E

WIPO/ECTK/SOF/01/2
ORIGINAL: English
DATE: May 2001

THE PRESIDENT OF THE
REPUBLIC OF BULGARIA

WORLD INTELLECTUAL
PROPERTY ORGANIZATION

INTERNATIONAL CONFERENCE ON INTELLECTUAL PROPERTY, THE INTERNET, ELECTRONIC COMMERCE AND TRADITIONAL KNOWLEDGE

organized
under the auspices of
His Excellency Mr. Petar Stoyanov, President of the Republic of Bulgaria

by
the World Intellectual Property Organization (WIPO)

in cooperation with
the National Intellectual Property Association of Bulgaria

Boyana Government Residence
Sofia, May 29 to 31, 2001

RECENT DEVELOPMENTS AND CHALLENGES IN THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS (IPRS)

Dr. Joseph Straus, Professor of Law, Universities of Munich and Ljubljana, Head of Department, Max-Planck-Institute for Foreign and International Patent, Copyright and Competition Law, Munich

TABLE OF CONTENTS

I. INTRODUCTION

1. The session, which I shall have the honour to moderate, will be dealing in particular with new developments in the protection of pharmaceuticals and biotechnological inventions, business methods and software patents. Moreover, also with electronic filing of patent applications and the future of the intellectual property system. You will understand that I, as a Member of the academic community involved in intellectual property, do not have much to say on electronic filing of patent applications. However, as Chairman of the Programme Committee of the International Association for the Protection of Industrial Property (AIPPI), the largest and oldest Association in the field, I have to convey to you a clear message of AIPPI's Membership, as expressed in a resolution adopted at the March Melbourne World Congress. The users of the patent system clearly and unanimously expressed their expectation that WIPO and the leading patent offices in the world will be applying unified standards, allowing a rapid and cost-efficient operation of the system.

2. Since I do not want to duplicate what the speakers will tell us tomorrow, I wish, in addition to some remarks directly related to biotechnological inventions and inventions in the area of computer software, to address some more general economic aspects of intellectual property rights and also some aspects of their international legal framework.

II. ECONOMIC IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS (IPRS)

3. Presumably never before in the history of intellectual property rights one could have observed within such a short period of time, as a decade or so, such an enormous gain in their economic importance. Taking patents as potentially most important and relatively easy to monitor form of intellectual property rights (IPRs), their number, for instance in the United States of America (USA) doubled from 1988 to 1998 to 160,000 patents and 260,000 patent applications.[1] In the European Patent Office the number of patent applications increased from 79,000 in 1995 to 140,000 in the year 2000, i.e. by 77 percent, with upward tendency.[2] Interesting and impressive are also figures on royalties paid for patent licenses in the USA, which increased from US$3 billion in 1980 to 15 billion in 1990, only to exceed the magic mark of US$100 billion in 1997;[3] or, for instance, the fact that commodities constituted 62 percent of the market value of the manufacturing industry in the USA in 1980, but less than 30 percent in 1998. For businesses that sell products or services on cutting-edge technologies that figure, for instance in Japan, are even less than 20 percent.[4]

4. These figures indicate that patents are increasingly sought not only or not even predominantly to securing the exclusive exploitation of inventions in own production or service businesses, instead, inventions and patents have become an independent commodity to be used as a source of revenues or bargaining object. Company statistics reveal, for instance, that IBM has received in the USA since 1972 some 20,000 patents, in 1998 alone some 2,700,

---

1 Rivette and Kline, Rembrandts in the Attic - Unlocking the Hidden Value of Patents, Boston 2000, pp. 4 s.

2 According to the recently published statistics of the European Patent Office.

3 Cf. Berman, The Emergence of an "Invisible" Asset Class, in: Berman, Hidden Value: Profiting from the Intellectual Property Economy, London 1999, p. 12; cf. also Rivette and Kline, op. cit., pp. 6 ss.

4 Kondo, Roles of the Intellectual Property Rights System in Economic Development in the Light of Japanese Economy, AIPPI Journal of the Japanese Group January 2000, pp. 28 ss. (at 34).

of these more than 1,000 for computer software. In the same year IBM cashed in more than US$1 billion in patent license royalties.[5]

5. Companies, however, are no more the exclusive customer of patent offices and user of the IPR system. Especially US universities have become a potent player in the field. Whereas, in 1974, they were granted 177 patents, that number in 1997 was 2,436, and they filed in that year some 6,000 applications. In the same year US academic institutions received US$ 611 million in royalties and fees (up 19 percent from 1996) from 6,974 active licenses.[6] It has been reported that in 1999, technology transfer from universities to industry contributed US$38 billion to the economy, creating over 300,000 jobs and forming hundreds of new companies.[7]

6. In view of these developments it should not come as a surprise that the new knowledge based economy has recently been characterized as "Intellectual Property Economy" or "Intellectual Capitalism."[8] Nor should one be surprised that this situation prompted the Japanese Patent Office, in 1999, to create a "Strategy Index for Intellectual Property Rights" as a reference to enable companies to objectively evaluate their own intellectual property strategy. Moreover, the Japanese Patent Office prepared "Patent-Related Evaluative Indexes" aimed at enabling companies to objectively evaluate patent rights which are to be transferred, distributed or used as security for a loan.[9]

