establishes itself as a major supplier for developing countries, barriers are being put up to inhibit the free flow of trade. The WTO was set up to ensure that trade flows "as smoothly, predictably and freely as possible." Its multilateral dispute-settling mechanism has been functioning reasonably well, though it has its share of critics.

All this is set to change with bilateral free trade agreements (FTAs). Secret negotiations have been on — since 2007, with early 2012 as the deadline — between the Government of India and EU for finalising the India-EU FTA. Indeed, one needs to ask why these negotiations are conducted without consulting Parliament and State Governments.

*PROPOSED TRIPS REGIME*

The basis of bilateral FTAs is reciprocity, but reciprocity between unequal partners never works — well, it always works against the interests of the less equal party. To illustrate how unequal: India's GDP is 3 per cent of the EU's GDP; while India accounts for just 1.8 per cent of the external trade of EU, the EU accounts for 20 per cent of India's trade; India's largest source of FDI is EU, while India accounts for 1 per cent of EU's total FDI.

The India-EU FTA aims to liberalise "substantially all trade" between the two trading blocks on a "reciprocal" basis and apart from trade in goods, the FTA will have substantive provisions on services, investment, public procurement, intellectual property (IP) rights and some other areas.
The proposals on IP are likely to create new hurdles for generic medicine manufacturers in particular. The IP measures demanded are 'TRIPS Plus' — that is beyond what is mandated by TRIPS/WTO. These include data exclusivity, patent term extensions, enforcement measures, border measures, increase criminalisation of IP infringement under the guise of acting against "counterfeit" medicines.

Acceding to data exclusivity measures would delay entry of generics in India. It will require generic manufacturers to repeat the clinical trials already done by the originator company. Such an act would be a violation of human rights, where proving bio-equivalence to the originator's products would have sufficed.

In Guatemala, a study published in 2009 in *Health Affairs* concluded that IP measures on data exclusivity and patents of the CAFTA (Central American Free Trade Agreement) were "responsible for the removal of several lower-cost generic medicines from the market in Guatemala and for the denial of entry to a number of others."

Another way to delay entry of generics — and this was being demanded earlier in the EU-India FTA talks — is the extension of patent term beyond the TRIPS-mandated 20 years, calculated usually from the

date of filing of the patent. The move is to “compensate” for the time taken by the patent office to examine the patent and by the Drug Controller General of India to approve for marketing and manufacture.

*BROADER PUNITIVE STEPS*

Closely allied to these are IP enforcement measures: injunction provisions, border measures, and third party liability. Border measures in the proposed FTA legitimise the seizure of goods on visual inspection/mere suspicion of IP infringement, and even destroy seized goods — this is what happened in the several seizures of medicine exports from India to Africa/South America while transiting Amsterdam. This interferes with India's freedom to export generic medicines to countries in need and the right of such countries to import such medicines.

TRIPS allows for seizure only on violation of copyright/trademark and, that too, at the border only. The proposed TRIPS-Plus border measures applies not only to import, but to export, re-export, goods in transit and the duty of intermediaries to disclose information.

Also on the anvil is a proposal — called third party liability — to hold to task everybody involved in the supply, sale and manufacture of “counterfeit” goods. And this would make liable those in the trade chain as well as suppliers of bulk medicines and excipients used to make the medicine.

Injunction provisions being suggested in the FTA will make it incumbent on the Indian judiciary to give preference to IP status of medicines over the health rights of the poor, sometimes giving injunctions even before patent validity is established.

*INVESTMENT PROPOSALS*

Investment in EU-India FTA is being sought to be defined to include “IP rights, goodwill, technical processes and know-how as conferred by law.” Foreign investors, if the investment proposals go through, would be able to sue the Government of India if any measures (say price control or compulsory licensing) taken by the Government, are seen not to protect their investments (read IP / patent rights, or profits or “goodwill”).

The resulting arbitration will be before secret arbitral tribunals in places like London or Singapore. The decisions arrived at are binding and cannot be challenged under national laws.
Till date, at least 81 governments have been sued in more than 400 investment treaty arbitration claims. Millions, and in some cases billions, have been paid by governments to investors, as a result of such arbitration. Chapter 11 of the North American Free Trade Agreement (NAFTA) has helped North American investors sue Mexico, a developing country, and of course helped US investors sue the Canadian government and the other way around.

Investment proposals, first conceived in then West Germany, in 1957, are a “legal monster” that refuses to go away. Finally, the chickens have come home to roost with recent news of Germany's nuclear phase-out being challenged by the Swedish energy company, Vattenfall.
A Government of India that is reluctant to issue compulsory licenses will be further inhibited, when such draconian investment proposals are in place, to use TRIPS flexibilities for public health reasons.

