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India, EU ink deal to end drug seizure for now

Times News Network, The Times of India - Mumbai Edition

29 July 2011, New Delhi: India and the European Union have reached an interim settlement to ensure that none of the 27 members of the economic and trading bloc will detain 'Made in India' consignments of generic medicines, which are transiting through Europe. "Finally, EU has come around and we have agreed on an interim settlement... which means EU will not make any detention within its territory of pharmaceutical products coming from India. We will wait for the final settlement but we have not lost our right to agitate on the matter again," Rajiv Kher, additional secretary in the commerce department, told reporters. This means that India will not withdraw its case against the European Union in the World Trade Organization's dispute settlement body. India had moved the WTO after consignments of generic or non-patented medicines shipped to Latin America were seized by European customs authorities on charges of intellectual property rights violations. Subsequently, Brazil joined the discussions. About 17 detentions took place between October-December 2008 at Schiphol Airport at Amsterdam. These consignments, destined for Latin American countries, were initially detained and later destroyed or returned to India."Mere transit does not give you the right to detain (a consignment) when it is not meant for you," Kher said. Kher said that as per the bilateral understanding, EU would not only stop such detentions but also amend its regulation under which its member countries resorted to such an action. The settlement is interim as the EU Parliament is expected to take about 12-18 months to amend the legislation and then India will examine that law."We will finally withdraw the dispute only after getting convinced," Kher, who is India's negotiator at the WTO said. India is not completely satisfied with the draft amendment prepared by EU and has taken up the matter with the authorities. But New Delhi is convinced that given the backlash from the civil society and support from members of European Parliament there should not be any hurdles in passage the amendment. Though European customs authorities have not seized any consignments since December 2008, Indian drug makers are under constant fear of seizure of consignments meant for Latin America, the largest market for locally-produced generic drugs. Indian companies have also started using alternate ports such as Johannesburg for transit. Indian pharmaceutical exports total about $10 billion per annum, most of which are generic drugs.

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No blanket ban by EU on ayurvedic medicines: Azad

New Delhi, August 02 (PTI): The European Union has not imposed any blanket ban on Ayurvedic medicines. It has, however, formulated a directive on traditional herbal medicinal products (THMPD), which has restrictive impact on India's exports of herbal medicinal products to EU, Health Minister Ghulam Nabi Azad said in the Rajya Sabha today. In reply to a written question, the minister said Ayurvedic products are currently exported as dietary supplements, for which as of now, there is no registration requirement in most of the countries. However, some countries require notification of such products. Many products have been notified in different countries (Italy, Belgium, Finland and others) by some Indian companies, he said. The minister said India has been doing bilateral consultation with the European Union on Traditional Herbal Medicinal Products Directive since 2004 and has raised its concerns on this issue in the Technical Barriers to Trade (TBT) Committee of the WTO.

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India, EU reach an understanding over not detaining generic drugs from India

India Pharma News

9 December 2011, New Delhi: Jyotiraditya M. Scindia, Minister of State for Commerce & Industry informing Rajya Sabha, the upper house of the Indian Parliament, said that India and European Union (EU) reached an 'Understanding' to guide border enforcement of intellectual property in the EU and thus will not detain Indian generic medicines while in transit through EU. It may be noted that India had initiated dispute settlement consultations on May 11, 2010 at the World Trade Organisation (WTO) with the European Union (EU) after several rounds of discussions directly with EU could not produce any results. The issue was taken up by India when generic medicines while in transit through EU were detained invoking the EC's Regulation 1383/2003 against goods suspected of infringing intellectual property rights (IPRs). As per the understanding reached between the two parties, EU has agreed to replace Regulation 1383/2003 with a new regulation. The European Commission has already approved a proposal for a new regulation and said that the proposed new regulation is being reflected upon in EU's Parliament.

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A European pill best avoided

S. Srinivasan, Business Line (The Hindu)

The proposed India-EU FTA will compromise our generics segment and health security.

January 3: Even as India's generic pharma industry establishes itself as a major supplier for developing countries, barriers are being put up to inhibit the free flow of trade. The WTO was set up to ensure that trade flows "as smoothly, predictably and freely as possible." Its multilateral dispute-settling mechanism has been functioning reasonably well, though it has its share of critics.

All this is set to change with bilateral free trade agreements (FTAs). Secret negotiations have been on — since 2007, with early 2012 as the deadline — between the Government of India and EU for finalising the India-EU FTA. Indeed, one needs to ask why these negotiations are conducted without consulting Parliament and State Governments.

PROPOSED TRIPS REGIME

The basis of bilateral FTAs is reciprocity, but reciprocity between unequal partners never works — well, it always works against the interests of the less equal party. To illustrate how unequal: India's GDP is 3 per cent of the EU's GDP; while India accounts for just 1.8 per cent of the external trade of EU, the EU accounts for 20 per cent of India's trade; India's largest source of FDI is EU, while India accounts for 1 per cent of EU's total FDI.

