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Natco in patent war with BMS

Rupali Mukherjee, Times of India

Mumbai, August 1, 2012: Natco, which successfully managed to reduce prices of Bayer's cancer drug Nexavar by 97% through the country's first compulsory licence recently, is headed for another major confrontation. This time the tussle is with drug MNC Bristol-Myers Squibb (BMS) over Dasatinib, a crucial medicine used in chronic myeloid leukemia, and is expected to set yet another precedent for the Indian generics industry fighting against patent rights of MNCs. Natco's version of the drug costs around Rs 9,000 a month as against BMS' price of nearly Rs 1.5 lakh.

The key patent issue, which will come for hearing on Wednesday in the Delhi high court, will throw open a debate on granting "injunctions" against the generic industry, which in pharma parlance mean—orders to shut down the marketing and supply of low-priced generic medicines. Sources say Natco Pharma is also filing a contempt petition against BMS in the ongoing case over the Dasatinib drug. That's not all. On Wednesday, Natco Pharma will file a reply on the contempt petition filed by the drug MNC, rubbishing BMS' claims as "false assertions".

The case will be keenly watched by the pharma industry and public health experts, and may finally decide the availability of affordable Dasatinib, in the country. What seems to have triggered the current round of battle is Natco's recent launch of its version of Dasatinib after obtaining approval of the drug regulatory authority from Uttarakhand. BMS then managed to get an order cancelling the company's licence, which the generic company has now been able to undo, sources told TOI.

While Natco declined to offer comments on the issue, Bristol-Myers Squibb said it does not comment on ongoing litigation. Industry experts said the debate is now on the issue of injunctions and its interpretation. The crux of the dispute seems to be a Delhi HC order passed in June, which is being interpreted in different ways by the two companies. BMS is understood to have interpreted it as an injunction to refrain Natco from selling its drug, as it was "infringing" its patent. On the other hand, Natco is believed to have taken a stand that it is not an injunction as its drug is not infringing the BMS patent, sources say.

In their pursuit of intellectual property (IP) enforcement agenda, MNC drug companies normally want injunctions passed against generic firms. In such cases in the past, courts have considered the impact on access to treatment and balanced IP with health, before ordering an injunction. The June order by the court is part of the ongoing case which BMS filed against Natco in 2009, where it argued Natco had plans to make generic versions of Dasatinib.

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How an Indian Patent Case Could Shape the Future of Generic Drugs

Elliot Hannon, TIME

August 21, 2012, New Delhi,: India's rising global presence is often associated with its booming tech sector. But in many poor countries, India's role is that of a low-cost pharmacy. The country has become a leading supplier of affordable HIV/AIDS and Tuberculosis medications and is the second leading provider of medicines distributed by UNICEF in the developing world. This, however, may change.

On Wednesday, the Indian Supreme Court is set to hear a landmark patent case that could limit Indian companies' right to make inexpensive copies of pricey drugs developed and patented in the U.S. and Europe. The high-profile case — the first of its kind to reach India's highest court — has created a sharp divide between defenders of intellectual property rights, who demand that India do more to protect patented drugs developed in the West, and international aid groups who say excessive pharmaceutical patenting stifles generic competition that makes life-saving medication accessible to patients around the world. "This case is key because the scaling up AIDS treatment around the world has come from Indian made medicines," says Leena Menghaney, manager of Doctors without Borders' access to medicines campaign in India. "If they did not exist or were not available most governments would not have ventured into starting large scale AIDS treatment programs."

At the heart of the current dispute is the breakthrough cancer drug Glivec (Gleevec in the U.S.). Novartis, the Swiss drug company that helped develop the drug, is appealing the rejection of its 2006 patent application in India. In the U.S., where patent laws make it easier to register a patent claim, a monthly dose of Glivec can cost as much $5,000. In India, locally made generics cost patients $200.

In 1970, the Indian government disallowed the patenting of drugs, paving the way for Indian pharmaceutical companies to freely produce medicines pioneered by foreign drug companies at a fraction of the cost. Today, India's pharmaceutical industry is worth $10 billion a year and is one of the nation's largest sectors. The price of HIV/AIDS treatment, a first-line combination of stavudine, lamivudine, and nevirapine, which cost patients $10,000 a year in 2000, now sells for $150 worldwide, due primarily to Indian companies' low cost manufacturing. This rush of cheap drugs, which are also produced in the U.S. and Europe, now provides medication for 80% of the 6 million people receiving treatment in the developing world today, according to Doctors Without Borders.

In 2005, as a requirement of admission into the WTO, India reenacted patent protections for intellectual property, which included medicines. The Indian patent law, however, set the bar much higher than in the U.S. "India has time and again really expressed a strong preference for public health concerns over private patent rights," says Shamnad Basheer, a professor of intellectual property law at the National University of Juridical Sciences in Calcutta. Earlier this year, the Indian patent office reasserted its preference for generic competition, stating that if a patented drug in the Indian marketplace is not made widely available at a reasonable price, then generic manufacturers are entitled to make their own versions of the drug and pay a royalty to the patent holder.

Novartis' first attempts at patenting Glivec were rejected in India because it was considered to be an updated version of an existing Novartis drug, and therefore not eligible for patent protection. To protect consumers of low-cost medicines — and its pharmaceutical industry — Indian patent law aims to curtail a process known as 'evergreening,' in which pharmaceutical companies make sometimes minor improvements to an old medicine, allowing them to renew their patent. Under India' s tough standards, modifications that do not improve the efficacy of the drug are not eligible for extended patents.

Novartis cites modifications that make its new drug more effectively absorbed into the bloodstream, an improvement that was granted a patent in the U.S. in 2001. "All the drugs that come out from USDA are

not new molecules that are formed every year," says Ranga Iyer, former head of the Organization of Pharmaceutical Producers of India. "They are newer versions of penicillin and other drugs. Do we call that evergreening? No. There's a lot of work going on to do that." Iyer and other critics of India's patent laws claim they are stifling innovation on new groundbreaking drugs. "If you tell an innovator to set prices low enough that everybody can afford it, how can a company recover cost?" says Iyer. "If innovation is not protected, people will not innovate."

But international pharmaceutical companies aren't the only ones innovating. Generic drug manufacturers have also pioneered new treatments, creating pediatric HIV/AIDS drugs to cater to a segment of the market in developing countries that the big global drug manufacturers tend to overlook. Breakthroughs often come from publicly funded labs making the cost of research and development not as high as it seems, says Yusuf Hamied, chairman of the Indian pharmaceutical company CIPLA. "If you look at the world's top 50 drugs being sold today, they are being marketed and sold by companies that did not invent them," says Hamied. "I respect patents. I'll pay a royalty. But I shouldn't be denied the right to produce drugs for poor people at reasonable prices."

For both proponents and critics of India's patent laws, the supreme court's interpretation will set an important precedent. Foreign drug companies see India as a growing market, but perhaps more importantly as a potential model for other developing countries' patent regulations. If the court rules in favor of Novartis' claim, aid groups worry it will set off numerous new patent claims making it impossible for India to produce cheap generics of all sorts. But the court is unlikely to lower the standard thereby granting Novartis a patent, says Shamnad Bhasheer. The Indian laws were designed specifically to favor public health interests, and the court would likely only lower the standard if it believed that innovation, particularly by Indian companies, was being stifled.

