**EXPERT REPORT RW (C)**

# ECONOMIES OF SCALE ARE IMPORTANT AND A COMPULSORY LICENSE MUST PERMIT EXPORTS SO THAT A DOMESTIC PRODUCER CAN REACH EFFICIENT ECONOMIES OF SCALE

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The World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) specifies that most compulsory licences must be issued predominantly for supply of the domestic market of the country issuing the licence.[1] However, this provision does not apply to compulsory licences issued to remedy anti-competitive practices.[2] In other words, countries issuing compulsory licences to remedy anti-competitive practices have freedom to authorise licencees to export to other countries.[3]

In August 2003, the Council for TRIPS reached a decision on a mechanism to permit exports to countries issuing compulsory licences.[4] This decision removes some of the restrictions on countries exporting under certain TRIPS compulsory licensing rules.[5] *But it has no effect on countries' already-established and unhindered right under TRIPS*

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[1] World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), 31(f).
[2] TRIPS 31(k).
[3] Of course, those countries cannot import products manufactured pursuant to a compulsory licence unless they themselves have issued a compulsory licence or unless the product is not patented in the importing country.
[4] *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of 30 August 2003, WT/L/540, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. The decision was accompanied by a clarifying statement from the chairperson of the TRIPS Council. *The General Council Chairperson's Statement*, 30 August 2003, available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm

The action by the TRIPS Council was mandated by the Doha Declaration on the TRIPS Agreement and Public Health, which committed WTO members by the end of 2002 to develop a solution to the problem posed by the TRIPS Agreement for countries with a small market for any particular drug. While countries with small markets (a category which will vary by drug and on occasion will include even large, wealthy nations) clearly maintain the right under TRIPS Article 31 to issue compulsory licences to import pharmaceutical products, many potential exporters faced a TRIPS limitation. Their problem is that, if the product is patented in the potentially exporting country, generic producers there cannot manufacture or export the product. And, under TRIPS rules (Article 31(f)), even if a compulsory licence is issued in the exporting country, it must be predominantly for supply of the domestic market.
[5] The agreed-upon procedure for implementation of Paragraph 6 of the Doha Declaration is quite complicated. A news release from the WTO summarised the problem and solution as follows:

> Article 31(f) of the TRIPS Agreement says products made under compulsory licencing must be "predominantly for the supply of the domestic market". This applies directly to countries that can manufacture drugs — it limits the amount they can export when the drug is made under compulsory licence. And it has an indirect impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licencing. …
> This 30 August 2003 agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision. All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.
> Decision Removes Final Patent Obstacle to Cheap Drug Imports, World Trade Organisation news release, 30 August 2003, available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

*to authorise exports to remedy an anti-competitive practice.*[6] Thus the August 2003 decision of the TRIPS Council has no impact at all on South African competition authorities' ability to authorise exports to remedy anti-competitive practices such as those alleged in the *Hazel Tau* case. That authority is unquestioned.

There are simple policy reasons that make inclusion of a right to export critically important in compulsory licencing cases where it is permissible. For the country issuing the licence, exports will enable domestic manufacturers to achieve the economies of scale necessary to operate efficiently. This will enable domestic firms to produce more efficiently, with major benefits not just for the licencee firm, but for the consumers who will benefit from the lower prices that follow from more efficient production in the generic sector. There are benefits as well for countries that may receive exports from the country issuing the licence -- their consumers also will be able to access generic products from producers able to manufacture more efficiently. This benefit will be particularly important in smaller market countries that cannot hope based on their own market to achieve many of the benefits of scale economies.

**The importance of economies of scale in pharmaceutical manufacturing**

There is little dispute that economies of scale are particularly acute in the pharmaceutical industry.