The India-EU FTA aims to liberalise "substantially all trade" between the two trading blocks on a "reciprocal" basis and apart from trade in goods, the FTA will have substantive provisions on services, investment, public procurement, intellectual property (IP) rights and some other areas.

The proposals on IP are likely to create new hurdles for generic medicine manufacturers in particular. The IP measures demanded are 'TRIPS Plus' — that is beyond what is mandated by TRIPS/WTO. These include data exclusivity, patent term extensions, enforcement measures, border measures, increase criminalisation of IP infringement under the guise of acting against "counterfeit" medicines.

Acceding to data exclusivity measures would delay entry of generics in India. It will require generic manufacturers to repeat the clinical trials already done by the originator company. Such an act would be a violation of human rights, where proving bio-equivalence to the originator's products would have sufficed.

In Guatemala, a study published in 2009 in Health Affairs concluded that IP measures on data exclusivity and patents of the CAFTA (Central American Free Trade Agreement) were "responsible for the removal of several lower-cost generic medicines from the market in Guatemala and for the denial of entry to a number of others."

Another way to delay entry of generics — and this was being demanded earlier in the EU-India FTA talks — is the extension of patent term beyond the TRIPS-mandated 20 years, calculated usually from the date of filing of the patent. The move is to "compensate" for the time taken by the patent office to examine the patent and by the Drug Controller General of India to approve for marketing and manufacture.

BROADER PUNITIVE STEPS

Closely allied to these are IP enforcement measures: injunction provisions, border measures, and third party liability. Border measures in the proposed FTA legitimise the seizure of goods on visual inspection/mere suspicion of IP infringement, and even destroy seized goods — this is what happened in the several seizures of medicine exports from India to Africa/South America while transiting Amsterdam. This interferes with India's freedom to export generic medicines to countries in need and the right of such countries to import such medicines.

TRIPS allows for seizure only on violation of copyright/trademark and, that too, at the border only. The proposed TRIPS-Plus border measures applies not only to import, but to export, re-export, goods in transit and the duty of intermediaries to disclose information.

Also on the anvil is a proposal — called third party liability — to hold to task everybody involved in the supply, sale and manufacture of "counterfeit" goods. And this would make liable those in the trade chain as well as suppliers of bulk medicines and excipients used to make the medicine.

Injunction provisions being suggested in the FTA will make it incumbent on the Indian judiciary to give preference to IP status of medicines over the health rights of the poor, sometimes giving injunctions even before patent validity is established.

INVESTMENT PROPOSALS

Investment in EU-India FTA is being sought to be defined to include "IP rights, goodwill, technical processes and know-how as conferred by law." Foreign investors, if the investment proposals go through, would be able to sue the Government of India if any measures (say price control or compulsory licensing) taken by the Government, are seen not to protect their investments (read IP / patent rights, or profits or "goodwill").

The resulting arbitration will be before secret arbitral tribunals in places like London or Singapore. The decisions arrived at are binding and cannot be challenged under national laws.

Till date, at least 81 governments have been sued in more than 400 investment treaty arbitration claims. Millions, and in some cases billions, have been paid by governments to investors, as a result of such arbitration. Chapter 11 of the North American Free Trade Agreement (NAFTA) has helped North American investors sue Mexico, a developing country, and of course helped US investors sue the Canadian government and the other way around.

Investment proposals, first conceived in then West Germany, in 1957, are a "legal monster" that refuses to go away. Finally, the chickens have come home to roost with recent news of Germany's nuclear phase-out being challenged by the Swedish energy company, Vattenfall.
A Government of India that is reluctant to issue compulsory licenses will be further inhibited, when such draconian investment proposals are in place, to use TRIPS flexibilities for public health reasons.
Additional investment proposals are being sought in the name of "fair and equitable treatment" and "full protection and security" to investors. These terms are undefined as the case law on this is still a work in progress and it is left to the arbitral tribunals to determine what is "fair and equitable". Arbitral decisions often aren't concerned with the public health motivations behind any regulatory action.

A related requirement that is being put forward is granting European investors the same treatment as domestic investors. This isn't fair, as governments giving preferential treatment to local stakeholders, say SSIs, can be sued. Indeed, some of the proposed "performance requirements" provisions make it illegal to ask foreign investors to use local inputs and local personnel.

At stake is access to low-priced medicines for millions of poor patients in Africa and Latin America who source medicines from India's generic medicine industry.

The EU Parliament routinely instructs the European Commission on what stands are to be taken on various contentious issues in the FTA. We would wish our Parliament and our courts take suo moto action to take the India-EU FTA out of the closet and put it in public domain, before letting the Government sign on the dotted line — and sign away, perchance, our health security, and the livelihoods of the poorest. (The author is associated with LOCOST, Medico Friend Circle and All India Drug Action Network.)

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Dutch customs seize Indian drugs in transit, industry frets

Joe C Mathew, Business Standard

New Delhi Jan 23, 2012: Domestic drug makers, who were relieved after the European Union assurance in July 2011 to end the seizure of Indian generic drugs in transit, were in for a shock last month when Dutch authorities seized 29 cartons of medicines destined to South America from India. Timely intervention of Pharmaceutical Export Promotion Council (Pharmexcil) and the Ministry of Commerce ensured that the cartons, shipped by Mumbai based Ajantha Pharma, got cleared within two weeks, but the recurrence of the seizure has shaken the confidence level of Indian drug exporters.