7. It should also be noted in this context that recent economic empirical studies have revealed that strengthening intellectual property rights can be an effective means of inducing additional inward Foreign Direct Investment, although it is only one component among a broad set of important factors, such as taxation, investment regulations, production incentives, and competition rules.[10] Moreover, it has to be recalled, that the development of a competent indigenous technological capacity is equally of utmost importance. It calls for public and private investment in education and training and the removal of impediments to the acquisition of human capital. Economists also found out that patents, copyrights, and other intellectual property rights can encourage dynamic competition even if they may sometime diminish competition among existing products. Although they can raise the costs of imitation, they likely do not retard competing product introduction. Since they provide greater certainty to firms, they lower the costs of transferring technology, and facilitate monitoring of licensee operations.[11]

---

5 Cf. Berman, op.cit., pp. 14 s.

6 Gruetzemacher, Khoury, and Willey, License Pricing - The Role of Company and University Complementary Assets, Les Nouvelles, September 2000, pp. 116 ss., at 122.

7 Cf. Hall and Scott, University-Industry Partnership, 291 Science 553 (26 January 2001).

8 Cf. Granstrand, The Economics and Management of Intellectual Property - Towards Intellectual Capitalism, Northhampton , Ma. 1999, pp. 1 ss.

9 Kondo, AIPPI Journal of the Japanese Group, January 2000, 34.

10 Cf. Maskus, The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer, 9 Duke Journal of Comparative & International Law 109 ss., at 122 ss. (Fall 1998); See also Mansfield, Intellectual Property Protection, Direct Investment and Technology Transfer: Germany, Japan and the USA, 19 Int. J. Technology Management 3 ss., at 16 (2000).

11 See Maskus, 19 Duke Journal of Comparative & International Law 149 (Fall 1998).

III. REASONS FOR THE NEWLY ACQUIRED RATING OF INTELLECTUAL PROPERTY RIGHTS (IPRS)

8. A complex texture of various factors has led to the economic and, consequently, also political rating of intellectual property rights: on the one hand, the enormous advances in science and technology, in particular in communication and information technologies, biotechnology and life sciences in general[12] and, on the other hand, the global trade policy developments, which followed the conclusion of the GATT-Uruguay Round with the establishment of the World Trade Organization and the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994. The implications of the globalized economy which have emerged since then are enormous and as far as the future perspectives are concerned, difficult if at all to predict and their discussion, by all means, entirely beyond the task of this talk. It seems, however, useful just to recall, that one of the consequences which has already materialized is the fact that each day more currencies are moved around the globe than the volume of the entire world trade of four months![13] This is mentioned only in order to emphasize the exposure of intellectual property rights as traditionally territorially limited rights related to intangible, thus ubiquitous objects, to this new technological socio-economic and political environment.[14]

9. As to the impact of the rapid progress in science and technology, inventions in the field of information and communication technologies and biogenetics had been and, in part, still are faced with differing statutory frameworks in the United States of America and Japan, on the one hand, and Europe, as well as most other countries, on the other. Whereas the 35 U.S.C. does, in principle, not provide for any special treatment of specific technologies, for instance, the European Patent Convention (EPC) of 1973 in its Articles 52 (2) - (4) and 53 (a) (b) excludes from patent protection, *inter alia*, discoveries and computer programmes as such, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body (as non susceptible of industrial application), plant or animal varieties or essentially biological processes for the production of animals or plants, and inventions, the publication or exploitation of which would be contrary to *´publič* or morality. However, simple prohibitions of exploitation by law or regulation in some or all of the Contracting States of the EPC do not suffice.

---

[12] Without going into any detail reference is made only to the enormous achievement of accomplishing the raw sequence of the human genome (see the special issues of the Science Magazine (Vol. 291, 16 February 2001) and Nature Magazine (Vol. 409, 15 February 2001)) and the future steps leading to functional and structural genomics and, eventually, proteomics (cf. on these perspectives and developments, e.g., Gwynne and Heebner, Functional Genomics - Genomic Revolution Phase, 291 Science 681 ss. (26 January 2001); Meldrum, Sequencing Genomes and Beyond, 292 Science 515 s. (20 April 2001); Service, Structural Biology Gets a $150 Million Boost, 289 Science 2254 s. (29 September 2000); Misteli, Protein Dynamics: Implications for Nuclear Architecture and Gene Expression, 291 Science 843 ss. (2 February 2001); Böck, Invading the Genetic Code, 292 Science 453 s. (20 April 2001); Thornton, From Genome to Function, 292 Science 295 s. (15 June 2001)). For an economic perspective of biotechnology see Gwynne and Heebner, Biotechnology: A Global Perspective, 292 Science 2105 ss. (15 June 2001).

[13] According to an Editorial of Inacker, Glas und Beton, Frankfurter Allgemeine Zeitung of May 22, 2001, p. 1.

