Contents

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.

[Back to top]

India, China plan to jointly oppose EU regulation on API at WTO forum

Joseph Alexander, Pharmabiz.com

New Delhi, August 6, 2012: India and China may together move the World Trade Organisation (WTO) against the European Union (EU) regulation on bulk drugs which may affect the current exports of Active Pharmaceutical Ingredients (APIs) from both the countries to Europe.

EU has changed the rules for importing active substances into EU for medicinal products for human use and the amended regulation would come into effect fully by July 2013. It would make mandatory the current good manufacturing practices (cGMP) certificate from the local authority for all bulk drugs exports.

Sources said the Commerce Ministry had already taken up the matter with the EU authorities as the directive is expected to pose serious challenge to the API exports and is meant to secure the EU pharma supply chain.

Under the technical barrier to trade (TBT) provisions, India can raise the issue at the WTO forum and it is learnt that India would possibly make a joint statement with China at the next meeting of the WTO. China Chamber of Commerce had already written to Pharmaceutical Export Promotion Council of India (Pharmexcil) on the possibility of making joint representation, it is learnt.

China's share in EU's API imports is 12 per cent while India commands only two percent share in the API imports into the EU. Hence, China is going to be affected more than India.

The Commerce Ministry has also sought the opinion of the Bulk Drug Manufacturers Association over the issue.

Meanwhile, the industry representatives are also trying to take up the issue with Drugs Controller General of India (DCGI). Industry had pointed out that the DCGI was not authorized or conversant enough with EU GMP standards to issue certification. The companies will have to produce such certificates even after their manufacturing facilities and products (meant for exports) get all regulatory clearances directly from the EU drug regulatory authorities in that case.

[Back to top]

China to slap anti-dumping duties on Indian antibiotic

K J M Varma, PTI

August 16, 2012, Beijing: China has decided to slap anti- dumping duties on sulfamethoxazole (SMZ), an antibiotic imported from India.

China's Ministry of Commerce (MOC) said it will impose anti-dumping duties of 17.2 percent on Andhra Organics Ltd and Virchow Laboratories Ltd, and 36.4 percent on other Indian SMZ exporters, state run Xinhua news agency reported.

The decision was taken after the ministry by it concluded its one-year mid-term examination, the agency said.

Chinese Commerce Minister Chen Deming is scheduled to visit New Delhi later this month to take part in the Joint Economic Group meeting of the two countries, which will also be attended by his Indian counterpart Anand Sharma.

In 2007, the Chinese Commerce ministry imposed anti- dumping duties of between 10.1 percent and 37.7 percent on imports of SMZ from India.

The ministry launched the mid-term review on August 17 last year after China's Shouguang Fukang Pharmaceutical Company sought adjustment of tariff rates saying Indian SMZ producers increased their dumping efforts in China since the imposing of anti-dumping duties, the report said.

[Back to top]

Bayer petition against Natco over manufacture of Nexavar dismissed

Divya Rajagopal, Economic Times

September 16, 2012, Mumbai: In a major boost to generic drug makers , the Intellectual Property Appellate Board of Chennai has dismissed German drug maker Bayer's plea, seeking a stay on the the Compulsory License issued to Hyderabad based drug maker Natco to manufacture the anti cancer drug Nexavar, media reports say. The CL issued by the Controller of Patents in March this year, had given Natco the permission to manufacture and sell the kidney cancer drug at less than 3% of the cost charged by the German drug maker.

"We are yet to see the copy of the order, and cannot comment on the ruling", said M Adinarayana, Company Secretary Natco. Bayer could not be reached for a comment on the story. The next step for Bayer would be to knock on the doors of the Supreme Court, analysts say.

Compulsory license is a patent system under the World Trade Organisation (WTO) where a government allows a company to manufacture a patented drug , without the consent of the innovator company. In march this year, India granted its first ever CL, by ordering Natco to sell the cancer drug at Rs 8800 for a month's therapy, and pay 6% royalty to Bayer on the total sales.

India is in the middle of raging patent battle, where domestic drug makers are locked into a bitter legal battle with the multinationals over their patented products. Last week, the Delhi High Court ruled in favour of Cipla regarding a patent infringement suit filed Swiss drugmaker Roche, over its cancer drug Tarceva. Another Swiss drugmaker Novartis, awaits the most awaited ruling from the Supreme Court, over its cancer drug Glivec. Novartis has challenged Section 3(d) of the Indian Patent Act which deems "frivolous" inventions as non patentable.

India has close to 2.5 million cancer cases every year, the World Health Organisation says, and the anti-cancer drug market is estimated to be 1,500 crore. However health activists say that the cost of cancer drugs is still abnormally high and affordable for a large number of patients.

[Back to top]

Drug patents on the rise: 3,488 in 5 years

Sushmi Dey, Business Standard

September 24, 2012, New Delhi : For those who say India is a country of generic drugs, this could be a revelation. India granted as many as 3,488 patents to pharmaceutical products between 2005 and 2010.

Compare India's pharma patent number with that of Brazil, another BRIC (Brazil, Russia, India and China) nation, in a similar time band. A research paper, "Pharmaceutical Innovation, Incremental patenting and Compulsory Licensing" by Carlos M Correa, a professor at University of Buenos Aires, points out that just 278 patents were granted in Brazil between 2003 and 2008.

According to the same paper, 951 pharma patents were granted in Argentina between 2000 and 2007; and 439 were approved in Colombia between 2004 and 2008. However, in South Africa, where patents are simply registered without much verifications and patentability requirements, 1,426 were registered in 2008 alone, the paper added.

While data reveals patentability has encouraged local drug innovation in India, experts suggest the country needs stricter checks and balances to prevent incremental innovation.

It was in 2005, India changed its patent law and started granting patents in medicines. That year, only three pharma patents were granted. The number rose to 113 in 2006 and 772 in 2007. The trend continued with as many as 1,369 patents being approved in pharma in 2008 and 1,046 in 2009, as per the Indian patent office.

Experts attribute this significant change in the patent regime to entry of product patents. According to an intellectual property right (IPR) lawyer, India granted as many as 970 pharmaceutical product patents between 2007 and 2011.

In 1994, India, along with various other developing countries, signed the World Trade Organisation's (WTO) agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which mandated it to start granting patents on medicines no later than 2005. Unlike many countries, India used the transitional period provided in the agreement to the full. It changed its patent law only in 2005 to comply with the TRIPS agreement and started granting patents to drugs.

The change in the intellectual property scenario has also triggered significant shifts in India, particularly in the pharma sector. While research and development activities have substantially increased with various domestic companies investing to develop new chemical entities, Correa points out the large number of grants can only be explained by patents over incremental innovations. The concerns, therefore, have also raised debates on interpretation of provisions like section 3 (d) of the Indian Patent Act which prevents patenting of frivolous and incremental innovations. An current case in the Supreme Court, between Swiss drug maker Novartis and the government along with a host of generic drug makers, is revolving around interpretation of this provision.

"Though India has introduced the provision of section 3 (d) in its patent law, it has not been implemented uniformly, which is important," says Leena Menghaney, campaign co-ordinator (India), Medecins Sans Frontieres, which campaign for access to essential medicines across the world. Agrees Amit Sengupta, the co-convenor of Jan Swasthya Abhiyan, a public health advocacy movement. According to Sengupta, it is not enough to have section 3 (d) theoretically, implementation of the provision is important which will happen only through proper examination of grants.

More recently, the government granted compulsory licence to domestic drug maker Natco allowing it to manufacture the generic version of Bayer's anti-cancer drug Nexavar, even as the latter has a patent on it. The move is aimed at safeguarding public interest as Nexavar is an expensive drug.

Experts say pharmaceutical companies in India need to be IP conscious. "The pharma industry is going to be affected in the next 15-20 years due to IP issues. Therefore, the companies need to be IP conscious now," says Prathiba M Singh, patent and trade mark attorney and managing partner of Singh & Singh Law firm.