The seizure turns significant in the backdrop of the fast nearing India-EU Free Trade Agreement, which got delayed due to the differing stance taken by both groups on trade of specific items including pharmaceuticals.

“Indian industry was happy after EU said there would be no more seizures. The current development has caused anxiety among the domestic exporters. It has disturbed the industry once again”, P V Appaji, executive director of Pharmexcil, said.

On July 28, 2011, the Ministry of Commerce & Industry had announced that India and EU had reached an understanding on the issue of seizure of Indian generic drugs in transit. “European Union has proposed a settlement of the dispute by confirming the detailed principles agreed in the understanding to guide border enforcement of intellectual property in the EU. In addition, EU agreed to India’s request for adoption of guidelines which would confirm the principles agreed to in the understanding with a view to give greater and immediate legal certainty for producers and traders”, the ministry had stated.

It was also clarified that EU had agreed to change its regulations to reflect these principles. In return, the EU sought an assurance that India would go back from its plans to request the World Trade Organisation to establish a dispute settlement panel on the particular issue.

India initiated dispute settlement consultations on 11 May, 2010, at the WTO with the EU on the issue of detention of Indian generic medicines while in transit through the EU. The dispute was triggered by at least 16 instances of detentions/seizure at EU ports, particularly in the Netherlands, of Indian generic drugs destined for export to Latin American and other countries.

The detentions were made by invoking the EC’s Regulation 1383/2003 which contains customs procedures for taking action against goods suspected of infringing intellectual property rights (IPRs). India was joined by Brazil in this dispute; Brazil also filed a similar complaint against the EU before the Dispute Settlement Body of the WTO. Industry officials hoped that the issue will be solved permanently once the European Commission adopts EU proposal for the new regulation.

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Drug exports up 30% in first half of FY12

Joe C Mathew, Business Standard

New Delhi Jan 30, 2012: An analysis by the Pharmaceutical Export Promotion Council (Phar-mexcil) early this month showed exports of basic drugs, finished medicines and fine chemicals jumped 30 per cent to Rs 24,661 crore during April-August 2011 as compared to Rs 18,967 crore recorded over the same period the previous year.

The rupee depreciation had some impact on the figures, as revenue growth was 19 per cent in dollar terms.

The US market, which grew 13.6 per cent (in dollar terms) to $1,199 million (Rs 5,902 crore) during this period, continues to be the biggest export destination for Indian drugs, with 23.2 revenue share of the total.

Exports to most other regions grew. Several African, CIS, South Asian and European countries recorded 39 per cent growth, said P V Appaji, executive director, Pharmexcil.

He said the market access programmes organised by the ministry of commerce in CIS and African countries, and the economic cooperation treaty with Japan, were beginning to show positive results for the pharmaceutical industry.

Exports to Japan, the 26th largest destination for Indian drugs on Sunday, grew 36.7 per cent to $217 million (Rs 1,065 crore) during April-August as compared to 10.9 per cent growth in the same period of 2010. Export revenue from Japan during April-August 2010 was $158 million (Rs 779 crore).

“The UK is the second best destination, with a high growth rate of 29.9 per cent. Exports to Germany, Russia, Vietnam, Canada, Spain, Australia and Japan have grown exceptionally well and are between 30 and 61 per cent,” said Appaji.

Industry experts said the effect was greater due to the low growth in pharma exports in 2010-11.
“The impact of global recession hit pharma companies very late. Hence, last year’s export growth was very low, giving rise to a higher growth percentage this year,” a Mumbai-based analyst said.
Appaji agreed the recent slowdown in the European economy may not have yet impacted the sector. Though the ministry of commerce gets monthly updates on export figures from the Directorate General of Commercial Intelligence and Statistics without much delay, export promotion councils access the data with a lag of four to five months.

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Natco gets India's first compulsory licence

C.H. Unnikrishnan , Livemint

Mar 13, 2012,Mumbai: In a landmark decision, India's intellectual property office on Monday allowed Hyderabad-based Natco Pharma Ltd to make and sell a copycat version of German drug maker Bayer AG's patented cancer treatment Nexavar. It's the first time that an Indian company has been granted the so-called compulsory licence to market a generic version of a patented drug.

The drug, patented by Bayer in India in 2008, is used in the treatment of liver and kidney cancer, and costs Rs. 2.8 lakh for a month's dosage. After Bayer rejected Natco's request for a commercial licence to manufacture Nexavar, the Indian company in September applied for a compulsory licence to make a copy of the drug, claiming the patent holder had failed to meet the needs of the local market.

A compulsory licence allows a generic drug producer to make and sell its version of a patented drug without the consent of the patent holder.

According to the World Health Organization, India has an estimated 29,000 patients with liver and kidney cancer.

