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**TACD RECOMMENDATIONS ON HEALTH CARE AND
INTELLECTUAL PROPERTY**

AND

EUROPEAN COMMISSION SERVICES' RESPONSES

The Commission Services consider that the "Health care and Intellectual Property" issue embraces a wide variety of aspects, such as development, health care, funding, transfer of technology, production capacity, education etc. Intellectual property rights (IPR), and in particular the TRIPs Agreement, continue to be given a prominent place in the debate. The Commission Services submit that the "Access to Health" is a complex problem with many different aspects involved and that it cannot be reduced to a pure IPR problem. A key issue in this debate is the lack of purchasing power on the side of the developing countries and the need for enhanced government awareness.

The Commission Services are in the process of examining how to address this matter in order to be able to offer sustainable and efficient methods to combat the lack in many developing countries of "Access to Health". Concerted action among stakeholders involved in this debate is necessary to create positive results and strong government commitment is key. The Commission Services are willing to use the existing flexibility of the TRIPs provisions and combine it with other trade related initiatives in order to address and to eliminate the lack of "Access to Health". However, the use of intellectual property rights e.g. compulsory licenses will only have a limited effect when combating the lack of "Access to Health" as this is caused by a series of multifaceted factors.

TACD RECOMMENDATION ON ACCESS TO MEDICINES IN DEVELOPING COUNTRIES

- 1. TACD recommends that public health considerations be paramount in trade policies as they relate to access to medicines.**

The US and EU governments should review trade policies to ensure that developing countries do not face trade related barriers for access to essential medicines and other medical technologies, in a manner consistent with the World Health Assembly (WHA)

Revised Drug Strategy, EB103/4, which calls upon member countries:

- 1. to reaffirm their commitment to developing, implementing and monitoring national drug policies and to taking all necessary concrete measures in order to ensure equitable access to essential drugs;**
- 2. to ensure that public health interests are paramount in pharmaceutical and health policies; and**
- 3. to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs;**

TACD asks the US, the EU and its member countries to report back to the TACD on the steps taken to implement the WHA Revised drug strategy in trade policy.

- 2. TACD supports the creation of a WTO Working Group on Access to Medicines.**

This working group would identify problems concerning access to medicines, provide a public health framework for the interpretation of key features of WTO agreements, and evaluate and propose changes in the WTO rules that would expand access to medicines.

3. **TACD recommends the US, the EU and other developed countries enter into an agreement to support far higher levels of R&D for neglected diseases.**

Today there is very little research and development on diseases such as malaria, chagas disease and other illnesses that have an impact on the poor. R&D efforts for neglected diseases should be designed with access in mind, and address issues such as reasonable pricing and the allocation of intellectual property rights.

4. **TACD recommends the US, the EU and its member countries enter into agreements with the World Health Organization (WHO) to give the WHO licenses to use publicly funded health care inventions in developing countries.**
5. **TACD asks the US and the EU to support patent exceptions for the export of medicines.**

The EU and the US should send communications to the WTO supporting interpretations of WTO TRIPS provisions that would permit patent exceptions for production of medicines for export, when the legitimate rights of patent owners are protected in the export market. For example, patent exceptions should permit the production and export of a medicine to a country that had issued a TRIPS compliant compulsory license for medicine. A failure to address this issue will substantially undermine the usefulness of compulsory licensing of medicines in countries with small domestic markets.

6. **TACD demands that The US and EU governments stop putting pressures on developing countries to adopt levels of intellectual property protection for medicines that exceed the requirements of the WTO TRIPS accord.**

This is consistent with Article 1 of the TRIPS, which states that WTO member countries "shall not be obliged to . . . implement in their law more extensive protection than is required by this Agreement."

EUROPEAN COMMISSION SERVICES' RESPONSE

- The "access to medicines" issue is an important component of promoting access to health in developing countries. The services of the Commission recognise the need to address the latter issue in a broad context and to ensure coherence between different policy instruments. The issue of "access to health" is very complex and of great concern to the services of the Commission. Therefore, there is a need for a broad dialogue and joint solutions in order to strengthen the ability of developing countries to ensure and improve health.
- On 31 May 2000 at the EU-US Summit in Queluz the EU and the US presented a joint statement on access on accelerated action on HIV/Aids Malaria and Tuberculosis in Africa, which addresses the serious challenges posed to the citizens of Africa by these diseases. The EU and the US agreed to join forces and to develop new mechanisms and partnerships in response to the threats posed by HIV/Aids, malaria and tuberculosis. The Commission services are committed to develop this co-operation and to address a series

of issues in a synergetic way in order to improve public health in developing countries. In particular in relation to the creation of international partnerships, increasing public awareness, improved R&D in drugs and vaccine initiatives and the establishment of funding and resources.

