Blocked in transit

As aggressive IP enforcement continues at the hands of EU ports, should goods in transit be protected when they are without a doubt intended for markets where their use is legitimate? ***Aashruti Kak*** *surveys the complications involved*

On October 15, 2008, a consignment of clopidogrel bilsulphate API, heading to Columbia, manufactured by Ind-Swift Laboratories, was seized at an EU port on the grounds of suspicion that it was counterfeit. A month after this, two consignments from Cipla, heading to Peru, met the same fate. Then on December 12, 2008, another consignment was stopped; this time it was Dr Reddy's Laboratories' (DRL) losartan API that was on its way to Brazil. The seizures were made at a Netherland port following complaints filed by the patent holders (filed by Merck in DRL's case and sanofi-aventis in Ind-Swift's case) of the withheld substances, who claimed that the consignments were either counterfeit or a blatant case of IP infringement.

The manufacturers of the above mentioned products, however, maintain that their products were legitimate generics, which did not violate any patent rights in either the exporting or the destination countries.

'Right' to seize?

As per the WTO General Agreement on Tariffs and Trade (GATT), traditionally, goods in transit are exempt from normal restrictions that are associated with patents or other intellectual property (IP) rights, when en route to a market where the use is legitimate (TRIPS Article 51). As visible by the constant seizure of goods by EU custom authorities, the definition of these goods is totally different as per the new EU directives.

The TRIPS agreement is the basis for all global IP related issues, especially where country-to-country disputes are involved. "As per TRIPS provision under Section 255, cross border measures really do not include patents and in transit materials, because a majority of issues of counterfeit are related to quality and misbranding (wrong branding)," informs Dr Gopakumar Nair, Patent Attorney and CEO, Gopakumar Nair Associates. "The European government has passed a new EU directive which says that EU can accept applications from IP holders and can notify the granted form of IP-copyright, trademark and design. Unfortunately, patents are also included there," he says. The patent holders can register themselves with EU custom authorities on payment of a fee and they have to give certain guarantees and undertakings regarding the costs involved (storage and handling) if goods are seized, which would be met by them. This means that Merck, Bristol-Myers Squibb, Nycomed or other Big Pharma companies have all registered patents, with trademarks registered with the custom authorities. "The custom authorities do not see what aspect of the seized drug or form or dosage of it is patented. Any form of that drug passing through the port will be under watch, and the authorities as well as the applicant will be informed, who in turn will take the call of challenging the originality of the drugs stationed at the port," says Nair. The applicant then has

to file a suit within three days of being informed, if the goods are perishable, and 10 days if the goods are non-perishable; and the goods will be detained as soon as the applicant notifies the custom authorities that they would be filing a suit. Immediately after the goods are seized, the company, whose consignment is stopped, will be intimated, who will have to ask the authorities to draw a sample from the consignment to clear its counterfeit status.

Nair says that the counterfeit status can be determined by simple tests and procedures. "While testing for quality for example, if there is reasonable doubt that generic aceclofenac tablets do not have aceclofenac and may have something else, they are labeled counterfeit by the authorities. But if a branded medicine like Lipitor (atorvastatin) is patented in a country and the Lipitor infringing drugs are travelling as generics which are genuinely licensed, manufactured and contain atorvastatin, from a country where it is genuine to make it, there is no infringement because there is no patent on Lipitor," he says. From the port, if the medicine is moving to another country where it is also free for marketing, and if it passes through a country, which has a patent, it is not fair to seize these goods claiming patent violation.

Counterfeit, IP infringement, or wordplay?

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Secretary General
Indian Pharmaceutical Association

The EU has aggressively tightened the noose regarding its customs procedures through a number of proposed joint and regional trade agreements. The new Anti-Counterfeiting Trade Agreement (ACTA) requires the seizure of goods that infringe on patents, even if they are goods in transit. About 21 countries are already a part of ACTA. As per this agreement, the definition of counterfeit is—'if there is any drug which is not originating from the original manufacturer, the drugs as well their history will be rendered counterfeit.' "It is wrong, but that is the agreement countries have bound themselves with. Take for example, Uganda has become a member, because it is an aid relieving country and it will sign anything that the US or Europe will tell it to sign. We can see the same situation in Uganda as we see in Europe—any goods transiting through Uganda, going to Zaire, Congo or any other country nearby will be seized even if it involves a US or EU patent. These are badly drafted laws," opines Nair. He continues, "By agreeing with ACTA these countries are violating the World Trade Organisation (WTO) provisions, according to which these countries are bound with the duty to not impose non-tariff barriers. This way, they are not only harming their own trade, but intercontinental trade as well; legal under the European law but illegal under WTO provisions." However, the EU customs authorities claim that their regulations are in complete conformity of the TRIPS agreement and the WTO rules.

Besides ACTA, further risks to goods in transit are also reflecting in the International Medical Products Anti Counterfeiting Taskforce's (IMPACT) 'Principles and Elements for National Legislation against Counterfeit Medical Products' and World Customs Organization's (WCO) Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE). Not only is the definition of goods in transit being misinterpreted, but that of counterfeit goods is also

being twisted beyond its shape. According to WHO, counterfeit medicines "are those which are deliberately and fraudulently mislabeled with respect to identity or source." Fairly, it covers both branded and generic drugs with the right ingredients but fake packaging, with wrong ingredients, without active ingredients or with insufficient active ingredients. Granted that the WHO-IMPACT is a great effort to combat counterfeiting, but many organisations (associations, pharma manufacturers and NGOs) allege that the initiative is being used as a shield to protect IP rights of MNCs.

