BRIEFING PAPER

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Patent Rights on Goods in Transit: A Threat to Access Affordable Medicines

Introduction

As the volume of international trade drastically increased, transit traffic became an issue of great importance. That's why most of the countries have an obvious interest in securing the freedom of transit. Article V of the General Agreement on Tariffs and Trade (GATT) provides for freedom of transit. It states that there shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. It further states that except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of contracting parties shall not be subject to any unnecessary delays or restrictions and shall be exempt from customs duties and from all transit duties or other charges imposed in respect of transit, except charges for transportation or those commensurate with administrative expenses. It establishes most-favoured-nation (MFN) treatment for such transit with respect to all charges, regulations and formalities.

In other words, Article V of GATT calls on the contracting parties, on the one hand, to facilitate transit, and on the other, provide a conducive regulatory environment in terms of streamlined customs and administrative regulations, subject only to reasonable charges for the service provided. However, the Article does not provide detailed guidelines for applying these principles in practice. Hence, the traders face various difficulties, particularly in the form of different customs policies and procedures, excessive procedural requirements, including redundant documentation and inspection and imposing an undue financial burden.

Now to make it even worst, some transit countries particularly in the European region have started enforcing their intellectual property (IP) protection laws on those goods in transit that do not enjoy IP rights in either the exporting or the importing country. This appears to be a clear violation of transit rights of GATT/World Trade Organisation (WTO) members.

Recent Developments

In recent times, Dutch customs authorities have seized several consignments of generic drugs of Indian companies on grounds of alleged IP violations. One such seizure took place on December 04, 2008 when the customs authorities of the Netherlands seized a consignment containing generic medicines en route from India to Brazil. This generic drug, i.e. Losartan Potassium, is an active pharmaceutical ingredient used in the production of medicines for arterial hypertension and was being traded between two leading pharmaceutical companies of the respective countries. After 36 days of retention at Netherlands, the customs authorities released the cargo, which was directed back to India, rather permitting it to sail ahead to Brazil.

Box 1: Cipla Consignment Seized on Grounds of Patent Infringement

It is not just drug makers Ind-Swift and Dr Reddy's Laboratories' export consignments that were confiscated by Customs authorities in Amsterdam on the grounds of patent infringement. Home-spun drug major Cipla too encountered a similar problem when its export consignment to Peru was seized.

Details on the size of Cipla's consignment and the type of medicines being exported were not available, but the company official indicated that Cipla has abandoned the consignment as the cost of litigation was disproportionate to the value of the consignment. In the past incidents faced by Indian drug makers, Ind-Swift's consignment was headed for Venezuela and Dr Reddy's was for Brazil.

Source: The Hindu Business Line, February 04, 2009

Initial reports held that this seizure of the cargo was based on a request lodged by a company that holds patent rights on 'Losartan Potassium' in the Netherlands on grounds that their rights were being violated. However, the statement made by Brazil to the Trade Related Aspects of Intellectual Property Rights (TRIPs) council later revealed that the Dutch authorities acted and have regularly been acting ex-officio, following procedures required or authorised by EC Council Regulation 1383, of 22 July 2003. This regulation refers to the customs actions regarding goods suspected of infringing intellectual property rights (IPRs).

Brazil and India argue that it is irrelevant whether or not the medicines are protected by patent rights in Netherlands since these drug consignments were not headed for the Dutch market but were in mere transit towards Brazil. Moreover, trade in generic medicines is not only perfectly legal under international IP law but also this drug 'Losartan Potassium' does not enjoy IP rights in either of their countries and is a perfectly IP legitimate generic drug in both India and Brazil. Hence, the trade of such a drug is also perfectly legitimate and the measure taken by the customs authorities in Netherlands clearly violates the freedom of transit enshrined in GATT Article V[1] .

In addition, it is been found that Dutch customs authorities have seized several such consignments of generic drugs of Indian companies on grounds of alleged IPR violations. One such recent incident that deserves to be mentioned here is the Dutch seizure of an Indian consignment containing antiretroviral drugs for HIV/AIDS treatment that were bound to Nigeria. The seized consignment of drugs was manufactured by Aurobindo Pharma of India and ordered by UNITAID[2] on behalf of the Clinton Foundation for distribution in Nigeria. However, the consignment was later released and brought to Nigeria instead to sailing them back to India due to the strong intervention of UNITAID and few international non-governmental organisations (NGOs).

