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FOLLOW-UP OF DOHA MINISTERIAL CONFERENCE: INTELLECTUAL PROPERTY ASPECTS

UNICE PRELIMINARY COMMENTS

Further to the discussions which took place in Doha last November, UNICE would like to register its concerns and recommendations on a series of questions in the field of intellectual property, which will be the subject of further debate in the context of the new Round of Trade Negotiations and beyond.

The present document seeks to explain European industry's viewpoint on the following series of questions:

- Implementation and enforcement of the TRIPs Agreement;
- Solutions to be found to Paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health;
- Geographical indications;
- Technology transfers; and
- Relationships between the Convention on Biological Diversity, traditional knowledge and the TRIPs Agreement.

1. IMPLEMENTATION AND ENFORCEMENT OF THE TRIPS AGREEMENT

UNICE strongly shares the view that trade liberalization can make a huge contribution to the generation of resources for the financing of development since it is in the interest of all the parties around the negotiating table to gain from the WTO system. Trade can serve as a key driving-force behind their economic growth for the benefit of their own people.

In that respect, the Doha Ministerial Conference was the appropriate time for China and Taiwan to become Members of the WTO, paving the way for further important accessions such as the Russian Federation.

These completed accessions or forthcoming accessions also raise concerns for European industry, acknowledging that failure by a number of developing countries to implement the TRIPs Agreement in a proper and timely fashion will seriously call into question the viability and the value of this Agreement.

UNICE shares the view that the TRIPs agreement is one of the major achievements of the Uruguay round, defining minimum standards for intellectual property protection and aiming to guarantee the worldwide level playing-field for protection of intellectual property necessary to reduce distortions and impediments to international trade.

• IMPLEMENTATION

The priority for strengthening intellectual property protection at international level is to ensure effective and timely implementation of the TRIPs agreement and pursue the work programme embodied in the Built-In Agenda.

On 1 January 2000, the transition period for implementation of the TRIPs agreement by developing countries (LDCs) expired in accordance with Article 65.2

5.5/1/1



TRIPs. If some of them were prepared to meet this deadline actively, many others tended to see this date as a starting point to bring their legislation into line with the Agreement.

In addition, the TRIPs Agreement grants least-developed countries a further additional period until 1 January 2006 to make the required changes to their legislation. Besides, the Doha Declaration on the TRIPs Agreement and public health foresees an *ad hoc* extension to the existing derogation for least-developed countries; namely, " *the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement." UNICE generally supports this provision.*

UNICE deplores the fact that many developing countries did not meet the 1 January 2000 deadline for implementing intellectual property laws in line with TRIPs requirements, and urges these countries to meet their obligation at the earliest possible date.

• ENFORCEMENT OF THE TRIPS REQUIREMENTS

UNICE believes that timely and complete implementation is not the only prerequisite to be fulfilled before engaging further negotiations: effective enforcement is also necessary to give sense to the Agreement.

For instance in China, the 1995 customs law is meant to be TRIPS-compliant, going even further than other customs laws since it covers all intellectual property rights and not only trademarks and copyright. However, there are some general points that require attention, going beyond the basic statutory provisions.

Another case is the Russian Federation. UNICE welcomes the fact that the Russian government has announced that the country will apply the TRIPs Agreement, without any transition period, upon its accession to the WTO. However, European industry is highly concerned by the lack of effective compliance and enforcement of the legislations with the TRIPs minimum requirements, raising a series of problems which will not be solved on the date of accession (e.g. trademark and copyright piracy is currently so widespread in Russia that government bodies can no longer ignore the problem: activities are flourishing despite the fact that an appropriate legislative system has been established, creating new challenges).

Accordingly, UNICE believes that efforts should concentrate on enhancing the implementation and enforcement of the TRIPs Agreement. Experience from different WTO members should be drawn on for implementing the Agreement in an efficient manner.

2. PARAGRAPH 6 OF THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

2.1. STATE OF PLAY SINCE DOHA

Further to the crisis on access to medicines, the Doha Declaration on TRIPs and public health decided on a mandate to the TRIPs Council to find an expeditious solution to the problem that *"WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector"* could face in making effective use of compulsory licensing under the TRIPs Agreement. The TRIPs Council has to report to the General Council on a solution before end-2002.



