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RECENT DEVELOPMENTS AND CHALLENGES IN THE PROTECTON OF INTELLECTUAL PROPERTY RIGHTS

STRIKING NEW BALANCES: THE PROTECTION OF PHARMACEUTICALS AND THE FUTURE OF THE INDUSTRIAL PROPERTY SYSTEM IN EUROPE A CENTRAL AND EASTERN EUROPEAN PERSPECTIVE

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A BALANCED VIEW OF INTELLECTUAL PROPERTY

1. Those visiting the WIPO website may, and I believe should, carefully read and consider the following words of wisdom:

> *" With each passing day, the importance of intellectual property increases for governments and policy-makers, for industry and the global, regional and national markets, for the general public and consumers everywhere in the world. A robust and dynamic intellectual property system supports and encourages technological innovation and artistic creativity. This brings more investment and technology transfer, more and better products and services available to more people everywhere, and a more beautiful and enjoyable artistic environment. Most importantly, intellectual property – the fruit of human endeavor – contributes to the common good of all." (Dr. Kamil Idris: Welcome to the website of the World Intellectual Property Organization (WIPO) – A Message from the Director General).*[1]

2. It is exactly this balanced view of intellectual property that national governments and policymakers should take when considering intellectual-property-related issues. The growing importance of intellectual property may be perceived also in the impact of intellectual-property-related decisions and achievements on many important aspects of human life and social development. Therefore, the political importance of intellectual property is on the increase. In many fields, no well-founded strategic decisions may be taken, no truly workable economic and social projects launched, without the relevant intellectual property considerations having been duly taken into account. And this is true the other way round, too. The extension of the impact of intellectual property to ever more aspects of human and social activity inevitably broadens the scope of issues where it is not sufficient to take account of intellectual property considerations alone, but equally important to examine and weigh the effects of the application of intellectual property in other fields. It is this side of the coin that I would like to study and describe in more detail. The industrial property protection of pharmaceutical products is certainly one of the areas that can provide the best examples for all these considerations.

3. A recent study of the World Health Organization stated the following:

> *"It is generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products. In the first place this is because consumers are not in a position to judge, for example, the quality of drugs, hence the need for a monitoring and surveillance system ensured by the State. Secondly, this is because drugs play a significant role in that they are an integral part of the realization of a fundamental human right – the right to health. That is why they are classified as essential goods, to emphasize that they have to be accessible for all people." (Germán Velásquez, Pascale Boulet: Globalization and access to drugs: Implications of the WTO/TRIPS Agreement).*[2]

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1 http://www.wipo.int/about-wipo/en/dgo/index.html.

2 WHO/DAP/98.9.

4. On the basis of an analysis of the Preamble and Articles 1, 7 and 8 of the TRIPS Agreement, the authors of this study take the firm view that

> *"These general provisions were included in the Agreement to make for a balance between the rights of patent holders and their obligations vis-à-vis society. Member States may therefore base certain particular provisions of their national regulations on these principles. They can also bring their regulations into line with the obligations of the Agreement in such a way that their national objectives for the protection of intellectual property also accord with those imposed in other sectors of State activity which the latter deems to be necessary, provided such regulations do not contravene the Agreement."*
>
> *"From a social and health policy perspective, the provisions open up the possibility of establishing national regulations, taking into account the imperative of guaranteeing the best possible access to drugs."*

5. All this can also be seen from the perspective of the forthcoming eastward enlargement of the European Union. The above-quoted considerations are relevant in that context, too.

6. While the importance of effectively protecting intellectual and industrial property rights has by all means to be recognized, it should also be stressed that there are other legitimate policy objectives pursued by both the European Union and Central and Eastern European countries. Intellectual property rights are neither conferred nor exercised in a social or political vacuum, therefore it cannot be a legitimate aim to achieve a level of protection for those rights that would prejudice the vital public interest in social and economic welfare. National governments should be left some room for maneuver in order to enable them to achieve an appropriate balance between the various interests in view of the peculiar circumstances of their society and economy. This has been recognized by Articles 7 and 8 of the TRIPS Agreement. It is also to be recalled that under the EC Treaty there are objectives other than the establishment of an internal market that the Community has set out to achieve. Pursuant to Article 3(p) of that Treaty, a contribution to the attainment of a high level of health protection is one of the activities of the Community. Furthermore, Article 152 (formerly Article 129) provides that a high level of human health protection must be ensured in the definition and implementation of all Community policies and activities.