[14] On the complex and tense relationship between the territoriality principle as laid down in the Paris Convention for the Protection of Industrial Property, the TRIPS Agreement and other IP international conventions, on the one hand, and the implications of globalization, on the other, cf. Ullrich, Technology Protection According to TRIPS: Principles and Problems, in: Beier and Schricker (eds.), From GATT to TRIPS - The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim/New York 1996, pp. 357 ss. (381 ss.).

10. Despite this apparently enormous difference in the statutory provisions as regards biogenetic inventions, the difference in patent granting practises and in court case law, apart from patenting of therapeutic and diagnostic methods and plant and animal varieties, between the USA and Europe has been rather gradual.

III. UNITED STATES OF AMERICA (USA)

11. In the US, as a consequence of a 1980 land mark holding of the Supreme Court in the *Diamond vs. Chakrabarty case*, in which the Court declared "anything man-made under the sun" eligible for patent protection, all kinds of biological material, including higher life forms are deemed patentable subject matter. Patents have been routinely granted for plants, including claims related to plant varieties since 1985 and since 1987, in principle, also for animals. As regards patents for plants and plant varieties, this practice was approved, in 2000, by the Court of Appeal for the Federal Circuit (CAFC) in re *Pioneer Hi-Bred International vs. J.E.M. AG Supply, Inc.* and others.[15] However, the Supreme Court recently granted *certiorari* in this case and a decision might be expected in the course of 2001.[16]

12. Notwithstanding the objections raised in the public against patents on life forms, the US lawmaker has resisted all attempts to introduce into the Patent Act any exclusionary provision or other special provisions related to biotech inventions, except for declaring patents on medical or surgical procedures unenforceable against medical practitioners (35 U.S.C. § 287 (c)). The much debated issue of patents on DNA fragments (so-called Expressed Sequence Tags - ESTs)[17] has not been subjected to any legislative measure. However, the US Patent and Trademark Office, primarily in response to concerns expressed by the National Institutes of Health (NIH), in 2000 adopted new Utility and Written Description Examination Guidelines, which now require that a claim is supported by a specific, substantial, and credible utility or a well established utility. Thus, ESTs continue to be eligible for patent protection, however, under more stringent conditions: a general utility does not suffice, neither does a throw away utility; but a probe/marker for a disease or diagnostic target specific to a disease state would be considered to be specific and substantial and patentable.[18] As to the written description requirement, which under the US law is separate and distinct from the enablement requirement (35 U.S.C. 112 (1) (2)), the description meets the standard if an expert can reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. Initial burden is on examiner to establish *prima facie* case.[19]

13. As regards computer software, a Presidential Commission on the patent system in the mid-1960s recommended that the US patent laws be amended to provide that computer programmes not be patentable. However, this recommendation was never enacted by Congress. Nevertheless, the US Patent and Trademark Office following that recommendation rejected most applications for software patents. This has changed only in the wake of a number of the Supreme Court and the US Court of Customs and Patent Appeal's decisions,

---

[15] See Straus, Biotechnology and Patents, 54 CHIMIA 293 ss., 294 (2000), with further references.
[16] Case No. 99-1996 (to be published in 531 US).
[17] Cf., e.g., Heller and Eisenberg, Can Patents Deter Innovation? The Anti-Commons in Biomedical Research, 280 Science 698 ss. (1 May 1998); Barton, Changing Intellectual Property Issues in the Biotechnology Industry, 18 Biotechnology Law Report No. 1, 1999, pp. 1 ss.
[18] Revised Interim Written Description Examination Guidelines of December 21, 1999, 64 Fed. Reg. 71440.
[19] Revised Interim Written Description Examination Guidelines of December 21, 1999, 64 Fed. Reg. 71434.

which, although not explicitly confirming patentability of such inventions, effectively lowered the threshold for such patents. Some 40,000 software or software-related patents have been granted since. Eventually, in two decisions the Court of Appeals for the Federal Circuit (CAFC) in 1999, namely the *State Street Bank vs. Signature and AT&T vs. Excel Communications Inc.*, proclaimed that anything that achieved a "practical, useful and tangible result" was eligible for patenting. Thus, a computerised system for managing a stock fund, i.e. a business method, was held patentable. As a consequence, the insurance, financial services and advertising areas were opened for patenting, and a large number of patents filed subsequently.[20]

IV. EUROPE

14. In Europe claims related to biological material other than animals or plants so far had not encountered any other difficulties as those generally related to the patentability requirements of novelty and inventive activity in the European Patent Office' (EPO) patent granting practice either. About 3,000 patents have been granted for monoclonal antibodies, cell lines, plasmids, and DNA-sequences of various origin.[21] As regards generic inventions in animals and plants, after some considerable uncertainties, caused by a Technical Board of Appeal decision in 1995 (*Plant Cells/Plant Genetic Systems (PGS)*),[22] which rejected a claim that related to a non-biologically transformed plant, possessing in its genome a stable integrated DNA nucleotide sequence encoding a protein with specific properties, as a claim directed to "plant varieties" and as such being banned from patent protection under Art. 53 (b) EPC, the Enlarged Board of Appeal, in December 1999, eventually clarified the situation in the *Novartis* case. The Enlarged Board of Appeal held that "a claim wherein specific plant varieties are not individually claimed is not excluded from patent protection under Art. 53 (b) EPC." The applicant may claim his invention in the broadest possible form, i.e. the most general form for which all patentability requirements are met. The Board also stated explicitly that the subject matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties. Such an invention cannot be protected by a plant breeder's right, which is concerned with plant groupings defined by their whole genome but not by individual characteristics.[23]