The grant of an exclusive right is an essential element of an effective patent system. By contrast, compulsory licensing is when a government allows someone else, among other things, to produce and export a patented product or process without the consent of the patent owner. In the context of the latest public discussion on TRIPs and public health, this was usually associated with pharmaceuticals. However, this can also apply to patents in any field since the TRIPs Agreement prohibits discrimination between fields of technology.

2.2. EUROPEAN INDUSTRY'S CONCERNS

WE RECOGNISE THE GRAVITY OF THE PUBLIC HEALTH PROBLEMS AFFLICTING MANY DEVELOPING AND LEAST-DEVELOPED COUNTRIES, ESPECIALLY THOSE RESULTING FROM HIV/AIDS, TUBERCULOSIS, MALARIA AND OTHER EPIDEMICS "¹

UNICE understands the conditions under which the Doha Declaration on the TRIPs Agreement and public health was decided, and shares the view that this issue requires concrete solutions tailored to fit the problem, comprising intellectual property as well as other factors.

European industry strongly believes that any solution to be found to Paragraph 6 of the *ad hoc* Declaration should be in line with the initial discussions which led to this Declaration; namely the need to be able to respond to public health crises such as HIV/AIDS, tuberculosis and malaria in very specific geographical disease areas.

In that respect, the terms usually used of "poor countries" and "poorest countries" should be defined and, once defined, those with sufficient manufacturing capacity should be excluded.

• "[MINISTERIAL CONFERENCE] INSTRUCT THE COUNCIL FOR TRIPS TO FIND AN EXPEDITIOUS SOLUTION TO THIS PROBLEM AND TO REPORT TO THE GENERAL COUNCIL BEFORE THE END OF 2002 "²

UNICE believes that the final text of the response to Paragraph 6 should include a clear definition of what is meant by *"no or insufficient manufacturing capacity"*, which is of course the very basis of the mandate to seek a solution to the *"problem"*. Any expression such as *"serious public health problems"*, if adopted in the *"solution"* is open to varying interpretations and, therefore, potential abuse.

It is most important to restrict whatever solution is proposed as much as possible so that intellectual property protection is not undermined. In that perspective, **<u>careful</u>** <u>**language should be adopted**</u>.

Against this background, UNICE would like to suggest that a preliminary study of the countries qualifying as having no or insufficient local manufacturing capacities should be undertaken by the WTO Secretariat.

UNICE understands the urgency of finding a solution but also believes that the TRIPs Council should proceed in stages, without speeding up the process to find a response which might put at stake the whole edifice of the TRIPs Agreement to the detriment of all WTO members.

2.3. SOLUTIONS PROPOSED TO PARAGRAPH 6

European industry is of the strong opinion that the issues raised in the *ad hoc* Declaration require concrete solutions tailored to fit the problem.

 $^{^1}$ Paragraph 1 of the Doha Declaration on the TRIPs Agreement and public health (14 November 2001); WT/MIN(01)/DEC/W/2

 $^{^2}$ Paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health (14 November 2001); WT/MIN(01)/DEC/W/2



UNICE identified five situations which can be considered as offering a response to the request formulated under Paragraph 6 of the Doha Declaration on TRIPs and public health. For each of these situations, UNICE would like to offer the following remarks, set out its preferences and eventual recommendations.

<u>In any case</u>, it is fundamental that efforts are focused on the safeguard measures under which the compulsory licensing exemptions will be issued (e.g. to avoid products diversion and abuse for commercial purpose, transparent mechanism, product and geographical coverage).

• INTERPRETATION OF ARTICLE 30 TRIPS

In a Communication submitted before the TRIPs Council last March, the European Communities suggested to *"interpret the limited exceptions clause of Article 30 of the TRIPs Agreement in a way which would allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems".*³

In UNICE's view, any solution linked to Article 30 (in particular, the case of an authoritative interpretation of this provision) would be seriously detrimental to the whole Agreement on a long-term basis. This could lead the way to a series of complex legal problems as well as to a substantial amendment of the TRIPs Agreement by potentially generalising to all industrial products a solution perceived to be merely relevant to access-to-medicine situation, therefore creating a risk of legal uncertainty and further discussions which could occur in the case of disputes.