[Back to top]

European Union wants India to allow extended patent life for drugs

Amiti Sen, Economic Times

October 3, 2012, New Delhi: The European Union is making frantic efforts to convince India to liberalise its patent regime as part of the proposed bilateral free trade agreement.

Negotiators from the 27-member bloc have been insisting that India allow European pharmaceutical companies to extend the life of their patented drugs in the Indian market beyond the commitments made under the Trade Related Aspects of Intellectual Property Rights (TRIPS).

They argue that the European parliament does not allow bilateral trade deals that does not include an agreement on intellectual property. Patents worth an estimated $150 billion, held by European pharmaceutical companies, are set to expire over the next five years.

"Although India sent out a strong message last year during the negotiations that it would not agree to go beyond the commitments made under TRIPS, the EU is now saying that it has to get some concessions beyond the mandate of TRIPS," an Indian official told ET.

Following EU's insistence, India agreed in August to hold special sessions on TRIPS and services. Last week, several rounds of talks were held between senior officials from the two sides in Delhi, but they failed to reach a conclusion.

With patents on many blockbuster drugs set to expire soon, an estimated $250 billion in sales are at risk between now and 2015, according to data from Evaluate Pharma, an on-line pharmaceuticals research company.

US drug major Pfizer has already reported a sharp dip in profits after the patent on its cholesterol-lowering drug Lipitor ran out last year. European drug companies including Sanofi-Aventis and Astro Zeneca are among companies that are likely to get hit over the next few years.

What the EU primarily wants from India is data exclusivity, which refers to exclusive rights of a company over the clinical data for its drugs, without actually holding a patent for it.

"This would allow patent holders to make slight changes in formulations once the patent life of a product comes to an end and immediately file for data exclusivity," the official said.

"Since generic producers, or manufacturers of copied version of the originally patented drugs, are not allowed to produce drugs with data exclusivity for 10 years, the product would have several years of extended protection."

India gives patent protection for a period of 20 years, which it considers adequate. "We are not in favour of giving data exclusivity at all as it could make life saving medicines unaffordable in the country," the official said.

"The EU wants to carve out a deal that would not affect live-saving medicines. We have to see what they have in mind."

The Indian pharmaceutical industry is the third largest in the world in terms of volume.

[Back to top]

Pfizer says to appeal over India drug patent refusal

Penny MacRae, Agence France Presse

5 October, 2012: US drug giant Pfizer said Friday it will appeal against an Indian ruling overturning a patent for a cancer drug, saying the decision raises questions about intellectual property protection in India.

Indian generics heavyweight Cipla opposed the granting of the domestic patent for Pfizer's Sutent, which is used to combat liver and kidney cancer.

The patent office's decision went to the heart of India's patent act, which says a patent cannot be granted for a drug unless changes make it significantly more effective and innovative.

"The patentee (Pfizer) has miserably failed to demonstrate any improved activity" warranting a patent, the patent office said in its decision.

"The invention that is claimed in the patent does not involve any inventive step... and hence (is) not patentable," Nilanjana Mukherjee, senior patent officer, said.

A spokesman for Cipla, which revolutionised AIDS treatment by supplying cut-price drugs to the world's poor and which has been campaigning to be able offer other low-cost generic medicines, had no immediate comment.

But Pfizer managing director Jazz Tobaccowalla said the company believes the ruling "undermines intellectual property rights in India".

"We will vigorously defend our basic Sutent patent," the Pfizer executive said in a statement, adding the company would appeal against the ruling to India's Intellectual Property Appellate Board.

The patent decision marked another win by Cipla against a global pharmaceutical company.

In September, a court threw out a patent infringement case launched against Cipla by Swiss drugmaker F. Hoffmann-La Roche over the Mumbai firm's version of a lung-cancer drug, ruling it had a different molecular makeup.

The cases have been watched worldwide as they involve interpretation of stricter drug patent protection rules introduced by India in 2005 to comply with World Trade Organization regulations.

India has some of the toughest criteria for drug companies to obtain patents, said D.G. Shah, secretary general of the Indian Pharmaceutical Alliance, an industry body.

"These rulings show (foreign) companies need to take into account that India will not permit tweaking of formulations for getting a patent. If they had those expectations, they were unrealistic," Shah told AFP.

Medical charities have expressed concern that compliance with WTO rules could reduce the country's role as a supplier of low-cost medicines. India is the world's leading exporter and manufacturer of non-branded medicines.

But Western firms looking to countries such as India for sales growth have voiced criticism of brand protection in India.

Earlier this year, an Indian ruling allowed a local firm to produce a vastly cheaper copy of German pharmaceutical giant Bayer's patented drug Nexavar for liver and kidney cancer.

India's patents chief ruled the price Bayer charged was "exorbitant" and told the firm to give a "compulsory licence" -- permitted under WTO rules for public health reasons -- to Indian firm Natco Pharma to make a less costly version.

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

[Back to top]

India revokes Roche hepatitis patent

Penny MacRae, Agence France Presse

2 November 2012: An Indian panel Friday revoked a patent granted to Swiss giant Roche for a hepatitis C drug, marking the latest setback for global pharmaceutical firms in the country's $12 billion medicine market.

The Intellectual Property Appellate Board overturned the patent awarded by the Indian Patent Office to Hoffmann-La Roche's drug Pegasys, citing a lack of evidence that it was a "new class" of drug.

The ruling represents another blow to western drug firms in India that have been looking to the country of 1.2 billion people to boost sales but are worried about patent protection and fear competition from its generic knockoffs.

While Roche can still challenge the decision in India's courts, patients' advocacy groups called the ruling a significant victory.

"If we get the manufacture of lower-costing generic drugs, millions suffering from hepatitis C, both in India and globally, will benefit," said patients' rights lawyer Anand Grover.
"This is a big win for hepatitis C patients," Grover told AFP.

India is the world's leading exporter and manufacturer of cheap, non-branded medicines, mainly to other poor, developing countries.

Earlier this year, the same board allowed a local firm to produce a vastly cheaper copy of Bayer's patented drug Nexavar for liver and kidney cancer, saying the $5,300 price charged by the German company was "exorbitant".

The decisions involve interpretation of new patent protection rules introduced by India in 2005 to comply with World Trade Organization regulations.

The patent appeal board said on Friday it had found no proof that Pegasys was a "new class" of drug. "In the end, the invention is held to be obvious," the board said, ordering the patent to be "set aside". The ruling was in response to an appeal against the patent filed by a Mumbai non-profit group, The Sankal Rehabilitation Trust, which helps drug users who frequently contract hepatitis C through use of dirty needles.

Hepatitis C, a viral disease transmitted largely through infected blood that can lead to liver cirrhosis and cancer, represents a huge public health problem in India and globally.

Patients with chronic Hepatitis C had to purchase Pegasys at a market price of up to 436,000 rupees ($8,750) for a course of treatment, a price that is beyond the means of most poor patients, the Sankal trust said.

Some 10 million to 12 million Indians, including 50 percent of injecting drug users, are infected with the virus, but many receive no treatment because of the high cost, according to the trust."People are dying due to hepatitis C because they cannot afford to buy the medicine," said trust director Eldred Tellis.

There was no immediate reaction available from Roche, which was granted a patent to market Pegasys in 2006.

[Back to top]

Drug exports under brand name to stay

Rupali Mukherjee, Times Business

6 November 2012, Mumbai: Pharma companies can breathe a tad easier. It is learnt that the government has dropped plans to enforce a ban on use of brand names while exporting medicines. Recently, the health ministry had directed the industry to use generic names for medicines instead of brands while applying for manufacturing licences. The government was planning a similar ban in export licences as well.

