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Nilambur teak to get geographical indication tag soon

T P Nijish, Times of India

Malappuram, 30 September 2013: Nilambur teak will soon become the first forest resource from India to get GI (geographical indication) tag of World Trade Organisation (WTO).

The Kerala Agricultural University (KAU) has initiated the steps for the registration of the Nilambur variety of Teak or Malabar Teak, which is known for log dimensions and desired wood figure.

As part of the initiative the KAU organized a state-level workshop on 'GI tag for Nilambur Teak: Opportunities and legal paths', at Nilambur on Saturday. It was organized in support of the GI Registry Chennai. The College of Forestry and Intellectual Property Right (IPR) cell of KAU had jointly organized another workshop recently to discuss the potential of getting a GI registration for wood products manufactured using Nilambur teakwood.

A GI is a name or sign used on certain products, which corresponds to a specific geographical location or origin. The GI tag ensures that none other than those registered as authorised users are allowed to use the popular product name

At present 18 indigenous products from Kerala are in the GI list of India. They are Aranmula kannadi, Alleppey coir, Navara rice, Palakkadan matta Rice, Malabar pepper, Alleppey green cardamom, maddalam of Palakkad, Screw Pine craft, cocunut Shell crafts, Pokkali rice, Cannanore home furnishings, Kuthampully sari, Kasargod sari, Wayanadan rice, Vazhakkulam pineapple, Payyannur pavithra ring, Central Travancore jaggery and Chendamangalam dhoties.

The head of the department of silviculture and agro forest of KAU, Dr T K Kunhamu, said that the representative of the office of GI registry at Chennai, who visited Nilambur a couple of days ago was satisfied and convinced of the importance of the wood item. He hoped that the prestigious status would be accorded to Nilambur teak soon. "We will be provided with a logo, which can be used for the trade of teak items, across the world," he said.

The KAU had helped secure GI registration for Wayanadan rice, Payyannur Pavithra Ring, Central Travancore jaggery, Pokkali rice, Aranmula mirror and Kuthampully sarees.

The vice-chancellor of KAU, Dr P Rajendran said that it was very appropriate and befitting that the Nilambur teak becomes the first forest product to get GI tag from India and it would help establish legal rights of Nilambur teak.

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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.

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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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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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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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India-EFTA free trade pact talks stuck on IPR issue

PTI

New Delhi, 19 January 2014: Negotiations for the free trade agreement between India and EFTA, four-member grouping that includes Switzerland, was stuck on the issue of intellectual property regime (IPR).

"EFTA (European Free Trade Association) wants India to commit more in IPR, a proposal which was not agreed by the Indian officials. India has clearly conveyed its stand on the matter to them. We are now waiting for their response. They have to accept India's stand," an official told PTI.

The EFTA is a grouping of four countries -- Switzerland, Iceland, Norway and Liechtenstein.

"In IPR, EFTA are asking for mutual recognition for Geographical Indicators. But it is not permissible under Indian laws. They are also demanding for data exclusivity, which India is completely opposed to," the official said.

Data exclusivity provides protection to the technical data generated by innovator companies to prove the usefulness of their products.

In pharmaceutical sector, drug companies generate the data through expensive global clinical trials to prove the efficacy and safety of their new medicine. Switzerland has huge interest in this sector.

By gaining exclusive rights over this data, innovator companies can prevent their competitors from obtaining marketing licence for low-cost versions during the tenure of this exclusivity.

An expert on the IPR said that the issue cannot be discussed at the bilateral level.

"Developed countries are pressing hard the developing countries to liberalise norms to grant patents. However, bilateral forums are not the right place to discuss these things," National Intellectual Property Organisation Director T C James said.

India and the four-nation bloc has started the negotiations for the free trade agreement (FTA) in 2007 and both the sides have completed 13-14 rounds of talks till now.

Recently, the Swiss government has said that the negotiations for the pact are expected to concluded by 2014.

Further, India is expected to get greater market access in services sector in those four countries besides in textile.

"EFTA members manufactures high-end products and India needs that," the official added.