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Will India keep Novartis at bay?

SushmiDey, Business Standard

New Delhi September 6, 2012: The outcome of the case will have huge ramifications.Much of the world — from patients to pharmaceutical companies to health activists and even governments — is watching an intense battle currently being fought by Swiss pharma giant Novartis in India's Supreme Court. The company wants to patent and sell its anti-cancer drug, imatinibmesylate, known as Glivec, in India but, so far, its efforts have failed. This is a high-stake contest, with serious implications for many of the above constituents. At the heart of the dispute is the Indian government's contention that Glivec, which treats myeloid leukaemia and some gastrointestinal cancers, is simply a retooled avatar of a pre-existing version patented in the US in 1993, and, therefore, doesn't deserve one here. The core issue, then, is over the degree of innovation required to obtain a patent in India. Section 3(d) of the Indian Patent Law prevents what the industry calls 'evergreening' — a process of churning out a version of the medicine with incremental modification and no innovation, simply in order to prolong the life of the patent.

The case has an acrimonious history. Novartis had filed for a patent in 2006, which was denied. Then, in 2007, the Madras High Court rejected Novartis' plea. The company also lost the case at the Intellectual Property Appellate Board, which rejected the company's appeal in 2009. Novartis, then, decided to take the case to the highest court in the country.

Is Novartis 'evergreening'?

Novartis describes the case as a crucible for the future of pharma investment. "Novartis is seeking clarity on the patent law in India," says Novartis India Vice-Chairman & Managing Director RanjitShahani.

"Knowing we can rely on patents in India benefits the government, industry and patients, because research-based organisations will know if investing in the development of better medicines for India is a viable long-term option."

Besides, Novartis cannot be accused of evergreening, says Shahani. According to the company, imatinibmesylate is the salt form of an older medicine, imatinib, and the new version represents a 30 per cent increase in the bioavailability of the medicine. "Scientists at Novartis developed the mesylate salt of imatinib and then the beta crystal form of imatinibmesylate to make it suitable for patients to take in a pill form, which would deliver consistent, safe and effective levels of medicine. This process resulted in a viable drug which revolutionised cancer treatment," says Shahani.

However, health activists argue that granting a patent on such incremental innovations would be violating the basic principles of inventive science. "The selection of a salt of the active ingredient with the purpose of improving bioavailability is well known in pharmaceutical art, and is an often-used form of what is known as 'evergreening'," says LeenaMenghaney of Medecins Sans Frontieres, which campaigns for access to essential medicines.

The drug has been granted a patent in 40 countries, including China, Russia, Mexico and Taiwan. The Supreme Court will hear final arguments in the case on September 11.

Pharmacy to the world

India provides half the world with AIDS medication, most of it in the generic form. Various developing countries, and now even developed ones, depend on India for low-cost, quality drugs, hence the country's

nickname, 'pharmacy to the world.' If Novartis wins its case, this spigot of cheap drugs to those who cannot afford them could be turned off.

One reason India has become such a big drugstore: Until 2005, India did not grant patents on medicines, which allowed drug makers to manufacture and sell generic versions at a much lower price. Eventually, India's stance on patents changed after it joined the World Trade Organization (WTO) and signed the trade-related aspects of intellectual property rights (TRIPs) agreement. From then on, patents would be applied in India as well. However, the Doha round gave a large degree of flexibility to governments to decide what kind of innovation was patentable, what should be the criteria included in 'novelty', what constituted an 'inventive step', and so on. There was another important clause from the Doha Declaration: "Each member has the right to grant compulsory licence and the freedom to determine the grounds upon which such licences are granted."

The government was, thus, able to legitimately award NatcoPharma a compulsory licensing deal that made it possible for the company to sell Bayer's anti-cancer drug, Nexavar, used in the treatment of liver and kidney cancer, for Rs 8,880, versus Rs 2.8 lakh under Bayer.

Arm-twisting

It is widely understood that the US and Europe are both petrified that Glivec and Nexavar are just the tip of the iceberg, and that if the patent suit was rejected, an avalanche of drugs that cost a fortune at home would continue to be sold to half the world in the form of cheap generics. Consequently, they have been exerting substantial pressure on India to stop these kind of decisions, calling them a violation of a global standard in intellectual property rights.

Pharmaceutical and biotechnology companies say that the enormous amount spent on researching and developing these drugs necessitate a rigorous policing of patents.

But, do they? Yusuf Hamied, the outspoken chairman of Cipla, says that over 50 per cent of blockbuster drugs sold by big pharma companies are actually developed by third-party researchers and then sold to the industry, allowing companies to make "super-profits," simply because of their comparatively low R&D spend on that drug. Industry sources say that Novartis collaborated with scientist Brian Drucker and the Oregon Health Science University for Cancer, where Drucker was a researcher, for the development of Glivec.

Nevertheless, health groups are worried that the US and Europe are trying to influence the matter through free-trade agreements (FTAs) like the one proposed between India and the European Union (EU).

According to AmitSengupta of Jan SwasthyaAbhiyan, most of the free-trade agreements have actually incorporated provisions that go beyond the TRIPs agreement signed at the WTO. Experts say that the India-EU FTA negotiation agenda, which is being discussed since 2007, includes medicine data exclusivity, intellectual property enforcement measures and patent term extension, among others, and, if it is enacted, it may enforce changes in the Indian patent law. "Once data exclusivity is granted, it would not be possible to make generic drugs, or even ensure the public use of patent rights, like compulsory licensing," Sengupta said.

Fallout

Health activists and patients say that secondary patenting is not only a threat to affordable medicines but also to innovation of meaningful drugs. "There is no bar on granting patents on new molecules, but by

giving patents to 'me-too' versions of older molecules, one can actually abuse the patent system. Why should a company go for new R&D if the threshold for the incentive is so low?' says Menghaney.

Then, there's the issue of what would happen to existing drugs that are made here on the cheap. "If the court decides in favour of Novartis then there is a possibility that various old cases where patents were denied on the basis of Section 3 (d) would be reopened. Besides, there are many drug patent applications from companies across the world, for drugs which are not made in India so far and generics for which are available here. It is possible that a large number of new patent applications can be made here then," Sengupta said.

That's not the best news for patients in India or in other developing countries who depend on cheap medicines to stay alive.

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India generics giant wins cancer drug patent case

AFP

September 9, 2012: Indian generics giant Cipla says it has scored a "landmark" court win in a patent challenge launched by Switzerland's Roche Holding over the Mumbai firm's version of a lung-cancer drug.

Delhi High Court Justice Manmohan Singh on Friday ruled that Cipla's drug, Erlocip, did not violate the Roche patent on its anti-lung cancer medication Tarceva due to its different molecular make-up.

"It's a landmark judgment in a patent case," Pratibha Singh, a patent lawyer who represented Cipla, told Mint newspaper. "The court has taken all efforts to analyse claims of both parties in terms of legality and scientific evidence."

No further details of the judgment were available.

The Cipla court case was being watched worldwide as it involved interpretation of stricter drug patent protection rules introduced by India in 2005 to comply with World Trade Organization regulations.

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

Roche's Tarceva is priced at 140,000 rupees ($2,533) for a month's supply, though it has discount schemes to make the drug more affordable for poorer people, the newspaper said, while Cipla's version is priced at 25,000 rupees.

