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India may join global forum to safeguard drug exports

Raji Reddy Kesireddy, Economic Times

5 September 2013: India is considering joining a global forum that prescribes standards for medicine manufacturing to safeguard its drug exports to the member countries. Called the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), it currently comprises 43 drug importing countries.

The move assumes significance in the backdrop of Indian drugmaker Ranbaxy being recently penalised $500 million (aboutRs3,350 crore) by the US government for shoddy manufacturing practices. The United States and the European Union are among the key members.

Under an agreement, drug regulators of member countries ensure compliance with standards rather than individual manufacturers. PV Appaji, director general of India's Pharmaceuticals Export Promotion Council (Pharmaexcil), said the country's drug exports could suffer in the medium to long term if India does not join the league. "It is going to impact our export growth as more and more countries are now looking for PIC/S compliance. India should join the league at the earliest."

Sudhanshu Pandey, joint secretary at the commerce ministry, said while joining the forum will help exports grow, there were broader issues. "As there is the requirement that the whole pharma industry, including non-exporters, be compliant with the standards, the issue needs to studied more carefully." He said the commerce ministry held talks with officials of Drug Controller General of India (DGCI) and the health ministry is examining the likely impact of joining the forum.

The Indian pharma industry, which currently has the largest number of US Food and Drug Administration-approved manufacturing facilities outside the United States, does not want to risk losing out on drug exports and prefers the country join the forum quickly. The industry saw its exports growing to $14.5 billion (Rs79,500 crore) during 2012-13, up from $13.2 billion (Rs 63,500 crore) a year ago. "With the US and the EU already a part of this (forum), other countries are joining too," said a spokesperson of drugmaker Dr Reddy's Laboratories.

It could, howeer, hurt companies that are today just about meeting the minimum required standards, the spokesperson said. "Membership would probably become important in the coming years if not so immediately," said Arun Sawhney, chief executive and managing director of Ranbaxy Laboratories. "The Indian regulator should work towards making India a member of PIC/S within the agreed timeframe."

Joining the forum will also help the Indian pharma industry improve quality standards, said Ganadhish Kamat, Lupin's executive vice president-quality assurance. It will "help boost exports and strengthen India's credentials as amongst the best quality manufacturers of pharmaceuticals globally."

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Emerging markets like Brazil, South Africa initiate reforms in patent laws in line with India's IP policy

Economic Times

New Delhi, 24 October 2013: Days before the Supreme Court ruled that Novartis' cancer drug Glivec is not a new invention good enough to be granted patent in April, a top executive of Pfizer had told a US Congress sub-committee, "India's action reverberates far beyond its borders."

That was perhaps the worst fear of Big Pharma, and it seems to be coming true with key emerging markets Brazil and South Africa initiating reforms in their patent laws in line with India's intellectual property policy. And global experts now expect other developing countries to follow suit.

"Both Brazil and South Africa have been greatly influenced by India's decision to incorporate TRIPS (Trade Related Intellectual Property Rights) flexibilities designed to prevent evergreening of patents and to increase access to affordable medicines," Brook Baker, professor at Northeastern University School of Law, Boston, told ET.

Most global experts ET spoke to feel that the globally debated Supreme Court judgment on Glivec became a critical trigger in reviving patent reforms debate across emerging economies.

"I think that the Indian legislation has influenced both the South Africa draft IP policy and the Brazilian proposed reform of the patent law," Carlos Correa, eminent IP expert and a professor at the University of Buenos Aires, said.

Brazil earlier this month tabled in its Parliament proposed changes in its patent policy that "clarifies matters that are not considered to be inventions: such as new use patents and new forms of known substances — along the lines of the Indian Patent Act as revised in 2005". It also recommends "increase in the standard of inventive step in order to promote incremental innovation, along the lines of the Indian Patent Act".

South Africa, in a draft patent policy on which it has invited public comments, has recommended allowing opposition to a patent before and after it is awarded "to effectively foster spirit of granting stronger patents". The draft released last month says, "A country like India resorted to pre and post-grant opposition to facilitate a possibility of opposing weaker patents… This procedure has been a success to challenge 'weaker patents'."

Both Correa and Baker think Section 3(D) of Indian Patent Act, which bars award of patent to frivolous and obvious incremental innovations and was at the heart of the Supreme Court's Glivec judgment, has been a clear inspiration for Brazil.

"The Indian influence is perhaps most evident in case of Brazil in relation to the standard of patentability, since the proposed reform partially relies on the concepts incorporated in Section 3(D) of Indian Patents Act," Correa said.

Experts now feel many smaller economies in the Africa and Latin America will initiate similar patent reforms to protect public health interests at home.

“One can expect that with these two powerful technologically proficient developing countries making the move, other developing countries are likely to follow suit,” Shamnad Basheer, an IP expert, said.

According to Basheer, Big Pharma's anguish at India striking a different patent chord was not so much about the relatively minuscule Indian market and their expected losses from patent invalidations and compulsory licensing. It was more about the fear of other countries following suit and this fear is now playing out.

Baker said that by moving in the same direction, India, Brazil and South Africa — all BRICS members — are also demonstrating an IP leadership that is having positive precedential effect in other countries such as Uganda and Zambia among others.

The development comes when India’s jurisprudence on patents is still evolving and the court's decision on many important patent battles such as the one between US multinational Merck Sharp & Dohme and domestic firm Glenmark on diabetes drug Januvia would shape the Indian patent landscape further.

Leena Menghaney of Medecins Sans Frontiers feels that the Supreme Court decision on Glivec provided an impetus for public health groups to accelerate this debate in Brazil and South Africa where public interest and treatment groups are running ‘fix the patent laws’ campaigns relentlessly to reduce abuse of the patent system by pharma companies. Not everyone agrees though.

MM Kleyn, fellow of the chair of intellectual property at the University of Stellenbosch in South Africa, said that apart from some arbitrary references in the draft that South Africa should follow the mould of “similar economies such as Brazil, India and Egypt” and few brief references, “there is no supporting empirical evidence or research that allows for any form of systematic and consequential analysis of the draft policy of South Africa”.

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Govt may issue compulsory licences on diabetes drugs

C.H. Unnikrishnan, Mint

Mumbai, 5 December 2013: India, with at least 60 million diabetes patients, may consider issuing compulsory licences for some patented diabetes management drugs sold in the country in an effort to make them accessible and affordable.

A committee formed by the ministry of health and family welfare to recommend ways to ensure access to essential drugs to patients will suggest that compulsory licences be issued for at least two patented therapeutic drugs, according to two people familiar with the development.

Affordability is a key issue in countries such as India with a large number of poor or low-income households and the low reach of medical insurance (less than 15% of the population has a health cover, according to a report by consultant EY, previously known as Ernst and Young).

“We have received a number of requests from health and patient groups and not-for-profit organizations for considering compulsory licensing option for several costly patented drugs in therapies, including cancer, heart diseases, HIV AIDS, diabetes among others,” said one of the two persons cited above. The person, an official at the ministry of health and family welfare, asked not to be identified.