Additional investment proposals are being sought in the name of “fair and equitable treatment” and “full protection and security” to investors. These terms are undefined as the case law on this is still a work in progress and it is left to the arbitral tribunals to determine what is “fair and equitable”. Arbitral decisions often aren't concerned with the public health motivations behind any regulatory action.

A related requirement that is being put forward is granting European investors the same treatment as domestic investors. This isn't fair, as governments giving preferential treatment to local stakeholders, say SSIs, can be sued. Indeed, some of the proposed “performance requirements” provisions make it illegal to ask foreign investors to use local inputs and local personnel.

At stake is access to low-priced medicines for millions of poor patients in Africa and Latin America who source medicines from India's generic medicine industry.

The EU Parliament routinely instructs the European Commission on what stands are to be taken on various contentious issues in the FTA. We would wish our Parliament and our courts take *suo moto* action to take the India-EU FTA out of the closet and put it in public domain, before letting the Government sign on the dotted line — and sign away, perchance, our health security, and the livelihoods of the poorest. *(The author is associated with LOCOST, Medico Friend Circle and All India Drug Action Network.)*

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# India, EU reach an understanding over not detaining generic drugs from India

India Pharma News

9 December 2011, New Delhi: Jyotiraditya M. Scindia, Minister of State for Commerce & Industry informing Rajya Sabha, the upper house of the Indian Parliament, said that India and European Union (EU) reached an 'Understanding' to guide border enforcement of intellectual property in the EU and thus will not detain Indian generic medicines while in transit through EU.

It may be noted that India had initiated dispute settlement consultations on May 11, 2010 at the World Trade Organisation (WTO) with the European Union (EU) after several rounds of discussions directly with EU could not produce any results. The issue was taken up by India when generic medicines while in transit through EU were detained invoking the EC's Regulation 1383/2003 against goods suspected of infringing intellectual property rights (IPRs).

As per the understanding reached between the two parties, EU has agreed to replace Regulation 1383/2003 with a new regulation. The European Commission has already approved a proposal for a new regulation and said that the proposed new regulation is being reflected upon in EU's Parliament.

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# Deadline for comments on IPR streamlining extended

PTI

New Delhi, December 05, 2011: The deadline for comments on proposed streamlining of the intellectual property rights (IPR) filing process by setting up separate establishments to handle trademark and patent applications has been extended by the government till December 31, 2011.

At present, both trademark and patent applications are handled by a single body, the Controller General of Patents, Designs, Trade Marks and Geographical Indications.

Last month, the Department of Industrial Policy and Promotion (DIPP) had floated a discussion paper on the proposal, seeking comments from stakeholders by November 30.

"The date of receipt of views and suggestions on the discussion paper on the proposal to review the organisational structure of the Office of Controller General of Patents, Designs, Trade Marks and Geographical Indications extended from November 30, 2011 to December 31, 2011," the department today said.

The DIPP said the objective of the exercise is to enhance the efficiency of the CGPDTM through organisational restructuring.

The DIPP had said it is considering whether to make autonomous establishments for handling trademarks and patents, which would generate their own revenues and sustain themselves.

Following the implementation of WTO norms on IPRs, there has been a significant increase in the number of applications filed for trademarks, patents and designs in the country and a consequent increase in the volume of connected statutory proceedings.

"The work on a single authority of the CGPDTM arising out of all these statutes has become unmanageably heavy," the paper said.

With just 26 trademarks examiners and 1.42 lakh filings in 2009-10, every official needed to handle 5,459 filings on average, far more than the 3,800 applications handled by a Chinese examiner, it had said.

In comparison, the Indian situation is more demanding.

"Since this is an impossible task, pendency is natural and has been increasing," the paper had said.

Autonomy would ease operational problems and give the flexibility to hire technically qualified personnel, the DIPP said.

As per the proposal, the CGPDTM would be divided into two entities. One would handle trademarks and

GI registry and the other would cater to patents and designs.

As per the DIPP, over 4.40 lakh applications for trademarks and 76,000 for patents were pending in 2009-10. [Back to Top]

# India, EU ink deal to end drug seizure for now

Times News Network, The Times of India - Mumbai Edition

29 July 2011, New Delhi: India and the European Union have reached an interim settlement to ensure that none of the 27 members of the economic and trading bloc will detain 'Made in India' consignments of generic medicines, which are transiting through Europe.