- The Commission services consider that there is no need to create a specific WTO standing working group on "access to Medicines". This is already covered by WHO and existing bodies established by the WTO, such as the TRIPs Council where "access to medicines" in developing countries and their link to intellectual property rights can be addressed, if need be.
- The Commission services are opposed to any trade pressure on developing countries to implement "TRIPs plus" legislation.
- The Commission services note that the TRIPs agreement is a carefully balanced set of Treaty obligations but continue to attach considerable importance to having high levels of intellectual property protection throughout the world. Nevertheless, Article 31 of the TRIPs Agreement, in conjunction with Article 27.1 of TRIPs, is a legal instrument which may be used by all WTO Members to the extent that the conditions of that provision are fulfilled. Where appropriate, and in order to improve "access to medicines in developing countries", the Commission services consider that the use of these provisions is acceptable.
- However, production for export without the consent of the patent owner during the patent term, in developing or developed countries, is inconsistent with Articles 28 (which grants the patent holder exclusive right to produce the protected product in the territory where the protection applies) and 31 of TRIPs and is not supported by the Commission services.
- The Commission services are paying attention to the need for enhanced R&D in neglected diseases and are exploring ways and means to support such R&D activities.
- High risk and long-term R&D investment and clinical trials in new innovative drugs must indeed be encouraged by patent protection if the flow of technical innovation by pharmaceutical companies and public research institutions is not to be discontinued. However, the industry should realise that the protection of intellectual property rights goes along with the responsibility that it has for developing pharmaceuticals, which are public health priorities for developing countries, and making them available and accessible. This applies both to R&D based pharmaceutical and generic companies in developed as well as developing countries.
- Lastly, whilst the Commission services consider that seeing the problem of access to medicines in developing countries simply as a pharmaceutical price problem is an oversimplification, the Commission services invite the pharmaceutical sector to consider the adoption of innovative approaches to pricing of key pharmaceutical products. In this respect, decisions to allow international exhaustion of patent rights not only create a situation where the pharmaceutical industry's main profit centres could be undermined, but could also lead to the risk that companies will seek to charge a "world price" for pharmaceuticals.

TACD RECOMMENDATION ON DATA EXCLUSIVITY AND HEALTH REGISTRATION DATA

- 1. TACD opposes the harmonization of data exclusivity for pharmaceutical registration data to 10 years. The US and the EU both provide periods of "data exclusivity" in the regulatory approval of pharmaceutical drugs: in the US this is 5 years, in the EU it is 10 years. The EU period was originally designed to compensate for a lack of patent protection on pharmaceutical in some EU member countries, and the lack of patent protection on medicines from biotechnology. This rationale is no longer valid with the new WTO TRIPS rules that require broad patent protection in all EU member countries.**
- 2. TACD recommends that companies that seek data exclusivity protections be required to disclose the costs of investments. Data exclusivity provisions are part of a growing class of sui generis forms of protection that are designed to protect investment, rather than innovation. Because data exclusivity isn't a reward for invention (which is already rewarded by patents) but rather a protection of investment, there should be greater transparency of the basis for the protection and a reasonable relationship between the investment and the protection.**
- 3. TACD asks the EU and the US to report on trade disputes that are related to introduction of generic forms of Paclitaxel in the EU Market. TACD should be provided with copies of all correspondence and memorandums that have been sent between the US and the EU or its member countries on the trade related aspects of Paclitaxel registration in the EU. The US and the EU should also report to the TACD who invented Paclitaxel, and who sponsored the clinical trials used for EU and US marketing approval.**
- 4. TACD asks the European Commission's DG Enterprise to report on the barriers to entry for generic forms of Paclitaxel in the EU market.**
- 5. TACD asks DG SANCO to report on the public health consequences of barriers to entry for generic forms of Paclitaxel in the EU market.**

EUROPEAN COMMISSION SERVICES' RESPONSE

The Commission services note that the issue of data exclusivity in the pharmaceutical sector was also raised at the TransAtlantic Business Dialogue held in Berlin in October 1999. At that time, the Commission services noted that this is an issue on which views vary within the industry. The services also noted that the EU already has the best data protection for new products in the world - in some cases 6, but more usually 10 years.