“Looking at the basic criteria such as size of patient population and the severity of access issue, diabetes seems an ideal case and there are possibilities for inviting the committee’s attention to requests for making diabetes therapy more affordable to Indian patients,” added this person.

The ministry is yet to identify the drugs for compulsory licensing.

“There needs to be more discussions and debate on this. The government may also try to talk to the patent holders (to provide) for voluntary licences to interested parties,” said the second person, who is a senior official at the Intellectual Property Office. This person too did not want to be identified.

A compulsory licence would allow a drug maker to use patented technology to manufacture a generic version of the product. The government can invoke the provision if a patented product is proven to be unaffordable to a large portion of local consumers or if there isn’t enough supply to meet demand. The government resorts to issuing a compulsory licence as the final option when the patent holder is not ready to either make the product accessible to the consumer or refuses to issue a voluntary licence to another manufacturer.

“OPPI believes that compulsory licensing of a patented invention is not a sustainable or viable solution to addressing India’s healthcare challenges. We believe compulsory licences should be used only in exceptional circumstances, such as in times of a national health crisis. If used arbitrarily, compulsory licences will serve to undermine the innovative pharmaceutical industry and will be to the long-term detriment of the patient,” said Ranjana Smetacek, director general, Organisation of Pharmaceutical Producers of India (OPPI), in an emailed response. OPPI is a lobby of foreign pharmaceutical companies in India.

But generic drug makers and the patient groups have often argued that since some of the drug patents granted in the country are not justified, the government either identify those patents to get them revoked or take corrective measures.

“Market monopoly for drugs through patent rights, sometime with frivolous claims, are not justified and the government should ideally notify all such patents as potential candidates for compulsory licences if they violate the laws of the country,” says Murali Neelakantan, global legal head at drug maker Cipla Ltd. In general, drugs made under compulsory licences are much cheaper than those that are patented although patent-holders claim this is because the generic manufacturer hasn’t had to spend the billions that typically go into drug research.

By 2020, India may have 120 million diabetics, according to industry data, including that from the Diabetes Association of India.

Although India’s local drug industry makes and sells many generic diabetes drugs, some of them are very old molecules and considered inferior to the latest drugs, including new-generation gliptins, which are under patent protection. There are, at least, half a dozen different molecules in this group that have already been introduced in the global pharmaceutical market.

In June, the health ministry banned the popular generic drug pioglitazone, citing side effects and also in the wake of the introduction of better new drugs. The ban was revoked later as at least three million patients were still on the drug.

Increased demand for new-generation medicines has encouraged some generic drug makers to introduce these medicines at the risk of violating patents. To be sure, profits, rather than public interest, may be behind most of the launches.

Mumbai-based Glenmark Pharmaceuticals Ltd introduced the generic version of Sitagliptin, patented by US drug maker Merck and Co., in 2013. A patent infringement case filed by Merck against Glenmark is currently pending before the Delhi high court.

Merck and Glenmark did not offer comments on grounds that the matter is sub-judice.

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Free trade agreements contain provisions that restrict access to medicines: UNITAID

The Times of India

New Delhi, 6 April 2014: UNITAID, a global health initiative has warned against bilateral and regional trade agreements, pushed mostly by Europe and the US, as such agreements go well beyond traditional trade concerns and include provisions that force extensive obligations related to intellectual property and investor protection which would restrict access to medicines.

The UNITAID in its report titled, "Trans-Pacific Partnership Agreement (TPPA): Implications for Access to Medicines and Public Health" said that the intellectual property obligations proposed in such agreements exceed the minimum standards of the multilateral World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS Agreement. These agreements will delay generic market entry and competition and will thus lead to increased prices of pharmaceuticals and the consequent increase in public expenditure for health programmes or in out-of-pocket costs for patients, warned the report.

"Generic competition, particularly from India, persists in reducing prices today, with the prices of first-generation HIV medicines at less than 1% of their 2001 prices. In carrying out its mandate, UNITAID relies on the ability to leverage the effects of competition to reduce prices of pharmaceuticals and to increase access to treatment," pointed out UNITAID adding that the relationship between competition law and intellectual property rights ought not to be understated. India too is currently negotiating a free trade agreement (FTA) with the European Union which has many of the provisions that UNITAID has warned against.

UNITAID is a global health initiative hosted by the World Health Organization (WHO) in Geneva and is in great part financed by a solidarity levy on airline tickets. UNITAID is in the business of negotiating lower prices for drugs and diagnostics which are distributed through several international organizations such as Clinton Health Access Initiative, the Global Fund, Stop TB Partnership, Medecins Sans Frontieres and so on.

The UNITAID report analysed the provision of the TPPA as it has been positioned as a "model" for the 21st century, implying that the same or similar provisions are likely to appear in future trade agreements, including those involving developing countries. Public interest and public health groups, as well as a number of United Nations agencies, have voiced concern over the "TRIPS-plus" provisions in such trade agreements. "A dramatic illustration of the direct impact of TRIPS-plus rules captured global attention when, in 2007 and 2008, shipments of generic medicines from India to other developing countries were detained at European ports on allegations of intellectual property infringement. One of the shipments included an HIV medicine, abacavir sulfate, the purchase of which had been funded by UNITAID and which was destined for a project implemented by the Clinton Foundation in Nigeria," pointed out the report.

"Although in the WTO developing countries succeeded in pressing for the adoption of the Doha Declaration on the TRIPS Agreement and Public Health— which confirmed the right of countries to adopt public-health-friendly and access-sensitive provisions in complying with the TRIPS Agreement's obligations—the TRIPS-plus provisions in subsequent FTAs limited the effectiveness of the Doha Declaration and undermined flexibilities in TRIPS," stated the report after examining the effect of FTAs

already in place and their impact on the developing countries involved in such agreements.
While the promotion of trade and economic growth is certainly important, it must be balanced against the need to ensure a population's access to needed medicines and its long-term health and well-being, said the report.

How some FTAs provisions undermine public health
* Seek to lower the standards of patentability
* Weaken disclosure requirements when filing for patents which will delay entry of generics when patent period ends
* Try to remove the safeguard of pre-grant opposition, permitting the grant of a greater number of patents on medicines and medical technologies
* Extend the minimum 20-year patent term to compensate for delays in the drug regulatory approval and patent granting processes, thus further delay generic entry

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No change in pharma FDI norms: Sharma

Business Line (The Hindu)

New Delhi, 29 November 2013: Facing strong opposition from the Finance Ministry and the Planning Commission, the Government has decided against revising the foreign direct investment (FDI) limit for the existing pharmaceutical companies.

The Union Cabinet, which met here on Thursday, has rejected a proposal in this regard.

“We are not reducing (the FDI cap in brownfield pharmaceuticals) for the moment,” Commerce and Industries Minister Anand Sharma told reporters on Friday.

The proposal before the Cabinet was to prescribe three broad categories.

New projects will continue to have 100 per cent FDI. Existing projects producing non-rare/non-critical drugs will also have 100 per cent FDI.

However, a third category for existing projects producing critical or rare drugs was created. This category will have 49 per cent foreign equity and it will be combination of FDI and FII (Foreign Institutional Investors).