The objective of the FTA is to reduce trade tariffs for mutual benefit.Two-way trade between India and EFTA stood at USD 34.48 billion in 2012-13 as against USD 37.5 billion in 2011-12.

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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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Registering trademarks turns cheaper for firms

C.H. Unnikrishnan, Mint

Mumbai, 3 February 2014: India's patents and trademarks office has issued guidelines on the working of the Madrid Protocol, the treaty that India signed last year allowing Indian companies and citizens to register their trademarks globally.

The new system, which works on a single registration fee to be paid in India, will help firms and brand owners save on the otherwise huge expenditure incurred in filing separate international trademark applications for all the individual countries.

The guidelines have been largely accepted by the stakeholders, including brand owners and law firms that handle trademark matters.

But some experts say it may have a revenue impact on trademark agents and law firms as the filing of Indian applications by foreign firms will see a significant drop.

"We do not see any issue as such in the working of Madrid agreement," said Essenese Obhan, founding partner at Obhan and Associates, a Delhi-based law firm that specializes in intellectual property, including patents and trademarks.

"Though it is a fact the international filings in India will go down thereby affecting the filing of cases, it will open up more opposition cases as trademark filings from foreign countries in India through the Madrid agreement will be more now," added Obhan.

Under the new system, a local company that wants to register its trademark in multiple countries can file a single international application at the Indian trademark office in Mumbai and at zonal offices in Kolkata, Delhi and Chennai. Following this, the Indian office, after verification and certification, will forward the application to the trademark cell—called the International Register—of the World Intellectual Property Organization (WIPO) in Geneva. Trademark registrations under the Madrid Protocol emphasize the key role of locally registered trademark as it is the base for international applications.

The guidelines that will help trademark officials in India to function according to the mandates of the treaty, specify that a local brand owner can file an international application through the new system only if they have already registered or applied for the trademark in India.

Indian patents and trademarks office guidelines clarify that an international trademark registered in foreign countries is mainly based on the validity of the local trademark and that therefore any invalidation or modification of this trademark will directly affect the trademark registered in others countries through the Madrid Protocol. Since India is also a member-country of the Protocol, all the other signatories can also file their trademarks through the international registry operated by the WIPO.

According to the Indian guidelines, the fee for a single filing for international registration has been set at Rs.processing fee. Both the fees need to be paid at the Indian office. Earlier, brand owners had to pay a fee ranging from $700 (around 2,000 for the local process and an additional Swiss Frank 650 for the WIPO Rs.43,000) to $1000 (around Rs.62,000) in each country, along with charges for hiring local agents

to handle the application as well as the pre- and post-registration procedures. “It saves a significant cost for brand owners and companies who want to register their trademarks in the international markets,” said Sumathi Chandrashekaran, an intellectual property lawyer specialised in trademark law.
An industry executive agrees.

“The treaty (Madrid) provides us an easy route to protect our trademarks in most of the markets that we are focusing on, without having to deal with these registrations individually in each of the countries,” an executive of an engineering firm said, requesting anonymity. “Although we need to keep our lawyers alert on any opposition or damage on the trademarks in the foreign destinations, the registration cost has become a fraction of what it used to be in the past.”

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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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India hardens trade stance against US, wants disputes to go to WTO

Sidhartha, Times of India

New Delhi, 22 February 2014: The government is set to ask all its officials to stay away from any interaction with a delegation from the US International Trade Commission (USITC), a quasi-judicial agency, probing the impact of India's trade and investment regime on the American economy in what is seen as the latest sore point in economic ties between the two countries.

The move follows a meeting in the ministry of external affairs on Friday and comes after the government took the view that its laws and policies are its sovereign functions, while the US actions are unilateral. "The hearings relate to our patents regime and industrial and trade policies, which are governed by multilateral agreements, of which the US is also a signatory. So, if there is a dispute, it has to be settled at a multilateral forum like the WTO. No country can apply its own law extra-territorially," said an official privy to the discussions.

As a result, it has been decided that the USITC's request for meetings with officials in close to a dozen department will be turned down, leaving it with the option to hold talks with private companies and industry bodies.

