

## Contents

Rising exports to US, EU clouded by order dip from other regions .....	3
US Immigration Bill: IT Inc sees rays of hope .....	4
PM-Sharif meet to focus on trade .....	6
India, a headache for US IT firms .....	7
US not to impose countervailing duty on Indian shrimp exports.....	8
Coffee exports fall 5.3% on low demand from US, EU.....	9
No major impact seen on travel, IT firms; exports may take a hit.....	10
India's IPR regime - Moving beyond the myths of US pharma .....	12
U.S. Declines to Counter India Claims Of Illegal Subsidies for Energy Programs .....	14
US pharma firms lobby to protect patents in India .....	16
India, US to work on understanding on investment issues .....	18
Local sourcing mandatory in Phase II of solar projects.....	19
India slaps duty on US, EU imports of chemical used in perfume .....	20
India to resume visa fee hike dispute with US in WTO.....	21
US pushes India again for early phase-out of textile sops .....	22
India Tries To Ease Impact Of Electronics Testing Rule; U.S. Industry Balks .....	23
India slams US move to tighten H-1B visa rules .....	24
India faces trade action from US.....	25
India, US seek to better drug-making processes .....	27
India-US ties under stress over trade, investment issues .....	29
India hardens trade stance against US, wants disputes to go to WTO.....	31
Patent laws safe from US challenge: India .....	32
India hardens stance, accuses US of protectionism .....	34
India-US trade stand-off: a tale of two reports .....	35
Targeting India's IP laws undermines WTO's legitimacy .....	37
Open to discussing IP norms at WTO: Sharma .....	39
US insists India give WTO data on food security scheme.....	40
US, India to hold second round of talks on solar trade dispute.....	41
India will not use compulsory licence as 'Robin Hood tool' .....	42
Indian food industry poses trade barriers: USTR.....	44
Froman Says U.S. Will 'Re-Engage' With India On IPR After Spring Elections .....	45
Solar mission: US wants India to do away with local sourcing norms.....	47
US, EU oppose India's local sourcing norms in telecom.....	48
India may drag US to WTO over unilateral IPR action .....	50

Govt prepares to battle US pressure on patents .....	51
India-US ties headed for rough weather over drug IP issue.....	53
US defers decision on downgrading of India's intellectual property regime .....	55
India will not join US' unilateral IPR law probe .....	57
India Rejects U.S. Panel Request in Solar Dispute, Probes State Programs .....	59
<b>Indian drug makers to benefit as US expedites generic clearances</b> .....	61
India may back solar duties after probe says US, China dumped .....	63

# Rising exports to US, EU clouded by order dip from other regions

Amiti Sen, Business Line (The Hindu)

New Delhi, 2 September 2013: There is an upside to the falling rupee. Exports are up thanks to that and more orders from the US and the EU. But the party poopers could be the rising input costs and a fall in demand from Latin America, Asia and Africa.

The Commerce Ministry's disaggregated export data for the first quarter of this fiscal reveal a small increase in dispatches to the US and the EU that account for a third of exports. However, exports to Latin America, and parts of Asia and Africa, that together also account for a third of the total orders, fell.

India's exports grew 11.64-per cent in July after dipping for two months; the disaggregated numbers for the month becomes available only with a lag. Overall exports during the first quarter fell 1.64 per cent. "Orders are certainly going up, especially from the EU and the US. But the bounce back in exports has been affected by a fall in demand in other important markets in Asia, North Africa, East Africa and Latin America," a Commerce Ministry official told *Business Line*.

While six of India's top 10 export items such as textiles and garments, drugs and pharmaceuticals and petroleum products posted a growth in the first quarter, other important sectors such as engineering goods, gems and jewellery and electronics, continued to fall. Engineering export, which was a top performer less than two years ago, has taken a hit due to a fall in demand from Africa. "Orders from Africa are now mostly going to China that offers credit for a much longer period and at lower rates than we do," pointed out Anupam Shah from the Engineering Export Promotion Council.

## *Rising Prices*

Availability of high quality steel, too, is affecting the sector as international steel production has been stagnant and prices have been rising.

Apart from steel, rising prices of other inputs such as petroleum and chemicals will also affect exports, says Ajay Sahai from the Federation of Indian Export Organisations.

[\[Back to top\]](#)

# US Immigration Bill: IT Inc sees rays of hope

Debojyoti Ghosh & P P Thimmaya, Financial Express

9 September 2013: The \$76-billion Indian IT & BPO export services industry — worried about the fallout of the proposed Immigration Bill in the US — has been receiving better appreciation of their concerns from lawmakers, setting the stage for a likely positive outcome of the legislation.

Talking to FE, Som Mittal, president of Nasscom, India's IT-BPO trade body, said: "We are clearly seeing that there is a more positive alignment to our views with a growing realisation in the US that what is bad for Indian IT would also be harming them."

This assumes significance as both the US Senate and House of Representatives were in recess for August, with the new session expected to start from the second week of September. It is expected that the House would take up the Immigration Bill shortly.

The Bill in its present form as passed by the US Senate in June, 2013 would inflict considerable damage on the Indian IT industry with numerous provisions, especially the outplacement clause. This clause states that firms with 15% and more H-1B dependent employees are debarred from deploying their resources at customer locations.

This is seen as one of the measures proposed to save US jobs. Indian IT companies like TCS, Infosys, Wipro, and HCL Technologies are heavily dependent on the H-1B visas to carry out operations in the US, their largest market.

Gordon Coburn, president, Cognizant, a US-headquartered IT major with large presence in India during the Citi 2013 Global Technology Conference, said, "As we talk to more and more members of the Congress about this (Immigration Bill) and educate them on the issues, I think there is an increasing understanding and awareness that some of those outplacement clauses are not good for our customers." He further said: "We're seeing an increasing understanding that the outplacement clause would be bad for American competitiveness."

Indian IT companies have been crying hoarse about the various negative connotations in the Bill, which has provisions like increased visa fees, stringent conditions on placing Indian employees in American companies, besides the outplacement clause. The Bill has been passed only by the Senate, but the one which has got approval from the judiciary committee of the House of Representatives — called the skilled Immigration Bill — does not have any outplacement clause, which is a big positive for the Indian IT industry.

Mittal told FE that a greater number of US technology firms are now supporting their initiatives. "Indian IT companies predominantly provide services on technology platforms of American companies and any shift in this balance would adversely affect everybody," he said.

Prime Minister Manmohan Singh will be holding a meeting with US President Barack Obama on September 27, when this topic is expected to come up for discussion. Wipro chairman Azim Premji has written to the Prime Minister seeking his intervention on the matter.

The commonly-held belief about Indian technology companies operating in the US has been that they were garnering a large percentage of work permits, displacing American workers. Indian firms on the

other hand have always said that shortage of IT services skills in the US had created such a situation. Howard Greenberg, partner, global immigration leader, KPMG Canada, has said that the US will further open up on immigration. “There is a recognition that global competition for talent is heating up and that includes Indians.”

