Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil

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The confiscation by Dutch customs authorities of a shipment of the pharmaceutical 'losartan' in transit from India to Brazil is one of the most troubling post-Doha Declaration actions affecting public health interests of developing countries. The totality of the circumstances highlights so many serious problems that a brief essay can hardly do the situation justice.

The Dutch customs action was based on patents held by Merck Sharp & Dohme B.V., as licensee of Dutch patents alleged to protect losartan in the Netherlands under Council Regulation (EC) No. 1383/2003 concerning customs actions against goods suspected of infringing certain intellectual property rights (hereinafter 'EC IP Border Regulation'). Merck's Dutch lawyers notified the 'confiscation'[1] at Schiphol Airport to the shipper, Dr Reddy's Laboratories on 24 December 2008. Merck's lawyers expressly demanded 'destruction' of the allegedly infringing goods. They requested a waiver from Dr Reddy's to state, *inter alia*, "The undersigned herewith declares to surrender the consignment …"[2] The terms of EC IP Border Regulation may permit a patent infringement action against goods in transit through an EU airport.[3] In this respect, Dutch authorities may have been acting within the text of the applicable EU regulation. That does not, however, legitimise the confiscation from the standpoint of international law, or from the standpoint of responsible global trade or public health policy.

The action by the Dutch authorities was not an 'accident of the law'. Rather, it resulted from years of deliberate planning by the European Council and Commission. In light of the critical report recently issued by the European Competition Directorate regarding originator pharmaceutical industry patenting practices,[4] it is paradoxical that the EU is taking extraordinary steps to extend the effect of those patents so as to block legitimate trade among developing countries. But this is a long-standing paradox of the European Union. EU authorities take a hard line against pharmaceutical industry abuse within the Union, but apply entirely different standards to external trade. The European Parliament, apparently to little avail, has been trying to alleviate this internal/external dichotomy-in-standards. The recent actions directly contradict sentiments expressed by the Parliament.[5]

The confiscation is contrary to the letter and spirit of the Doha Declaration on TRIPS and Public Health, for which the Dutch were a major developed country proponent. This suggests a lack of coherence and co-ordination among the competent Dutch government departments and agencies. The action has exacerbated the concerns of a number of developing countries that several initiatives to address counterfeit drugs might have a 'hidden agenda' to attack legitimate trade in generics. Once again, the public legitimacy of the WTO is under attack as a consequence of a hyper-extended approach to intellectual property law by some of its developed country Members. Pascal Lamy, in his dual role as former EU Commissioner for Trade and present WTO Director-General, faces an interesting test of his capacity to distance himself from 'Community interests' in addressing the matter.

New Territory for GATT Article V Interpretation

From the standpoint of application of GATT rules, the present dispute is in comparatively new territory. GATT Article V addresses goods in transit. It mandates "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 provides that "all charges and regulations imposed by contracting parties on traffic in transit to or from the territories of other contracting parties shall be reasonable." The application of an internal Dutch patent though the EC IP Border Regulation to goods in transit through a Dutch airport may well be an 'unreasonable' regulation imposed on a product with minimal jurisdictional contact with the Netherlands. Regrettably, GATT Article V has been the subject of limited analysis and/or GATT 1947/WTO dispute-related activity.[6] On preliminary assessment, most analysis and dispute-related activity relates to circumstances differing significantly from those in the present case.

TRIPS Provisions

With respect to the TRIPS Agreement, its Article 51 provisions on border measures require that certain suspension procedures be made available with respect to counterfeit trademarked and copyright pirated goods. These provisions permit, but do not require, that suspension procedures regarding other infringements of intellectual property rights be made available. The latter 'permissive' rule preceded the Doha TRIPS and Public Health Declaration. That document, discussed below, is an interpretative agreement with respect to trade in pharmaceuticals that should preclude application of the permissive rule in cases such as the Dutch seizure.

The TRIPS and Health Declaration

The Doha Declaration on the TRIPS Agreement and Public Health, which stands as an agreement among WTO Members regarding interpretation of the TRIPS Agreement,[7] provides that "we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The EU interpretation of the TRIPS Agreement as embodied in the EC IP Border Regulation conflicts with the right of Brazil to protect the public health of its citizens and to promote access to medicines for all of them. The EU has adopted a standard of protection beyond that required by the TRIPS Agreement, and beyond that required by the Paris Convention. It is applying patent law in a way that is not 'supportive' of public health.

The EC IP Border Regulation will prevent developing countries from making use of EU transport carriers and ports to implement Article 31*bis* of the TRIPS Agreement.

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In the present case, it would have made no difference if India had issued a compulsory license for export under Article 31*bis* (which obviously was not required), and Brazil had issued a compulsory license authorising import (which also was not required), because the internal Dutch patent would presumably not have been affected by those licenses. There are no relevant exception provisions in the EC IP Border Regulation, despite alleged EU support for the Article 31*bis* solution. This is again contrary to the letter and spirit of the Doha Declaration.

