

Denmark and Italy Trade-related intellectual property rights, access to medicines and human rights

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Summary

1. Denmark and Italy, as members of the European Union (EU), have committed themselves to facilitating access to affordable drugs, as a part of the EU's Programme for Action to fight HIV/AIDS, malaria and tuberculosis.¹ Denmark has also individually committed itself to "accommodating the needs of developing countries to safeguard public health interests through the widest possible access to lifesaving copycat drugs, whilst bearing in mind the need for developing new drugs."² Despite these efforts, much still needs to be done by Denmark, Italy, other EU members and the international community at large if access to affordable treatment for the poor is to become a reality by the Millennium Development Goal of 2015.

2. Under the International Covenant on Economic, Social and Cultural Rights (Covenant) State parties are obliged to take steps "individually or through international assistance and cooperation" towards achieving the full realization of Covenant rights (article 2(1), as interpreted by CESCR General Comment No. 3 (1990)). In relation to the right to health, which includes access to affordable medicines, this obligation requires State parties to respect the enjoyment of the right to health in other countries, to prevent third parties from violating the right to health in other countries, and to ensure that State party actions as members of international organizations take due account of the right to health (article 12, as interpreted by CESCR General Comment No. 14 (2000)).

3. There is a risk that Denmark, Italy and other EU members could support trade rules that make it harder for them to respect, protect and fulfil their human rights obligations. Of particular concern are strict trade-related intellectual property (IP) rules in bilateral and regional trade agreements and technical assistance programmes. These strict IP rules could stop Denmark, Italy and other EU members with drug manufacturing capacity from exporting cheaper generic versions of patented drugs to developing countries. Therefore, it is important that Denmark, Italy and other EU members strongly denounce these rules. It is also crucial that Denmark, Italy and other EU members rapidly implement the generic drug export mechanism of the World Trade Organization (WTO) General Council Decision of 30 August 2003. Finally, it is important that Denmark, Italy and other EU members actively use and promote the export mechanism to provide cheaper generic medicines to developing countries.

4. 3D -> Trade - Human Rights - Equitable Economy is a not-for-profit organization based in Geneva, Switzerland, working to ensure that trade rules are developed and applied in ways that promote an equitable economy.³ We believe that human rights mechanisms such as the Committee

¹ European Commission Communication, *EC programme for Action, Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction, Outstanding policy issues and future challenges*, COM(2003) 93 Final, 26 February 2003.

² Danish Ministry of Foreign Affairs, *Denmark's first reporting on Goal 8, Goal 8: Establishing a Global Partnership*, 2003.

³ For information on 3D's work in general, or on 3D's project on the impact of trade-related intellectual property rules on access to medicines and human rights, please visit www.3dthree.org or contact Davinia Ovett, Programme Officer, 3D -> Trade - Human Rights - Equitable Economy, dovett@3dthree.org

on Economic, Social and Cultural Rights can help attain this objective by reminding States that rules relating to international trade must not undermine human rights obligations.

5. This submission to the members of the Committee on Economic, Social and Cultural Rights outlines our human rights-based concerns regarding the impact of strict IP rules on the ability of Denmark, Italy and other EU members to fulfil their international obligations under the right to health. We recommend that Denmark, Italy and other EU members use their vote in the European Council of Ministers and in international organizations to stop strict IP rules in bilateral and regional trade agreements and in technical assistance programmes from violating the right to health in developing countries.

6. The final page of this submission sets out some specific issues we suggest Committee members might raise with representatives of Denmark and Italy.