[\[Back to top\]](#)

# PM-Sharif meet to focus on trade

Mihir S Sharma, Business Standard

**New Delhi, 26 September 2013:** While the situation on the Line of Control in Jammu and Kashmir will definitely be discussed when Prime Minister Manmohan Singh meets his Pakistani counterpart, Nawaz Sharif, in New York on the sidelines of the United Nations General Assembly, it was emphasised by high-level sources on Wednesday that progress on trade would be made, as there is a concrete agenda to be followed for that.

The sources, who spoke on the condition of confidentiality, said that a significant step forward in exporting electricity to Pakistan could happen as early as next week. It had been held up, they claimed, not for political reasons but because the Pakistani side was evaluating its technical and commercial viability. However, it is believed that process is close to conclusion, and Pakistan may express formal interest in cross-border electricity trade, sending a delegation on the subject, within a week. Sharif and Singh are likely to meet on Sunday.

In another significant development, the Nuclear Power Corporation of India Limited, or NPCIL, will likely move forward within a few days on evaluating the terms of a possible contract with nuclear supplier Westinghouse. A limited exploratory agreement might be in place between the two companies, according to the highly-placed sources, before Singh meets US President Barack Obama on Friday. This is in spite of concerns expressed domestically that US companies, including Westinghouse, wish to dilute the nuclear liability legislation passed by the Parliament beyond recognition.

A lack of progress in transforming the US-India civil nuclear agreement of 2008 into real projects on the ground is often cited as a major cause for a chill in bilateral relations. However, officials close to the prime minister strongly denied that the United States had any ground for disappointment, and suggested that such claims may just be an American negotiating tactic.

Singh will also make a pitch for more US investment in India. Although the recent diplomatic coolness between India and the US has been driven in large part by the souring of US business on the India story, officials insisted that the outreach was not unusual. Reporters were told that a ramped-up pitch for investment will be the one consistent theme of all major upcoming foreign visits, including to China. The PM is scheduled to meet a group of US CEOs in New York City later this week.

Fears that this was a lame-duck visit by a PM ending his term in office were rubbished by officials, who said that regardless of elections or political transitions, there has always been continuity to what New Delhi has done on national security.

[\[Back to top\]](#)

# India, a headache for US IT firms

PTI

**Washington, 26 September 2013:** The influential American IT and telecom industry on Wednesday sought intervention of the Obama Administration against what they alleged are “discriminatory” Indian policies, which they claimed has resulted in several hundred millions of dollars of losses in the last quarter.

“In discussions with our member companies, we have quantified the potential Q4 losses at several hundred million dollars, with billions of dollars of lost exports and sales at risk in 2014 if these requirements remain in place. If left in place, these policies could shut out US technology companies from a critical emerging market,” information technology industry council said in a letter to Obama Administration.

The letter dated September 24 against India’s “compulsory registration order” which goes into effect on October 3, has been jointly written to the US commerce secretary, Penny S. Pritzker; the US trade representatives, Mike Froman, and the Caroline Atkinson, the deputy national security advisor to the United States President for international economic affairs.

Under the new “compulsory registration order” issued last year by the department of electronics and information technology, the ITIC alleged that the new equipment cannot be imported into or sold in India after April 3, 2013, which now has been extended to October 3, unless it is tested and registered with Bureau of Indian Standards-approved testing labs in India.

[\[Back to top\]](#)

# US not to impose countervailing duty on Indian shrimp exports

PTI

New Delhi, 23 September 2013: The United States has said it will not impose countervailing duty on imports of frozen warm water shrimp from India and six other countries.

The United States International Trade Commission (USITC) has said that the US industry is "neither materially injured nor threatened with material injury" by reason of imports of frozen warm water shrimp from countries including India, China, Ecuador, Malaysia, and Vietnam.

As per the WTO Agreement on Subsidies and Countervailing Measures, a country can launch its own investigation and ultimately charge extra duty (countervailing duty) on subsidised imports which it finds are hurting domestic producers.

"As a result of the USITC's negative determinations, US Commerce will not issue countervailing duty orders on imports of these products from India. The decision brings a great relief to Indian shrimp industry and its exports," an official statement said today.

According to an industry estimate, India's seafood exports including frozen shrimp stood at USD 3.5 billion in 2012-13. About a fifth of the exports were to the US.

The decision comes ahead of Prime Minister Manmohan Singh's scheduled visit to Washington later this week.

The USITC imposed a 5.85 per cent countervailing duty on Indian shrimp exports last year in response to alleged price advantages enjoyed by Indian exporters due to government subsidies.

The final decision of the USITC came in favour of India and six other countries and negate the US Department of Commerce's (USDOC) decision.

"Due to this, none of the seven countries including India need to pay duties for their shrimp exports to US," it said.

In December 2012, the Coalition of Gulf Shrimp Industries filed a petition claiming that subsidies provided by the Indian government to its shrimp industry gives an unfair advantage to the country's shrimp exports to the US, resulting in Indian exporters selling their products at lower prices.

It also said that if countervailing duty was imposed, it would have helped Thailand and Indonesia to monopolise the US shrimp market, and market access of Indian shrimp would have been affected.

[\[Back to top\]](#)



# Coffee exports fall 5.3% on low demand from US, EU

Mahesh Kulkarni, Business Standard

Bangalore, 30 September 2013: India's coffee exports fell 5.34 per cent to 2,99,266 tonnes in the year ended September 30, as demand from the US and the European Union (EU) remained subdued. In the previous coffee year (October 2011 to September 2012), India had exported 3,16,164 tonnes.

“The decline in exports was mainly due to weak demand from European nations such as Italy, Spain, Greece and Portugal, as buyers were looking for cheaper coffees,” exporters said. Realisation from exports declined 1.3 per cent to Rs 1,51,379 a tonne between October 2012 and September 26, 2013, against Rs 1,49,459 a tonne in the previous coffee year. In value terms, total coffee exports fell 4.1 per cent to Rs 3,530 crore, against Rs 4,725 crore in the previous year, according to the Coffee Board.

A sharp drop in the prices of the arabica variety last financial year contributed to the decline in exports, as a large number of farmers withdrew sales, exporters said. Arabica prices declined 20-25 per cent.

“Arabica coffee prices ended within a cent of a more than a four-year low on Thursday, as big supplies of the beans and tepid demand encouraged selling. Prices were down about 20 per cent for the year; roasters appear to be waiting for even lower prices due to large supplies, particularly from Brazil. LIFFE robusta coffee futures hit an almost three-year low last Thursday, as expectations of a large crop from top grower Vietnam weigh on prices. LIFFE robusta coffee futures for November delivery settled \$43 lower at \$1,663 a tonne,” the Coffee Board said. India primarily exports coffee to Italy, Germany, Russia, Belgium and Spain.