The seizures of goods were recently followed by interventions by India and Brazil, which was supported by 16 other members—Pakistan, Indonesia, Thailand, China, Egypt (coordinator of the Africa Group), Nigeria, Burkina Faso, South Africa, Peru, Ecuador, Argentina, Bolivia, Cuba, Costa Rica, Paraguay and Venezuela. D G Shah, Secretary General, Indian Pharmaceutical Alliance, informs, "These members expressed concern over the extra territorial application of IPRs, violation of the letter and spirit of TRIPS Agreement and GATT provisions on freedom of transit and negating the public health provisions of TRIPS and subsequent ministerial decisions. They also demanded that EC explain the consistency of their enforcement measures with the TRIPS Agreement."

Many points have since been raised regarding the 'misuse' of the new EU directives. Firstly, no goods can be stopped on the grounds of counterfeiting unless there is proof. Secondly, the EU ports are just a stop over point for these consignments, which means that if the goods are counterfeit, it is the business of the destination country to test and prove the quality and IP status of the of that consignment. Thirdly, these instances of seizures have raised a lot of issues regarding the efficacy of systems and standards, as well as the competency of customs authorities at the ports to seize these goods. "The problem comes when the customs authorities are not competent enough to sit in judgment, and this is the same with most countries. This grievance has to be legally resolved," asserts Nair.

Patent litigations can go on for three to four years. There is a difference between decisions in the lower courts in the US, the federal courts, and the Supreme Court; hence, there are a lot of issues and technicalities involved in the matter. Nair explains that authorities at ports do not have the competence to seize goods in the name of patent infringement. Their authority is only limited to saying 'yes ' or 'no' in terms of trademark, that too if the goods are proven to be counterfeit. The proof is based on the sample that is drawn from the cargo and sent for analysis. Whether the drugs are substandard or spurious or are not the original company's product is dependent solely on the test reports.

TRIPS obligations and flexibilities

Article 41.1 of TRIPS provides that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" and Article 41.2 provides that the procedures shall be "fair and equitable." These are the 'general obligations' that run through Part III of TRIPS Agreement on Enforcement of IPRs.

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The flexibility of TRIPS, Nair says, is

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that it recognises that in transit goods seizures are not a requirement under the rules. Also, wherever there are technicalities involved about patentability criteria etc any seizure of any goods has to be of very short duration because the goods can be damaged or may perish. If a patent litigation goes on for four to five years the goods cannot wait that long and the storage and handling costs at the port will become more than the value of the goods.

"TRIPS as well as every other patent law in the world has a provision for 'parallel imports'—egal goods originating from source other than the original can be bought even if there is a higher priced product in the market. India permits that under Section 107A (b), but under EU laws, this is illegal," says Nair. Many countries, especially the signatories to ACTA and IMPACT are adopting 'maximum standards'—TRIPS plus-which can impede access to generic medicines, most importantly in developing countries. What the EU is doing is propagating 'territoriality' by instigating measures to destroy such consignments, which is a direct TRIPS violation. This is having drastic implications on international public health programmes, leading to denial of public health to the needy population hampering of access to medicines, which is a straight violation of human rights.

Not only that, the adoption of TRIPS Plus has already compelled many companies to change their transit routes, opting for more expensive and inconvenient safe routes, affecting cost competitiveness of the Indian generics business, apart from the export loss on goods detention or return on goods after seizure.

Double standards

Interestingly, India has also enacted a customs rule. The only difference between the ACTA rules and Indian rules is that India does not specifically say that transit goods are to be seized, whereas in many countries under the ACTA, the definition of imports visibly includes transit goods. "There was a High Court judgment where they have included goods in transit as imports. For instance, goods going from Kolkata port to Nepal or Bhutan will be considered as imports unless they have been specifically included

under domestic laws. Unfortunately, this has not gone through the Parliament; it has been just very surreptitiously done. The customs authorities have just notified a rule and that has become effective," informs Nair. He gives an example of a similar case, of a person named Sivakumar in Thiruchi, Madurai, who had taken a patent on dual sim card technology. He stopped all imports of Samsung and others by following the same procedure—by registering with the customs authority of India, which notified Sivakumar when the dual sim phones reached all the major ports and the phones were seized at the respective ports under Sivakumar's cost. So India is also doing the same to other countries.

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The WHO needs to immediately assess the risks that these EU directives pose to public health programmes. Nair believes that one of the basic principles under global trade is retaliation. If Super 301 is to be recalled, India, along with other countries, should also chalk

out retaliatory measures on the same lines. Patents need to be excluded from all trade agreements pertaining to goods in transit and charity should begin from home. "India and Brazil have threatened to challenge. India and all like-minded countries must come together and organise an infrastructure for trade between them without using the facilities of developed countries. Firstly, all exporters should consolidate their goods and can take periodic direct cargo flights from here to South America or other destinations. Secondly, we should boycott all the ports where the goods have been seized. All of this could be expensive in the interim. There is no way that the majority interests can be taken care of without sacrificing the minority interests. India needs to figure out a long term policy or strategy to overcome this," he says.

In the time of recession, everyone is going to export their unemployment. EU is using underhand measures to ensure that their domestic interests are saved, but we are not doing enough to protect our domestic interests. Today, India and China are in the position to dictate. Nair says, "The moment you are subservient to others you lose your power. We should give top priority to domestic and national interests, and the national entrepreneurship support mechanism."