It was not immediately known whether Roche would appeal the ruling.

The decision could act as a precedent for a string of other Indian generic firms also facing patent challenges from Roche over their versions of Tarceva.

The Delhi ruling came ahead of a high-profile battle expected to start Tuesday in India's Supreme Court over a bid from Swiss firm Novartis for patent protection for its top-selling cancer treatment drug Glivec.

The Novartis case could have significant implications for multinational drug firms, determining how much protection they will receive under India's patent law from cheaper generic rivals.

Novartis filed in 2006 a patent application in India for Glivec, used to treat blood and gastrointestinal cancer but a lower court rejected the request, saying the drug was a new formulation of an existing product.

The Novartis' challenge goes to the heart of India's patent act, which says a patent cannot be granted for an old drug unless changes make it significantly more effective.

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Bayer petition against Natco over manufacture of Nexavar dismissed

DivyaRajagopal, 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 makerNatcoto 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 drugmakerNovartis, 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.

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India: Balancing Public and Private Interests In The Intellectual Property Regime

PatralekhaChatterjee, Intellectual Property Watch

18 September 2012, New Delhi: In this month, there have been two court orders in India that underscore the complexities underlying the country's intellectual property regime. Last Friday (14 September), the Chennai-based Intellectual Property Appellate Board (IPAB) which is responsible for hearing appeals on patent applications, rejected a petition by German pharma major Bayer AG, seeking a stay on an order of India's Controller of Patents granting a compulsory licence (CL) to Indian generic drug maker NatcoPharma Limited, for a drug used to treat liver and kidney cancer. "We are happy. That is all I want to say at this point," M Adinarayana, Natco company secretary, told Intellectual Property Watch by telephone soon after the IPAB came out with its order.

Public health advocates have welcomed the order. "This decision once again affirms that courts can and should act in the interest of public health in the case of pharmaceutical products," LeenaMenghaney of Medecins Sans Frontieres' Access Campaign said in a public statement. The case is India's first compulsory licence (CL).

At the time of writing, Bayer's future course of action is not known. In May this year, in an emailed statement, Bayer told Intellectual Property Watch, "We will rigorously continue to defend our intellectual property rights which are a prerequisite for bringing innovative medicines to patients." James Love, director of Knowledge Ecology International (KEI), said in a statement, "It is possible and indeed likely that Bayer will continue to litigate this issue, which will soon be scheduled for another hearing on its merits, now that the stay has been rejected."

"It is important that the U.S. and German governments, and the European Commission, resist the temptation to interfere with the Indian legal system while this matter is litigated," Love said. "What is at stake is nothing less than the right to live."

"The decision," Love continued, "is also a test of the 2001 WTO Doha Declaration on TRIPS and Public Health, which says that WTO Members should implement their patent laws 'in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.'" KEI, an international nongovernmental group, has been working on the access to medicines movement for more than 20 years. TRIPS is the 1994 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

Other Key Cases

The IPAB order in the Bayer versus Natco case comes hot on the heels of the Delhi High Court ruling this month involving Cipla, another Indian generic drug maker, and two pharma multinationals, namely Swiss drug maker F. Hoffmann-La Roche Ltd. and the New York-based OSI Pharmaceuticals Inc. In this case, Cipla was being accused of infringing Roche's patent on cancer drug Tarceva, which Cipla sells under the brand name Erlocip.

The Delhi High Court in its order on 7 September held that Roche's patent on the drug is valid. However, it also said that Cipla did not infringe Roche's patent as it has been selling the polymorph B (variant of the basic drug compound) form of the drug which is known as erlotinib in generic terms. The two recent court orders provide a backdrop to another landmark case involving Indian generic drugmakers and a multinational pharma company that is in the news this week.

Today, 18 September, arguments in the final hearing of the much-talked about Glivec patent case were scheduled to resume in the Supreme Court. Swiss drug major Novartis AG is challenging the denial of patents to its blood cancer drug called by its brand name Glivec in India (Gleevec in the United States). In this case, Novartis is pitted against the Government of India, top Indian generic drug manufacturers (Natco, Cipla, Hetero, Ranbaxy) as well as the Cancer Patients Aid Association(CAPA). Newly appointed Additional Solicitor General ParasKuhad is representing the Union of India; CAPA's case is being argued by Anand Grover, another top Indian lawyer who is also currently the United Nations Special Rapporteur on the Right to Health. Other top Indian lawyers like Harish Salve are defending the generic companies.

The legal dispute in the Glivec case centres around a provision of India's 2005 patent law, called Section 3(d), which states that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant." The dispute brings to the fore a fundamental question: what is an "invention"? Or more precisely, how much innovation is required to obtain a patent in India?

The ongoing case in India's highest court is the final act in a legal battle that has been going on since 2006 when Novartis unsuccessfully pitched for a patent for Glivec. The case has already moved through various rungs of India's legal system including the IPAB and is now in the country's top court.

Final Arguments

The final arguments in this case began on 11 September in a packed room in India's Supreme Court, For many in the court room, it seemed like a crash course in chemistry as GopalSubramanium, a distinguished lawyer and formerly the country's solicitor general and now senior counsel for Novartis, quoted chunks from various chemistry textbooks and cited international conventions to make his client's case that Glivec was indeed a genuine medical breakthrough, had been granted a patent in nearly 40 countries and was deserving of a patent in India. Treatment with Glivec, the Novartis brand, costs about 1.2 lakh Indian rupees (or around USD 2,250) per month. The monthly tab for the Indian generic versions is below 10,000 Indian rupees (about USD 185).

Novartis says it is not fighting this legal battle for money but to vindicate its "honour". During the court hearing, the company's lawyers have repeatedly sought to draw attention to its patient assistance programme in India. Novartis claims that 85 per cent of the patients in India were being provided Glivec free of cost. "The purpose is not to make money from the poor. This is not the purpose but am I not entitled for patent for our drug? We are fighting the case on principle," Subramanium said in the Court last week. Public health advocates point to the discretionary nature of such assistance programmes.

Novartis lawyer Subramanium has argued in court that the grant of patent to Glivec would not hurt public health in India as "authorities were free under the law to direct the company to compulsorily part with licences relating to the drug any time three years after the grant of patent," as the legal correspondent of one Indian newspaper pointed out in his report.

The flexibility issue is a severely contested territory. In a report titled "India's patent laws under pressure" this month in The Lancet, one of the world's most prestigious medical journals, Peter Roderick and Allyson M. Pollock pointed out: "The Obama Administration has been consistent in its efforts to stop compulsory licences, with the Deputy Director of the US Patent and Trademark Office describing the granting of this licence as the "most egregious" example of anti-TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) behaviour. "

But significantly, these provisions of India's IPR regime are inspiring health and IPR activists in other developing countries.

"The Treatment Action Campaign (TAC) and Medicins Sans Frontieres are currently lobbying for South Africa to adopt a number of the public health safeguards that are upheld in India's law. In our campaign, we have looked at the Indian laws as a model of pro-public health interpretation of TRIPS," Catherine Tomlison of TAC's Fix the Patent Laws Campaign told Intellectual Property Watch.