15. As regards the patentability of computer software in Europe, be it in the case law of the Boards of Appeal of the European Patent Office, be it in the relatively abundant case law of the German Federal Supreme Court or the Federal Patent Court, only a short remark should be made. It visibly suffers of the explicit exclusion from patentability of computer programmes as such, which is neither present in the US, nor in the Japanese Patent Act; it is at pain to provide for protection for inventions, which in the opinion of the judges and Board of Appeal Members are to be viewed as having technical character; however, with some exceptions, as for instance in the case of operability programmes or system programmes, the outcome of such applications is quite unpredictable and also dependent on how the claims are drafted. As examples only headnotes of three more recent decisions should be quoted. According to a

---

[20] For simplicity reasons reference is made only to Toren, Software and Business Methods are Patentable in the US, Patent World, September 2000, pp. 7 ss. For the situation in Japan cf. Tessensohn, Business Method Patents in Japan, Patent World, November 2000, p. 8; and for statistics on this type of patents Morris, Some Data About Patents in Class 705, Intellectual Property Today May, 2001, pp. 51 ss.

[21] Notice of the EPO of July 1, 1999, OJ EPO 1999, 573 at 574.

[22] OJ EPO 1995, 545.

[23] OJ EPO 2000, 111 - Transgenic Plant/Novartis II.

1998 Technical Board of Appeal Decision, "a computer programme product is not excluded from patentability ... if, when it is run on a computer, it produces a further technical effect which goes beyond the 'normal' physical interactions between programme (software) and computer (hardware)" (*Computer Programme Products/IBM*);[24] the German Federal Patent Court, in 1996, held, "if a claimed teaching relates to an algorithm, comprising the indication of purpose, namely 'receiving signals transmitted through a noisy channel,' teaching is restricted concerning its content to technical quantities and can be protected by a patent. It is not an obstacle to the technical character that the 'contribution of the invention to the state of the art' exclusively consists of the provision of mathematical rules and therefore, as such, lies in a non-technical field" (*Viterbi Algorithm*).[25] On the other hand, the German Federal Supreme Court in a decision handed down last year stated, that a specifically programmed computer is to be attributed technical character even if it is used for word processing and that the technical character of such a device does not depend on whether it produces a further technical effect (*Sprachanalyseeinrichtung - Device for Language Analysis*).[26] However, here the claims were related to a device and not to a programme/method.

16. It may be added that, at least for the time being, the idea of deleting the exclusion from patentability for computer programmes as such has failed. At the Diplomatic Conference for the Revision of the EPC in November 2000, a respective proposal of the Administrative Council was voted down. The reason being, at least in part, was the present efforts of the EU-Commission to propose a Directive in this field.[27] We all look forward to seeing its outcome. However, at present the introduction of the patentability of business methods does not seem to be seriously considered. To me it seems clear that such a decision should be taken based on macro-economic considerations by the EU lawmaker and neither by patent offices nor courts.

V. THE REGIME UNDER THE EUROPEAN DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

17. Let me add, in respect of the protection of biotechnological inventions, that the European lawmaker did not and actually could not follow the US approach. Lacking a central judicial authority for deciding on validity and infringement of European patents, which only could secure a EU-wide harmonized interpretation of the European-bundle patents, the only way for setting unified standards and securing, as far as possible, a harmonized interpretation, was to adopt a respective Directive. It took the EU ten years of debate in the Council and the European Parliament, before in July of 1998 the Directive 98/44 on the Legal Protection of Biotechnological Inventions was adopted.[28] In order to achieve its aims, namely to, on the one hand provide for high an harmonized standards of protection, comparable to those in force in the US and Japan, and, on the other hand, establish a balance between the commercial need of researchers and industry and the ethical concerns of some parts of the public at large, which have been strongly opposed to the idea of patenting living matter, the Directive eventually provided for clarification in two directions: namely, what has to be viewed as

---

[24] OJ EPO 1999, 609.

[25] 31 IIC 442 (2000), Comment by Betten.

[26] 2000 GRUR 1007.

[27] Cf. Nack and Phélip, Diplomatic Conference for the Revision of the European Patent Convention, 32 IIC 200 ss., at 203 s. (2001).

