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**Master Programme in Human Rights and
Intellectual Property Law**

The right to health and right to
intellectual property in the EU.
Analysis of the internal and
external policies.

Master thesis

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To my family,
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Abbreviations

ChFR	Charter of Fundamental Rights of the European Union
DG	Directorate General
ECHR	European Convention on the Protection of Human Rights and Fundamental Freedoms (referred to also as European Convention on Human Rights)
Eur. Court H.R.	European Court of Human Rights
EJIL	European Journal of International Law
EU	European Union
EC	European Community
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
IPR	Intellectual Property Rights
IP	Intellectual Property
MFN	Most-Favored-Nation
NCE	New Chemical Entity
SEA	Single European Act
SPC	Supplementary Protection Certificates
TEU	Treaty on the European Union
TEC	Treaty on the European Community
TRIPs	Agreement on Trade Related Aspects of Intellectual Property
UDHR	Universal Declaration on Human Rights
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

It is very common nowadays to speak of an “information society” in which control of information or information based knowledge has replaced control over matter as an ultimate source of economic power. The intellectual creations protected through patents, trade marks, copyrights etc constitute often a huge part of the companies’ intangible assets.¹ As value added is increasingly reliant on non-material inputs into products or services, the concept of information as an economic resource becomes more and more dominant, overshadowing its other roles. This shift in objectives and ever increasing role of information in wealth creation also significantly influences political affairs. States, acknowledging that success within the global economy depends crucially upon knowledge creation, view intellectual property through the prism of economic pragmatism and in terms of competitive advantage of their industry in the free market world.²

The growing pressure from powerful business society to assure maximum protection for “intangible assets” does not remain without effect on legal regimes, which through defining the intellectual property³ and the types of protection that accrue to its creators, shape the realization of this right.⁴

¹ For example, the value of the trade mark *Coca Cola* (calculated only for the products with the brand on them and for others, sold by the company) was calculated at 69.6\$ billions in August 2002. What is interesting however brands usually are not listed on corporate balance sheets, even though they can go further in determining a company's success than a new factory or technological breakthrough. That's because nurturing a strong brand, even in bad times, can allow companies to command premium prices. For more see: *BusinessWeek and Interbrand Special Report on the 100 Top Brands*, August 5, 2002; <http://www.businessweek.com/magazine/content/02_31/b3794033.htm>, on 2002-11-07

² In 1997 U.S. government unilaterally imposed import duties on \$260 million of Argentine exports in retaliation for Argentina's refusal to revise its patent legislation to conform to U.S. standards. In the same year U.S. made pressure on Thailand. Very famous by now is also dispute between thirty nine pharmaceutical companies and the South African Government over the provisions of the Medicines and Related Substances Control Amendment Act, which aimed to balance patent protection against the need to provide medicines at an affordable price to those in need. Under strong domestic and international pressure the companies withdrew their case in April 2001 after a settlement was agreed.

Another well known example is the dispute settlement case between the US and Brazil, in which the U.S. questioned the compatibility with TRIPs of Article 68 of Brazil's Industrial Property Law (Law 9.279/96), which allows the Brazilian government to grant a compulsory license where there is a lack of local manufacture of the patented product. However, under pressure from public opinion the U.S. government withdrew the case

³ The term ‘*intellectual property*’ is of generic nature and refers to the creations of human mind, the human “intellect”. It came into regular use during the 20th century. Analogically, the intellectual property rights are those rights which are derived from human intellectual creativity and that protect interests of the inventors by giving them property rights over their creations and inventions. For the short outline of the evolution of the IPRs see: Drahos, Peter, “Intellectual Property and Human Rights”, *Intellectual Property Quarterly*, No. 3 (1999)

⁴ For example, the patent is often seen just as “an instrument of economic policy to stimulate further risk taking in the investment of resources in the development of new product and

Intellectual property has ceased to be a preserve of a specialized branch of private law. It has become one of the hottest topics in international trade law.⁵ After all, not without a reason one of the economic theories of legislation, the theory of public choice argues that legislation is essentially a market process in which legislators and interest groups transact business in a way that sees the public interest subordinated to private interest.⁶ According to Peter Drahos, the intellectual property rights, taking into account their contemporary role, are to be seen as “rights of exploitation in information”⁷. Such a purely materialistic approach is perhaps best visible and reflected in the TRIPs Agreement⁸, which via trade linkage aims to produce “a singular globalised conception of the legitimate protection of intellectual property through the harmonization of the effects of diverse legislation across members of the WTO”⁹. Although we can find in it certain flexibility¹⁰ which leaves States some space to reconcile the TRIPs standards and policies with domestic economic and social conditions, taking into account the formulation of TRIPs provisions it is clear that they constitute barely an exemption to the rule.¹¹ Also, the *DOHA Declaration on the TRIPs agreement and public health*¹², which affirmed the flexibility of the TRIPs

technology”. See: WIPO Worldwide Academy, Collection of Documents on Intellectual Property, WIPO Worldwide Academy, Geneva, 2001, p. 153

⁵ Govaere, I., *The Use and Abuse of Intellectual Property Rights in EC law*, London: Sweet & Maxwell, 1996

⁶ See: Drahos, Peter, “Intellectual Property and Human Rights”, *Intellectual Property Quarterly*, No. 3 (1999)

⁷ Drahos, Peter, “The universality of intellectual property rights: origins and development”, *Intellectual Property and Human Rights, WIPO/OUNHCHR panel discussion to commemorate the 50th Anniversary of the UDHR*, Geneva, November 9, 1998, p. 14

⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter: TRIPs) constitutes Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization signed on April 15, 1994. All of the TRIPs Agreement is binding on all members of the WTO.

⁹ May, Christopher, *A Global Political Economy of Intellectual Property Rights. The new enclosures?*, The Routledge, London & New York, 2000, p. 85

¹⁰ f.ex. article 7 (*Objectives*), article 8 (*Principles*), article 27.2 and article 27.3 (*Patentable Subject Matter*), Article 30 (*Exceptions to Rights Conferred*), Article 31 (*Other Use Without Authorization of the Right Holder*) of the TRIPs Agreement. Some exemptions and safeguards are contained also in Article XX (provides for an exception to GATT rules, including national treatment, when necessary to protect health and other public goods) and XXI of the GATT.

See: Correa, Carlos M., “Implementing National Health Policies in the Framework of WTO Agreements”, *Journal of World Trade*, 34 (5) 2000, p. 89-12; Hoe Lim, “Trade and Human Rights”, *Journal of World Trade*, 35 (2) 2001, p. 275-300,

<http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs>

¹¹ Correa, Carlos M., *op. cit.*, p. 106. Correa states that article 8.2 not only incorporates “necessity test” for the measures, but seems to subject it to an additional “compatibility” test

¹² Declaration on the TRIPs agreement and public health adopted on 14 November 2001 at the Doha Ministerial Conference, WT/MIN(01)/DEC/2; Declaration confirms that “the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health”. The IPR protection required by TRIPs “should be interpreted and implemented in a manner supportive of WTO Members right to protect public health and, in particular, to promote access to medicines for all.”

Agreement (in particular with regard to patents), states that the public health concerns have priority before pharmaceuticals patent protection – though very positive development and a good example of a possible coherent reading of the WTO provisions taking into account potentially relevant human rights law is barely an exemption which was possible thanks to the mobilization of the public opinion worldwide.

Carlos Correa writes that “in a context of a growing pressures for trade liberalization, clarifying the extent to which a State can impose restrictions on trade in response to public health considerations has become a critical issue”.¹³ But should not the question be how we should frame the trade so that it does not override higher values? Should not the question be as to where shall we draw the line in order to find the just balance between competing human rights, particularly when some of them are of more direct importance for trade than others?

It seems that States tend to forget about their human rights obligations and their own recognition of their primacy over other provisions, including those referring to the free trade itself. Already in the Vienna Declaration of 1993, States recognized that “*human rights are the first responsibility of Governments*”¹⁴. If it is so, should not they implement the TRIPS standard (or any other IP standards) bearing in mind both their human rights obligations while using the flexibility inherent in the TRIPs Agreement?

It is worth a reminder in this short introduction that all states are bound by UN Charter’s article 55, according to which they are obliged “*to promote: a) higher standards of living, full employment, and conditions of economic and social progress and development; b) solutions of international economic, social, health, and related problems; and international cultural and educational cooperation; and c) universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.*”¹⁵

UDHR, which specifies the human rights provisions mentioned in the UN Charter, refers to those objectives in its Preamble. What is more, out of 114 Members of the WTO who have undertaken to implement the minimum standards

¹³ Correa, Carlos M., “Implementing National Health Policies in the Framework of WTO Agreements”, *Journal of World Trade*, 34(5), 2000

Creation of the WTO not only expanded process of trade liberalization and globalization, but unfortunately at the same time made linkage of HR and trade, by for example the use of MFN (in case of US or EU clearly the single most powerful economic lever) not only meaningless but also against the international consensus. What is more the standardization it brought about influences the internal law of states, for example, by requirement of introduction of patent protection on pharmaceuticals, what can have effect on realization of human rights. Therefore one could expect that after taking away some of the human rights enforcement tools from the hands of States, the WTO will assume greater responsibility for the protection of human rights around the world, also through the relevant, human rights spirited interpretation of the WTO agreements, TRIPs among them.

¹⁴ Vienna Declaration and Programme of Action adopted by consensus by the World Conference on Human Rights on 25 June 1993, UN Doc. A/CONF.157/23, 12 July 1993, article 1.

¹⁵ In fact, the clauses of the UN Charter are among the guiding principles of the Union, cited in the preamble of its founding Treaty of Rome (1957).

of IP protection in the TRIPs Agreement, 111 have ratified the ICESCR (all EU Member States among them). Why do I mention this here? It is because the right to intellectual property in human rights sense was delineated first in article 27 of the Universal Declaration of Human Rights, on which the provisions of ICESCR were built up on (article 15).¹⁶

Indeed, there is both the ground and an urgent need of challenging the exclusivity of the rule setting in the intellectual property area by the technically minded economic private law experts. The human rights instruments give quite precise indication where and how to approach the issue of intellectual property in order to find the right balance between the rights of creator and the rights of others, between the right to intellectual property and other human rights. We just need to reach and apply.

There is one more reason to argue that intellectual property as understood by private commercial law, is not as ‘untouchable’ as it is often argued by its proponents, who are afraid that human rights considerations will limit the scope of intellectual property rights protection. In 2000, in the Ecuador Arbitration, the WTO permitted for the first time the use of withdrawal of intellectual property rights as a remedy.¹⁷ To be more accurate, the WTO gave the Government of Ecuador a green light to suspend its TRIPs obligations to the European Communities. There are two sides to this decision. On one hand the WTO arbitrators proved that the private rights of individuals (intellectual property rights) can be trumped by the need for the WTO Dispute Settlement Body to approve a sanction on the insubordinated State – thus leaving us with question if also other human rights (after all there exist a right to Intellectual Property) would be ‘temporarily switched off’ in case it would be needed in the name of free, liberalized market. On the other hand – it proves, that the observance of TRIPs provisions can be ‘hibernated’, if that is what the restoration of the barrier-free market needs. If then one can do so in the name of the “market”, then surely it should be possible in a situation when human rights, as for example the right to health, are endangered. After all they have primacy over any other rights.

In this paper the author undertakes to analyze the tension within the right to intellectual property itself and its relation to other human rights – exemplified here by the right to health and in particular one aspect of it – access to drugs, against the law and practice of the EU. The analysis of the practice of EU in

¹⁶ See also the resolution of the Sub-Commission on the Promotion and Protection of Human Rights which reaffirms that the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author is a human right, subject to limitations in the public interest. “*Intellectual Property Rights and Human Rights*”, Sub-Commission on the Promotion and Protection of Human Rights, Fifty-second session, agenda item 4, E/CN.4/Sub.2/2000/7, adopted on August 17, 2000

¹⁷ European Communities – Regime for importation, Sale and Distribution of Bananas-Recourse to Arbitration by the European Communities under Article 22.6 of the DSU, Report of the Arbitrators, 24 March 2000, WT/DS27/ARB/ECU, paragraphs 141, 144, 173 (d), 157. Ecuador has not exercised this retaliation authority so far. For more see: Charnovitz, Steve, “The WTO and the Rights of the Individual”, *International Trade*, March/April 2001, pp. 98-108

respect to the right to intellectual property will focus on patent rights as this is believed most relevant for this discussion.

Why health and why exactly access to drugs? Apart from the obvious statement that health¹⁸ allows us to enjoy our lives, it carries also economy related aspects associated with it. Economic development itself is considerably dependent upon the health level of the population, as people's productivity depends on their level of nutrition and general well being. If the society is to function properly and enjoy economic well being, a healthy population is needed as the proper functioning of the economy suffers from illness-related absenteeism.¹⁹ In many countries the health sector is an important part of the economy: it is an important employer²⁰, it absorbs relatively large amounts of national resources both as a "consumer of goods" and is as a significant, if not a leading player in research and development²¹. Health budgets can reach over 10% of annual state budgets²², even if health care becomes dominantly privatized through major insurance schemes and the (re-) institution of private hospitals/clinics.²³ After all, for the population to be, and remain healthy, adequate health policy and a proper infrastructure (which would protect a society against outbreaks of epidemics) needs to exist.²⁴

¹⁸ For the purposes of this paper I will follow the 1946 WHO Constitution, which defines **health** as "a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity" and stresses that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". For further explanation see chapter on the right to health.

¹⁹ If we happen to live in a welfare-state we can expect receiving sick-pay from social care (and therefore from taxes, which in other situation could be used for example for giving incentives to the economy) for every day (even a single one) of not being in work due to the sickness. Such an approach may lead of course to abuses – which in turn may lead, as in Sweden, to these type of expenditures achieving too high a level, so legislative restrictions – like the rule that the first day (karensdagen) of the sick-leave is not paid for by the state – may occur.

See also: van Krieken, Peter - *Health gaps and Migratory Movements*, RWI Report No. 31, Lund 2000, p. 9;

See also: Eze C. Osita - "Right to Health as a Human Right in Africa", *The Right to Health as a Human Right. Workshop – The Hague*, Dupuy, Rene-Jean (Ed.), 27-29 July 1978, Sijthoff and Noordhoff 1979, p. 83

²⁰ According to the 1996 Labour Force Survey, more than 10% of those in employment were in employed in health. What is more, health is one of the fastest growing sectors in the 1990s, expanding on average at just under 3% a year. See: Communication on the development of Public Health policy <<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm#41>>

²¹ In the EU the average total expenditure on health as a percentage of the GNP is 8,2%, whereas in developing countries it is as low as 2%. See: van Krieken, *op.cit.*, p. 36

²² The public expenditure on health (as a percentage of the total public expenditure) is 12,4% in the EU, whereas 23,5% of it constitutes private expenditures. In the US the figures are respectively: 14,8% and 56,1%. See: van Krieken, *op.cit.*, p. 36

²³ van Krieken, Peter, *op.cit.*, p. 10

²⁴ "Factors enhancing and jeopardizing human health reach far beyond the sector of health and encompass, at the societal level access to employment and /or income-generation, access to housing, adequate nutrition, water and sanitation. History has showed that improvements in water and sanitation, nutrition, or housing, has been far more beneficial for the enhancement of health than curative, or even preventative health measures.",

Unfortunately, due to the high figures during the last decade, health care system reforms have been dominated by mainly economic objectives and motives, with governments searching for a balance between the rights of patients to health care on the one hand, and cost containment and cost control on the other.²⁵ This balance will be increasingly harder to achieve taking into account that as a consequence of lengthening life expectancy²⁶, the increase in the number of persons suffering from diseases and conditions related to old age is occurring.²⁷

At the same time health and ways to improve it are the focus of technological innovations and biomedical research, they are brought into a direct relationship with intellectual property protection regimes. Unfortunately as the 1990s - decade of HIV/Aids pandemic - proved, only margin of sick people took advantage of newly developed medicines – others simply cannot afford them. One of the reasons for this is because of the TRIPs Agreement patent protection of new pharmaceuticals. That protection is meant to allow drug companies to recoup the cost of new medicines development²⁸ and thus give them incentive for further research. A higher cost of a new product is not properly linked to the “manufacturing cost” but rather to its previous development process, whereas the development of “copy”, i.e. generic version of the new drug, requires foremost the identification of the original product ingredients. Therefore without a patent regime the innovator would obviously be at a disadvantage with regard to competition. However, in market reality companies often abuse this semi-monopoly status by pricing drugs at excessive level.

Even though access to medicines is dependent not only on affordable prices, but also upon rational selection and use of medicines, sustainable adequate financing, reliable health and supply systems, it is still those drugs that constitute the crucial part of the treatment process. Therefore both their availability²⁹ as well

Tomaševski, Katarina – International law-making for the protection of human and environmental health; in: *Reading material for: Human rights within the EU*, VT-02

²⁵ Den Exter, André and Hermans, Herbert – “The Rights to Health Care: A changing Concept?”, *The Right to Health Care in Several European Countries – Expert Meeting*, held in Rotterdam, the Netherlands, April 27-28, 1998, Studies in Social Policy, Kluwer International 1999, p. 1 and 169

²⁶ To a large extent a result of an improved health care system, particularly within EU.

²⁷ In particular from cancers, cardio-vascular diseases, physical disabilities and mental disorders and other neuro-degenerative disorders. It had been estimated that by the year 2000, 8 million people in the Community were affected by Alzheimer's disease. Additionally it is expected that by 2020, there will be 40% more people aged 75 and above than in 1990. *Communication on the development of Public Health policy*, <<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm#41>>

²⁸ See also: Juan Ignacio Arango F., “Regulation, policies and essential drugs”, *Medicines and the New Economic Environment*, Lobo, Felix and Velasquez, German (eds.), Editorial Civitas, Biblioteca Civitas Economia y Empresa, 1998, pp. 165 - 195

²⁹ That it is ‘economy’ and not ‘heart’ that lies behind the pharmaceutical industry one can easily see when comparing statistics. Though for TNCs, developing countries account for more than 80% of their market, new research is targeted at a rich northern market (see: Muddassir, Rizvi, “TRIPs will push health care beyond poor”; <www.twinside.org.sg/title/beond-cn.htm>). Less than 10% of the \$ 56 billion spent each year globally on medical research is aimed at the health problems affecting 90% of the world's population. While pneumonia, diarrhea, TB and malaria account for more than 20%

as their price are of great importance. Not everybody can afford the \$10 000 -15 000 person/year treatment with brand named drugs for a lengthy period.³⁰ On the other hand, a \$350 - 600 person/year³¹ treatment with generics is not only more accessible and affordable for people, but also in situations when it is provided by the state or humanitarian organizations, it allows the treatment of more lives with the same limited, and always insufficient amount of money. Not only developing countries look into the cost of medicines while trying to work out a health care programme that would ensure appropriate care to the biggest number of its citizens.³² Recently the U.S. President himself proposed a solution to rising prescription drug costs, ordering government to block pharmaceutical companies from filing multiple patent-protection lawsuits that can stall cheaper/generic drugs for years.³³ In 2001 the average brand name drug cost more than \$72 per prescription, while the average price for generic drugs, just as safe and effective as the brand name drugs, were just \$17 per prescription.³⁴

Since, in developing countries, most people currently pay for health care, including drugs, out of their own pockets, in their case access to medicines³⁵

of the diseases burden of the world, they receive less than one per cent of the funds devoted to health research. What is more, some drugs developed in the 1950s and 1960s to treat tropical diseases have begun to disappear from the market altogether because they are seldom or never used in the developed world. (Singh, Someshwar, "Health: TRIPs and WHO further marginalizing world's poor", <www.twinside.org.sg/title/who2-cn.htm>; 2002-04-14). Among the 1223 New Chemical Entities developed during 1975-1997, 379 are considered therapeutic innovations. However only 13 of them were meant for tropical diseases with only four developed after targeted research (Muddassir, Rizvi, "TRIPs will push health care beyond poor", <www.twinside.org.sg/title/beond-cn.htm>).

³⁰ It is particularly true in case of countries where the expenditure on health per person a year may be as low as \$10. See: Avert, HIV & AIDS drugs in Africa, <<http://www.avert.org/aidsdrugsafrika.htm>>, 13/02/2002

³¹ Cipla (Indian company that manufactures generics) offer for Medicines sans Frontiers. See: Gathii, James T., "Construing Intellectual Property Rights and Competition Policy consistently with facilitating access to affordable AIDS drugs to low-end consumers", *Florida Law Review*, September 2001

³² "Governmental efforts in the United States thus far have been devoted to ensuring that once patents have expired, patients with Federal Medicaid prescription drug insurance (a program covering only the poor) are given strong incentives to choose generic rather than higher-priced branded drugs. This is done through 'maximum allowable cost' measures that reimburse only the price of the least expensive generic substitute. Most hospitals in the U.S. maintain formularies that stress cheaper generics when they are available." in: Scherer, Frederic, "The New Structure of the Pharmaceutical Industry", *Medicines and the New Economic Environment*, Lobo, Felix and Velasquez, German (eds.), Editorial Civitas, Biblioteca Civitas Economia y Empresa, 1998, pp. 195-212

³³ Brand-name drug manufacturers sometimes file lawsuits against generic drug producers poised to put less expensive products on the market. The lawsuits invoke the 1984 Hatch-Waxman Act, which was meant to promote competition in the drug industry but which also gives the brand-name makers up to **30 months** of additional patent protection while litigation proceeds.

³⁴ News Flash, White House hopes to make generic drugs available more quickly by blocking patent suits, <www.nj.com/printer/printer.ssf?/newsflash/get_story.ssf?/cgi-free/getstory_ssf.cgi>, 2002-10-21

³⁵ For this paper the term 'access' is understood to include both availability and affordability criteria.

is particularly sensitive to cost.³⁶ At the same time it is also the affordability that is most likely to be affected by trade agreements in the first place. Of course, the consumer prices vary widely, within and amongst countries for a variety of reasons.³⁷ Some of the factors which have influence on the price of drugs can be addressed only on a national level (taxes, pricing mechanism, tariffs, etc.), others however like the international IPR framework, are connected to and influenced by the universal trade system. Therefore it is so important what kind of attitude to those issues has and with what type of solutions comes up one of the major players on the global market. As the gap between the substantive law of the GATT and regional economic organizations closes, the EC law on intellectual property and its expectations towards other countries has an importance which extends beyond the shores of Europe.

That partly answers the question why the author decided to analyze the approach of the EU. An additional reason is the willingness to check if the strong (at least verbally) commitment to human rights of the European Union, which proclaims in the Treaty of Amsterdam that it “*is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms and the rule of law*”, is equally strong when in conflict with very easily measurable interests.³⁸

Indeed, the EU is a powerful and uniquely representative actor on the international scene and in the WTO-arena, it is no exception. It has the responsibility, reinforced by the capacity and financial resources, to significantly influence the human rights policies of other States as well as those of international organizations. However, if the EU wants to enforce human rights compliance in third states, it has to lead by example. Therefore the need to analyze how the EU deals in practice with more contentious issues in order to see if EU really stands behind its declarations and demands towards other countries is evident.

³⁶ States are either too poor to afford it – which is true only in a few cases, or simply have distorted budgetary allocations – which constitute majority.

³⁷ For example, differences in demand, presence, if domestic R&D and/or generic industry, purchasing capacity, tariffs, taxes, intellectual property rights, pricing mechanisms and the degree of competition between patented and generic medicines

³⁸ To what extend is the EU legally bound in the field of human rights? It depends of course on the status of the EU in international law. As we know, the EU does not have legal personality, which all three Communities, which together built the first pillar of the EU have. Following this, the EU (though not Communities) cannot bear obligations under international law, including international human right standards. However such a strict approach would deny the practical need to address the EU’s commitment to human rights. Notwithstanding that somewhat obscure status of the EU under international law, the fact remains that the EU is perceived as an international actor. Also the EU Treaty itself provides that the EU shall respect human rights. Therefore the question as to what extend the EU is bound by human rights consequently deserves a more elaborated answer than simply maintaining that the EU lacks legal personality. See also: Bulterman, Mielle, *Human Rights in the Treaty Relations of the European Community. Real Virtues or Virtual Reality?*, School of Human Rights Research Series, Intersentia, Antwerpen – Oxford – New York, 2001, p. 65 et seq.

In the following chapters I will attempt to explain what position human rights have in general in EU law. Against this background the right to health and the right to intellectual property will be analyzed in order to have a picture of the balance between them existing (if such balance exists) in EU law. Following this focus will be on how the EU approaches health sensitive aspects of intellectual property in its relations with Developing Countries on the one hand, and the Candidate Countries on the other. The various factors which have an influence on EU practice will be highlighted.

As for methodology - this thesis is mainly based on research work carried out at the library of the Raoul Wallenberg Institute (Lund) and UNOG Library (Geneva), as well as relevant materials and information found on the Internet. Here I would like to express my gratitude to Prof. Katarina Tomaševski. Without the possibility of discussing the points of concern with her and without her comments this thesis surely would not be complete. Additional study visits and interviews were conducted at the WHO, WTO and UNCTAD. I am in particular thankful to Thirukumaran Balasubramaniam (WTO, Technical Officer DAP and EDM), Pedro Roffe (Project Director, UNCTAD), Dr. Jens Gobrecht (WHO, Associate Professional Officer, Strategy Unit and Relations with EU) as well as Peter Ungphakorn (WTO, Information Officer) and Simon Walker (OHCHR, Human Rights Officer, Research and Right to Development Branch), whose valuable information and comments helped me to understand the nature of relations between the EU and respective international organizations, as well as these institutions comprehension of the rights discussed in the paper.

Last but definitively not least – my special gratitude to Professor Mpazi Sinjela (WIPO Worldwide Academy Director) for his encouragement and guidance throughout the whole programme and supervision of this thesis.

All mistakes and omissions are those of the author.

2 Human rights in the EU

Though the EU declares its strong commitment to human rights and the protection of fundamental rights as is nowadays seen as one of the basic tenets of the EC law, it seems to lack a fully-fledged human rights policy. Neither the EC Treaty nor the EU Treaty contains a list of fundamental rights, and the Charter of Fundamental Rights could barely make it to the level of political declaration. Even though the economic integration within EU is almost complete, the social dimension is still lagging behind.