Though this was yet another move by the government to make drugs cheaply available to patients, it threatened to snowball into a major problem for the industry, which mops up over $12 billion through exports. The move would have resulted in confusion, delays and loss of export turnover for companies.
The government is expected to clarify the issue of export licences by issuing a notification over the next few days. "Based on our discussions with officials, the government has agreed that it will not ban the use of brand names in export licences. We have sought a clarification (on the issue) from the health ministry, and this is expected soon," an official from the Indian Drug Manufacturers' Association said.

The industry was apprehensive that the certificate of pharmaceutical product (CoPP) issued by the government for exports will also be issued in the generic name. The certificate is mandatory for exports in many countries.

Significantly, the government may agree to drop its controversial ban on the use of brands in the domestic market as well, the official added. For instance, if a company manufacturing Crocin applies for a renewal of licence, then it will be issued in the name of 'Paracetamol', its generic name, and not the brand name ‘Crocin’. For those applying for a fresh licence of a new medicine, it would be issued in the generic name.
This would become an even bigger problem and lead to confusion and loss of revenue for companies when many players export the same molecule. Several companies have already earned a huge recall value in overseas markets through their brands.

The issue proved to be another dampener for the industry, which is already reeling under anxiety over impending price controls and recent policy flip-flops.

However, experts point out that in certain cases prices shoot up due to the marketing efforts undertaken by the company in building and promoting its brand.

[Back to top]

Andhra Pradesh power cuts to hit pharmaceutical exports target

Raji Reddy Kesireddy, Economic Times

Hyderabad, 12 December 2012: Severe power cuts in Andhra Pradesh - a state that accounts for some 40% of India's bulk drug exports - have forced the Pharmaceutical Exports Promotion Council (Pharmexcil) to slash the country's pharmaceutical export growth projections for this fiscal by 5%. India, whose pharmaceutical exports rose nearly 25% to $13.2 billion (about Rs 71,500 crore now) in the 2011-12 financial year, may end up posting only a little over 17% growth this fiscal, hurt by power shortages, said Pharmexcil director general PV Appaji.

Also, margins of pharma companies are likely to come under pressure as most of them will be forced to execute export orders by using costly diesel generators during the power cuts.

Poor monsoons and fuel supply constraints to both gas- and coal-fired power plants have forced the AP power transmission companies to resort to major power cuts, hurting industrial customers the most.
"After taking into account the production losses in AP, among other factors, the Indian pharmaceutical exports this fiscal are expected to reach only $15.5 billion," Appaji told ET.

He said other factors weighing on export targets include the European economic crisis and the preference by certain economies-such as Latin American countries and Russia-to encourage local manufacturers.
Power supplies to AP industries fell 35% short of total requirements in peak summer. The shortage is hovering around 25% now, said MV Rajeswar Rao, secretary general of trade body Federation of AP chambers of commerce and industry (Fapcci).

While the overall industrial production loss due to the shortages was estimated at about 40%, the pharma sector suffered some 15% losses with many mid-sized and major companies relying on expensive alternative arrangements, he said.

Dr Reddy's Laboratories, Aurobindo Pharma, Mylan Laboratories, Divi's Laboratories, Hetero Drugs, Natco Pharma, Virchow Laboratories, Suven Life Sciences and Nueland Laboratories are among the key pharma companies with manufacturing facilities located in AP. ET could not ascertain how many of them suffered losses in exports or margin declines because of the power cuts.

M Narayana Reddy, former president of Bulk Drugs Manufacturers' Association and managing director of Virchow Laboratories, said the industry is likely to witness at least 10% additional operating costs this fiscal owing to alternative power supply arrangements.

For the six months period ended September 2012, pharma exports from the country amounted to $7.02 billion, which translates to a growth of 13% over the same period of last fiscal.

Pharmexcil's Appaji said the Indian pharmaceutical industry is unlikely to achieve the ambitious exports target of $25 billion by March 2014 set by the government as the industry would have to grow at over 60% during next fiscal alone to meet it.

An analyst with a Mumbai-based brokerage, who did not want to be identified, said regardless of reaching ambitious growth targets, Indian pharma exports are growing at a healthy 17% CAGR (compound annual growth rate) notwithstanding only a 12% CAGR in global generics spending.

[Back to top]

India revokes patent for Merck asthma drug

Agence France Presse

12 December 2012: India has revoked a patent for an asthma drug held by US-based Merck following a challenge from local pharmaceutical giant Cipla, marking a new blow to global drug firms in the Indian market.

The development is the latest in a string of patent revocations by India and involves interpretation of patent protection rules introduced in 2005 to comply with World Trade Organisation regulations. The drug produced by Merck & Co, a global health care company, was "not inventive", said the order announced late Tuesday.

Schering Corp, later acquired by Merck, had applied for a patent for the asthma drug in 2004 and was granted it in 2011.

Medical charities have expressed concern that compliance with WTO rules could reduce the country's role as a supplier of low-cost medicines. India is the world's leading exporter and manufacturer of non-branded medicines.

But Western firms, looking to countries such as India for sales growth, have voiced criticism of poor brand protection in India.

[Back to top]

India economy: Cure or overdose?

Economist Intelligence Unit

3 January 2013: In November 2012 the Indian government revamped its drug policy, increasing the number of drugs that are subject to price regulation. Although the government's aim of making drugs more affordable is laudable, foreign drug-makers have expressed concerns that the policy may impact India's ability to attract investment in the pharmaceutical sector. The government will continue to exert a heavy influence on drug prices in India, setting itself up for increasingly frequent clashes with foreign manufacturers in the process.

Under the new policy, the ceiling price of a particular drug will be calculated by taking the arithmetic mean of the prices of all the brands that have more than 1% market share for each category of drug. By doing this, the government hopes to lower the prices of costly brands and make drugs more affordable. The Indian pharmaceutical market is valued at some US$12bn a year and is the fourth-largest in the world in volume terms. According to PricewaterhouseCoopers, a consulting firm, the market is forecast to expand to US$50bn by 2020, making the country a lucrative market for foreign drug manufacturers. However, overseas firms are concerned that the new policy is overly restrictive, arguing that fierce competition already ensures that generic medicines sold in India are among the cheapest in the world.

The government, backed by other advocates of enhanced price controls, argues that market distortions often mean that consumers do not enjoy the benefits of competition. A lack of awareness of cheaper alternatives, and the fact that doctors continue to prescribe expensive branded drugs, means that consumers pay high prices for medicines. The new policy updates the previous regulations, which were introduced in 1995, and increases the number of drugs on the National List of Essential Medicine to 348, from 74 previously. The drugs added to the list include treatments for cancer and HIV.

However, doubts persist over the efficacy of the new policy, as pharmaceutical companies can exploit loopholes to get around price controls. According to an international science journal, Nature, this could actually drive up the prices of existing generic drugs. For example, in India drugs with the same formulations are currently sold at a range of prices. UK-based GlaxoSmithKline sells an antibiotic under the brand name Augmentin for US$4.85, whereas local Indian versions are sold at US$1.20. Nature contends that the new policy will drive down the price of Augmentin, but points out that the revised price may still be higher than that of local versions. However, companies that currently produce low-cost variants could stop promoting and eventually cease producing these drugs if consumers move towards recognisable brands, thereby killing off the low-price end of the market. The policy also applies to specific dosages of drugs, thus creating loopholes according to which companies may adjust their drugs' dose levels in order to evade the price regulations.