Currently, the FDI limit for both, the new or greenfield pharmaceutical projects and existing or brownfield projects, is 100 per cent. However, the approval route is automatic for the new ones, while for existing projects, the proposal needs clearance from the Foreign Investment Promotion Board (FIPB). The Cabinet proposal was prepared in the backdrop of increasing number of mergers and acquisitions of existing pharmaceutical companies. The proposal also talked about tightening some norms such as mandatory investment in R&D and doing away with non-compete clause.

However, not only change in FDI provisions, but also many of the stringent norms barring one was rejected. Sharma said the non-compete clause would be done away with. Such a clause prevents the acquired entity from producing similar products by the acquirer.

RBI data show that during April 2012 and June 2013, brownfield pharmaceutical projects got $2,034 million worth of FDI while greenfield ones attracted just $90 million.

It means over 96 per cent of total FDI in pharmaceutical projects are merely substituting domestic capital by foreign capital rather than adding new capital.

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100% FDI in pharma stays; Govt notifies policy

Business Line (The Hindu)

New Delhi, 8 January 2014**:** India will continue to allow 100 per cent Foreign Direct Investment (FDI) in existing pharmaceutical companies despite concerns over continued availability of affordable life-saving drugs raised by some ministries and departments.

Domestic companies selling their facilities or operations to foreign players, however, will not be barred from starting a fresh venture in the same area as the "non-compete" clause will not apply in deals except in special cases.

The Department of Industrial Policy & Promotion (DIPP), on Wednesday, formally notified both the decisions taken by the Union Cabinet six weeks ago following extensive inter-ministerial consultations.

"The Government has reviewed the position in this regard and decided that the existing policy would continue with the condition that 'non-compete' clause would not be allowed except in special circumstances with the approval of the Foreign Investment Promotion Board," the DIPP said in a Press Note.

There have been a number of high profile acquisitions of Indian pharmaceutical companies over the last few years which includes the recent take-over of Bangalore-based pharma firm Agila Specialties by US-based Mylan Inc and Piramal Healthcare by US company Abbott Lab.

The DIPP had sought reduction of FDI limit for brownfield pharma projects from 100 per cent to 49 per cent in "critical'' areas as it feared that acquisition of Indian companies could vitally affect availability and affordability of generic (off-patent) medicines.

In an earlier note, the DIPP had pointed out that most of the FDI that has come into the pharma sector in the country has come in brownfield projects and soon the existing facilities in the country that produce cheap life-saving medicines may completely be taken over.

The Department of Science & Technology and the Health Ministry also shared the DIPP's concerns. The Department of Science & Technology, had expressed concern that takeover of Indian pharmaceutical companies by foreign investors could lead to a waste of Government efforts, research and resources as many of these companies sourced their technologies from Government laboratories under the CSIR.
The Finance Ministry and the Planning Commission were, however, of the view that there should not be any changes in the existing FDI policy as it would serve as a deterrent for foreign investors.

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India slaps $787/tn anti-dumping duty on Chinese paracetamol

PTI

New Delhi, 30 October 2013: India has imposed anti-dumping duty of USD 787 per tonne on import of Paracetamol, a widely used medicine, from China for five years to protect interest of domestic players from the cheap shipments.

"The anti-dumping duty imposed (on Paracetamol) under this notification shall be effective for a period of five years...," said the Central Board of Excise and Customs (CBEC) in the Revenue Department.

The duty will be at USD 787 per tonne, it said.

The duty has been slapped on recommendation of the Directorate General of Anti-dumping Duty, which carried out a review of the impact of the levy on its import from China.

The anti-dumping duty, a WTO compatible levy to discourage imports, was first imposed on the bulk drug in 2001 and extended through different stages till September 2013.

The DGAD after a 'Sunset Review' had concluded that despite the anti-dumping measures, dumping of paracetamol originating in or exported from China has continued unabated causing injury to the domestic industry.

"Should the present anti-dumping duties be revoked, dumping of the subject goods may in all likelihood intensify, causing further injury to the domestic industry," the Authority had concluded while recommending to the revenue department continuation of the levy in August.

Paracetamol is a bulk pharmaceutical active ingredient, displaying analgesic and antipyretic properties. It is used in a number of OTC drug formulations in the form of powders, granules, injectibles and tablets.

The DGAD carried the review or probe for 15 months January, 2011 to 31st March, 2012.

Import of the drug increased from 6,385 tonne in 2008-09 to 10,834 tonne during the period of investigation (POI).

Capacity utilisation of the domestic industry was 85 per cent in 2008-09, but it has come down to 79 per cent in the POI. The annual demand for the drug is about 25,380 tonnes.

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India slaps $9/kg anti-dumping duty on a bulk drug from EU

PTI

New Delhi, 20 October 2013: India has slapped anti-dumping duty of up to USD 9 per kg on import of a bulk drug from the European Union to protect the domestic industry.

The Revenue Department has imposed the duty - a levy to discourage cheap imports - on bulk drug Cefadroxil Monohydrate originating in or exported from the EU for five years. It has been levied following recommendations by the Directorate General of Anti-dumping and Allied Duties (DGAD). The duty "shall be levied for a period of five years (unless revoked, amended or superseded earlier)," a notification by the Central Board of Excise and Customs said.

Depending on different factors, the duty will be USD 7.88 and USD 9.03 per kilogramme on import of bulk drug.

The DGAD had carried a probe in the imports and concluded the bulk drug entered the Indian market from EU below normal value resulting in dumping and thus causing "material injury" to the domestic industry. The investigation was done after DGAD received an application from pharma major Lupin, Mumbai, on behalf of the domestic industry, alleging dumping of the bulk drug "originating in or exported from the European Union". Hyderabad-based Aurbindo Pharma had supported the application.

Bulk drug Cefadroxil Monohydrate is an active pharmaceutical ingredient (a raw material) used for the manufacturing of pharmaceutical formulations.

Countries initiate anti-dumping probes to check if domestic industry has been hurt because of a surge in below- cost imports. As a counter-measure, they impose the duty, which is WTO compatible.

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UK watchdog restricts drugs from India's Wockhardt

AFP

Mumbai, 22 October 2013: Britain's health regulator has restricted exports from a factory of Indian pharmaceutical firm Wockhardt, the company said Tuesday, the third such plant to face restrictions.

Britain's Medicines and Healthcare Products Regulatory Agency (MHRA) has cancelled Wockhardt's "good manufacturing practices" certificate for a factory in Kadaiya (Daman) in western India for noncompliance with its manufacturing standards.

The factory will however be allowed to test, make and supply to Britain certain drugs critical to public health, the statement to the stock exchanges said Tuesday.

The fresh blow comes days after the MHRA recalled five drugs made by Wockhardt from a plant in Chikalthana in Maharashtra state.

In recent months both the US and UK watchdogs issued import alerts on drugs made at another Wockhardt manufacturing unit in Waluj, Maharashtra in western India, citing quality concerns.

The firm's shares fell 4.29 percent to 458.2 rupees after Tuesday's setback, and Wockhardt said the impact of the fresh export curbs "will only be known once it receives further communication from MHRA".