UNICE does not support any approach, which would involve Article 30 TRIPs.

• AMENDMENT OF ARTICLE 31(F) TRIPS

The approach suggesting the use of the existing flexibility contained in Article 31(f) by amending it was also put forward by the European Communities, advocating to "amend Article 31 of the TRIPs Agreement in order to carve out an exception, under certain conditions, to Article 31(f) for exports of products needed to combat serious public health problems and produced under compulsory licences".⁴

In UNICE's view, any **amendment** (or addition of a new paragraph) to the Agreement provisions in order to carve out an exemption from Article 31(f) TRIPs would open a Pandora box for further widening of the Agreement. Such approach is **unacceptable** for European industry since any amendment or addition would create a precedent for an opening of discussions in other areas of the TRIPs Agreement, or even to other fields of technology.

UNICE <u>does not support</u> any approach, which would involve any kind of amendment to Article 31 TRIPs.

• MEMORANDUM AGREEMENT ON ENFORCEMENT OF ARTICLE 31(F) TRIPS

In a previous submission to the European Communities and its Member States, UNICE invited the Commission to consider alternative solutions to those involving an amendment of Article 31(f) or an interpretation of Article 30. One of the alternatives suggested by UNICE is to have a Memorandum annexed to the TRIPs Agreement under which WTO Members would agree not to enforce Article 31(f)

³ Communication from the European Communities and their Member States to the TRIPs Council: concept paper relating to paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health, 1 March 2002, p.4

⁴ Communication from the European Communities and their Member States to the TRIPs Council: concept paper relating to paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health, 1 March 2002, p.4



unless certain clearly defined conditions are strictly met. These conditions should be in line with the initial discussions which led to the *ad hoc* Declaration in Doha; namely the need for a certain class of poor countries to be able to respond to public health crises such as HIV/AIDS, tuberculosis and malaria if TRIPs prevents this⁵.

The background of UNICE's proposal is the apprehension by European industry of the application of the principle of non-discrimination between fields of technology embodied in Article 27(1) TRIPs Agreement as well as the fear that the solution to be found to Paragraph 6 might lead to an opening of the TRIPs Agreement.

UNICE **<u>supports</u>** such an option at the condition that absolute safeguard measures are foreseen.

• MORATORI UM ON DISPUTE-SETTLEMENT

In UNICE's view, this proposed alternative should be closely considered since an agreement of the WTO members on a moratorium on dispute-settlement would have the merit to avoid amendment of the TRIPs Agreement.

The application of the solution could be overseen by the TRIPs Council, including provisions to ensure that the medicine is not diverted into higher paying markets away from the people it is intended to help. If a country thought that a condition of the moratorium was breached, it could bring dispute proceedings, as the conditions of the agreed moratorium would not apply. It would be for the Disputes Panel to decide whether there has been a breach of the conditions.

UNICE **would support** such a solution at the condition that absolute safeguard measures are foreseen.

• WAIVER AUTHORITY UNDER ARTICLE IX MARRAKECH

In UNICE's view, the use of Article IX of the Marrakech Agreement should be closely considered by the TRIPs Council as a suitable solution to the request made under Paragraph 6. This provision relates to waiver in exceptional circumstances by a Ministerial Conference of an obligation imposed by TRIPs on a WTO Member.

The General Council or Ministerial could agree that a conditional waiver (the conditions relating to the countries of importation, the products concerned and antidiversion measures) would be granted to a country that applies for it and that the waiver will be renewed annually unless it is shown that the conditions have not been complied with.

In UNICE's view, a waiver solution would gather the following advantages:

- It does not involve any opening of a general provision of the TRIPs Agreement;
- It benefits from an established instrument (Art. IX Marrakech Agreement) which can be used quickly and expeditiously;
- The automatic review and renewal of the waiver permits it to last as long as needed;
- This is a transparent process; and
- It allows an individual solution to a specific problem in a certain country.

Besides, UNICE also understands that the implementing conditions and the precise legal framework under which a waiver for TRIPs questions would be applicable remain to be further studied in order to ensure that such an approach will provide a sustainable solution.

⁵ Letters sent by UNICE to European Commissioner Pascal LAMY, Directorate General for Trade, and European Commissioner Frits Bolkestein, Directorate General for Internal Market, date 25 February 2002.