Only the principle of equal pay for men and women has been codified from the very beginning in article 141 (ex. article 119) TEC.

In the absence of an arrangement in the founding treaties and in response to the challenge of the supremacy of Community law over national constitutional law by the constitutional courts of Germany³⁹ and Italy⁴⁰, it was the European Court of Justice (acting on the basis of the Article 220 TEC) that first recognized the existence of fundamental rights at Community level and extended them in its decisions.⁴¹ Under its case-law, fundamental rights form part of the “*general principles of Community law*” and are equivalent to primary law in the Community legal hierarchy. That means that measures adopted by Member States either to implement Community measures or which, in one way or another fall within the scope of Community law, must be in accordance with minimum human rights standards.⁴² This was a judicial U-turn *par excellence*. The Court

³⁹ “*Solange*” case, German Handelsgesellschaft case, Bundesverfassungsgericht, 29 May 1974, [1974] 2 CMLR 551

⁴⁰ “*Frontini*” case (No. 183) Corte Constitutionale 27 December 1973, [1974] 2 CMLR 386

⁴¹ For more detailed information see for example: EU Annual Report on human rights (2001/2002), 12747/1/02 Rev 1 COHOM 11, Brussels, 16 October 2002; annual Resolutions of the European Parliament on respect for human rights in the European Union (for example A5-0050/2000; 11350/1999 – C5-0265/1999 – 1999/2001(INI); A4-0468/1998). In its resolutions the European Parliament always refers to UDHR and subsequent Conventions adopted in the human rights field as well as recalls that human rights are set of universal and interdependent rights applicable to all human rights. More on the role of EP, Council and Commission in respect to Human rights in, for example, Alston, Philip (ed.) – *The EU and human rights*, Oxford, Oxford University Press, 1999; Clapham, Andrew – *European Union – the human rights challenge*, Vol. 1, Human rights and the European Community: a critical overview, Baden-Baden: Nomos, 1991; Cassese, Antonio; Clapham, Andrew and Weiler Joseph (eds.) – *European Union the human rights challenge*, Vol. 2 – Human rights and the European community: methods of protection; Vol. 3 Human rights and the European Community: the substantive law; Baden-Baden: Nomos, 1991

⁴² See in particular: *Stauder v. Ulm* (Case 29/69 [1969] ECR 419), *Wachauf v. Federal Republic of Germany* (Case C-5/88 [1989] ECR 2609). The fundamental rights upheld by the Court include: the principle of equality which implies that different situations must not be treated identically or comparable situations treated differently (CJEC, 28 June 1990, *Firma Hoche* case C-174/89, Reports p. I-2681); freedom of religion (CJEC, 27 October 1973, *Vivien Prais v/ Conseil* case 130/75, Reports p. 1589); freedom of expression and information (CJEC, 18 June 1991, *E.R.T* case C-260/89, Reports p. I-2925); the right to protection of private life (CJEC, 26 June 1980, *National Panasonic v/ Commission* case 136/79, Reports p.

then continued in this new direction in a number of cases. Furthermore a kind of reaffirmation of those principles was included in ECJ *Opinion 2/94*⁴³. While negating the ability of the Community to accede to the ECHR, the ECJ stated that “respect for human rights is a condition of the lawfulness of Community acts” and “fundamental rights form an integral part of the general principles of law whose observance the Court ensures”. It also explained in point 5 that for that purpose, “the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories. In that regard, the European Convention on Human Rights, to which reference is made in particular in Article F(2) of the Treaty on European Union, has special significance.”

This interpretation has been reaffirmed by the Treaty of Amsterdam⁴⁴, which inserted into TEU a new article 6 (2), which commits the EU to respect fundamental rights, as guaranteed by the ECHR and “as they result from the constitutional traditions common to the Member States, as general principles of Community law”.⁴⁵ Additionally the Preamble of the European Community Treaty refers to the fundamental social rights by pointing to the 1961 European Social Charter (Council of Europe) and the 1989 Community Charter of the Fundamental Social Rights of Workers. The Amsterdam Treaty has formally empowered the European Court of Justice to ensure the respect of fundamental rights and freedoms by the European Institutions (article 46 (d) TEU). The EU can suspend certain rights of a Member State deriving from the application of the Treaty (article 7 TEU), if it has determined the existence of a serious and persistent breach of these principles by that Member State.

It might be worth mentioning here, that according to European Court of Human Rights case-law, Member States are accountable under the European Convention on Human Rights for the effects which Community law has in their domestic legal systems.⁴⁶ This should make them more concerned about the

2033); the right to property (CJEC, 14 May 1974, *Nold* case 4/73, Reports p. 491); the right to access to the courts (*Johnston and Heylens*); the right to a fair trial (CJEC, 29 October 1980, *Landweyck et al v. Commission*, joined cases 209/78 - 215/78, Reports p. 3125), and many more.

⁴³ Arnall, Anthony, “Left to its own devices? Opinion 2/94 and the Protection of fundamental rights in the European Union”, *The General Law of E.C. External Relations*, Dashwood, Alan and Hillion, Christophe (eds.), Sweet & Maxwell, London, 2000, pp. 61-78

⁴⁴ Came into force in May 1999. See: The EU and Human Rights (Draft: 28 March 2001), <<http://www.europa-eu-un.org/documents/infopack/en/infopack07EN.doc>>, 2002-11-09

⁴⁵ Article 46 TEU gives the ECJ power to apply article 6(2) in cases which fall within its jurisdiction by virtue of other provisions of the Treaty.

⁴⁶ See: *Matthews v. UK*, judgment of 18 February 1999; *The Cantoni v. France* judgment of 15 November 1966 and the decision of 7th March 2000 in *T.I. v. UK.*; It is the Member States which are respondents and they alone, even where the measures under challenge result from an obligation which Union law has placed on the member country. In such a case, where Strasbourg finds violation of the ECHR, the state concerned is held responsible for the measures, even though it cannot itself change or remedy them since it cannot usurp the role of the Union institutions and bring the offending measure into line with the European Court of Human Rights judgment.

human rights implications of EU laws, policies and actions. After all, those are the Member States which are respondents and them alone, even where the measures under challenge result from an obligation which Union law has placed on the member country. If the Court in Strasbourg finds violation of the ECHR, the state concerned is held responsible for the measures, even though it cannot itself change or remedy them since it cannot usurp the role of the Union institutions and bring the offending measure into line with the Court judgment.⁴⁷

The 1993 EU summit in Copenhagen formulated political criteria to be met by countries applying for EU membership. It stated that “membership requires that the candidate country has achieved stability of institutions guaranteeing democracy, the rule of law, human rights and respect for and protection of minorities.” Respect for human rights principles is listed also in article 49 TEU as condition for joining the EU by Candidate countries, though competence of the ECJ to review the human rights ‘conditionality’ in the accession penal sanctions procedures is currently very limited and unclear.

Additionally, since 1995 “human rights clauses” became a standard part of any agreement between Community and Third Countries.

References to the protection of human rights and fundamental freedoms are also to be found in article 11 (1) 5 TEU as well as in article 177 (1) and (2) TEC, while the ECHR and ESC is mentioned in the preamble to the Single European Act.

However, the most appraised human rights document that emerged within this economy oriented organization is the Charter of Fundamental Rights of the European Union proclaimed jointly by the Council, the European Parliament and the Commission in December 2000.⁴⁸ The importance of the Charter arises not only from the fact that it is the first strictly human rights document, which combines in a single text the civil, political, economic, social and societal rights hitherto laid down in a variety of international, European or national sources⁴⁹ - though still not a binding law - adopted by the EU, but also because it brings into the EU area of interest new issues or gives the already existing ones new dimensions.⁵⁰ It also establishes clearly that it aims to protect the fundamental

⁴⁷ Fischbach, Marc (Luxembourg Judge at the European Court of Human rights) – *The European Convention on Human Rights and the European Union Charter of fundamental Rights – complementary or competing?*, The Council of Europe’s European Convention on Human Rights and the European Union’s Charter of fundamental rights: Judges symposium – Luxembourg – 16 September 2002, <http://www.coe.int/T/E/Communication_and_Research/Press/events/6.-Other_events/2002-09_Symposium_of_judges_-_Luxembourg/>, accessed on 2002-10-16

⁴⁸ The Charter of Fundamental Rights of the EU (later referred to as ‘the Charter’) was proclaimed at the meeting of the European Council held in Nice from 7 to 9 December 2000.

⁴⁹ In principle, the Charter represents ‘established law’, i.e. it gathers together in one document the fundamental rights recognized by the Community Treaties, the Member States’ common constitutional principles, the European Convention of Human Rights and the EU and Council of Europe Social Charters.

⁵⁰ Even though according to the European Council guidelines the future Charter were to contain the fundamental rights and freedoms as well as basic procedural rights guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and derived from the constitutional traditions common to the Member States, as

rights of individuals with regard to action undertaken by the EU Institutions and by the Member States in application of the EU Treaties.

Although not binding – in Nice, EU Member States opposed incorporation of the Charter of Fundamental Rights into the Treaties - the Charter already grows in importance.⁵¹ Citizens are invoking it ever more frequently in their approaches (complaints, petitions and letters) to the EU institutions.⁵² Also the advocates-general, soon after it was proclaimed, while presenting opinions in disputes over fundamental rights, made it an instrument for interpreting Community law and used it as a guideline of particular importance.⁵³ From their opinions a two-fold function of the Charter may be inferred, that as a kind of guide for interpreting the scope of existing fundamental rights and, the other, as a means of identifying, among existing rights, those which are fundamental.⁵⁴

What is however of utmost importance is the fact that also the Court of First Instance of the European Communities refers to the Charter in its judgments. In the judgment in the *Max.mobil Telekommunikation Service v. Commission*⁵⁵ case, which concerns the right to sound administration and the right to effective redress, the court notes that the Charter includes such rights and, relying on Article 6§2 EU, finds that the Charter confirms these common

general principles of Community law; as well as to include the fundamental rights that pertain only to the Union's citizens, while also the economic and social rights as contained in the European Social Charter and the Community Charter of the Fundamental Social Rights of Workers (article 136 TEC), insofar as they do not merely establish objectives for action by the Union were to be taken into account, in fact the drafting Convention went beyond its mandate by for example providing greater protection than under the ECHR as in case of article 9 (the right to found a family), article 14 (the right to vocational and continuing training), article 47(2) and (3) (the right to a court is not confined to civil and criminal disputes) or article 35 of the Charter.

⁵¹ Muszynski, Mariusz and Hambura, Stefan - Duzo znaczy, choc nie wiaze. Karta Praw Podstawowych, *Rzeczpospolita*, 2002.08.26

⁵² EU Annual Report on human rights (2001/2002), 12747/1/02 Rev 1 COHOM 11, Brussels, 16 October 2002, p.19

⁵³ The many relevant opinions include those of advocates-general Jacobs, Alber, Léger and Tizzano. See: Opinion on CJEC, 21 March 2002, *Unión de pequeños agricultores v/ Conseil* case C-50/00P, not yet published in Reports; Opinion on CJEC, 6 December 2001, *Hautala* case C-353/99P, Reports p. I-09565; Opinion on CJEC, 26 June 2001, *BECTU* case C-173/99, Reports p. I-4881; Opinion on CJEC, 17 May 2001, *TNT Traco*, case C-340/99, Reports p. I-04109

⁵⁴ Jarabo, Dámaso Ruiz, "Current reforms of Community judicial protection", The Council of Europe's European Convention on Human Rights and the European Union's Charter of Fundamental Rights: Judges' Symposium – Luxembourg, 16 September 2002, <www.coe.int/T/E/Communication_and_Research/Press/events>, visited on 2002-11-01

⁵⁵ CFIEC, 30 January 2002, *Max.mobil Telekommunikation Service / Commission*, case T-54/99, not yet published in Reports.

Paragraph 48: "Since the present action is directed against a measure rejecting a complaint, it must be emphasized at the outset that the diligent and impartial treatment of a complaint is associated with the right to sound administration which is one of the general principles that are observed in a State governed by the rule of law and are common to the constitutional traditions of the Member States. Article 41(1) of the Charter of Fundamental Rights of the European Union (...) confirms that '[e]very person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union.' (...) See also paragraph 57.

traditions. For the second time the Court of First Instance referred to the Charter of Fundamental Rights in its judgment of 3 May 2002 in the case *Jégo-Quéré et Cie Sa v. Commission*⁵⁶, concerning the admissibility of an application against Commission fishing regulations. Although in accordance with established case-law, it found that inadmissibility was unavoidable because the measure was one of general scope which could not concern the applicant individually.⁵⁷ The Court stated that common constitutional traditions, the European Convention on Human Rights and the Charter of Fundamental Rights recognize the right to an effective remedy and admitted that in this specific case, the applicant was denied such a remedy. The denial was found as there could be no trial in a national court, giving rise to a reference for a preliminary ruling unless the individual violated the Community regulation, which could not be demanded of him. Moreover, the Court of First Instance ruled that liability disputes afforded only an incomplete appraisal of lawfulness, since violations were only penalized if sufficiently serious. That being so, it found that the right to an effective remedy required a revision of previous case-law.⁵⁸

It is interesting to note that in this judgment the Court of First Instance places the Charter on the same footing as the European Convention on Human Rights. What is also very new and of enormous importance is the fact that the Court of First Instance holds that a person is "individually" concerned by a Community measure of general scope "if the provision certainly and currently affects his legal situation by restricting his rights or by imposing obligations upon him. In this respect, the number and situation of other persons also affected or likely to be affected by the provision are irrelevant"⁵⁹. Why? Because if this tendency will continue, soon it should be possible to challenge before the ECJ measures of general nature, if those happen to contradict human rights. Hopefully, the Court will continue to refer to the rights encompassed in the Charter, thus bringing them to the attention of the Union.

⁵⁶ CFIEC, 3 May 2002, *Jégo-Quéré et Cie Sa v. Commission*, case T-177/01, not yet published in Reports

⁵⁷ The purpose of actions for annulment is to have binding legal instruments of the Council, Commission, Parliament or the European Central Bank annulled. If EU citizens or firms are involved in such an action as plaintiff or defendant, the action must be brought before the Court of First Instance (CFI). However, citizens and firms can only proceed against decisions that are personally addressed to them or, though addressed to others, have a direct individual effect on them. This is deemed by the Court of Justice to be the case if a person is affected in so specific a way that a clear distinction exists between them and other individuals or firms. This criterion of 'immediacy' is intended to ensure that a matter is only referred to the Court of Justice or the CFI if the fact of the plaintiff's legal position being adversely affected is clearly established along with the nature of those adverse effects; this may present problems in cases where Community legal acts still have to be implemented by the Member States. The 'immediacy' requirement is also intended to prevent 'relator suits' from being filed. However this requirements makes it very difficult for individuals to contest measures of general nature such as f.ex. regulations or directives.

⁵⁸ Paragraph 47 of the *Jégo-Quéré* judgment

⁵⁹ Paragraph 51 of the judgment

3 Right to health

“It is my aspiration that health will finally be seen not as a blessing to be wished for, but as a human right to be fought for”

UN Secretary General, Kofi Annan

3.1 Definition of health. Scope of the right to health.

Before moving on to analyzing the legal position of the right to health in the EU, let us first define “health” itself? For the purposes of this paper I will follow the 1946 WHO Constitution, which defines *health* as “*a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity*” and stresses that “*the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being*”.

According to the Preamble of the WHO Constitution, *health* is to be maintained and achieved not only through the provision of health care services⁶⁰, but also through the dissemination of information, social services and the co-operation on the part of the public⁶¹. Thus the WHO addresses both preventive health efforts and curative health efforts.⁶²

As we can see the WHO not only defines what health is, but states also that every person has a right to *highest attainable standard of health*.

To understand this right literally would lead to the ridiculous assumption that an individual could demand from the state assurance that one never gets sick and that ones life lasts, of course in good health, at least the average statistical length⁶³: dangerous non-enforceable fantasy which could water-down other rights and

⁶⁰ “Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures”, WHO Constitution

⁶¹ “The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people”, WHO Constitution

⁶² Toebe, B.C.A., *The Right to Health as a Human Right in International Law*, School of Human Rights research Series, Volume 1, Intersentia – Hart 1999, p. 33

⁶³ “Since health, unlike commodity, is not available on demand, it follows that any attempt to interpret the basic rights of the citizen in a modern society as giving him an active claim to the enjoyment of good health must be regarded as mistaken from the very outset.” In: von Wartburg Walter P., “A right to health? Aspects of Constitutional Law and Administrative Practice”, *The Right to Health as a Human Right. Workshop – The Hague*, Dupuy, Rene-Jean (Ed.), 27-29 July 1978, Sijthoff and Noordhoff 1979, p. 117

undermine truly justified claims. As Kass⁶⁴ stated, ‘*Health is a state of being, not something that can be given, and only in indirect ways something that can be taken away or undermined by other human beings*⁶⁵. *It no more makes sense to claim a right to health than a right to wisdom or courage.*⁶⁶’ States cannot ensure good health or eternal life. But they can and shall create certain basic conditions through which the health of people is protected or even enhanced. Their responsibility for their peoples health can be fulfilled only by ‘*the provision of adequate health and social measures*’⁶⁷, with obligations understood to encompass both the underlying preconditions necessary for health and the provision of medical care. Also the UN CESCR interpreted in the General Comment no. 14, right to health as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, health occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health.⁶⁸ The general Comment also sets out four criteria by which to evaluate the right to health: availability, accessibility, acceptability and quality.

After all, those are States that have power and resources to assure that ‘normal’ market rationing mechanisms are not the only allocative devices in the health sector, that the income is not the deciding factor in determining who has access to health care and how much of it is received.⁶⁹ This does not mean however that under the right to health people have the right to demand the cost-free health care services or free drugs, etc. No, they do not have such right. But they do have the right to demand access, both in the meaning of its availability and

⁶⁴ Kass, *Regarding the End of Medicine and Pursuit of/and health, The Public Interest* (40) 1975, p. 39, quoted in Toebes 1989, *op.cit.*, p.12

⁶⁵ I would just add: with exception of the grave violations of humans rights as in cases of torture and intentional health deprivation.

⁶⁶ Though recent scientific discoveries might shed a new light onto this. Scientists have just declared to find a gene responsible for the feeling of fear and reactions connected to it, and they hope to find other genes responsible for other psychological reactions. Additionally even now, when it is possible to identify genes responsible for some syndromes/sicknesses, a question may rise whether such ‘prevention’ should not be provided by state. See: *Strach moze byc zwiazany z genami*, Onet.pl <www.onet.pl> za P.A.P., dk/2002-05-04,

⁶⁷ Constitution of the World Health Organization, Preamble. The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (*Off. Rec. Wld Hlth Org.*, 2, 100), and entered into force on 7 April 1948.; For comments on the right to health see apart from Toebes, B.C.A., *The Right to Health as a Human Right in International Law* listed above also Gruskin, Sofia and Tarantola, Daniel, “Health and Human Rights”, *The Oxford Textbook of Public Health*, Detels, Roger; McEvan, James; Beaglehole, Robert and Tanaka, Heizo (eds.), 4th Edition, Oxford University Press, 2002

⁶⁸ “*the right to health must be understood as a right to the enjoyment of a variety of facilitate, goods, services and conditions necessary for the realization of the highest attainable standard of health*”

⁶⁹ See also: Fein, Rashi, “Economic aspects of the right to health care”, *The Right to Health as a Human Right. Workshop – The Hague*, Dupuy, Rene-Jean (Ed.), 27-29 July 1978, Sijthoff and Noordhoff 1979, p. 215 & next

affordability, to the appropriate infrastructure, medicines, as well as taking care of the factors which constitute preconditions for health. To say it simply: recognition of health as a fundamental right brings with it the responsibility of the state to ensure access to health care, including access to drugs, essential drugs in particular. The State has to ensure therefore, that together public and private sectors make drugs accessible (meaning also affordable) to the entire population. This might require subsidizing the drug costs for the poorer part of the population, adopting measures improving the geographical accessibility or adopting effective control programmes for communicable diseases and if necessary carrying the costs of making them geographically and financially accessible to all having in view high costs to society if they are not implemented, etc.⁷⁰

The other issue is the understanding of the notion ‘*highest attainable standard*’ – after all in one of the least-developed countries this standard’ might be quite low, while in the rich countries it would be very high⁷¹. How can we determine or decide what is the ‘highest attainable standard’? Shall we understand it as an entitlement to be ‘above average’ or shall we see it as the

⁷⁰ WHO, Action Programme on Essential Drugs, *Public-Private role in the Pharmaceutical sector. Implications for equitable access and rational drug use*, Health Economics and Drugs, DAP series No. 5, WHO/DAP/97.12, p.26. In the same publication (p. ii) WHO listed the essential state responsibilities in the pharmaceutical sector:

- “- policy making (developing, implementing and monitoring national drug policies),
- drug regulation (licensing and inspecting premises and manufacturers, registration of drugs, control of marketing and independent drug information, and post-marketing surveillance)
- professional standards (education and licensing standards for pharmacists, doctors and other health professionals, developing and enforcing codes of conduct)
- access to drugs (subsidizing essential drugs for the poor and for communicable diseases, supplying drugs through government health services and ensuring universal access)
- rational use of drugs (establishing standards, educating health professionals and supporting public and patient education).”

⁷¹ A good examples of such discrepancy is the case decided by Finnish Court in relation to the Right to adequate health and medical services: *Finish Supreme Administrative Court, 27 November 2000, No. 3118*

"A municipal senior physician had decided to order, as part of the medical treatment provided by the city, one or two pairs of special shoes per year, although various expert reports clearly showed that the person wore out, because the nature of her disability, several pairs of shoes per year. The Uusimaa Provincial Administrative Court dealt with the case as an administrative dispute and dismissed the claim basing itself on the position that there was no specific legal obligation for the municipality to provide such aids as orthopedic shoes. The Supreme Administrative Court, however took the position that what was at issue in the case was the obligation to the municipality, under public law, to provide the necessary aids for medical rehabilitation. Such a right was based on, inter alia, Section 19.3 of the Constitution. The court found that the city had neither shown that it was not able to provide the aids needed by the applicant nor that there would have been reasons acceptable under Section 6 of the Constitution to give priority to other health or medical services to the effect that the individual needs of the applicant could not be met. As the city had failed to comply with its duty to arrange for adequate aids for medical rehabilitation, stemming from Section 19.3 of the Constitution and other applicable provisions of law, the Court ordered the city of Helsinki to provide the applicant with orthopedic shoes in accordance with her medically assessed needs."

It is hard to expect such level of health services be provided in the poorest countries.

maximum. The highest average protection that a given State is able to assure to everybody within the public finances available (independent of whether it meets our standards of the 'live in dignity'), or shall we see it as minimum level which assures that one can get what one needs in order to live in dignity?

To sum up - when using the expression right to health for practical reasons⁷², as a shorthand expression referring to the more elaborate international treaties, we should remember that the state obligations/duties⁷³ correlative to the individual's right consist only in creating and assuring conditions for an individual to pursue the ultimate goal - health.⁷⁴

It may be also worth a mention at this stage that the WHO Constitution is not the only instrument that mentions the right to health. In fact all the major human rights documents praise either directly or indirectly⁷⁵ the right to health, even if definitions they are using vary to some extent. Some of the most important ones will be listed below, as they are binding on States independent from the fact of their EU membership. The point is that even if EU law does not encompass certain aspects of the right to health, States are still obliged under the international public law to fulfill their obligations imposed by the international treaties they

⁷² Most often used, best in line with the character of the international human rights treaty provisions, the need to recognize that not only a right to health care but also a right to a number of underlying preconditions for health such as access to safe drinking water and environmental health are also encompassed by this definition. See also: Toebes, B., *op.cit.*, p. 17

⁷³ Of course opinions on the point to which extend making health care available for people is an obligation of States are also very divided and very often influenced by political believes. See for example:

- Leonard Peikoff, *Health care is not a right*, Speech delivered at the Town Hall Meeting on the Clinton Health Plan on Dec. 11, 1993, <<http://www.bdt.com/pages/Peikoff.html>>;

- David Kelley, *Is there a right to health care?*, Institute for Objective Studies, <<http://www.vix.com/objectivism/Writing/DavidKelley/HealthCare.html>>

⁷⁴ It is worth mentioning at this point that international human rights instruments, often come into more or less direct interaction with international trade law, which is based to a large extend upon reciprocal international (bilateral and multilateral, both regional and universal) treaties reflecting the commercial *quid pro quo* and aiming to a large extend at reduction of existing trade barriers and expansion of international trade and economic development, one of not many customary rules saying that states are free to regulate their economic and monetary affairs internally and externally as they see fit. Such trade objectives not always go hand in hand with the ethic and legal obligations towards individuals, particularly when they are of a 'soft-law' character. This type of approach often lacks to understand the role that the trade can play in the employment, health, education and culture of individuals around the world, and does not take into consideration the obligation of the States towards them.

⁷⁵ For example, article 6 ICCPR: The Human Rights Committee stated in its General Comment nr. 6 (UN 1982) (HRI/GEN/1/Rev.5) that "the right to life has been too often narrowly interpreted. The expression "inherent right to life" cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics." Also article 7 ICCPR states that "No one shall be subjected to torture and cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical and scientific experimentation".

ratified and guarantee certain rights to individuals.⁷⁶ However, at the same time they also need to take into consideration other obligations they accepted - such as international trade law regime, the importance of which increased after creation of the WTO⁷⁷. Solutions reached in the WTO Agreements profoundly changed the trade in goods and services, and affected not only external relations but also the internal situation of the WTO Members, particularly those that (like most EU Candidate Countries) found themselves in an increased vulnerable position, in particular due to the fact that they did not have long-established health systems that would be strong enough to cope with new challenges and legal demands. The strictly binding character of the above norms is surely not helping to formulate stronger human rights provisions in such economy-related areas as health, or to bring to life declarations encompassed in non-binding documents of regional character such as Charter of Fundamental Rights.