In a 62-page order, the Controller General of Patents, which completed hearing both companies in February, said a compulsory licence under Section 84 of the Patents Act has been granted to Natco to make the drug.

The patent office stipulated that Natco price the drug at Rs. 8,880 for a pack of 120 tablets (a month's dosage) and pay 6% of net sales as royalty to Bayer.

"We will stick to the terms on pricing and drug accessibility to patients," said a spokesperson for Natco. The company's stock gained 6.17% on BSE to close at Rs. 314.95 on Monday; the benchmark Sensex rose 0.48%.

Section 84 lays down that three years after the grant of a patent, any entity may apply to the patents office for a licence to sell a generic version of the drug on grounds that the patented version has not worked in India, that the requirements of the public haven't been met or that it isn't available to users at a reasonable price.

The order is globally significant because India hadn't previously invoked the compulsory licensing provision although several developing countries, including Brazil and Thailand, have used the provision to increase citizens' access to expensive, life-saving drugs.

"The order will have a global impact as developing as well as developed countries were eagerly following this case to see how the world's largest democratic country uses these patent laws," said Gopakumar Nair, a patent expert and intellectual property consultant. "The order paves the path for using the flexibilities provided by trade-related intellectual property rights against the abuse of patent rights."

Bayer is currently fighting a patent infringement case with another local drug maker, Cipla Ltd, on the drug, and is awaiting a verdict in the case from the Delhi high court.

The order by the patents office said Natco was being permitted to produce a generic version of Nexavar because it had established that the drug wasn't affordable in the local market. The patentee continued importing the drug, but was able to provide it to only a small fraction of patients.

“We are disappointed by the decision of the patent controller in India to grant a compulsory licence for Nexavar,” Bayer India’s spokesperson Alok Pradhan said in an email response. “We will evaluate our options to further defend our intellectual property rights in India.”

The foreign drug makers’ lobby, the Organisation of Pharmaceutical Producers of India, echoed its disappointment.

“Today’s announcement to issue a compulsory licence is disappointing, as such measures cannot be the permanent solution of improving access to innovative medicines in India, while creating an appropriate ecosystem to foster innovation in the country,” said Tapan Ray, director general of the group.

Mint had in February reported that Bayer, during hearings on the matter, had been asked to justify the high price of the drug. Natco claimed in its application that the patentee could supply Nexavar only to a fraction of the patient population in the local market because the majority couldn’t afford it.

Bayer argued that it will be difficult for the company to reduce the price because it had incurred a substantial cost in developing the drug, while saying that it supplied the drug at a discount to the needy through its patient access programme.

The patents office’s order showed that the company had failed to furnish data specific to the drug to establish its claims.

“During the hearing, the patentee submitted that the cost of making the invention and developing a new medical entity like the drug in the case works out to be about €1.8 billion (around Rs. 11,775 crore today),” controller general P.H. Kurian said in the order.

“However, the figure arrived was for the cost of R&D (research and development) for five years preceding 2010... In the absence of any definite figure on the cost of developing the drug and making it available to the market, including the patenting, etc.... I am unable to arrive at the actual cost...,” the order said.

Natco’s lawyer Rajeshwari H. had in the hearing stated that since Nexavar (generically known as sorafenib) was developed as an orphan drug, which typically receives grants from governments and other agencies as such a product is meant for meeting the needs of a tiny patient segment that is otherwise ignored by commercial entities, the cost may not have been substantial.

The US Food and Drug Administrationhas on its website identified sorafenib as an orphan drug.

“This decision heralds the start of a new era in the history of pharmaceutical patents and public health,” said Shamnad Basheer, a professor of intellectual property law at the National University of Juridical Sciences, Kolkata. “It will effectively spur other generic manufacturers to apply for compulsory licences and we’ll soon see the start of a phase where prices of patented pharma drugs drop significantly, at least in developed countries, where the threat of a compulsory licence looms large.”

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Bayer challenges India cancer drug ruling

AFP

6 April: NEW DELHI — German pharmaceutical giant Bayer AG has challenged a ground-breaking Indian ruling that allowed a local firm to produce a vastly cheaper copy of its patented drug for kidney and liver cancer.

India's patents chief ruled in March the price Bayer charged for the drug, Nexavar, was "exorbitant" and ordered the firm to give a so-called "compulsory licence" to make the medicine to Indian company Natco Pharma.

"We will rigorously continue to defend our intellectual property rights which are a prerequisite for bringing innovative medicines to patients," Bayer spokesman Aloke Pradhan told AFP in an emailed statement on Saturday.

The patent controller's order "damages the international patent system and endangers pharmaceutical research", Pradhan said.

It was not immediately known when the appeal, filed with the country's Intellectual Property Appellate Board on Friday, would be heard.

Drug firms insist they need patent protection for medicines to recoup costs of long years of research and development.

Under the World Trade Organization's TRIPS Agreement, which governs trade and intellectual property rules, compulsory licences are a legally recognised means to overcome barriers in accessing affordable medicines.

The Indian ruling in March marked the first time a so-called "compulsory licence" for production of a patented drug had been granted in the country of 1.2 billion, known as a global generics drug powerhouse.