According to the European Federation of Pharmaceutical Industries and Associations,

> It is well established that the lowest cost of production of medicines can be achieved where manufacturers are able to consolidate facilities and focus factories on high volume, robust processes. Pharmaceutical manufacturing has huge economies of scale: it would be the best approach economically to produce 1,000 tons of a product at 'good manufacturing practice' (GMP) quality from a current supplier producing 100 tons per annum at GMP.[7]

Economies of scale in the pharmaceutical industry are such that marginal costs continue to fall until very large markets are obtained.

Canada, a country with a robust generics industry, has found that its market -- the eighth largest in the world -- is too small to achieve the economies of scale necessary for most efficient operation.

For most of the twentieth century, Canada had in place a routine compulsory licencing scheme for pharmaceuticals. However, until 1969, compulsory licences were used relatively infrequently. In 1969, Canada implemented a major reform in its compulsory licencing law, so that it was both possible to import active ingredients and to export finished products under a pharmaceutical compulsory licence. The reform made

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[6] The entirety of the Doha Declaration Paragraph 6 issue dealt with limitations on exports due to TRIPS Article 31(f). Article 31(k) specifies that Article 31(f) does not apply to compulsory licences issued to remedy anti-competitive practices ("Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f).").

[7] European Federation of Pharmaceutical Industries and Associations, *Local Production: Protectionism, Technology Transfer or Improved Access?*, available at www.efpia.org/4_pos/access/localprod.pdf. See also Warren Kaplan, *Local Production of Pharmaceuticals and Vaccines*, paper presented at the World Bank, 2 June 2003, available at wbln0018.worldbank.org/HDNet/hddocs.nsf/0/2adc484a5d57888f85256d350054080f/$FILE/EXECUTIVESUMMARYJUNE2.DOC

attainment of economies of scale possible, and compulsory licencing became much more common. Between 1969 and 1992, there were 1,030 applications to import or manufacture compulsory licenced medicines, of which 613 licenses were granted. By comparison, between 1935 and 1969, there were 49 applications for compulsory licenses to manufacture either patented foods or medicines, of which 22 were granted.[8]

A 1997 Industry Canada survey of Canadian drug manufacturers found that economies of scale were listed as a key factor establishing the fundamental competitiveness of pharmaceutical manufacturing.[9] The Canadian market was not large enough to achieve desirable economies of scale, according to industry executives:

> Our survey results indicate that Canadian executives of multinational subsidiaries regard the economies of scale of full size plants in the US or Europe as a distinct advantage for those facilities over Canadian plants.

The importance Canada attaches to generic pharmaceutical exports to achieve economies of scale was highlighted in a World Trade Organisation dispute between that country and the European Union. The case involved, among other issues, Canada's early working (or "Bolar") provision, which enables generic pharmaceutical manufacturers to import, manufacture and use patented pharmaceutical products for the purpose of conducting tests needed to earn regulatory approval to put a product on market. The idea behind early working provisions is to enable generic firms to earn regulatory approval while a product is still patented, so they can put a product on the market as soon as patent protection expires. Canada's early working provision permits generic firms to use patented products for regulatory tests not only for eventual sale in the Canadian market, but in other markets as well. In successfully defending this element of its early working provision, Canada explained that generic firms need access to the global market if they are to obtain the economies of scale necessary to operate efficiently. The WTO dispute settlement panel recited Canada's arguments as follows:

> Both the brand name and generic pharmaceutical industries were global in nature. Very few countries had fully integrated brand name or generic drug industries within their borders. Even in large countries, generic producers frequently had to obtain ingredients such as fine chemicals from producers in other countries. Many countries had no generic industries at all and had to obtain generic (as well as brand name) products from other countries. *Smaller countries that did have generic industries did not have domestic markets sufficiently large to enable those industries to operate on an economic scale. Those industries had to export in order to be able to manufacture in sufficient quantities to achieve economies of scale, so that domestic consumers could receive the benefits of cost-effective generic products.* (emphasis added)
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> The United States agreed that a "pre-expiration testing" exception was a reasonable exception to the exclusive rights conferred under the TRIPS Agreement. However, the market in the United States was large enough for generic producers to manufacture on an economic scale. Very few countries were in that position. "Pre-expiration testing" exceptions that had the effect of confining all activities to a single country were of little use to countries that,

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[8] Jerome Reichman and Catherine Hasenzahl, *Non-voluntary Licencing of Patented Inventions: The Canadian Experience*, 2002, available at http://www.ictsd.org/iprsonline/unctadictsd/docs/reichman_hasenzahl_Canada.pdf.