Let us come back however to those instruments that are useful in trying to achieve the balance between the human rights and economy. One of the first documents to put obligations on States is, as was already mentioned, the UN Charter's articles 55 and 56, which follows the spirit of the respective paragraph in the preamble of the WHO Constitution, which states that *'the health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States'*.

The UN Charter was soon followed by the UDHR (1948) declaring in article 25 that *'Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, medical care and necessary social services, and the right to security in the event of (...) sickness, disability, (...), old age or other lack of livelihood in circumstances beyond his control'*, thus indicating that the State would face some obligations in this respect. In 1966 a new standard setting instrument appeared stretching the scope of State obligations. In article 12 ICESCR the States Parties to it declared that they *"recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"*⁷⁸ and added in para.2 a description of what they should undertake in ensuring the well-being of its subjects:

⁷⁶ It is of enormous importance for us, because as we will see later the EU approach to the structure and delivery of health and medical care is fully based on the subsidiarity principle (article 3 TEC), which means that these aspects of health care are fully left to the appreciation of states.

⁷⁷ The final 'Marrakesh Agreement' on the World Trade Organization - international body dealing with the rules of trade between nations, entered into force on 1 January 1995 for 81 members, representing more than 90% of international trade, including the 'Triad' of the USA, European Community and Japan. Among the 27 multilateral agreements appended to the text of the WTO accord, there is the new General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreements have three main objectives: to help trade flow as freely as possible, to achieve further liberalization gradually through negotiation, and to set up an impartial means of settling disputes. See: Malanczuk, Peter – *Akehurst's Modern Introduction to International Law*, 7th revised edition, Routledge, 1997, p. 228 et seq.; <www.wto.int>

⁷⁸ Note the much telling lack of 'social well-being'.

“The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”⁷⁹

We also find references to the right to health in the Convention on the Elimination of All Forms of Discrimination Against Woman (articles 10, 12, and 14), Convention on the Elimination of All Forms of Racial Discrimination (article 5) and Convention on the Rights of the Child (article 24⁸⁰).⁸¹

On the regional level we should pay special attention to the European Social Charter’s⁸² article 11, titled *The right to protection of health*, which as we will see later, constituted the point of reference for the drafters of the article 35 of the ChFR. Article 11 ESC reads: *“With a view to ensuring the effective exercise of the right to protection of health⁸³, the Contracting Parties undertake, either directly or in co-operation with public or private organizations, to take appropriate measures designed inter alia:*

- 1. to remove as far as possible the causes of ill-health;*
- 2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;*

⁷⁹ One of these ‘general comments’ concerns the nature of treaty obligations of Party states according to article 2 (1) ICESCR. According to the ICESCR Committee, the main obligation in article 2 (1) is to take steps ‘with a view to progressively achieving the full realization of the rights recognized’ in the Covenant. The extent of policy freedom, inherent to progressive realization has been restricted by ‘minimum core obligations’ a country should meet. One of the first documents to deal with health and set the basis for the minimum core content of the right to health care (preceding the General Comment on article 12) was Alma-Ata Declaration (1978) of the WHO. This declaration emphasized the importance of primary health care and non-discrimination in access to health care. More extensive reading also includes preventive health care and the promotion of positive environmental and health care circumstances.

⁸⁰ “States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. ”

⁸¹ Governments made also on various occasions commitments in respect of ensuring the realization of the right to health: Earth Summit in Rio Agenda 21, Chapter 6, paras. 1 and 12; the International Conference on Population and Development (Cairo Programme of Action, Principle 8 and para. 8.6); the World Summit for Social Development in Copenhagen (Copenhagen Declaration, Commitment 6), the Habitat II conference in Istanbul (Habitat Agenda, paras. 36 and 128), UN Fourth World Conference on Women (Beijing Declaration, paragraphs 17 and 30; Beijing Platform for Action, paragraphs 89 and 106). See also: <www.pdhre.org/rights/health.html>

⁸² The ESC adopted within Council of Europe system has been ratified by all EU Member States. I am not referring in this paper to the Revised Social Charter as it is currently signed by 13 and ratified barely by 4 States belonging to EU. In fact, each of the various attempts to update the ESC both substantially and/or procedurally have garnered a lukewarm reception.

⁸³ It is worth to notice the us in article 11 is the formulation of the right as a “right to protection of health”.

3. *to prevent as far as possible epidemic, endemic and other diseases.”*

What is quite striking when we read the above provisions is the fact that ‘health-provisions’ often recall other socio-economic rights that are directly relevant to enjoyment of the right to health, such as right to education or to *improved environmental and industrial hygiene*. It seems that there exist an “implied acceptance of the interrelation and interdependence between the right to health as such and economic, social, cultural and educational matters”⁸⁴. Another positive development is the universal recognition of the fact that the solution to health problems is very often not a matter that can be dealt with successfully only within national borders, but that certain health problems are better solved by international cooperation.

I think it is possible to conclude that there exists a certain agreement (as seen on the example of the above cited provisions) on the point that the general scope of the right to health, encompasses corresponding duties of states which can be divided into two groups:

- health care (including both curative and preventive health care) as traditionally understood,
- taking care of a number of underlying preconditions for health (such as safe water, proper sanitation, adequate nutrition, environmental health, occupational health, education).⁸⁵

However, because such broad scope may and does result in a certain lack of clarity of the content of both groups of obligations, there is a tendency among the scholars and bodies dealing with these issues, towards delineating certain core components of the right to health, while stressing at the same time that States are under obligation to take steps towards the full realization and enjoyment of this right.⁸⁶ That means, as I understand it, that States are obliged without exception to ensure the full realization of the right to health in its core scope, whereas at the same time they are strongly encouraged and even obliged to ensure as wide enjoyment of *the highest attainable standard* as possible in their particular economic, political and social situation. Drawing inspiration from the Health For All and Primary Health Care strategies of the WHO, which stipulate that “*there is a health baseline below which no individuals in any country should find themselves*”⁸⁷, Birgit Toebees rightly suggests, in my opinion, the following core content of the right to health:

Concerning health care:

⁸⁴ Eze C. Osita, *op.cit.*, p. 81

⁸⁵ Toebees, B., *op.cit.*, p. 140 and next; Toebees B. - “The right to health”, *Economic, Social and Cultural Rights*, Eide A. (ed.), Dordrecht – Kluwer Law International, 2001, p. 174 et seq.

⁸⁶ After all already the expression *the highest attainable standard* indicates that there is no certain, unchangeable standard level of health protection, that it changes along with development of new technologies and new, more effective ways of treatment, it depends on the social context, etc.; Toebees B., “The right to health”, *Economic, Social and Cultural Rights*, Eide A., Dordrecht 2001, p. 175 et seq.

⁸⁷ WHO, *Global Strategy for Health for All by the year 2000* (WHO resolution WHA.34.36) 1981, Ch. 3, p.31, § 1

- Appropriate treatment of common diseases and injuries;
- Immunization against the major infectious diseases;
- Provision of essential drugs;
- Maternal and child health care, including family planning.

Concerning underlying preconditions for health:

- education concerning prevailing health problems and the methods of preventing and controlling them;
- promotion of food supply and proper nutrition;
- adequate supply of safe water and basic sanitation.

As we could see an individual's right to health is not something that the State can guarantee like for example the right to freedom. Health is a product of a combined action of a series of variables, some of which go beyond human control. However, the State is obliged to assure the combination of situations which, like food, nutrition, medical assistance, immunization hygiene, and other core elements of the right to health, contribute to the improvement of health.⁸⁸

In this chapter we analyzed how the right to health is understood on the universal level. What however are the standards, what is the meaning of the right to health in the EU? What place in relation to other rights and interests (which, like competition issues or intellectual property rights, because of their nature are much closer to the basic spirit of EU) does this right have in EU? What obligations do Member States have under EU law, which they do not have under universal instruments? What position does this right have in the internal and external policies? I will try to answer these questions in the next chapters.

3.2 Definition and understanding of the right to health in the EU.

⁸⁸ For very clear exemplification of the links between health and human rights see the Graphics on p. 8 of the "25 Questions and Answers on Health and Human Rights", Health and Human Rights Publication Series, Issue No. 1, July 2002, WHO 2002

3.2.1 Historical Background

Though both the Treaty on the European Coal and Steel Community and the Euratom Treaty referred to health and contained several provisions, for example, relating to restricting free movement of goods on health grounds and to the health and safety of workers, originally the 1957 Treaty of Rome did not contain any formal basis in the field of public health. Focused on an economic side of the integration process, the EC only later realized the existence of the strong relationship between trade, education, poverty and health.

It was not until 1997 that the Council of Ministers of Health began to meet on an occasional basis. This resulted in acts such as “decisions of the Member States meeting within the Council” or non-binding resolutions. Instruments of this kind – whose legal impact is sometimes uncertain – began really to proliferate after the signature of the Single European Act (1986) and emergence of the concept of a “Citizens’ Europe” which added new concerns such as the environment, health, and consumer protection. It was foremost article 100a (now article 95), under which the Commission (since the Amsterdam Treaty it applies also to the European Parliament and the Council of Ministers) is required to “*take as a base a high level of protection*” in its proposals concerning health, safety and consumer protection, that created a legal springboard for completing the internal market. During this period, despite the absence of a clear legal basis, public health policy had developed in several areas, which included:

- Medicines – legislation introduced since 1965 has sought: high standards in medicine research and manufacturing; harmonization of national drug licensing procedures; rules of advertising, labeling and distribution;
- Research – medical and public health research programmes date back to 1978, on subjects such as age, environment and life-style related health problems, radiation risks, and human genome analysis, with special focus on major diseases;
- Mutual assistance – in case of disaster and extremely serious illness.

Still, it was first the Maastricht Treaty (EU Treaty) that provided a real major impetus for public health policy by introducing it into the EC Treaty. In parallel to article 3 which raised health protection to the rank of a Community objective⁸⁹ (though subject to strong considerations of subsidiarity), a specific article on public health - an article 129 (now renumbered article 152⁹⁰). This article, which was highlighted by the insertion into a separate “Public Health” Title, opened the way to formal cooperation between Member States in this area. Soon afterwards (in November 1993) the Commission published its response to the new health provision, identifying in its “*Communication on the framework for*

⁸⁹ Though not to the level of an separate policy.

⁹⁰ I will refer to this Article as to the Article 152.

action in the field of public health” eight areas for action.⁹¹ While most welcomed the Commission’s communication as recognizing the importance of an EU health policy/issues, its disease-by-disease approach has been criticized as limited. At the same time, calls have been made for a more horizontal, interdisciplinary approach, which led to the adoption of a new Communication (COM(1998)230) in which the Commission presented its vision of the future EU health policy indicating three strands⁹²:

- better information exchange: this could lead to better integration of health requirements in other policies;
- rapid reaction to emerging health risks: to include communicable disease surveillance and control, phytosanitary and veterinary matters, rare diseases, environmental risks, blood and organ safety and risks from medicinal and chemical substances;
- better disease prevention and health promotion: this would build on the existing disease-specific programmes and bring in other issues such as mental health, nutrition and alcohol dependence.

Recently, on 23 September 2002, the European Parliament and the Council adopted the *New Programme of Community Action in the field of public health*⁹³, proposed by the Commission on 16 May 2000 together with the *Communication on the Health Strategy of the European Community*⁹⁴. It takes account of the review of the existing situation and recent legal and political developments. The results of the aforementioned review were set out in the *Commission Communication of April 1998 on the development of public health policy in the EC* and indicated that although the principles and underlying philosophy of the 1993 communication on the framework for action in the field of public health remained valid, priorities, structures and methods were all in need of fundamental review and reformulation. Taking this into account the *New Programme*, which will come into effect on 1 January 2003, has three main objectives:

- improvement of health information and knowledge for the development of public health, whereby “*attention should be given to the right of the Community population to receive simple , clear and*

⁹¹ For details see: European Parliament Fact Sheets–Public health, <www.europarl.eu.int/factsheets/4_10_3_en.htm>

⁹² How those strands were transformed into the current 2001-2006 Public health plan will be discussed in the coming sub-chapter.

⁹³ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002, <http://www.europa.eu.int/eur-lex/en/dat/2002/l_271/l_27120021009en00010011.pdf>

⁹⁴ COMMUNICATION FROM THE COMMISSION to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the development of public health policy in the European Community, <<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm#0>>

*scientifically sound information about measures to protect health and prevent diseases, with a view to improving quality of life*⁹⁵;

- enhancement of the capability of responding rapidly and in coordinated fashion to threats to health, and
- promotion of health and prevention of disease through addressing health determinants across all policies and activities.

We have to remember however, that in accordance with the principles of subsidiarity⁹⁶ and proportionality⁹⁷ set out in article 5 of the Treaty, Community action on matters which do not fall within the exclusive competence of the Community, public health among them, should be undertaken only if, and in so far as, by reason of its scale or effects, its objective can be better achieved by the Community. Therefore, as the main power in the public health area remains in the hands of the Member States, the Community's role is mainly to support their efforts by helping them create and implement coordinated objectives, structures, programmes and strategies, which enhance the capabilities of individuals, institutions, associations, organizations and bodies in the health field by facilitating the exchange of experience and best practices and by providing a basis for a common analysis of the factors affecting public health.⁹⁸ Community measures have focused on horizontal initiatives providing for information, education, surveillance and training in the field of health, the drafting by the European Commission of reports on the state of health in the European Community and the integration of health protection requirements into the Community policies.

However, such specific public health problems as drug addiction, cancer, AIDS or blood transfusion chains in the Member States, which coupled with the increasingly free movement of patients and health professionals within the EU, highlighted the fact that national policies sometimes have repercussions far

⁹⁵ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002; Preamble, section (1)

⁹⁶ The subsidiarity principle, embodied in the EC Treaty (Article 5), is taken over from Roman Catholic social doctrine. There are two facets to it: the affirmative statement that the EC must act where the objectives to be pursued can be better attained at Community level, which enhances its powers; and the negative statement that it must not act where objectives can be satisfactorily attained by the Member States acting individually, which constrains them. In practice this means that all Community institutions, and Commission particularly, must always demonstrate that there is a real need for Community rules and common action. To put it other way: when it is not necessary for the Community to take action, it is necessary that it should take none.

⁹⁷ The principle of proportionality has entered Community law through the decisions of the Court of Justice. It means that the need for the specific legal instrument must be thoroughly assessed to see whether there is a less constraining means of achieving the same result. The framework legislation, minimum standards and mutual recognition of the Member States' existing standards should always be preferred to excessively detailed Community rules.

⁹⁸ Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002. For example, Directive 92/59/EEC of the Council of 29 June 1992 on general product safety; Directive 93/42/EEC of the Council of 14 June 1993 concerning medical devices;

beyond national frontiers and stressed the need for an international response and enhanced cooperation between the Member States. As a result of the acknowledgment of this fact the global multiannual programmes have been mounted in priority areas such as cancer, drug addiction, AIDS and transmissible diseases.⁹⁹ It led also to improving matters by amending and making tougher the wording of article 129 of the EC Treaty by the Treaty of Amsterdam, which also renumbered it as article 152.

It is thanks to the aforementioned changes that the Community can now adopt measures aimed not merely at contributing but also at *ensuring* a high level of human health protection. Thanks to this new, wider scope of the revised article 152 among the areas of cooperation between Member States we find not only diseases and major health scourges but *all causes of danger to human health*, as well as the *general objective of improving health*. The Council may also adopt measures setting high quality and safety standards for organs and substances of human origin, blood and blood derivatives. Additionally veterinary and plant-health measures directly aimed at protecting public health are now adopted under the co-decision procedure. This is a new development, as the European Parliament previously only had a right to be consulted on the adoption of health measures linked to agriculture.

After this general overview of the history behind current public health policy of the EU it is time to move to the in-depth analysis of the health concerned provisions found in European law.

3.2.2 Right to health in the EU/EC law

3.2.2.1 Article 3 TEC

As was already mentioned, health protection was raised to the rank of a Community *objective* by the Treaty on European Union which amended article 3 of the Treaty establishing the European Communities through insertion of the point (p), according to which for the purposes set out in article 2¹⁰⁰ the activities of the

⁹⁹ Major initiatives launched included 1987 *Europe against cancer* and the 1991 *Europe against AIDS* programmes. In addition several key resolutions were adopted by the Council's health ministers on health policy, health and the environment, and monitoring and surveillance of communicable diseases. See also: <www.europarl.eu.int/factsheets/4_10_3_en.htm>

¹⁰⁰ Article 2 TEC: The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing common policies or activities referred to in articles 3 and 4, to promote throughout the Community a harmonious, balanced and sustainable development of economic activities, a high level of employment and of social protection, equality between men and women, sustainable and on inflationary growth, a high degree of competitiveness and convergence of economic performance, a high level of protection and improvement of the quality of the environment, the raising of the standard of living and quality of life, and economic and social cohesion and solidarity among Member States.

Community shall include, as provided for in this Treaty and in accordance with the timetable set out therein, “*a contribution to the attainment of a **high level of health protection***”.

3.2.2.2 Article 152 TEC

Article 152 of the Treaty establishing the European Community stipulates, using the same wording as article 3, that “*a **high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities***”.

The EC Treaty does not follow the exact wording of the right to health as it is found in the ICESCR or in WHO constitution. Both of these talk about the “*highest attainable standard of health*” which indicates that no standard is absolute (as standards are evolving constantly, together with technical and scientific development, which means that obligations of states towards its subjects should also evolve with time) and which carry with themselves a continuous obligation to look into possibilities to improve existing systems and schedules.¹⁰¹ I think however that, though not being so strong and powerful as its Covenant counterpart, the idea of a “high level of human health protection” also includes a certain level of flexibility and evolution/improvement, because the idea of what constitutes a high level of protection, also changes under the influence of new discoveries and evolving social context.

Furthermore, a high level of *human health protection must be ensured* in the definition and implementation of *all* Community policies and activities. In other words, this requirement applies to all the common policies, especially Development Policy and CAP. It also binds, as mentioned before, all political players. Quite significant is the deliberate use of the word “*ensure*” which leaves no space for doubts whether or not the action of the Community in assuring the proper place and level of the human health must be successful. We should not however equate the obligation of ensuring health protection in development or trade with the existence of an implicit recognition of the individual right to health.

According to article 152 TEC, Community action, which in accordance with the *subsidiarity principle* shall complement national policies, must be directed towards improving public health, preventing human illness and diseases, and removing sources of danger to human health. Such action shall cover the fight against the major threats to health, the promotion of research into their causes, their transmission and their prevention, as well as health information and education. The Community is also obliged to complement the Member States’ action in reducing drugs-related health impairment, including information and prevention.

¹⁰¹ van Krieken P, op.cit., p. 16 et seq.

In article 152 we find also, in some detail, the measures that the Council of Ministers must take in co-decision with Parliament¹⁰²:

- measures setting high standards of quality and safety for organs and substances of human origin, blood and blood derivatives;
- measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
- incentive measures designed to protect and improve human health, *excluding* however any harmonization of national law.

If we will take a closer look at the previous paragraph, we will notice that actions that the Community is obliged to undertake, with the exception of actions aimed at preventing human illness and diseases which can also include measures typical for health care prevention, fall clearly within this part of scope of the right to health which concerns the underlying preconditions for health. What then, about those aspects of the right to health which would concern more 'traditionally' understood health care? If we look closer at the text of the article 152 we will be struck by the number of places in which the principle of subsidiarity is stressed in one way or the other (encourage cooperation; lend support; complement national policies; foster cooperation with third countries; adoption of incentive measures, excluding however any harmonization of the laws and regulations of the Member States) leaving many aspects of the right to health outside EU control. Crucial in this respect is paragraph 5 of the article 152, which states that *Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care*. It seems that as a result of this provision Member States are totally free in deciding about all the aspects of health care (structure of the health care services, refunded drugs lists, etc.) without interference from the EU institutions.

That does not mean however, that they are free to do anything they want, or, what's even more dangerous taking into consideration the positive character of the obligations related to the right to health, not to do. After all, each and every state belonging to the EU, also signed or ratified also other international instruments (for example: ICESCR, ESC, UDHR, WHO Constitution), thus compelling themselves to fulfill all the obligations those instruments would impose, what in some instances may lead to a necessity of introducing a higher standard than the EU one (for example: highest attainable level of health – high level of health).

¹⁰² It might be worth mentioning that Parliament has consistently promoted the establishment of a coherent public health policy. It has also actively sought to strengthen and promote health policy through numerous opinions and own-initiative reports on issues including: radiation protection for patients undergoing medical treatment or diagnosis; respect for life and care of the terminally ill; a European Charter for Children in hospital; research in biotechnology including organ transplants and surrogate motherhood; safety and self-sufficiency in the EU's supply of blood for transfusion and other medical purposes; hormones; drugs; ionizing radiation; EU health card.
<www.europarl.eu.int/factsheets>; 24.03.2002

3.2.2.3 Article 35 of the Charter of Fundamental Rights

The law, and in particular the EU law, is in constant change. In order to understand how the right to health is currently understood within the EU, it is not enough to look purely at the binding provisions. If we want to know how the right to health will evolve hopefully in the near future, we should have a closer look at article 35 of the ChFR, which states:

*“Everyone has the **right of access to preventive health care** and the **right to benefit from medical treatment** under the conditions established by national laws and practices.*

A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”

The first striking difference between the above article 35 ChFR and article 152 of the EC Treaty is the reference to ‘everyone’, the shift from impersonal obligation of ensuring high level of human health protection to the right of access and right to benefit. Such a shift seems to indicate the readiness of the EU to move further in the field of health protection and not only to fulfill the key objectives traditionally belonging to the states field of action (public health policy), but to recognize the individual right to health as such. Is however such interpretation not going too far, if we take into consideration the second sentence of article 35?

Quite helpful in determining the content and meaning of this article can be the official explanations to the ChFR issued by Council of the EU¹⁰³.

According to the explanations found there, the principles set out in article 35 ChFR are based on article 152 of the EC Treaty and on article 11 of the European Social Charter. The second sentence of article 35 ChFR built upon article 152(1) of the EC Treaty.

As the second sentence of the article 35 ChFR is a copy of article 152 (1) TEC, this does not bring anything new to this field. Consequently, I will currently concentrate on the first part of article 35 of the Charter, as the way that the EU fulfills its obligation towards this paragraph, requires a thorough analysis. One which will be performed in the next chapter.

What is surprising for me is the distinction between the **right of access to preventive health care**, and the **right to benefit from medical treatment under the conditions established by national laws and practices**. Why is the right of access (availability and affordability) limited only to preventive health care, which as I understand it, includes only precondition measures for health and prevention measures (vaccination)? Is it based on the belief that if we provide a majority with a health-friendly environment, there will not be a need for a proper

¹⁰³ Council of European Union, Charter of Fundamental Rights of the European Union. Explanations relating to the complete text of the Charter, December 2000, <www.europa.eu.int>

curative medical treatment? Such assumption could not stand up alone however. Alternatively, if we take into consideration the fact that preventive health care should concern the whole world population, compared to the medical treatment, enveloping only a fraction of such (however big it is), it might seem justified that the drafters of the article 35 put so much pressure on the preventive measures being accessible to everybody.

This possible formulation can also support grounds for arguing, that on a larger scale at State level, there is no need to wait until a population becomes victim to epidemics. In order to make use of this right to access and to prevent this epidemic occurring, for example, use the opportunity to ‘brake’ patent, albeit when there is still no ground (not high enough number of infected people) to declare a state of emergency but when the country cannot already afford to pay for some drugs. Such interpretation of this provision may be a bit too far fetched however.

An alternate suggestion to the meaning of the right of access is that the individual cannot be prevented from taking advantage of health care and other facilities having impact/influence on health, when one can or even cannot afford them. In other words, is it obligation of the state to provide, for example safe water, even if the given person is not able to pay for it? In this respect it might be useful to refer to article 11 ESC. We do not find in it any statement suggestion that health, and particularly medical care and treatment, are to be free of charge. In fact, such statements were deleted from the original draft proposal of the Consultative Assembly during the preparatory works.¹⁰⁴ Does the same apply to preventive health care, which is obviously of bigger importance for State parties? This question is to be left unanswered at this point.

When talking about the “*right to benefit from medical treatment under the conditions established by national laws and practices*”, legislators took their escape in the subsidiarity principle, leaving such matters to the state to decide. This however, may not be such a bad solution, because such society embedded, budget depending, and socially sensitive issues like what should be the structure of the medical care system, or what should be included on the list of refunded drugs (of which a good example is the recent discussion on what should be included on new refunded drugs list in Poland) should be decided as close to the citizens as possible. Of course, certain basic standards are needed, but it seems that the WHO¹⁰⁵ is taking effective care of it, so there is no such urgent need to move it to the EU sphere.

Commentary to the ChFR suggests that when trying to understand the meaning of article 35 ChFR we should refer to article 11 ESC. We have to notice however, that the field covered by this article is rather large and quite hard to draw conclusions from concerning what the precise obligations are, and in consequence, what the failures of States are with regard to the realization of this provision. A big help in this situation can be the first *Conclusions of the*

¹⁰⁴ Toebe B., op.cit., p. 63 et seq.

¹⁰⁵ For example, WHO Guidelines for Developing National Drug Policies, 1988, <www.who.int>

*Committee of Independent Experts*¹⁰⁶, in which it was declared that States can be in compliance with this provision if they provide evidence on the existence of a medical and health system which comprises of six enumerated elements¹⁰⁷. These relate to *health care* (access to health care, with special emphasis on access for mothers, children, and the elderly; and control of epidemics and endemic diseases) and to *underlying preconditions for health* (environmental health; food; alcohol and drugs; health education; financial commitment to health services).