Developing countries negotiating Economic Partnership Agreements with the EU have been repeatedly advised of the potential difficulties they may face based on the enforcement provisions in the intellectual property sections of those agreements.[8] Those sections are modelled on EU enforcement directives and regulations. This case involving India and Brazil provides a clear illustration of the risks from the standpoint of the protection of public health.

The EU is applying its internal regulatory standards to goods in transit through its airports. Such transit involves minimal jurisdictional contact with EU territory. Following the logic of applying internal patent law to goods in transit, the EU may presumably apply its internal environmental standards to goods in transit between the United States and India or Japan. This logic might extend to requiring compliance by US and Indian manufacturers with internal EU labour law. It is not evident why the EU approach should not apply to processes as well as products since there are no apparent limits. It is an extreme concept of trade regulation to suggest that goods in transit must comply with ordinary local regulatory requirements in order to avoid confiscation by local customs authorities. Such a permissive rule will wreak havoc with international trade.

Non-violation nullification or impairment causes of action are not presently permitted under the TRIPS Agreement. And, developing countries with good reason have resisted incorporation of such causes of action under TRIPS. This case would, however, present an excellent opportunity for India and Brazil to argue that the benefit of the TRIPS bargain is being nullified or impaired by the actions of the European Union. India and Brazil had a legitimate expectation that products not subject to patent in their territories could be traded freely between them. This expectation is evidenced in the first preambular paragraph of the TRIPS Agreement, stating Members' desire "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."

It is a wonder that European air and sea transport carriers, and the air and sea ports through which they transit, are not voicing strong objection to this new extension of EU confiscatory policy. It would seem that the economy of the Netherlands is at least somewhat dependent upon the reputation of its air and sea ports as reliable and secure transit points. Although in the short term costs may increase, Indian, Chinese and other exporters to Latin America and elsewhere may need to avoid European transit. The EU concept of extraterritorial patent extension logically appears to cover European aircraft and European vessels, so it may be better for Indian, Chinese, Brazilian and other exporters also to use carriers that are not subject to this form of excessive regulation. In the medium to longer term, air and sea transport carriers of Asia, Latin America and the Middle East will benefit from the new EU fortress policy.

Merck was a principal architect of the campaign against South Africa's 1997 Medicines Control Amendments Act. Failure of that originator-industry campaign, championed by the European Commission (among others), ultimately generated intense public backlash against the WTO and the TRIPS Agreement. That backlash provided the impetus for the Doha Declaration on the TRIPS Agreement on Public Health. The actors in this drama have not changed. Oddly enough, Merck's Brazilian affiliate (Merck Sharpe & Dohme Brazil), issued a Note of Clarification stating that it "has not at any time requested the seizure of that product" and "always works in partnership with the Brazilian government in order to seek effective ways to allow all in need to have access to important medicines." To borrow from Lord Sydney Templeman's classic observation in the *Revlon* case, Merck Brazil cannot evade responsibility by "substituting the monkey for the organ grinder."[9]

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ENDNOTES

[1] The term 'confiscation' is used by Amsterdam-based attorneys Lovellis LLP for patent holders Dupont and Merck, to describe the action reported by Dutch Customs Administration Noord (letter from Annemarie Kwaspen, Lovellis LLP, to Dr Reddy's Laboratories, Ltd., Hyderabad, India, dated 24 December 2008).

[2] The parties settled the matter with agreement that the goods would be returned to India, and with Dr Reddy's acknowledging validity of the losartan patent in Europe.

[3] See EC IP Border Regulation, e.g., at Article 1(b) and cross reference to Articles 37 and 183 of Regulation (EEC) No 2913/92, which is further implemented by Regulation (EC) No 1891/2004, and amended by Regulation (EC) No 1172/2007 of 5 October 2007.

[4] Staff Working Paper, Pharmaceutical Sector Inquiry, Preliminary Report, 28 Nov. 2008.

[5] See, e.g., European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, PA_TA(2007)0353, at paras. 8 and 16; and recommendation of the Committee on International Trade to the European Parliament on the proposal for a Council decision on the acceptance of the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005, PE 390.562v02-00, 22 Oct. 2007.

[6] See, e.g., Note by WTO *Secretariat, Article V of GATT 1994 – Scope and Application*, TN/TF/W/2, 12 Jan. 2005 (Updating G/C/W/408, 10 Sept. 2002).

[7] See Frederick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. Int'l Econ. L. 469 (2002).

[8] See, e.g., Frederick M. Abbott and Jerome H. Reichman, Study, *Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union*, Directorate General External Policies of the European Union, EXPO/B/INTA/2007/14 June 2007 PE 381.392

[9] See Revlon vs Cripps & Lee, UK Court of Appeal [1980] FSR 85, 22 Nov. 1979.