I. International human rights obligations and access to medicines

7. Having ratified the International Covenant on Economic, Social and Cultural Rights, State parties have a primary responsibility to respect, protect and fulfil Covenant rights at the national level. They also have an international obligation to take “deliberate, concrete and targeted” steps “through international assistance and cooperation, especially economic and technical” towards full realization of Covenant rights (article 2(1), as interpreted by CESCR General Comment No. 3 (1990)). In relation to the right to health, the international obligation under article 12(1), as interpreted by CESCR General Comment No. 14 (2000), requires State parties to: respect the enjoyment of the right to health in other countries; facilitate access to essential medicines in other countries; prevent third parties from violating the right to health in other countries, if they are able to influence these third parties by way of legal or political means; and ensure that their actions as members of international organizations take due account of the right to health.⁴ A further crucial aspect of the right to health is the obligation to ensure access to information and participation of the population in health-related decision-making at the community, national and international level.

8. Therefore, Denmark, Italy and other EU members, as a sovereign States, and also as members of the EU and international organizations such as the WTO, should take “deliberate, concrete and targeted” steps towards the full realization of the right to health at the national and international level.

II. The WTO TRIPS Agreement and the right to health

A. The TRIPS Agreement policy flexibilities and public health

9. Denmark, Italy and all other developed country Members of the WTO were required to implement the Agreement on Trade-Related Intellectual Property Rights (TRIPS Agreement) by 1st January 1996. The TRIPS Agreement aims to provide a minimum standard of IP protection in all WTO member States. Due to strong concerns about the adverse impact of TRIPS patent rules on the cost of medicines, WTO members adopted the WTO Doha Declaration on TRIPS and Public Health in November 2001 (Doha Declaration). This political commitment reaffirms the fact that countries can make use of all the policy flexibilities available in the TRIPS Agreement to “protect public health and, in particular, access to medicines for all.” These crucial flexibilities include, among others:

- **Compulsory licensing and government use:** the ability of the relevant authorities to grant and define when to issue a license to manufacture, use or sell a generic equivalent

⁴ Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14 (2000), The right to the highest attainable standard of health*, E/C.12/2000/4, 11 August 2000.

version of a patented drug without the consent of the patent holder, as long as the patent holder is compensated.

- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the re-sale of their products. This enables the importation of patented or generic drugs from countries where they are sold more cheaply (termed “parallel importation”).
- **Exceptions to patent rights:** the ability to allow the manufacture and testing of a drug prior to the expiry of the patent, in order to obtain regulatory approval for making a generic drug once the patent expires (termed “bolar provision”).
- **Prohibition of anti-competitive practices:** the ability to penalize pharmaceutical patent owners that abuse their dominant position in contractual relationships and engage in prohibitive pricing.

10. In June 2003 the European Commission (EC) sent a Communication to the WTO TRIPS Council on the implementation of the Doha Declaration.⁵ This Communication emphasizes the EC’s commitment to the objectives of the Doha Declaration and supports developing and least developed countries ability to use compulsory licenses to obtain cheaper generic versions of patented drugs. The Communication also outlines the EC’s support for “differential” drug prices and the use of voluntary licenses as a way to ensure parallel imports of lower cost patented and generic drugs to developing and least developed countries.⁶ Although differential pricing and voluntary licenses can help reduce the cost of drugs in developing countries, they are not flexibilities explicitly reaffirmed by the Doha Declaration, such as compulsory licenses. Also, it is important to note that differential pricing is a voluntary scheme that is dependent on the goodwill of pharmaceutical manufacturers. Therefore, if developing countries want a sustainable supply of cheap medicines, they should be encouraged to use compulsory licenses and government use licenses.

11. Denmark, Italy and other EU members should take steps to ensure that the EU’s implementation of the Doha Declaration facilitates access to affordable medicines in developing countries. To achieve this goal, it is important that differential prices and voluntary licenses granted by pharmaceutical manufacturers and backed by the EU’s Programme for Action⁷ are not promoted to the detriment of compulsory licenses and government use licenses that give developing countries more autonomy in their supply of drugs.