In these first Conclusions, the ESC Committee declared that attention should be paid to the financial organization of health care services, however this specific attention cannot be deducted or interpreted from subsequent conclusions of the ESC Committee. In fact the organization of health care services in States seems largely to be left unmentioned by the ESC Committee, whereas considerable attention has been paid to the measures taken by State parties to control the spread of epidemic and endemic diseases. It seems in light of the above comments, that the approach taken by the EU (leaving the organization and scope of assuring the “*right to benefit from medical treatment*” for the Member States to decide) is fully in line with, if not letter, then the practical implementation of article 11 ESC. Also measures undertaken by the EU in respect to underlying preconditions for health and health education, seem to be in line, or even once more further reaching than the implications of article 11 ESC (though the ESC Committee has paid considerable attention to such issues as environmental pollution and its effects on people’s health).¹⁰⁸

To sum up, I would risk a conclusion that, although article 35 seems to indicate EU openness to shifting its approach from ‘public health’ to ‘individual right to health’ recognition, with all its consequences, at the same , current practice shows that the EU is neither eager, nor ready, to significantly change its approach in practice and to undertake new obligations, particularly if they carry financial burden.

3.2.2.4 ECHR

¹⁰⁶ Toebes B., op.cit, p. 155 et seq.; Case Law on the European Social Charter, Strasbourg 1982, p.104, Conclusions I, p. 59

¹⁰⁷ 1) Public health arrangements making generally available medical and para-medical practitioners and adequate equipment consistent with meeting its main health problems (ensuring a) proper medical care for the whole population, and b) the prevention and diagnosis of disease); 2) special measures to protect the health of mothers, children and old people; 3) general measures aimed at preventing air and water pollution, protection from radio-active substances, noise abatement, food control, environmental hygiene, and the control of alcoholism and drugs; 4) a system of health education; 5) measures such as vaccination, disinfection, and the control of epidemics, providing the means of combating epidemic and endemic diseases; 6) the bearing by collective bodies of all, or at least a substantial part, of the cost of the health services. *Idem*

¹⁰⁸ Toebes B., op.cit., p. 157 et seq.

It was already mentioned that article 6 TEU raised the ECHR (and the rights and freedoms guaranteed therein) to the rank of *acqui communautaire*. Being a part of EU law, the ECHR can be effectively used in determining the scope of the right to health and state obligations. How? - one can rightly ask - as 'right-to-health' falls within the category of social and economic rights that are in principle outside the scope of the ECHR, being regulated at Council of Europe level primarily in the European Social Charter (which all the countries signed and ratified) and Revised Social Charter (which is just at the beginning of the ratification process).

In certain circumstances one can evoke article 3, which deals with inhuman and degrading treatment. In an early ruling in the matter *Tanko v Finland*¹⁰⁹, the Commission indicated that a lack of care may amount to a situation in which article 3 may be violated. Furthermore, on another occasion¹¹⁰ the Court ruled that article 3 also applies to inhuman treatment brought about by unintentional acts, and that expulsion of a foreigner dying from AIDS to a country which lacks appropriate means of treatment would constitute a violation of this provision.¹¹¹

It would seem that if a State cannot expel a foreigner to a country where he won't be provided with the medical/health care needed, even more so, it is obliged to make sure that its own citizens can make full use of their right to health even if they are not able to pay for it. But it is not necessarily so.

Other possibilities of approach are an appeal on the right to life (article 2). In *Tavares v. France*¹¹² the applicant, whose wife had lost her life in a French hospital as a consequence of serious complications following delivery of a child, argued that France was in violation of Article 2 of the ECHR. Although the Commission rejected that contention, it has however repeatedly voiced its earlier standpoint according to which certain regulatory measures aimed at protecting life and concerning the hospital system, were inherent in Article 2. Cases like the above mentioned, might serve as a reminder that the Convention's point of view is, that in allocating resources a certain minimum level of health care services be maintained.

A State could be held responsible in the situation where a person in urgent needed (for example laying on the street, or coming to hospital and not being given the emergency help) of a treatment, which is vital for his/her life, would be refused it.

¹⁰⁹ *Tanko v Finland*, 23634, 19 May 1994; the Commission considered the application not to be admissible.

¹¹⁰ Eur. Court of H.R., *D. v UK*, Judgment of 2 May 1997, ECHR Reports 1997-III. The patient in question was in danger of being removed from the UK to St. Kitts, a country without basic treatment facilities, after serving a sentence of 6 years imprisonment. Because of the exceptional circumstances in the concrete case the Court found that a removal of the patient would amount to inhuman treatment.

¹¹¹ See also: Koch, Ida Elizabeth, „Social Rights as Components in the Civil Right to Personal Liberty: Another Step Forward in the Integrated Human Rights Approach?“, *Netherlands Quarterly of Human Rights*, Vol. 20, No. 1 March 2002, pp. 29-51

¹¹² Decision of the Commission, Application no. 16593/90. Decision of 12 September 1991 (unpublished).

On the other hand, it is rather unlikely that the Court will move in the near future towards such an interpretation of article 2 and article 3 as to allow litigation from terminally ill people for whose treatment, their country is not paying. In fact, the Court has been very reluctant to raise and address such ‘border cases’, mainly due to the high costs they might put on States (who would not be able to afford them). Most of such ‘right to health’ related cases are either declared non-admissible, or solved through the friendly settlement approach.¹¹³ What one cannot forget here is the fact that, as the WHO puts it in its Report 2000 (p. XIV) “*if services have to be provided to all then not all services can be provided*”. Due to resource limitation, it is a very hard balance that every country needs to strike/achieve, and the lower the level or the closer it is to the final beneficiaries, the better.

Of course we can and should agree that many countries whose population is suffering from numerous diseases should simply reprioritize their expenditure objectives and relocate money from, for example, military expenditures to the public health sector/field. This however will not cause a drastic change in case of poorer countries (though it would make it more legitimate and proper for them to appeal for foreign help to meet those goals). In fact, the biggest and most-serious enemy of health is poverty, both for states and individuals. Unfortunately, in our ‘globalised’ world where everything, including health-care, is increasingly subject to the ‘market forces’ of economics, and everybody is talking about harmonizing trade policies – not many dare to lobby for harmonizing the socio-economic conditions in the world. Many governments, left to themselves, either because of lack of political will or the necessary resources, do not provide their people with basic health facilities. In the developing countries it is not rare that barely 20% of drugs are distributed through government-run institutions like hospitals in the region, for example in South Africa which seems to be one of the richest countries in Africa, because of the weakness of the health-system ca. 80% of drugs are purchased directly by people.¹¹⁴ In such a situation, there is a lot international and local pressure upon politicians that any policy decision relating to the enactment of a new national legislation on intellectual property protection should take into consideration the effect of increased drug prices on the poor consumers.

How is it then in the EU? Does it lead by the example it sets in its internal policy, or are human rights, and particularly the right to health treated as matters arising primarily in the EU external relations rather than its internal affairs?

¹¹³ An informal talk with Mr. Luzius Wildhaber, President of the Eur. Court of H.R., 20.04.2002

¹¹⁴ Muddassir Rizvi, “*TRIPs will push health care beyond poor*”, <www.twinside.or.g/title/beyond-cn.htm>, 14-04-2002

4 Right to intellectual property

According to the official site of WIPO – intellectual property is a generic term which refers to creations of the mind: inventions, literary and artistic works, symbols, names, images, and designs used in commerce; and is divided into two categories: Industrial Property and Copyright.¹¹⁵ It is widely understood to be one of the forms of property (just intangible one) and is governed predominantly by private law, formulated in way that allows the rights holder to exclude others from its use, for example no invention can be commercially made, used, distributed or sold without the patent owner's consent. Once the rights conferred on the rights holder expire and the protection ends, the creation enters the public domain, thus enriching the general public and making it possible to use it to enhance future creations on a bigger scale.

Could however intellectual property rights as found in private law be conceptualized as means of realizing the right to intellectual property understood as human right? After all human rights, including right to intellectual property are primarily about the rights and obligations between individuals and States and belong to the sphere of international public law. On the other hand the WTO agreements, including TRIPs¹¹⁶, are best characterized as multilaterally negotiated contracts specifying the legal ground rules for international trade relations, thus representing international legal commitments taken by a State vis-à-vis another State, while at the national level the intellectual property rights are considered to be strictly of contractual nature/ private law nature/ with state setting rules in case the general interest/ public interest would be in question.

Is there at all such a right as the right to intellectual property?

Despite the fact that the right to property is recognized in the UDHR, and the main reasons it is not incorporated in the international covenants are political, though it is recognized in the Protocol No. 1 to the ECHR and subsequent European Court of Human Rights case law as well as in a number of other universal or regional human rights instruments; despite the fact that the right to intellectual property is recognized in the UDHR and the ICESCR, there are still voices that suggest, for example Schermer¹¹⁷, that most property rights¹¹⁸ cannot

¹¹⁵ Industrial property includes inventions (patents), trademarks, industrial designs, and geographic indications of source. Copyrights includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

¹¹⁶ However in my opinion, TRIPs somewhat differs from this division, in the sense that it indirectly accords rights to citizens. Citizens acquire the substantive rights not directly from TRIPs, but from the governments via the implementation of their WTO obligations

¹¹⁷ Schermers, Henry G., “The International Protection of the Right to Property”, *Protecting Human Rights: the European Dimension*, Matscher, Franz and Petzold, Herbert (eds), Carl Hemanns Verlag KG, Köln, 1998, pp. 565 - 580

be included in the category of fundamental human rights, because those are “human rights of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement”, not to mention that both private international and public international law recognize the right of sovereign states to regulate property rights and to adjust them to economic and social circumstances¹¹⁹. I would dare to say that those restrictions on the enjoyment of the right to property do not deprive it of its human rights status.

First of all, it is hard to imagine that the development of human personality and the protection of individual interests within a group can take place in the absence of property rules that guarantee the stability of individual possession. Secondly, even though governments continuously change the rules relating to property (tax law, use of land etc), taking into account the social interest in the property and whole set of circumstances, they can do so as long as they stay within - to use the term from ECHR area – the margin of appreciation.¹²⁰

In the case of property, this “flexibility area” is somewhat broader, stemming from the complexity of the objectives of property and the need to balance the competing human rights interest. This is even more sharply visible in the case of the right to intellectual property. However, such limitations as only 20 years long protection on patent, or making protection dependant on registration, are supposed to reflect the balance between the “*moral and material interests (of creators) resulting from any scientific, literary or artistic production*” and the interest of everyone else “*to take part in cultural life and to enjoy the benefits of scientific progress and its applications*”¹²¹, where the enjoyment of the benefits of the scientific progress and its applications can mean simply the possibility of using the medicine. Just as in the case of the right to life, governments are required not merely to refrain from killing individuals but also have to take steps to prevent individuals from doing so (i.a. through insertion of the relevant provision in the criminal code). In the same way, the intellectual property private laws should ensure the fulfillment of both above mentioned

¹¹⁸ Except for those need-based personal property rights, without which the exercise of other rights like the right to life would be meaningless. In his eyes intellectual property rights should not therefore be at all considered as human right as they are subjected to even further going restrictions (limited period of protection – 20 years for patents, registration requirement, etc).

¹¹⁹ See: Drahos, Peter, “Intellectual Property and Human Rights”, *Intellectual Property Quarterly*, No. 3 (1999), p. 360

¹²⁰ The African Charter on Human and Peoples Rights in article 14 does guarantee the right to property, although it then goes on to recognize that that right may be encroached upon in the “*interest of public need or in the general interest of the community*”. The American Convention on Human rights in article 21(1) recognizes a right to property which no one is to be deprived of “*except upon payment of just compensation*”. In article 1 of Protocol No. 1 to the ECHR we also find that the right to peaceful enjoyment of one’s possessions can be limited by State, which, within given limits, can “enforce such laws as it deems necessary to control the use of property in accordance with the general interest”. For more on margin of appreciation see for example: Van Dijk, P. and Van Hoof, G.J.H, *Theory and Practice of the European Convention of Human Rights*, 3rd ed. (1998), Hague

¹²¹ Article 15.1 ICESCR, similar provisions in article 27 UDHR.

functions of the human right to intellectual property, should be treated instrumentally. While drafting intellectual property laws one has to remember that intellectual property rights are not just good in themselves, but are to be understood as essential preconditions for cultural freedom, participation and scientific progress. Also, while they ensure that creators' moral and material rights are protected so as to insure incentives for further creations and encourage scientific progress, they should facilitate rather than constrain cultural participation and enjoyment of the benefits of scientific progress.

How is it however in reality? How did the EU cope with such issues?

4.1 Pre-Charter period

In the economy driven, globalised world the right to property, including the right to intellectual property, is of fundamental importance. Without ownership rights it would be impossible to frame the whole concept of capitalism and free trade. It should not therefore be surprising that the Communities recognized at the very beginning of their existence the right to property as a fundamental right common to all national constitutions and also reflected in the First Protocol to the European Convention for the Protection of Human Rights. This approach was also repeatedly reaffirmed in the ECJ case-law, initially in *Hauer* judgment¹²². What is worth underscoring is that the Court already recognized then, that the right to property, "far from constituting an unfettered prerogative, must be viewed in the light of the social function"¹²³.

Why I am paying so much attention to the European Court of Justice? Because its judgments can have a big influence, *de facto* nullifying one, on national legislation concerning intellectual property rights, for example in the *Magill* case, the broadcasters which held copyright in their programme listings could not prevent the publishers of weekly guides from using listings without a

¹²² *Hauer v Land Rheinland-Pfalz* (Case 44/79) [1979] ECR 3727, point 4 and 17: "The right to property is guaranteed in the Community Legal Order in accordance with the ideas common to the constitutions of the Member States, which are also reflected in the First Protocol to the European Convention for the Protection of Human Rights."

Other cases touching upon the right to property include: *Ferriera Valsabbia SpA and Others v. Commission* (Concrete Reinforcement Bars), *Schröder HS Kraftfutter GmbH & Co KG v Hauptzollamt Gronau, Wachauf v. The State* (Bundesamt für Ernährung und Forstwirtschaft), *R v. Commissioners of Customs and Excise, ex parte Faroe Seafood Co Limited and Others*, *Bosphorus Hava Yollari Turizm Ve Ticaret AS v. Minister for Transport, Energy and Communications, Ireland*.

¹²³ *Hauer v Land Rheinland-Pfalz* (Case 44/79) [1979] ECR 3727, point 7: "In the same way as the right to property, the right of freedom to pursue trade or professional activities, far from constituting an unfettered prerogative, must be viewed in the light of the social function of the activities protected thereunder."

license.¹²⁴ On the other hand, we have to keep in mind that as the Luxembourg Court has itself held, it has no power to examine the compatibility with the European Convention on Human Rights of national rules which do not fall within the scope of Community law.¹²⁵

However, except for the Court, until the Charter of Fundamental Rights, the EU did not consider property, including intellectual property rights as a specific form of property, in terms of a human right. In fact, it did not occupy itself with the question of property as such at all. In line with article 295 (ex article 222) TEC, which states that *‘this Treaty shall in no way prejudice the rules in Member States governing the system of property ownership’*, the EU left the regulation of property, including intellectual property to the Member States, and barely set up a series of secondary legislation in this field with the main aim of harmonizing certain aspects of it or in case of a new areas setting frames with the aim to increase competitiveness of the Communities.¹²⁶ Much telling is the fact that the only time, except for the article 295, when property is mentioned in TEC, is in connection with the Common Commercial Policy (CCP). As CCP shall be based on uniform principles, the EU secured in article 133 paragraph 5 (ex article 113) TEC, that the Council, acting unanimously on a proposal from the Commission and after consulting the European Parliament, may extend the application of provisions regulating the implementation of the CCP to international negotiations and agreements on services and *intellectual property*, insofar as they are not covered by these provisions.

This approach, according to which intellectual property rights’ main role is to protect intangible assets as to insure the competitive advantage of Europe, is also often met in statements of Brussels Officials, for example, yet back in 2000 the Commissioner for Internal Market stated that *‘the key to success is the creation of an open and competitive Europe (...)’* and while stressing the “need to encourage as much innovation as possible and thereby make it attractive for industry to invest in Europe”, he found it *‘particularly important to put more emphasis on the protection of intellectual property rights’*.¹²⁷

¹²⁴ *RTE and ITP.*, Joined Cases C-241/91P and C-242/91P (*Magill appeal*). The decision of the Court was justified on the ground that the function of copyright does not encompass the protection of facts.

¹²⁵ See the Judgment in Joined Cases C-60 and C-61/84 *Cinéthèque v Fédération Nationale des Cinémas Français* [1985] ECR 2605, paragraph 25; the Judgment in Case C-12/86 *Demirel v Stadt Schwabisch Gmund* [1987] ECR 3719, paragraph 28, the Judgment of 18/06/1991, *ERT/DEP* case (Rec.1991,p.I-2925)

¹²⁶ As, for example, the official site of the Commission states, the Internal Market DG focuses in particular on the "knowledge-based" aspects of the Single Market, trying to adapt it to the new economy, through such traditional instruments as harmonizing the laws of the Member States relating to intellectual property rights to avoid barriers to trade (Industrial Property Overview, <http://www.europa.eu.int/comm/internal_market/en/ndprop/overview.htm>, 2002-10-17). For a list of selected EU secondary law act see the Supplement B.

¹²⁷ Speech by EU Commissioner Frits Bolkestein, *“The Protection of Industrial Property in Europe and its place in the world”*, Alicante, 29 May 2000, last visited on 2002-11-04, <http://www.europa.eu.int/comm/internal_market/en/speeches/spch194.htm>

It is not surprising then, that the secondary legislation (foremost directives and regulations) being developed mostly by technically minded intellectual property legal experts, and thus influenced by the professional values they share, as well as general preference for economic values within EU, just sporadically include provisions that carry the spirit of the human rights in them.¹²⁸ For example the provision in article 6 of *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, which states that ‘*Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality*’¹²⁹ or the ‘*ordre public*’ clause in the article 53 (a) of the signed by all EU Member States European Patent Convention¹³⁰, which provides that patent should not be granted for inventions ‘*the publication or exploitation of which would be contrary to ‘ordre public’ or morality*’.¹³¹ However even those have received very narrow interpretation¹³², which indicates that respect for human dignity and rights was not conceived as the guiding principle. Even fewer instruments contain provision establishing similarities to the one in article 7 of the Directive 98/44/EC which establishes the Commission's European Group on Ethics in Science and New Technologies, whose task is the evaluation of all ethical aspects of biotechnology.

4.2 Right to intellectual property in the EU/EC law

The right to property, including the right to intellectual property, as encompassed by the article 17 of the Charter of Fundamental Rights, in stating that:

“1. *Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her*

¹²⁸ We can find so called *ordre public* and *morality clauses*. *Ordre public* concerns the fundamentals from which one cannot derogate without endangering the institutions of a given society.

¹²⁹ See also art 4, 5, 6 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

¹³⁰ Note that European Patent Convention (referred to also as the Munich Convention) though signed by all EU Member States in 1973, is not a Community, but an international regime. EU is currently working on establishing the Community Patent, see: <http://www.europa.eu.int/comm/internal_market/en/indprop/patent>

¹³¹ It might be interesting to recall here that also article 27.2 of the TRIPs Agreement includes provision stating that “*Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health (...)*”

¹³² Drahos, Peter - “Intellectual Property and Human Rights”, *Intellectual Property Quarterly*, No. 3 (1999), p. 369

possessions, except for in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law insofar as is necessary for the general interest.

2. *Intellectual property shall be protected.*”

is without any doubt based on Article 1 of Protocol No. 1 to the ECHR. In the text of the provision, the drafters decided even to keep the wording known from the ECHR, i.e. that of one's *possessions*. Taking into account the continuous jurisprudence since the *Handyside case* and *Marckx case*¹³³ in which the Strasbourg Court has always attributed a broad meaning to that term, there is no doubt however that it contains in substance the right to property, as indicated in article 17 of the Charter title.¹³⁴

Though the wording has been after all somewhat updated, it is clear from the article 52(3) and article 53 of the Charter, that because the right as such was taken from ECHR, then it has the same meaning and scope as the corresponding right in the Convention. That means that limitations on the right to property may not exceed those provided for in ECHR, i.e. the restrictions are justified only if they are provided by law (lawfulness), and limited to the extent to which they are deemed “necessary” by a State for the protection of the “general interest”.¹³⁵

On the other hand, property can be subject to the possibility of being afforded greater protection under Union law's than the Convention.¹³⁶ As one can notice, building on the law established by Strasbourg, the article focuses more than the ECHR on deprivation. It also replaces the phrase “enjoyment of one's possessions” with more practical enlisting of the “*right to own, use, dispose*” and includes even a provision which explicitly protects inheritance (“*and bequeath*”). Also *compensation* has been explicitly included – though only in the case of

¹³³ In the *Marckx case* the court held that “Article 1 is in substance guaranteeing the right to property”, Judgment of 13 June 1979, Series A, No. 3, p. 27

¹³⁴ Eur. Court H.R., *Handyside case*, Judgment of 7 December 1976, Series A, No. 24, para. 62; Eur. Court H.R., *Marckx case*, Judgment of 13 June 1979, Series A, No. 31, para. 63. The reason given by the Court for adopting such a broad concept has been the very breadth afforded the definition of ‘property’ itself in general Public International Law, from which the Convention adopts its notion of property. See also: Ruffert, Matthias – “The Protection of Foreign Direct Investment by the European Convention on Human Rights”, *German Yearbook of International Law*, No. 43 (2000), p. 122

¹³⁵ Article 1 of Protocol No. 1 to ECHR; *Hauer v Land Rheinland-Pfalz* (Case 44/79) [1979] ECR 3727, p. 19

¹³⁶ Council of European Union, Charter of Fundamental Rights of the European Union. Explanations relating to the complete text of the Charter, December 2000, <<http://ue.eu.int/df/default.asp?lang=en>>, last visited on 2002-11-09;

Fischbach, Marc (Luxembourg Judge at the European Court of Human rights) – “*The European Convention on Human Rights and the European Union Charter of fundamental Rights – complementary or competing?*”, The Council of Europe's European Convention on Human Rights and the European Union's Charter of fundamental rights: Judges symposium – Luxembourg – 16.09.2002, <http://www.coe.int/T/E/Communication_and_Research/Press/events/6.-Other_events/2002-09_Symposium_of_judges_-_Luxembourg/>, visited on 2002-10-16

deprivation.¹³⁷ What is however of the biggest importance for this paper, is the explicit inclusion of the protection of the intellectual property in paragraph 2 of article 17 of the Charter. Why? Because of its growing importance and Community secondary legislation as we read in the annotations to the Charter. But there are also other, more important grounds for that i.e. the fact that ECHR standard was found to be insufficient in view of the development of Community and national laws..

Though the Commentary attached to the article 17 states that the guarantees laid down in paragraph 1 of article 17 (referring to property in general) shall apply as appropriate to intellectual property, this would not be enough to protect the full scope of intellectual property rights. Though the European Court of Human Rights confirmed in its case-law that the guarantee of the right to property, whether movable or immovable, is not confined to tangible property in a private law sense¹³⁸, but includes all vested rights, **including intellectual property rights**¹³⁹. However the point of departure still appears to be **the economic value of the right**¹⁴⁰, which means that as long as the economic value of property rights is not affected, no responsibility under Article 1 is engaged.¹⁴¹ Whereas, as we know, the rights attached to intellectual property include not only economic but also moral rights, which allow the author to take certain actions to preserve the personal link between himself and the work (for example recognition of the authorship).

The EU, particularly in accordance to the comments to the Charter, correctly understands the term of intellectual property as to cover literary and artistic property as well as patent and trademark rights and associated rights. Its secondary law encompasses both the material and moral aspects of the intellectual property. It would be strange if intellectual property rights, recognized in their full scope within business oriented intellectual property regime of secondary legislation, were to be interpreted in respect to one human rights document – the ChFR – differently.

¹³⁷ van Banning, Theo R.G. - *The Human Right to Property*, School of Human Rights Research Series, Vol. 14, Intersentia, Antwerpen – Oxford – New York, 2002

¹³⁸ The Court confirmed i.a. in the *Gasus Dosier- und Födertechnik GmbH case* judgment, that the notion of „possessions’ has an autonomous meaning which is not limited to ownership of physical goods: certain other rights and interests constituting assets can also be regarded as property rights and thus as „possessions“.

¹³⁹ See: Peukert, Wolfgang – *Artikel 1 des 1 ZP (Schutz des Eigentums)*, in: Frowein, Jochen Abr./Peukert, Wolfgang – *EMKR Kommentar*, 2nd ed., 1996, para. 6, together with note 19; Decision of the European Commission of Human Rights of 4 October 1990, *Smith Kline and French Laboratories Ltd vs. Netherlands*, Application No. 12633/87: “*The Commission finds that a patent accordingly falls within the scope of the term “possessions” in Article 1 of Protocol No. 1*”.

¹⁴⁰ Eur. Court H.R., *Case of Van Marle and Others*, Judgment of 26 June 1986, Series A, No. 191, para. 41; See also: Peukert, Wolfgang, *op.cit.*;

¹⁴¹ Van Dijk, P. and Van Hoof, G.J.H, *Theory and Practice of the European Convention of Human Rights*, 3rd ed. (1998), Hague, pp. 618 – 623; That means also that the object of the possessions must be adequately definable in relation to the claims based thereupon.

As the protection of a full scope of intellectual property rights by referring just to ECHR seems impossible¹⁴², the question arises, how shall we interpret the very laconic provision - “*intellectual property shall be protected*”.

According to the official commentary to the Charter, we can use reference to guarantees laid down in paragraph 1 of article 17. On this basis, one could argue that despite the impersonal language of article 17 paragraph 2, everybody shall be able to enjoy ‘exclusive rights’ in its intellectual creation - one’s intellectual property, subject however to the legally recognized rights and interests of others, or generally speaking public/general interest, for example enjoyment of particular right can be made conditional on registration; certain usage envisaged by the creator can be prohibited on the grounds of public security. There is no doubt that certain measures provided for by the State restricts the use of the property in this regard. The third sentence of paragraph 1 of article 17 provides an important indication in so far as it recognizes the right of a State to regulate the use of property by law “*insofar as is necessary for the general interest*”. This corresponds to the second paragraph of article 1 of the Protocol No. 1, which as was already mentioned allows State “*to enforce such laws as it deems necessary to control the use of property in accordance with the general interest*”. Thus both the ChFR and Protocol No. 1 to the ECHR accept in principle the legality of restrictions and give the national authorities an almost unlimited power to impose them upon the use of property. Yes, they both provide that restrictions are allowed to the extent to which they are deemed “*necessary*” by a State for the protection of the “*general interest*”, but is it a real limitation taking into regard the margin of appreciation?