Against this background, <u>UNICE believes that strong consideration and support</u> should be given by the TRIPs Council to the use of Article IX Marrakech as being an appropriate solution to the request made under Paragraph 6.

3. <u>GEOGRAPHICAL INDICATIONS</u>

3.1. STATE OF PLAY SINCE DOHA

In accordance with the TRIPs provisions⁶, it was decided in Doha to pursue the completion of the ongoing negotiations on a multilateral registration system for geographical indications for wines and spirits by the Fifth Ministerial Conference in 2003.

In addition, Doha also decided that the extension of the existing "enhanced protection"⁷ for wines and spirits to all industrial products should be examined in parallel with the negotiations for a multilateral register.

3.2. EUROPEAN INDUSTRY'S CONCERNS

• MULTILATERAL REGISTER

UNICE supports the European Commission proposal for the creation of a multilateral register.

The main advantage of setting up a multilateral register (MR) remains recognition of the criteria of making use of the geographical indication, and the presumption that the geographical denomination registered constitutes a geographical indication according to Article 22 TRIPs.

However, UNICE is also of the opinion that, <u>before an agreement is reached</u> within the TRIPs Council on the main elements of the future MR, close consideration should be given to the practical aspects and <u>implementing</u> <u>mechanism</u> of the future register.

A multilateral register secretariat could be monitored by WIPO since this organisation has experience with registers and treatment of intellectual property in general and alternative dispute resolution proceedings (e.g. domain names). In UNICE's view, the WTO would not be a suitable forum since it has no structure for it, and its dispute settlement procedure is set up for actions between countries and not between individuals.

Only the geographical indications responding to the criteria of Article 22 TRIPs and benefiting from legal protection in the country of origin (or a protection linked to a registration in a national register – e.g. AOC) could apply for an international registration. A preliminary search and examination procedure would be necessary before the protection is granted.

In addition, this international register should also foresee the conditions under which such the geographical indication granted could be used.

In case of litigation, the judge should take into account the registration of the geographical denomination, acknowledging it as being protected as a geographical indication within the meaning of Article 22 TRIPs. However, the defendant should bear the burden of proof that the geographical denomination does not fulfil the conditions of Article 22 TRIPs. If the judge recognises the geographical indication as valid, he/she will have to take into consideration the conditions of use identified in the international multilateral register in order to assess whether or not the use was made in an abusive way.

⁶ Article 23 TRIPs

⁷ Articles 23 and 24 TRIPs



• EXTENSION OF GEOGRAPHICAL INDICATION PROTECTION

The majority of UNICE's members is of the opinion that the ongoing negotiations have to be regarded as falling under Art. 24(1) and do not constitute a reopening of TRIPs in general.

UNICE understands that there are some inconsistencies in the current system, discriminating between wines and spirits and other industrial products. This situation is primarily to the detriment of the consumers; in particular when it comes to counterfeiting practices or parasitic copying.

The use of the geographical indication should only be made <u>in absolute connection</u> with products coming from a very specific region. Well-knownness, tradition and quality should also be considered necessary prerequisites.

Besides, UNICE also shares the view that the establishment of additional product protection might unavoidably lead to the urgent need for policing that extension by <u>setting-up product-control systems</u> to guarantee the constant quality of these products since the use of geographical indications is their marketing tool. In that respect, UNICE would like to invite negotiators to reflect on a means whereby such a quality control would be created in an efficient way before engaging in further negotiations. Experience from different WTO members could be taken into account when drawing up guidelines.

As far as the negotiations for an extension are concerned, UNICE is of the opinion that, at first, extension to all kind of agricultural products and processed food should be included. In a second stage, extension to industrial products, in particular handicraft type products should be envisaged⁸.

4. <u>TECHNOLOGY TRANSFER</u>

Both the *ad hoc* Declaration on TRIPs and public health and the Decision on Implementation-related issues and concerns refer to the implementation of Article 66.2 TRIPs, reaffirming that these provisions are mandatory and that developed country members shall submit by the end of 2002 a detailed report on the incentives they have provided to their own companies pursuant to their commitment under Article 66.2. The information contained in this report should be updated on an annual basis.⁹

Intellectual property protection provides incentives for the adaptation of imported products and technology to local conditions and the development of domestic innovation, technology and culture.