[28] OJ EC No. L 213/13 of 30.7.1998.

patentable and what has to be excluded from patentability in respect to inventions related to biological material, i.e. "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system." Since the EPC does not form part of the legal order of the European Union and, thus, the EPO is not bound by legal instruments of the Union, it was of utmost importance that the Administrative Council of the European Patent Organization, in order to comply with the requirement for uniformity in harmonized European patent law, with effect as of September 1, 1999, transformed the EU-Directive into the Implementing Regulations to the EPC, by introducing the new Rules 23b-23e.[29]

18. Under the basic rule of the Directive, inventions which satisfy the usual patentability requirements constitute patentable subject matter "even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used." This holds true also for biological material which previously occurred in nature, if it is isolated from its natural environment or produced by means of a technical process. The Directive, thus, confirms the long-standing practise of, for instance, German courts, followed by the EPO, on the patentability of naturally occurring substances and imposes its application on all naturally occurring biological material as defined. In particular, this applies also to elements isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene. However, the explicit confirmation of the patentability of DNA-sequences of human origin under the EU-Directive is made dependent on some additional requirements so far not explicitly provided for either under the EPC and its new Implementing Rules, or in the US Patent Law. First, in a Recital it is stated that a mere DNA-sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. Thus, the notion of the patentable invention itself seems to have experienced a more stringent authentic interpretation making the indication of "a function" to one of its integral parts. In this context "a function" according to the prevailing view may not be equated with "biological function" of for instance an EST or the gene of which it is part, but has to be understood as any function responsible for a technically applicable result, e.g. to be used as a specific diagnostic marker, or for the specific identification for forensic purposes,[30] and secondly, the patentability requirement of industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as filed. Moreover, in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, the requirement of industrial application is met only if the application specifies which protein or part of a protein is produced or what function it performs. The Directive also explicitly requires that the industrial application must be disclosed already in the application. Also, it is ensured that generic inventions in plants and animals are patentable if their industrial applicability is not limited to one variety.[31]

19. On the other hand, the Directive taking into account ethical considerations, explicitly excluded from patent protection the human body, at the various stages of its formation and development, including germ cells. Furthermore, it exemplified in which cases by all means the exploitation of an invention would be contrary to *ordre public* or morality. This applies to processes for cloning human beings, uses of human embryos for industrial or commercial

---

[29] OJ EPO 1999, 437; cf. also Notice of July 1, 1999, OJ EPO 1999, 573.

[30] Cf., e.g., Oser, Patenting (Partial) Gene Sequences Taking Particular Account of the EST Issue, 30 IIC 1 ss., at 17 (1999).

[31] Reference is made here only to Straus, 54 CHIMIA 295 s. (2000), with further references.

purposes, and processes for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to man or animal, and also of animals resulting from such processes. It may be observed here, however, that neither the general exclusion of therapeutic and surgical methods, nor the new specific exclusionary provisions result in a total lack of protection for methods and substances involved in somatic gene or somatic cell therapy. Since substances or compositions for use in such methods are patentable, not only methods for their production, but also intermediaries and, eventually the end product - the drug itself - involved in somatic gene therapy and somatic cell therapy, such as vectors, somatic cells, as well as transformed somatic cell, to be injected, infused, etc. should be viewed as patentable. Outside patent protection, contrary to the situation in the United States and for instance Australia, remain only entire therapeutic methods, including the steps of removing human tissues and injecting, etc., the drug.[32]

VI. TRIPS AGREEMENT

20. It is common sense that the TRIPS Agreement has revolutionized international protection of IPRs, and, in particular of patents, by imposing the general obligation, unknown prior to 1994, of making patents available for any invention, whether products or processes, in all fields of technology provided that they are new, involve an inventive step and are capable of industrial application. No discrimination is allowed as to the place of invention, the field of technology and whether products are imported or locally produced.[33]

21. Under the influence of the EU and Developing Countries, however, Members of WTO were allowed to exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, whereby laws protecting human, animal or plant life or health or to avoid serious prejudice to the environment, are to be viewed as constituting a part of the *ordre public*. As in case of the EPC, simple prohibitions of exploitation do not suffice. In this respect it is generally accepted that a country which excludes from patent protection an invention under this tag, may not allow its commercialization.[34] In addition, Members of the WTO may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as plants or animals other than micro-organisms, and essentially biological processes for the production of plants or animals. In this context it is important to note that under the TRIPS Member States of the WTO have to provide for patent protection for non-biological and micro-biological processes and that such protection, in connection with the rights conferred covers also the direct products of such processes, thus, even if plants or animals are at hand. Members also have to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. By imposing patent protection for micro-organisms, it would seem, that biological material of a lower taxonomic rank, such as viruses, plasmids, cell lines, etc. should also be viewed as belonging

---

[32] Cf. Straus, 54 CHIMIA 295 ss. (2000); Bostyn, One Patent a Day Keeps the Doctor Away? Patenting Human Genetic Information and Health Care, 7 European Journal of Health Law 229 ss., at 239 ss. (2000); Straus, Patentrechtliche Probleme der Gentherapie, 1996 GRUR 10 s., at 13.

[33] Cf. for details Straus, Implications of the TRIPS Agreement in the Field of Patent Law, in: Beier and Schricker (eds.), From GATT to TRIPS - The Agreement on Trade-Related Aspects of Intellectual Property Rights, Weinheim 1996, pp. 160 ss., at 178 ss.