The outlook for exports in 2013-14 isn't very promising. The Coffee Board has said in 2013-14, production would be at least 10 per cent lower than post-blossom estimates. In its post-blossom estimates earlier this year, it said production would stand at 3,47,000 tonnes. In 2012-13, production stood at 3,18,200 tonnes.

“Based on the conditions in February and March, when the growing regions received good blossom showers, we had estimated we would record 3,47,000 tonnes. However, due to a drought in the two subsequent months and the heavy rains in June, July and August, we anticipate a drop of about 10 per cent against the post-blossom estimates,” Coffee Board Chairman Jawaid Akhtar had told Business Standard earlier this month.

This means for 2013-14, India's bean production could be about 3,12,000 tonnes. However, growers estimate it at 70,000-2,90,000 tonnes. Exporters said low production would hit exports in the next crop year, too.

[\[Back to top\]](#)

# No major impact seen on travel, IT firms; exports may take a hit

Business Line (The Hindu)

New Delhi/Kolkata, 1 October 2013: Even as the US Government began the partial shutdown process on Tuesday, travel and infotech companies here said they did not anticipate any major impact. But industry bodies pointed out that exports to the US could take a hit.

Rana Kapoor, President of Associated Chambers of Commerce and Industry of India, in a statement said, “The shutdown of the US Government will certainly hit Indian exports because of crippling of trade facilities at the ports and airports.”

## *Visa Issue*

Tour operators said the shutdown was not likely to have any major impact on travellers. Karan Anand, head-relationships, Cox & Kings Ltd, said obtaining a US visa would not be a problem as consular services at US embassies and consulates around the world were largely funded by application fees not annual appropriations.

“Visa applications filed by foreigners wanting to enter the US will continue to be processed. Flight operations across all airlines to the US will not be affected,” he said.

But, if leisure tourists have any of the 401 national park service sites, including the iconic Statue of Liberty, on their itinerary, it will have to be changed, as all national parks and such sites will remain shut. However, Anand said, “Indian customers prefer going to theme parks such as Universal Studios, Disney World in Los Angeles or indulge in shopping. They do not prefer national parks.”

Tour operators also said that this was not a big season for Indian leisure tourists to travel to long-haul destinations such as the US.

Subhash Goyal, Chairman, STIC Travel, said, “Most leisure tourists do their long-haul travel during summers. Usually honeymooners are looking to book trips to the US in this season and some are opting for other options.” For corporate travellers, it’s going to be business as usual.

IT industry body Nasscom, said, “A majority of the business that our industry has is with the private sector, and is not directly dependent on federal spending. Hence, we do not see an immediate economic impact. If the shutdown continues for an extended period, there will be an overall macroeconomic impact that may affect the industry.”

It added that some services such as visa processing time that depend on federal budgets are expected to see delays.

## *Engineering Exports*

The US Federal Government shutdown may hit Indian engineering exports to that country, Anupam Shah, Chairman, EEPC India, an engineering export promotion body, said in Kolkata on Tuesday.

The US consumed nearly one-tenth (11 per cent) of India's \$57-billion engineering exports last year. Exports to the US were down 12.3 per cent during April-August this fiscal.

According to Shah, the shutdown — which was announced by the US Government after the two houses of Congress failed to agree on a new budget — would substantially reduce the demand. “As the US economy closes down, our export might slow down as well. The consumers will be spending less and individuals will be left without pay, (resulting in a sharp decline in demand),” Shah said at a press conference here.

According to him, delay in port services in the US would also impact export operations, if the shutdown issue was not resolved immediately. “Commercial ports do not come under emergency service category. So, there will be delay in port services like clearing of goods from ports owing to staff shortage. This may result in huge demurrage for exporters,” he said.

### *Growth and Benefits*

Meanwhile, Shah said exporters were upset with the Finance Ministry's decision to cut back duty-drawback benefits on some engineering products.

The reduction in duty drawback, neutralised the benefits of devaluation of Rupee against US dollar. EEPC has lowered its growth expectations to 10 per cent (from 15-20 per cent) this fiscal, Shah pointed out.

The engineering export promotion body has sought a financial support worth around Rs 500 crore to upgrade technology in the engineering products sector to boost export growth.

According to a PTI report, “The Indian pharma industry is not selling drugs to the US Government. It is selling mostly private. So, the US government shutdown will not have any impact on the India pharma industry,” said the Indian Pharmaceutical Alliance Secretary General D.G. Shah.

[\[Back to top\]](#)

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

Hemant Krishan Singh & Aman Raj Khanna

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[\[Back to top\]](#)

# U.S. Declines to Counter India Claims Of Illegal Subsidies for Energy Programs

Daniel Pruzin, WTO Reporter

4 October 2013: The U.S. has declined to counter claims made by India that a number of U.S. state and municipal authorities may be providing subsidies for promoting renewable energies that are illegal under global trade rules.

Last April India asked the U.S. to explain how local content requirements under the state of Michigan's 2008 Clean, Renewable, and Efficient Energy Act (Public Act 295) and solar energy programs offered by the city of Austin, Texas, complied with Article 2 of the World Trade Organization's Agreement on Trade-Related Investment Measures (TRIMs).

Article 2 prohibits investment measures that are in violation of the national treatment principle established under Article III of the General Agreement on Tariffs and Trade (GATT). Article III:4 in particular requires WTO members to provide imported goods the same treatment afforded domestically produced goods with respect to all laws, regulations and requirements affecting their internal sale.

In a communication forwarded to WTO members Oct. 4, the U.S. provided India with information on how Michigan's program works, including an acknowledgment that any energy system containing a threshold level of 50 percent Michigan-made equipment will earn incentive credits that go toward meeting the state's requirement that at least 10 percent of a state electric provider's retail supply portfolio include renewable energy by 2015.

However, the U.S. did not respond to India's request for an explanation of how the local content requirements comply with Article 2 of the TRIMs Agreement. The U.S. did note that the incentive credits in question accounted for only 0.0021 percent of all renewable energy credits granted by Michigan in 2012.

In regards to the Commercial Solar Photovoltaic Performance-Based Incentive Program offered by Austin Energy, a publicly owned power company and a department of the city of Austin, the U.S. said a previously mentioned incentive for use of equipment manufactured or assembled in the Austin Energy service area has been removed from the guidelines for qualification for the rebates. The U.S. did not address India's concerns regarding a second program, Austin Energy's Residential Solar PV Rebate Program. India said both Austin programs offer higher rebates and higher payments for solar power generated from equipment which is at least 60 percent manufactured or assembled in Austin Energy's service area.