It is acknowledged that valuable products and commercial technology are predominantly in the hands of private sector innovators who have the ability to determine where and how that technology will be exploited. This approach received contradictory reactions, which can actually not be ignored. On the one hand, these reactions raise the problem that, assuming that intellectual property rights availability would be a pre-requisite for international technology transfer, it can logically be concluded that companies would be encouraged to transfer technology where intellectual property protection is strong enough to charge fees high enough to ensure coverage of the innovation cost, or alternatively by means of foreign direct investments where they maintain control over these technologies. On

⁸ Indicative list of products, which could qualify as handicraft: Bruges lace, Murano glass, Swiss watches, Limoges porcelain, and Florentine leather.

⁹ § 11.1 Doha Decision on Implementation-Related Issues and Concerns, 14 November 2001, WT/MIN (01)/W/10



the other hand, opponents point out that intellectual property rights inhibit technology transfer¹⁰.

Technology and products transfers require a propitious environment. A number of factors have to be identified in order to create a climate and emulate opportunities for technology transfers and, inherently, capacity-building¹¹. Intellectual property constitutes only one of these factors (e.g. taxation, infrastructure, training) but a necessary one.

European industry remains committed to supporting governmental action, demonstrating and promoting technology transfer to least-developed countries; but also believes that such cooperation can only be effective if it is underpinned by legislative and technical commitments from the countries for which the transfer is intended (e.g. implementation and enforcement of legislation in compliance with the TRIPs Agreement).

5. CONVENTION ON BIOLOGICAL DIVERSITY AND TRADITIONAL KNOWLEDGE

In Doha, WTO Members decided to "instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimensior".¹²

UNICE shares the view that it is time to address the issues of defining and protecting traditional knowledge and encouraging satisfactory contractual arrangements in order to avoid losses on all sides.

European industry believes that these questions have to be regarded as major regulatory challenges linked to identification of forthcoming development and use of intellectual property rights in the field of genetic resources and environment. In that context, **UNICE believes that WIPO is the most appropriate body to deal with these issues.**

UNICE acknowledges and supports that:

- The regimes existing under the Rio Convention on Biological Diversity and the TRIPs Agreement generate two different bodies of law, which exist in parallel;
- These texts complement each other since they do not govern the same subject matter and, therefore, must be implemented alongside each other (see Annex);

¹⁰ UNCTAD/ICTSD Capacity building project on intellectual property rights and sustainable development, "Preliminary Draft for A Policy Discussion Paper" (20 November 2001)

¹¹ UNCTAD points out that "the provision by host countries of an enabling environment for technology transfer should take into account the following considerations: vocational training and recruitment of technical staff, relationship with local public or private research centres and consultancy firms, joint efforts by enterprises and Governments, encouraging capacity building for assessing, adopting, managing, and applying technologies through inter alia: human resources development, strengthening institutional capacities for R&D and programme implementation, assessments of technology needs, and long-term technological partnerships between holders of technologies and potential local users". See UNCTAD, "Outcome of the expert meeting on international arrangements of transfer of technology", 4 July 2001, TD/B/COM.2/EM.9/L.1.

¹² §19 of Doha Ministerial Declaration, 14 November 2001, WT/MIN(01)/DEC/W/1



- Article 27.3 (b) TRIPs is not the right forum, and should not be the vehicle, for addressing the widely differing issues, which have been voiced by a number of countries; and
- Technical assistance needs to be further provided to support developing countries in the approximation of their legislation in order to promote the objectives of Article 15 CBD and to avoid the creation of a climate conducive to the implementation of inequitable arrangements.

UNICE strongly believes that there is a need to draw up recommendations on the most appropriate means of recognising and protecting traditional knowledge as subject matter for intellectual property rights. In that respect, UNICE is highly supportive of the fact that WIPO is examining this issue.

Regarding the need of bringing biodiversity related issues into a possible new WTO Round, UNICE believes that this issue needs to be further discussed once the discussions in WIPO are concluded. At that time, should there still be a need for addressing the issue under a WTO mandate, therefore UNICE will suggest combining the question of protecting traditional agricultural knowledge of traditional farmers and indigenous peoples with the negotiations on geographical indications.

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