Following an authorization by the Senate Finance Committee and the House of Representatives' Ways and Means Committee, USITC is on a "fact-finding" mission and is looking at all Indian policies and tariffs since 2003 that support local industries and may discriminate against US imports, investment and jobs. In addition, there is focus on foreign direct investment (FDI) and intellectual property rights (IPR).

IPR has been a special focus area for US drug majors as they have been hit by India's insistence that it will only grant patent protection for products where a "genuine" invention has taken place and not for mere modification of an existing item. There is widespread annoyance with patent revocations on these grounds. Similarly, Big Pharma is complaining about the decision to waive the patent for a cancer drug and let an Indian company manufacture it at a substantially lower cost.

The government has maintained that Indian laws are compliant with WTO rules and there was nothing wrong with them. Separately, the US Trade Representative is scheduled to listen to the arguments of Alliance for Fair Trade in India (AFTI), comprising American lobby groups, as part of the hearings for the Special 301 Report, an annual listing of IPR and trade practices in other countries. AFTI comprises groups that represent sectors such as pharma, solar energy, telecom equipment, biotech and music-all areas where the American industry complains that India has "engaged in a persistent pattern of discrimination that is hurting" manufacturing and services industries and jobs in the US.

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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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WTO becomes India's protector, not predator

SA Aiyar, Times of India

New Delhi, 2 March 2014: When the World Trade Organisation (WTO) was created in 1995, critics protested that India must not join this vehicle of US imperialism, whose tough patent rules would ruin India's agriculture and pharmaceutical industry. They could not have been more wrong. Both Indian agriculture and pharma have flourished under WTO rules. And today, the WTO is India's greatest ally against US pressure on patents.

US drug companies complain that India has rejected patents for some blockbuster drugs (like Novartis' Gleevec), while issuing a compulsory licence (which ignores patent rights) for Bayer's anti-cancer drug. They say India is flouting established norms on intellectual property rights (IPR), cheating patent owners of billions, and conferring a bonanza on Indian producers of cheap substitutes (generic drugs). US companies want the US International Trade Commission to investigate India's treatment of IPR, and recommend sanctions (under Section 301 of US trade laws) if required.

Few countries stand up to the threat of US sanctions : the costs typically exceed the benefits. But India has refused to co-operate even in a USITC visit to New Delhi, saying its bureaucrats are too busy with other things. India has told the US that WTO rules provide for all members to settle patent disputes through that body, not through unilateral action. India is confident that its IPR rules are WTO compliant. For that very reason, the US has avoided WTO, and is attempting bilateral pressure instead.

Indian patent laws are far more restrictive than those of the US or Europe, but WTO rules allow this. Critics claimed falsely in 1995 that WTO rules would condemn India to servitude. In fact they allowed India considerable freedom to be strict on patents, allowed price control, and allowed the forced issue of compulsory licences for drugs critical to public health.

Foreign companies complain that India rejects patents given widely across the globe (as with Gleevec). India says it has since 2005 granted over 4,000 drug patents (mainly to US companies) and issued just one compulsory licence. This conforms fully to WTO rules.

If the issue goes to the WTO, India will point out that even the US courts have rejected hundreds of drug patent applications. The US government itself has used compulsory licensing and price control for drugs regarded as critical for public health (as in the anthrax scare after 9/11). So, India looks on a good wicket.

Still, the dispute will not disappear. The US says that although thousands of patents may have been given, only 45 are for innovative drugs, of which nine are being contested. It accuses the government of trying to favour Indian companies making cheap generics. This is not untrue.

Some Indian NGOs want wholesale rejection of patents to keep medicines cheap. That would be cheating on India's pledges to WTO. It would also be counterproductive, inviting retaliatory sanctions. India is full of adulterated, sub-standard and bogus drugs, so let nobody pretend our conditions are ideal, or that all Indian drug producers are noble promoters of cheap medicine.

In a recent study, India ranks at the bottom of 25 countries in IPR protection. Arguably this classification is unfair (strictness in issuing patents is interpreted as weakness). But certainly IPR protection in India

leaves a lot to be desired. Bollywood will tell you how piracy plays havoc with copyright, echoing complaints from Hollywood. Software piracy is rampant, hurting Indian IT companies as well as foreign ones.