B. Additional mechanisms: the WTO General Council Decision of 30th August 2003

12. The WTO General Council Decision of 30th August 2003 (General Council Decision) was adopted in order to find a solution to a problem left unresolved by the Doha Declaration on TRIPS and Public Health: this problem came from the fact that the TRIPS Agreement limited the export of drugs under compulsory license by requiring that it be ‘predominantly’ for domestic use. This limitation on export made it hard for countries without drug manufacturing capacity to fully use compulsory licensing. The General Council Decision is a waiver to this limitation and creates an import/export compulsory licensing mechanism that allows drug manufacturing countries to export drugs to countries that cannot make them themselves. So far, the mechanism has only been implemented by Canada and Norway⁸ and has not yet been used, as developing countries can still

⁵ European Commission, *Communication from the EC to the TRIPS Council on the implementation of the Doha Declaration on the TRIPS Agreement and Public Health*, (282/03 Rev 1), 2 June 2003.

⁶ Differential pricing is when a drug manufacturer grants a reduced price to developing or least developing countries only. Voluntary licenses are licenses for the manufacture, sale or export of a drug granted with the patent owner’s consent.

⁷ See Note 2 above.

⁸ Canada, *Patent Bill C-9, An Act to Amend the Patent Act and Food and Drugs Act*, 4 May 2004.

<http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend.htm>

Norway, *Regulations amending the Patent Regulations (in accordance with the decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a))*, 14 May 2004.

<http://odin.dep.no/ud/engelsk/p2500832/p30003923/032121-290002/dok-bn.html>

easily buy cheap generic drugs from India, the largest generic drug exporting country, until the end of 2004. On 1 January 2005 however, India will implement the TRIPS Agreement patent rules, which will have an impact on the supply of generic versions of new drugs to developing countries. In order to ensure sufficient availability of generic versions of patented drugs after 2005, all pharmaceutical exporting countries must implement the General Council Decision as soon as possible.

13. Denmark exports more than 90% of its pharmaceuticals and is, per capita, the second largest exporter of pharmaceutical products in the world.⁹ Italy is also an important pharmaceutical producer, currently ranked fifth in Europe.¹⁰ As pharmaceutical exporters, it is crucial that Denmark and Italy, as well as other EU countries with drug export capacities, implement the General Council Decision. The EC is preparing a draft proposal for a regulation implementing the General Council Decision into European law. This draft should be adopted by the EC in late October 2004 and submitted to the European Council and European Parliament for approval at the end of the year. The proposal will be made public once it has been adopted by the EC.

14. Denmark, Italy and other EU members should ensure that the final regulation does not contain any restrictions or conditions that are not in the original General Council Decision, such as the limitations included in the Canadian Bill C-9.¹¹ Once the regulation is approved, Denmark, Italy and other EU members should take all appropriate steps to implement it into national legislation and use the mechanism as soon as possible to export drugs to developing and least developed countries.

III. IP rules in bilateral and regional trade agreements and human rights concerns

A. Threats to access to medicines in bilateral and regional trade agreements

15. A number of recent bilateral and regional trade agreements negotiated by industrialized countries have included strict IP rules (termed TRIPS-plus rules) that will have dramatic effects on the ability of countries to reduce the cost of medicines. These TRIPS-plus rules are gradually dismantling all the flexibilities in the TRIPS Agreement that were reaffirmed by the Doha Declaration. They are also undermining the mechanism of the General Council Decision of 30 August 2003 before it has even been implemented. The most alarming of these rules can be found in the United States' Free Trade Agreements (FTAs) with developing countries and include:

- **Extension of the patent term** beyond the twenty year period required by the TRIPS Agreement.
- **Limitations on exports of drugs made under compulsory license**, contrary to the WTO General Council Decision.
- **Limitations on parallel imports of patented drugs**, contrary to the spirit of the Doha Declaration.
- **Exclusivity over test data** for up to five years granted to patent owners of drugs not yet marketed or registered in the country. Such exclusivity undermines compulsory licensing under the TRIPS Agreement and General Council Decision.
- **Marketing authorization rules** requiring generic drug manufacturers to obtain the consent of patent owners in order to use test data for marketing approval. Since generic manufacturers cannot afford to re-do these tests, the rules nullify compulsory licensing flexibilities under the TRIPS Agreement and General Council Decision.