India has long been a key provider of cheap generic medicines to the developing world as it did not issue drug patents until 2005, when it was obliged to adhere to WTO intellectual property regulations.

But after a new patent law was introduced in 2005, newer medicines are increasingly being patented in India, keeping prices high.

Under the ruling, Natco will pay Bayer a six percent royalty on sales of the drug and sell the medicine for 8,800 rupees ($165) a month -- compared to the 280,000 rupees ($5,320) the company charges, which is more than 30 times as much.

Patent controller P.H. Kurian granted the right to Natco to produce the drug after concluding Bayer's pricing made it "out of reach" of most Indian patients.

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

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Drug makers critical of EU non-tariff barrier

Joe C Mathew, Business Standard

New clause makes it compulsory for Indian drug regulator to check quality

New Delhi, April 15, 2012: Indian companies supplying drug raw materials (bulk drugs) to European countries have just discovered a 10-month-old directive of the European Union (EU), taking effect January 2013, which can create a new non-tariff-barrier for exports.

A clause says Indian drug regulatory authorities must certify the products exported by these companies maintain quality and follow the good manufacturing practices prescribed by EU drug regulators. Domestic drug makers say the Drugs Controller General of India is neither authorised under the law or conversant enough with the EU GMP Standards to issue such a certification.

The companies will have to produce such certificates even after their manufacturing facilities and products (meant for exports) get all regulatory clearances directly from the EU drug regulatory authorities.

The directive, promoted with the stated aim of protecting people from falsified medicines, is essentially a protectionist measure to save the EU bulk drug industry. In the absence of such certification, API (active pharmaceutical ingredient) manufacturers in India will not be able to export APIs to EU member-states.

Any consignment without such certification will be seized, says D G Shah, secretary general of the Indian Pharmaceutical Alliance, an association of leading domestic drug makers.

“We were not aware of this clause until some of the domestic drug exporters started getting letters from their importing partners in the EU, demanding such certifications. We have approached the government as the industry alone cannot resolve this issue,” Shah added.

Indian manufacturing facilities already hold the highest number of regulatory clearances from European authorities. The EU accounts for a little more than a quarter of India’s annual bulk drug exports, worth Rs 20,000 crore.

The directive (2011/62/EU) of the European Parliament (dated June 8, 2011) -- essentially meant to amend an existing code relating to medicinal products for human use, to prevent the entry of falsified medicinal products -- makes it compulsory that all bulk drugs reaching EU ports should be accompanied by a written quality confirmation from the competent authority of the exporting third country. So, the Indian drug regulator will now have to confirm that the products exported were produced in units maintaining GMP standards equivalent to those of the EU.

The directive also wants the Indian regulator to subject such manufacturing plants to regular and surprise inspections, to ensure effective GMP enforcement and report any findings relating to non-compliance.

At the moment, all exporting countries, including EU members and the US, have their own regulatory approval and inspection systems to ensure the quality of medicines that reach their supply chain. While non-compliance can result in penalties and even an export ban, the Indian drug regulator has never before been made responsible for the quality of such products.

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India likely to press for more access to Japanese pharma market

PTI

New Delhi, April 29: India is likely to press for further opening of pharmaceutical sector by Japan to help domestic industry take advantage of the comprehensive free trade agreement and increase its share in the Japanese market.

The issue is expected to figure in the meeting of Commerce and Industry Minister Anand Sharma and Japanese Minister of Economy, Trade and Industry Yukio Edano tomorrow, a commerce ministry official told PTI.

Both the sides would review the agreement, the official said.

"At present India's share is less than 1 per cent of total Japanese pharmaceutical market. India will urge the Japanese side to remove all non-tariff barriers so that real benefits envisaged under the comprehensive economic partnership agreement (CEPA) are materialised," the official said.

The CEPA between India and Japan came into effect from August 1 2011. Both the sides expects that it would boost bilateral trade to USD 25 billion by 2014.

Indian pharmaceutical industry was set to gain in a big way from the pact as Japan, the world's second largest market, had agreed to cut duties on imports of Indian generic drugs.

As per the pact, the Japanese government would accord no less favourable treatment to the applications of Indian companies than it accords to the like applications of its own persons for drug registration. This would greatly help Indian pharmaceutical companies.

An industry expert said that Indian companies are still facing non-tariff barriers in Japanese market.

With a view to reducing the overall cost of healthcare, Japan may be keen to expand the share of generic medicines, the official said, adding "the demand of generic medicines in the Japanese market and the capability of India to meet this demand will prove a win-win situation for both the countries".

Both the sides are also expected to emphasis on starting negotiations on nursing and health care professional service as soon as possible.

Besides, both the ministers would review the progress of Delhi- Mumbai Industrial Corridor (DMIC), India's USD 100 billion ambitious infrastructure project. Japan has expressed intention to invest USD 4.5 billion (about Rs 23,400 crore) in the project.

The two-way trade between the countries has increased to USD 18.31 billion in 2011-12 from USD 13.82 billion in 2010-11.India's exports to Japan mainly includes petroleum, gems and jewellery, transport equipment and machinery, while imports include iron and steel, electronic goods, chemicals and metals.