Finding the WTO inadequate, the US now aims to forge one free trade deal with Europe (Transatlantic Trade and Investment Partnership), and another with Japan and the Pacific Coast (Trans Pacific Partnership), apart from dozens of bilateral deals. All these will have far stricter IPR rules than the WTO, and indeed aim to make WTO irrelevant. India needs to guard against this by being more pro-active in WTO, and not revel (as in the past) in the role of a spoiler.

India's future lies in high-tech areas. Let's be clear: these need IPR protection. By rejecting labour flexibility, India has forsaken the labour-intensive export route to prosperity taken by the Asian tigers and China. Its key export successes are in brain-intensive areas — software, BPO, pharmaceuticals, engineering goods. India will keep rising up the brainpower ladder.

Its comparative advantage lies in skills, and need a climate encouraging such skills. India should be strict on drug patents. But it must reject the NGO attempt to sabotage all IPRs, claiming these are western impositions on the poor. Brainpower should be paid for no less than manual labour. We need a proper balance between the needs of consumers and brainpower producers. The US goes too far, but so do our NGOs.

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India hardens stance, accuses US of protectionism

Business line

New Delhi, 4 March 2014: Commerce Minister Anand Sharma said that India's Intellectual Property Rights laws were not lax and were within the ambit of the WTO norms, even as he alleged that the US indulged in trade protectionism. He also indicated that it is only the multinational pharmaceutical lobby which is opposed to India's patent regime.

"India has raised issues regarding high and unacceptable protectionism, also the visa issues, objecting to temporary movement of skilled professionals, visa fee enhancement," said Sharma addressing media persons here.

He added that India's patent regime is "fully compliant with the intellectual property rights norms of Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of WTO and has never deviated from nor diluted these norms."

"The patent related issues are being raised by some lobbyists in a particular sector, which is crucial not just for India but for every country of the world to ensure availability of life saving medicines at affordable prices," said Sharma.

"What is being asked of India is TRIPS plus, which India will never agree to. India will adhere in letter and spirit the multilateral agreement as negotiated and signed. Issue they refer to is a part of India patents act, which is aimed to prevent the ever-greening of patents," he said.
India has never invoked compulsory executive authority (which India can) for compulsory licensing. The US Federal Drug Authority has invoked executive authority for three anti-cancer drugs for putting them under compulsory licensing.

Sharma added that Novartis's patent for Glivec was denied by the examiner of patents, not the Indian Government. The rejection of that patent was upheld by appellate authority and the Supreme Court as well.

Sharma trained his guns on Gujarat Chief Minister and BJP's Prime Ministerial candidate, Narendra Modi, saying he should explain why he opposed the GST. GST alone could have added two per cent to the GDP growth, he said.

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India-US trade stand-off: a tale of two reports

Pt Jyothi Datta, Business Line

Mumbai, 5 March 2014: The television drama *The West Wing*, set in the White House, bears an uncanny resemblance to the trade tug-of-war seen at present between India and the US. Recent episodes of the programme show US officials getting involved in heated back-room activity on intellectual property (IP) and protests from US knowledge-worker unions as jobs get "vacuumed" out to India.

The political drama may not be too far from the truth, as India finds itself in the eye of a trade-related storm in the US, with much of the fury directed at India's track-record of protecting IP, after the country amended its Patents Act in 2005.

In fact, two US reports are expected, in April and November, assessing India's performance on IP protection and trade policies, respectively.

And while US trade and Government representatives voice their anxiety over India's "deteriorating" IP environment, India has stood its ground, insisting that its laws were in line with commitments to World Trade Organization-led agreements.

At the heart of these highly-charged discussions are concerns over market access for businesses in both countries. After all, trade negotiations involve a give and take. That's why there is no ignoring the two US reports and their possible impact on contentious issues, including IP protection (of data generated during research) and clinical trials (testing drugs on humans).