It said it did not make any products for the United States market from the Kadaiya plant.

India's government has defended its lucrative generic drug industry, which accounts for nearly $15 billion in annual exports, as safe and tightly regulated.

India's pharma giant Ranbaxy, after facing a lengthy legal battle in the United States, was hit by a new setback last month.

The US Food and Drug Administration (FDA) banned imports from Ranbaxy's "ultra modern" Mohali plant in northern India in September, whose renovation was supposed to mark a turning point for the Indian generics giant after years of run-ins with US regulators.

Now three of Ranbaxy's plants have been hit by an import ban to the United States, its largest market.

In May, Ranbaxy had pleaded guilty to US charges of selling adulterated antibiotic, epilepsy and other drugs, and agreed to a record $500-million fine.

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India's IPR regime - Moving beyond the myths of US pharma

Hemant Krishan Singh & Aman Raj Khanna

3 October 2013: It is time for the Indian government to address the growing trust deficit with foreign pharmaceutical manufacturers on the question of IPRs and improve the enforcement of patent protection The meeting between Prime Minister Manmohan Singh and US President Barack Obama on September 27, 2013, saw reaffirmations of what the leaders described as an "outstanding" and "indispensable" partnership, and of the US' support for the emergence of a "strong India". Implicit in their approach was the recognition that beyond the domestic political gridlock that currently preoccupies both leaders, India and the US also face daunting economic challenges. Understandably, the primacy of economic issues and invigorating economic growth was in the forefront of the Obama-Singh meeting agenda.

At this juncture, it is important for India and the US to rise above transactional bickering and realign their sights towards the vast potential of bilateral economic ties. This necessitates a constructive engagement on economic issues that the leaders apparently achieved but evidently continues to elude powerful interests among the US business lobbies and Congress.

It would appear from a spate of recent "opinion" pieces in US business journals that the tirade against India's allegedly discriminatory business practices has only continued to escalate. Lobbyists for US' pharmaceutical industry are demanding action by the Congress and the administration against India's so-called "mercantilism", including through retaliatory measures designed to halt India's "misappropriation" of intellectual capital.

Such blatant propaganda is both unsustainable and unproductive, and only serves to further deteriorate the business climate between India and the US. It is also unusual.

As noted economist Arvind Subramanian of the Peterson Institute observed in his article "The curious case of the protectionist dog that has not barked" (Financial Times, July 10, 2013), the huge structural trade shock from an unprecedented surge of Chinese exports in recent years did not elicit a significant US response, or anything more than a whimper of demands for protectionist actions.

India-US business interactions are hardly based on head-to-head competition, except marginally in the case of information technology services and generic medicines. India can be blamed for shackling its economy but hardly of rampant mercantilism. It would be reasonable to conclude that the drumbeat of complaints against India that have already led to the launch of an investigation of India's trade practices by the US Federal Trade Commission are basically motivated by business rivalries.

It is well recognised by Indian policymakers that urgent steps are necessary to improve India's investment climate and revive economic growth. These must include, inter alia, strengthening the enforcement of intellectual property rights (IPRs).

That said, there is no truth to the argument that Indian laws and regulations single out the US for discriminatory treatment, or exact punishment on US businesses and workers.

Between April 2010 and March 2013 alone, India's Controller General of Patents, Designs and Trade Marks awarded as many as 1001 pharmaceutical patents, of which 771 (a staggering 77 per cent) were

granted to foreign firms, largely from the US and Europe. In fact, the two greatest beneficiaries during this period were US-based pharma giants Eli Lilly and Pfizer, who between them secured a total of 68 patents.

India has made tremendous progress on IPR protection since acceding to the WTO in 1995 and introducing its new patent system in 2005. India's patent laws and policies have remained well within the rights and obligations accorded by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The provisions of India's Patent Act of 2005 are fully TRIPS-compliant, including with regard to necessary safeguards for the protection of public interest, national security, bio-diversity and traditional knowledge.

Decisions taken by the Indian courts on patent cases are in keeping with the enforcement of Indian law that imposes tough standards on the patentability of incremental innovation, while rewarding "true innovation". In its landmark judgement against Myriad Genetics on June 13, 2013, the US Supreme Court ruled that naturally occurring genes cannot be patented. This reinforces the precedent that countries such as Brazil and India have set in challenging patent proliferation and evergreening that is prevalent in advanced economies such as the US, in the interest of providing affordable health care products for their citizens.

In finding a way forward, it is time for the Indian government to address the growing trust deficit with foreign pharmaceutical manufacturers on the question of IPRs. Within the broad framework of the existing law, the concerned Indian authorities must try to improve the enforcement of patent protection, including through swift action against infringements, facilitating effective recall mechanisms and punishing violators. India needs to ensure a balanced and predictable IPR regime, where unwarranted interpretations of the law or arbitrary enforcement of compulsory licences are minimised.

On its part, the US - and the international - pharmaceutical industry needs to revisit its approach to doing business in India, particularly its pricing of life-saving drugs. It must accept that practices developed primarily for the excessively high-cost US health care market, dominated by insurance exchanges and restrictively high pricing, are neither feasible nor likely to find traction in the public interest in India, or elsewhere among emerging economies, for that matter.

On several other areas of concern to US business, there are signs of forward movement. India has already taken action to review the provisions of its preferential market access policy. Hopefully, the coming months will also see improvements on taxation and transfer pricing issues.

India, meanwhile, awaits redressal by the US of its concerns over the free movement of highly-skilled workers under the proposed US immigration Bill, and progress on the totalisation of social security contributions paid by Indian H1B workers.

Placing the India-US economic relationship on an accelerated trajectory requires serious bilateral engagement under the US-India Trade Policy Forum as well as fast-tracked progress on a bilateral investment treaty. Hopefully, the reassuring outcomes of the recently concluded Singh-Obama meeting will help restore a more reasoned discourse on trade and investment issues that will prove far more beneficial than laundry lists of recrimination and demands for retaliation.

H K Singh holds the Wadhwani US Chair at ICRIER, New Delhi. Aman R Khanna is research associate with the Chair.

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US pharma firms lobby to protect patents in India

Amiti Sen, Business Line (The Hindu)

New Delhi, 24 October 2013**:** US pharma majors are putting pressure on the Government to stop issuing permits to domestic companies for making low-priced copies of patented life saving drugs.
Top officials from a number of US drug makers such as Pfizer, Mylan and Merck recently met the Department of Industrial Policy & Promotion (DIPP) Secretary to lobby against use of compulsory licences by India, a DIPP official told *Business Line*.

A compulsory licence is a permit issued by a Government to local industry for producing copied versions of patented medicines without the consent of the patent holder.

The delegation, organised by the US India Business Council (USIBC), also tried to dissuade the Government from putting in place restrictions on foreign direct investment in pharmaceuticals and urged it to enforce stricter intellectual property rules.

India has been maintaining that it is not against intellectual property protection and considers issuing compulsory licences only under extreme conditions abiding strictly by global rules on intellectual property prescribed by the TRIPS Agreement, the official said.

