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The European Commission has proposed a new Regulation on October 29, 2004 to allow the export of generic versions of patented pharmaceuticals to developing countries. The proposed "Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems" establishes a procedure for granting compulsory licenses for patents and supplementary protection certificates concerning the production and sale of generic pharmaceuticals, which are intended for export to countries affected by a public health crisis.

According to the WHO, a generic drug is a pharmaceutical product which is identical, or bioequivalent to, a brand-name product in dosage, safety, strength, quality, performance characteristics, and intended use. Generics as effective alternatives to higher-priced originator pharmaceuticals are generally produced and marketed when the patent on the brand-name product has expired or when a voluntary or compulsory license has been granted. Under a system of compulsory licensing, developing countries affected by a public health crisis will be able to override patents on pharmaceutical products and order generic versions from manufactures in other countries. Most national laws do not allow compulsory licenses for export, because recently the TRIPS-Agreement limited compulsory licensing to situations predominantly aimed at supplying the domestic market.

The Doha Declaration, adopted at the Fourth Ministerial Conference of the World Trade Organization in November 2001, agreed to address the difficulties raised by this restriction for developing countries and explicitly clarified for the first time the flexibilities of the TRIPS-Agreement in combating public health problems. The Declaration underlines the flexibilities inherent in the TRIPS-Agreement and refers to possibilities in case of a public health crisis by encouraging the use of a creative interpretation "in a manner supportive of public health". The Declaration also clarified the compulsory licensing provisions of the TRIPS-Agreement and confirmed the WTO members' right to issue compulsory licenses as well as the freedom to determine the grounds upon which such licenses are granted. Recognizing that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of these provisions, Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution.

In fulfilling the mandate given by the Doha Declaration, the WTO

General Council adopted the Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPS-Agreement and Public Health on August 30, 2003. The Decision waives certain obligations concerning the question of compulsory licenses set out in the TRIPS-Agreement to address the specific needs of those WTO members lacking sufficient manufacturing capacities in the pharmaceutical sector. The Implementation Decision now allows countries to manufacture patented pharmaceuticals under a compulsory license and to export them to eligible importing countries, provided that various conditions are met.

Due to the fact that the European Communities and their member states were actively involved in the negotiations leading to the Implementation Decision, the Community wants to contribute to the agreed system by implementing the WTO decision of August 30, 2003 into its legal order. The proposed Regulation will therefore set up the necessary legal and regulatory framework for pharmaceutical companies to manufacture and export generic versions of patented medicines to countries in need.

Within the Community, systems for granting compulsory licenses are organized at national levels by individual member states. However, uniform implementation of the Decision is needed to ensure that the conditions for granting a compulsory license for export are the same in all European Union member states. Because of the various options available to exporting countries, the objective of the proposed regulation, to establish a harmonized procedure for granting compulsory licenses, can be better achieved at Community level. Uniform rules should also be applied to avoid a distortion of competition for operators in the European single market and to prevent re-importation of medicines manufactured pursuant to the regulation into the territory of the Community. In view of this need for a uniform implementation, the Commission has proposed implementation by way of a Regulation.

According to the draft, the competent national authorities can grant compulsory licenses for the production of patented pharmaceuticals if certain conditions are fulfilled. Eligibility for benefits will be based on notifications and declarations to the WTO. Under the system, the importing country must have notified the WTO of the required medicines. The license can only be issued by a least developed country in accordance with the WTO decision of August 30, 2003. Nevertheless it will be optional for other countries to make use of the compulsory licensing system by notifying their requirements to the TRIPS Council.

It would then be up to the pharmaceutical manufacturer to apply for a compulsory license under the pro-

posal by contacting his national authorities. As a consequence, the system could accelerate the introduction of generics as manufacturers will be able to produce pharmaceuticals ahead of the expiration of the originator's patent in Europe, and secure a market for their generic products.

However, the system has raised concerns, especially on the part of the pharmaceutical industry, that products manufactured pursuant to the Regulation could be diverted and re-imported into the European Union. Therefore the Commission's proposal would prohibit re-importation into the EU of pharmaceuticals produced under a compulsory license. To ensure that medicines sold for export under a compulsory license reach those patients who actually need them, and to protect patent holders, customs authorities will be authorized to take action against re-importation at external borders. The Commission's proposal would also allow the patent holder to use existing national procedures to enforce his rights against re-imported products. In addition, compulsory licenses issued under the Regulation could be terminated if re-importation occurs.

As the EU does not necessarily require a medicinal marketing authorization from the licensee for the export of pharmaceuticals, importing countries have a legitimate interest in obtaining medicines that are safe and effective. Therefore provisions have been made for licensees to seek a scientific opinion from regulatory authorities under the EU's scientific opinion procedure for evaluating medicines under Regulation No. 726/2004 in order to ensure the safety of the medicines. Furthermore the Regulation provides exemptions from data exclusivity rules which usually require manufacturers to wait several years before they are authorized to use data from previous clinical trials. Thus the derogations from data protection would allow a faster registration of generics by drug regulation authorities for the issuing of a compulsory license. The Regulation also ensures that a marketing authorization does not expire for reasons of non-use in the European Union.