7. It is in this context that reference should be made to the Council conclusions of 18 May 1998 on the single market in pharmaceuticals. In these conclusions the Council has recognized that "*industrial policy must necessarily take account of the particular nature of this sector, which relates to health and social policies,*" and that "*it is for Member States to ensure affordable access for their citizens to the benefits of medicines.*" In addition, the Council has considered that Community policy should address the need to *"facilitate the delivery of health care in Member States at levels which are affordable and in ways which maximize, as far as possible, patients' access to medicines."*

HEAVEN'S DOOR OR A NECESSARY EVIL?

8. A country applying for membership in the European Union has to accept the Community legal order, the famous *acquis communautaire* as a whole. This is the general rule but there are exceptions to all general rules. Those exceptions, which are intended to reflect and ease the "pains of adaptation" of the applicant country, are to be defined at accession negotiations and have to be included in the Accession Treaty concluded after those

negotiations. These general principles apply in the field of intellectual property too. Hungary, like many other countries of the region, submitted its application for EU membership in 1994, and accession talks began in the framework of an intergovernmental conference in 1998. At those negotiations the following main intellectual property issues for substantive talks were identified:

- pre-patent-expiry development work;
- data exclusivity;
- supplementary protection certificates for medicinal products, and
- parallel imports.

9. I would like to provide an overview of these issues, mainly, but not exclusively, from the perspective of EU accession. The process of joining the EU, including accession talks, is far from being a fairytale. One might think that it was like knocking on Heaven's door, yet some are of the view that European integration is nothing but a necessary evil. Admittedly, the unconditional enthusiasm for European integration, which was quite understandable at a certain early stage of the sweeping economic and political changes that have taken place in Central and Eastern Europe, is now over. What has replaced it is a hard bargaining process, a give-and-take game of conflicting interests in which, eventually, we need to strike a proper balance between those interests; there is no other way. The western part of our continent cannot take a one-sided, almost selfish approach without running the risk of undermining the whole integration process and being ultimately counterproductive. In other words, countries of Central and Eastern Europe should not only look after their own interests but also look after them without embarrassment.

PRE-PATENT-EXPIRY DEVELOPMENT WORK *("Roche-Bolar")*

10. The EU has several times criticized Article 19(6) of the Hungarian Patent Act (Act No XXXIII of 1995 on the Protection of Inventions by Patents, hereinafter referred to as "the Patent Act"), 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."*

11. The Hungarian Government has maintained that this provision of the Patent Act conforms to both the WTO TRIPS Agreement and the Community Patent Convention, although the latter has never entered into force. Contrary to the statements made by the EU side at the accession negotiations, there seems to be no "*system among the EU Member States"* that would or should be applicable to "*pre-patent-expiry development work carried out by generic companies."* Furthermore, the case law of present Member States seems to diverge on this issue.

12. Article 19(2) of the Patent Act does provide for all the exclusive rights that are listed by Article 28 of the TRIPS Agreement, in other words the acts subject to the right holder's consent are the same under the Patent Act as those listed in the TRIPS Agreement. In addition, under Article 30 of the TRIPS Agreement, Members are permitted to provide limited exceptions to the exclusive rights conferred by a patent as long as such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests

of third parties. Both the drafting history of the Agreement and a comparative law analysis prove that Article 30 of the TRIPS Agreement allows Members to designate acts done for experimental purposes as exceptions to the exclusive rights conferred by a patent. In fact, a number of Members, including Canada, Japan and the United States of America, have done so. Article 7 of the TRIPS Agreement lends further support to this interpretation by stating, obviously with the aim of striking a balance between the various objectives of the Agreement, that protection and enforcement of intellectual property rights should perform their functions *"... in a manner conducive to social and economic welfare,"* and that there should be *"... a balance of rights and obligations."* The reference in Article 30 to the "legitimate interests" of third parties is intended to achieve the desired balance, as the category of *"third parties"* includes society at large, consumers of such regulated products (that is, the individual users of the health care system and the public and private sector entities that pay for them) and would-be rival producers of those products. The use of generic medicinal products results in considerable savings for the public healthcare system, and thereby contributes to its viability and the promotion of public health. Thus society at large and consumers of the healthcare system in particular have an undeniably legitimate interest in ensuring the availability of competitively priced generic medicines as soon after patent expiry as possible.