Hectic parleys

In fact, the new Government that will take over after the elections could well be walking into a trade minefield, if both reports paint India as a difficult terrain to do business in. It would leave India less head-room to negotiate, forcing policymakers to concede on some issues, say industry watchers.

With stakes being high, discussions leading up to these reports are no less dramatic, punctuated with late-night conference calls by US trade representatives to explain to Indian media why they felt they were getting the short-end of the stick from Indian trade policies.

The US Chamber of Commerce's Global Intellectual Property Center (GIPC) pegged India at the bottom of 25 countries, in its International IP Index report.

By highlighting countries leading or lagging in fostering a strong IP framework, the GIPC Index provides a tool for policymakers to strengthen innovative potential and for business leaders to assess risk and investment, the GIPC note explained.

Two reports

To counter such views, Indian industry representatives flew to Washington last month to explain India's trade policies to the US International Trade Commission (USITC).

Triggered by trade and Government complaints against India, the USITC was investigating the impact of India's trade policies on American companies and jobs. Its report is expected in November.
On a parallel track, discussions are also under way leading to the US' Special 301 report, slated this April. The annual exercise evaluates US trading partners on their IP protection record.

In its 301 submission, GIPC suggested that India be designated a "Priority Foreign Country, given the rapid deterioration of the nation's IP environment".

A key grouse for US trade involves implementation of the Patents Act (amended to honour product patents) – particularly after a couple of key judgements went against pharmaceutical multinationals – Novartis and Bayer.

But as both countries play to their respective political and business constituencies, the coming month will unravel if the road ahead for Indo-US trade will continue to be rocky, or not.

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Targeting India's IP laws undermines WTO's legitimacy

Lalit K Jha,PTI

Washington, 6 March 2014: A Geneva-based intergovernmental organisation of developing countries has slammed America and developed world countries for pressurising India over its IP (intellectual property) laws, which it alleged undermines the legitimacy of WTO.

"The Indian IP laws include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health," South Center said in a statement Tuesday vehemently opposing any US move to take any action against India.

"These are fully in line with the TRIPS Agreement and reaffirmed by the Doha Declaration on TRIPS and Public Health," it said.

The statement comes after the US International Trade Commission (USITC), a federal American agency, has initiated a probe against India's domestic trade and investment policies particularly intellectual property laws.

Several US-based organisations have urged the US Trade Representative (USTR) to include India as a priority foreign country in the Special 301 review for 2014, alleging that India lacks adequate and effective protection of intellectual property rights (IPRs).

"The South Centre views these recent developments as most inappropriate, as it is against the spirit of the landmark Ministerial Declaration on TRIPS Agreement and Public Health," it said in a statement.
"India and other developing and least developed countries have the right to use the flexibilities in the TRIPS Agreement to the fullest extent for advancing public health needs and other development priorities," South Centre said.

The legal and regulatory measures that India has used for protecting public health are fully consistent with the WTO TRIPS Agreement.The continued threat of unilateral trade sanctions by the US to developing countries through USITC investigations and the Special 301 review undermines the legitimacy of the WTO, particularly the TRIPS Agreement and the WTO's dispute settlement system.

"It is regrettable that India or any other developing countries may be designated as a "priority foreign country" under the "Special 301" provisions of the US Trade Act of 1974," the South Center said adding that the mere threat of sanctions by placing a country in any specific category in the US watch list would appear to violate the WTO Dispute Settlement Understanding.

A WTO panel noted, in a dispute brought in 1999 by the EU against Section 301 of the US law, that "the threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members.

"It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to

foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures," the statement said.