"Finally, EU has come around and we have agreed on an interim settlement... which means EU will not make any detention within its territory of pharmaceutical products coming from India.We will wait for the final settlement but we have not lost our right to agitate on the matter again," Rajiv Kher, additional secretary in the commerce department, told reporters.

This means that India will not withdraw its case against the European Union in the World Trade Organization's dispute settlement body. India had moved the WTO after consignments of generic or non-patented medicines shipped to Latin America were seized by European customs authorities on charges of intellectual property rights violations. Subsequently, Brazil joined the discussions.

About 17 detentions took place between October-December 2008 at Schiphol Airport at Amsterdam. These consignments, destined for Latin American countries, were initially detained and later destroyed or returned to India."Mere transit does not give you the right to detain (a consignment) when it is not meant for you," Kher said.

Kher said that as per the bilateral understanding, EU would not only stop such detentions but also amend its regulation under which its member countries resorted to such an action. The settlement is interim as the EU Parliament is expected to take about 12-18 months to amend the legislation and then India will examine that law."We will finally withdraw the dispute only after getting convinced," Kher, who is India's negotiator at the WTO said.

India is not completely satisfied with the draft amendment prepared by EU and has taken up the matter with the authorities. But New Delhi is convinced that given the backlash from the civil society and support from members of European Parliament there should not be any hurdles in passage the amendment.

Though European customs authorities have not seized any consignments since December 2008, Indian drug makers are under constant fear of seizure of consignments meant for Latin America, the largest market for locally-produced generic drugs. Indian companies have also started using alternate ports such as Johannesburg for transit. Indian pharmaceutical exports total about $10 billion per annum, most of which are generic drugs.

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# US steps up lobbying efforts against compulsory licensing

C.H. Unnikrishnan, Mint

The US has stepped up efforts to lobby with the Indian government to restrict the country's use of a global trade law that allows local companies to make and sell copies of patented drugs or other products in special circumstances.

The move has irked activists, patent experts and drugmakers in India, who have written to the government protesting the US's campaign.

The US was the most annoyed when India in February issued its first compulsory licence to Hyderabad-based Natco Pharma Ltd to make a cheaper copy of German firm Bayer AG's patented cancer drug Nexavar.

The decision inspired other emerging economies, including China, to follow suit. China amended its patent law in June to allow so-called compulsory licensing to keep healthcare affordable.

The US's deputy under secretary of commerce for intellectual property and deputy director of the US Patent and Trademark Office (PTO), Teresa Stanek Rea, admitted in a 27 June meeting of the US house committee that the office had "someone on the ground in the embassy in Delhi who constantly engages with all of the respective officers in India to discuss with them the importance of not granting CL (compulsory licence) in a situation where it is not wanted."

*Mint* has reviewed a copy of Rea's statement to the house committee.

Kalpana Reddy, first secretary, intellectual property, at the US embassy in New Delhi could not be reached for comment.

According to patent experts in India, the grant of a compulsory licence by a country, invoking its statutory rights as a member of the World Trade Organization (WTO), is the equivalent of a court decision based on submissions from all the parties involved, including the patent holder.

Compulsory licences are granted when a patent is proved to be not working for the benefit of the public. In Bayer's case, the provision was invoked because the patented drug is too expensive to be afforded by a sizeable population that needs it, they said.

"Any intervention in this process either by engaging government offices or individual officials will be considered unwarranted and it is in violation of the judiciary practices," said a New Delhi-based patent attorney who declined to be identified as he works with several US pharma clients.

The Indian Pharmaceutical Alliance (IPA), a lobby representing top Indian drugmakers, has written to foreign secretary Ranjan Mathai asking if it was legitimate for diplomats stationed in India to indulge in such lobbying to protect the commercial interests of private companies.

“Foreign trade or diplomatic missions in any country can have dialogues with local government on protecting their own interests and it’s nothing illegitimate as Indian decisions are in the best interest of this country ultimately,” an official in the ministry of foreign affairs said.

“As far as the compulsory licensing of (Bayer’s drug) is concerned, government of India has already made its stand very clear to the US government and such decisions will take place even in future if need arises,” said this official, who was assigned to respond to a *Mint* query on behalf of Mathai.

Tapan Ray, director general, Organisation of Pharmaceutical Producers of India, a lobby representing foreign drugmakers in India, said it was only natural for the US government to discuss the issue with New Delhi.

“Compulsory licensing in India had raised concerns among the innovative companies in the world including US, and that government seems to have clarifications on this. Naturally, when there are concerns raised by domestic industry, the government will try to engage in dialogues with the respective government,” he said.