A patent war looms

India's pharmaceuticals policy currently does not cover patented drugs. However, a landmark patent case that is currently before India's Supreme Court could alter healthcare regulations significantly. The court heard the final arguments in the case between the Indian government and a Swiss drug-maker, Novartis, towards the end of 2012, marking the final stage of a seven-year legal battle. At the centre of the dispute is India's stringent Patents Act, which prohibits "evergreening"-a practice that allows drug companies to make small changes to molecules and then patent the new forms of their drugs when their patents are close to expiry. This has the effect of preventing the manufacture of generic drugs, as it enables pharmaceutical companies to renew the patents on their products repeatedly. Novartis is challenging a decision by India's patent office that rejected its application for a patent for its highly successful anti-cancer drug, Glivec, in 2006. The company has argued that the denial of the patent contravenes India's obligations under the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights. The Indian government has said that Glivec

does not represent a breakthrough in therapeutic treatment and is merely a new form of an old drug.

In 2012 the Indian government invoked a compulsory licensing provision to force a German drug-maker, Bayer, to licence its anti-cancer drug, Nexavar, to an Indian manufacturer despite the fact that the drug was still under patent. The generic version of the drug is now sold at around one-thirtieth of the price at which Bayer markets Nexavar. Ensuring affordability is the main consideration behind the Indian government's approach towards drug pricing. According to Doctors Without Borders, an international non-governmental organisation (NGO), in countries where Novartis has patented Glivec one month's supply of the drug per patient costs around US$2,600, whereas in India generic versions are available for US$200 a month. The Novartis case is also expected to have international ramifications. India is the world's largest exporter of cheap generic drugs, and global aid groups and NGOs have said that a win for Novartis could end the country's role as "the world's pharmacy", leaving millions of people in Asia, Africa and South America without access to affordable life-saving drugs.

Concerns over intellectual property

Foreign firms see the Novartis case as a key test of India's commitment to protecting intellectual property. They have argued that granting a patent acknowledges innovation that could potentially save lives. Overseas drug companies are also concerned about the government's shifting position on foreign investment in the pharmaceutical sector. Until 2012 foreign firms were allowed to make equity investments of up to 100% in their ventures in India. However, the government has recently introduced regulations forcing companies to meet certain norms before investing in India, including selling drugs at low prices. Foreign firms are also required to procure approval from the Foreign Investment Promotion Board before investing in domestic companies.

The changes were partly a reaction to a spate of acquisitions of Indian pharmaceutical firms by global companies in recent years, sparking fears that such takeovers would lead to higher drug prices in the country. India will seek to meet its obligations under various WTO agreements, but the government is keen to ensure that drugs remain affordable. Although this could have a negative impact on foreign firms' investment plans in the country, India's overall demographics and strong growth prospects will mean that it remains an attractive market for multinational pharmaceutical companies.

[Back to top]

Drug pricing: Govt decides to bypass three patents

Reghu Balakrishnan, Business Standard

Mumbai, 15 January 2013: The government's move to issue compulsory licences (CLs) for three more patented cancer drugs is a jolt to multinational pharmaceutical companies.

The plan is to issue CLs for Trastuzumab (or Herceptin, used for treating breast cancer), Ixabepilone (used for chemotherapy in breast cancer treatment) and Dasatinib (or Sprycel, for leukaemia). These cost an average of $3,000-4,500 (Rs 1.64-2.45 lakh) for a month's treatment.

Last March, the Hyderabad-based Natco Pharma had won the first ever CL, to manufacture its generic version of Bayer's patent-protected anti-cancer drug, Nexavar. With the licence, Natco sold the drug at Rs 8,880 for a pack of 120 tablets, a month's therapy, as against Rs 2.8 lakh, the cost at which Bayer sells Nexavar.

According to section 84 of the Indian Patents Act, a CL can be issued if the patented drug is unavailable, unaffordable or not supplied properly. With CL, domestic companies can manufacture and market generic versions, paying a royalty to the patent holder company.

Natco had, in fact, begun selling the generic version, Dasatinib, of Bristol-Myers Squibb's Sprycel last year, without waiting for any CL. The matter went to court. Now comes the government's decision to legalise the move. Natco is pricing Dasatinib at Rs 9,000 for a month, as compared to BMS' Rs 1 lakh for a month's treatment. BMS also makes Ixabepilone, for which a CL decision is being taken.

The chief executive of an Indian generic company, engaged in a dispute with MNCs, said on condition of anonymity, "Most patented cancer drugs cost $5,000-6,000 a month. How many patients in India, where there is no public insurance facility, can afford these prices?"

Unless MNCs are ready to change the strategy for the 1.2 billion people here, issuing a CL is the only option to make drugs affordable to the population, he added.

The Cancer Patients Aid Association (CPAA) has welcomed the government move. Y K Sapru, its founder-chairman & CEO, said, "Giving a CL for a few more anti cancer drugs is a very good move, especially for Herceptin, which was required by a large number of breast cancer patients, who were dying because the drug was not affordable."

The government should increase the list of drugs for which a CL is granted, as there are several life-saving anti-cancer drugs which are totally unaffordable, he added.

Ranjit Shahani, president of the Organisation of Pharmaceutical Producers of India, the association for MNC pharma companies said, "Issuing CLs is a matter of concern. There are access programmes by MNCs for medicines which, very often, bring down the prices significantly." He said Novartis' cancer drug, Glivec, was given free for 16,000 patients in India, claimed to be about 95 per cent of the patients, through The Glivec International Patient Assistance Program (GIPAP).

In March, Roche had given a manufacturing and marketing license for Herceptin to Pune-based Emcure Pharma. Herceptin is priced between $3,000 and $4,500 for a month's treatment.

"There has to be an interactive dialogue between the government and multinational pharma companies regarding the price difference," said Shahani. Mails to Roche and Bristol-Myers Squibb did not elicit any response.

In March, responding to India's issue of the first CL, to Natco, John Castellani, president and chief executive officer, The Pharmaceutical Research and Manufacturers of America (PhRMA), said, “The research-based pharmaceutical industry fully supports the objective of improving access to innovative medicines. However, CLs cannot solve India’s larger problems regarding access to medicines and healthcare. In the absence of the investment made by our members, and the resulting research and development, there would be no generic medicines for the world’s patients. The responsibility to promote development of new drugs lies with all countries, not solely those in the developed world." PhRMA represents leading pharmaceutical research and biotechnology companies in the US.

[Back to top]

Natco's compulsory licence for selling generic copies of Bayer's cancer drug Nexavar upheld by IPAB

Sanjay Vijayakumar & Divya Rajagopal, The Economic Times

Chennai/Mumbai, 4 March 2013: An independent authority has ruled in favour of the government's decision to allow a domestic pharmaceutical company to make inexpensive copies of German multinational Bayer's anticancer drug priced at Rs 2.8 lakh a month.

By saying that Natco Pharma can produce Nexavar, a patented medicine used to treat liver and kidney cancers, the Intellectual Property Appellate Board has in effect endorsed the so-called compulsory licensing regime under which Indian companies can make cheap versions of expensive life-saving drugs. "The court does not decide for, or against, a company. It takes a decision based solely on public interest," Justice Prabha Sridevan, chairman of IPAB, who pronounced the ruling at a marathon sixhour sitting. "The price of a drug should be seen from the point of view of the public affordability and not based on R&D expenses."

In March last year, India granted its first ever compulsory licence, by ordering Natco Pharma to sell the cancer drug at Rs 8,800 for a month's therapy, and pay 6% royalty to Bayer on the total sales, which was disputed by Bayer. "In three years, Bayer has not taken any steps in revising the marketing strategy and cut the price of the product," said Justice Sridevan on Monday. The judge also noted that since 2010, Bayer has only been importing the drug for its philanthropic activities in India and not a single import was made for commercial use. Natco, which has been asked to increase the royalty it pays to Bayer to 7% from 6%, welcomed the decision while Bayer was dismayed.
"We strongly disagree with the conclusions of the IPAB. Bayer is committed to protecting its patents for Nexavar and will rigorously continue to defend our Intellectual Property rights within the Indian legal system. We will pursue the case in front of High Court in Mumbai with a writ petition," Bayer told ET in an emailed response after the verdict. "The order of the Intellectual Property Appellate Board (IPAB) weakens the international patent system and endangers pharma research." The Ipab order is the latest setback to multinational pharmaceutical companies which have been delivered a string of defeats in a country where it is becoming established that affordability of medicines trumps the privileges of patent-holders.