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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 will not use compulsory licence as ‘Robin Hood tool’

Amiti Sen, Business Line (The Hindu)

New Delhi, 26 March 2014: India’s trade and economic policies are facing increased global scrutiny with the US attacking the country’s intellectual property regime and several countries questioning the procurement and pricing mechanisms for agricultural products. Commerce Secretary Rajeev Kher, in an interview with *Business Line*, explains why the international spot light is on India and how it is to be dealt with. Excerpts:

Recently, India has been facing flak at the World Trade Organisation for its policies related to pricing and exports of commodities such as wheat, rice and sugar. Why?
This is a reflection of how generally global trade is taking place. Countries are finding it hard to explore new markets and are trying to encash on any opportunity, real or perceived, that comes their way.
India has over the last few years become a significant player in agriculture. There are countries with relatively smaller export profile that have suddenly started perceiving everything as a threat. For example, Pakistan (that has raised concerns about India’s non-Basmati rice subsidies and exports) does not face a threat at all from India as it does not export non-Basmati rice. So this is all getting muddled in a discourse that is uninformed.

What about the concerns raised by WTO members on pricing of wheat exports?
India has done very well in wheat exports and has been getting good prices. Of course traditional exporting countries feel threatened. And because India has been at the forefront of the food security dialogue and the debate on stock holding that has been taking place (at the WTO), some countries may be looking at it as an opportunity to try and find faults with its policies. So the increased noise is a cumulative effect of all these factors.

Is India in a position to satisfactorily answer all the concerns raised?
The WTO’s Committee on Agriculture has been meeting. These issues have been raised there and we will answer them. We are confident that most of them can be answered well.

Isn’t the US demand that India notify its domestic subsidies at the WTO a valid one?
We have notified our domestic support only up to 2003. It is important for us to make those notifications. This is all work in progress. So far we were busy with issues like the Bali (Ministerial) debate. We are back on the job and will try to notify at the earliest.

What, according to you, is driving the escalation in tension between the US and India on trade related matters?
The two countries have relatively different approach on significant issues which is linked to their levels of economic development. For instance, on the issue of intellectual property rights (IPR), India wants to ensure that everything that happens in this country must try and serve the public good. The US approach is obviously different.

The other factor is that in the US, policy evolution is essentially part of lobbying in sectors. Some US companies have started seeing India as a country with a big market where certain policy developments can obstruct their access. They also fear that it could have a contagion effect on other markets. This is driving them to lobby hard with their Government.

Aren't US pharmaceutical companies losing out because of relaxed IPR in India?
It will be wrong to say that actions that are being attributed to India such as compulsory licences (CLs) and Section 3 (d) will adversely affect their (US) trade. This is a perception that is being built by companies that fear that other countries are going to follow India's policies. In reality, a number of American pharma companies over the last four-year period have increased their businesses significantly.

How do you see the two countries settling the issue?
Ultimately we have to talk and understand that each has compulsions. Nobody in India has said that we will use compulsory licence as a 'Robin Hood tool'. In the last so many years, we have used it just once. The US must accommodate India's interests. At the same time India has to ensure that the use of CLs is not arbitrary.

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Froman Says U.S. Will 'Re-Engage' With India On IPR After Spring Elections

World Trade Online

4 April 2014: U.S. Trade Representative Michael Froman signaled yesterday (April 3) during a House Ways and Means Committee hearing that the U.S. wants to resolve issues relating to India's intellectual property (IP) policies through negotiation rather than litigation, but that it is waiting to do so until after India's parliamentary elections this spring.

"Clearly right now, they're in the midst of an election, and we look forward to re-engaging with them as the election is completed and a government is put in place. And this will be one of the chief issues on the agenda," Froman said, responding to a question about India's IP policies.

He also signaled that the U.S.-India Trade Policy Forum (TPF) would not likely take place until after the elections, which are scheduled to begin April 7 and will conclude on May 12, with the results being announced shortly after that. The ruling Congress Party is facing a strong challenge from the center-right Indian People's Party, or BJP.

Froman acknowledged that the U.S. has the ability to pursue a dispute settlement case against India at the World Trade Organization, but he made it clear that the U.S. prefers a negotiated solution. "Ultimately there are mechanisms for bringing dispute settlement cases, but we are trying to work ... in a constructive way with India to focus on the array of issues that they can deal with on access to medicines, short of taking actions on patents or compulsory licenses," he said.

For instance, he identified lowering tariffs on imported medicines and dealing with distribution issues as ways India could facilitate better access to medicine without taking actions on patents or compulsory licenses. "That's the kind of dialogue we hope to have with the new government of India," he said.