"The US companies were extremely worried that their patented drugs face threat in the Indian market as compulsory licences allowing their local production could be issued anytime. We assured them that such licences are not issued on a day-to-day basis and are guided by prescribed rules," the official said.

The DIPP informed the delegation that it had sent back three proposals for compulsory licences forwarded by the Health Ministry as it was not satisfied with the arguments given and wanted more evidence on why there was a need to issue them. Some experts are of the view that India may already be wilting under pressure from the US industry and Government.

"The US industry thrives on employing pressure tactics to get its way. The fact that India has visibly gone slow in its drive to ensure availability of cheap life-saving medicines to the public through compulsory licences shows that all the noise being made might be working," a WTO expert from a Delhi-based research institute pointed out.

India has been facing huge protests from the US and the EU after it issued its first compulsory licence last year to Hyderabad-based company Natco for selling generic or copied versions of Bayer's anti-cancer drug Nexaver.

The Indian Patent Office allowed Natco to sell the copied version at Rs 8,800 for a month's treatment compared to Bayer's version priced at Rs 2.8 lakh, making treatment affordable to thousands of patients afflicted with kidney cancer.

With patents worth an estimated $150 billion held by drug majors set to expire between 2010-2017, companies are desperate to protect their valid patents all across the globe and also renew their old patents.

The US companies also want India to be less stringent while deciding on granting fresh patents. Last year, the Indian Patent Office revoked Pfizer's patent for cancer drug Sutent as it was seen as being obvious and not inventive. This led to a lot of heartburn between the two countries.

India's proposed legislation to restrict take-overs of existing pharmaceutical companies by foreign companies is now a fresh worry for the West.

"The pharmaceutical companies did not want restrictions to be in place for FDI in the sector, either in greenfield or brownfield projects," the official said.

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India faces trade action from US

Times of India

New Delhi/Washington, 11 February 2014: Days after the US downgraded India's aviation regulator's safety ratings, Washington is expected to announce trade-related measures in what is seen as a retaliatory move against the government's recent stance on the patent regime.

The US Trade Representative (USTR) is expected to announce its move at around midnight (India time) a day after the US Chamber filed a submission to the USTR regarding the Special 301 Report. USTR Michael Froman and General Counsel Timothy Reif will hold a news conference to announce action related to India, the agency said earlier in the day in a heads-up to journalists. The Indian Embassy in Washington DC too scheduled a briefing by its economic and commerce wings soon after the expected US action. All this comes ahead of a re-scheduled visit to New Delhi of energy secretary Ernesto Munoz, which was postponed from January because of the Devyani Khobragade row.

"The submission highlights key challenges faced overseas by US creative and innovative industries, as indicated in the 2014 GIPC Index released last week… The GIPC believes that USTR's Special 301 Report provides an important tool to assess those countries that fail to abide by their IP rights obligations as outlined in trade agreements and international rules. Most notably, this year's submission recommends that USTR designate India a Priority Foreign Country in order to strengthen engagement with India to address the rapidly deteriorating intellectual property environment in this market," the Global Intellectual Property Centre (GIPC) said in a background note on Monday afternoon.

The Special 301 Report is an annual US report on the adequacy and protection of intellectual property in various countries. Even in the 2013 version, India had come in for special mention.

Drug multinationals have been lobbying with the US government for retaliatory action against India for its special provisions in the patents law that require the patent holder to prove that a genuine invention has been made and the matter on which special rights are sought is not a mere upgradation of an existing product. Citing this provision, Indian patent authorities have denied rights to some medicines for which global giants had sought patents. The provision—section 3(d) of the Patents Act—had been challenged, the Supreme Court had upheld its validity.

During consultations with the US authorities, Indian officials have said that even the American law allows denying frivolous patents. In fact, similar steps have been taken by several other countries, some in Europe.

Separately, drug companies are cut up with the Indian government over its decision to waive patent rights for a cancer drug and allow a local company to produce the same medicine at a cheaper rate. Although both the moves have been hailed by the civil society and patient groups, Big Pharma is upset, prompting the US government to act.

Indian authorities, however, said that there is no warning from the US so far. Commerce & industry minister Anand Sharma on Monday raised serious concerns over the USFDA's actions against Indian pharma companies and "disproportionate penalties", saying making affordable drugs does not mean they are spurious.

During a meeting with US Food and Drug Administration (USFDA) Commissioner Margaret A Hamburg, Sharma as well as health minister Ghulam Nabi Azad flagged the concern.

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India, US seek to better drug-making processes

Financial Express

New Delhi, 11 February 2014: The US Food and Drug Administration and its Indian counterpart on Monday decided to collaborate on inspection of drug units for good manufacturing practices (GMP) compliance and seamless sharing of regulatory information between them. The move, both sides reckon, will ease tensions between Indian drug companies and the US regulator which have escalated recently. This comes even as the US trade representative was slated to announce later in the day a trade enforcement action against India for its disgruntlement over India planning to issue a clutch of "compulsory licences" to local firms sidestepping some patents the US values.

Margaret Hamburg, commissioner of the US FDA, as part of her first, week-long visit to India, inked an agreement with Union health minister Ghulam Nabi Azad under which the two countries will exchange "information relevant to lack of compliance with accepted good manufacturing practices, good clinical practices, or good laboratory practices, as appropriate, by manufacturers and sponsors of medical products".

Drug companies that have faced adverse regulatory action by the FDA in recent months include Ranbaxy Laboratories, Wockhardt and Strides Acrolab. On January 23, the FDA banned the import of products manufactured by Ranbaxy at its plant at Toansa, the company's fourth plant to face regulatory action from the FDA, after its Mohali, Paonta Sahib and Dewas plants.

Analysts see the agreement as a sign of the two countries appreciating the mutual benefits of pharmaceutical trade between them — India with its 530 FDA-approved plants is keen to sustain and enhance its exports to the US while the Obama administration's healthcare plan relies significantly on cheaper generic drugs from countries like India.

India's pharma exports increased 10% to $14.6 billion during 2012-13, with shipments to the US accounting for about 26% of that. The country's pharma exports are soon to surpass domestic drug sales in value.

Curiously, USTR Michael Froman was expected to discuss the trade action against India at a news conference in Washington at 2 p.m. local time (1900 GMT), in what is seen as yet another sign of the mounting US pressure on India to make its patenting regime "more liberal." India's patent law has provisions that make it difficult to patent incremental pharmaceutical drugs that don't satisfactorily improve upon the existing therapies in terms of efficacy. The US is also sore over India not adopting a "data exclusivity" law that could prevent "unfair commercial use" of the information furnished by innovator drug companies with regulators by third parties. Speaking to reporters on Monday, commerce minister Anand Sharma, however, denied any official intimation by the USTR of the reported imminent trade enforcement action.

The FDA commissioner's India visit comes at a time when several pharma companies in India have come under FDA fire because of alleged serious shortcomings in their production and quality standards. Hamburg, during her interaction with the health minister, said that "there is huge expectation and dependence of public on the regulator to ensure the quality of what the people consume through drugs and food" without specifying any quality problems. She added that "there should be a common set of

standards so that people have quality, safe and efficacious drugs," emphasising the need for compliance with US GMP standards, which are the considered very strict globally.