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Government of India plans to reduce pharma industry's dependence on China

Khomba Singh, The Times of India

6 June 2012, New Delhi: The government has initiated a process to reduce Indian drug industry's growing dependence on China for raw materials, including the critical penicillin, which is needed to manufacture most of the anti-infective drugs.

An industry executive told ET that the Organisation of Pharmaceutical Producers of India (OPPI) has submitted a list of drugs sought by Commerce Minister Anand Sharma when the Group of Ministers met on May 25.

The minister had asked the industry body to share details of the drugs, out of the 74 price controlled bulk drugs whose production has either shifted to China or whose manufacture in India has become dependent on imports from China.

India needs to be self-sufficient to achieve its goal of becoming a major global supplier of low-cost drugs, an industry executive said, adding that the OPPI, an association of multinational firms, conveyed this to the commerce ministry officials.

India fixes the retail prices of drugs that are made from 74 bulk drugs - active pharmaceutical ingredients or intermediates, the basic chemical used to make a medicine. Though the 62,000-crore Indian industry ranks among the global players in finished drugs, it has to depend on China for raw materials.

The minister had raised this issue in the earlier meeting of the group of ministers on April 25, recommending an inter-ministerial consultation to tackle this "serious threat in the drug security of the nation". He had pointed out that the country was dependent on China for penicillin, the key raw material for most antibiotics in the country.

According to industry body Indian Pharmaceutical Alliance's secretary general DG Shah, health ministry data shows that about two-thirds of raw materials used by Indian companies are imported from China.

"We are practically dependent on China. This is a serious issue," he said.

Most anti-infective drugs, accounting for about 20% of the Indian drug market, are made using two derivatives of penicillin, Pen G or 6APA, Shah said.

Last year, the commerce ministry had unsuccessfully recommended imposing anti-dumping levy on penicillin imported from China and Mexico. It was alleged that whenever Indian companies tried to revive their local manufacturing plant for penicillin, the Chinese companies slashed prices indiscriminately to scuttle competition. Most Indian companies that used to manufacture penicillin have closed their units.

The finance ministry had shot down the commerce ministry proposal due to concerns that prices of popular antibiotics would increase significantly if levies were to be imposed on Chinese imports to encourage Indian companies.

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No WTO violation by issuing licence for Nexavar: Sharma

Press Trust of India

June 14, 2012, Sao Paulo: Commerce and Industry Minister Anand Sharma today said India has not violated any provision of multi-lateral trade agreement by issuing compulsory licence (CL) for patented anti-cancer drug — Nexavar — to be produced and sold at a much cheaper cost in the country.

"We have not violated of any WTO agreement...This (invoking CL) is very much in conformity with the international agreement under the WTO," Sharma said here while addressing industry leaders of pharmaceutical sectors.

Sharma is leading a Ficci business delegation, mainly consisting of players from pharmaceuticals industry, to Brazil. In March, Hyderabad-based Natco Pharma was allowed to manufacture and sell cancer-treatment drug Nexavar at a price over 30 times lower than charged by patent-holder Bayer Corporation, under compulsory licensing (CL). The German firm has already filed an appeal against the Indian Patents Office's order with the Intellectual Property Appellate Board. As per the WTO agreement, a CL can be invoked by a government, allowing someone else to produce a patented product or process without the consent of the patent owner in public interest. India's intellectual property rights regime is fully TRIPS-compliant, the minister said, adding that the developed nations have invoked CL more than developing economies. "In case of India, this was the process of adjudication. It was not an executive invocation," he added. He said around the same time when India had issued the CL for anti-cancer drug, the US government, through an executive order, placed an order with Indian company for anti-cancer drug. Natco was allowed to sell the drug at a price not exceeding Rs 8,880 for a pack of 120 tablets required for a month's treatment compared to a whopping Rs 2.80 lakh a month charged by Bayer for its patented Nexavar drug. Seeking greater cooperation in pharmaceutical sector, the minister informed the industry leaders that India is the third largest medicines producer in the world and produces 20% of world's generic drugs. According to sources, the minister took up several problems of Indian pharmaceutical sector during his meeting with Brazilian Minister of Development, Industry and Foreign Trade Fernando Pimentel.
"The minister raised the issue of requirement of multiple testing despite having approvals from agencies like USFDA, delayed registration of products in Brazil, delay in port clearances and fast tracking of issuing of import licenses," sources said. On the occasion, industry leaders too raised their problems and concerns which they are facing here.

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India, Brazil & China defend generic drugs at WTO

Amiti Sen, Economic Times

New Delhi, June 25, 2012: India, Brazil and China have defended the right of poor countries to access cheap generic medicines at the World Trade Organisation, resisting attempts by the US, Japan and some other developed countries to club counterfeits or copies of patented drugs with fake or spurious ones.

"The cases of seizure of high quality generic or off-patent drugs by third countries that hold patents for these could gain legitimacy if counterfeits are confused with fakes," an Indian official told ET. "We cannot allow this as it could seriously hinder access to cheap drugs by the poor."