Also, India's Pharmaceuticals Export Promotion Council[3] (Pharmexcil) in 2008, reported that consignments from a number of small and medium-sized Indian bulk drug makers had recently been seized at ports in Germany, France, the UK and the Netherlands, all on claims of IPRs violations. These instances have caused great concern to the developing and least developed countries (LDCs) due to their systemic and far reaching implications.

Threatening Access to Essential Drugs

Besides going against the spirit of a rule based trading system and impeding free trade, such acts represent a distorted use of the international IP system and circumscribe TRIPs flexibilities. Concerns are already raised since the activities of medicine distribution to needy populations in the developing world would soon be severely hampered if on key transit routes such risk of patent infringement exists in the transit country. Any repeat of such actions may have an impact on exporters' choice of transit routes, which may affect the economics of trade of pharmaceutical products and consequently, have a deleterious effect on access to essential drugs and public health budgets of recipient countries. As a result, the seizure of drugs has added new fuel to the already ongoing debate between rich and poor countries over how best to ensure that people in the developing world can have access to affordable medicines[4].

Box 2: Gramophone Company of India Vs. Birendra B Pandey [AIR 1984 SC 667]

This case was related to the importation of pirated audio cassettes from Singapore destined for Kathmandu, which landed at Calcutta port and were waiting for despatch to Nepal when it was found that they were pirated. On an application by the appellant to the Registrar of Copyrights the cassettes were confiscated. The appellant company brought the case to restrain their onward transmission to Nepal. Defendants contended, among others that there is no infringement of the Copyright Act, because there was no importation in the local market, as envisaged by the Act. However, the Supreme Court favouring the appellants in its judgment held that the term 'import' used in the Copyright Act covered the activity of transit. Thus, India defined 'import' as covering even those goods which are under 'transit'.

If this stand is taken in analysing the present case then the final decision could go against the interest of both India and Brazil, favouring Netherlands. But the gramophone case dealt with copyright violation on which international law is different and clearly against such violations.

For example, Article 51 of the TRIPs Agreement obliges WTO Members to suspend release into free circulation of pirated copyright goods, while it uses only permissive language to allow authorities to have similar provisions for alleged IP infringements other than counterfeiting and piracy. The present case is of patent infringement or alleged counterfeiting of generics. The policy context as well as international opinion as manifested by international law and treaties is completely different here. Both the export of generics by India and their import by Brazil are legal and supported by the flexibility provided under the TRIPs agreement in balancing public health and IP rights and reaffirmed by the amendment to the TRIPs agreement carried out in 2005. Besides, the Gramophone decision was delivered in the pre-TRIPs era and on many issues do not stand the test of time.

16 public health, consumer and development groups have already sent separate letters to the heads of the World Health Organisation (WHO)[5] and the WTO voicing their concerns over recent seizures by Dutch customs authorities. They have asked the WHO to immediately undertake an assessment of the risks to public health programmes presented by such seizures and any anti-goods-in-transit provisions that exist in current or proposed trade agreements, including those relating to anti-counterfeiting initiatives.

Importance of Generic Drugs

According to the WHO, a generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, which is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights. Moreover, these drugs are marketed under a name other than the brand name and are as effective as, but much cheaper than, brand-name drugs. It is because of this low price, generic drugs are often the only medicines that the poorest can access.

The TRIPs agreement does not prevent governments from requiring accurate labelling or allowing generic substitution. Indeed, it is argued that competition between drug companies and generic producers has been more effective than negotiations with drug companies in reducing the cost of drugs, in particular those used to treat HIV/AIDS.

India is already a leader in generic drugs and a large number of patients and doctors in developing countries do rely on affordable medicines from India. Despite the fact, more than half of the population even in these countries still cannot afford a less priced generic copy of a drug. For instance, the controversial Novartis drug, *Glivec* is priced at over Rs 1 lakh per month while its generic copies cost Rs 10,000 per month.