"It is great news as the prices of drugs have dropped by 97%. This provision in Indian law, which allows generic competitors to apply for compulsory licensing is very important to check the abuse of patent system in terms of prices, availability, meeting the needs of the public," said Leena Menghaney, campaign coordinator at Medecins Sans Frontieres, an international, independent organisation for medical humanitarian aid.

The most high-profile patent case is the one being fought by Novartis in the Supreme Court over its cancer drug Glivec. The Swiss company sought and failed to receive patent protection from IPAB, which said that the innovation was only incremental. While the Natco-Bayer dispute is regarded as a test case for the compulsory licensing regime, India's patent law amended in 2005 does not recognise incremental innovation for patenting. This has led to a number of disputes in which the global pharmaceutical companies have ended on the losing side. By disallowing patents for incremental innovation, India has fostered a thriving generics industry which is able to supply affordable drugs to hundreds of millions of poor people around the world. In March, the patent controller issued a 'compulsory licence' for the first time allowing generics company Natco to make Nexavar.

"Though this ruling has set a precedent for future compulsory licensing applications, large Indian drugmakers will be reluctant to apply for a compulsory licence due to their partnerships with multinational drugmakers. However, rulings like these sow a seeds of doubt in the minds of multinational drugmakers about the reliability of the intellectual property regime in India," said Sujay Shetty, head of the life sciences practice at PricewaterhouseCoopers.

[Back to top]

BDR Seeks Compulsory Licence for Cancer Generic

Divya Rajagopal, The Economic Times

Mumbai, 19 March 2013: A small Mumbai-based pharma firm has applied for a compulsory licence (CL) for an anti-cancer drug patented by American drug giant Bristol-Myers Squibb (BMS), a move that is likely to intensify the battle between domestic and foreign firms over the controversial facility.

A BDR Pharma executive on Monday said that the firm has applied to sell a generic version of BMS's patented anticancer drug Dasatanib at a much-lower price through compulsory licensing."Yes, we have filed for CL and our main goal is affordability for Indians suffering from the disease and making it available to all patients," Dharmesh Shah, MD, BDR Pharma, told ET.

BDR wants to sell the drug at.8,100 against BMS's price of.1,60,000 for a month's dosage.

CL is a provision under the Trade Related Intellectual Property Rights (TRIPS) programme of the WTO, which permits governments to allow generic companies to produce patented drugs without the consent of the patent holder.

India is a signatory to TRIPS and has provided the facility of compulsory licensing in its laws.

CL became controversial in India after Hyderabad-based Natco Pharma got permission last year from the patent office to sell cheaper versions of German drugmaker Bayer's kidney cancer drug Sorafenib.

Bayer had strongly argued against CLs saying such a move is against India's adoption of strong patent-protection laws.

However, Intellectual Property Appellate Board (IPAB) in March ruled in favour of Natco's CL.

Multinational companies, which have always complained against the lack of patent protection in India, say they are being robbed of millions of dollars in revenue through CL.

They add that the patient-protection programmes run by many foreign companies ensure availability of cheap drugs, but this is disputed by patient groups in the country which say the cost of drugs still remains high.

Compulsory licensing, according to them, reduces the cost of drugs and is needed in a country where many poor patients don't have access to affordable healthcare.

BDR says that it has filed for CL under Section 84 of the Indian Patent Act.

Under this section, a company can file for CL three years after the patent has been granted for a specific drug.

The application will now be reviewed by the government and there is no certainty that a CL will be granted.

The patent office will have to examine all issues such as the affordability of drugs and whether the patent has worked in the territory of India.

Last week, the world's largest drugmaker Pfizer complained about the growing "anti-IP developments in India" in a representation to a US House of Committee on Trade."Despite being a member of the WTO and an important global trading partner, India has systematically failed to interpret and apply its IP laws in a manner consistent with recognised global standards.

We have seen a growing trend of anti-IP developments in India and this is creating a significant uncertainty in the market and negatively impacting our industry and Pfizer," Roy Waldron, chief intellectual property counsel, Pfizer, had said.

BMS did not respond to the email query sent by ET.

BMS has tried to ward off generic rivals to drug such as Natco and Hetero Drugs by suing them.

Shamnad Basheer of Spicy IP, the blog which first broke this news on Monday, says this application is an encouraging move and might set the ball rolling for other companies to explore the CL route."Many of us were worried that after Natco, no other company would file for compulsory licence, considering the long legal tussle that comes with this issue," says Basheer.

Big Cos Dissent

MNCs have complained about lack of patent protection in India, saying they are robbed of millions of dollars in revenue through CL. MNCs claim that many foreign cos ensure availability of cheap drugs.

[Back to top]

A fool's game

The Economist (Reproduced in financial express)

New York, 1 April 2013: Novartis spent nearly 15 years seeking a patent in India for Glivec, a medicine for chronic myeloid leukemia. That quest reached its dead end, at last, on April 1st. India's Supreme Court rejected the Swiss drugmaker's patent application. Glivec (marketed in America as "Gleevec") is a blockbuster, earning the Swiss drugmaker $4.7 billion last year. Its prospects in India are now zilch.

The case was watched closely by virtually everyone with an interest in selling medicines or benefiting from them, including drug firms, trade officials and patient advocates. Drug companies, facing paltry growth in rich countries, want to sell medicines to developing ones where demand for new drugs is rising along with rates of chronic disease. But governments are keen to boost their own pharmaceutical firms and are wary of patented drugs' high costs. As a result, brawls over patent protections and prices have broken out from Brazil to Thailand.

The fight is particularly fraught in India. It has the world's biggest generics industry, an adolescent patent law, growing demand for medicines and an inability to pay for all of them. PwC, a consultancy, expects Indian drug sales to grow from $16 billion in 2011 to $49 billion by 2020. Nearly three quarters of the sales come from generic drugs, and this is unlikely to change, reckons PwC. The Supreme Court ruling, and another one last month, help to explain why.

Innovative drug companies have faced two key questions in India. First, will India's young patent regime, in place since 2005, provide the same protection as those in America and Europe? Second, will Indian regulators tolerate high drug prices? The answer to both questions seems to be "no".

The Supreme Court defended India's right to deny patents to incremental improvements. It ruled that Glivec was merely a new form of an older drug and did not constitute a patentable invention. "This is a huge relief," said Unni Karunakara, the president of Médecins Sans Frontières, which cares for patients in poor countries. Novartis is less pleased, declaringt hat the ruling "discourages future innovation in India."
The April ruling follows another by an Indian appeals board in March. In that case, the board upheld a decision to let Natco, a generic drugmaker, sell copies of Bayer's patented kidney-cancer drug Nexavar. Bayer had not made the drug available to Indians at a sufficiently low price.

With these rulings, India has become the most extreme case of a problem plaguing Big Pharma from Berlin to Beijing: how to convince governments and consumers to pay for their drugs. Some companies will continue to seek high prices for worthy medicines. Others may chase sales by lowering prices to boost volumes. Either strategy will carry risks.

[Back to top]

Waiving drug patents global trend

Sidhartha, The Times of India

New Delhi, 1 April 2013: For the past several months, Indian officials and ministers have spent a lot of time explaining to their overseas counterparts that India has only used provisions of an international treaty to waive Bayer Corporation's patent right on a cancer drug. After all, the impact has been a sharp price reduction for those suffering from renal cancer — from Rs 2.8 lakh to Rs 8,000.