In a recent meeting of the WTO's Trips Council, developed countries such as Canada, Switzerland and the EU said they considered counterfeiting to be one of the most serious problems to be discussed by the council. These countries said counterfeit medicines not only cause economy loss but also put the lives of patients at risk as they could be "dangerously sub-standard".

India, Brazil and China, however, argued that infringing intellectual property rights should not be confused with sub-standard products.

Intellectual property violation in medicines should not be mixed with sub-standard products and the issue of fake drugs should be discussed at other forums and not the World Trade Organisation, the three countries said at the meeting in Geneva.

"It is an attempt by developed countries to paint all generic medicines produced by developing countries with a dark brush and create doubts on the quality of such drugs," said Abhijit Das, head of the Centre for WTO Studies at Delhi-based Indian Institute of Foreign Trade.

India should resist such attempts as developed nations are trying to make the intellectual property regime more stringent through WTO as their attempts to do it through the ACTA, the proposed anti-counterfeit agreement between some countries, failed because of opposition by the European people, Das added.

Interestingly, many developed countries, led by the US and the EU, had earlier tried to convince WHO to include fake drugs in the definition of counterfeits. India, with the support of countries like Thailand and Indonesia, managed to convince the WHO that merging of definitions was not only unwarranted but could also be counterproductive in terms of supply of cheap medicines to the poor.

Counterfeits are copies of patented drugs that may have infringed intellectual property rights of patent holding companies. However, a product that is considered a counterfeit in one country may not necessarily be so in another as it may be off-patent there. Therefore, if counterfeits are considered as fake, countries that hold patents to particular drugs could destroy consignment of copycat version of those drugs that pass through their ports on health grounds without fear of retribution.

"In most cases the generic or off-patent drugs that are produced in developing countries are of very high quality," another Delhi-based WTO expert said. "Just because they would be considered counterfeits in countries where patents to these still exist does not automatically mean that they are also spurious drugs. These are two entirely different issues and should be dealt separately."

Last year there were several cases of seizures of Indian generic medicines on way to South America and Africa at European airports following complaints from patent holders of those medicines in Europe.

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India eyeing access to Russian pharmaceuticals market

Nayanima Basu, Business Standard

New Delhi, July 4, 2012: India has urged Russia to open its booming $19-billion pharmaceuticals market and expedite the list of 500 drugs that it currently imports from India. During his recent visit to St Petersburg, Commerce, Industry and Textiles Minister Anand Sharma urged Russian authorities to let Indian pharmaceutical companies form joint partnerships with Russian companies.

India has asked the Russian side to establish a nodal agency to create a joint committee for implementation of memorandum of understanding between Indian and Russian pharma companies, especially in the field of quality control and standard requirements on conformity assessment of pharmaceuticals and bio-pharmaceuticals.

Russia's pharmaceuticals market grew to $19 billion in 2011 from $6.6 in 2005, growing at a compound annual growth rate of 23 per cent. However, there are a number of non-tariff barriers Russia imposes which makes it difficult for foreign companies to enter this market, in terms of drugs registration and research and development of new drugs.

India has already nominated its own nodal agency— The National Institute of Pharmaceutical Education and Research (NIPER) — under the Department of Pharmaceuticals. However, the Russian side is yet to nominate an appropriate nodal agency.

“There is considerable scope for enhancement of trade as well as investments, in the pharmaceutical sector. As the list of 57 strategically identified medicines is now available, we may expect further cooperation in the pharmaceutical sector,” a senior commerce department official told Business Standard.

India is also planning to actively participate in Russia’s ‘Pharma 2020 Programme’ that would facilitate setting up of production units in Russia, besides, streamlining the registration process and sharing of information on drugs imported by Russia and on production volumes of strategically identified medicines.

Indian pharmaceutical products are of international standards and 30-40 per cent cheaper than other markets on an average. Indian pharmaceutical market is the third largest in the world, in terms of production volume and fourteenth in terms of value. Pharmaceutical exports constituted about 4-5 per cent of India’s total exports in the last five years. India’s pharmaceutical exports constitute 58 per cent of generics drugs, 40 per cent of active pharmaceutical ingredients and two per cent of ayurvedic or herbal products.

India produces about 8 per cent of the world’s generic drugs. Some of the major export destinations are the US, the UK and Germany. Bilateral trade between India and Russia in 2011 stood at $5.965 billion. Both sides have set a target of achieving $20 billion trade by 2015.