Froman made these comments in response to a question from Rep. John Larson (D-CT) on what options USTR has to force India to change its IP policies, which characterized as "discriminatory."

Various U.S. businesses and private-sector associations over the past year have ramped up their criticism India's IP policies, particularly on instances of patent invalidation and compulsory licensing by the Indian government in its pharmaceutical sector. These groups have called for USTR to label India as a priority foreign country under its "Special 301" process, which evaluates foreign countries' IP regimes.

Froman described India's patent rules, compulsory licensing policy, and its innovation environment in general as being issues of "great concern."

He said the Obama administration has held high-level dialogues with Indian officials, including Prime Minister Manmohan Singh, about IP issues and how India can achieve ensure access to medicine without compromising the patent system.

Rep. Erik Paulsen (R-MN), who said he shares Larson's concerns over India's IP policies, pressed Froman on when the next TPF would take place. The TPF is a bilateral ministerial dialogue that has not met since 2010, though Froman has met several times bilaterally with India's trade minister.

Froman responded that the forum would not meet until after the Indian elections, but said the U.S. and Indian governments have been doing preparatory work for the TPF since September.

"We laid out a work program for our staffs to work through outstanding issues in preparation for our Trade Policy Forum," Froman said. "And that work is ongoing. Now [India] is in the midst of an election season, and I think everyone's perspective is we should wait until they get past the election in order to re-engage on that."

Froman added that he is "fully committed" to restarting the Trade Policy Forum, and that he wants its meetings to produce results. "And that's why I want to make sure it's adequately prepared," he said.

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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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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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India may drag US to WTO over unilateral IPR action

Times of India

New Delhi, 22 April 2014: India will drag the US to the WTO if Washington decides to put New Delhi in the "Priority Foreign Country" list for intellectual property rights (IPR), which could lead to trade curbs on domestic firms, sources said.

This was decided at a high-level meeting called by cabinet secretary Ajit Seth to discuss problems related to IPR issues with the US, especially in the pharmaceutical sector. "Indian IPR laws are fully compliant with WTO and other international norms. Any unilateral action taken by the US will be violative of WTO and India will suitably respond by dragging the US to WTO's dispute resolution mechanism," sources said.

US industry, particularly the pharma sector, and trade lobbies have been putting pressure on their government to place India under the Priority Foreign Country list for IPR. Under the US Trade Act, a Priority Foreign Country is the worst classification given to those that deny adequate and effective protection of IPR or fair and equitable market access to US entities relying on IPR protection.

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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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India will not join US' unilateral IPR law probe

Business Line (The Hindu)

New Delhi, 1 May 2014: India has refused to participate in any unilateral investigation carried out by the US on the country's intellectual property laws, but is prepared to discuss the matter bilaterally.

"It is the US that has decided to carry out such an investigation, but we don't have to be a party to it. We are not bound by our commitments at the WTO or bilaterally," Commerce Secretary Rajeev Kher said at a press conference on Thursday.

The office of the US Trade Representative on Wednesday stopped short of blacklisting India as a 'priority foreign country' in its 'Special 301' report on countries with lax intellectual property regimes. The USTR kept India on the 'priority watch' list and said it will carry out an 'out of cycle' review of the country's IP regime when the new government is in place.

Open to discussion

Kher said that though India's intellectual property regime was fully compliant with WTO rules and the Trade Related Intellectual Property Rights regime, it did not mind discussing any concerns that the US may have on the matter.

The Commerce Secretary is to meet the Deputy USTR Wendy Cutler next month to discuss trade issues, including intellectual property, following which there will be a meeting of the Trade Policy Forum — the platform for bilateral trade policy talks.

"I had a conversation with Deputy US Trade Representative Wendy Cutler last evening on the report. I made it clear that India is willing to engage in bilateral conversation and TPF was the best mechanism for this," he said.

US-based pharmaceutical multinationals have been lobbying hard to get India included in the 'priority foreign country' list, which would have led to unilateral trade sanctions against the country.