13. The report of the WTO panel in the proceedings initiated by the European Communities and their Member States against Canada has confirmed the Hungarian view, stating that national legislation allowing experiments and tests to be carried out by generic manufacturers for the purpose of regulatory approval during the patent term is not inconsistent with the TRIPS Agreement.[3] However some legislative refinement might be necessary in Hungary to make the relevant provision of the Patent Act neutral from the viewpoint of technological fields.

14. Article 19 of the Hungarian Patent Act does not contravene the relevant provision [Article 27(b)] of the Community Patent Convention either. And the same applies to the Commission's proposal for a Council Regulation on the Community Patent.[4] The Patent Act differs from the Convention and the Regulation only in identifying an example of acts accomplished for experimental purposes. The interpretation of this provision of the Convention varies from Member State to Member State. There is, however, a tendency towards expanding the research exception. This is evidenced by two recent judgments of the German Supreme Court (*Bundesgerichtshof*) in the Clinical Trials cases (*Klinische Versuche* I and II). In the second case, the Supreme Court held that clinical tests to establish the efficacy and human tolerance of a drug containing a patent-protected ingredient would not infringe the patent even if they were planned and carried out with the commercial goal of obtaining data for the necessary legal pharmaceutical permission, provided that the tests also advanced the state of the art in some way.[5] In Italy, a decision of the District Court of Milan held that a patent holder could not prevent a generic manufacturer from experimental activity in connection with an application for regulatory review during the term of the patent.[6]

15. At Community level, a recent ruling of the Court of Justice of the European Communities[7] has confirmed the competence of the Member States to decide whether, and on what conditions, they will allow patent owners to oppose the submission by third parties of

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3 Case WT/DS 114.

4 COM (2000) 412 final, Art. 9(b).

5 BGH Urt. vom 17. April 1997 - X ZR 68/94[OLG. Düsseldorf], [1998] RPC 423.

6 E.R. Squibb & Sons Inc. v. Giovannia Aguggini, 12 June 1995, 1996 Giur. annot. di Dir. Industriale 13.

7 Case C-316/95, Generics BV v. Smith Kline & French Laboratories Ltd, [1997] ECR I-3929.

samples of medicinal products manufactured in accordance with the patented process to the authority competent for issuing marketing authorizations.[8] In addition, it can reasonably be expected that the comprehensive legal review of the "Bolar" issue contained in the WTO panel's report will have a significant impact on any new case law developed in the national courts of EU Member States.

16. We have, of course, taken note of the EU's latest statement[9] that the outcome of the WTO panel proceedings "does not affect the possibility for the EU to maintain its high level protection." We have never questioned this. But it is also beyond any doubt that the EU has not made use of that possibility so far, and has not adopted any specific legislation on the issue, with which Hungary would then have to comply upon accession.

17. Therefore, until the issue is completely clarified and settled within the Community and among its Member States, Hungary does not intend to take any relevant legislative action, as it would certainly be premature.

DATA EXCLUSIVITY

18. Under Article 39.3 of the TRIPS Agreement

> "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.*

19. This provision should not be construed in isolation from other parts of Article 39 of the Agreement. It has to be borne in mind that the whole Article is devoted to effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention. Therefore, Article 39.3 of the TRIPS Agreement cannot be interpreted in such a way as to mean that Members are required to establish a special legal regime for the protection of undisclosed tests or other data submitted for the regulatory approval of pharmaceutical products. This is clearly only an option open to Members. Nevertheless, Members are no less free to choose other means of ensuring that such data are protected against unfair commercial use. Those means may include the application of general rules against unfair competition, in particular those protecting trade secrets (undisclosed information). This interpretation is further justified by the reference that Article 39.1 of the TRIPS Agreement makes to Article 10*bis* of the Paris Convention. Hungary has opted for a solution of this kind

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8 *In addition, the European Parliament adopted a Resolution on the outlines of an industrial policy for the pharmaceutical sector in the European Community (No A4-0104/96, OJ C 141, 13.5. 1996. p.63). In paragraph 17 of that Resolution, the following statement has been made:* [The European Parliament].