[34] Cf. Correa, The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection, 1994 EIPR 327 ss., at 328.

to the subject matter mandatorily to be protected under the TRIPS Agreement.[35] As regards other rights of intellectual property, such as copyright and related rights, trade marks, industrial designs, geographical indications and layout-designs of integrated circuits, it should suffice to note that TRIPS also has secured high standards of protection in this regard, however, that such standards existed, at least in part, internationally already before 1994.

22. New and of far-reaching consequences are the TRIPS provisions relating to the enforcement of intellectual property rights. These provisions for the first time in the history introduced international obligations related to civil and administrative procedures and remedies, provisional measures and special requirements related to boarder measures, as well as criminal procedures, and acquisition and maintenance of intellectual property rights and related *inter partes* procedures. Together with provisions dealing with dispute prevention and settlement, these parts of the TRIPS Agreement are of utmost importance for the functioning of the IPR system. At the same time, it seems to be equally true that these provisions pose the greatest challenge to the WTO Members, since only well-educated and trained civil servants and judges are in a position to comply with all the requirements in a way, which could secure a balanced functioning of the system. Especially in areas such as patents, which imply highest complexities of techniques and law, not only Developing Countries and countries in transition, which have enjoyed until recently the transitory period for implementing TRIPS rules, but also developed countries with lesser experience in litigating intellectual property rights, might be faced with serious problems, which, this should also be added here, may equally affect the owners of intellectual property rights as well as the potential infringers.[36]

VII. CHALLENGES

23. Despite the somewhat uneasy feelings, which the exclusionary provisions of the European type, mostly copied also by Developing Countries and countries in transition, may have caused, in view of the exponential growth of the numbers of intellectual property rights registered world wide and the ever increasing economic value they occupy in the globalized economy and also lacking a clear negative experience in respect to patents granted for inventions in specific fields of technology, one would expect a general satisfaction among the users of the patent system and also among the critical observers of that system. As remarked earlier, this is partly so, however, in the meantime also eloquent voices have been raised, questioning the entire system of IPRs.

24. For instance, *Lester C. Thurow* from MIT recently entitled a widely observed article with “Needed: A New System of Intellectual Property Rights,” which he introduced by remarking that fundamental shifts in technology and in the economic landscape are rapidly

---

[35] Cf. for more details Straus, Biodiversity and Intellectual Property, AIPPI Yearbook 1998/IX, 99 ss., at 109 s. For a different view see Correa, Implementing the TRIPS Agreement in the Patent Field - Options for Developing Countries, 1 Journal of World Intellectual Property 75 ss., at 79 (1998).

[36] With reference to Article 7 TRIPS it may be emphasized that although the main aim of TRIPS is to strengthen intellectual property rights, its provisions have always to be interpreted in a way so as to equally take into account the legitimate interests of patent owners as well as those of their competitors (cf. Abbott, The Enduring Enigma of TRIPS: A Challenge for the World Economic System, 1 Journal of International Economic Law 497 ss., at 513 (1998); Oddi, TRIPS - Natural Rights and a "Polite Form of Economic Imperialism," 29 Vanderbilt Journal of Transnational Law 415 ss., at 432 ss. (1996); Straus, Reversal of the Burden of Proof, the Principle of "Fair and Equitable Procedures" and Preliminary Injunctions Under the TRIPS Agreement, 3 Journal of World Intellectual Property 808 ss., at 809 (2000).

making the current system of intellectual property rights unworkable and ineffective. It was designed more than 100 years ago to meet the simpler needs of an industrial era, it was an undifferentiated, one-size-fits-all system. Although treating all advances and knowledge in the same way may have worked when most patents were granted for new mechanical devises, *Thurow* added, "today's brain power industries posed challenges that are far more complex."[37] *John Barton* from Stanford recently proposed a three-step reform of the patent system, suggesting to raise the standards for patentability, to decrease use of patents to bar research, and to ease legal attack on invalid patents.[38] *John R. Thomas* from the George Washington University Law School, under the title "Post-Industrial Patents and Personal Liberties," frustrated by business method patents, and even more so with patenting abortion, patenting law and patenting speech, as he put it, dissatisfied by the inactivity of the US lawmaker recently sought solution in the Constitution serving as a meaningful restraint "upon the excess of the dizzying ambitious of the contemporary intellectual property community."[39] *William Kingston* from the Trinity College in Dublin concluded his contribution on "Innovation needs patents reform" demanding that legal changes had to be made to try to adjust the administration of patents to the reality that invention and innovation now primarily result from investment rather from individual creativity."[40] Less outspoken, however, highly concerned as regards the impact of the TRIPS Agreement on the economies of Developing Countries *Jerome H. Reichman* from the Duke School of Law, in his contribution "Securing Compliance with the TRIPS Agreement after US v. India," advocates a "detailed strategy for implementing the TRIPS Agreement that could enable most developing countries to lessen the social costs and increase the gains likely to accrue from stronger international intellectual property protection." In his view, "the Developing Countries should strive to achieve the maximum degree of competition in their domestic markets that is consistent with a good faith implementation of the international minimum standards of intellectual property protection under the TRIPS Agreement."[41]