"In our campaign we are calling for South Africa to reject new use and new formulation patents, as rejected in section 3(d) of India's patent laws," Tomlison said. "Currently South Africa does not exclude new uses and new patents from patentability and as a result many medicines are under patent and extremely expensive in South Africa, where affordable generics are available in India."

"We are also calling for South Africa to require examination of patent applications and to allow for opposition by third parties. We have looked extensively at the Indian experience in implementing examination and opposition as well as the financial and capacity requirements. The Indian experience has shown us that implementing patent examination not only pays for itself with user fees but also generates a significant amount of money for government that can be put back into service delivery. We have been informed by South Africa's Department of Trade and Industry that the IP policy should be made available this month and that the public comment process will last three months," she added.

Other African countries, including Botswana and Swaziland, are also in the process of amending their laws to better utilise the flexibilities allowed under TRIPS to protect health. Botswana, for example, has adopted pre-grant opposition.

A spokesperson for MSF told Intellectual Property Watch that MSF has chosen not to comment on the Novartis hearings because it felt that doing so might interfere with the judicial process, but the medical and humanitarian NGO was taking a very keen interest in the case and awaiting the outcome of the court's decision.

Speaking on the wider context, however, Michelle Childs, director of policy advocacy for the MSF Access Campaign, told Intellectual Property Watch: "It's now more important than ever that developing countries use all the public health flexibilities in international trade law; this includes effective compulsory licensing provisions to ensure access if a patent has been granted, but medicines are unavailable or priced out of reach for those who need them. Countries need all the tools at their disposal - it is not an either/or choice; you need preventative measures to stop monopolies being wrongly granted, as well as an antidote to high priced patented medicines."

Will India strike the balance between patents, patients and profits? It is hard to predict. The ongoing cases raise fundamental questions about the definition of "invention", what qualifies for a patent under India's IP regime and the challenges of striking a balance between public and private interests in an emerging economic power, where, paradoxically, the vast majority are still not covered by health insurance and where most people have to pay for their own treatment.

The final outcome of the cases may not be known for weeks, possibly months. But one thing is clear: they could change the game in the health care sector as well as the intellectual property rights regime in India and across the developing world.

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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 and2010.

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 LeenaMenghaney, campaign co-ordinator (India), Medecins Sans Frontieres, which campaign for access to essential medicines across the world. Agrees AmitSengupta, the co-convenor of Jan SwasthyaAbhiyan, 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.

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European Union wants India to allow extended patent life for drugs

AmitiSen, 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.

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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 NatcoPharma 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.

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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.

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India's patent fix

SushmiDey, Business Standard

4 November 2012: While the government has been battling patents on traditional Indian remedies abroad, the Patent Office back home has granted a handful of such patents, causing an embarrassment of sorts. The Department of Industrial Policy and Promotion in the Union Commerce Ministry recently revoked a patent granted by the Indian Patent Office to Avesthagen, the Bangalore-headquartered life sciences company, for a diabetes medicine made from extracts of jamun, lavanpatti and chandan (sandalwood) because these indigenous plants are an integral part of the traditional medicinal systems (Ayurveda, Unani and Siddha) and have been used from time immemorial for diabetes management. The government used a "rarest of rare" provision in the Patents Act to quash the patent because it was "mischievous to the state and generally prejudicial to the public". The company had argued, The Times of India reported, that the three plants were chosen from a long list of 100 plants and a short list of 10 plants, there was considerable research and innovation in the invention, the patent validates the traditional medicinal systems and farmers would benefit from it. But that didn't cut much ice with the department.

That's because the patent was turning out to be quite an embarrassment for the department. The government has for long been resisting attempts globally to patent traditional Indian knowledge. It has successfully fought attempts to patent haldi and neem, which have for centuries been used by Indians to cure wounds and diseases. For instance, in 1997, the Council of Scientific and Industrial Research had challenged and won a case against a US patent on turmeric given to a research group from University of Mississippi Medical Center. In fact, the government had got the European patent authorities to turn down a similar request by Avesthagen two years ago. A patent to Avesthagen on its home turf would have weakened India's case in international forums. That's why it had become essential to revoke the Avesthagen patent. After this case, the government has realised, there might be four of five such patents granted by the Patents Office using indigenous plants and fruit like amla, methi, karela (bitter gourd) and ashwagandha. It is not difficult to imagine what will be the fate of these patents.

India has argued that traditional knowledge cannot be patented because that will interfere with the lives of ordinary people. Those who use traditional medicine are often farmers and workers in villages, tribes or forest dwellers — poor people who cannot pay for patented cure. It is also a politically sensitive matter. Any government that allows such patents will in no time be accused of selling out to unscrupulous drug makers. Still, drug makers and life-sciences companies are always on the lookout for traditional knowledge. This is perhaps because the efficacy of these herbs and plants is already proven, and that cuts the go-to-market time as well as research costs. With the pipeline for new drugs almost dry, this helps in a big way. The Indian pharmaceutical market is pegged at almost 60,000 crore — it would be considerably bigger if the traditional medicines are included. Civil society activists call it bio-piracy.

India ventured pretty late into the world of intellectual property protection when compared to other countries. The country signed the World Trade Organisation's agreement on Trade Related Aspects of Intellectual Property Rights in 1994 and changed its patent law only in 2005, a cushion of over 10 years. Till then, only process patents were valid in the country; thus, you could make any product in the world so long as you used a different method. From January 1, 2005, product patents also began to be recognised. Since then, India has been granting patents merrily: as many as 3,488 drug patents have been registered with the Patent Office between 2005 and 2010. The figure is huge as compared to other emerging economies like Brazil, Argentina, and Columbia. A research paper, Pharmaceutical Innovation, Incremental patenting and Compulsory Licensing, by Carlos M Correa, a professor at the University of Buenos Aires, points out that just 278 patents were granted in Brazil between 2003 and 2008, 951 in Argentina between 2000 and 2007, and 439 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 numbers suggest that India has become quite popular amongst patent seekers, though it may not always be for the right reasons. Balancing the two objectives of promoting innovation and improving availability and affordability, India has in recent years granted a number of patents for products whose novelty can be questioned: a broom, a wound dressing, a permanent calendar, a toilet seat cover, a belt buckle and a sanitary napkin. The charge is that patents are often granted to known substances with minor modifications or a mixture of such substances, which is not really innovation. The Avesthagen case has brought the spotlight on the issue. In the past also, patent was granted to an edible herbal composition comprising mixtures of at least two Indian herbs selected from a group comprising jamun, karela, baingan (eggplant) and gurmar for their efficacy in reducing sugar levels. Strictly speaking, the Patent Office ought to consider each patent application on merit and need not pander to the whims and fancies of the Commerce Ministry. The issue is if the patent law explicitly lays down that traditional knowledge cannot be patented and if that condition is being flouted.

"The Indian patent law does not allow patents on traditional and combination medicines but the patent examiners are influenced by jurisprudence of other countries and do not interpret the law in Indian public interest in the Indian context," says KM Gopakumar of Third World Network. Gopakumar points to Section 3 (j) of the Indian Patent Act which says that a plant or animal, in whole or any part of it including seeds, other than micro-organisms, is not patentable. "Even though there is no explicit exclusion of genes or DNAs under this section, it is clear that this exclusion includes gene, cell lines, DNA et cetera," he says. However, gene patents continue to exist in India, mainly because the patent examiners are of the view that a genetically modified gene sequence or amino acid sequence is novel when it involves an inventive step and has industrial application. This anomaly, or leniency, could be the source of the government's current embarrassment.