## *Local Content*

The U.S. has yet to address India's questions raised last April regarding similar local content requirements in the Los Angeles Department of Water and Power's Solar Photovoltaic Incentive Program, the state of California's Self Generation Incentive Program (SGIP) and solar energy incentive programs in the states of Delaware, Minnesota, Massachusetts and Connecticut. Water utilities in South Carolina, Pennsylvania, West Virginia and several New England states have been mandating domestic content for equipment use in water projects, India charges.

The matter was also raised at a meeting of the WTO's TRIMs Committee Oct. 4. U.S. officials told the meeting that they were in discussion with the Los Angeles Department of Water and Power about its program and would provide more information at a later date. The officials also said they were still awaiting further clarification from India regarding its questions on the state water utilities programs.

India posed its questions regarding the U.S. state and municipal programs after the U.S. announced Feb. 6 that it was initiating WTO dispute settlement proceedings to address what it said were illegal domestic content requirements in India's national solar energy program, the Jawaharlal Nehru National Solar Mission (JNNSM).

According to the Office of the U.S. Trade Representative (USTR), India initially required that developers of solar photovoltaic projects employing crystalline silicon technology use solar modules manufactured in India. India later expanded the domestic sourcing requirement to cover crystalline silicon solar cells as well.

India has also drafted new provisions that might expand the scope of the domestic content requirements to include solar thin film technologies, which comprise the majority of U.S. solar exports to India, USTR charged. India also offers solar energy developers participating in the JNNSM a guarantee that the government will purchase a certain amount of solar power at a highly subsidized tariff rate, provided they use domestically manufactured solar equipment instead of imports.

Local content requirements have become a growing concern for WTO members. In addition to India's complaint regarding the U.S. state and municipal programs, the TRIMs committee also heard complaints from the U.S., Japan and the European Union regarding local content provisions in Brazil's telecommunications and automotive sectors, Indonesia's telecommunications and energy sectors, Nigeria's oil and gas industry, Russia's auto investment program, Ukraine's electric power sector and Uruguay's wind power projects.

### *Electronic Products*

On a positive note, the U.S., Japan and the EU said they were pleased with recent indications that India was preparing to remove domestic content requirements in government procurement for electronic products. India's Department of Information Technology issued a policy notice in February 2012 requiring that procured electronic products having national security implications contain at least 30 percent domestic content.

Last year a WTO dispute panel struck down local content requirements in the Canadian province of Ontario's green energy program (88 WTO, 5/7/13). The panel backed complaints from Japan and the EU that the minimum domestic content provisions in Ontario's Ontario's Feed-In-Tariff (FIT) violated Article III:4 of GATT by affording less favorable treatment to imported equipment and components for renewable energy generation facilities than that given to like products originating in Ontario.

According to a report issued Sept. 25 by the Information Technology & Innovation Foundation (ITIF), a Washington-based think tank, local content requirements reduce global trade in goods and services by almost \$100 billion per year. In particular, the ITIF argued, a rapidly growing number of countries, including Argentina, Brazil, China and India, "have come to embrace a new kind of mercantilist trade policy that seeks to pressure foreign enterprises to 'localize' economic activity so that these countries can create domestic jobs."

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# India, US to work on understanding on investment issues

Lalit K Jha, PTI

Washington, 14 October 2013: With India among the fastest growing sources of investment into the US, the two countries have agreed to further strengthen bilateral economic ties and work towards a greater understanding of investment related issues.

"Indian foreign direct investment (FDI) in the US increased from USD 227 million in 2002 to almost USD 5.2 billion in 2012, making India one of the fastest growing sources of investment into the US," Finance Minister P Chidambaram and his American counterpart Jack Lew said in a joint statement after their meeting here yesterday.

During the fourth annual meeting of the India-US Economic and Financial Partnership held at the IMF headquarters here, the two leaders agreed that the economic and financial relationship between India and the US continues to deepen and strengthen.

"Despite a challenging global economy, US-India bilateral trade in goods and services grew from USD 59.9 billion to USD 92.5 billion between 2009 and 2012," the joint statement said. "Total FDI inflows from the US into India, from April 2000 to July 2013, are USD 11.492 billion," it said.

Chidambaram and Lew agreed to continue working towards a greater understanding on all investment related issues including taxation and IT enabled services, an equitable and principled resolution of ongoing tax disputes and strengthened bilateral ties in this regard, the joint statement said.

The two leaders agreed to continue to cooperate on deepening capital markets and strengthening financial regulation.

"We committed our financial sector experts to holding the next meeting of the Financial Regulatory Dialogue, which brings together our respective financial sector regulators, to consult on the full range of domestic and international regulatory concerns, in India in 2014," the joint statement said.

[\[Back to top\]](#)

# Local sourcing mandatory in Phase II of solar projects

Metis Energy Insider

21 October 2013: Cocking a snook at the US, which had objected to compulsory local sourcing conditions imposed in the first phase of India's National Solar Mission, the country is all set to extend similar norms to the second phase as well.

Domestic sourcing conditions would, however, be imposed on just 50 per cent of capacity earmarked for the second phase, a senior Government official has said.

But, this may fail to pacify the Americans as the Ministry for New & Renewable Energy (MNRE) has decided to expand the coverage of local sourcing norms to include solar thin films, mostly imported from the US during the first phase.

Interestingly, this MNRE move comes despite the Commerce Ministry warning it against continuing with its domestic sourcing clause, given it could lead to further acrimony at the World Trade Organisation.

## *Second Phase*

The MNRE is coming up with tenders for a 750 MW grid connected solar projects under the second phase of the Jawaharlal Nehru National Solar Mission on October 24.

Phase-1 of the Solar Mission only stipulated compulsory purchase of solar modules from local companies, and not thin films. Both modules and thin films can be used in solar projects, and are interchangeable. "We made a mistake in the first phase by not including thin-film in the local sourcing norms as it led to power producers importing cheap thin films rather than use domestically produced modules," the official said.

## *Flouting Norms?*

The US dragged India to the World Trade Organisation in February this year for stipulating local sourcing norms in Phase-1 of the Solar Mission on the grounds that it flouted norms that discourage discriminatory practices against foreign companies.

MNRE is of the view that it is important to continue protecting the fledgling domestic solar industry as it is operating way below capacity.

In 2013, analysts expect close to 1 GW worth of project installations in India, of which only 10-15 per cent will use domestically made cells and modules, even though the domestic industry has a capacity to provide for 100 per cent of these installations.

Since WTO rules are not binding on sourcing done by the Government, MNRE is hopeful that by restricting local sourcing clause to just half the projects, it may escape action, as it could claim that power produced is being used by the Government. However, proving this may be difficult.

[\[Back to top\]](#)

# India slaps duty on US, EU imports of chemical used in perfume

PTI

New Delhi, 27 October 2013: India has imposed anti-dumping duty of up to USD 0.36 a kg on import of a chemical, used in manufacture pharmaceuticals and fragrance products, from EU, US and Korea to protect domestic players from cheap shipments.