Azad, however, defended the quality of drugs exported from India stating that "being affordable should not mean that they are cheap and spurious". He added that developing countries such as India who have a growing pharma industry should be allowed to grow.

Apart from Ranbaxy, Wockhardt and Strides Acrolab, other Indian firms have also received warning letters regarding manufacturing practices at their units, leading to concerns in some circles that Indian companies are being singled out by the regulator as it supplies low-cost drugs to the developed markets.

As part of the agreement signed on Monday, regulators from both the countries will "inform the respective regulatory authorities before undertaking inspections, so that host-country inspectors may join inspections as observers".

The 21st commissioner of the FDA, Hamburg also met commerce minister Anand Sharma, later in the day, to discuss collaborative strategies to enhance export of pharmaceutical products, agricultural products, spices and marine products. India is the second largest provider of generic drug products and the eighth largest exporter of food products to the US.

Commerce ministry officials said that Sharma, during his meeting with Hamburg, said that the authority was not giving enough opportunity to Indian pharmaceutical companies to explain themselves before taking action against them for flouting quality norms.

The commerce ministry proposed that it would come up with a paper voicing its concerns with a view to seeking a resolution to the problem at an early date, officials added.

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India-US ties under stress over trade, investment issues

Sachin Parashar, The Times of India

New Delhi, 24 February 2014: With calls in the US for designating India a Priority Foreign Country (PFC), the worst downgrading of status by the US Trade Representative for inability to protect intellectual property rights, the government is accusing US authorities of intimidating the health ministry over the issue of compulsory licences, which allow local firms to manufacture patented drugs, and simultaneously preventing other developing countries from acting against evergreening of drug patents.

A PFC tag can allow the US to impose unilateral sanctions against India for domestic laws which deny benefits to the US under any trade agreement.

Government sources here said there seemed to be a two-fold agenda behind the "cacophony' ' emanating from the US."Pressure is being created on India's health ministry to not consider drugs for compulsory licences and at the same time there is also a deliberate attempt to use India to scare away other developing countries like Indonesia and Brazil from introducing legislation to prevent evergreening of drug patents, like section 3 (d) of Indian Patents Act (IPA)," said a source.

US pharmaceutical companies like Pfizer have demanded that India amend its patents law by doing away with section 3 (d) altogether. This section prevents patenting new forms of a known substance in case it does not yield higher efficiency than the earlier substance. It was under this provision that the Supreme Court upheld a decision of India's Patent Office to deny a patent to Novartis for its drug Glivec.

India has also been disturbed by the proposed visit by US International Trade Commission (USITC) to probe the fallout of India's trade and investment policies on the US economy. The government has already asked its officials to not entertain the agency saying any dispute related to India's trade policies or patents regime should be addressed at WTO. While the US interlocutors have accused India of "continuous" use of compulsory licences (CL), which allows local firms to manufacture patented drugs, India has described this as a canard. The government has told the US authorities that India's controller-general of patents issued only one CL for a life-saving drug in March 2012, against a liver and kidney cancer product.

The government is trying to convince the Americans that Indian Patents Act is not an administrative matter under its jurisdiction but a quasilegal process, with a separate and independent appellate body to adjudicate such cases. The final court of appeal in these cases is India's Supreme Court."In fact, India's Patent Office rejected in October 2013 a CL petition (for Bristol Myer's product Desatinib, a blood cancer drug) showing that the system is capable of exercising fair decisions," said an official.

Indian officials say that despite the negative publicity over the business environment and IPR regime in India, some 1,500 pharmaceutical compounds or composition patents have been granted to nine firms between 1995 and 2012.

Stung by the negative publicity, India has accused lobbyists for IPR issues in the US such as Global Intellectual Property Center (GIPC) of taking up patents only with regard to the pharmaceutical industry.

It has highlighted before the Obama administration that, according to a study carried out by Ficci, losses caused by piracy in the US are estimated in the range of up to $50 million, especially in Virginia,

California and Chicago city.

"The Indian music industry has a list of 476 websites in the US that pirate Indian musical content, and this was shared with the US formally some months ago. Similarly, satellite TV programming from India is being pirated by websites in the US which illegally provide live content streaming;this includes a large number of major Indian TV channels," said an official

"The truth is GIPC has worked to vitiate the atmosphere with a highly skewed report, which for the last two years arrives at a prearranged conclusion that India has the worst IPR protection system even when compared to other developing countries," he added.

Indian officials accuse the US authorities of repeatedly shifting the goal posts even as India tries to address their concerns at the highest level."There is a growing perception in Indian official circles that despite significant efforts at the highest political level to address issues of concern to US interlocutors (taxation, transfer pricing, the rollback of Preferential Market Access), the Americans seem to want to pocket each positive and set out a fresh list of further demands. Or worse, to complain and nitpick at the granular level of every measure taken at their behest," said a source.

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Patent laws safe from US challenge: India

Amiti Sen, Business Line (The Hindu)

New Delhi, 25 February 2014: India has said its patent laws cannot be successfully challenged by the US either in a bilateral or multilateral forum as they strictly comply with the intellectual property agreement of the World Trade Organization (WTO).

Any US unilateral trade measure against India on the ground of inappropriate intellectual property protection in the country would be in violation of WTO rules and can be challenged there, an official in the Commerce and Industry Ministry told *Business Line*. There could also be retaliatory action by India.

US business chambers and advocacy organisations on Monday asked the Obama Administration to designate India as a Priority Foreign Country, which is a status imposed on countries that are most serious violators of intellectual property rights (IPRs). The US imposes trade sanctions against countries included in the list.

The campaign against India is being led by the US pharma industry that has been lobbying for a more favourable IPR regime in India so that it could get patents for upgraded versions of their drugs whose patents have expired. Revenues of pharmaceutical companies worth over $40 billion will be hit in 2014 because of patent expirations while in the following year it is likely to cross $50 billion.

The Ministry is not too worried about the developments, as India amended its patents legislation in 2005 to bring it in line with the WTO's Trade Related Intellectual Property Rights.

The US has revoked many more patents, granted more compulsory licences allowing copies of patented products and taken action in a greater number of cases favouring the public over the patent holder than India, the official added.

"We are not concerned about the noise that the US is making about our IP laws. The laws have been framed to protect our industry, safeguard the health needs of our poor and comply with international rules," the official said.

The US pharmaceuticals industry intensified its protests against Indian IP laws after India granted a compulsory licence to Indian company Natco to manufacture an anti-cancer drug produced by patent-holder Bayer on grounds of prohibitive pricing and unavailability.

Bitter pill

US drug-makers are particularly upset about rejection of a patent application made by Swiss company Novartis for an upgraded version of its cancer medicine by the Indian Patent Appellate Board.

The US Government now wants India to drop a particular section (Section 3d) in the Indian Patent Act that allows rejection of patents on grounds that the product for which patent is sought is not significantly different from an existing product.

Between 2007 and 2011, 283 cases were identified in US Federal District Courts where patent validity was determined of which patents were held to be invalid in 253 cases.