What they have not told foreign governments and companies is that in Italy, the authorities invoked the compulsory licensing provisions for a medicine that was meant for use by prostrate cancer patients but is now being used widely by anti-balding clinics. Similarly, the patent rights for a drug used to treat migraine were waived. And, it was done to "combat anti-competitive practices".

Egypt probably went a step further when in 2002, it waived Pfizer's patent rights on sildenafil, which the world is more familiar with as Viagra.

In all cases, it was provisions under WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) that were used. Countries ranging from India, France and Germany to Thailand, Mexico and Chile have local laws that allow their patent offices and anti-trust courts to waive patent rights and let cheaper versions of the medicine be manufactured on payment of royalty.

While countries such as Canada, Indonesia, Italy, Malaysia and African countries have used the provision on several occasions, India has used it only once in case of Bayer Corporation's Nexavar. Earlier this month, little-known BDR Pharma submitted an application seeking compulsory licence for dasatinib, another anti-cancer drug, while the health ministry is making a case for another two medicines to deal with cancer — trastuzumab and ixabepilone. "We will follow the process that has been laid down in the law, which involves giving a chance to everyone to present their case," said an official, who did not want to comment further.

There are countries such as the US that has relied on executive orders, with President Barack Obama issuing one last year to import drugs to deal with local "shortages". Although American industry says the powers are not the same as compulsory licence, Indian players say it serves the same purpose. A recent report suggested that the US FDA's move has helped prevent 128 drug shortages.

"We follow a judicial process that can be questioned in the high court and the Supreme Court. The US president's executive order can't be challenged," said D G Shah, secretary general of Indian Pharmaceutical Alliance (IPA) that represents domestic drug companies.

In fact, experts say that the US has used the anti-trust provisions to provide a compulsory license-like treatment to non-medicinal products.

"We have often told the US that we don't have such a thing like the anti-trust law and our compulsory licenses are based on the principles of affordability and ability to pay. There should be a balance between the rights that a patent holder has been granted and the benefits that should accrue to the public at large," said Biswajit Dhar, director general of Research & Information Systems, a Delhi-based think tank.

For Big Pharma, a compulsory license is an opportunity lost to make super-normal profits. The MNCs argue that the risks are high and therefore they have to resort to high prices. "The MNCs are perturbed due to the sheer size of the market and the fact that India is setting an example for other developing countries," said Abhijit Das, head of IIFT's Centre for WTO studies.

[Back to top]

European Union sets tough conditions under FTA

Asit Ranjan Mishra/Vidya Krishnan, Livemint

EU has proposed its customs authorities will have the right to seize drugs in transit in case of IPR infringements

New Delhi, 2 April 2013: The gains accruing to the Indian generic drugs industry as a result of the Supreme Court judgement on the Novartis case may be lost if India accepts demands by the European Union (EU) under the proposed free trade agreement (FTA) between the two sides.

According to a leaked intellectual property chapter of the India-EU FTA draft document posted on the website of a not-for-profit non-governmental organization Knowledge Ecology International, the EU has proposed that its customs authorities will have the right to seize drugs in transit if infringements of intellectual property rights (IPRs) are suspected. The EU has also demanded seizure of bank accounts and properties of drug exporters.

"In the case of an infringement committed on a commercial scale, the parties shall ensure that, if the applicant demonstrates circumstances likely to endanger the recovery of damages, the judicial authorities may order the precautionary seizure of the movable and immovable property of the alleged infringer, including the blocking of his/her bank accounts and other assets," it says.

However, there is no agreement so far on this issue and according to the leaked document, India has proposed that both parties shall ensure that goods in transit through their respective territories are not subject to any enforcement procedures relating to infringement of IPRs.

A commerce ministry official said on condition of anonymity that there was no question of India accepting the demands made by the EU on this front.

India is a major supplier of generic medicines to many African and other least developed countries. Generic medicine consignments by Indian firms have been seized in the past in transit at European ports several times on the grounds of alleged patent infringement. In 2008, there were 17 cases of medicine seizures in the Netherlands alone, according to a response from Dutch authorities to Health Action International, a non-profit organization, under a freedom of information request. Of these, 16 were shipped from India and one from China.

India launched a trade dispute against the EU and the Netherlands in May 2010 over the seizure of generic medicines in transit. However, it later withdrew this after the EU directed customs authorities not to seize any such drugs consignments.

Leena Menghaney, campaign coordinator (India) at Médecins Sans Frontières (MSF), said public health activists like her are worried about patent infringement litigation if India agrees to the EU's conditions with respect to IPRs.

"India has faced a lot of criticism in the past year due to compulsory licensing and the EU FTA negotiations. The kind of IP enforcement we saw today by the apex court will not be possible if India signs the EU FTA," she added.

Talks on the bilateral trade and investment agreement started in 2007. The two sides have missed at least four deadlines to complete negotiations.

India's trade minister Anand Sharma, while inaugurating the Mint Luxury Conference on 22 March, had said negotiators from both sides have made enormous progress and India expects to conclude talks at a ministerial meeting with EU trade commissioner Karel De Gucht scheduled for 14-15 April.

“It will be a most ambitious trade agreement for India covering 96% of India’s tariff lines. Those who are interested in wines, cheese and many of those other things, these are settled long back. The ministerial will follow on 14-15 April in Brussels, so that by that time negotiators have tied most of the remaining loose ends,” he had said.

MSF has announced that it will be protesting against the “protectionist” IP policies under EU FTA on 10 April.

Interestingly, Sharma said in a release on Monday that the Supreme Court judgement was a historic one and reaffirmed the position of Indian law and in particular, provisions of section 3(d), which mandates the need for a substantive innovation while deciding on a case for the grant of a fresh patent.

“Indian patent law is fully in conformity with our international obligations under the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement,” he added.

[Back to top]

India: pariah or pathbreaker of pharma world?

Patralekha Chatterjee, Daily News & Analysis

8 April 2013: This was not the 3D of movies, games and computer graphics. But it gripped the national imagination. The Supreme Court ruling last week dismissing Swiss drug major Novartis AG's bid for a patent for its cancer drug Glivec hinged on the interpretation of Section 3(d) of India's patent law which defines what are not "inventions" under Indian law, and therefore not patentable. It was an epic finale to a tortuous seven year-old legal battle that pitted Novartis against the Indian government, the country's leading generic drug makers and the Cancer Patients Aid Association.

The reactions to the verdict have been totally predictable. Health activists and patients' groups worldwide are delirious with happiness. No surprises there - India's generic drug industry makes cheaper versions of life-saving medicines that cater to the entire developing world. Novartis is unhappy, as is Big Pharma and its advocates.

Over the past few days, a stream of analyses has parsed the Court's verdict , especially in relation to Section 3(d) of the patent law which states that inventions that are a mere "discovery" of a "new form" of a "known substance" and do not result in increased efficacy of that substance are not patentable.

The Glivec case hinged on this provision, introduced by the Indian Parliament in the country's patent law in 2005 as a public interest safeguard to prevent patenting of new forms of known substances unless they exhibit enhanced efficacy.

This case triggered so much interest across the world because it touched upon one of the central challenges of our times - how to balance incentives for innovation with interests of public health and access to medicine.

Most people in this country pay for medical treatment out of their pocket and, therefore, anything that promotes cheap drugs is a big deal. Glivec enjoys patent protection in 40 countries. Novartis says most of those who are prescribed Glivec in India get the medicine free of charge from Novartis' patient assistance programme. This may be true. But the fact of the matter is that a month's dosage of Glivec, the branded drug, costs over a lakh. The generic version in India costs less than Rs10,000. I reckon most people in this country are taking the generic medicine.

The striking feature of the Glivec saga has been the use of war imagery to tell the tale - Western pharmaceutical firms are perceived to have received a "blow" and Indian generic drug makers are portrayed as the "victors".