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US ups the ante on Nexavar Generic, threatens to take India to WTO

Divya Rajagopal, Economic Times

Mumbai, 5 July,2012: The US House of Representatives and the US Patent and Trademark Office (USPTO) have threatened to drag India to the World Trade Organisation's dispute panel for issuing the first ever compulsory licence to a domestic company to manufacture generic version of Bayer's cancer drug Nexavar, saying the move violates international trade laws. "As opposed to criminal activity, these international patent trade problems in the civil laws space seem to be driven directly by the foreign government to benefit their domestic industry," said Bob Goodlatte, a Republican Party member and member of the House sub-committee on intellectual property. "It seems that they are getting a free pass as they devalue the patented innovation of the American companies. A WTO case can be brought on this dispute if the appeal doesn't work," he added. Compulsory licence (CL) is a provision under Trade Related Intellectual Property law (TRIPS), which empowers the government to allow someone else to produce the patented product or process without the patent owner's consent. In March this year, the Indian patent office issued compulsory licence to Hyderabad-based Natco Pharma on grounds that the patented version of Nexavar was too expensive for Indian patients, and by merely importing the drug to India, Bayer doesn't necessarily get a working patent in the country. The compulsory licence order reduced the price of Nexavar from Rs 2 lakh to Rs 8,800. Bayer has appealed against the order, but the hearing is yet to begin. USPTO, in a testimony to the House of Representatives, has said by granting licence, India has not compiled with the international standards of patent laws. "I was quite dismayed and surprised when India decided to grant CL... I think it didn't meet international standards and it was also not due to national crisis," said Teresa Stanek Rea, deputy director of the US Patent and Trademark Office. "We have someone on the ground in the embassy in Delhi who constantly engages with all the respective officers in India to discuss with them the importance of not granting CL in a situation where it is not wanted," she explained. However, legal experts back home have completely rubbished the claim that India's compulsory licence violates any international law, arguing Indian laws have such provisions which are permissible under TRIPS. "Whoever is saying that CL issued by India should be a subject matter of dispute in the TRIPS dispute panel needs to read the law properly," said Anand Grover, senior advocate, Lawyers' Collective. "The criticism of the US Representative is completely misplaced and ignorance can no longer be an excuse for making such remarks," he added.

Grover says since the patent order is quasi-judicial in nature, and not a government order, the issue cannot be termed as a bilateral dispute. However, the US patent office has gone on record saying they are lobbying with Indian drug regulators and the patent office to revoke the licence decision. "We are trying to continue our discussion with India's equivalent of USFDA and with regulatory authorities , engaging in discussions with them. Outside the US patent office context, we are doing everything we can to respect the rights of US innovators," said Stanek Rea. But DG Shah of the Indian Pharmaceutical Alliance says these 'threats' are mere pressure tactics by the US. "China, Thailand and Argentina have issued CLs taking a cue from India, and such public statements are the only option left with the US to impose its protectionist measures," he says.

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Indian drug firms lobby against EU's new directive

Vidya Krishnan, Mint

July 24, 2012: Indian drug companies are lobbying against a move by the European Commission to check the import of counterfeit drugs through a directive that comes into effect in about a year from now.

According to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) lobby group, the country's drug exports to the European Union (EU) were worth $1.93 billion (around Rs.10,769 crore) in 2010-11. If India fails to get an EU equivalence certificate by 2 July 2013, when the rule is set to go into effect, 30% of this could be affected, the lobby group said.

Industry and government officials say they don't have the manpower or the resources to be able to comply with the new directive.

Under the EU falsified medicines directive, each shipment of active pharmaceutical ingredient (API) or drug raw materials from India should be accompanied with a written confirmation, vouching that the quality of the exports conforms to EU standards. The legislation was adopted by the EU Council in May 2011 with the objective of preventing the entry of fake drugs.

Failure to provide this "equivalence certificate" would mean loss of business for India, said D.G. Shah, secretary general of the Indian Pharmaceutical Alliance (IPA) lobby group.

"The EU initiative is protectionist and while they are citing safety and public health as reasons, it is clear that they want to protect their domestic pharmaceutical companies from competition," he said. "We can only hope that the Indian government will respond appropriately, keeping this in mind."

The EU and the Indian drug companies have been in conflict before. In 2008, the Netherlands seized Indian drug consignments on the ground of patent infringement, triggering a trade dispute between India and the EU. The incident had prompted the Indian government to approach the World Trade Organization (WTO).

The term "falsified medicinal product" in the European Commission's directive is of particular concern in India.

"While the directive is pertaining to API, the word 'falsified' could be used broadly to apply to generic drugs made in India," said C.M. Gulati, editor of the *Monthly Index of Medical Specialities*, a journal on prescription drugs available in India. "If an Indian company makes a generic version of a drug patented by a multinational pharma company, it could come under this directive and be treated as a 'falsified' or spurious drug and be confiscated."

At a meeting with industry representatives on Monday, the department of pharmaceuticals (DoP) sought a response from the Drug Controller General of India (DCGI) about the feasibility of training Indian drug inspectors on EU standards.

"We have sought DCGI's position on the matter and we are concerned by the use of 'falsified'. We have also proposed a meeting with representatives from the commerce and health ministries on the matter. We do not want to delay this any further as our exports will be adversely affected," said Raja Sekhar Vundru, joint secretary, DoP.

The government appears to be convinced that the Indian drug companies have a case.

“We are looking at various alternatives, including approaching WTO...,” said a commerce ministry official who didn’t want to be named. A questionnaire sent by *Mint* to the European Commission did not elicit a response at the time of going to press.

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