Before trying to delineate the line between the general interest and individual right to intellectual property as a human right, I would like to point out that though both the ChFR and Protocol No. 1 to the ECHR provide that the restriction on the right to property must be necessary, there is no such requirement with respect to the expropriation itself. On the other hand, deprivation of the property requires compensation, whereas there is no such requirement in case of a restriction on a right. However due to the limited size of this paper, I will concentrate on the restrictions rather than deprivation, as in my opinion they are much more relevant in case of intellectual property rights.

Necessity

As for the margin of appreciation in respect to *necessity*, the jurisprudence of the European Court of Human Rights indicates that the measure undertaken by the State to limit the enjoyment of the right to property must be proportional, both as concerns enforcement measures and the underlying

¹⁴² Though I could imagine that to some limited extent certain moral rights could be protected under other provisions of ECHR, for example, the right to respect for private and family life, freedom of expression.

legislation.¹⁴³ This is because “this provision is to be construed in the light of the general principle enunciated in the first sentence of the first paragraph” and therefore there “*must exist a reasonable relationship of proportionality between the means employed and the aim sought to be realized*” by the regulatory legislation.¹⁴⁴ Taking into account that the EU included the provision concerning restrictions on the right to property with just small changes, we can say with almost 100% certainty that it will also follow the interpretation of the Eur. Court of H.R. in trying to strike a balance required between the general interest of the community and the requirements of the protection of the individual’s fundamental rights. Additionally, the fact that in article 17 ChFR we do not find the words ‘if (State) deems necessary’ but barely that regulation of the use is allowed ‘insofar is necessary’ might also have slight but positive impact on the interpretation, as it moves the necessity from the subjective sphere of the State discretion, onto more objective grounds, thus recognizing the Courts interpretation.

Despite all of the above, given the flexibility of the criterion and the wide margin of appreciation, it will not be easy to determine if the fair balance is achieved. Particularly as the Eur. Court of H.R. itself recognized in the *Mellacher and Others case* that in the pursuance of social policies, the States are entitled even to take measures which affect existing contracts.¹⁴⁵ Would the Court go so far if it was the public health policy?¹⁴⁶

General interest

In spite of the importance attached to human rights, there are situations where it is considered legitimate to restrict rights in order to achieve a broader general interest or public good as some instruments name it. As the ICCPR puts it, the *public good* can take precedence to “*secure due recognition and respect for the rights and freedoms of others, meet the just requirements of*

¹⁴³ Fair balance test: *Allan Jacobsson case*, Judgment of 25 October 1989, Series A, No. 163, p. 17; *Fredin case*, Judgment of 18 February 1991, Series A, No. 192, p. 17; *Mellacher and Others case*, Judgment of 19 December 1989, Series A, No. 169, p. 27; For commentary see: Van Dijk, P. and Van Hoof, G.J.H – *Theory and Practice of the European Convention of Human Rights*, 3rd ed. (1998), Hague

¹⁴⁴ *Allan Jacobsson case*, Judgment of 25 October 1989, Series A, No. 163, p. 17

¹⁴⁵ *Mellacher and Others case*, Judgment of 19 December 1989, Series A, No. 169, p. 27

“*In remedial social legislation and in particular in the field of rent control, it must be open to the legislature to take measures affecting the further execution of previously concluded contracts in order to attain the aim of the policy adopted.*”; see also: Van Dijk, P. and Van Hoof, G.J.H – *Theory and Practice of the European Convention of Human Rights*, 3rd ed. (1998), Hague, p. 639

¹⁴⁶ Let’s assume now that we are owner of the patent on drug Y and we just granted an exclusive license on manufacturing and distributing of our drug to company X. Now the State decided that for public health reasons (which are just as important), due to the shortages of supply of the medicine and limited funding, it will grant compulsory license on the drug. We cannot do much about it, but the company X who hoped for big profits when applying for the license, wants us to pay her the compensation in the amount equal to the losses it will occur due to the competition with the beneficent of the compulsory license.

morality, public order, and the general welfare, and in times of emergency, when there are threats to the vital interests of the nation".¹⁴⁷

How to define the "general interest" in relation to Intellectual Property – the ECHR gives just part guidance. The Strasbourg court has stated that "it will respect the legislature's judgment as to what is in the general interest unless that judgment be manifestly without reasonable foundation"¹⁴⁸. Thus a number of aims have been considered to be in the general interest, like social and economic policy aims in the fields of housing, alcohol consumption, protection of nature and of the environment, fight against drugs trafficking to name just a few.¹⁴⁹ Surely the Court would recognize Public Health as belonging to the 'general interest', being a 'public good'.

The question is, if it would recognize the protection of intellectual property understood as human right to be in the general interest, and thus not allow for its limitations? What is the 'general interest' in this case, taking into account the very nature and implicit balance of the intellectual property regime, which aims on one side at protecting the creation and ensuring incentive for the further developments and creativity, while on the other makes sure that the creation will come to the public domain thus contributing to the common heritage that everybody can built upon?

The ECHR, which has special significance in this respect of clarifying and establishing the existence and scope of the fundamental rights is not very helpful here. However, as the ECJ held in *ERT case*, *Hauer case* and in *Opinion 2/94*, the Court can also "draw inspiration from the constitutional traditions common to the Member States and **from guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories**".

Taking into account the fact that the concept which we want to fully clarify from the human rights point of view – *intellectual property*, there is no doubt that we should refer in the first place to the UDHR and the ICESCR.

Member states not only were significantly involved in the drafting of those two acts, but additionally all Member States are party to the legally binding ICESCR. Additionally, both those documents have been referred endless number of times in various resolutions of the European Parliament, European Commission communications, conclusions of the European Council etc. The EU is consequently also referring to them in connection with human rights clauses, which have been inserted more or less regularly since 1992 in all agreements with third states. It would be strange if the EU, while demanding other countries to comply with the UDHR and the ICESCR standard, would not do it itself. After all, in December 1998 in the *Declaration of the European Union on the Occasion of the 50th Anniversary of the UDHR*, the EU declared that both internally and

¹⁴⁷ article 4 ICCPR

¹⁴⁸ *Mellacher and Others case*, Judgment of 19 December 1989, Series A, No. 169, p. 27

¹⁴⁹ Van Dijk, P. and Van Hoof, G.J.H, *Theory and Practice of the European Convention of Human Rights*, 3rd ed. (1998), Hague, p. 640

externally, respect for human rights as proclaimed in the Universal Declaration is one of the essential components of the activities of the Union and underscored that the implementation of the Universal Declaration and of the other international human rights instruments, is of paramount importance for the universal character of the rights laid down therein to become a reality.

In interpreting intellectual property and its objectives in a manner consistent with the right to intellectual property as found in article 27 of the UDHR and article 15 ICESCR (which builds on UDHR, while making it additionally obligatory for states to undertake steps to the maximum of its available resources to achieve progressively the full realization of the right by all appropriate means, including particularly the adoption of legislative measures¹⁵⁰) the EU could make one more step in this direction, towards the realization of the rights.

What is very characteristic of the UDHR and the ICESCR is that they require States to recognize the right of everyone “*to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author*”, while they indicate that this right has an inherently complementary side according to which “*everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits*”¹⁵¹. Whereas, in contrast to private law intellectual property regimes, they recognize that an author, creator or inventor can be individual as well as a group or a community.¹⁵² To achieve those goals, States are mandated to undertake steps necessary for the conservation, development, and diffusion of science and culture as well as they are directed to undertake to respect the freedom indispensable for scientific research and creative activity.¹⁵³ From a human rights point of view, it is equally important to secure the rights of the author, creator or inventor and the moral interests and rights of the community to securing access to this knowledge. Additionally, human rights aspects, in particularly the human dignity and the realization of other human rights shall be taken into consideration when determining legally the subject matter which can be claimed as intellectual property and the scope of rights to creative works and scientific knowledge.¹⁵⁴

Furthermore, article 27 UDHR must be interpreted in relation to article 22 of the same document, which states that everyone is entitled to realization of the economic, social and cultural rights indispensable for his/her dignity and the

¹⁵⁰ article 2 ICESCR

¹⁵¹ article 27 UDHR

¹⁵² See also: Chapman, Audrey R. – “Approaching Intellectual Property as a Human Right: Obligations Related to Article 15 (1) (c)”. Discussion paper submitted in connection to the Day of General Discussion “*The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15.1 (c) of the Covenant)*” organized by the Committee on Economic, Social and Cultural Rights in cooperation with the WIPO, 27 November 2000, Economic and Social Council, Committee on Economic, Social and Cultural Rights, Twenty-fourth session, Item 3 of the provisional agenda, E/C.12/2000/12, 3 October 2000, p. 10

¹⁵³ article 15 ICESCR

¹⁵⁴ Chapman, Audrey R., *op. cit*

free development of his/her personality as well as in relation to article 4, according to which the State may place limitations as are determined by law on these rights in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.¹⁵⁵ Those provisions have one goal – to ensure that implementation of the human rights postulates adequately reflects not only the fundamental nature but also the indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, etc..

Therefore we can conclude that the ‘*general interest*’ in a human rights sense would require striking the balance between the twin sides of the right to intellectual property as such, while the right to share in scientific advancement and its benefits can be additionally supported by other human rights, for example the right to enjoy the benefits of scientific progress, also in the sphere of medicine science and its applications goes hand in hand with the right to health, which requires the proper access to drugs at the affordable price.

* * *

If the EU wants to avoid conflict between the intellectual property regime in a private law sense and international human rights law, encompassing the slowly emerging EU human rights system, in the form of the Charter, including the right to intellectual property, it should, while implementing the TRIPs Agreement, or revising existing standards or setting up new ones of *sui-generis* type within the EU, protect the social function of intellectual property. This will be easier if it will follow the inbuilt balance in the human rights definition of intellectual property and treat the human rights principles as a guiding principles during the process of shaping or adjustment of the legislation to the new context. It should recognize that the rights of the creator are conditional on contributing to the common good and welfare of the society, as opposite to the current practice of vesting the creators with semi-monopoly property rights, as well as being particularly sensitive to the interconnections between intellectual property rights in their full complexity and other rights, for example right to health, one part of which – access (availability and affordability) to drugs is closely linked to the patent protection granted for pharmaceuticals.

This process would be much easier if the EU developed an adequate process of review to anticipate potential harmful effects resulting from granting intellectual property protection to certain products, creations or processes.¹⁵⁶ Staying with the example of the interaction with the right to health, one could imagine that if such system of review would exist, the EU before implementing the

¹⁵⁵ Adalsteinson, Ragnar and Thorhallson, Pall – “Article 27”, *The Universal Declaration of Human Rights*, Alfredsson, Gudmundur and Eide, Asbjorn (eds.), Kluwer Law International, 1999, pp. 575 - 596

¹⁵⁶ Chapman, Audrey R., *op.cit.*, p. 14

TRIPs standards, would be expected to measure the impact of the introduction of the patents on pharmaceuticals and ensure, using all the flexibility allowed under TRIPs, introduction of such measures as for example compulsory licensing, parallel import, short data exclusivity period, *Bolar* provision, higher standard of novelty to avoid patent *evergreening*¹⁵⁷, or make sure that it refrains from introducing others like for example supplementary protection certificates, in order to limit the negative impact (i.a. higher prices) of new standards as much as possible, while still granting enough protection to give incentives to the creators.

¹⁵⁷ In the conclusions of his analysis in the “Trends in drug patenting. Case Studies”, (Corregidor, Buenos Aires, 2001) Carlos M. Correa stated the following: “There is no question that patents are valuable as a means of rewarding genuinely inventive, occasionally costly R&D activity. However, the analysis made shows how the system is blighted by the granting patents of dubious worth that make a negligible contribution or no contribution at all to technological progress, whose sole purpose is to serve as a barrier to legitimate third-party competition. If governments wish to have a credible and sound patent system, they need to make a considerable effort to define rigorous criteria for patentability, and especially to apply them in a responsible and consistent manner. The examples given also suggest that a substantial part of the R&D budget that pharmaceutical firms claim is devoted to the development of new products is, in reality, allocated to developing a vast array of patents around existing products, with the clear intent of expanding and/or extending over time the exercise of exclusive rights”

5 Moving from law to practice. How the legal balance is reflected in reality?

After analyzing the obligations of the EU in terms of the law and probable developments, it is time to have a closer look at the EU's everyday practice.

5.1 Internal perspective

Unfortunately the EU approach to human rights has a double standard character. As the analysis of the existing primary sources of Community law and their extension by the Treaty of Amsterdam seems to confirm the emergence of human rights as a 'transversal' Community objective, it does not find a reflection in reality. Although the EU supports, for example, UN measures to persuade governments to establish national human rights institutions, it does not have such an institution itself, and it has not even encouraged its own Member States to establish them. In saying this however, it must be noted that in May 1998 it adopted "*Common Position on Human Rights, Democratic Principles, the Rule of Law and Good Governance in Africa*" which proclaimed its objective of working 'in partnership with African countries to promote respect for human rights' and the other stated therein objectives, but it never adopted an equivalent policy which would commit the EU to work actively in Europe in relation to human rights.¹⁵⁸ Most of what we can expect from the EU in human rights terms is included in the European Council's "*Declaration on the occasion of the 50th Anniversary of the Universal Declaration on human rights*" of 10 December 1998 in which the EU merely *reaffirmed the importance* of a reinforced EU capacity to protect and promote human rights. Yes, there is a Charter, but we should not forget that it is not legally binding. All the positive developments aside, the fully fledged human rights internal policy is still lacking.

Additionally, as Philip Alston rightly notices, there is a strong tendency in the great majority of Community documents to focus on 'social policy', designed to promote 'social protection' or overcome 'social exclusion', rather

¹⁵⁸ see: Alston, Philip and Weiler, J.H.H., "An EU Human Rights Policy", *The EU and human rights*, Alston, Philip (ed.), Oxford University Press, p. 15

than focus on 'social rights'.¹⁵⁹ This difference between general social-sector funding and support for economic and social rights, is very significant. The EU would like to be seen as a good 'carer' who takes care of its citizens' social needs, without however, acknowledging their right to have those needs fulfilled and the ability to pursue them in court.

A similar situation is evident in respect to health, partly due to the fact that as "public health measures historically preceded the recognition of human rights, public health law developed without reference to individual rights"¹⁶⁰.

Public Health Policy

Only in 1993 did the Public Health Policy include a legal base (Maastricht Treaty, article 129), and though, as was mentioned earlier, this did not provide for harmonization of laws and regulations, it included such new elements as "contributing to a high level of health", "encouraging co-operation among Member states", "prevention of diseases" and "incentive measures". In order to respond to these new obligations, the Commission presented its "Communication on the Framework for Action in the Field of Public Health" on 24 November 1993. Eight public health programmes¹⁶¹, which were to constitute the key elements of this framework, have been proposed and subsequently established in this context. The added value in the Community's activities was supporting efforts of Member States in their activities, assisting in formulation and implementation of objectives and strategies, and contributing to the continuity of health protection provisions across the Community by dissemination of "best practice information". The framework included work in other areas as well, for example: a strategy on safety of blood and blood products; reports on health status in the EU; reports showing how health requirements are integrated in other Community policies; various studies on health priorities, health systems developments and surveys of public opinion; a strategy and legal instruments dealing with tobacco products (for example: advertising); and establishment of a network for the surveillance and control of communicable diseases.¹⁶² Furthermore annual reports were being prepared on health requirements in other policies, constituting a kind of overview of actions being undertaken in the context of these policies.¹⁶³

¹⁵⁹ For example, 'Social Action Programme 1998-2000, Commission Communication', Doc. COM(98)259 of 29.04.1998

¹⁶⁰ Tomaševski, Katarina, "International law-making for the protection of human and environmental health", in: *Reading material for: Human rights within the EU. VT-02*

¹⁶¹ 1) health promotion, information, education and training; 2) combating cancer; 3) prevention of AIDS and certain other communicable diseases; 4) prevention of drug dependence; 5) health monitoring; 6) injury prevention; 7) rare diseases, and 8) pollution-related diseases.

¹⁶² <http://www.europa.eu.int/comm/health/ph/eu_action/eu_action02_en.html>

¹⁶³ For example, a second modified proposal for a Fifth Framework Programme for Research and Technological Development (1998-2002), one of the priorities of which being the focus of Community's research policy on specific themes such as, in the area of health, the

This framework for action has been reviewed¹⁶⁴ and resulted in the adoption by the Commission on 16 May 2000 of the Communication on the Health Strategy of the European Community¹⁶⁵ (which takes account of the review of the existing situation and recent legal and political developments), and of a proposal for a Decision of the EP and the Council adopting a programme of Community Action in the field of public health.

This communication considered a number of developments in health status and health systems in the Community, as well as principles and prerequisites for public health action at Community level. These considerations lead to the conclusion that, although the principles and underlying philosophy of the 1993 communication on the framework for action in the field of public health remain valid, priorities, structures and methods are all in need of fundamental review and reformulation. Finally, the communication outlines a new Community public health policy six-year programme, which brings together in a more co-ordinated way, the previous activity under eight separate public health programmes, and focuses on:

- Improving information and knowledge for the development of public health,
- enhancing the capability to respond rapidly and in co-ordinated fashion to threats to health (for example through building on the existing communicable disease surveillance network, as well as measures to enhance the safety and quality of human blood and organs),
- Tackling health determinants relating to lifestyle (tobacco, alcohol, drug dependence etc.), socio-economic factors and the environment, through health promotion and disease prevention.¹⁶⁶

The programme¹⁶⁷, which is supposed to complement national policies, shall contribute to:

relationship between health, environment and food, the control of viral diseases, and the ageing population. Equally, the Commission's Joint Research Centre, contributes to the fight against cancer.

¹⁶⁴ There was a need considering how far the existing framework remained satisfactory and was able to respond to a number of important developments, such as emerging health threats and increasing pressures on health systems, as well as the enlargement of the Community and the new public health provisions in the Treaty of Amsterdam. Moreover, such a review was particularly urgent as most of the existing programmes were coming to an end in or about the year 2000 and proposals were have to be put forward in the near future; Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the development of public health policy in the European Community;

<<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm#0>>

¹⁶⁵ Communication from the Commission of 16 May 2000 to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the health strategy of the European Community (COM(2000)285 final)

¹⁶⁶ <<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm>>

¹⁶⁷ The total budget of the programme is 280 million EURO.

- ensuring a high level of health protection in the definition and implementation of all Community policies and activities, through the promotion of an integrated and inter-sectoral health strategy,
- tackling inequalities in health, and
- encouraging co-operation between Member States in the areas covered by article 152 of the Treaty.

Issues relating to enlargement, and to the integration of health requirements in Community policies, are to be dealt with by all three strands.

The most important thing, however, was the politically important Commission's decision to place "Health" as one of its key priorities. The Commission states repeatedly that it is essential to ensure consistency between health and other policies (such as single market, consumer protection, social policy, environment, research, enlargement), and also ensure that all the Community activities affecting health contribute to the overall strategy.

Work in the Commission was ongoing in the following areas:

- the inclusion in proposals with a particular relevance to health of an explanation of how and why health considerations were taken into account and the expected health impact;
- the development within the public health programme of criteria and methodologies for evaluating policy proposals and their implementation, possibly leading to a thorough impact assessment;
- joint strategies and actions in cooperation with other Community agencies; and
- strengthening of the mechanisms internal to the Commission to ensure co-ordination of health-related activities.

Additionally the Commission mentioned in particular the need for joint action to intensify co-operation in sectors such as research, pharmaceuticals and e-health, and recalled the strategy for sustainable development which it had recently adopted.

Adjusting Public Health Policy to include the right to health?

This development would be in line, and would give strength to the "right to health" as found in article 35, if the EU would promote such understanding of its public health policy. However today, the EU, at least in practice is referring to the health protection only within the public health context, and what is more, mostly (though not exclusively) issues constituting preconditions for health. Therefore, even though the EU developed a comprehensive programme and measures to assure certain, one could surely even say - high - level of public health protection within the EU, this does not mean that the EU is promoting the

individual right to health. This unsurprising duality of approach in the internal sphere stems also from the relationship between public health and right to health to the economy. While efficient health protection/care is in the EU interest as it ensures healthy labor force, the provision of the right to health is seen mainly, though not openly admitted, as an economic burden, enforceable in courts.

Surely it is very hard to ensure the dual achievement of the patients access to drugs at affordable prices and the creation of incentives for industry's innovation and industrial development simultaneously, balancing them with Member State's objective of containing their health care expenditure.¹⁶⁸ Member States face a number of common problems related to the financing, organization and management of their health systems. There is an increasing concern to raise overall standards, while at the same time to control health costs and secure the best value for money, due to financial limitations. In parallel, health systems, like other areas of the economy, are affected by the globalization of trade and industry and the pressures of competition, as well as the development of the Community internal market. The various initiatives in the field of managed care and the growth of evidence-based medicine, quality assurance and health technology assessment are all responses to these developments.¹⁶⁹

However, one can get impression that despite its concern for the rising health costs, the EU simultaneously introduces an even higher level of protection to intellectual property, which it still understands in practice in the typical economic private law sense, which is contradictory to the social function, which in turn intellectual property rights should support. It is also quite surprising that there were no coordinated proposals for introducing common measures such as: abbreviated registration procedures (focus on drug quality), product development and authorization during patent period, provisions which permit, encourage or require generic prescription and substitutes, or requirement that labels and drugs information contain generic names; which by increasing the generic drugs participation in the market would lower the cost of public health, thus allowing it to meet more needs at the same cost. No wonder then that as of the mid-1990s, generic dispensing differed greatly among the countries of the EU, spreading between 60% of prescription volume and 30% of sales value in Denmark and as low as 2% of sales value in Belgium, France and Italy, with Germany, the UK and the Netherlands staying somewhere in the middle with 20-40% of prescriptions dispensed generically. The wide variation in generic dispensing among these countries – which are generally able to ensure the quality of generic products – illustrates the impact which national policies and different local circumstances can have on generic use, and indicates how much influence the EU directive requiring the introduction of the generic drugs friendly solutions could have.¹⁷⁰

¹⁶⁸ The single market in pharmaceuticals,

<<http://europa.eu.int/scadplus/leg/en/lvb/121227.htm>>, 2002-04-26

¹⁶⁹ <<http://www.europa.eu.int/comm/health/ph/general/phpolicy2.htm#2>>, 2002-04-27

¹⁷⁰ WHO, Action Programme on Essential Drugs, *Public-Private role in the Pharmaceutical sector. Implications for equitable access and rational drug use*, Health Economics and Drugs, DAP series No. 5, WHO/DAP/97.12, p. 55

It is hard to expect the EU, despite the new trends having surfaced in the Charter of the Fundamental Rights (article 35), to look at health through a human rights lens. It would mean, the EU recognizing not only the technical and operational aspects of health interventions, but also the civil, economic, social and cultural factors that surround them, whereas in reality, the traditional public health approach, in the form of Public Health Policy, still prevails. Surely EU Public Health Policy names protecting and improving health as one of its priorities. After all, both public health and human rights both recognize the ultimate responsibility of governments to create the enabling conditions necessary for people to make and effectuate choices, cope with changing patterns of vulnerability, and keep themselves and their families healthy. However, using human rights concepts, one can look at the extent to which governments are “respecting, protecting and fulfilling their obligations for all rights – civil, political, economic, social and cultural – and how these governments actions influence both the patterns of mortality, morbidity and disability within the population, and what is done about them”.¹⁷¹ One can also, in the case of finding a government neglecting or infringing its obligations, try to bring it back into compliance by filing a case in the human rights court or other monitoring body. This is exactly what the public health lacks - the possibility of taking the Community or Member states to Court for introducing, for example, intellectual property protection measures that are contrary to the very concept of the right to health.

5.2 External relations of the EU

External relations of the EU are even more influenced by the clash of moral ambitions and economic interests than its internal affairs.¹⁷² On the one hand, European integration has promoted economic freedom while leaving social rights and policies in a secondary position, while on the other hand, it has also been often perceived as a safeguard of the welfare state. It is also argued that European integration gives a stronger voice of the European States in shaping the rules of global economic competition and protecting the ‘essentials’ of the welfare state.¹⁷³ Let us have a closer look at these issues.

¹⁷¹ Gruskin, Sofia and Tarantola, Daniel, “Health and Human Rights”, *The Oxford Textbook of Public Health*, Detels, Roger; McEvan, James; Beaglehole, Robert and Tanaka, Heizo (eds.), 4th Edition, Oxford University Press, 2002

¹⁷² For example, position in TRIPS as well as Doha and Post-Doha negotiations, position in negotiations with accession countries, EU policy vis-à-vis the former Yugoslavia, dispute between Member States over EU resolution on human rights abuses in China during the 1997 session of the UN Commission on Human Rights.