But to see it as a morality play is to miss the larger point. There will be differences of opinion between lawyers. But Novartis lost the case because it could not convince the Supreme Court judges that there was enough scientific evidence to demonstrate that it was different enough and more therapeutically effective than an earlier patent relating to Glivec. There is nothing to suggest that the Indian judiciary is biased against innovators, or that in the future, other multinational or local pharma companies applying for a patent in India will necessarily be disappointed.

The future is likely to be a shade of grey, rather than black and white. Generic drug makers may appear to have triumphed this time, and with other recent judicial verdicts in the country. But there are challenges ahead. Big Pharma has to also go in for a reality check. Affordability is a big issue, and not just in India. Unless there is differential pricing, it won't be smooth-sailing.

Big Pharma honchos predict dire consequences for India - no new life-saving drugs, no future as a research and development hub, and so on. Despite the sound and fury, I don't' think it is quite Apocalypse now.

Will India be a reduced to a pariah or will it continue to be seen as a path-breaker of the pharma world? Those who have been watching the Glivec saga from afar say that it is necessary to sift the rhetoric from the reality. With pharmaceutical profits decreasing in the developed world, pharma MNCs are increasingly looking to the developing world to expand profits. Everyone is banking on the emerging markets. Despite India's slowing economic growth, the country's pharma industry remains attractive. A 2011 report by the Confederation of Indian Industry and Pricewaterhouse Coopers says that the Indian pharma industry today is the third largest market globally in terms of volume and the 14th largest market by value. It is likely to be a $74 billion market by 2020.

Secondly, India is not the only country with public health safeguards in its patent regime. Many other developing countries have put in place such provisions into their patent law. For example, Argentina and Phillipines have something similar to India's Section 3(d) in their patent legislation.

Or take compulsory licensing (CL), another public interest safeguard allowed by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). India has been slammed for using it. But Indonesia, Thailand, Brazil, Malaysia, Zambia, Cameroon, Ecuador, and now even China are joining the ranks of those using CL.

Public health safeguards is a good thing. However, India should brace itself for political pressure from developed countries, home of pharma MNCs, in the coming days. One increasingly disturbing aspect of free trade agreements (FTAs), for example, is the inclusion of investor-state provisions that essentially allow companies - usually multinationals - to challenge the policies of signatory governments directly. US drug giant Eli Lilly & Co. is demanding $100 million in compensation for Canadian court decisions that stripped the company of its patent for a drug used to treat attention-deficit disorder. With India planning or negotiating a raft of free trade deals in the coming days, these are some of the issues to keep in mind.

[Back to top]

Only 3% of patents filed by MNC pharma firms under dispute: Study

Divya Rajagopal, The Economic Times

Mumbai, 16 April 2013: On April 1, when the Supreme Court rejected Swiss pharmaceutical major Novartis' plea for a patent on an updated version of its cancer drug Glivec, it evoked different reactions: Big Pharma cried foul terming the ruling as one that "discourages innovation and investments in India", while health activists hailed it as a step in the right direction.

Digging deep, ET discovered that multinational pharma companies have been granted over 1,000 patents since 2005, and out of 4,036 patents granted in the past six years, 1,130 have been awarded to multinationals. Among the large multinational pharma companies, British drug maker Astrazeneca tops the list with 180 patents, followed by Roche with 166 patents, while Sanofi and Novartis have 159 and 147 patents, respectively.

The data assumes significance, especially at a time when a growing number of multinationals are getting embroiled in litigation over patents in the country, but often ending up on the losing side.

As a result, big multinationals like Bayer, Novartis and Merck, among others, have complained that India's intellectual property environment is not conducive for doing business, even as health activists have been clamouring for affordable drugs for the poor.

This year, the Intellectual Property Appellate Board (IPAB), the quasi-judicial body that addresses the intellectual property disputes in the country, revoked the patent of Pfizer's anti-cancer drug Sutent and Roche's hepatitis C drug Pegasys after their patents were challenged in the country. It also refused to overturn the Compulsory Licence that was granted to Natco Pharma for German drug maker Bayer's anti-cancer drug Nexavar.

"The order of the IPAB weakens the international patent system and endangers pharmaceutical research," Bayer had said last month after the ruling against Nexavar. "The limited period of marketing exclusivity made possible by patents ensures that the costs associated with the research and development of innovative medicines can be recovered," it added.

However, patent experts dispute such claims, saying that few drug makers are challenging frivolous drug patents in India, and that the Indian patent office is actually liberal in granting patents.

"One is not sure about the quality of these patents granted by the patent office, since many of them were never opposed," said Shamnad Basheer, owner of Spicy IP, a blog that specialises in IP issues in India.
"Our study found that only 3% of the patent applications filed in India since 2006 were challenged. This demonstrates that given the various resource constraints faced by the Indian patent office, one can never really be sure of the patent quality unless the patent is challenged," he added.

Another study done by Columbia University's Bhaven Sampat along with intellectual property experts Kenneth C Shadlen and Tahir Amin found that of the 214 patents filed in India last year, only 3 patents were rejected exclusively for failing to prove better efficacy (Section 3d).

"Across industries in developing and developed worlds, policy makers wrestle with how to weed out "low-quality patents", says the study by these authors titled Challenges to India's Pharmaceutical patents. It also notes that in the United States, the Hatch Waxman Law of 1984 provides financial incentives to generic makers to challenge patents that have been improperly issued by the US Patent Office.

However, Big Pharma says that despite the number of patents granted, there's no assurance if these patents will remain safe.

"Even after the patent is granted, it effectively gets nullified as we saw with Pfizer and Roche, says Ranjit Shahani, chairman Novartis India and also the president of Organisation of Pharmaceuticals Producers in India, the lobby group of Big Pharma.

Shahani says that it's pointless talking about the large number of patents granted, admitting that the numbers so far 'violated' may be small, but it shows that India is not ready to provide the ecosystem necessary for encouraging innovative products to be launched even though it had joined the WTO 18 years ago.

[Back to top]

Little support for pharma MNCs on patent issue

Sidhartha, The Times of India

Geneva, 27 April 2013: Multinational drug companies that are complaining against the Indian government and patent authorities using flexibilities under the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property rights are finding little support in the international community.

WTO director Pascal Lamy told TOI in an interview that despite the recent debate following the Supreme
Court ruling upholding the Indian Patent Office's decision against a patent for Novartis anti-cancer medicine Glivec, there was no question over the law.

Terming the judicial decision as "independent" review, Lamy said, "It's a decision taken by the judiciary and it's independent. The flexibilities are there and they have never been questioned by anyone in the WTO. After all, they all agreed. The question was not on the rule and they are structured specifically to provide access to medicines."

The statement will come as good news for Indian government which had come under attack from Big Pharma, although it maintained that the decision was in line with the Indian patents law and was aimed at checking "evergreening" and keeping drug price affordable.

Data shows that the MNCs may be making unnecessary noise as Novartis alone had received close to 150 patents in India, while Roche topped the list of medicine patents that add up to over 160.

In fact, the other decision related to grant of compulsory licence or waiving the patent rights for Nexavar, a renal cancer medicine, produced by Bayer Corporation had earlier generated more heat.

But the Patents Office and the Indian government had justified the move saying local player Natco Pharma will sell the same medicine for as low as Rs 8,000 compared to Bayer's patented drug that costs over Rs 2.8 lakh.

Officials said that foreign governments are under pressure from the civil society that are backing cheaper drugs to help fight dreaded diseases such as AIDS and cancer and India is seen to be at the forefront of the fight.

Following, Natco's victory, there is demand for issuing compulsory licence for at least three other cancer drugs.