But anomalies remain between the Member States; a measure of harmonisation was signalled. This will need to be taken forward in the review of the licensing process: the Commission services expect to bring forward proposals for legislation by the end of this year.

As to whether data protection should be introduced to protect clinical trial data submitted in support of subsequent changes to a product, the Commission services will wish to explore four key points. The first is the economic implications of introducing such provisions. The second will be the need for absolute legal certainty about what types of changes will be covered. The third will be the importance of not setting up incentives for doctors to prescribe a product they know to be basically the same as the data-protected product but that is not licensed for a particular use. Lastly, the implications for competition within the pharmaceutical market will need careful consideration.

TACD RECOMMENDATION ON EARLY WORKING OF PATENTS AND RESEARCH EXCEPTIONS

- 1. TACD supports so called "Bolar" exceptions in patent laws to permit firms to test generic drugs and prepare data required for marketing approval by regulatory agencies, prior to the expiration of a patent. This is needed to ensure that consumers benefit from the timely introduction of competition when patents expire. Health and safety regulatory measures should not be misused as a barrier against competition.**
- 2. TACD asks the US and the EU to reject overly restrictive interpretations of anti-discrimination language in Article 27.1 of the TRIPS. Article 27.1 should not be interpreted as requiring a "one size fits all" patent law. The language in Article 27.1, that requires that "patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology," should not be interpreted as preventing countries from addressing public interest concerns in patents, when provisions to address those public interest concerns are consistent with the TRIPS framework. Article 30 of the TRIPS regarding exceptions to patent rights should be interpreted to permit countries to address public interest concerns, including those specifically related to fields of technology.**
- 3. TACD recommends that the EU not require Central and Eastern European (CEE) countries to eliminate "Bolar" exceptions from patent laws as a condition for EU membership.**

EUROPEAN COMMISSION SERVICES' RESPONSE

- The TACD proposes that developing countries provide for a so-called "early working" patent provision of patented pharmaceutical products under a compulsory license. The recently adopted WTO Panel report (WT/DS114) found that limited "early-working" type exceptions from patentability are not inconsistent with the provisions of the TRIPS Agreement.
- The Commission services consider that the interpretation of the anti-discrimination language in Article 27.1 of TRIPs must be seen in the light of the recent WTO decision (WT/DS114), which states that the rule of Article 27.1 of TRIPs does apply to exceptions of the kind authorised by Article 30 of TRIPs. Therefore, "limited exceptions" from patentability may not be applied vis-à-vis a certain field of technology e.g. pharmaceuticals.
- The Commission services favour intellectual property rights as, on a long term basis, they may create incentives for the pharmaceutical industry to provide for new and improved drugs for the benefit of the world population, in particular by ensuring that, for a certain period of time, the inventor of the product benefits exclusively from the income from the product concerned. This position is also supported by the fact that the EU, as a part of the accession negotiations, calls on CEEC to provide comparable levels of IPR protection to that in the EU. In this context, the CEEC countries are also bilaterally obliged, vis-à-vis the EU, to implement such legislation. Therefore, the EU

does not support discrimination within the existing level of intellectual property rights in central and eastern European 'Association Countries'.