What could be termed another abnormality in the system is that through patents are examined and granted by the Patent Office, they cannot be revoked by the same. A patent in India can be revoked only by the government. According to intellectual property rights experts, there are various gaps — technical and legal, in the patenting system that permit such irregularities. "Even if a patent is granted by the Patent Office, there is no set mechanism to rectify it," says an expert. Earlier, there was a provision under the law which allowed the Patent Office to suomotu revoke a patent if within one year of the grant evidence against the patent is cited. However, this was deleted in the law which came into place in 2005. Besides, experts also complain that the training programme of patent examiners itself is flawed. "Our patent officers are being trained by officials from the US and Europe, then how can you expect them to look at things from Indian perspective?" says Gopakumar.

All of this has not gone down well with drug makers. Their genuine innovations, they allege, are unnecessarily being called into question by vested interests. Meanwhile, it seems this fight over patents will only get worse. The Intellectual Property Appellate Board, on Friday, struck down the patent given in 2006 to Roche's hepatitis C drug, Pegasys. The board cited lack of evidence that the drug was any better than existing treatments and its high cost as the reasons for its decision. This was the first product patent granted in the country. Sankalp Rehabilitation Trust, an advocacy group for inexpensive medicine, has had challenged the patent, saying the drug was costly and gave the Swiss drug maker monopoly in the market. Earlier, in March, India had given homegrown drug maker Natco the "compulsory licence" to make cheaper copies of Bayer's cancer drug Nexavar. Novartis is battling in the Supreme Court an earlier decision to refuse it a patent on cancer drug Glivec.
It could get worse.

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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.

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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.

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Drug pricing: Govt decides to bypass three patents

ReghuBalakrishnan, 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 NatcoPharma 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.

RanjitShahani, 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 EmcurePharma. 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.

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

Sanjay Vijayakumar & DivyaRajagopal, 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 NatcoPharma 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 PrabhaSridevan, 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 LeenaMenghaney, 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 SujayShetty, head of the life sciences practice at PricewaterhouseCoopers.

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U.S. groups criticize India drug, tech, farm policies

Doug Palmer, Reuters News

Washington, 13 March 2013: U.S. industry groups on Wednesday called for the United States to increase pressure on India to reform high-tech, agricultural and pharmaceutical policies they said block U.S. exports and damage patent rights.

"India has essentially created a protectionist regime that harms U.S. job creators" in favor of the country's generic drug manufacturers, Roy Waldron, chief intellectual property counsel for Pfizer, said in testimony to the House of Representative Ways and Means trade subcommittee.

Waldron complained that last year India revoked Pfizer's patent for a cancer medicine, Sutent, "to allow Indian generic companies to manufacture and sell generic copies."

India also abuses compulsory licenses, which governments are supposed to use in limited circumstances to suspend drug patents, for the benefit of its domestic firms, he said.

Waldron urged U.S. government officials to vigorously pursue those concerns in direct talks with India and to "review all available policy tools" to pressure the world's largest democracy to better protect U.S. intellectual property.

The hearing comes as U.S. trade benefits for India are up for renewal under the Generalized System of Preferences program, which waives duties on thousands of goods from developing countries to help them create jobs.

"I want to ensure that U.S. job creators can compete there on a level playing field," said Representative Devin Nunes of California, the Republican chairman of the Ways and Means trade subcommittee, noting India's market of 1.2 billion people should offer huge potential for U.S. companies.

WTO Option

India is the largest recipient of benefits under the GSP program, which expires on July 31. It exported $3.7 billion worth of goods to the United States under the program in 2011, or roughly one-tenth of its total exports to the United States.

It does make sense to examine whether India should be removed from the GSP program given its growth in recent years, but it might be a mistake to portray that as an effort to punish the country, said Arvind Subramanian, a senior fellow at the Peterson Institute for International Economics.

"I would be a little hesitant about using that" since the move is probably not strong enough to change India's behavior, but would be seen in New Delhi as trade retaliation and damage the United States diplomatically, Subramanian said.

A better but more time-consuming option would be challenging more of India's policies at the World Trade Organization in the hope of winning rulings that would increase pressure on the government to reform, he said.

Last month, the U.S. Trade Representative's office filed a WTO case against elements of India's national solar energy program that it said discriminated against foreign producers in violation of a global trade

rule.

It has also challenged India's restrictions on U.S. poultry in a case that is to be decided by the end of this year.

Procurement Pains

Meanwhile, U.S. technology companies are frustrated by Indian government procurement policies that favor Indian electronics products over foreign, Dean Garfield, president of the Information Technology Industry Council, told the panel.

"The PMA (preferential market access) policy certainly does not bode well for our industry, threatening to shut us out of a significant portion of the Indian ICT (Information and communications technology) market," Garfield said.

U.S. companies are also disappointed that India is sitting on the sidelines in talks in Geneva aimed at expanding the 1996 Information Technology Agreement, which eliminated duties on scores of high-tech goods, he said.

India also has steep agricultural tariffs and regulatory barriers that keep out many U.S. farm exports, said Allen Johnson, a former U.S. chief agricultural trade negotiator.

Last year, India's agricultural exports to the United States topped $5 billion, a ten-fold increase since 1995, Johnson said. In comparison, U.S. farm exports to India last year were only $900 million, well below their potential, he said.

India's reluctance to reduce its farm tariffs has frustrated the United States in the long-stalled Doha round of world trade talks, Johnson said.

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BDR Seeks Compulsory Licence for Cancer Generic

DivyaRajagopal, 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 NatcoPharma 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.

ShamnadBasheer 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.

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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 UnniKarunakara, 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.

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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.

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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.

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

DivyaRajagopal, 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 NatcoPharma 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 ShamnadBasheer, 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 BhavenSampat 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 RanjitShahani, 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.

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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.

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Europe upholds Darjeeling tea's authenticity

Sutanuka Ghosal, Economic Times

7 Sep, 2012, KOLKATA: There's good news for the producers of Darjeeling tea, the champagne among tea varieties. The European Trade Council and the German Tea Association have agreed to confer the protected geographical indication (PGI) status on Darjeeling tea, the first commodity from India to get such a tag. This implies that the brew produced only in Darjeeling can be sold as Darjeeling tea in the European Union.

"As of now, blenders in EU countries generally mix 49% of any tea with 51% of Darjeeling tea and still sell it as Darjeeling tea. But it has now been decided that only those packets that contain 100% Darjeeling tea can be sold as Darjeeling tea," Tea Board chairman MGVK Bhanu told ET from Germany. The packets will also have the Darjeeling logo and PGI logo labelled on them.

Darjeeling was granted the geographical indication status by the European Union in October last year, authenticating its origin. However, the implementation of this status involves a phasing-out period within which products which do not conform to the law and are not authentic from the hill district of Bengal will be driven out of the market.

It has also been decided that the European Trade Council and the Darjeeling Tea Association along with the Tea Board will jointly promote Darjeeling tea in the European market.