Rea said in her statement to the house committee that India’s grant of compulsory licence did not satisfy international norms that allow for the provision to be invoked in a national crisis.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) that has set the international IP standard for WTO members, “very much allows compulsory licence as one of the flexibilities that can be used in case of national requirements, including emergencies,” said Gopakumar Nair, a patent lawyer and managing partner at patent law firm GN Associates.

“These unfortunate comments by the deputy commissioner of the US PTO are reflective of a growing tendency by developed countries to demonize compulsory licensing—a perfectly legitimate legal tool,” said Shamnad Basheer, an IP law professor at the National University of Juridical Sciences, Kolkata. “More importantly, compulsory licensing is not restricted to public health emergencies, as many would have us believe. In fact, the US itself routinely resorts to compulsory licencing, albeit through its courts which refuse to issue injunctions against infringers in many a case,” Basheer added.

The February order of the former controller general of India’s patent office, P.H. Kurian, to allow the compulsory licence generated positive responses from the international IP community.

The 62-page order “has sent a clear signal that the provision of compulsory licence in Indian patent law have teeth and that a patent holder selling medicine at unduly high prices faces real prospect of entry of low-cost competitors,” Arvind Panagariya, a professor at Columbia University, wrote in a column in *The Economic Times* on 30 May.

IPA said Rea had briefed the house committee only about one of the factors—the absence of local manufacturing of the drug—for India’s decision to grant the compulsory licence. But there were two other “compelling factors that forced India to grant the compulsory licensing of Bayer’s drug. These

include poor access of the drug to patients even after three years of the patent grant and the unaffordable high price," said Dilip G. Shah, secretary general, IPA.

Natco sells the Nexavar copy at Rs.8,800 for a month's treatment, way lower than Bayer's monthly dose price of Rs.2.8 lakh.

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# Indian drug firms lobby against EU's new directive

Vidya Krishnan, Mint

July 24, 2012: Indian drug companies are lobbying against a move by the European Commission to check the import of counterfeit drugs through a directive that comes into effect in about a year from now.

According to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) lobby group, the country's drug exports to the European Union (EU) were worth $1.93 billion (around Rs.10,769 crore) in 2010-11. If India fails to get an EU equivalence certificate by 2 July 2013, when the rule is set to go into effect, 30% of this could be affected, the lobby group said.

Industry and government officials say they don't have the manpower or the resources to be able to comply with the new directive.

Under the EU falsified medicines directive, each shipment of active pharmaceutical ingredient (API) or drug raw materials from India should be accompanied with a written confirmation, vouching that the quality of the exports conforms to EU standards. The legislation was adopted by the EU Council in May 2011 with the objective of preventing the entry of fake drugs.

Failure to provide this "equivalence certificate" would mean loss of business for India, said D.G. Shah, secretary general of the Indian Pharmaceutical Alliance (IPA) lobby group.

"The EU initiative is protectionist and while they are citing safety and public health as reasons, it is clear that they want to protect their domestic pharmaceutical companies from competition," he said. "We can only hope that the Indian government will respond appropriately, keeping this in mind."

The EU and the Indian drug companies have been in conflict before. In 2008, the Netherlands seized Indian drug consignments on the ground of patent infringement, triggering a trade dispute between India and the EU. The incident had prompted the Indian government to approach the World Trade Organization (WTO).

The term "falsified medicinal product" in the European Commission's directive is of particular concern in India.

"While the directive is pertaining to API, the word 'falsified' could be used broadly to apply to generic drugs made in India," said C.M. Gulati, editor of the *Monthly Index of Medical Specialities*, a journal on prescription drugs available in India. "If an Indian company makes a generic version of a drug patented by a multinational pharma company, it could come under this directive and be treated as a 'falsified' or spurious drug and be confiscated."

At a meeting with industry representatives on Monday, the department of pharmaceuticals (DoP) sought a response from the Drug Controller General of India (DCGI) about the feasibility of training Indian drug inspectors on EU standards.

“We have sought DCGI’s position on the matter and we are concerned by the use of ‘falsified’. We have also proposed a meeting with representatives from the commerce and health ministries on the matter. We do not want to delay this any further as our exports will be adversely affected,” said Raja Sekhar Vundru, joint secretary, DoP.

The government appears to be convinced that the Indian drug companies have a case.
“We are looking at various alternatives, including approaching WTO...,” said a commerce ministry official who didn’t want to be named. A questionnaire sent by *Mint* to the European Commission did not elicit a response at the time of going to press.

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