TACD RECOMMENDATION ON TRANSPARENCY OF PHARMACEUTICAL ECONOMICS

- 1. TACD recommends the US and the EU governments undertake the following measures:**
 - i) Any application for data exclusivity should include a disclosure of the costs of data collection.**
 - ii) The EU and the US should require firms that market pharmaceutical drugs in the US or the EU market to disclose, for each product,**
 - A. annual global (and national) revenues,**
 - B. costs of clinical trials, disaggregated by timing and nature of trial (Phase I, II, III, IV, etc), the number of patents and the duration of the trial,**
 - C. when the product involves licenses from third parties, the royalty payments and terms, and**
 - D. the role of the government in the development of the drug, including the awarding of grants, cooperative research and development agreements, licenses, tax credits and other subsidies.**
 - iii) Governments should publish data detailing the government's own costs of conducting clinical trials, which can be used as a benchmark for the cost of clinical trials.**
 - iv) The government should publish reports detailing public expenditures on the purchase of products developed initially with public funds.**
- 2. TACD recommends that consumers and policy makers obtain better information about pharmaceutical economics. One of the most vexing issues in pharmaceutical policy making is the paucity of data to justify pharmaceutical industry assertions regarding drug development costs, profit margins or other relevant economic data. Governments have been negligent in collecting independent data on pharmaceutical economics. Accurate data on the economics of the pharmaceutical industry are needed to evaluate a wide range of government policies, including, for example:**
 - i) patent extensions,**
 - ii) pricing,**
 - iii) market exclusivity for health registration data,**
 - iv) orphan drug market exclusivity,**
 - v) compulsory licensing,**
 - vi) government technology transfer policies,**
 - vii) scope of patents, and**
 - viii) taxes.**

There is a substantial public interest in having more detailed disclosures of private sector R&D investments, to address such questions as what is the percentage of R&D investments spent on development of new and innovative products, as opposed to "me too" therapies? How much of the private sector R&D budget is spent on non-essential medicines? What is the private sector allocation of spending between pre-clinical

development, clinical trials, and post approval R&D? How much R&D is spent on tropical illnesses and other diseases that affect the poor? How much did the drug benefit from public subsidies?

EUROPEAN COMMISSION SERVICES' RESPONSE

The Commission has already signaled - in its 1998 Communication on the Single Market in Pharmaceuticals - the value of increased information and market transparency. There is a valuable role that the TACD itself could play in ensuring that such information as is public is processed and made available.

TACD RECOMMENDATION ON PATENTS ON GENETIC DIAGNOSIS

TACD asks the European governments to immediately apply for compulsory licenses or to use patent exceptions, permitted under the TRIPs agreement, to address technologies used for the screening of genetic diseases. Consumers and patients are harmed by unreasonable uses of patents that monopolize the screening for genetically determined diseases such as the BRCA1 and BRCA2 patents associated with breast cancer. Public health authorities and laboratories in Britain and Sweden say that unreasonable use of such patents presents a threat to the public health, and reduced access to screening procedures.

TACD asks DG SANCO to report on the public health and ethical consequences of patenting of genes and technologies for screening of genetic diseases.

EUROPEAN COMMISSION SERVICES' RESPONSE

1. Introduction

The development of new medical products for the treatment of asthma and diabetes and the use of gene therapy in the fight against illness are only some examples which emphasise the increasing influence of biotechnology on society. In March of this year, the President of the United States and the Prime Minister of Great Britain issued a joint statement which called for the basic raw data on the human genome to be made freely available whilst at the same time recognising that intellectual property protection for gene based inventions has an important role in stimulating the development of important new health care products.

2. Protection of gene sequences or partial gene sequences under directive 98/44 on the legal protection of biotechnological inventions and under general patent law

In 1998, agreement was reached within the European Community on directive 98/44 on the legal protection of biotechnological inventions. This directive was the subject of lengthy and thorough discussions within both the European Parliament and among the Member States¹. Much consideration was given during these discussions to the ethical considerations surrounding biotechnological inventions. The resulting regulation seeks both to address these ethical considerations in full and to provide the necessary incentives to encourage research and development.

For inventions based on, or comprising of, gene sequences or partial gene sequences, the directive makes it clear that such inventions are patentable provided that they satisfy the normal criteria for any invention namely that they are novel, involve an inventive step and are capable of industrial application. The directive recognises that the discussion on the patentability of sequences or partial sequences of genes is not without controversy.

¹ The directive is currently being challenged before the European Court of Justice by a number of Member States.

Indeed the directive took note of some of the controversy surrounding some of the earlier patent applications for gene sequences that were filed and indeed granted before the directive was agreed. In particular the directive makes clear that patents should not be granted where the application is silent on the industrial application of the gene sequence. In addition, where a sequence or partial sequence of a gene is used to produce a protein or part of a protein then it is necessary to specify which protein is produced or what function is performed.

As for inventions related to the screening of genetic diseases, again under general patent law, if the normal requirements of novelty, inventiveness and industrial applicability are met then such inventions are patentable. It should however be noted that under the national patent laws of the Member States and under the European Patent Convention, methods for the treatment of the human body by surgery or therapy and diagnostic methods practised on the human body are not patentable.