According to the EU notification, the blenders in Europe have been handed out a caveat in the sense that only those who had products in the market five years before October 14, 2009, can continue selling their blended products as Darjeeling tea for the next five years. "There is hardly any Darjeeling tea left with the European buyers. Henceforth, only Darjeeling tea will be available in Europe," said SS Bagaria, chairman, Darjeeling Tea Association.

Industry officials estimate that around 40 million kg of tea gets sold as Darjeeling tea across the globe every year. In this context, the EU's decision is considered important. The process of granting a geographic indicator, which means that only the produce of a particular area can be sold by its generic name, started with India according the GI status to Darjeeling tea in 2003.

Since, it was mandatory to get home protection, the Indian government passed a Geographic Indicator and Protection Act in 1999 after which Darjeeling tea was given the GI status in 2003. The granting of GI status in the home country - India in the case of Darjeeling tea - is only the first step towards the protection of the commodity's generic brand.

In 2007, the Tea Board of India and the Darjeeling Tea Association invoked a provision in the EU Commission Regulation 5001 to ask Brussels to accord the PGI status to Darjeeling Tea.

"We have also made an application before the Japanese Property Right Organisation for granting of the Production of Regional Origin (PRO) in Japan and also before the Trade Administration Authority (TAA) of USA for granting of Community Collection Mark in the USA," said Sanjay Bansal, chairman of Ambootia Group. He added that PRO and TAA were similar to the PGI tag.

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Darjeeling tea growers get protection from European Union

Jim Yardley, Economic Times

Darjeeling, 18December 2012**:** Among connoisseurs, few teas surpass a good Darjeeling. The smooth and mellow taste commands a premium price, and the name itself evokes a bygone era when the British first introduced Chinese tea plants here in the Indian foothills of the Himalayas.

To Anil K Jha, the superintendent of the Sungma Tea Estate, all this would be extremely good for business, except that much of the tea sold globally as "Darjeeling" is not grown here. Foreign wholesalers often put the name on a blend of the real stuff and lesser teas. And in some cases, growers elsewhere simply slap a Darjeeling label on their tea.So Jha and other Darjeeling growers have followed the example of Scottish whisky distillers and French wineries, winning legal protection for the Darjeeling label under laws that limit the use of certain geographic names to products that come from those places.

In a decision this year, the European Union agreed to phase out the use of "Darjeeling" on blended teas. Now, just as a bottle of Cognac must come from the region around the French town of Cognac, a cup of Darjeeling tea will have to be made only from tea grown around Darjeeling.

"That flavor, that uniqueness that comes from here - it is nowhere else," Jha said as he stood among manicured tea bushes on a hillside about 5,000 feet above sea level, near the border with Nepal. "People have tried to replicate it, but have failed," he said.

The uniqueness of Darjeeling as a place certainly seems beyond dispute. On clear days, the white peaks of Kanchenjunga, the world's third-highest mountain after Everest and K2, floats over the hilltop city like an ethereal fortress. Beyond the noisy clamor of the city, many of the steep surrounding foothills are carpeted with tea estates, some planted more than 160 years ago when a British surgeon found that tea bushes thrived in the region's alpine setting.

The mountainous terrain also limits production. India produces almost 2 billion pounds of tea annually, more than any other country, but Darjeeling accounts for only about 1 percent of that output. The Darjeeling district has 87 certified tea gardens, as they are locally known, producing about 20 million pounds of tea every year, and the potential for expansion is almost nil.

That is why local tea growers grew annoyed that as much as 88 million pounds of tea were being sold as Darjeeling on the global market each year.

"Darjeeling tea has always been more expensive," said RanenDatta, a longtime adviser to local tea growers, noting that the wholesale price is about five times that of ordinary teas. "And we found that sellers all over the world were selling tea under the name Darjeeling."

And not only tea: A French company that makes lingerie has fought legal battles with the Tea Board of India to keep using the name."This brand name, Darjeeling, was being misused," Jha said. "The basic interest of Darjeeling was being killed."

Local tea growers had already fought to save their product from the vagaries of Cold War politics. During the era of British rule, Darjeeling tea was mainly shipped to Europe, which remained the primary market after Indian independence in 1947, when Darjeeling's tea gardens shifted from British to Indian ownership.

But as India drew politically closer to the Soviet Union, a deal to sell tea to Moscow ushered in a dark

period for Darjeeling. The Soviets ordered in bulk and mixed Darjeeling with pedestrian teas from Soviet satellite countries so it could be marketed more widely.

"Russians were not particular about the quality of Darjeeling," Datta said. "They took it if it was clear and black."

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We must protect traditional Indian products in the international market to boost growth

A.K.Kanungo, Times of India

21 January 2013: The recent slowdown in India`s exports calls for a re-examination of policies essential to propel India's foreign trade. One such policy is the recognition of geographical indications (GIs). What is currently under debate is the `unequal provision or treatment' meted out to developing countries. As a result they are unable to capitalise on the true potential of GIs.

These are a type of industrial property that identifies a good as originating from a particular place with a given quality, reputation or other characteristic of the good being attributable to its geographical origin. Much like trademarks, the economic rationale of GI is based on the `information asymmetry` between buyers and sellers in the market and the role of reputation, conveyed through distinctive signs, in tackling such asymmetry.

Thus, GI acts as a signalling device helping the producers to differentiate their products from competing products in the market and enabling them to build reputation and goodwill around their products, fetching a premium price. For instance, champagne originated from a place in France and has been recognised as a product whose reputation for quality or authenticity is intimately linked to its geographical origin. The product has not only emerged a major product in its export basket but also helps in promotion of tourism and cultural heritage.

There are many such examples in India â€" such as Kanjeevaram silk saris and PochampallyIkat â€" that can very easily contribute to Indian exports and soft power. But for them to contribute to foreign exchange, protection and equal treatment for developing countries like India need to be re-emphasised and negotiated. This will also protect the exclusiveness and heritage of such goods and the traditional skills that go into making them.

The issue has gathered momentum with the recognition of the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) of GIs as a form of intellectual property right. This enhanced the marketabi-lity of these products and demonstrated that GIs have great potential to play a major role in trade between countries.

It further increased the commercial significance of GIs, not known to many developing countries like India. This is not to say that GIs were insignificant in trade earlier. Quite to the contrary, the immense revenue potential of GIs necessitated their cross-border protection and thus was included in the ambit of the TRIPS agreement.

Article 22 of the agreement, which forms the core of GI protection, provides for a general level of cross-border protection of GIs in the course of trade. However, what distinguishes developed countries from India is a special provision. This special provision was made under Article 23 of the TRIPS agreement for protection of GIs in the form of wines and spirits. The major claimers of this kind of protection were the European countries with their very long tradition in making such products.
This special treatment to wines and spirits is developed country-centric. Developing countries, including India, have raised this issue in the ongoing Doha Round and in the recent meetings at the WTO. They seek the same higher level of protection for all GIs as was given under Article 23 for wines and spirits. Many handicraft products such as Kanjeevaram silk saris, PochampallyIkat, Chanderi fabrics, Madhubani paintings, Mysore Jasmine, Bidrimetalworks have been registered as GIs in India. Many food products and agricultural products are also registered. In fact, six foreign products have also been registered as GIs

in India. Today, more than 170 Indian products have been recognised as GIs in India. Evidently, the potential is immense.