More recently, the US Trade Representative overturned the decision of the US International Trade Commission to favour Apple Inc in the Apple versus Samsung case where action had been initiated by Samsung for infringement of their US patent. The executive order allowed Apple to continue selling cheaper versions of iPhone4 and iPad2.

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Open to discussing IP norms at WTO: Sharma

PTI

New Delhi, 24 March 2014: Rejecting the US' allegations on intellectual property rights (IPR), India said Sunday it was ready to discuss the matter at WTO as it had not breached any international agreement. "If they (the US) want a discussion in WTO (World Trade Organization), we are more than ready because we are not in any breach. We are very clear," commerce and industry minister Anand Sharma said. Sharma was replying to a question over the US' charges that India's IPR norms discriminate against American companies, particularly in the pharmaceutical sector.

"If there is any specific issue, they must inform us," the minister said, adding that he had told USFDA commissioner Margaret Hamburg that the US should keep in loop Indian authorities if they have any issues. Hamburg was here last month and had met Sharma.

The US is one of the largest importers of Indian generic medicines. The US Food and Drug Administration has recently banned import of drugs from Sun Pharma's Karkhadi facility in Gujarat for violation of manufacturing norms. The US had also raised concerns over issuance of a compulsory license (CL) by India to Hyderabad-based Natco Pharma to manufacture and sell cancer-treatment drug Nexavar.

Indian authorities have expressed their concern over the USFDA's audit inspections of Indian pharmaceutical companies and the disproportionate penalties imposed in some instances.

The USFDA has taken a series of actions against Indian pharmaceutical firms, restricting their shipments to the US, their largest export market.

The US health regulator on January 23 banned the import of products manufactured by Ranbaxy Laboratories at its plant at Toansa. This was the company's fourth plant to face regulatory action from the USFDA, after Mohali, Paonta Sahib and Dewas plants.

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India-US ties headed for rough weather over drug IP issue

Amiti Sen, Business Line (The Hindu)

New Delhi, 20 April 2014: Facing the threat of sanctions by the US for what it terms India's lax intellectual property (IP) rules, the Commerce Ministry is studying the possible impact on trade with the US if Washington goes ahead with its action.

The Office of the US Trade Representative is to come out with its annual Special 301 report by the month-end on the adequacy and effectiveness of IP rights protection by its trading partners. If the report classifies India as a 'priority foreign country' — as demanded by the US pharmaceutical lobby — Washington could impose economic sanctions against India that will include withdrawal of duty-free benefits or imposition of penal duties. The USTR's earlier reports have put India under the 'priority watch list', as a country that needs to tighten its IP regime.

A Commerce Ministry official told *Business Line* "that "since the US is one of our largest export destinations, it is important to understand how much our trade could get hit if sanctions are imposed. We may have to take steps to support sections of our industry that get affected".

Cabinet Secretary Ajit Seth has called a meeting of senior officials of the Ministries and Departments concerned, including Commerce, Industry and Pharmaceuticals, to discuss the imminent threat of sanctions.

'Unjustified'

New Delhi believes that the threat is unjustified as the category of 'priority foreign country' is reserved for very serious intellectual property law offenders, while India's legislation is in line with global specifications.

Ukraine is the only country on the list at the moment.

"We will examine in detail the options available under the dispute settlement undertaking of the WTO, in case it (India) does get categorised as a 'priority foreign country'," the official said. Retaliatory action, too, could be considered, he added.

US drug majors upset

Although India amended its patent laws in 2005 to bring them in line with the Trade Related Intellectual Property Rights of the World Trade Organisation, US drug majors are upset with Section 3 (d) of the country's patent law, which refuses to grant patents for incremental innovations.

With pharmaceutical companies expected to take a hit of over $40 billion in 2014 revenues and $50 billion the next year as their patents run out, the US is under pressure to force India to drop the provision. Pharmaceutical companies are also unhappy with New Delhi's decision of 2012 to grant a compulsory licence to an Indian company for the manufacture of a copied version of Bayer's cancer medicine, Nexavar. This move brought down the price of the drug by 90 per cent.

Harmful to both sides

The US India Business Council, the trade body representing businesses of both countries, has warned that economic sanctions imposed by the US on India could harm American companies as much as Indian businesses.

In 2012-13, the US was India's third largest trading partner, accounting for exports worth $36 billion and imports of $25 billion.

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Govt prepares to battle US pressure on patents

Nayanima Basu, Business Standard

New Delhi, 22 April 2014: The government held a high-level meeting on Monday to discuss apprehensions that the US government might impose sanctions against Indian companies on the ground of a lax intellectual property rights (IPR) regime.

Delhi, it was decided, would not tolerate such a move from Washington. “It has been decided that India will not cooperate with the US on any sort of investigation on Indian IPR or trade laws,” an official said after Cabinet Secretary Ajit Seth took a meeting of top bureaucrats over the issue.

India, it was decided, might take the US to the World Trade Organization (WTO) if such unwarranted action was taken, while keeping open the door for discussion to allay perceptions on Delhi's trade laws.

The Cabinet secretary reiterated that India was WTO-compliant on Trade Related Intellectual Property Rights, officials said. The government is also compiling cases where the US had breached IPR laws.

Officials attending included the secretaries for foreign affairs, commerce, industrial policy and health. India's ambassador to the US, S Jaishankar, is also discussing the issue with the US government.

The office of the US Trade Representative is expected to issue what is termed a “Special 301” report this month-end or early next month. This is an annual survey in which the USTR is supposed to identify countries which do not provide “adequate and effective” IPR protection or “fair and equitable market access to United States persons that rely upon IPR”.

There is apprehension that the USTR might put India on the Priority Foreign Country list for IPR; this names countries judged to have inadequate intellectual property laws or deny fair and equitable market access to US entities relying on IPR protection. Such countries may be subject to sanctions. As a part of such penal action, the US may withdraw benefits under the scheme of Generalised System of Preferences, which provides reduced tariffs for Indian goods entering US markets.

The US International Trade Commission, a quasi-judicial independent federal body which advises the US President, the USTR and the nation’s legislature on trade matters, had begun a probe into India’s trade and industrial policies on February 12.

Since US President Barack Obama’s 2010 India visit, American firms, especially a certain segment of the US pharmaceutical industry, have become extremely vocal about Indian policies on domestic content requirements and IPR.

Policy circles here believe the US is doing these to protect the interest of a handful of pharmaceutical companies, which command influence in policy making circles there. These include Pfizer, Bayer and and Swiss pharma major Novartis.

The department of industrial policy and promotion, under the commerce & industry ministry, has prepared a list of all cases since 1974 where the US is held to have breached IPR laws, rejected patents and invoked compulsory licensing, in sectors ranging from electronics to pharmaceuticals.

During the 2002-2012 period, 20 cases related to pharmaceuticals were invalidated by the US Federal District Courts, compared with 34 related to mechanical devices and 10 to medical devices. Between 2007 and 2011, about 280 cases were identified in the US Federal District Courts where patent validity was determined. Of these, the patent was held valid and enforceable in only 39 cases. In 253 cases, the patent was held invalid.