Meanwhile the legislative move has been broadly welcomed especially by civil society groups and industry based organizations. "The WTO decision and our proposed regulation can help save lives by helping countries in need to acquire affordable medicines, without undermining the patent system, which is one of the main incentives for the research and development of new medicines," said Internal Market Commissioner Fritz Bolkenstein. Trade Commissioner Pascal Lamy stated that "[b]y adopting this proposal the EU leads the way in ensuring access to affordable medicines for poor countries. It shows that we are delivering on our promises in the Doha Development Agenda." According to the UK-based aid agency

Oxfam, the European Union is "sending a positive political signal" to developing countries. However, Oxfam stresses that the legal mechanism provided for by the WTO is complex, and the Commission's proposal does not reduce that complexity. Therefore the proposed Regulation is considered to be a "good faith" interpretation of the WTO Decision of August 2003. However, the group believes that the Regulation could be improved by not requiring any negotiations with the patent holder before issuing a compulsory license for export in case of a public health emergency. As negotiations are potentially time-consuming, they are invariably liable to delay the use of the WTO mechanism.

Another point of concern is that under the Regulation, generic companies will only be allowed to export medicines to least developed countries or countries lacking pharmaceutical production capacities whose markets are often not large enough to allow manufacturers to offer lower prices. Additionally the countries concerned usually have limited abilities to pay even for the lowest prices available.

On a positive note, the European proposal puts no further restrictions on the medicines or diseases to which it applies, as was the case for example, in Canada. Legislative changes to the Patent Act and Food and Drug Acts, as proposed in Bill C-9, made Canada the first country to implement the WTO General Council Decision of 30 August 2003 to waive patent rights in order to permit developing countries the import of key drugs from other countries. However, concerning the products that may be manufactured and licensed for export, the Canadian regulation suffers from a fundamental defect. As enacted, the Bill includes a limited list of medicines, which is basically derived from the WHO's Model List of Essential Medicines. Although the federal Cabinet may, upon ministerial recommendation, add products to the list, these restrictions are contradictory to the Decision of August 2003, as all WTO members agreed that their legislation would not be limited to specific diseases or products. Such an approach creates delays and inevitably opens the door to pharmaceutical companies lobbying against an inclusion of their products.

On this issue, the European approach is far preferable as it is not limited to specific diseases or products, but refers to pharmaceutical products in general as defined in the WTO decision. The Canadian regulation on the other hand creates a positive precedent by allowing compulsory licensing also for the export to non-WTO members. As currently proposed, the EU Regulation would only permit export of generics to WTO members. However, the Canadian approach allows export to non-WTO members only subject to onerous conditions which limit the effective use of the mecha-

nism in practice.

On the question of prior negotiations with the patent holder, the Canadian model provides a clear definition of how long a generic manufacturer must attempt to obtain a voluntary license. The licensee may apply for a compulsory license if no agreement has been reached within a 30 day negotiation period. Another positive feature of Canada's law is its approach to compensation payable to the patent holder. Canadian law provides a clear formula linking the royalty rate on any contract to the importing country's ranking on the UN Development Program's Human Development Index (HDI). Comparing the HDI rankings of developing countries, the maximum royalty payable would be 4 per cent of the total value of the product exported under the compulsory license. If a patent holder is unwilling to pay the compensation, royalty rates will be fixed by the government on a strict application of the formula.

By contrast, the EU Regulation does not provide comparable legal certainty concerning the requirement to first seek a voluntary license from the patent holder, or on the remuneration to be paid. Under the European proposal the licensee has to provide evidence that he has made efforts to obtain authorization from the patent holder on "reasonable commercial terms and conditions", and within a "reasonable period of time". In determining a reasonable period of time, the competent authority shall take into account whether a national emergency or other circumstances of extreme urgency have been declared by the importing country. In addition the licensee shall pay an "adequate remuneration" to the patent holder as determined by the competent authority, taking into account the economic value of the specific use that has been authorized under the compulsory license.

Unfortunately the Regulation does not provide any guidance as to what constitutes a "reasonable period of time" or an "adequate remuneration" in the event of issuing a compulsory license. The fact that the Canadian legislation sets out a clear approach by specifying the period of negotiation and the compensation to be paid, leads to a high degree of legal certainty essential for providing incentives to generic manufacturers.

Overall, the European proposal is still more balanced than the Canadian approach, as it does not include a limited list of pharmaceutical products covered. Nevertheless there still remains considerable room for improvement. The Regulation could significantly be improved by setting out a clear and short time frame for prior negotiations with the patent holder, and more detailed conditions concerning the compensation to be paid in the event of compulsory licensing. In this regard Canada has found an appropriate

solution which should be followed in Europe, too. Because Canada has been the first country to implement the WTO decision of August 30, 2003, its legislation may offer useful experience to other countries that are also in the process of amending their patent legislation.

The proposed Regulation will now be discussed by the 25 European member states and is expected to be submitted for approval to the European Parliament early next year. The Regulation provides for review three years after entry into force, at which time it will be possible to assess the contribution it has made to the implementation of the mechanism established. To date, no WTO member has registered its intention to make use of the system established by the Decision. Recognizing that the issues surrounding access to medicines are complex, the WTO negotiations on the question of medicines remain contentious, as recent events demonstrate. At an informal meeting of the TRIPS Council held on December 1, 2004, the United States and other developed countries criticized a proposal from African Countries which aims to incorporate the August 2003 deal into the TRIPS-Agreement. According to the developed nations, the African proposal attempts to modify several provisions of the August 2003 decision, which was finalized after particularly hard negotiations especially with the U.S. The African proposal and the possibility of a permanent inclusion in the TRIPS-Agreement will now be discussed in informal consultations between WTO members. It remains to be seen whether the WTO decision of August 2003 and the Implementation at European Community level will have the effect in practice to actually increase the supply of medicines to developing countries.

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