¹⁷³ Maduro, Miguel Poyares, “Striking the Elusive Balance between Economic freedom and Social Rights in the EU”, *The EU and Human Rights*, Alston, Philip (ed.), Oxford University Press, p. 449

By virtue of article 6 (2) TEU, the EU¹⁷⁴ is bound to respect human rights in external relations.¹⁷⁵ Indeed, since the 1970s, the EC organs, even without any explicit legal basis, applied human rights in the framework of the European Political Cooperation in their relations to the third States. This legal basis is explicitly laid down in article 11 (1) TEU (previously article J.1 (2) of the Maastricht Treaty), which states that the development of respect for human rights and fundamental freedoms constitutes one of the five objectives of the Common Foreign and Security Policy (CFSP).¹⁷⁶ As for the right to health specifically, article 152 of the Treaty establishing the European Community stipulates that “a *high level of human health protection*” shall be ensured in “the definition and implementation of all Community policies and activities”. The European Union is also bound by its own declarations on respect for human rights which, according to the *Declaration on Human Rights*¹⁷⁷, are an essential part of its international relations and a cornerstone of European co-operation. On 28 November 1991, the Council and the representatives of the Member States meeting within the Council adopted a *Resolution on human right, democracy and development* laying down the guidelines, procedures and priorities for improving the consistency and cohesion of the whole range of development initiatives.¹⁷⁸

However the relevance of human rights for the external policies of the EU, extends beyond the CFSP. In addition to article 177 TEC (previously 130u), which provides that Community policy in the area of development co-operation shall contribute to the general objective of respecting human rights and fundamental freedoms, the EC framework of the ‘first pillar’ developed an external human rights policy by, inter alia, insisting on the insertion of specific human rights clauses in all agreements concluded with third countries.¹⁷⁹

Since the early 1990s, the EC has included a so-called “*human rights clause*” more or less systematically in its bilateral trade and cooperation agreements with third countries, and since the Council decision of May 1995, based on the initiative of the Commission¹⁸⁰, which the European Parliament

¹⁷⁴ *Op. cit.* (3)

¹⁷⁵ Even though the ECJ has no jurisdiction to review EU measures adopted in the context of the ‘second pillar’, there is no doubt that the common provision of Article 6 TEU binds the Union in all actions, including external relations. See also: Nowak, Manfred, “Human Rights Conditionality in the EU”; *The EU and Human Rights*, Alston, Philip (ed.), Oxford University Press, p. 688

¹⁷⁶ Main legal instruments of the EU within the CFSP are common strategies, common positions and joint actions (articles 13-15 of the TEU).

¹⁷⁷ It was adopted at the Luxembourg European Council on 28-29 June 1991.

¹⁷⁸ <www.europa.eu.int/comm/external_relations/human_rights/doc/cr28_11_91_en.htm>

¹⁷⁹ Nowak, Manfred, “Human Rights Conditionality in the EU”; *The EU and Human Rights*, Alston, Philip (ed.), Oxford University Press, p. 688 et seq.; See also: *Communication from the Commission to the Council and the European Parliament. The European Union’s role in promoting human rights and democratization in Third countries*, Brussels, 8.05.2001, COM(2001)252 final

¹⁸⁰ Communication from the Commission on the inclusion of respect for democratic principles and human rights in agreements between the Community and Third Countries (COM/95/216 FINAL); See also: Commission communication on the European Union’s role in promoting human rights and democratization in third countries of 8 May 2001 and General

wholeheartedly welcomed seeing it as “further step towards the adoption of practical measures to implement the EU’s human rights policy”¹⁸¹, in virtually ALL subsequently negotiated bilateral agreements of a general nature (excluding sectoral agreements). More than twenty such agreements have already been signed, including Association Agreements such as the Europe Agreements, Mediterranean Agreements and the Cotonou Agreement between the EU and Africa, Caribbean and Pacific countries.¹⁸²

The agreement model consists of a provision stipulating that respect for fundamental human rights and democratic principles as laid down in the UDHR (or in European Context, also the Helsinki Final Act and the Paris Charter for a New Europe) inspire internal and external policies of the parties and constitute an “essential element”¹⁸³ of the agreement, which sets up the right of the Community to *suspend or terminate* an agreement for reasons connected with non-respect of human rights by the third country concerned.

The clause does not transform the basic nature of agreements which are otherwise concerned with matters not directly related to the promotion of human rights. Neither does it imply the enactment of rules on human rights or the conclusion of specific human rights conventions establishing new standards in the international protection of HR in the sense in which these expressions were used by the ECJ in *Opinion 2/94*¹⁸⁴. It is a matter of treaty law, which does not depend on which view is taken on the potential of article 235 to serve as an enabling clause for human rights standard-setting.¹⁸⁵ The clause simply constitutes

Affairs Council (GAC) detailed conclusions issued On 25 June 2001 in response to it as well as the EU Annual Report on Human Rights (2001/2002), 12747/1/02 Rev. 1 COHOM 11, 16 Oct. 2002.

¹⁸¹ European Parliament Resolution on the Communication from the Commission on the inclusion of respect for democratic principles and human rights in agreements between the Community and Third Countries (COM(95)0216 – C4-0197/95) Official Journal C 320, 28/10/1996 p. 0261.

¹⁸² The EU and Human Rights, <<http://www.europa-eu-un.org/article.asp?id=1007>>, last visited on 2002-11-03

¹⁸³ A final provision dealing with non-execution of the agreement requires each part to consult the other before taking measures, save in cases of special urgency, which encompass breaches of an “essential element” of the agreement. Thanks to such solution “suspension or termination can thus take place, in a manner consistent with the rules of customary international law codified in the Vienna Conventions on the Law of Treaties (to which the EC is not formally a contracting party), without, however, the need to follow all the procedural requirements (and, in particular, the notification requirements) laid down in the Conventions. Before the human rights clause, the EC had to rely on general international law to suspend an agreement, as happened with regard to Ex-Yugoslavia in 1991”. See: Brandtner, Barbara and Rosas, Allan, “Human Rights and the External Relations of the European Community: An Analysis of Doctrine and Practice”, *EJIL* Vol. 9 (1998) No. 3; <<http://www.ejil.org/journal/Vol9/No3/art2.html>>, accessed on 2002-10-25

¹⁸⁴ ECJ *Opinion 2/94* on the Accession by the Communities to the ECHR [1996] ECR I-1759; see also: Arnall, Anthony, “Left to its own devices? Opinion 2/94 and the Protection of fundamental rights in the European Union”, *The General Law of E.C. External Relations*, Dashwood, Alan and Hillion, Christophe (eds.), Sweet & Maxwell, London 2000, pp. 61-78

¹⁸⁵ Brandtner, Barbara and Rosas, Allan, “Human Rights and the External Relations of the European Community: An Analysis of Doctrine and Practice”, *EJIL* Vol. 9 (1998) No. 3; <<http://www.ejil.org/journal/Vol9/No3/art2.html>>, last visited on 2002-10-25

a mutual reaffirmation of commonly shared values and principles - a precondition for economic and other cooperation under the agreements, and expressly allows for and regulates suspension/termination in case of non-compliance with these values.¹⁸⁶

The basic term of reference is the UDHR - resolution of the UN General Assembly and not a legally binding document as such. However it has become “increasingly accepted that the UDHR is not only of exceptional historical and political importance, but also reflects, at least at the level of general principles, existing general international law, whether seen as customary international law or as general principles of law recognized by civilized nations. In fact the EC’s treaty practice since the early 1990s refers to ‘democratic principles and basic human rights, as proclaimed in the Universal Declaration’. This is accepted by an increasing number of third countries via bilateral agreements and contributes to the creation of an presumption that the UDHR expresses customary international law, or at least general principles of law recognized by civilized nations.

The EU, being *founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms*¹⁸⁷ found it also important to include respect for human rights among principles listed in article 49 TEU as a precondition for accession of Candidate Countries to the EU. However, competence of the ECJ to review the human rights ‘conditionality’ in the accession penal sanctions procedures is currently very limited and unclear. As a point of note, in Agenda 2000¹⁸⁸ the Commission made reference to the compliance of applicant States to the ESC and the ICESCR, although minimum attention was actually devoted to the relevant rights.

Human rights observance may be also linked to *autonomous* acts of secondary Community legislation, like for example the Community’s unilateral scheme of Generalized Tariff Preferences, as set up in Regulation No. 3281/94 and No. 1256/96 in respect for certain industrial and agricultural products originating in developing countries, probably containing the Community’s most extensive set of actions related to third countries’ respect for (or neglect of) fundamental labor standards to date.

Still, it can be noticed that the actual practice of the EU in applying a policy of human rights ‘conditionality’ towards third countries remains somewhat selective and is often based on economic and political, rather than on purely legal or ethical grounds. Such ‘two-tier’ approach perhaps not very visible in the bilateral agreements, is easily seen in the EU policies and actions related to health and protection of pharmaceutical products, what often requires making a choice between economic interest and certain human rights: the right to health or the right to life being the most obvious ones.

¹⁸⁶ See also: the *Portugal vs. Council* (1996) case in which the ECJ observed that an important function of the human rights clause could be to secure the right to suspend or terminate an agreement if the third state had not respected human rights.

¹⁸⁷ Article 6 (ex Article F) TEU

¹⁸⁸ Commission of the European Communities, Agenda 2000, COM (97) 2000 final, 2 vols.

As was signaled above, the main reason why the right to health (concept usually associated with country's own population) came into scope in relation to external policy, was mainly its economic connotation, which increasingly gains in importance – even if we take into account, for example, only the fact that in recent decades new medical developments have been introduced at unprecedented rates, their impact being a major factor in rising costs. Trend that does not seem to change.

The issue of health, or more precisely individuals' health and public health implications of trade, received a great deal of attention just before the WTO Ministerial in Seattle (December 1999). The discussion was triggered by concerns that the compulsory licensing rules of the WTO TRIPs Agreement could hinder the development of policies to give patients in developing countries access to appropriate medicines for serious diseases, AIDS being at the center of the discussion. Subsequent analysis showed that the problem of access to health in developing countries is much more serious, and much more complicated. It can furthermore have an effect on the health of the Community population¹⁸⁹, which on the EU level, led the Commission, the Council and other interested parties to take a broad multidisciplinary approach to the problem, and combine their development, trade and humanitarian aid policies with steps leading to increased flexibility of respective (mostly TRIPs) provisions within the WTO framework, (as different from the disease-specific approach which dominated in the earlier programmes).¹⁹⁰

No other issue has received as much attention in post-Seattle Commission debate with business, NGOs and other interested parties, as health, or rather its difficult relation with intellectual property protection standards. In fact, in April 2000, DG Trade set up four issues groups: among them one on access to health and one on environment and sustainable development. Indeed, those two were put very high up on the agenda of the Commission, also due to the enormous public campaign at that time.¹⁹¹

The EU started to address health issues also within the Development¹⁹² and Poverty Eradication Policy¹⁹³, as well as strengthening the initiatives aiming at

¹⁸⁹ Also due to the increase in travel and in population mobility.

¹⁹⁰ The current broad strategy of the Commission for Action on HIV/AIDS, malaria and tuberculosis, which pursues to tackle the problem from all angles thus involving the directorates responsible for Development, Health and Research, as well as Trade, is a good example of such approach. What is also important, the Commission's Programme includes a commitment to working with the WHO, WIPO and WTO to address the link between TRIPs and health issues.

¹⁹¹ NGO dialogue: Introductory remarks by Commissioner Pascal Lamy, General Meeting, 23.11.2000, <http://europa.eu.int/comm/trade/speeches_Articles/spla39_en.htm>, 23/03/2002

¹⁹² Declaration of the Council and the Commission of 20 November 2000 on the European Community's development policy, based on the Communication from the Commission to the Council and the European Parliament of 26 April 2000 on the same subject; <www.europa.eu.int/scadplus/leg/en/lvb/r12001.htm>

¹⁹³ The principal aim of the Community's development policy being the reduction of poverty with a view to its eventual eradication, which finds its reflection in the fact that the resources available for development aid (EU provides half of all public aid to the developing countries and is one of their main trading partners in many cases) are allocated in

global epidemiological surveillance and mechanisms to respond rapidly to health threats and to help developing countries to improve their health systems. Why? It is not only the obligation to take health¹⁹⁴ into consideration when designing and implementing other policies, or to “ensure the consistency of its external activities as a whole in the context of its external relations, security, economic and development policies”¹⁹⁵. Predominantly it is the understanding of the fact that “poverty is an important reason that the babies are not vaccinated, clean water and sanitation are not provided, drugs and other treatments are unavailable, and mothers die in childbirth. (...) Health has become a more central concern in development, both as a contributor to, and an indicator of, sustainable development. While health is a value in its own right, it is also key to productivity”¹⁹⁶. The only effective way to improve health conditions is to improve the overall standard of living. Even if it is the poor health that continues to be a constraint on development efforts.

5.2.1 Intellectual property and health related aspects of the EU external policy in relations with Developing Countries

When talking about relations with developing countries, it is worth mentioning that human rights issues, among them health concerns, were treated as part of economic co-operation or as an aspect of EU (sustainable) development assistance and policy.¹⁹⁷ Such an early inclusion of the need to complement market access and rule-making with efforts directed at areas such as trade related aid, poverty reduction and access to medicines under the heading of promotion of a development agenda, which was among key objectives for the WTO New

accordance with their impact on the reduction of poverty (which gives the least developed countries priority). Poverty, which includes the concept of vulnerability, results from various factors. Therefore, the Community is determined to support poverty reduction strategies which integrate these many dimensions and are based on the analysis of constraints and opportunities in individual developing countries.

¹⁹⁴ Please refer to the chapter on the right to health in EU.

¹⁹⁵ Article 3 (ex Article C) of the Treaty on European Union.

¹⁹⁶ UN report “Health and Sustainable Development”, 4 April 2001.

If one thinks of poverty only as low income, then the health link is indirect: it is easier to earn a living and alleviate poverty when one is in good health. On the other hand, if we think of poverty as basic deprivation of the quality of life and of elementary freedoms, then ill health is an aspect of poverty. Bad health is *constitutive* of poverty.

¹⁹⁷ Development policy was already launched in 1958, but it was not until the Maastricht Treaty that the explicit legal basis for conducting such policy was created. Currently the EU and its Member States together provide more than half of all development assistance given in the world today (European Commission, Directorate-General for development – Understanding European Community Aid (1997), 1), out of which however only 10,5% is allocated to the social sector (10,5% of project aid between 1990-1995: ADE final report, Evaluation of EU Aid to ACP Countries managed by the Commission, Phase I (July 1997), 20). See also: Macleod, I., Hendry I. D. and Hyett S., *The External Relations of the European Communities, A Manual of Law and Practice*, Clarendon Press, Oxford, 1996, p. 307 et seq.

Round, seems to indicate that the EU takes a serious approach to these issues.¹⁹⁸ Particularly because, at the same time the EU stresses such new issues as environmental considerations and consumer protection, and argues that sustainable economic development cannot be achieved without paying attention to the effects of globalization on the environment and on public health.¹⁹⁹

The beginnings of the Community's development policy date from the signature of the Treaty of Rome. However it is only since the TEU came into force in 1993, that Community development cooperation, aimed at encouraging sustainable development that helps to eradicate poverty in developing countries and integrate these countries into the global economy, as well at helping to reinforce democracy and the rule of law whilst promoting respect for human rights and basic freedoms, has enjoyed a specific legal basis (articles 177 and 181 of the Treaty). This was achieved among other ways through insertion of the "human rights clause" mentioned above into the relevant agreements.

The development policy is either convention-based²⁰⁰ or unilateral, and the appropriations for development cooperation are granted according to two main approaches: a "geographical approach" centered on 3 zones (Mediterranean basin, Asia and Latin America, southern Africa) and a "thematic approach", using specific budget headings (the beneficiaries of this approach are all around the world, including ACP countries). Under the convention based system, the Cotonou Agreement (successor of the Lomé IV, which expired on 29 February 2000), based on 5 pillars – poverty reduction among them²⁰¹, is worth mentioning. As for the thematic approach our specific attention is required towards chapters devoted to sustainable development and the environment, water, food security and foremost health.²⁰²

¹⁹⁸ Issues: Towards a New Trade Round, October 2001, <<http://trade-info.cec.eu.int/europa/2001newround/nr.pdf>>

¹⁹⁹ European Trade Commissioner Pascal Lamy replies, Issues, op.cit.; see also: The non-trade impacts of Trade Policy – Asking Questions, seeking Sustainable Development, Informal Discussion Paper Rev. 1, DG Trade, 8.01.2001, <http://europa.eu.int/comm/trade/pdf/csc_idp.pdf>, 23/03/2002

²⁰⁰ The convention-based system related to the conclusion of international agreements, in particular the association agreements referred to in Article 310 of the TEC. These agreements are either multilateral (for example, the Lomé Conventions, Cotonou Convention) or bilateral (each of the Maghreb countries). The unilateral system is based on – Article 133 of the TEC, which governs the common commercial policy, the basis of the Generalized System of Preferences (GSP), designed as a way to facilitate access to the Community market for products from developing countries.

- Article 308, which allows the Community to develop financial and technical aid for Asian and Latin American countries, and thematic actions in areas such as food aid, humanitarian aid or the fight against AIDS.

²⁰¹ Other pillars: ongoing political dialogue, involvement of civil society, a new trade framework, a reform of financial cooperation.

²⁰² Within this sector we encounter:

- Programme of action on accelerated action against HIV/AIDS, malaria and tuberculosis (its objective being a coherent, global and accelerated action as part of the efforts to improve the standard of health amongst the world's poorest people with a view tackling the three major communicable diseases holding up development²⁰², through optimizing the impact of existing assistance in the context of Community development cooperation, through making

It is quite easy to formulate a bold programme, but much harder to implement it and really 'hold on to it' when involved in negotiations on other treaties. However one has to admit that this time the EU really kept its word and became an advocate for developing countries when it comes (among other points) to making essential medicines more affordable through a comprehensive global approach.

As indicated in the introduction, I will try to illustrate the EU approach in the context of the interaction of the right to health and industrial property system, paying particular attention to patents²⁰³. Protection granted by them is subject to strong controversies as it has implications on areas as sensitive as health and man's quality of life. Patent protection is a crucial instrument in the development of the pharmaceutical industry, which depends to a large extent on costly research and development programmes, the results of which being relatively easy to copy and thus making protection of the inventions more necessary than in other areas of industry. Patent systems, however, though enhancing innovation and development of new drugs, do restrict access to life-saving drugs, by raising the price of medicines, and thus, all else being equal, generally adversely affects on the health of the population of poorer states.²⁰⁴ This consequence of patent protection is inseparably linked to the exclusivity of it, which allows companies to impose extremely high prices on their products, which aim not only at cost-coverage but also at unreasonably high income, thanks to which, pharmaceuticals became the second largest by market value industry sector in the world.²⁰⁵

TNCs argue of course that a high price is a result of a need to recover the money invested in R&D, as well as the fact that the production, is found in countries where costs are relatively high. They try to indicate that being granted proper protection, they would be more eager to either move their production to 'lower production cost' countries or license their patents to developing countries.

essential medicines more affordable through a comprehensive global approach, through investing in research and development of global public goods used in the fight against the three diseases);

- Accelerated action targeted at major communicable diseases;
- Solidarity to confront AIDS - HIV/AIDS-related operations in developing countries (its objective being to formalize ongoing structural support to developing countries in their efforts to combat HIV/AIDS - Council Regulation (EC) No 550/97 of 24 March 1997 on HIV/AIDS-related operations in developing countries).

²⁰³ Patent – a title conferred by the State that attest the grant of exclusive rights to the inventor for the exploitation of his invention, which is supposed to serve as the reward or inducement that the state grants the inventor for his contribution to the solution of a problem in technology or industry. In return the inventor has to describe the invention clearly and in detail, so as to allow others, after the term of protection expires, to make use of it without the need of repeating its development phase or additional cost.

²⁰⁴ Drahos, Peter, "The universality of intellectual property rights: origins and development", *Intellectual Property and Human Rights*, WIPO/OUNHCHR panel discussion to commemorate the 50th Anniversary of the UDHR. Geneva, November 9, 1998, p. 27

²⁰⁵ Overtaking telecommunications and IT hardware and thus rising from fourth place last year according to 2002 FT 500 survey.: Financial Times, 10.05.2002, <<http://specials.ft.com/ft500/may2002/index.html>> <<http://globalarchive.ft.com/globalarchive/article.html?id=020509007571&query=FT500>>, visited on 11.05.2002

However, an OECD survey of international technology licensing named limited or unsatisfactory protection of industrial property rights as a significant hindrance to licensing in developing countries.²⁰⁶ “Stronger IPRs are also seen as a vehicle to promote economic development and developing countries alike, by improving both the stock of technological knowledge and the flow of that knowledge between countries. In this respect economic analysis has suggested a direct link between tighter IP protection and increased innovative activity, including through FDI and technology flows. This link rests on the assumption that the legal protection of intellectual property provides a necessary financial incentive for the investment of resources in technological innovation, and a means to ensure the efficient disclosure of new knowledge, thereby augmenting the socio-economic welfare of the wider community”²⁰⁷. This is also supported by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its paper on “The Importance of TRIPS Implementation” addressed to the U.S. Trade Representative for Services, Investment & Intellectual Property. It argues that “minimum international standards for intellectual property protection are part of the rule of law fabric essential to attract the foreign direct investment and technology transfer needed for sustainable economic growth”²⁰⁸. But is it really so?

Available evidence suggests that most R&D activity undertaken by TNCs continues to be highly concentrated in their countries of origin or in other industrialized countries, particularly in high-technology fields. Even substantial changes in IP protection, if they are not supported by more encompassing reforms and/or incentive creating programmes, are unlikely to change this situation. There are many other factors which have impact on FDI decisions and technology transfer: the economies of the scale associated with R&D activities, as well as other factors, such as the importance of proximity to scientific institutions and the new modalities of organization of R&D in closer connection with productive and marketing activities (the so-called third generation R&D). Predominantly it is due to them that in all these respects, any tendency to decentralize R&D activities will occur primarily among the industrialized countries themselves. Of course, there are also many examples of FDI in developing countries. However, in many of these cases the reason behind such, was not as altruistic as it may seem at first glance: R&D investment in such countries often aims at identifying and obtaining access to specific natural resources not available

²⁰⁶ OECD – International technology licensing: survey results; Paris, OECD, 1987, pp. 32 and 40

²⁰⁷ UN – *Transnational Corporations and Management Division*, Department of Economic and Social Development – Intellectual Property Rights and Foreign Direct Investment, NY 1993, p. 23

²⁰⁸ <<http://www.phrma.org/intnatl/news/2002-02-22.46.pdf>>, p. 8

at home.²⁰⁹ Only in few cases, the R&D into the diseases which mainly afflict the poor in developing countries, with limited purchasing power, was the goal.²¹⁰

Taking all the aspects mentioned above into account when analyzing the EU position *vis á vis* problems faced by developing countries²¹¹, it seems that when it concerns the interpretation of TRIPS, the EU is really in favor of such an understanding of this agreement that would allow developing countries and least-developed countries to adapt their intellectual property law to their (health) policy objectives.

It is of major importance, particularly if we consider the financial aspect of the implementation of the TRIPs Agreement, and the fact that it will result in dramatic rise of drug prices in many regions of the world.²¹² Starting from the assumption that the TRIPs Agreement can be implemented in ways that meet the WTO Members' public health objectives, as well as the rights of pharmaceutical companies, the EU is putting quite a lot of effort in order to have this approach accepted by all the interested parties. The EU continues to address this issue within international organizations, in particular the WTO.²¹³ During the Doha WTO Ministerial²¹⁴ the EU took the role of a rather honest broker on access to medicines, resulting in a separate *Ministerial Declaration on TRIPs and Public Health*, which seems to meet the long-term interests of all parties and reinforce the balance of rights and interests that exist in TRIPs (by promoting both access to existing medicines and the creation of new medicines). States not only confirmed that the TRIPs Agreement "*does not and should not*" prevent Members from taking measures to protect public health, and reiterated their commitment to the TRIPs Agreement, but also affirmed that the Agreement "*can and should be interpreted and implemented in a manner supportive of WTO member's right to protect public health and, in particular, to promote*

²⁰⁹ For more see: UN – Transnational Corporations and Management Division, Department of Economic and Social Development – Intellectual Property Rights and Foreign Direct Investment, NY 1993, p. 6

²¹⁰ The positive change is however slowly taking place, as we can notice the growing worldwide recognition of this problem. The initiatives are undertaken to fill this gap, involving as they do intergovernmental agencies, national governments and private foundations as well as the industry itself.

²¹¹ Pharmaceutical expenditure accounts for a substantial part of the health budgets of most developing countries. Until now, the prices of essential drugs have been kept under control by implementing national drug policies or by manufacturing the drugs themselves, by a process different from that originally used by the 'process patent holder'. However TRIPs agreement requires countries to introduce 'product' patents instead of 'process' patents. That type of patent protection often results in pushing up prices and crippling the local industry which does not have resources to develop new drugs.

²¹² For example as the India National Working Group on Patent Laws has pointed out in 1996 drug Zantac retailed in India for 18.53 rupees, in UK at the equivalent of 481.42 and in the USA at the equivalent of 1050.70. Under TRIPs India is obliged to introduce product patents for medicines. In Pakistan, where such protection already exists, Zantac now retails at the equivalent of 260.40 rupees (11.27 times its price in India). See: Drahos, Peter – *op.cit.*, p. 27

²¹³ Trade in action, Towards better recognition of Intellectual Property Rights, October 2001, <<http://trade-info.cec.eu.int/europa/2001newround/int.htm>>

²¹⁴ Declaration on the TRIPs Agreement and Public Health, Doha, 14 November 2001, WT/MIN(01)/DEC/2

access to medicines for all". States confirmed that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Together with this was the right to determine what constitutes "a national emergency or other circumstances of extreme urgency, it being understood that the public health crises, including those relating to HIV/Aids, TB, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency" and decide on their own rules depicting the implementation of parallel imports. Furthermore least developed countries (LDCs) have been given a 10-year extra period to provide pharmaceutical patents, this means that the deadline for compliance is now 2016 for LDCs, at the earliest.²¹⁵

Recently, on the occasion of TRIPs Council's post-Doha talks²¹⁶, the EU lodged a proposal to ensure access to medicines in developing countries where no domestic drug production occurs²¹⁷, thus addressing a key issue that remained unresolved after the WTO Ministerial. This clarifies that the options presented do not exclude other approaches and assure that the EU is open to discuss all approaches in the interest of finding a solution that would assure that the developing countries find enough flexibility in TRIPs to get the medicines they need while still fostering the Research and Development. The EU presented two options for solutions to the problem:

- an amendment to the article 31 (f) of the TRIPs Agreement so that the medicines can be produced elsewhere and exported to the country in need; or
- that article 30 of the TRIPs Agreement be interpreted in such a way as to allow medicines to be produced elsewhere for export to the country in need.

The goal of this proposal is to ensure that countries which have no sufficient capacity to manufacture essential drugs themselves, thus facing difficulties in making effective use of compulsory licensing under the TRIPs Agreement, may still fully benefit. Therefore, these possibilities exist to make available medicines affordable by other means.