"The anti-dumping duty imposed (on Methylene Chloride) under this notification shall be levied for a period not exceeding six months...", said the Central Board of Excise and Customs (CBEC) in the Revenue Department.

The duty has been imposed to discourage the import based on recommendation of the Directorate General of Anti Dumping and Allied Duties (DGAD).

Acting on the complaint of Chemplast Sanmar and Gujarat Fluorochemicals, the DGAD had carried out a preliminary probe into the imports and concluded that "subject goods (Methylene Chloride) have been exported to India from the subject countries (EU, US and Korea) below its normal value...(and) the domestic industry has suffered material injury".

The initial probe found that material injury has been caused by the dumped imports of the chemicals.

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

[\[Back to top\]](#)

# India to resume visa fee hike dispute with US in WTO

**Nayanima Basu, Business Standard**

**New Delhi, 4 November 2013:** Days after Indian information technology bellwether Infosys was made to pay a hefty penalty of \$34 million (about Rs 210 crore) to the US government over a visa fraud case, India is planning to resume the two-year old dispute with America for raising professional visa fees at the World Trade Organisation's (WTO) dispute settlement body.

It said the move had hurt Indian IT companies and was "specifically" targeted at them. India had formally approached WTO, seeking consultations with the US on this particular case in 2011-end and the matter went on till early 2012, even as the US government raised the fee for H-1B and L-1 visas in 2010. However, the case was not pursued, as the government "failed to obtain the required data" from Indian IT companies such as Infosys, Wipro and Tata Consultancy Services (TCS), officials told Business Standard. Now, armed with evidence, the government has decided to take up the issue.

"We have not given up on the case, we never did. We were waiting for evidence. We have received that evidence and now we are going to pursue it further," said a senior commerce department official. Although the government officially maintains that the particular move is not related to the Infosys civil settlement issue, top officials who are involved in the matter have told Business Standard that trigger is indeed the Infosys case. In its complaint to the WTO, India has said the US has violated WTO rules in services trade on commercial presence of a country in another, and in movement of professionals.

The US is using a particular law — Public Law 111-230 (Border Security Act) — that nearly doubled skilled worker H-1B and L1 visa fee, to as high as \$4,500 (about Rs 2.78 lakh) per applicant (from around \$2,320 (about Rs 1.43 lakh earlier), for any company in which foreigners are more than 50 per cent of its US work force. It was put into force from August 13, 2010 till September 30, 2014. However, under the James Zadroga Act, it got further extended to 2015.

The funding for the \$4.2 billion James Zadroga 9/11 Health and Compensation Act is partly drawn from imposition of tax on any foreign entity that receives a specified federal procurement payment equal to two per cent of the amount of such specified federal procurement payment.

Imposition of such two per cent tax on countries which are not signatories of the WTO Government Procurement Agreement such as India is discriminatory and may be inconsistent with US's international commitments, India has said in its complaint.

While H-1B visas are for non-immigrant specialty workers, L-1 visas are for intra-company transferees (L-1A category for managers or executives; L-1B for ICT specialists).

India now is also closely watching the development on the recent debate going on in the US on the immigration bill. Minister for External Affairs Salman Khurshid and Minister for Commerce and Industry Anand Sharma have said that some of the provisions in the bill are not conducive for Indian IT companies. They have not ruled out dragging the US to WTO on the issue also if the bill is passed in its present form.

[\[Back to top\]](#)

# US pushes India again for early phase-out of textile sops

Amiti Sen, Business Line (The Hindu)

New Delhi, 3 November 2013: The US has pushed India again to do away with its export subsidies to textiles and garment producers as these sectors are now competitive in the global market.

India will have to start phasing out its textile subsidies soon to conform with the Subsidies Agreement of the World Trade Organisation, a US representative said at a recent meeting of the WTO Committee on Subsidies & Countervailing Measures.

While India may not start phasing out export subsidies on textiles and garments immediately, the growing pressure at the WTO may prompt it to go slow in giving fresh subsidies to the sector, a Commerce Ministry official told *Business Line*.

“We have informed the WTO that India is working with stakeholders on this issue. However, we still needed clarification on certain points, including the definition of products involved,” the official said.

While export subsidies are prohibited under WTO rules, the multilateral trade body allows countries with per capita income below \$1,000 to give such incentives till exports are lower than 3.25 per cent of world trade in that particular commodity.

India’s share in the global market for textiles crossed the limit in 2007, according to WTO records, and is almost four per cent at the moment. However, since countries are given eight years to remove the subsidies, India has time till 2015 to do so.

India has been giving incentives to its exporters over the last few years for exporting to targeted markets and for exporting labour-intensive products to help them tide over the slowdown in global demand. Since textiles and garments are important job generating sectors, these have received generous incentives over the last few years. With the US and EU markets now looking up, the pressure on the Government to further give incentives is not high.

India had earlier pointed out at the WTO that many of the subsidies identified by the US and others are not subsidies and merely a reimbursement of input duties. It said before the phasing out takes place, there has to be a common understanding on what the subsidies are.

[\[Back to top\]](#)

# India Tries To Ease Impact Of Electronics Testing Rule; U.S. Industry Balks

World Trade Online

8 January 2014: The government of India has taken two last-minute measures designed to ease the impact of a new safety standards testing and registration rule that began applying to imports of electronic goods on Jan. 3, but U.S. industry sources this week continued to warn that the Indian rule holds the potential to create massive disruptions in trade.

The first measure taken by India effectively delays the requirement that all covered products bear a label printed with the necessary registration code until April 3. However, only companies that have put their products through the necessary testing process and already obtained a code will be eligible for this exemption.

Secondly, New Delhi has also slightly reduced the amount of paperwork that it will require of factories that manufacture products being shipped to India. But the government is sticking by its approach of requiring companies to have their goods be registered on a per-product, per-factory basis, according to industry sources.

Products shipped to India that are not tested, certified and labeled as required are to be stopped at the border under the regulation. Industry sources say it is difficult to estimate how many covered products have still not yet jumped through the necessary hoops and that they are still in the dark about the full ramifications of the new regulation's entry into force last week.

As of early December, industry sources counted a backlog of around 700 products whose testing reports had been received by Bureau of Indian Standards (BIS), but for which registration numbers had not been issued. In the past, industry groups have also warned that there are not enough testing labs to handle the volume of products that have to be certified in time to meet the deadline.

In addition, they have complained that the rule's requirements are duplicative, pointing out that many of the covered electronics are also tested for standards conformity by internationally accredited laboratories, and that the standards against which products are tested are the same as those evaluated by BIS-approved labs.

The industry has also gotten mixed signals about what the requirements are for highly specialized equipment, such as supercomputers or high-end servers. The Indian government has previously said this category of products is generally exempted from the new rule, but the exact terms of that exemption are unclear.