25. In view of the complexity of science and technology which intellectual property rights have to cope with and which at present can best be demonstrated by the relatively sudden advent and rapid development of the stem cell technology[42] or by the fact that it took researchers joined in the Human Genome Organization (HUGO) four years to sequence the first billion of DNA base pairs, four month to sequence the second one, and they then sequenced 300 million base pairs per month,[43] calls for legislative interventions to adjust patent laws to the assumed needs of new technologies, or to prevent patenting of specific technologies, at national, but even more so at regional and universal levels should be handled with great care. Notwithstanding their possible justification at times they are raised, and

---

[37] Harvard Business Review September-October 1997, 95 ss.

[38] Reforming the Patent System, 287 Science 1933 s. (17 March 2000).

[39] Draft Paper distributed at the Ninth Annual Conference on International Intellectual Property Law & Policy of the Fordham University School of Law, April 19 & 20, 2001, p. 1.

[40] 30 Research Policy 403 ss., at 421.

[41] Journal of International Economic Law (1998) 585 ss., at 587.

[42] Cf., e.g., Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocytes, 282 Science 1145 ss. (6 June 1998); Solter and Gearhart, Putting Stem Cells to Work, 283 Science 1469 ss. (5 March 1999); Brüstle et al., Embryonic Stem Cell Derived Glial Precursors: A Source of Myelinating Transplants, 285 Science 154 ss. (30 July 1999); Lumelsky et al., Differentiation of Embryonic Stem Cells to Insulin-Secreting Structures Similar to Pancreatic Islets, 292 Science 1389 ss. (18 May 2001); Vogel, Can Adult Stem Cells Suffice?, 292 Science 1820 ss. (8 June 2001).

[43] See Marshall/Pennisi/Roberts, In the Crossfire: Collins on Genomes, Patents, and 'Rivalry', 287 Science 2396 (31 March 2000).

notwithstanding the heavy international "machinery" which has often resisted even badly needed evolutionary and not revolutionary changes for nearly half a century, they may turn out within short period of time as inadequate or outdated.

26. Having regard to the long-standing experience with, for instance, patent protection in countries such as the United Kingdom and the United States, one can barely deny that absent any provisions dealing with specific technologies, patent offices and courts have by and large, though not always optimally, mastered the challenges posed to them by new scientific and technological developments. Even critics of the *Chakrabarty* decision of the US Supreme Court should have difficulties in denying its macro-economic benefit to the US, but also beyond. One should not forget that the rise of the new biotech industry in the United States and even more so the exponential funding of research and development in this area has also enriched others in their understanding of science and technology and brought products for patients worldwide.

27. These, however, should not be understood as a conservative pleading for a still stand. On the contrary, the developments of science and technology and the nearly frightening globalization process and its impact paralleled with the ever increasing flood of new patent applications, which already seriously endanger the functioning of the entire patent system have to be closely monitored and solutions sought. Although the entire system of intellectual property rights one day in the future might require a fundamental overhaul, and therefore long term intellectual efforts aimed at designing its likely structure are to be welcomed, at present the solutions needed can realistically be sought only in cautious improvements of the existing legal network administered by WIPO and WTO, respectively.

28. As indicated above, the exposure of the intellectual property rights system to the globalization process is enormous. In such circumstances further *harmonization* of, for instance, *substantive patent law*, after the adoption of the Patent Law Treaty of June 2000, seems to be a must. WIPO has already taken the first steps for adopting a Substantive Patent Law Treaty. Bearing in mind the experience with the failure of the first attempt at the Hague Diplomatic Conference of 1991,[44] one may express the strong desire that this time all parties involved will be able to question their own systems, regardless whether the instruments at hand are old or relatively new. I do not want to touch upon the nearly religious issue of "first to invent" or "first to file" system. We all should be able to recognize the merits of both of them, but examine them against the background of the most recent legal and technological developments. The same applies to such issues as that of the grace period. Europeans should be able to realize that things have changed since 1963. 38 countries by now, with one exception, all applying the first to file system, have the grace period in their patent laws. This may not be ignored whenever assessing the situation in the EPC Contracting States.[45] Also, the new changes of the US law, introducing a firm term of protection of 20 years and, as a rule, publication of all patent applications after 18 months, may have an impact on the US stand as to the first to invent system. Europeans, as well as Americans, Japanese, Australians and others should also realize the entirely changed information and communication environment and be willing to examine the provisions determining the relevant prior art. Art. 8 of the WIPO Draft Substantive Patent Law Treaty,[46] apart from the

---

[44] WIPO Doc. PLT/DC/3.

[45] On the complex issue of the grace period cf. Straus, Grace Period and the European and International Patent Law, Vol. 20 IIC Studies, Munich 2001.