In the end of October 2002, Commission also revealed a new plan, which is suppose to boost access to medicines for developing countries, in a way

²¹⁵ WTO Press/301 release, 28 June 2002, *Intellectual Property: TRIPs and Public Health, Council approves LDC decision with additional waiver*: The WTO council responsible for intellectual property, on 27 June 2002, approved a decision extending until 2016 the transition period during which least-developed countries (LDCs) do not have to provide patent protection for pharmaceuticals. It also approved a waiver for LDCs on exclusive marketing rights for any new drugs in the period when they do not provide patent protection.; <http://www.wto.org/english/news_e/pres02_e/pr301_e.htm>

²¹⁶ 5-7 March 2002, <www.wto.org/english/news_e/news02_e/TRIPs_reg_020307_e.htm>

²¹⁷ For details see: Concept Paper relating to paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health – Communication from the European Communities and their Member States, WTO IP/C/W/339; 4 March 2002, TRIPs Council, <<http://docsonline.wto.org>>, 23/03/2002

that will discourage them from using compulsory licenses.²¹⁸ According to the plan, the producers will be able to significantly increase supplies of medicines at lower, so-called tiered prices, keeping higher prices for the same items in the EU. Both patented and generic products can be put on a tiered-price list run by the European Commission. In order to be added to the list, medicines have to be made available either with a price cut of 80% off the average “*ex factory*” price in OECD countries, or at the cost of production plus 10%, and shall bear a logo allowing customs to easily identify them. Being on the list and bearing the logo will mean that imports of these products into the EU for free circulation, re-exportation, warehousing or trans-shipment will be prohibited. This hopefully would put an end to such practices as the recently discovered case of intercepting by Profiteers the low-cost shipments of three *GlaxoSmithKline* HIV/AIDS drugs to some of Africa's poorest countries, for the sole purpose of sending the drugs - worth almost \$18 million - back to Europe to be sold illegally at a hefty profit, which was possible, because the drugs were identical to those sold in Europe.²¹⁹ The plan constitutes on one hand the implementation of the *Programme for Action: Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction*, which the European Commission adopted in February 2001, establishing a broad and coherent Community response for 2001-2006, to address the global emergency caused by these three major communicable diseases. On the other however, it is difficult not to notice that at the same time, separate discussions are underway at the WTO involving TRIPS about the terms under which countries in need of medicines may invoke compulsory licenses to manufacture or import them.²²⁰ It is clear that the EU

²¹⁸ *Commission clears plan to boost access to medicines for developing countries*, DN: IP/02/1582; Brussels, 30 October 2002; see also: Proposal for a COUNCIL REGULATION to avoid trade diversion into the European Union of certain key medicines of 30.10.2002; <www.europa.eu.int/comm/trade/csc/med07.htm> or <www.europa.eu.int/comm/trade/pdf/propreg_med.pdf>, last viewed on 2002-11-05

²¹⁹ HIV/AIDS: Low-Cost Drugs For Africa Diverted To Europe For Illicit Profit, 03.10.2002, <<http://www.unfoundation.org/unwire/current.asp#29368>>, last viewed on 2002.10.03

²²⁰ On Nov. 14-15, 2002, the WTO Ministerial Meeting took place in Sydney, with much discussions focusing on amending international patent rules to provide poor countries with access to cheap generic medicines. As was already said, the WTO allows countries to override patent right in order to meet public health needs, but under current trade rules, generic copies must be predominantly for domestic use. Developing countries, which current right to import drugs is due to expire in 2005, strive therefore for such interpretation of TRIPS that will allow import beyond after this date. Although the industrialized drug-producing nations have agreed in principle to provide generic medicine access, U.S., EU, Japanese and Swiss representatives are also seeking to limit that access in order to protect their drug makers. Among the major issues points of discussion is also the question of what drugs would be covered by the agreement. The U.S. wanted to confine the patent exemptions to HIV/AIDS, malaria and tuberculosis; EU wanted only ‘grave’ public health problems included, while developing countries wanted all drugs and medical equipment covered. Under the compromise, developed countries have agreed to demands by poorer countries that the WTO agreement on trade-related aspects of intellectual property regulations (Trips) be amended to allow imports of generic drugs to treat HIV/Aids, malaria and tuberculosis. In addition, developed countries have suggested they will allow the provision to be extended to other serious public health problems, to be identified by the

hopes that if poorer countries get their medicines at a significantly reduced price, they should not need to invoke compulsory licenses, which undermine, according to the developed countries approach, the intellectual property regime.

As we see, if there is a will, there is also a solution.

5.2.2 Enlargement process – the approach towards Candidate Countries. Case study Poland and Hungary

EU angle

It is unfortunate that the EU takes a different approach when it comes to applicant countries. While making, by means of article 49 of the TEU, accession of the Candidate Countries dependent on their respect for the principles set out in article 6 (1) TEU, which include commitment to the protection of human rights (one of them being right to health), it seems to forget about its own obligations under international law. It also appears not to consider that the health situation in CEE countries compares poorly with the situation in the existing EU member states, i.e.: there is lower life expectancy and poorer health status with fewer resources to improve this situation. This is not to say that the EU is uninterested in the improvement of the health care system in the Candidate Countries, as it is not true. The best example of which, is one of the last Health Council meetings (held in Luxembourg, 5 June 2001) during which the Council members took note of a report by Commissioner Byrne on health in the candidate countries, which was a follow-up to the Council conclusions, adopted in November 1999 on this theme. The Commission underlined in particular, the need to ensure the participation of the applicant countries in the new Community Health Programme²²¹, as well as in all the other relevant activities in the field of the public health, such as PHARE, Research and structural instruments and programmes. This was in order to further the use of these programmes for health development, and to ensure that they are in a position to implement the European Community's health-related legislation. Another example of the positive and effective steps undertaken in order to include associated states into the already existing health-related-framework is the *health*

affected developing state. See also: Williams, Frances, "Patents hurdle tops agenda at Doha talks", *Financial Times*, Nov 14, 2002; Marsh, Virginia, "Cheap drugs deal boosts trade talks", *Financial Times*, Nov 15, 2002

²²¹ See Preamble section 40 and article 10 of the Decision No 1786/2002/EC of the European Parliament and of the Council of 23 September 2002 adopting a programme of Community action in the field of public health (2003-2008), OJ L 271, 9.10.2002, <http://www.europa.eu.int/eur-lex/en/dat/2002/l_271/l_27120021009en00010011.pdf>, Article 10 (b): The programme shall be open to the participation of "the associated countries of central and eastern Europe, in accordance with the conditions laid down in the Europe Agreements in their Additional Protocols and in the Decisions of the respective Association Councils".

in schools programme organized in cooperation with the Council of Europe²²². Opening the Community's public health programmes to the participation of candidate countries which will assist them in the process of adaptation to the Community policy in this field is another praiseworthy step; particularly that all Candidate Countries (just as Member States) are required to bring their legislation in line with the directive on tobacco products, and assure that the necessary structures exist in order to make possible their participation and carrying out related tasks in the network provided for in the decision on a network on communicable diseases²²³.

Still, the EU approach takes more account of the consequences of the enlargement of the Community towards Central and Eastern Europe, than the consideration of the consequences of the accession for these countries. This could even risk a statement that it is possible to notice a kind of dualism in the EU's approach, i.e. that the EU supports a healthy friendly approach as long as its economy is not affected too much. However, when promoting a health friendly approach is contrary to its economic interests or result in too big costs or disadvantages for its economy, the EU is not so eager to accept certain arguments and standpoints. The perfect example of this is the one I already described in relation to developing countries, i.e. the TRIPs Agreement and in general IP-related provisions. This time however it is in connection with the applicant countries, where the market situation in general resembles the situation on the Polish market, for example, where even though foreign medicines, mostly original, brand-name drugs constitute only 25% of the all drugs sold, the income they bring oscillates at around 73%.²²⁴ The market value of all original drugs (mostly imported) in Poland in 2000 was estimated at 5 710 million PLN (ca. 1 500 million USD) whereas the value of generic drugs²²⁵ at 5 280,7 million PLN (ca. 1 321 million USD), including the imported drugs at 2115,6 million PLN.²²⁶ If these

²²² Such programmes and initiatives, often lacking from the side of the national governments, are extremely important, particularly when we take into consideration the fact that such behavior patterns developed in childhood and adolescence as smoking, limited exercise, poor nutrition etc. are major risk factors for many (though not exclusively) lifestyle-related diseases in adulthood.

²²³ Those two documents are currently the only ones constituting the community legislation in the field of public health; <www.europa.eu.int/comm/dgs/health_consumer/enlargemnet/enlarg_health01_en>; 2002-04-28

²²⁴ Statistic data provided by CASE Foundation, which from 1992 analyzes economic reforms in CEE; in: Walewski, Pawel – Trzeba wstrzasnac! Zeby pacjent byl zdrowy, a lek tani, *Polityka*, nr 14/2001 (2292), <<http://polityka.onet.pl/artykul.asp?DB=162&ITEM=1025883>>, visited on 2002-04-09

²²⁵ generic = an off-patent medicine. Until patent expires, only the company that discovered a new medicine may produce it. After patent expiry any company may produce the same generic compound. Generic medicines benefit all, particularly economically weaker environments to maintain affordability of medicines and public health-care level.

²²⁶ Substantiation of the Government Project of an act on an amendment of the Act on Industrial Property. Rządowy projekt ustawy o zmianie ustawy – Prawo własności przemysłowej, Druk nr 300 z 26-02-2002, pp. 8, 9; <www.sejm.gov.pl> or <<http://ks.sejm.gov.pl:8010/proc4/opisy/300.htm>>, 2002-04-27

Analysis done by AzyX Polska, a company that monitors the pharmaceutical market, provides quite similar numbers, stating that 2000 sales of pharmaceuticals in Poland stood at

numbers do change, it is likely it will not be in favor of the Candidate State's domestic industry.²²⁷

Candidate Countries angle

It is not suggested that applicant countries are without any fault. Preoccupied with health care reform²²⁸, (as a result of the rapidly decreasing resources, general deteriorating health status, increased demand for health care and the push towards improving the quality of it²²⁹), governments in Central and Eastern Europe have failed to develop broader health policies. These policies are built up of examples such as: the means to ensure much needed control of illicit drugs, tobacco and alcohol; comprehensive responses to HIV/AIDS or other communicable diseases; improvement of housing; and raising the standard of living, which has resulted already in the return of tuberculosis in some parts of the region.²³⁰

Not much attention was given even to the domestic generic industry. It is rather surprising, because in the situation of increased participation of the society in the cost of health care, it would seem to be logical to support this branch of the industry. One has to be aware of the fact that big discrepancies between income made on imported and domestically-produced drugs, like in Poland, stem partially from the fact that foreign producers enjoy free pricing, or at least can negotiate the prices of their drugs with the Ministry of Health. The prices of the drugs produced by the domestic industry however, were authoritatively dictated by the Ministry of Finance, which put the domestic producers, mostly involved in production of generic drugs, in a very unfavorable position.²³¹ Furthermore it

nearly 1.2 billion units, worth zł.10.5 billion. According to Dr. Zdzisław Sabillo, chairman of the Association of Representatives of Pharmaceutical Companies in Poland, this market is still growing. In 2001, drug sales increased by around 9 percent. See: Preparing for EU impact – The Warsaw Voice July 1, 2001 No. 26 (662); <<http://www.warsawvoice.pl/v662/Business10.html>>; 21.05.2002

²²⁷ It is enough to recall the situation in Italy, which reestablished in 1978 patent protection on pharmaceuticals abolished ca. 40 years earlier. The national industry accounting in 1979 for 48% of the pharmaceutical market, dropped after the introduction of patents to 41% in 1988. Additionally, in the Italian trade balance in medicines and pharmaceuticals a surplus of \$40.6 million in 1978 turned into a deficit of \$826.8 million in 1989. See: Transnational Corporations and Management Division, Department of Economic and Social Development - Intellectual Property Rights and Foreign Direct Investment, United Nations, NY 1993, p. 28

²²⁸ Which has not been uniformly successful, 'best' example being Poland, where the health care reform did not even start to function properly, and is already undergoing a major change

²²⁹ Den Exter, André and Hermans, Herbert – The Rights to Health Care: A changing Concept?, in: The Right to Health Care in Several European Countries – Expert Meeting, held in Rotterdam, the Netherlands, April 27-28, 1998, Studies in Social Policy, Kluwer International 1999, p. 1

²³⁰ ISN Security Watch - Ukraine grapples with TB epidemic, <<http://www.isn.ethz.ch>>

²³¹ A new Price Law (Ustawa z dnia 5 lipca 2001 r. o cenach, *Dziennik Ustaw Nr 97, poz. 1050*) came into effect on December 12th, 2001. The provisions currently concern only reimbursed drugs but may be extended to hospital products. The intention is to treat both

seems that until recently ‘governing elites’, for various reasons, promoted the expensive, foreign, brand-drugs to domestic generics, as if believing that only what is expensive and imported could be good. This in turn shows a non-understanding of the value of possessing a well developed, modern, domestic generic industry (for example what the Indian government understood a long time ago), in a situation when the domestic industry is not able, for financial reasons, to compete with foreign/international companies in the original drugs sector.²³²

It was only on September 6th, 2001 that the Polish Parliament passed a new Pharmaceutical Bill²³³, which partially is to enter into force on October 1st, 2002. Only partially, because some of the provisions, according to Article 3 of the Act²³⁴ of September 6th, 2001 on Provisions Introducing the Pharmaceutical Bill (which accompanied the Pharmaceutical Bill), will enter into force only on the date of EU accession.

This however, does not change the fact that during the vital accession-negotiations period, the EU concentrated on market integration rather than on improvement of health or other social aspects. Even today, there exists a number of possibilities to assure that after joining the EU, the generic medicines industry in applicant countries continues to exist and develop itself, and supply the population with relatively cheap drugs²³⁵. The EU in its proposals and negotiation standpoints, is putting forward its economic stance, pushing for an extended protection of the profitable original drugs, which brings huge incomes to manufacturers while simultaneously draining money out of the payers pockets and

domestic and foreign products in the same way but instead of freeing domestic prices, both foreign and domestic products will be subject to the current administrative price fixing procedure. Prices will be set by the Minister of Health (MoH) together with the Minister of Finance (MoF). Reimbursement will be determined by the MoH based upon a recommendation from a Drug Management Team which includes three representatives from each of MoH, MoF, Ministry of Economy (MoE) and a non-obligatory representative from the Union of Health Insurance Funds.

²³² In 1999, 293 generic drugs and 75 new drugs were registered in Poland. Only foreign producers introduced the latter on the Polish market.; in *Preparing for EU impact – The Warsaw Voice* July 1, 2001 No. 26 (662); <<http://www.warsawvoice.pl/v662/Business10.html>>, 21.05.2002

See also: Szuba, Tadeusz J., “O leki dla wszystkich: Zburzyc mity”, *Sluzba Zdrowia*, nr 38-39 (2931-2932); 11-15 maja 2000

²³³ Ustawa z dnia 6 wrzesnia 2001 r. Prawo farmaceutyczne, *Dziennik Ustaw* Nr 126, poz. 1381

²³⁴ Ustawa z dnia 6 wrzesnia 2001 r. Przepisy wprowadzajace ustawie - Prawo farmaceutyczne, ustawie o wyrobach medycznych oraz ustawie o Urzedzie Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, *Dziennik Ustaw* Nr 126, poz. 1382 as amended by Ustawa z dnia 20 marca 2002 r. o zmianie ustawy - Przepisy wprowadzajace ustawie - Prawo farmaceutyczne, ustawie o wyrobach medycznych oraz ustawie o Urzedzie Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, *Dziennik Ustaw* Nr 32, poz. 300.

²³⁵ We should not forget that CEE countries have relatively low per capita incomes. Even though for example drugs in Poland are by 30% cheaper than in other Central-European countries and almost 4 times cheaper than in the EU, one also have to take into consideration that the participation of patients in the cost of the drug reaches almost 60%, whereas according to the WHO experts already 50% participation constitutes a barrier limiting drug accessibility. In: Walewski, Pawel, “Trzeba wstrzasnac! Zeby pacjent byl zdrowy, a lek tani”, *Polityka*, nr 14/2001

putting the generic industry in a very uncompetitive position. This money, if used to acquire generics, would surely help larger amounts of people.

There are many possibilities to deal with this problem in such a way that would allow the achievement of balance between the interest of patients, payers and both branches of the pharmaceutical industry. Among these possibilities, are the ones which would make generics available on the market sooner and decrease their cost to the advantage of the people²³⁶. They include so-called “*Bolar*” provision, shorter data-exclusivity periods, parallel imports, compulsory licensing without the need to declare the state of emergency/without waiting till the number of sick will rise achieve epidemic level.

I will analyze a few of these options in order to show that the EU had possibilities of taking a more social and health friendly approach during the negotiation process, while still protecting its brand-drug industry interests.²³⁷

5.2.2.1 Pre-patent Expiry Development and Registration Work for Generic Medicines (*Bolar* provision)

The possibility of conducting pre-patent expiry²³⁸ (during the patent period of the original product) development, testing and experimental work required for the registration of generic medicines ensures that there is no delay for

²³⁶ In Poland, for example, the price of the generic drug is ca. 30% lower in the moment of its introduction onto the market and causes the rise of its consumption also by 30% within a year, what naturally influences the development of the pharmaceutical industry. If no generic drug is available, the State budget loses the possibility of additional reimbursement to the cheaper drugs by 30%, i.e. the same amount by which the price of such drug is lower. See: Substantiation of the Government Project of an act on an amendment of the Act on Industrial Property. Rzadowy projekt ustawy o zmianie ustawy – Prawo własności przemysłowej, Druk nr 300 z 26-02-2002, p. 8,9; <www.sejm.gov.pl> or <<http://ks.sejm.gov.pl:8010/proc4/opisy/300.htm>>, 2002-04-27

²³⁷ I will concentrate only on 3 issues leaving some others - like widely discussed in the literature compulsory licenses - aside due to space limits. Additionally I will concentrate on the negotiations between EU and Poland (sometimes referring also to Hungary) – that is due to the fact that Poland has by far the largest pharmaceutical market of the six countries, and will easily retain this position in the period up to the year 2004, reaching a market size of more than US\$4.5 billion and lifting its share from 50.0% in 1999 to 53.0% in 2004 (while respectively Hungary 16.1%, Czech Republic 12.6%, Slovak Republic 7.3%, Slovenia 6.6%, Bulgaria 4.3%); <http://www.ims-global.com/insight/news_story/news_story_000228.htm>

²³⁸ The “*Bolar exemption*” had been added to the U.S. patent statute in 1984, following the ruling of the Court of Appeals for the Federal Circuit in *Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc.* In that case, a generic manufacturer had used a patented invention to test and apply for marketing authorization of its version of a patented medicine. The Court had determined that the common law “experimental use” defense only covered experimentation for scientific, not commercial, purposes, and that the generic manufacturer’s activities therefore amounted to an infringement of the relevant patents.

those product to come onto the market after patent expiry. Such a delay would constitute a *de facto* patent extension. In fact the incorporation of such a development and testing provision restores to some degree at least, a level playing field between trade blocks. However this is additionally distorted by the Supplementary Protection Certificate Regulation 1768/92.²³⁹ Hungary had such provisions in its Patent Law²⁴⁰, while Poland introduced it recently²⁴¹. Slovenia has such provisions in its draft law.²⁴²

Despite the lack of a harmonized approach in the EU²⁴³, and the economic importance of the CEE generic industry for the future internal market, the EU was, and is, demanding that pre-patent expiry provisions be abolished in the associated countries. Furthermore, EU negotiators during the WTO Panel claimed that these provisions were illegal under the TRIPs Agreement, and that they are not part of the common practice of EU Member States. However, a WTO Panel decision²⁴⁴ has upheld the right of pre-patent expiry development work. It stated that such legislation is compatible with obligations under the TRIPs Agreement. Additionally, as there is no common practice in the EU, it is unclear why the demanding to applicant countries of prohibition of such provisions is being made. In the present situation, CEE countries should only be required to adopt international law.

Apart from this, it seems that “*Bolar*” provisions would not hinder the originator industry in the EU since the registration of generic medicines during the patent period is already allowed, as long as testing is done outside the present Member States. However, it (abolition of pre-patent expiry testing provisions) will be enough to destroy the generic industry in the CEE countries.

²³⁹ It is important to note that in the case of the USA the “*Bolar*” provision was granted as part of a package which included granting special market exclusivity extensions for originators.

²⁴⁰ Article 19 (6) of the Hungarian Patent Act (Act No XXXIII of 1995 on the Protection of Inventions by Patents) which reads as follows: “*the exclusive right of exploitation shall not extend to ...b) acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the registration of medicines.*”

²⁴¹ Article 69 (1) (iv) of the Polish Act of June 30, 2000 on Industrial Property Law (date of entry: 22 August 2001) states that “*the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorization, being, due to intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products*” shall not be considered an infringement of a patent.

²⁴² Such provisions exist also in the USA, Canada, Japan, Australia, Israel.

²⁴³ The issue is not part of the *acquis* (is not covered in any EU Treaty, Regulation, Directive, Decision, ECJ judgment) and the nature of experimental work is left to the discretion of individual EU countries. Currently none of the Member States explicitly provides such a possibility under its national law. The issue was only addressed till now by case law. In the UK and Netherlands it is stated that the provision of samples is not possible during the patent period. In Germany it is possible as long as it is a part of the general investigation of research. In Italy testing is allowed during an extended patent term (SPC). In Portugal Ministry of Industry indicated that development work is possible. Additionally in April 1996 European Parliament supported the introduction of pre-patent expiry testing for generics.

²⁴⁴ EU v. Canada, WT/DS114/R of 17 March 2000. See particularly statement of Poland.

5.2.2.2 Supplementary Protection Certificates (SPC)

Supplementary Protection Certificates (SPCs) were introduced by Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.²⁴⁵

Their main purpose is to give up to 5 years of patent extension for medicinal products beyond the patent term of 20 years²⁴⁶, in order to compensate pharmaceutical companies for the loss of market exclusivity caused by long regulatory requirements for authorization of a pharmaceutical product. The *acquis communautaire* requires the introduction of SPCs into the national legislation of the EU Member States. In January 1999, DG XV (Industrial Property) of the European Commission clarified that only medicinal products authorized from the date of accession on would be subject to SPCs, i.e. products that were granted a marketing authorization before the date of accession cannot have an extension of patent term. Now however, EU negotiators, under the influence of the brand-drugs producers²⁴⁷, are demanding that SPCs be backdated in order to cover pharmaceutical products authorized before the date of accession as well (in case of Poland from the January 1, 2000), claiming that it is needed to compensate originator companies for the lack of patent protection in CEE countries and to ensure a harmonized approach. It should be argued however, that product patents have existed in CEE countries since the beginning of 1990s (even before some EU Member States had such provisions in the national law²⁴⁸), not to mention the fact that CEE countries have also introduced Reversal of Burden of

²⁴⁵ It came into force in 1993. However, countries that did not have patent protection for medications in 1992 were allowed to introduce SPC five years later.

²⁴⁶ Regulation provides however for different starting times for EU Member states, for example, transitional period was granted to Spain, Portugal and Greece to introduce SPCs into their legislature.

²⁴⁷ For example, EPIA (European Federation of Pharmaceutical Industries and Associations) demands in its Position Paper „EU enlargement – Intellectual Property Issues” made public in October 2000 that:

SPC should apply to all products that are on the market on the date of implementation and for which the patent has not expired;

Commercial testing prior to patent expiry - despite the outcome of the TRIPs action against Canada, it should remain EU policy to resist the *Bolar* provision in accession candidates, as in the EU 15, because it represents an unacceptable weakening of IP and is therefore not in the interests of encouraging a strong innovative pharmaceutical industry;

There should be a derogation from the principle of free movement of goods (transitional derogation from the parallel trade) in respect of any product which has a lesser degree of intellectual property protection in an accession country than it does in EU15.

Regulatory Data Protection – accession candidates should introduce a 10-year period of exclusivity - not linked to the expiry of the patent on the product - for the regulatory data, before reference can be made to the data in an abridged approval. (It is worth mentioning that possibility of such linkage is currently envisaged by Directive 65/65, so what the EPIA is aiming for is introduction of stricter provisions in the accessing countries even if such regulations will not exist in EU15, what will highly disadvantage the CEE pharmaceutical generic industry.)

²⁴⁸ Austria – 1987, Greece – 1992, Portugal – 1992, Spain – 1992, Finland – 1995

Proof for Process Patents. Additionally it seems, that the retroactive application of SPCs is beyond the legal requirements of accession. The Polish government's proposal²⁴⁹ for the amendment of the Act on Industrial Property of 2001 comes forward with a proposition of introduction of SPCs after Poland joins the EU.

The most important argument however against introduction of the retroactive application of the SPCs and against the requirement of their immediate introduction upon accession as such, is the one put forward by Hungary in the explanation to its request for a transitional period of 5 years for the application of the above mentioned Council Regulation. As there is a considerable difference in the price level of generic and original (brand) pharmaceutical products, the introduction upon accession to the EU of supplementary protection for medicinal products would have a detrimental financial impact on the social security system and would adversely affect patients' ability to cover the expenses of health care. This, in view of the general health situation, should be avoided. According to estimations, the introduction of supplementary protection would concern a high number of medicinal products and would substantially increase the expenditure and the deficit of the national health fund.²⁵⁰ The same argument is relevant for all applicant countries.

One may also wonder if there would be a solution which would combine SPCs with enhancing the domestic production. Mexico ensures for example, patent protection period of 20 years, and allows for its extension for 3 additional years in case of pharmaceutical patents that have been licensed to Mexican firms. Assuming that the pharmaceutical companies will be interested in obtaining additional period of protection, making SPCs dependent on the obligation either to produce the protected pharmaceutical in the country, or to license it to domestic companies, might result respectively in foreign direct investment or domestic companies getting access to those parts of IPRs which are not codifiable in patents, specifications etc. This is of major importance as the assimilation and use of formal technologies requires complementary knowledge of a "hand-on" nature which can only be acquired through the actual use of the technology. Moreover, it is often from such tacit knowledge that additional (or incremental) innovation accrue.²⁵¹ Having earlier access to certain types of information would surely increase competitive position of generic producers after patent expiration, because they would not waste time after its expiration for something which could have been done earlier.