According to one source, the Indian Department of Electronic and Information Technology (DEITY) in one instance said that exporters of such equipment would not need special exemption letters in order for their products to be allowed into the country by the Indian customs authorities. However, in a subsequent exchange, DEITY delivered just such an exemption letter to a company that had submitted a request for an exemption four months earlier – raising questions about whether such documentation will be considered necessary by the government of India.

[\[Back to top\]](#)

# India slams US move to tighten H-1B visa rules

Agence France-Presse

Washington, 6 February 2014: Indian Ambassador to the US S. Jaishankar said that India would see a decision to restrict certain temporary visas for skilled workers as a sign that the US economy is becoming less open for business.

“We think this is actually going to be harmful to us. It would be harmful to the American economy and, frankly, it would be harmful to the relationship” between the two countries, Jaishankar told AFP in an interview.

“Once I feel I’m not getting a fair deal, I am less responsive to the concerns of the other party. Then tomorrow if an American company comes and says, ‘You know, we’ve got this set of problems,’ the temptation for me is to say, ‘I’m out for lunch’,” he said.

The Republican leadership of the House of Representatives recently laid out general principles for an overhaul of immigration – whose main goal would be to give legal status to the estimated 11 million undocumented foreigners in the US.

A version passed last year by the Senate, which is led by US President Barack Obama’s Democratic Party, offers automatic immigrant visas for foreigners who earn advanced science degrees at US universities.

But it changes rules on so-called H-1B visas, which are issued to skilled workers who come temporarily to the US.

The Senate bill, while increasing the overall number of H-1B visas available, would hike fees and restrict additional H-1B visas for companies considered dependent on such foreign workers. The move came after complaints by US companies and labour groups that Indian tech firms bring in their own, lower-paid employees rather than hiring Americans.

Jaishankar charged that the changes attacked the business model of India’s IT industry, which he said was making the US economy more competitive by helping companies operate round-the-clock.

[\[Back to top\]](#)



# 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.

[\[Back to top\]](#)

# India, US seek to better drug-making processes

Financial Express

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# US insists India give WTO data on food security scheme

Amiti Sen, Business Line (The Hindu)

17 March 2014: Targeting India's food security programme, the US has questioned its efficiency and has said that the country should spell out measures to increase the programme's effectiveness. It has also demanded that India submit all relevant statistics and documents on the programme to the World Trade Organisation (WTO) in order to gain immunity against penalties in case subsidies breach specified limits.

"The matter would come up for detailed discussion at the meeting of the WTO's Committee on Agriculture next week," a Government official told Business Line. India fought hard at the WTO's Ministerial Meeting in Bali in December to keep procurement subsidies under India's Food Security Programme out of the list of subsidies classified as 'trade distorting'. In case 'trade distorting' subsidies breach 10 per cent of production value, a country is subject to penalties.

## *Conditional reprieve*

While a permanent solution to the problem was deferred in Bali, developed countries promised not to take any action if subsidies breached the given caps. However, the reprieve is subject to the condition that India submits all information and documentation that are sought by members on particular programmes involving subsidies.

Attacking India's food subsidy programmes, the US said that the cost of India's food subsidy bill is approximately twice the amount it would cost to provide all households living below poverty with enough cash to cross the poverty line. "This highlights the large costs the Government incurs in procuring, storing, and distributing foodgrains that could otherwise be more effectively used to alleviate poverty in India," a US submission to the WTO pointed out. Pointing specifically at the National Food Security Act 2013, the US said that India should point out if there is any specific language in the Act to address these concerns (related to efficiency). It also asked India to highlight the steps being taken to implement its current policies more efficiently. "The US has started treading into India's sovereign policy making space under the guise of need for increased transparency for subsidy programmes. The country has no business questioning the efficiency of India's programmes," a trade expert from a Delhi-based research organisation said.

## *Complicated process*

India has also been asked to submit the documentation on the domestic subsidy involved in the Food Security Programme. The process could be complicated as it would involve taking into account all the procurement done by the Government at various stages in every State, the prevailing market price at that time and the minimum support prices (MSP) paid to farmers.

While India has not yet breached the 'trade distorting' subsidy cap, it may do so, especially in case of rice, once the Food Security Programme is fully implemented. India has long been fighting for exclusion of subsidies for procurement under the food security programme.

[\[Back to top\]](#)



# US, India to hold second round of talks on solar trade dispute

Amiti Sen/Richa Mishra, Business Line (The Hindu)

New Delhi, 18 March 2014: The second phase of India's solar mission will come under the scrutiny of the US this week as the two countries begin consultations on compulsory local-buying requirements for certain components used in the programme.

The US has alleged that the domestic sourcing requirements flout World Trade Organization (WTO) norms as they discriminate against foreign companies.

The consultations, scheduled on March 20-21, will give an opportunity to India to explain its stand. If the US is not satisfied it may ask the WTO to set up a dispute settlement panel to fight the case.

“We are ready to explain our position. Our arguments remain the same as those made when the US had complained against the first phase,” a Government official told *Business Line*.

## *Govt procurement*

Since the power produced by the projects under the Jawaharlal Nehru National Solar Mission will be bought by a Government agency, India has argued that all equipment purchases fall under the category of ‘Government Procurement’.

As India is not a member of the Government Procurement Agreement of the WTO, it is not obligated to follow multilateral rules laid down for Government procurement.

India has already faced one round of consultations on the matter in 2013 after the US complained against the first phase that stipulated that all solar modules have to be purchased locally.

It launched a fresh complaint in February after the second phase of the mission — that will produce 750 MW of energy — continued with the sourcing norms. Although half of the project in the second phase will not have to conform to local sourcing conditions, for the remaining half it has been mandated that domestic procurement will also cover solar thin films.

“The US had gone slow after filing the first complaint as it had hoped that India would discontinue the domestic sourcing clause in the second phase. Since that did not happen, it has launched a second attack,” another official said.

The US counter-argument to India's defence is that since the local sourcing condition has been applied on purchase of power equipment and not power (which will be bought by the Government), it cannot qualify as Government procurement.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# Indian food industry poses trade barriers: USTR

Lalit K Jha, PTI

Washington, 1 April 2014: The US has said Indian policies in the food and poultry sector pose significant barriers in bilateral trade.

"Since 2003, India has imposed unwarranted SPS requirements on US dairy imports, which have precluded US access to India's dairy market, one of the largest in the world. India has insisted on onerous certification requirements and refused to accept US food safety and animal health standards as effective," the US Trade Representatives (USTR) said in its annual report on Sanitary and Phytosanitary (SPS) Barriers to Trade. The report said that India maintains zero-tolerance standards for certain plant quarantine pests, such as weed seeds and ergot. Such zero tolerance standards block US wheat and barley exports to India. Bilateral discussions to resolve these issues continue.

Expressing its displeasure on Indian policy in pulses, the USTR said this requires that shipments of all pulses to India be fumigated with methyl bromide (MB) at the port of origin.