[9] Coopers and Lybrand, commissioned by Industry Canada, *Best Practices Benchmarking Study of Canadian Pharmaceutical Manufacturing*, 1997, available at http://strategis.ic.gc.ca/SSG/ph01374e.html.

> unlike the United States, depended on international trade to obtain generic products. …
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> A "pre-expiry testing" exception that did not permit activities in respect of foreign regulatory approval was useful only to those countries with markets large enough to sustain domestic generic industries on an economic scale. It failed to recognise that most countries depended on international trade for their supply of generic drugs.[10]

Canada is not an outlier in finding economies of scale so crucially important for the pharmaceutical industry. "Economies of scale have acted as a significant entry barrier to effective competition in pharmaceuticals," according to a report prepared for the Australian Rural Industries Research and Development Corporation. Access to international markets is seen as critical to enabling efficient production in the Australian market: "Large scale has been a particular problem for Australian manufacturing which has had problems in accessing markets beyond the relatively small Australian market."[11]

Even for pharmaceutical producers in the U.S. and EU markets, the economies of scale from exports can help reduce unit costs.[12] It is for the purpose of achieving economies of scale that compulsory licenses issued to remedy anti-competitive practices in the United States typically include the right to export.

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[10] *Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their member States Report of the Panel*, World Trade Organisation, WT/DS114/R, 17 March 2000, section 4.38.

[11] Wondu Holdings Pty Limited, Prepared for Rural Industries Research and Development Corporation, *New Pharmaceutical, Nutraceutical and Industrial Products: the Potential for Australian Agriculture*, November 2000, 106, available at http://www.rirdc.gov.au/reports/Ras/00-173.pdf.

[12] See Pharmaceutical Researchers and Manufacturers Association (PhRMA), *Frequently Asked Questions*, available at http://world.phrma.org/faq.html ("When there are different prices across markets (e.g., lower prices in developing countries), manufacturers can maximize overall output and serve all markets. This benefits both developing countries (by increasing the availability of products) and developed ones (by lowering prices through economies of scale in production)."); Board of International Health, Institute of Medicine, *America's Vital Interest in Global Health: Protecting Our People, Enhancing Our Economy, and Advancing Our International Interests*, 1997, chapter 5, available at http://search.nap.edu/readingroom/books/avi ("In congressional hearings in 1982 concerning federal and state expenditures for the purchase of children's vaccines, however, the U.S. vaccine industry was savaged for allegedly subsidising vaccines for the poor children of the world by charging high costs to U.S. families and taxpayers. As a result, U.S. vaccine manufacturers have declined to tender bids to UNICEF ever since.

However, a recent study by Mercer Associates for UNICEF indicated that the criticisms levelled at the U.S. vaccine manufacturers in 1982 were unwarranted. The report pointed out that vaccines would have been developed and produced to protect American children, regardless of international needs. Further, the report found that it was the excess capacity in the vaccine industry that enabled global manufacturers to provide sufficient vaccines to UNICEF at marginal cost and for marginal profits.