It needs to be reiterated that the benefits of the registration of a product as GI are actually realised only when these pro-ducts are effectively marketed and protected against illegal copying. Effective marketing and protection require quality assurance, brand creation, post-sale consumer feedback and support, prosecuting unauthorised copiers, etc. Thus, the registration is only the first step in creation of a market for the GI.

Further, this protection first gains significance in the domestic context before international protection becomes relevant. However, for internationally recognised products like Darjeeling tea, which have an expansive export market, international protection is of crucial importance.

There is a direct link between the cultural diversity that exists in India with its varied peoples, traditions and flavours and the legal protection of GIs that the products of cultural activity can have. There is also a link to local communities, in towns and villages, which possess traditional knowledge of making these products which in themselves are part of their traditional cultural expressions.

Thus, legal protection to GIs also extends to protection of traditional knowledge and traditional cultural expression contained in the products. In doing so, not only are livelihoods protected but employment gene-ration is also encouraged. In fact, owing to the premium prices that many GIs command today, it is possible to preserve many traditional skills.

Since many of these GI pro-ducts belong to the textile and tea areas and are largely exported to EU countries, there is merit in negotiating to implement equal treatment for Indian GI products. After all, the EU is still India`s largest trading partner. GIs have the potential to be an engine for our growth. Indian policymakers should heed this and negotiate harder to give Indian GI products their true reward.

The writer is with the Indian Institute of Foreign Trade, New Delhi.

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Amul wants protection for dairy farmers

Anand, Business Line (The Hindu)

27 March 2013: Amul, the iconic milk brand of the country's largest dairy co-operative, Gujarat Cooperative Milk Marketing Federation (GCMMF), on Tuesday, urged the Union Commerce Ministry to take care of farmers' interests while negotiating the proposed free trade agreement with the European Union. It urged the Government to have a re-look at the proposed EU-India FTA.

Import duty

Amul strongly opposed for providing any advantage in import duty on certain dairy products. R.S. Sodhi, Managing Director of GCMMF that which markets Amul, has written to the Union Minister of Commerce along these lines recently.

In a statement here, Amul said it is important to note that the EU does not permit import of dairy products from India in the name of SPS (Sanitary and Phyto Sanitary) measures, saying that Indian milch animals are not maintained, according to the EU standards and, hence, the dairy products are not safe for consumption.

Interestingly EU also subsidises its milk farmers by giving various incentives on export of their dairy products which actually make their products cheaper than the cost.

EU wants to export such subsidised dairy products to India, without giving access to the Indian dairy products to its own market which has a large NRI population, he said.

GI protection

The EU demands also reveal that it wants protection of some of the cheeses such as Gouda, Feta and Emmenthal under the Geographical Indication (GI) protection, meaning that Indian cheese producers cannot give such names to their cheese.

At the same time, the EU wants to sell Indian ethnic products such as paneer and lassi in their own market without giving any similar protection to India.

It is also noteworthy that in areas where India is richer, for example in traditional knowledge such as Ayurvedic medicine and genetic resources such as neem, the EU is refusing to take the measures to stop bio-piracy (i.e., protect biological resources by patenting them without paying royalties).

Essentially, Sodhi said, the EU is asking India to give more monopoly protection in the areas (GIs) where it has more intellectual property.

This will cost Indian consumers (who have to pay higher prices) and Indian producers (who will no longer be able to clearly identify their products and so are highly likely to lose sales) who are already in nascent stage of agro food processing industry.

He pointed out that the EU is actually anticipating a huge market opportunity in India once the comprehensive FTA is ratified. India needs to be "extremely cautious" at this approach of the EU to ensure that the country's interests are not hampered.

Sodhi requested the Ministry to take up the matter ‘very strongly’ against this protection, especially when majority of 80 millions Indian farmers (many of whom are marginal and landless) are very much dependent on milk business by keeping one or two cattle which provide their daily livelihood.

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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.

LeenaMenghaney, 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.

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India calls for binding treaty on traditional knowledge

Business Line (The Hindu)

New Delhi, 8 April 2013: India has called for a binding treaty to protect traditional knowledge at the World Intellectual Property Organisation so that action can be taken by countries against infringement of such rights by others.

Commerce Minister Anand Sharma, who addressed a high-level policy dialogue at WIPO in Geneva on Monday, made a case for flexibilities for developing countries in meeting their intellectual property commitments to address social challenges.

WIPO is a specialised agency of the United Nations that promotes protection of intellectual property (IP) rights world over through cooperation between countries.

The Minister said that countries of the South, which bear a disproportionate burden of poverty, hunger and disease, give priority to provide affordable healthcare solutions for their citizens. Political leadership is faced with an ethical dilemma and tries to find creative solutions which would strike the right balance, he said.

“It is my belief that while all countries are obligated to honour their international commitments, inherent flexibilities must be provided to developing countries to address these pressing social challenges,” he said.

Sharma maintained that the legislative regime in India which circumscribes the IP rights is a robust one and strikes a balance between the interests of the IP creators and the larger interests of IP users.

“It fosters technological innovation by providing inherent incentives through exclusive private Intellectual Property Rights, but also recognises the need to protect the interest of users’ rights,” said the Minister. Highlighting India’s initiative of creating a unique digital library of traditional knowledge which has over 250,000 entries specifying the source and the efficacy of each product, Sharma expressed concern about extensive bio-piracy through patents being awarded for traditional knowledge.

“India has been at the forefront for bringing this agenda on the negotiating table and for the last one decade, we have been trying to build a consensus for a binding treaty on traditional knowledge. I hope that WIPO shall be able to bring these negotiations to culmination,” the Minister said.

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Global trademark registration: India joins Madrid Protocol

PTI

New Delhi, 8 April 2013: India on Monday joined the Madrid Protocol which will enable domestic companies and entrepreneurs to obtain cost effective global trademark registration.

Commerce and industry minister Anand Sharma, who is in Geneva, said: "We recognize that this instrument will provide an opportunity for Indian companies, which are increasing their global footprint, to register trademarks in member countries of the protocol through a single application, while also allowing foreign companies a similar dispensation."

Sharma is at the World Intellectual Property Organization (WIPO) headquarters for a high level policy dialogue.

The treaty will enter into force with respect to India on 8 July, according to the WIPO statement.
It said that Sharma on Monday deposited his country's instrument of accession to the Madrid Protocol for the International Registration of Marks at WIPO, bringing the total number of members of the international trademark system to 90.

The Madrid System for the International Registration of Marks offers trademark owners a cost effective, user friendly and streamlined means of protecting and managing their trademark portfolio internationally.

Welcoming India's accession, WIPO director general Francis Gurry said that New Delhi's participation in the Madrid system gives brand owners around the world the ability to extend their protection to the important Indian market, through a single, simplified and cost-effective procedure.

It said that India is the 14th of the G-20 economies to accede to the Madrid Protocol.

"India's accession to the international trademark system, as with the recent accessions by Colombia, Mexico, New Zealand and Philippines, signals an era of significant geographical expansion of the Madrid system, which offers greater benefit to right holders worldwide," Gurry added.

It said that 2012 saw the highest number of international trademark applications ever filed under the Madrid system, with 44,018 applications.