All the more, generic drugs are in no comparison to counterfeit medicine. Counterfeit drugs are those that are deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and may include products with the correct ingredients or the wrong ingredients, lacking active ingredients, with incorrect quantities of active ingredients, or fake packaging.

Given these important differences between generic and counterfeit products, any move to curb the free flow of lawfully produced generic medicines would seriously undermine the production and trade of good quality generic medicines, and consequently access to affordable medicines.

Box 3: Abstract of the Debate Held in the European Parliament

Members of the European Parliament have strongly opposed the recent seizure and raised the issue within the European Commission. They have voiced deep concern on the instant of seizing drugs including losartan potassium shipped from India to Brazil.

"Seizures of generic drugs within the EU are becoming an increasing widespread problem. In December 2008 Dutch customs officials seized a shipment of the ARV Abacavir which had been purchased by UNITAID and which was in transit from India to Nigeria. Abacavir is a generic drug and is recognised as such by the WHO. The impact of such seizures on developing countries is serious and, in the worst case, the treatment of patients can be interrupted", they said.

They claimed that seizure by the Dutch customs authorities is in contradiction with the TRIPs Agreement and with the EU's commitments under the Doha Declaration. It also contradicted the position expressed several times by the European Parliament, they said, calling for necessary changes in the laws to allow free and legitimate trade.

The Commission, however, appears to have glossed over the strong objection by their parliamentarians and just stated that it fully understands the concerns expressed as to the need to ensure the fluidity of trade in generic medicines to developing countries and fully subscribes to this objective. The Commission only agreed to monitor the situation and remain attentive to any (mis)application of EU legislation that may lead to undue hampering of the legitimate trade in generic medicines or to the creation of legal barriers to prevent movement of drugs to developing countries.

Source: www.europarl.europa.eu and various news reports

Application of Article V of GATT at DSU

The conditions of international trade and the requirements for transit have changed since Article V was originally formulated in the late 1940s, and comments from business, international organisations and WTO-

members, in particular developing ones, have suggested a number of obstacles and shortcomings in relation to transit[6]. However, though WTO Members had claimed infringement of GATT Article V a number of times, but all those disputes were amicably settled by the parties themselves well before the establishment of a panel or shortly afterwards. Consequently, this Article on freedom of transit was never interpreted either by a GATT/WTO panel or by its Appellate Body.

For instance, an incident raising questions related to the interpretation of freedom of transit arose in 1989 when Germany decided to ban by January 01, 1990 the circulation of 212,000 Austrian lorries during night hours in the whole area of the Federal Republic of Germany, a decision supposedly taken after Austria announced its intention to limit traffic of certain heavy trucks of all nationalities on some of its roads during night hours with effect from December 01, 1989. Austria considered this measure taken by Germany to violate Article V due to its exclusive targeting at trucks of Austrian origin, and requested consultations before requesting to set up a Panel[7]. The case was later settled by mutual agreement.

A violation of Article V was also claimed in 1996 by the European Communities in the US - The Cuban Liberty and Democratic Solidarity Act of 1992 by asserting that Article 6005 (b) of this Act denied goods and vessels of the Communities transit through US ports[8]. It was alleged that the provision in question prohibited vessels carrying goods or passengers to or from Cuba, or carrying goods, in which Cuba or a Cuban national has any interest, from entering any US port, as well as vessels, which have entered a Cuban port for trade in goods or services, from loading or unloading freight in US ports within 180 days following departure from the Cuban port. The Dispute Settlement Body (DSB) established a panel at its meeting on November 20, 1996 but, at the request of the EC in April 1997, the panel suspended its work. The panel's authority lapsed on April 1998, pursuant to Article 12.12 of the Dispute Settlement Understanding (DSU).

Violations of Article V were also claimed with respect to measures imposed by the Slovak Republic concerning the transit of cattle[9]. Switzerland claimed that the measures imposed by the Slovak Republic have a negative impact on Swiss exports of cheese and cattle. One of the allegations was that some of the measures were inconsistent with Art V of GATT. Likewise, a complaint by Canada and a subsequent request for consultation on September 1998 with the US in respect of certain measures, imposed by the US state of South Dakota and other states, prohibiting entry or transit to Canadian trucks carrying cattle, swine, and grain. Canada alleged that these measures adversely affect the importation into the United States of cattle, swine, and grain originating in Canada. Canada alleges violations of Article V (as well as some other provisions)[10].