[Back to top]

New bulk drug export norms to comply with EU standards

The Hindu

New Delhi, 23 May 2013: The Commerce and Industry Ministry, on Thursday, issued new guidelines for pharmaceutical makers to comply with the European Union (EU) Good Manufacturing Practice (GMP) standards. In a statement issued here, the Ministry says such a move will give a boost to pharma exports from India. \India has demonstrated its keenness to meet international requirements for exports of pharmaceutical products yet again by taking timely action for complying with the new procedural requirements of the EU for import of Active Pharmaceutical Ingredients (API) into the EU,. the statement adds. Active Pharmaceutical Ingredients, commonly referred to as bulk drugs in the industry, are used in making medicines. The new legislation, which will come into force from July 2, requires a written confirmation by a competent authority nominated by the government that the API has been manufactured in accordance with the EU GMP standards, the Ministry says in the statement. The authority will also give a written confirmation that the manufacturing facility, where the API is produced, is subject to control and enforcement of GMP standards and is equivalent to those in the EU countries. EU Directive

The EU had issued a new directive on June 8, 2011, to lay down a community code relating to medicinal products for human use and to ensure that the defective products do not reach consumers. The directive lays down a system of control over the entire supply chain for pharmaceuticals. \Various EU industry members have been expressing their concern over the ability of India to comply with the new procedure by the July 2 deadline. However, India is optimistic that its pharma industry will be able to meet regulatory requirements within the given timeframe. This landmark achievement underlines the seriousness of India towards pharma exports. Compliance by pharma industry with the EU directive is expected to have a positive impact on the companies as many of them are aspiring to export to developed countries, the statement adds.

[Back to top]

India's stance on compliance raises fears of copycat action

Amy Kazmin, Financial Times

29 May 2013: Throughout the 1990s, India was the bete noire of western pharmaceutical companies. It was a country that did not recognise drug patents and had a large generics industry churning out low-cost copycat medicines for domestic use and to export to other developing countries. India was expected to fall in line with global intellectual property rights standards in 2005 when New Delhi adopted a patent law ostensibly compliant with its obligations to the World Trade Organisation, which it joined in 1995. However, the refusal in April of the Supreme Court to grant a patent to Swiss group Novartis for its cancer drug Glivec is seen as the latest sign that Indian attitudes towards drug patents are little changed. The ruling follows a series of recent Indian decisions to override or revoke patents on cancer and hepatitis C drugs from "big pharma" companies such as Bayer, Pfizer and Roche. These rulings have raised hackles among western companies and fears that other emerging markets could soon follow India's lead. "We still don't have an ecosystem [in India] that encourages patents," Ranjit Shahani, managing director of the territory for Novartis, says. "Most of the patents granted are either revoked or violated, or a compulsory license is issued." Jason Rutt, a patent lawyer at Rouse, an intellectual property law firm, says: "The trend that has emerged is that India is an unfair place for innovative pharmaceutical companies. Pharmaceuticals are a global market and you would expect everybody to behave the same way in each country." India's parliament deliberately drafted the patent law to set a high standard for inventiveness and to ensure sufficient flexibility for generic companies to provide low-cost medicines if the original patented drugs were too expensive for local consumers. Indians buy around $13bn worth of drugs a year - tiny compared with the US at $400bn - but the market is growing by more than 10 per cent annually. India exports about $13bn worth of pharmaceuticals a year, about 40 per cent of which go to the US and the EU. India's law tries to prevent "ever greening" - the practice of companies renewing patents on old drugs by making minor changes - under section 3d, which states new patents can only be issued on previously known molecules if the modified versions show much improved efficacy. Unlike most countries, where only governments can seek a compulsory license authorising production of low-cost copies of patented drugs, India permits generics companies and patient groups to apply directly to patent authorities for such licenses. Western companies fear other developing nations, such as South Africa, may take the cue and dilute patent laws - making it tougher to obtain or extend patents and easier for patents to be overridden. That is worrying for the industry as it seeks growth in emerging markets to compensate for pressure on margins in advanced economies and tries to fund innovative drug research. "India has said: 'We are the thought leaders in terms of the ever greening of patents'," says Kiran Mazumdar-Shaw, founder of Biocon, a Bangalore-based biotech company. "Others are jumping into the fray saying: 'This is a good decision and we want to follow the path'."

Yet given the high stakes, India is likely to come under intense pressure to adhere more closely to global patent practices. Pfizer has appealed to the US government to make India's failure to adequately protect intellectual property an important issue in bilateral relations. The response of western governments has so far been muted. But India's Congress party-led government is considering a batch of compulsory licenses for costly cancer drugs. If those go ahead, western pharmaceutical companies will surely find a way to make their fury felt. "If you are a country that has a patent law, and a WTO commitment, don't make it a sham," says Mr Shahani. "There will be a point where the red line will be crossed."

[Back to top]

Commerce Dept bats for pharma exporters

Business Line (The Hindu)

New Delhi, 3 June 2013: The Commerce Department has come out in strong support of the Indian pharmaceutical industry facing criticism from the media on quality issues following a series of action taken by the US drug controller against top Indian companies. Debunking media reports on the suspect quality of drugs manufactured in India for exports, the Department has said that the pharmaceutical sector is a highly regulated one and the US continues to be a top buyer of Indian generic or off-patent medicines. "Statistics reported by Pharmexcil (drugs export council) indicates strong presence of Indian industry in the US and the reports of US FDA penalising Indian companies are only a small aberration," an official release of the Commerce Department said. Last month, Indian generic pharmaceutical manufacturer Ranbaxy was fined by the US Food and Drugs Administration (USFDA) for selling adulterated drugs in the US. Later in the month, the FDA issued an import alert against Indian drugmaker Wockhardt for violating manufacturing processes in its Aurangabad plant. Close on its heels, another Indian pharmaceutical major Hospira got a warning letter from the FDA following concerns about contamination of finished drugs at its manufacturing plant in Tamil Nadu. This led to a series of media reports, both in the country and abroad, raising questions on the quality of low-priced generic drugs being produced in India. The Commerce Department, in its release, said the allegations were not supported by facts. India is the fourth largest producer of drugs by volume in the world and continues to account for 15 per cent of generics sold in the US in volume terms. "The pharmaceutical sector is a highly regulated one and exports are heavily guided by various regulatory regimes of the importing countries. There is also a requirement for continuous monitoring of quality related aspects including complaints of sub-standard / falsified drugs from various countries," the release said. All organisations concerned in the Government are constantly interacting to ensure that India's image as a safe exporter is protected from all angles, the release said, adding that the Government is working with the industry on a "trace and track" mechanism which would enable monitoring of the supply chain possible at the tertiary, secondary and primary levels.

[Back to top]

Exim Bank to offer long-term finance to pharma companies

PTI

Mumbai, 15 July 2013: In a bid to boost export capability of Indian pharmaceutical companies, Export-Import Bank of India (Exim Bank) has decided to expand the scope of its finance to them for extended repayment periods.

Eligible export-oriented companies can avail finance from Exim Bank for a maximum repayment period of 10 years with a moratorium of upto 36 months, a statement issued here said.

Cost of compliance with USFDA norms is high as an USFDA approved API manufacturing facility can cost up to Rs 30 crore to Rs 40 crore and formulations manufacturing plant may cost about Rs 50 crore to Rs 60 crore while average gestation period for setting up these plants is about 18-24 months, the release said.

Despite having potential to increase their share in global exports, many Indian pharmaceutical companies suffer due to their inability to meet the stringent compliance norms of European countries and the USA.
According to Exim Bank, the size of the Indian pharma industry was around USD 29 billion in 2011-12, but in value terms, it constituted only 1.2 per cent of the global pharmaceutical market. To increase market share, the industry needs to penetrate deeper in the regulated markets which calls for accreditation of more facilities of Indian manufacturers.

To meet the expectations of the Indian industry and to cope with longer average gestation period to meet USFDA or other similar regulatory requirements, Exim Bank has decided to provide term finance to pharmaceutical companies, with maximum repayment period of 10 years, Exim Bank said.

[Back to top]