"In August 2004, the United States asked India to permit the exportation of US pea and pulse consignments to India without fumigation at the port of origin provided they are inspected and, if necessary, fumigated at the port of arrival," it said.

"India has enacted, but not implemented a requirement that shipments of all pulses to India be fumigated at the point of origin, allowing MB fumigation on arrival, but has offered no permanent solution. The most recent extension expires on March 31, 2014. The United States continues to seek a permanent resolution to this issue," the report said.

Noting that the Indian import certificate for pork requires importers to make an attestation that the imported pork does not contain any residues of pesticides, veterinary drugs, mycotoxins, or other chemicals above the MRLs prescribed in international standards, the report rued that these certificates fail to identify specific compounds and their corresponding international limits, creating uncertainty for importers.

Similarly, the animal health attestations that India requires for the exportation of pork to India are vague, and India requires extra inspections that do not appear to be consistent with international standards, it said.

"India also prohibits imports from the United States of pork products obtained from animals raised outside the United States, notwithstanding the safety of those products. Further, import certificates are valid for only six months and must be obtained for each imported lot."

"The United States will continue to press India to lift its unwarranted restrictions and to revise its import certificates so as to clarify any legitimate requirements and be valid for a reasonable period of time," USTR said.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# Solar mission: US wants India to do away with local sourcing norms in new projects

Amiti Sen/Richa Mishra, Business Line (The Hindu)

2 April 2014: The US is mounting pressure on India to do away with the condition of local-buying of components in the next batch of solar power projects under the country's ambitious national solar mission.

In a formal consultation held last week at the World Trade Organisation (WTO), the two countries could not reach an understanding on the validity of the domestic buying condition in the projects granted so far under the mission.

*Next batch soon*

“The US has not yet disclosed whether it will ask the WTO to set up a dispute settlement panel for a full-fledged fight with India on the issue. But, it is certainly trying to intimidate us so that the domestic sourcing clause is not included in the second batch of projects in the second phase of the mission,” a Government official told Business Line.

“What we could assess at the meeting is that it will see how many American companies can qualify for the second round of projects, and then may be work out its action plan,” the official added.

India plans to roll out the next batch of projects after the general elections. The capacity of projects under the second batch is yet to be finalised.

The US argument against the local buying clause in the solar projects under the Jawaharlal Nehru National Solar Mission launched in 2010 is that it discriminates against foreign manufacturers of components and thus violates WTO norms.

It lodged its first complaint against India early last year after 950 MW solar projects were granted by the Ministry of New and Renewable Energy in two batches, with a condition that all solar modules for the projects have to be purchased locally.

The second complaint was made last month after the Ministry granted projects totalling 750 MW under the first batch of the second phase. Although India has tried to make peace by restricting local sourcing norms to just half the projects in the second phase, the US is miffed by the fact that its scope has been expanded by including thin films.

*Government purchase*

India has so far argued at the WTO that since sourcing of power generated under the solar mission is done by a Government-owned agency, the purchases are, in fact, Government procurement which does not fall within the purview of the multilateral agency. Only members of the WTO's Government Procurement Agreement, a pluri-lateral agreement involving a handful of countries, are governed by the rules on Government purchases.

[\[Back to top\]](#)

# US, EU oppose India's local sourcing norms in telecom

Kalyan Parbat, Economic Times

Kolkata, 14 April 2014: India's local sourcing and testing rules aimed at tightening network security and spurring domestic telecom manufacturing have ruffled feathers in the US and Europe.

Barely hours after a powerful US trade body accused the country of encouraging protectionism in the telecom arena, the European Union (EU) has questioned India's plans to locally screen network gear from July 1 despite it having been cleared in globally certified labs. Both say such a move to double test the same equipment will not just delay supply of critical products but also increase cost of telecom services, hurting consumers.

In a recent internal meeting, the EU said testing should be repeated only if a telecom product undergoes significant changes that impact its core safety properties.

It has demanded that India must also drop "the in-country security testing requirement", for those products not covered by Common Criteria Recognition Arrangement (CCRA), a top industry executive aware of the discussions told ET. That is in addition to EU's opposition to India locally testing IT products which are already CCRA-approved.

The CCRA is the top global agency that defines testing rules to certify IT products used in telecom networks and counts the US, UK, Canada, Germany, France Japan and India as among its members. In this light, EU has sought clarifications on whether India would allow certified labs in Europe to also test pure network gear not covered by CCRA. The opposition is especially since India is yet to develop a telecom gear testing ecosystem on a global scale. It has, in fact sought "an update on India's lab capacity to conduct local testing", another official familiar with the EU meeting said.

The EU's concerns stem from DoT's decision to locally screen all telecom network elements, including IT products used by telecom operators in India from July 1. More so, since DoT is yet to spell out the non-IT network devices that will be screened locally.

Mainline telecom equipment used in mobile networks includes base stations, mobile switching centres, network management & billing systems and transmission devices. But DoT also plans to locally test pure IT systems such as routers, switches and storage devices that go into modern mobile and broadband networks.

The EU has also exhorted "India to frame local testing norms aligned with prevailing global standards for 3G networks", the official quoted above added. Neither the EU nor the European Commission replied to ET's email queries in this light.

The EU's views mirror concerns voiced by the Telecommunications Industry Association (TIA), a leading US trade body representing manufacturers and suppliers of high-tech communications networks, which recently said India must not embrace telecom policies that "rely on protectionism".



"There is no evidence that location of an internationally accredited testing lab corresponds with the level of security assurance provided to it or the product itself," the TIA recently wrote in a letter to the US International Trade Commission.

"There are long-standing, internationally accredited labs conducting such testing and location does not have a bearing on the accuracy of the test as long as the lab has achieved appropriate certification," it added.

The TIA had also warned that India risked supply chain disruptions and increased costs for telecom service providers (TSPs) and their vendors as it currently lacked the requisite "lab testing capacity". It said the local testing deadline should be deferred, failing which, potential supply chain disruptions could hit consumer pricing.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)

# 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.

[\[Back to top\]](#)



# 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.

[\[Back to top\]](#)

# India Rejects U.S. Panel Request in Solar Dispute, Probes State Programs

World Trade Online

30 April 2014: India is fighting back against U.S. charges that its national solar program violates World Trade Organization rules, both by rejecting the U.S.'s first request for a dispute settlement panel last week and by questioning solar power programs that have been enacted by four U.S. states.

The U.S. is challenging the local content requirements in both phases of India's Jawaharlal Nehru National Solar Mission (JNNSM), an initiative designed to boost the country's solar power sector. The U.S. made its first panel request on the Indian solar program at the April 25 meeting of the WTO Dispute Settlement Body (DSB).

But India rejected that request at the meeting, saying it believed a mutually agreed solution was still possible and therefore was not in a position to agree to the panel's establishment.