Another dispute, leading to a request for the establishment of a panel, arose in 2000 wherein the European Communities claimed that a Chilean prohibition on unloading swordfish in Chilean ports (either to land them for warehousing or to tranship them onto other vessels) violated Article V by making transit through its ports impossible for swordfish[11]. Following a provisional arrangement between the two parties, in April 2001, Chile and the European Communities agreed to suspend the process for setting of the panel[12].

Finally, in February 2002, Slovenia brought to the attention of the Council for Trade in Goods a ban imposed by Croatia on road transit of oil and oil products through Croatian territory which it argued violated Article V, particularly paragraphs 2, 4 and 6 of that Article[13]. The concern was later expanded to also include additional measures subsequently introduced by Croatia, covering oil and oil products as well as several chemical products (internationally classified as dangerous goods), and referring to road transit and international road carriage. Slovenia asserted that these measures were in direct conflict with Article V and as well as with some other provisions of GATT[14]. It was only after few consultations on the issue and the issue was settled amicably.

Conclusion

Till date, there is neither any precedent laid down nor any clear and explicit provision in the multilateral trading system which a country could rely upon to counteract when situations like this emerge. There is a need to clarify whether countries should be free to aggressively enforce patent and other intellectual property claims against goods in transit, or should goods in transit be protected when they are clearly intended to markets where their use is legitimate? The recent developments may pave the way to have this clarity if the affected countries approach the DSU to sort their differences with EU.

In this case, what needs to be specifically made clear is whether the EC Regulation No 1383/2003 goes beyond the obligations required under the TRIPs Agreement in relation to customs authorities as set out in Article 51 of the TRIPs Agreement? Unless clarified, the provisions in the Regulation would pose a serious threat on Indian companies, most of which use the EU route to transport pharmaceutical products to markets where the patent is not recognised or the product is off-patent. Going for a different route is not viable always since the cost of transport would drastically add to the cost of producing thus adversely impacting the India's ability to remain competitive, consequently affecting the availability of much needed medicines in developing countries to which India exports.

Reference

- Article V of the GATT 1994 – Scope and Application, Secretariat of the World Trade Organization 2002, WTO document G/C/W/408

Endnote

1 "Brazil statement on the generics seizure issue to the WTO General Council" Februay 03, 2008

2 UNITAID is an international drug purchase facility, established to provide long-term, sustainable and predictable funding to increase access and reduce prices of quality drugs and diagnostics for the treatment of HIV/AIDS, malaria and tuberculosis in developing countries

3 EU anti-counterfeiting rules being misused by pharma corporate criminals, *Pharma Times*, Feb 24, 2009. Accessible at <www.pharmatimes.com/WorldNews/article.aspx?id=15363&src=EWorldNews>

4 "India statement on the generics seizure issue to the WTO General Council" February 03, 2008

5 WHO has come in support of these groups by stating, *inter alia* that ensuring that the interests of trade and health are appropriately managed, also means that the flow of legitimate medicines, including generic medicines, is not impeded. Refer www.pharmabiz.com/article/detnews.asp?articleid=48831&sectionid=&z=y

6 WTO Trade Facilitation Symposium 9-10 March 1998, Report by the WTO Secretariat G/C/W/115 and the International Forum on Trade Facilitation: 29 - 30 May 2002: For more information see www.unece.org/trade/forums/forum02/index.htm

7 Federal Republic of Germany - Restriction of Circulation of Austrian Lorries - Request for Consultations under Article XXII:1 by Austria, DS14/1

8 United States - The Cuban Liberty and Democratic Solidarity Act - Request for the Establishment of a Panel by the European Communities, WT/DS38/2, October 08, 1996

9 WT/DS133

10 WT/DS144

11 WT/DS193/2, November 07, 2000

12 WT/DS193/3 and WT/DS193/3/Add.1

13 G/C/W/346, February 05, 2002

14 G/C/W/346/Add.1, 1 March 2002

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