2.1. Limitations on patent rights.

A patent is essentially a contract between the inventor and the state. In return for fully disclosing his invention to the public, the inventor is provided with a limited monopoly. This monopoly, which typically extends for a maximum of 20 years, provides the inventor with the right to prevent others from making or using his invention. It does not provide a positive right of use. The use of the invention will remain subject to other laws including those for example to protect fundamental human rights.

The information disclosed by patent applications provides an extremely useful source of technical information for those seeking to design around or further develop patented inventions. To enable them to do these things, patent laws generally contain exceptions to patent infringement covering basic non-commercial research and also experimental use of the patented invention.

Patent laws also include safeguards such as compulsory licensing to prevent the abuse of patent rights. Such abuse could comprise for example failing to provide the market on reasonable terms, or the denial of licences to another patent holder who is dependant on that licence to exploit his invention.

3. Ethical Considerations

As noted above, considerable thought was given during the negotiations on the directive to the ethical implications of the patenting of genes. The position that was agreed by both the European Parliament and the Member States after much discussion was that patents for inventions comprising of or based on gene sequences should be allowed. This position took account of the opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission. Indeed the Group of Advisers, while fully recognising the stimulus provided by patents for medical research, considers that patentability criteria must take also into account ethical principles and that the intended use of the patent must be sufficiently specific and identified. Furthermore, the directive gives explicit mandate for the Group to evaluate ethical aspects of biotechnology.

The directive does however recognise the rapid pace of developments in this field and therefore tasks the Commission with reporting on the implications for a basic genetic engineering research of failure to publish, or late publication of, papers on subjects which

could be patentable. This report should be published in the second half of 2000. The directive also requires the Commission to report on an annual basis on the developments and implications of patent law in the field of biotechnology and genetic engineering.

4. Public health considerations

While it is incontestable that the application of genetic research, and in particular, the unravelling of the genome, will make possible great advances in medicine and to health care, both the far-reaching potential of these new developments and the sheer speed at which science is now progressing have inevitably raised concerns among many people. These have to be taken seriously because without public acceptance and support, the potential of the new techniques will never be properly realised. Similarly, in view of the major potential consequences for health care provision and health systems of the use of genetic screening and genetically-based medicine, it is essential that such new techniques are not introduced in a haphazard way and that efforts are made to ensure that they are in line with public health priorities.

To give some examples of the potential of these new techniques, it will be possible to target drugs at groups and individual patients much more accurately than at present. This will help ensure that the drugs are fully effective and greatly reduce the risks of inappropriate treatment and adverse reactions. Second, new interventions can be used for prevention both in relation to relatively rare diseases related to one specific gene (e.g; cystic fibrosis) and to those related to several or where genes lead to susceptibility to certain illnesses (eg cancer and heart disease). As well as improving the overall health of the population, this should lead to important economic gains from better targeting of preventive interventions and treatment and thus better use of scarce resources. But all these possibilities will benefit public health only if the specific screening tests and subsequent treatment are properly tested and evaluated before being used. Moreover, for those found to be safe, of high quality and efficacious, to become regarded as standard diagnostic and treatment procedures, they must be available to health authorities at reasonable prices.

Thus public health must consider the safety, quality and efficacy of screening tests and subsequent health interventions, as well as the questions of who is screened and treated, how much this will cost, who pays the costs (both of the screening and the treatment) and what are the consequences of such screening (eg in relation to whether individuals can get insurance cover and in relation to health insurance funds). The introduction of this new technology therefore requires careful thought and sensitive handling.

Moreover, with the Public Health Article (152) of the Treaty, which was modified and strengthened by the Amsterdam Treaty, the Community has been given new powers to take measures setting high standards of quality and safety on blood, organs and substances of human origin in order to protect human health. In addition there is an obligation on the Community to ensure a high level of health protection in developing and implementing all Community policies. The Commission takes these responsibilities very seriously, and over the coming years will be putting forward its proposals to implement these new responsibilities.

The granting of patents for inventions in the health area can provide a means of mobilising resources and developing and making available new medicines in areas where they are needed. It is however clearly important that patents taken out in this area are not used to

hinder the development of applications in related areas or to deny access to the health services.

In the light of this, the Commission will continue to monitor and report on the implications of patent law in the field of biotechnology in general and genetic engineering.