Under WTO rules, India can reject the first panel request, but not a second one. The U.S. can wait for the next DSB meeting in May to make its second request or it can call for a special meeting to take place before then.

At the DSB meeting, the U.S. repeated the points it made in its panel request – that India's local content requirements in both Phase I and Phase II of the JNNSM violates the national treatment obligations of Article III.4 of the General Agreement on Tariffs and Trade.

The U.S. is also charging that India is violating Article 2.1 of the Agreement on Trade-Related Investment Measures, which forbids countries from applying investment measures that are inconsistent with its national treatment obligations. The U.S. is not alleging a violation of the WTO Agreement on Subsidies and Countervailing Measures (ASCM), which it had previously done in its first request for consultations.

Solar power developers participating in the JNNSM are required to purchase domestic-made solar cells and modules to enter into power purchase agreements with Indian power companies, according to the U.S. panel request. If they meet the local content requirement, these developers can also receive additional benefits and advantages, the U.S. charges.

The U.S. and India held consultations over the first and second phases of the JNNSM on March 20, 2013, and March 20, 2014, respectively. However, those consultations did not resolve the dispute.

The U.S. panel request came two days after environmental groups including Greenpeace and the Sierra Club urged U.S. Trade Representative Michael Froman to drop the WTO challenge. The groups argued that the need to stop global climate change should outweigh commercial considerations for U.S. solar firms.

"While it is critical to support and build a U.S. solar industry, the development of our solar industry should not come at the expense of India's ability to develop its solar industry," the April 23 letter said. At the same time India is fending off the U.S. challenge, it is shining the spotlight on renewable energy incentive programs put in place by the U.S. states of Minnesota, Delaware, Connecticut and

Massachusetts that provide benefits for companies that use renewable energy equipment manufactured in that state.

In questions submitted to the U.S. in April 2013, India asked the U.S. to explain how these programs are not prohibited subsidies as outlined in Articles 3.1 and 3.2 of the ASCM. Under the ASCM, prohibited subsidies are ones that are contingent upon export performance or on the use of domestic over imported goods.

For instance, the Massachusetts program identified by India provides an additional rebate if companies use "a significant component" that was manufactured by a company with "a significant Massachusetts presence."

The U.S. responded to the questions in a seven-page reply that was circulated to all members on April 24. In each case, the U.S. provided a detailed explanation of the programs, but did not directly address India's allegations that the programs in question were inconsistent with the ASCM.

[\[Back to top\]](#)

# 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.*

[\[Back to top\]](#)

# India may back solar duties after probe says US, China dumped

Natalie Obiko Pearson, Mint

New York, 14 May 2014: India may recommend duties on US and Chinese solar imports after finding evidence of dumping, broadening a global trade dispute in the \$130 billion market.

More than 20 overseas suppliers, including First Solar Inc and Yingli Green Energy Holding Co, sold equipment in India for as little as half the cost as in their home markets and undercut local prices by as much as a third, according to a summary of a 1 1/2 year probe by the Ministry of Commerce & Industry sent to the parties involved on Tuesday and obtained by *Bloomberg News*.

The document indicates the ministry will recommend duties on imports from the US, China, Taiwan and Malaysia, said Jagdish Agarwal, spokesman for the Solar Independent Power Producers Association, which opposes tariffs.

If Asia's third-biggest solar market imposes duties, it would escalate a protectionist trend that's threatening the viability of projects as they compete against conventional power sources. The US applied tariffs as high as 250% on Chinese products in 2012, and the European Union followed with its own measures a year later. Australia on Wednesday announced a dumping probe.

India, which had virtually no solar power in 2010, has built \$10 billion worth of projects and driven down the cost of generation by half, making it cheaper today than grid power in Delhi and Mumbai. Tariffs will derail that trajectory, making solar power more expensive and causing projects to fail, said Vinay Rustagi, joint managing director of Bridge to India Energy Pvt., a New Delhi-based consulting company.

*'Wafer-thin margins'*

It will make most large-scale projects, currently developed on wafer-thin margins, unviable, Rustagi said. Developers, who depend on imports for 90% of panels, could back out of projects, government programs may be scrapped, and India could set itself back two years on its goal to make solar competitive with conventional power, he said.

Tuesday's document was the first indication of which side India's government is favoring since the start of the probe in November 2012. The dispute pits local panel and cell makers against project developers and overseas manufacturers.

We disagree that we have dumped imports, Tempe, Arizona-based First Solar, the largest US panel-maker, said in an e-mailed statement. The preliminary decision by the Indian authorities, if upheld, would make serving the Indian market very difficult.

The ministry has until 22 May to decide whether to impose duties before the case expires. Any tariffs it proposes could take six months to implement and may be scrapped by a new government, said Bridge to India's Rustagi.

Results in national elections will be announced in two days. Narendra Modi, the frontrunner who pioneered India's first incentives for large-scale solar power, has called for a clean-energy revolution during the campaign.

### *Inferior quality*

The document upheld many of the arguments submitted by domestic makers Indosolar Ltd., Websol Energy System Ltd and Jupiter Solar Power Ltd, concluding that the domestic industry suffered material injury due to dumped imports.

The ministry dismissed arguments by the opposing side that Indian products are inferior in quality. Opponents including China Sunergy Co, Canadian Solar Inc, JA Solar Holdings Co. cited World Trade Organization rules, which say an anti-dumping probe can't be initiated if the producers supporting the application account for less than 25% of national production. Indosolar, Websol and Jupiter account for just 12% of production, according to the opponents' submissions.

### *Project dropped*

The value of photovoltaic imports into India has reached \$2.4 billion since 2010 when the nation started its solar program, according to commerce ministry data. Domestic manufacturers benefited little from that growth, idling 70% of their production capacity after losing orders to foreign competitors.

Duties won't create globally competitive Indian manufacturers because they can't match the scale of Chinese rivals, according to Bridge to India. BlackRock Inc-backed SunEdison Inc dropped a project in India last month on doubts that local producers can meet demand.

The annual production capacity of China's Yingli, the world's biggest panelmaker, dwarfs the largest Indian maker by 10 times, according to data compiled by Bloomberg. If India imposes tariffs, developers would probably look to Singapore and South Korean suppliers instead, said Jenny Chase, head of solar analysis for Bloomberg New Energy Finance in Zurich.

Parties involved in India's anti-dumping probe have until 16 May to respond to the document. Yingli spokeswoman Qing Miao wasn't available when called at her office and didn't respond to an e-mail requesting comment. JA Solar Holdings Co. and Canadian Solar Inc., also among the biggest Chinese exporters to India, didn't respond to inquiries.

Commerce secretary Rajeev Kher and D.P. Mohapatra, a director in the ministry who signed the document, didn't respond to e-mails and phone calls seeking comment.

[\[Back to top\]](#)