²⁴⁹ The draft SPC provision closely follows EU Directive 1768/92. In fact this proposal which took recently a form of an Act amending the Act on Industrial Property (Ustawa z dnia 26 kwietnia 2002 r. o zmianie ustawy – Prawo własności przemysłowej), which just passed the Lower Chamber of the Parliament (Sejm) and now awaits procedure in the Upper Chamber (Senat), states in article 1 (7) that provisions concerning SPC are to be granted in Poland on conditions provided for in the EU law as of the day when Poland will acquire EU membership.

²⁵⁰ Ficsor, Mihály – *Intellectual Property issues and EU Accession*, Presentation at the EGA Annual Conference 2000, 4-6 October, 2000, Kraków; <www.egagenerics.com>

²⁵¹ for more see: UN – Transnational Corporations and Management Division, Department of Economic and Social Development – *Intellectual Property Rights and Foreign Direct Investment*, NY 1993, p. 24

5.2.2.3 Data exclusivity

A new medicine normally has to go through a series of safety tests before it is granted marketing approval. The question then arises as to whether the resulting test data (like comprehensive documentation on the safety and effectiveness of their new drugs), the origination of which involves considerable efforts and costs, can be relied on by the Regulatory Authority years later when reviewing an application for marketing approval for a generic version of the medicine. This avoids the need for the 'generic' applicant, who presented the results of bioequivalence testing, to submit new data and speeding up commercialization of the generic medicine.

In TRIPs it is Article 39.3 that obliges the WTO Members to protect undisclosed test or other data against unfair commercial use, when those WTO Members require submission of such data as a condition of approving the marketing of pharmaceutical products. The EU's data exclusivity laws (which countries seeking EU accession will of course be required to introduce) as provided for in Directive 65/65 EEC (amended by Directive 82/21/EEC), give the first market authorization holder of a New Chemical Entity (NCE) a guaranteed period of such data exclusivity, which in fact can be understood also as a market exclusivity. This is done by way of the Regulatory Authorities only accepting an application for generic medicines after the expiry of the 6 or 10-year period.²⁵² The data exclusivity provision effectively prevents the Regulatory Authorities from checking whether a generic applicant is 'essentially similar' to the original product. After this given period, Regulatory Authorities are able (internally) to refer to the data of Part III and IV of the originator file (such as the data files compiled by the pharmaceutical companies for application for drug regulatory approval) in order to assess the generic application for safety and efficacy²⁵³. Data exclusivity is therefore a misleading term, as more appropriate term would be market exclusivity.

Though there is no harmonized data protection period and Member States operate one of three periods: 10 year, 6 year period which does extend beyond the patent protection, and 6 year exclusivity period which does not extend beyond patent protection, the accession countries are confronted with demands of a 10 year period, not linked to the expiry of the patent on the

²⁵² Half of EU countries actually operate a 6-year period of data exclusivity not a 10-year period, and in three cases the period must not extend beyond the patent period. Moreover, Iceland and Norway and most countries seeking EU accession are expected to opt for a 6-year period. In U.S. protection period is five years net, with an additional three years for new indications of existing products.

²⁵³ Generic companies do not use the data of the originator, but part of the generic application requires cross-reference to the originator product to establish *essential similarity*.

product²⁵⁴, and applicable to all indications and formulations, not just the first approval of an NCE (whereas in the EU, data exclusivity only covers the first authorization of a medicinal product and cannot be given for additional indications, strengths or dosages).²⁵⁵ Luckily for the domestic generic industry, candidate countries governments are able to at least partially resist the pressure. Even though data exclusivity might give additional incentives for innovation, one cannot unfortunately exclude a scenario in which extended data exclusivity provision would undermine genuine innovation by encouraging originator companies to focus their activities on product changes, rather than focusing on developing new innovative and beneficial products.

Poland currently provides for a 3-year period of data exclusivity for confidential test data. However, the new Pharmaceutical Bill of September 6th, 2001 is to enter into force on October 1st, 2002 with exception of - among others - Article 15.2 and 15.3²⁵⁶ that will enter into force on the date of acquiring EU membership by Poland. The Law provides for a 6-year period of data exclusivity providing that there is still a valid patent. A 10-year period is provided for high-

²⁵⁴ Even though the possibility of linkage is currently envisaged by Directive 65/65 although it is not applied by any EU15 Member State. It is only the brand drug industry that argues that such linkage is, in theory, part of the *acquis communautaire*, and Directive should be amended to remove any possibility of linkage.

²⁵⁵ EPIA (European Federation of Pharmaceutical Industries and Associations) Position Paper „EU enlargement – Intellectual Property Issues”, October 2000, <www.epia.org/4_pos/economic/EnlargIP.pdf>, 2002-03-14

EGA Position Paper, “TRIPs Article 39.3 does not require Data Exclusivity Provisions (A critical issue for access to medicines), July 2000, <www.egagenerics.com/facts_figures/intellectual_property/position_paper_TRIPs.htm>, 2002-03-15

²⁵⁶ Article 15. 1. Podmiot odpowiedzialny nie jest zobowiązany do przedstawienia wyników badań toksykologicznych, farmakologicznych i klinicznych, jeżeli może wskazać, przez odniesienie do opublikowanej literatury naukowej, że składnik czynny bądź składniki czynne produktu leczniczego mają ugruntowane zastosowanie medyczne oraz uznana skuteczność i bezpieczeństwo stosowania.

2. Podmiot odpowiedzialny nie jest zobowiązany do przedstawienia wyników badań toksykologicznych, farmakologicznych i klinicznych jeżeli może łącznie wykazać, że:

1) produkt leczniczy jest odpowiednikiem produktu leczniczego, który został dopuszczony do obrotu na terytorium Rzeczypospolitej Polskiej,

2) podmiot odpowiedzialny za wprowadzenie na rynek oryginalnego produktu leczniczego wyraził zgodę na wykorzystanie wyników badań farmakologicznych, toksykologicznych i klinicznych oryginalnego produktu leczniczego do oceny odpowiednika produktu leczniczego.

3. Podmiot odpowiedzialny nie jest zobowiązany do przedstawienia wyników badań toksykologicznych, farmakologicznych i klinicznych, jeżeli może łącznie wykazać, że:

1) produkt leczniczy jest odpowiednikiem produktu leczniczego, który został dopuszczony do obrotu na terytorium Rzeczypospolitej Polskiej,

2) od daty dopuszczenia oryginalnego produktu leczniczego do obrotu na terytorium Unii Europejskiej do daty złożenia wniosku upłynął okres 6 lat, chyba że ochrona patentowa leku oryginalnego na terytorium Rzeczypospolitej Polskiej wygasła wcześniej; w przypadku produktu leczniczego pochodzącego z istotnie innowacyjnej technologii, dopuszczonego do obrotu zgodnie z art. 3 ust. 2, okres powyższy wynosi do 10 lat, niezależnie od terminu wygaśnięcia ochrony patentowej na terytorium Rzeczypospolitej Polskiej.

tech products registered through the centralized EU procedure.²⁵⁷ Under the Implementation Law, these provisions will come into force only after Poland accedes to the EU. However, the period of protection starts from the first marketing authorization worldwide. Although the law provides for six years for original products registered in the EU, the term begins to run from the initial registration date in the EU, significantly reducing the effective period of data exclusivity giving Polish regulatory delay. This means, that prior to Poland's EU accession, the scientific information in the research that went into creating new drugs will remain openly available to whoever would like to review it, including generic drug producers. In addition, the law introduces patent linkage.²⁵⁸ Of course the absence of registration data protection in Poland prior to the country's admission to the EU would be advantageous for domestic generic drug producers. According to the *'Rzeczpospolita'* daily, the patents for a number of attractive drugs will expire soon, giving Polish pharmaceutical plants the chance to launch generic production without having to carry out expensive research.

The brand drug companies argue that the new regulations conflict with the Association Agreement Poland signed with the EU, and the TRIPS agreements on the commercial aspects of intellectual property law. By signing the Association Agreement, Poland promised to ensure protection of intellectual, industrial and commercial property rights at a level identical with that existing in the EU five years after the agreement came into force, i.e. January 1, 1997. In the EU, exclusive copyrights for the protection of pharmaceutical registration data are binding for six to 10 years. According to the TRIPS agreements, Poland has the duty to protect registration data against dishonest commercial use.

What is the situation in other CEE countries? Current Hungarian law contains no provisions that would protect the confidential test data submitted by pharmaceutical companies to regulatory authorities as a condition of marketing approval. There exist no restrictions on its Regulatory Authority with regard to reliance on the original filing data for any specific time period. In fact, the health regulatory authority has permitted registration of second filing applications, which rely on the original filing, without the originator's consent, even in cases where the time between the original filing and the second filing is less than five years and in some instances as little as a few months. The health Regulatory Authority has taken the position – stated, for example, in a recent reply to U.S. companies questioning the process – that in the absence of such restrictions clearly prescribed by legislation, it would not deal with the issue. The Hungarian Government has claimed that its Unfair Competition Law (UCL) of 1994 is sufficient to fulfill Hungary's obligations under Article 39.3.

On April 12, 2001, Hungary issued a decree that will protect the confidential test data submitted by research-based pharmaceutical companies as a condition of marketing approval as of January 1, 2003. In addition, the data

²⁵⁷ In the EU, a period of 10-year data exclusivity for all centrally approved products is mandatory.

²⁵⁸ PhRMA Special 301 Submission Watch List Countries, <<http://www.phrma.org/intnatl/news/2002-02-22.46.pdf>>, p. 53

exclusivity term would begin at the date of the first marketing authorization in the EU. Since Hungarian marketing authorizations are typically issued later than authorizations in the EU with its central and mutual recognition approval procedures, the Hungarian reference to a third country can considerably shorten the data exclusivity period.

Moreover, despite a formal marketing authorization, a pharmaceutical company may not market the product before the price of the product approved by the Government is published in the Official Gazette. This requirement typically takes one year, but recently it has taken up to two years, thereby reducing a would-be six-year period correspondingly.

Finally, although the period of protection for confidential data is a maximum of six years, the data exclusivity period ends earlier than six years – possibly at zero years – if and when the patent expires earlier.²⁵⁹

* * *

There are many other issues which one could develop in the similar manner such as compulsory licenses²⁶⁰, parallel import, provisions which would put obligation on the brand-drug producers to indicate in the registration certificate and in the list of the registered drugs next to pharmacologically active substances also all auxiliary substances (which would spare the costs of unnecessary duplicated research), etc.

However, already the above examples show clearly that the approach taken by the EU vis-à-vis applicant countries – stands in opposition not only to its declaration of devotion to public health development and obligation to take into consideration assuring high level of health in designing other policies, but also runs against the explicit balance provided for in the human right to intellectual property,

²⁵⁹ The legislation concerning data exclusivity which is considered as unfavorable to brand drug industry caused controversy not only in EU. Also PhRMA requested U.S. Government that Poland and Hungary be included in the 2002 “Special 301” Watch List (Identification of Countries Under Section 182 (“Special 301”) of the Trade Act of 1974, as amended, 66 Federal Register 66492 - 66493 (December 26, 2001), and that the U.S. Government continue to seek assurances that the problematic issues are quickly and effectively resolved. PhRMA Special 301 Submission Priority Watch List Countries, p. 49, <<http://www.phrma.org/intnatl/news/2002-02-22.46.pdf>>

²⁶⁰ For example, interesting solution found in Article 68 of Polish Act on Industrial Property that defines abuse of a patent right as preventing a third party from working the invention “dictated by public interest considerations, and [where] consumers are supplied with the product in insufficient quantity or of inadequate quality, or at excessively high prices.” what explicitly brings price into the range of possible rationales for issuance of a compulsory license. Polish law does not contain also require that the use shall be authorized predominantly for the domestic market. In addition, Article 84(2) provides that the amount of the royalty shall be “in proportion to the market value of the license.” (TRIPs Article 31(h) says that the remuneration shall be adequate in the circumstance of each case, “taking into account the economic value of the authorization.”).

not to mention the basic objective outlined in article 7 TRIPs, i.e. to seek the enforcement of intellectual property “in a manner conducive to social and economic welfare, and to a balance of rights and obligations” and flexibility inherent in article 8 TRIPs which leaves space for adoption of measures necessary to protect public health (...) and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

6 Conclusions

Back in 1970, Prescatore stated that “the protection of fundamental rights and freedoms will never become a question of paramount importance in the Communities”, though he acknowledged that “the problem it raises cannot be treated as if it were totally irrelevant”.²⁶¹ Despite similar statements from other authorities, with the end of the Cold War, the references to human rights and democracy in the TEU and the establishment of a Common Foreign and Security Policy with improved instruments for foreign policy cooperation, hopes have been raised that human rights might come play a more prominent role within the EU, in particular within the European Foreign Policy. So they did. Similar development within the EU internal dimension did not however take place. Economic competition and conflicting national interests as well as binding international agreements of which the EU is a party (like TRIPS for example) seem to continue to restrict Europe’s commitment to human rights to declarations of concern rather than action.²⁶²

Surely, the human rights situation in EU Member States is on average much better than in many of the third countries it enters into various agreements with. However in the area of social, economic and cultural rights, to which the two rights described in this paper, i.e. right to health and right to intellectual property, belong, there is not a clear top borderline, against which a State could measure their compliance with human rights obligations. They are supposed to undertake measures according to all the circumstances and particularities of their country, and to the maximum of their resources, which means that it is a constant process of progressive realization, with individual benchmarks moving constantly higher throughout the process. Even if there is a high level of compliance with, for example, the right to health, surely endorsing in legislation the balance between health concerns and the need to keep intellectual property protection at the incentive-providing level can be seen as progressive realization at the more sophisticated level.

Even now however, despite the openness inherent in the Charter of Fundamental Rights and its increasing importance, we are still lacking explicit and legally binding recognition of many human rights, particularly those not found in the ECHR. The human right to the highest attainable standard of health, (as opposed to seeing it through the public health prism or as a good or commodity with a charitable construct), is among them. It is also no longer enough to view intellectual property as an issue strictly of a contractual, private law nature, with

²⁶¹ Prescatore, P., “Fundamental Rights and Freedoms in the System of the European Communities”, *AJCL*, Vol. 18 (1970)

²⁶² Toby King, Human Rights in European Foreign Policy: Success or Failure For Post-Modern diplomacy?, *EJIL* Vol. 10 No 2, <www.ejil.org/journal/Vol10/No2/ab3.html>, 2002-11-03

the state setting rules in case the general interest/ public interest would be in question.

It is high time to also recognize that in legislation design and review, human rights provide a useful tool to determine effectiveness and appropriateness of such in line with both human rights and public health, or innovation enhancement goals. Therefore legislature based on the human rights approach to health and intellectual property can really be an important vehicle towards ensuring the promotion and protection of these respective rights.

Well developed public health policy or innovators friendly intellectual property regime is not enough – as laws they are framed by are sometimes used by states as a ground for limiting the exercise of human rights. Public health law may for example contain strict rules on quarantine and isolation, which can effectively run against such human rights like the right to personal liberty or freedom of movement. Let us not forget in this context the positive lesson that the HIV/AIDS pandemic has taught us, when the scale and nature of the problem has caused many countries to adopt a human rights based approach when revising their public health laws, including in relation to quarantine and isolation, as well as their intellectual property regimes.²⁶³

If the EU really stood behind its human rights declarations and concerns voiced, one could expect that in the near future it will raise the status of the Charter to a legally binding one, and will use human rights as a framework for health development and creativeness enhancement. One could expect that it will begin to assess and address the human rights implications of any health policy or intellectual property law, programme or legislation, and foremost will make human rights an integral dimension of the design, implementation, monitoring and evaluation of health-related policies and programmes in all spheres, including political, economic and social.²⁶⁴

The Treaty of Amsterdam marked a significant step forward when it affirmed that the Union ‘... shall respect fundamental rights, as guaranteed by the European Convention [on Human Rights] ... and as they result from the constitutional traditions common to the Member States, as general principles of Community law’. However it still remains for these solemn words to be matched by the same institutional, legislative and administrative follow-up which characterizes other areas. The failure to take adequate measures is particularly striking since the very same Treaty Article provides that ‘[t]he Union shall provide itself with the means necessary to attain its objectives and carry through its policies’. Unfortunately, as for now, the human rights policies of the European Union are beset by a paradox. On the one hand, the Union is a staunch defender of human rights in both its internal and external affairs, while on the other it is not eager to weaken its position on the world economy stage because of human

²⁶³ Gostin, L. and Burris, S and Lazzarini Z., “The Law and Public Health: A study of infectious disease law in the United States”, *Columbia Law Review*, Vol. 99 No. 1, 1999

²⁶⁴ WHO, *25 Questions and Answers on Health and Human Rights*, Health and Human Rights Publication Series, Issue No. 1, July 2002, WHO 2002

rights, full realization of which, and particularly vesting individuals with a right to challenge their infringement before the Court, it still seems to conceive as danger.

This leads to a growing contradiction between the obligations which the Union seeks to place on certain third countries as regards human rights²⁶⁵ - in particular in connection with development aid and association agreements - and the absence of any external review of decisions of the Union itself. It seems illogical that ratification of the European Convention on Human Rights by candidate countries is one of the preconditions for Union membership whereas the review machinery of the European Convention on Human Rights is still not applicable to the Union itself or its legal measures.²⁶⁶

Surely, it is possible to challenge some violations of human rights before the ECJ, which under article 220 EC has final jurisdiction in all matters of Community law, but is it really possible to speak of autonomy in the field of human rights and fundamental freedoms? I find it very hard to reduce these values to a mere field of competence of the Europe Union. After all, the ideal of human rights lies in their universality.

It is interesting to notice here that thought European integration has in the first place promoted internal economic freedom while originally leaving social rights and policies, not to mention human rights in their full sense, in a secondary position, it has been often perceived as a safeguard of the welfare state and promoter of human rights.²⁶⁷ It is high time now to live up to one's own fame. One way to do it, could be to consider once more certain amendments to the main Treaties that would allow for EU accession to the ECHR, when revising them during the major reform planned for 2004. Current events and the establishment of the Convention gives some hope that at least the legal status of the Charter of Fundamental Rights will be raised, and EU citizens finally will be able to take advantage of its provisions before the ECJ.

Internal and external dimensions of human rights policy can never be satisfactorily kept in separate compartments however. They are, in fact, two sides of the same coin. If the EU wants to enforce HR compliance in third states, it has to lead by example. In the case of the Union, there are several additional reasons why a concern with external policy also necessitates a careful consideration of the internal policy dimensions. Not only the development and implementation of an effective external human rights policy can only be undertaken in the context of appropriate internal institutional arrangements. In an era when universality and indivisibility are the touchstones of human rights, an external policy which is not underpinned by a comparably comprehensive and authentic internal policy can have no hope of being taken seriously. Particularly even in the external policy which is to such a high extent made conditional on respect for the human rights,

²⁶⁵ Remarkably the Council's Declaration at Luxembourg in December 1997 on the occasion of the 50th anniversary of the Universal Declaration of Human Rights focused almost exclusively on the external relations dimensions of the issue.

²⁶⁶ Fishbach, *op.cit.*

²⁶⁷ See also: Maduro, Miguel Poiars - "Striking the Elusive Balance between Economic freedom and Social Rights in the EU", *The EU and Human Rights*, Alston, Philip, Oxford University Press, p. 449

we can notice a tension between moral ambitions and economic interests.²⁶⁸ It is exactly here that the real priorities come to the surface.

Mary Robinson once said “*Human Rights bring to the (...) discussion a unifying set of standards – a common reference for setting objectives and assessing the impact of actions taken*”. Such approach would not require drafting of the whole intellectual property laws or public health laws anew – it would merely require adherence to a common baseline of internationally agreed norms and standards. After all, even the WTO’s constitution contains references to the UN Charter that binds governments to human rights duties and obligations and sets a ground for human rights friendly interpretation of the agreements. Taking human rights into consideration throughout all its actions and planning should be even more obvious in the case of the EU, where primary law is filled with human rights references.

In accordance with that both in the WTO as well as in the EU regulations one should avoid ‘exemptions-led’ approach to broad human rights issues. Human rights issues cannot be parceled into ‘human rights clauses’ or ‘social clauses’ – which could be than also misused for protectionist purposes but need to be integrated into the very objectives of the organization as expressed in its preambular mission statement or as one of the principles.. or in case of the EU – maybe constitute part of the new constitution.²⁶⁹

For that however, we have to start conceive the dialogue between human rights and private law in complementary terms. “Viewing intellectual property through the eyes of human rights advocates will encourage consideration of the ways in which the property mechanism might be reshaped to include interests and needs that it currently does not. Intellectual property experts can bring on the other hand to the aspiration of human rights discourse, regulatory specificity, which is of utmost value as at a certain point, the diffused principles that ground human rights claims to new forms of intellectual property will have to be made concrete in the world through models of regulation, which will have to operate in a world of great cultural diversity”²⁷⁰ – which does not constitute a small challenge.

²⁶⁸ For example: position in TRIPs as well as Doha and Post-Doha negotiations, position in negotiations with accessing countries, EU policy vis-à-vis the former Yugoslavia, dispute between Member States over EU resolution on human rights abuses in China during the 1997 session of the UN Commission on Human Rights.

²⁶⁹ Mehra, Malini – “Human Rights and the WTO: Time to Take on the Challenge”, <www.wtowatch.org/library/admin...>, accessed on 2001-07-15

²⁷⁰ Drahos, Peter - “Intellectual Property and Human Rights”, *Intellectual Property Quarterly*, No. 3 (1999)

Supplement A - Relevant Provisions

GENERAL:

Treaty establishing the European Community

Article 3 (ex Article 3)

1. For the purposes set out in Article 2, the activities of the Community shall include, as provided in this Treaty and in accordance with the timetable set out therein:

(a) the prohibition, as between Member States, of customs duties and quantitative restrictions on the import and export of goods, and of all other measures having equivalent effect;

(b) a common commercial policy;

(d) measures concerning the entry and movement of persons as provided for in Title IV;

(g) a system ensuring that competition in the internal market is not distorted;

(h) the approximation of the laws of Member States to the extent required for the functioning of the common market;

(k) the strengthening of economic and social cohesion;

(l) a policy in the sphere of the environment;

(m) the strengthening of the competitiveness of Community industry;

(n) the promotion of research and technological development;

(p) a contribution to the attainment of a high level of health protection;

(r) a policy in the sphere of development cooperation;

(s) the association of the overseas countries and territories in order to increase trade and promote jointly economic and social development;

(t) a contribution to the strengthening of consumer protection;

2. In all the activities referred to in this Article, the Community shall aim to eliminate inequalities, and to promote equality, between men and women.

Treaty on European Union

Article 6 (ex Article F)

1. The Union is founded on the principles of liberty, democracy, respect for human rights and fundamental freedoms, and the rule of law, principles which are common to the Member States.

2. The Union shall respect fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 and as they result from the constitutional

traditions common to the Member States, as general principles of Community law.

3. The Union shall respect the national identities of its Member States.

4. The Union shall provide itself with the means necessary to attain its objectives and carry through its policies.

ECJ Opinion 2/94 on the Accession by the Communities to the ECHR

5. Fundamental rights form an integral part of the general principles of law whose observance the Court ensures. For that purpose, the Court draws inspiration from the constitutional traditions common to the Member States and from the guidelines supplied by international treaties for the protection of human rights on which the Member States have collaborated or of which they are signatories. In that regard, the European Convention on Human Rights, to which reference is made in particular in Article F(2) of the Treaty on European Union, has special significance.

6. (...) Respect for human rights is a condition of the lawfulness of Community acts. (...)

INTELLECTUAL PROPERTY:

Universal Declaration of Human Rights, 1948

Article 17

1. Everyone has the right to own property alone as well as in association with others.
2. No one shall be arbitrarily deprived of his property.

Article 27

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

International Covenant on Economic, Social and Cultural Rights, 1966

Article 15

1. The States Parties to the present Covenant recognize the right of everyone:

- (a) To take part in cultural life;
 - (b) To enjoy the benefits of scientific progress and its applications;
 - (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
1. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
 2. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
 3. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

Charter of the Fundamental Rights of the European Union, 2000

**Article 17
Right to property**

1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except for in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law insofar as is necessary for the general interest.
2. Intellectual property shall be protected.

HEALTH:

Treaty establishing the European Community

**Title XIII (ex Title X) Public health
Article 152 (ex Article 129)**

1. A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.

Community action, which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education.

The Community shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

3. The Community and the Member States shall foster cooperation with third countries and the competent international organizations in the sphere of public health.

4. The Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) incentive measures designed to protect and improve human health, excluding any harmonisation of the laws and regulations of the Member States.

The Council, acting by a qualified majority on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

5. Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. In particular, measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.

Charter of the Fundamental Rights of the European Union, 2000

Article 35 Health care

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection

shall be ensured in the definition and implementation of all Union policies and activities.

Supplement B - Selection of the EU secondary legislation concerning intellectual property

Council Directive 92/100/EEC of 19 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property

Council Directive 87/54/EEC of 16 December 1986 on the legal protection of topographies of semiconductor products

First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks

Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs

Council Resolution of 14 May 1992 on increased protection for copyright and neighboring rights

Council Directive 93/98/EEC of 29 October 1993 harmonizing the term of protection of copyright and certain related rights

Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark

Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights

Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases

Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs

Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonization of certain aspects of copyright and related rights in the information society

Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs

Directive 2001/84/EC of the European Parliament and of the Council of 27 September 2001 on the resale right for the benefit of the author of an original work of art

Council Directive 93/83/EEC of 27 September 1993 on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission

Supplement C - Doha declaration on the TRIPs Agreement and Public Health

WORLD TRADE ORGANIZATION

MINISTERIAL CONFERENCE

Doha, 9 - 14 November 2001

WT/MIN(01)/DEC/2

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize 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.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We 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.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that 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.

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