Compulsory licence

The drug companies are upset with India's 2012 decision to grant a compulsory licence to an Indian company for manufacturing a copied version of Bayer's cancer medicine Nexavar; this move brought down prices by 90 per cent. They also want India to drop Section 3(d) of its Patent Act, which does not allow 'ever-greening' by refusing patents for incremental innovations.

India says that its position on all the areas of their concerns, which also include the issue of data exclusivity and patent linkages, was well evolved, legally sound and complied with WTO norms.

Kher said that India was not apprehensive about the 'out of cycle' reviews as it had not broken any law. "It appears to be a wise decision on the part of the US not to hasten to get into a decision which would have adversely affected bilateral trade relationship and a larger economic engagement between the two countries, particularly at a time when we are at a stage of political transition," he said.

The US was India’s third largest trading partner in 2012-13 accounting for exports worth $36 billion and imports of $25 billion.

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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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India needs to modify IPR regime to attract FDI: EU

PTI

New Delhi, 7 May 2014: India needs to modify its Intellectual Property Rights (IPR) regime and fast-track legal system to attract foreign investments, a report said Wednesday. "India must sort out some contours of its IPR regime. The legal system must be fast-tracked and the use of compulsory licensing (CL) for essential pharmaceutical drugs must be the exception and not the norm," it suggested. The report has been released by the Europe India Chamber of Commerce (EICC) and European Business and Technology Centre (EBTC) in co-operation with the European Business Group.

The US industry too has raised concerns over India's IPR laws particularly in the pharmaceuticals sector. However, Indian government has maintained that its IPR laws are in compliance with WTO norms and rules.

The report also said that over the last two years, Indian Government has taken several steps to remove FDI barriers in a range of sectors but "it calls for swift implementation" of those measures. It said: "Modalities such as land acquisition, revenue sharing and others must be discussed and debated by the states and the Centre before a formal policy decision is taken."

"Many EU companies find out that the actual market scenario in India is distinctly different from their original understanding." Reforms also need to be initiated in trade facilitation and export promotion, it added.

"Companies that invest in India need to have lot of patience and deep pockets to sustain cash flow uncertainties. They should focus on the potential and not the short-term challenges," EICC's Research Head Adith Charlie said.

Further, it claimed that European companies had spent USD 198 billion in India during the last 10 years.

"In the same period, Japanese and US firms channelised USD 138 billion and USD 50.7 billion respectively into their India units. This gives EU enterprises the distinction of being the largest inbound investor into India," it said. EU firms have spent USD 118 billion on 2,566 greenfield (new) projects and also acquired interests in 1,442 companies for USD 80 billion.

"Tactical Greenfield investments, landmark acquisitions and steadfast dedication through uncertain economic cycles have been the key ingredients of the success enjoyed by European companies in India," it said quoting EICC Secretary General Sunil Prasad.

The study found that despite the challenges facing the Indian economy, EU firms are optimistic about the next 5 years.

"The common consensus is that the next government would usher in a fresh round of growth," Prasad added.

The report titled 'European Companies in India: Reigniting Economic Growth', said that EU companies collectively provide direct employment to 1.5 million Indians. Of this, about 562,335 new jobs were

added in the last 10 years alone through the greenfield route, the report added.

"To ensure continued high levels of FDI, essential to India's future economic growth, government and industry alike must engage in novel thinking and disciplined implementation - only then will the so urgently required paradigm shift happen," EBTC Director Poul Jensen said.

It said that huge potential is there in sectors such as education, energy, food processing, life sciences, advanced engineering and infrastructure.

Meanwhile, Ambassador of EU Delegation to India Joao Cravinho said in the report's foreword: "The sheer scale, diversity, and regulatory and tax complexity of India can be overwhelming for a foreign company.

"Companies have to be patient and committed to experience sustainable growth in the country over the longer term."

He added that the EU is committed to strengthening trade relations with India and "we are confident that the conclusion of the EU/India Broad-based Bilateral Trade and Investment agreement is possible in the near future".

The total India-EU bilateral trade was USD 94.43 billion during April-February, 2012-13. It was USD 109.86 billion for the entire 2011-12 fiscal.

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