Under the WIPO-administered Madrid system, a trademark owner may protect a mark in up to 88 countries plus the European Union by filing one application, in one language (English, French or Spanish), with one set of fees, in one currency (Swiss Francs).

Trademarks are a key component of any successful business marketing strategy as they allow companies to identify, promote and license their goods or services in the marketplace and to distinguish them from those of their competitors, and cement customer loyalty.

A trademark symbolizes the promise of a quality product and in today's global and increasingly electronic marketplace, a trademark is often the only way for customers to identify a company's products and services.The international trademark system is governed by two treaties, namely, the Madrid Agreement Concerning the International Registration of Marks (1891) and the Madrid Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989).

Meanwhile, a commerce and industry ministry statement said Sharma in Geneva has defended the flexibilities provided under the WTO for developing countries in honouring their intellectual property commitments to meet their social challenges.

Sharma said the developing countries which bear a disproportionate burden of poverty, hunger and disease for historical reasons have an aspiration to provide affordable healthcare solutions for their citizens.

Quoting Sharma, the ministry statement said: “It is my belief that while all countries are obligated to honour their international commitments, inherent flexibilities must be provided to developing countries to address these pressing social challenges”. The minister said that India always strikes a balance between the interests of the IP creators and the larger interests of the IP users. “It fosters technological innovation by providing inherent incentives through exclusive private IPRs, but also recognises the need to protect the interest of users’ rights,” he said.

Further, the minister raised the issue of the intellectual property rights (IPRs) associated with genetic resources, traditional knowledge and folklore such as curative aspects of neem and haldi. “India has been at the forefront for bringing this agenda on the negotiating table and for the last one decade, we have been trying to build a consensus for a binding treaty on traditional knowledge. I hope that WIPO shall be able to bring these negotiations to culmination,” he said.

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U.N body calls for balanced 'social benefit' IP regime

The Hindu

Istanbul, 24 April 2013: The World Intellectual Property Organisation (WIPO), a United Nations body, has pointed out the need for a second interpretation of global intellectual property law, one that balances social benefit with the need to protect investment.

This balancing could help reconcile the differences between developing nations such as India, and the concerns of multi-national companies and developed nations, according to Francis Gurry, Director-General of the WIPO.

"I think there are two definitions of intellectual property. One has been defined by the need to innovate, and, therefore, the need to protect investment. The second way is that it should not solely be about protecting the interests of investment, but instead should be about balancing social benefit with the whole mix," Dr. Gurry told The Hindu here on Wednesday.

He was here to attend the 7th Global Congress on Combating Counterfeiting and Piracy.

Dr. Gurry's comments come at a time when the Supreme Court's recent decision to deny Swiss major Novartis a patent extension for cancer drug Glivec has prompted some multi-national drug firms to re-think their India research and development investments.

Replying to a query, Dr. Gurry said that there could be a shift towards a social benefit intellectual property regime at some point in the future.

"While I don't want to comment on the Novartis decision, I think that, yes, an intellectual property regime that balances social benefit perhaps could be in the offing. In the end, it is basically a problem of variance in purchasing power between countries. There is a global market, but no global consumer as of yet," Dr. Gurry said. "In the end, the right balance must be found repeatedly. We will have more and more situations like Novartis in India, and we must see how IP can not only be about protecting investment, but also social benefit," Dr. Gurry added.

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India wants copyright laws eased for visually impaired

Anubhuti Vishnoi, The Indian Express

New Delhi, 13 May 2013: Home to one-fourth of the world's visually-challenged persons, India will play a key role in negotiating a historic international treaty next month that will ensure that the community's access to globally-published material is not stymied by rigid copyright rules.

The Extraordinary General Assembly of the World Intellectual Property Organization (WIPO) has called a diplomatic conference in June (17th-28th) 2013 in Marrakesh, Morocco, to conclude the WIPO Treaty for Visually Impaired Persons/Persons with Print disabilities.

The treaty holds the promise of ushering in a "more flexible copyright regime adapted to current technological realities" and would benefit over 300 million blind or visually impaired/reading impaired persons. The move is pertinent because majority of world's visually-impaired persons live in developing or least developed countries and only a small fraction of published material is available in accessible formats like Braille, audio books, large print formats and digital and assistive books.

The treaty aims to create a global framework to allow visually impaired persons access all published material in accessible formats freely or at a reasonable price. In May 2012, India brought in the Copyright Amendment Act that permits a visually impaired person to convert any book into accessible formats without copyright permission from publishers. India is now advocating that this level-playing field be extended worldwide. The proposal is likely to hurt global publishers.

The Union Human Resource Development (HRD) ministry will soon seek Cabinet nod for the terms on which it will negotiate the international treaty. "It is imperative that international publishers also allow free conversion of books to accessible formats as the bulk of technical books across subjects still come from the West. That apart, in this digital age, Braille alone is not the answer. Both India and Africa have been trying to get this through", said an HRD official.

The official said that while Europe and the US agrees with the idea, they want to bring in far too many conditions as they feel that unconditional access could lead to dilution of their copyright. "But bringing in too many conditions and limitations will only create hurdles and defeat our very purpose. The Morocco conference will be critical and will have to find a fine balance," the official added.

Dr Sam Taraporevala, Director, Xavier's Resource Centre for the visually challenged and Vice President Committee on Policy Intervention Daisy Forum of India, has already written to the HRD minister PallamRaju requesting him "to ensure India plays a key role in signing and ratifying the treaty".

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India asks US to tighten patent regime to curb misuse

Amiti Sen, Business Line (The Hindu)

New Delhi, 31 July 2013: Turning the tables on the US that has been criticising India for lax intellectual property rules, New Delhi has asked Washington to tighten its own laws to discourage increasing practices of 'ever greening' and 'trolling' by US drug companies which lead to wrongful profiteering and patent extension.

Commerce and Industry Minister Anand Sharma, during his recent visit to the US, took up the issue of patents misuse by US companies in his meetings with US Trade Representative Michael Froman and US Commerce Secretary Penny Pritzker.

Trolling is a process through which an individual or a company buys a patent, often from a bankrupt company, and threatens to sue other companies manufacturing a product similar to the patented one without itself manufacturing the product.

Ever-greening, on the other hand, is a process through which patent holders try to extend patents beyond its normal life by making minor changes in the product.

"The Minister stressed on the need for the US Government to strengthen patent laws in his meeting with officials. Even the US courts have given verdicts against the process of trolling," Commerce Secretary S.R. Rao told *Business Line*.

India also said that it would not make any changes in its intellectual property regime to make it more favourable for patent users as urged by the US because it was in compliance with the global agreement on patents also known as the Trade Related Intellectual Property Rights (TRIPS).

"We said that India is already TRIPS compliant and has no intention of going TRIPS plus," Rao said. The US industry has been complaining against India's decision to grant a compulsory licence to Indian company Natco to manufacture an anti-cancer drug produced by patent holder Bayer as it was priced prohibitively high in the country.

The Supreme Court's decision upholding the Indian Patent Appellate Board's rejection of a patent application made by Swiss company Novartis on the ground that it was not a substantial improvement over its older drug for which patent protection had run out also came in for heavy criticism from multinational drug companies.

The US Trade Representative, in its special report on countries with low patent protection, has been consistently placing India in the Priority Watch List.

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