The withdrawal of U.S. companies from the UNICEF purchasing scheme has not only deprived the industry of the chance to contribute to a dramatic reduction in child mortality, but has also caused a loss of comparative advantage in the global marketplace and has limited the industry's strategic options. For example, the continued use of multitiered pricing has enabled European manufacturers to price products in their core markets to cover the full cost of production, investments in R&D, marketing, and all overhead costs, while also allowing them to sell large volumes of low-price vaccines to the poorest countries of the world. These global sales have, in turn, enabled manufacturers to take advantage of economies of scale in production and for the cost per dose. As the Mercer study points out, because vaccine production is a fixed-cost business, revenue from each additional dose sold at a price above the marginal cost directly contributes to profits. The ability to pursue multitiered pricing strengthens the competitiveness of national industries, provides adequate prices—and thus revenues—for product innovation, and allows manufacturers to sell higher volumes at a lower per-unit cost." (internal citations omitted))

**Helping close the global essential medicines access gap**

It is now accepted beyond dispute that there is a crisis in providing essential medicines, especially but not limited to antiretrovirals and other AIDS-related medicines, to people in developing countries. One way for developing countries to address this problem is to issue compulsory licences to enable generic competition for drugs while they remain on patent (or, in the case of least-developed countries, not to enforce pharmaceutical patents at all). But as the WTO's Doha Declaration on the TRIPS Agreement and Public Health highlighted, even if small market countries have the ability to import medicines which are compulsory licenced or not patented in their markets, there must be manufacturers who are legally able to export to them.[13]

If middle-income markets such as South Africa authorise exports when issuing compulsory licences to remedy anti-competitive practices, they will give small market countries manufacturers from which they can import.[14]

Authorisation of exports when issuing compulsory licences to remedy anti-competitive practices would work to fulfil one of the aspirations of the formulators of South Africa's Competition Act, to develop and implement competition policy in a fashion mindful of South Africa's impact on economically weaker countries in the region.[15]

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[13] WTO's *Doha Declaration on the TRIPS Agreement and Public Health*, para 6.

On the distinct but related issue involved in the Canada-European Union case on Canada's early working provision, Canada justified its policy of permitting manufacturers to use patented products not only on the grounds that it would benefit its own industry and consumers, but that, by speeding entry of generic competition in developing countries, it would help meet the global need for access to essential medicines. *Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and Their Member States Report of the Panel*, World Trade Organisation, WT/DS114/R, 17 March 2000, section 4.38.

[14] As Professor Scherer noted in a paper presented at the World Bank before the August 30 resolution of the Doha Paragraph Six issue,

> The requirement under TRIPS that any compulsory drug patent licence be authorised predominantly for the supply of the domestic market is most likely to pose serious problems to less-developed nations that lack the infrastructure and technical capabilities to build a domestic industry able reliably to supply modern pharmaceutical products. Even Canada, with high income per capita, excellent universities, and a population during the 1970s of roughly 22 million, found it necessary to import many of the bulk pharmaceuticals ultimately supplied under compulsory licences. Thus, smaller less-developed nations will have to issue their compulsory licences mainly for importation rather than domestic production. This in turn requires that competitive world market supply sources exist. The "predominantly" term in Article 31(f) clearly implies that some exportation under compulsory licence in the exporting nation will be allowed. Efforts to clarify this question under the Doha Round of international trade negotiations ended in stalemate. A restrictive interpretation would severely limit the ability to achieve effective world market competition. If satisfaction of LDCs' needs through importation is allowed, the principal suppliers are likely to be large nations such as India, China, or Brazil. It will also be important that such would-be exporters recognise their comparative advantage in being the world's principal suppliers under compulsory licence and are not discouraged from assuming that responsibility.

F.M. Scherer, "The Economics of Compulsory Drug Patent Licencing," Paper presented at Workshop on Key Issues in Improving the Accessibility to Drugs in Developing Countries, Session 3: Compensation and Compulsory Licences: implementing the Doha Declaration and advancing the UN Millennium Development Goals, World Bank, June 2, 2003, Washington, DC.

[15] *Proposed Guidelines for Competition Policy: A Framework for Competition, Competitiveness and Development*, Department of Trade and Industry, 27 November 1997, 2.4.2.