⁹ European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures*, 2003

¹⁰ European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures*, 2003; ISPE, 'Country Profile: A look at the Pharmaceutical Industry in Italy', *Pharmaceutical Engineering*, Vol. 22, No. 5, September/October 2002.

¹¹ Canadian HIV/AIDS Legal Network, *Canada's Bill C-9 and the Compulsory Licensing of Pharmaceuticals for Export to Countries in Need*, July 2004

16. The former European Commissioner for Trade, Pascal Lamy, in a speech made in June 2004 referred to TRIPS-plus rules, saying that he was “seriously concerned by some of the free trade agreements recently adopted between industrialized countries and developing countries: some of their IP provisions go far beyond [developing countries’] level of development and reduce worryingly their options of making use of the TRIPS flexibilities.”¹² Denmark and Italy have not made an equivalent public statement on the issue of TRIPS-plus rules in bilateral and regional trade agreements.

17. Denmark, Italy and other EU members have an obligation under the right to health, as interpreted by CESCR General Comment No. 14 (2000) to “prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law.” It is therefore important that Denmark, Italy and other EU members openly support the former European Commissioner for Trade’s statement and take steps to ensure that IP rules in bilateral and regional trade agreements do not violate the right to health in developing countries.

B. The European Union’s IP policy in bilateral and regional trade agreements

18. The EU is negotiating a number of bilateral and regional trade agreements, of which the EU-Mercosur negotiations (Argentina, Brazil, Paraguay and Uruguay) and the EU economic partnership agreement (EPA) negotiations with Africa, Caribbean and Pacific (ACP) regional groupings. The EU-Mercosur negotiations were scheduled to conclude on 31 October 2004, but have been postponed until early 2005. The EPA negotiations with ACP regional groupings were formally launched during 2003 and 2004 and the first regional trade agreements should be concluded by 2007.

19. The European Commission (EC) has stated that it would not pursue a policy of unilateral pressure on third countries to adopt TRIPS-plus standards.¹³ Despite such statements, there is still cause for concern that the EC could include TRIPS-plus rules in bilateral and regional trade agreements. Civil society groups have raised fears that the EC could demand at least ten year exclusivity over pharmaceutical test data in its bilateral and regional trade agreements, as the ten year term applies within the European Union. This rule would go even further than the five year data exclusivity advocated by the United States in its Free Trade Agreements (FTAs). If the EC promotes ten year data exclusivity in its bilateral and regional trade agreements it risks undermining developing countries’ ability to use compulsory licenses and the General Council Decision to reduce the cost of essential medicines.

20. Another issue of concern is the EC IP enforcement strategy in developing countries. The EC strategy document of 23 June 2004 proposes to “make the enforcement clauses in future bilateral and bi-regional agreements more operational and to clearly define what the EU regards as the highest international standards in this area and what kind of efforts it expects from its trading partners.”¹⁴ The strategy also proposes to encourage EU companies to lodge complaints of IP violation “in cases of non-compliance with required highest standards of IP protection.” Although IP enforcement strategies are necessary to tackle piracy and counterfeiting, there is a risk that they could limit access to medicines and thus undermine the realization of economic, social and cultural rights in developing countries.

¹² Pascal Lamy, European Commissioner for Trade, *Speech at the International Conference on the 10th Anniversary of the WTO TRIPS Agreement*, 23 June 2004, http://europa.eu.int/comm/commissioners/lamy/speeches_articles/spla233_en.htm
http://www.europa.eu.int/comm/commissioners/lamy/speeches_articles/spla233_en.htm

¹³ European Commission, *Trade Policy Dialogue with Civil Society, Sustainable Development and Trade*
http://europa.eu.int/comm/trade/pdf/dcs_rep.pdf

¹⁴ European Commission, *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, 23 June 2004.