Refusing to deal with the matter bilaterally, the government has apparently told its American counterpart that such issues should be discussed only at multilateral platforms like the World Intellectual Property Organization and WTO. However, following the Novartis and Bayer-Onyx cases here, the US is concerned that other countries such as Brazil, China and in Africa might follow India's model of compulsory licensing.

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US defers decision on downgrading of India's intellectual property regime

Economic Times

New Delhi, 1 May 2014: The United States on Wednesday deferred decision on India's intellectual property regime, providing partial relief from the much anticipated downgrade that could have led to trade sanctions against the country.

The US Trade Representative (USTR) would now conduct an 'out of cycle' review for India's case later this year.

ET had on Wednesday cited this as the first and the most likely possibility for the US to adopt, in the backdrop of ongoing elections in India.

The USTR reviewing whether India's intellectual property environment has deteriorated enough to warrant a label of 'priority foreign country', a label which could trigger American trade sanctions against India.

The prospect of engaging with a new political establishment, which may have fresh takes on many contentious issues raised by the US government may have prompted it to adopt a 'wait and watch' approach. However the US TR has not minced words in harshly attacking a series of recent patent related policy moves and legal pronouncements here.

The US trade government agency held that 'IP protection and enforcement challenges are growing, and there are serious questions regarding the future of the innovation climate in India across multiple sectors and disciplines'.

In the pharmaceutical sector and increasingly in other sectors, such as the agro-chemicals and green technology sectors, some innovators face serious challenges in securing and enforcing patents in India, said US' special 301 report which grades select countries on what it thinks have defaulted in providing IP protection.

On the expected lines, the US TR is sharply critical of India's judicial and subsequent policy interpretation of section 3(d), which aims to sieve out frivolous patents and thwart attempts of 'evergreening' of patents and compulsory licensing .

The report says that section 3(d) may be setting different standards for patenting different 'inventions', by setting a higher threshold for drugs. India's interpretation could limit the patentability of potentially beneficial innovations such as drugs with fewer side effects, decreased toxicity, improved delivery systems, or temperature or storage stability and those innovations which enjoy patent protection in other countries, the report said.

The US would monitor developments around compulsory licensing of patents in India. Seeking greater transparency on current 'inter-ministerial process that is considering over a dozen patented medicines as candidates for government- initiated compulsory licenses', US has urged India to take inputs from innovators in such matter.

It has also expressed concern over India promoting compulsory licensing in its National Manufacturing Policy as a tool for government entities to implement technology transfer in the clean energy sector.

By allowing opposition of patent before and after the grant, India allows applications to be tied up in costly challenge proceedings for years. The patent term for innovator begins from the application filing date, thus impeding an applicant's ability to make investments and conduct business, US feels.

It has also demanded data protection for pharma innovator firms without which it cribs 'companies in India reportedly are able to copy certain pharmaceutical products and seek immediate government approval for marketing based on the original developer's data'.

Online piracy in India, which has the third largest userbase worldwide at 120 million users and the rampant practice of video piracy through camcording disturbs US.

US Chamber of commerce, which has been lobbying for pressure on India, welcomed the decision.

"We are encouraged that USTR recognizes the growing concerns with India's deteriorating IP environment, and support the decision to initiate an 'out-of-cycle' review of India. We hope that this step will generate much needed dialogue for the US and Indian governments to address the concerns identified in the Report. We look forward to working with the next Government of India to promote a robust IP climate" said US Chamber of Commerce's Global Intellectual Property Center (GIPC) Executive Vice President Mark Elliot.

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Indian drug makers to benefit as US expedites generic clearances

Sushmi Dey, Business Standard

New Delhi, 12 May 2014: Indian drug makers, slammed for months in the US over issues related to quality and intellectual property rights, might soon get to breathe easy. Companies seeking approval for their generic drugs in the US may expect a significant lowering of review period by regulator from October onwards.

“The majority of GDUFA (Generic Drug User Fee Amendments) performance goals do not begin until Fiscal Year 2015. At that time, there will be a specified goal of reviewing Abbreviated New Drug Applications in 15 months,” a spokesperson of US Food and Drug Administration (US FDA) said, adding the move does not guarantee an approval action.

The US Federal government’s fiscal year begins on October 1 and ends on September 30.

Gradually, the regulator will also move to a 10-month review clock in fiscal year 2017. Currently, the regulator takes around three years to review ANDAs, industry officials say.

This is expected to translate into major gains for domestic drug makers like Sun Pharma, Lupin, Glemark, Dr Reddy's Laboratories, Cadila Healthcare and Torrent Pharma, which have a significant presence in that country's $30-billion generic drug market.

"Faster approvals will help companies bring in more products to the market. October onwards, we are certainly expecting more launches in the US," a senior executive of a domestic pharmaceutical company, asking not to be named, told Business Standard.

The move comes in the wake of increased focus on the US' Patient Protection and Affordable Care Act, popularly called Obamacare, which aims to lower healthcare spending in America. International reports suggest prices of medicines, including those of generics, have risen significantly in the past year.

According to a survey by America's National Community Pharmacists Association, prices of some of the medicines spiked more than 1,000 per cent in 2013.

The US Food and Drug Administration's (US FDA's) proposed move to fast-track clearances to generic drug applications from October is aimed at bringing in more products to the market, so that more competition governs prices, says sources and industry officials in the know of the latest developments.

However, foreign generic drug makers like Teva, Mylan and Sandoz, which already have a considerable presence in the American market with extensive product pipelines across segments, are likely to face competition with other generic players entering early and vying for larger market share.

"Early penetration of more generic players will also allow faster price erosion. That will help bring down healthcare cost in favour of Obamacare, but might hurt existing players' interests," the senior executive said.

Indian companies, which account for 10-12 per cent of the total US generic market, will also benefit from

the move because these companies have been paying hefty fees to the regulator since 2012 while applying for generic drug approvals there. However, instead of expediting approvals, US FDA prolonged the clearance time for applications to be filed before 2017. This disappointed generic drug makers, which planned to launch products during the patent cliff.

"Delays in product approvals, coupled with fees for filing of ANDAs (abbreviated new drug applications) have been a major concern for the past few years. Our revenue growth was stalled because of these delays, while our cost rose substantially because of fees," a senior management official from another pharma company explained.

During US FDA Commissioner Margaret Hamburg's visit to India earlier this year, representatives from domestic companies like Sun Pharma, Ranbaxy, Cadila Health and Torrent Pharma had also raised the issue of delay in product approvals hurting their revenues.

Also, generic drug makers were concerned that once they applied for approvals, their products were vulnerable to potential patent infringement litigation, which might add to their cost, while sales of these products were yet to take off.

Given that India is the largest foreign supplier of generic medicines to the US, which in turn is the biggest market for domestic companies, faster generic drug approvals will help both sides.

Industry estimates show, major domestic drug makers like Sun Pharma, Lupin, Glenmark, Dr Reddy's and Cadila Health annually file 15-20 generic drug applications each. Even smaller companies like Torrent Pharma and Alembic file five to 10 ANDAs every year.

This story is a slightly modified version of the one that appeared in the print edition.

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