[46] WIPO Doc. SCP/5/2 of April 4, 2001.

grace period provisions, basically reflects the solutions adopted or influenced by the Europeans. It may sound somewhat anachronistic, but the experience with the European Patent Office, where, under certain conditions, it may take 10-12 years to establish what has been orally disclosed in a scientific conference, might put a question mark behind a definition of relevant prior art, which includes everything which has been made available to the public anywhere in the world.[47] The more so, if one may expect that, for instance, Internet disclosures will be treated or should be treated as oral disclosures.[48] Harmonizing substantive patent law and adjusting the skills of examiners of the main patent offices in the world, not necessarily only of the big once, should pave the way for the establishment of mechanisms for mutual recognition of the search and examination results and thus enable the system to cope adequately with the ever increasing number of patent applications.[49] It should be entirely clear, that, as a rule, a duration of patent granting proceedings of up to 15 years and more would be detrimental to the system as a whole. This cannot be emphasized strongly enough.

29. I also share concerns as to the overall impact of the TRIPS Agreement, should WTO Members, especially those belonging to the group of developing countries and countries in transitions, not be able to establish a well-functioning administration and judiciary, including the bar. They are crucial to the well-functioning of the system as such. What *Lord Woolf of Barnes*, Master of the Rolls from UK, recently noted in his Millennium Lecture entitled "The Additional Responsibilities of the Judiciary in the New Millennium," for the UK judiciary, is more than relevant for judiciaries of countries in transition and developing countries, and those countries members of WTO with less experience in adjudicating intellectual property rights. *Lord Woolf* not only pointed out the importance of resources, which the judiciary is in need of, but especially the need for the courts to be provided with all the relevant comparative and academic material to be considered as it should be, if a thorough approach to constructive law making is to be adopted.[50] He also observed that the advocate's primary role is to advance his clients case and that it would be unreasonable to expect the advocate to become involved with all the wider issues with which the court should be concerned. Furthermore, he noted that it can be unreasonable to expect the client to pay for Counsel's time in exploring arguments which are of no interest to the client.[51] Bearing this in mind, the importance of well-trained and responsible judges dealing with TRIPS cases must be more than apparent. The future of the TRIPS Agreement will to a large extent depend on fair and equitable proceedings. Only a skilful judiciary can ensure that the standards applied are in compliance with theTRIPS , may they be, as *Jerome Reichman* put it, consistent with a good faith

---

47 See for details Straus, op. cit. footnote 45, at pp. 24 ss.

48 Cf. Verhulst and Riolo, Prior Art Disclosure on the Internet: A European Perspective, Part 2: The Internet as Prior Art, Patent World 16 ss. (February 2000). WIPO has already addressed the issue of disclosures on the Internet, see WIPO Doc. SCP/4/5 of September 19, 2001, "Disclosure of Technical Information on the Internet and its Impact on Patentability," document prepared by the International Bureau.

49 Cf. Kondo, AIPPI Journal of the Japanese Group, January 2000, 36, who named three conditions necessary for achieving this goal: (i) Confidence-building activities, such as cooperation on searches; (ii) harmonization of the substantive aspects of systems; and (iii) simplification of procedures.

50 In Markesinis (ed.), The Clifford Chance Millennium Lectures - The Coming Together of the Common Law and the Civil Law, Oxford-Portland Oregon 2000, pp. 133 ss., at 137.

51 Lord Woolf, ibidem.

implementation of the international minimum standards.[52] One should neither offer less nor ask for more than required. Otherwise the system could be seriously harmed.[53]

30. Of course, there are many other challenges to intellectual property rights awaiting satisfactory solutions. Some of them are of apparent importance, some of a more hidden one. Only two of the first category should be mentioned: Protection and exploitation of genetic resources, implying the relationship between the TRIPS Agreement and Convention on Biological Diversity, and Protection of Traditional Knowledge. They both will be addressed by other speakers during this Conference.

VIII. CONCLUSION

31. I shall conclude by emphasizing the ever present importance of a responsible administration of the patent system which includes the strict application of protection requirements. Patent Offices should be aware of the macro-economic effects of their activities. A too narrow or a too broad scope of protection, or, for instance, a too lax application of patentability requirements which may lead to perpetuating of patent protection by patents covering incremental improvements, do not affect only the patentee and his direct competitors but may lead to economically harmful market entry barriers or even true innovation obstacles.[54] This is an aspect which is equally important for developed as well as for developing countries and countries in transition, but so far has not received adequate attention.

[End of document]

---

[52] Journal of International Economic Law (1998), 587 (see above No. 24). When addressing the situation of developing countries in the context of intellectual property rights, Lester Thurow observed: 'The economic game of catch-up is not the game of keep ahead. Countries playing either game have the right to a world system that lets them succeed.' (Harvard Business Review September-October 1997, p. 100).

[53] Cf. Straus, 3 Journal of World Intellectual Property 823 (2000).

[54] See for experience with such effects of patent granting practices Gimeno, The Patent System in Action - Company Views, in: European Commission (ed.), Patents as an Innovation Tool, Patinnova '99, Luxembourg 2000, pp. 321 ss.