21. Denmark, Italy and other EU members should monitor the EC's commitment not to include TRIPS-plus rules in bilateral and regional trade agreements. They should also ensure that the EC's IP enforcement strategy in bilateral and regional trade agreements is balanced with international human rights obligations.

IV. Technical Assistance Programmes

22. Denmark, Italy and other EU members provide IP technical assistance to developing countries individually, and as members of the EU and international organizations such as the WTO and the World Intellectual Property Organization (WIPO). The United Kingdom Commission on Intellectual Property Rights¹⁵ and a number of other IP experts¹⁶ have expressed concern that technical assistance programmes provided by bilateral and multilateral donors do not fully promote TRIPS flexibilities reaffirmed by the Doha Declaration on TRIPS and Public Health. The European Commission (EC) in its Communication to the WTO TRIPS Council of June 2003 addressed these concerns by calling upon "all technical assistance providers, and in particular multilateral organizations (...) to fully integrate the Doha Declaration in their policies and practices."¹⁷

23. Denmark, Italy and other EU members must ensure that bilateral, EU or multilateral IP technical assistance provided to developing countries promotes TRIPS flexibilities as reaffirmed by the Doha Declaration and does not adversely impact upon the right to health of the poor and most vulnerable. Denmark, Italy and other EU members should ask the EU and multilateral donors such as the WTO and WIPO to undertake a social and human rights impact assessment of the IP technical assistance provided to developing countries.

V. Trade policy-making: access to information and participation

24. Decisions regarding the impact of trade-related IP rules on health have been largely delegated by EU members to the supranational level. The European Commission (EC) prepares trade policy proposals and consults with the European Council of Ministers (Council) to achieve a common position. The Council designates a Committee (known as the '133 Committee') with responsibility for advising the EC on trade matters.¹⁸ Instructions from the 133 Committee define the EC's position in international trade negotiations. Strong civil society concerns have been expressed regarding the opacity of the 133 Committee process: agendas of meetings, documents discussed and decisions made are not publicly available.¹⁹ Furthermore, there is currently no public information on the EC's proposal for a regulation implementing the WTO General Council Decision of 30 August 2003 and there is no information on whether a consultation will take place with civil society.

Denmark

25. In Denmark, the national trade decision-making process is more transparent and participatory than at the EU level. Since 1998 the Danish civil society groups participating in trade policy-making are organized into a "Beach Club" that is composed of sixteen thematic working groups. The working groups send reports and recommendations either to the Danish government or to Parliament. The working group on TRIPS has actively participated in raising health concerns.

¹⁵ UK Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, September 2002.

¹⁶ Sisule Musungu and Graham Dutfield, *Multilateral agreements and a TRIPS-plus world: the World Intellectual Property Organisation (WIPO)*, QUNO TRIPS Issues Papers 3, 2003.

¹⁷ European Commission, *Communication from the EC to the TRIPS Council on the implementation of the Doha Declaration on the TRIPS Agreement and Public Health*, (282/03 Rev 1), 2 June 2003, paragraph 20.

¹⁸ The name of this committee refers to article 133 of the EC Treaty. This article gives the European Commission the authority to conduct trade and tariff negotiations with third countries in consultation with a special committee appointed by the European Council of Ministers.

¹⁹ Trocaire, *Democratising the EU's Trade Policy Making, Policy Roundtable*, Dublin, 7 November 2003.

<http://www.trocaire.org/policyandadvocacy/eupresidency/tradeseminarreport.htm>

The Danish Parliament passed a resolution on 6 November 2003 following the failure of the WTO trade negotiations at the Cancun WTO Ministerial in September 2003. The working group on TRIPS succeed in balancing the language of the resolution with competing interests from the Danish pharmaceutical industry and obtaining a reference calling upon the government to implement the “WTO agreement on developing countries’ increased access to prescription drugs.”²⁰

Italy

26. The national trade decision-making process of Italy is participatory, involving private and public interest groups. Public-interest Italian NGOs participate in a Working Group on the WTO which was officially consulted prior to the WTO Ministerial Conference in Cancun in September 2003. Following Cancun, the Working Group has held a number of informal meetings with civil society groups. It is however the impression of health public-interest NGOs that despite these consultations, their concerns are not taken into account in the formulation of the official Italian trade policy.

27. Access to information and participation in decision-making on health-related matters at the community, national and international level is an obligation under the right to health.²¹ Denmark, Italy and other EU members should take steps to ensure that the EC draft regulation on the implementation of the General Council Decision is made public, and organize a consultation with public interest civil society groups before the regulation is adopted. Denmark and Italy should also continue consulting with national civil society on trade-related health matters and take initiative at the EU level in promoting consultation, transparency and human rights consistency of trade policy.

Conclusion

28. Denmark, Italy and all EU members have both national and international obligations under the Covenant on Economic, Social and Cultural Rights. They must comply with their international obligation to respect the enjoyment of the right to health in other countries. In regard to this obligation, Italy and other EU members must take measures to avoid intellectual property rules in bilateral and regional trade agreements that risk making access to medicines harder and thus violating the right to health in developing countries. Also, Denmark, Italy and other EU members must ensure that bilateral, EU and multilateral IP technical assistance promotes the use of TRIPS flexibilities, as reaffirmed by the Doha Declaration, to ensure access to affordable medicines in developing countries. Moreover, Denmark, Italy and other EU members should promote trade policy-making processes at the national and EU level that are transparent and consultative, particularly on issues that affect the right to health.

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**Denmark and Italy: issues of concern on access to medicines and the ICESCR
Suggested issues for Committee members to raise with the States parties**

Access to affordable medicines (article 12(2) ICESCR, as interpreted by General Comment No. 14(2000))

Question 1: Which steps has the State party taken to respect the enjoyment of the right to health in developing countries?

²⁰ *Danish Parliament Resolution* (unauthorised translation by Danish 92 Group), 6 November 2003.

²¹ See CESCR General Comment No.14 (2000), Note 4 above.

Recommendation 1: the State party should take into account its obligation to respect the enjoyment of the right to health in developing countries in all aspects of its trade policy making, including as member of the European Union, and of international organizations such as the World Trade Organization and the World Intellectual Property Organization.

Question 2: Has the State party taken all appropriate measures to ensure that the EC regulation implementing the WTO General Council Decision of 30 August will promote, and not hinder the right to health?

Recommendation 2: The State party should ensure that the EC regulation implementing the WTO General Council Decision of 30 August will take account of the right to health and not include any additional restrictions or conditions that could undermine access to affordable medicines in developing countries.

International cooperation and technical assistance (article 2(1) as interpreted by General Comment No. 3(1990))

Question: Has the State party taken steps to ensure that the intellectual property technical assistance provided by the EU and international organizations such as the World Intellectual Property Organization does not undermine the flexibilities reaffirmed by the WTO Doha Declaration on TRIPS and Public Health?

Recommendation: the State party, as a member of the EU and of international organizations, should do all it can to ensure that intellectual property technical assistance programmes are in conformity with the obligations of States parties under the Covenant, in particular the right to health.

Access to information and consultation on health issues (article 12 ICESCR, as interpreted by General Comment No. 14(2000))

Question: Has the State party taken measures to ensure access to information and consultation with public interest civil society groups on the proposed EC regulation implementing the WTO General Council Decision of 30 August 2003?

Recommendation: the State party should ensure access to information on EC trade policy that may affect the right to health and other human rights, and ensure consultations with public interest civil society groups on the proposed EC regulation implementing the WTO General Council Decision of 30 August 2003.