"17. Considers that in order for the EU to be competitive in the growing European and international non-proprietary markets, measures should be introduced which enable pharmaceutical companies to begin, in advance of patent and supplementary protection certificate expiry, such laboratory experiments and regulatory preparations as may be required only for the registration of generic pharmaceuticals developed in the EU to be available on the market immediately, but only after the expiry of a patent or supplementary protection certificate for a proprietary product."

9 CONF-H 39/00, CONF-H 14/01.

by relying on Article 4 of the Hungarian Competition Act.[10] The provisions of that Article comply, in full, with all the requirements deriving from Article 39 of the TRIPS Agreement. Moreover, there are further grounds under Hungarian legislation for preventing breaches of confidentiality. Under Article 84 (4) of the Civil Code and Article 156 of the Code of Civil Procedure, the court may issue a provisional measure to prevent breach of confidentiality. The application of these general provisions is not excluded by the Competition Act.

20. There is nothing in Article 39.3 of the TRIPS Agreement that would support any allegation that, as long as a WTO Member does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS. Some argue that government action is required by Article 39.3 of the Agreement to prevent breaches of confidentiality. The wording of the Article contradicts this argument, however, because it refers to *"protection,"* in other words private rights to be exercised and enforced primarily by the right holders themselves (see the preamble of the TRIPS Agreement and the note on Article 3).

21. No one has ever claimed so far that a special legal regime for data exclusivity exists in all industrialized countries, let alone in all WTO Members to which the TRIPS Agreement has already become applicable. Therefore, establishing a special legal regime is not the only way Members comply with Article 39.3 of the Agreement.

22. Furthermore, current Hungarian practice in this regard is also in line with paragraph 4 of Article VI of the Hungary – U.S. Agreement and its Protocol concerning regulatory approval of products. Paragraph 4 of the Protocol reflects the parties' agreement that the following procedure is in conformity with the provisions of paragraph 4 of Article VI of the Agreement (which are substantially identical to those contained in Article 39.3 of the TRIPS Agreement):

> *"When applying for… a marketing approval of a generic product, the applicant (the "second" submitter) can prove the equivalence of its own product with the original one, on the basis of a sample of the commercially available original product, while referring to the original documentation if needed. When deciding on the approval of the "second" application, the competent authority bases its decision on the examination of the documentation attached to this application. During the procedure the authority in question does not reveal any information in any form on the documentation of the original product."*

23. Current Hungarian practice is in line with these provisions, which means that, in compliance with Article 39.3 of the TRIPS Agreement, no data are disclosed in the Hungarian marketing approval procedure.

24. To sum up, Hungarian legislation does provide for protection against unfair commercial use and disclosure of undisclosed test or other data in full conformity with Article 39.3 of the TRIPS Agreement. Protection against unfair commercial use is ensured by the application of general competition law rules, while undisclosed test or other data are never disclosed in the regulatory approval procedure.

25. Rules on data exclusivity have been harmonized in the European Union by a Council Directive.[11] After concluding the negotiations with the EU on the relevant chapters of

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10 Act No LVII of 1996 on the Prohibition of Unfair Market Practices and the Restriction of Competition.

11 Directive 65/65/EEC as amended by Council Directive 87/21/EEC.

EU law, the Hungarian Government has decided to introduce data exclusivity provisions into Hungarian pharmaceutical legislation by a Decree of the Minister of Health. This decision has not been taken, however, to remedy any alleged breach of TRIPS obligations but rather with a view to preparing for EU accession. It is for this reason that the recently adopted Decree[12] has followed the EU Directive, making use of the various options provided for in it.

26. Full alignment with the EU Directive has been ensured by the new Decree not only with the aim of meeting EU accession criteria in this regard but also on the assumption that the EU Directive is consistent with the TRIPS Agreement. However, it needs to be stressed that the application of general competition rules, together with the guaranteed secrecy of the documentation of the original product, is sufficient to comply with the TRIPS Agreement. A special legal regime, such as data exclusivity, can only be regarded as a TRIPS-plus possibility, that is, as an additional legal means going beyond what the TRIPS Agreement requires. It is an optional second "layer" of protection, on top of the already TRIPS-consistent competition law and other provisions.

27. As regards the new Decree of the Minister of Health providing for data exclusivity, the following points need to be highlighted:

- Although the general rule is that the Decree enters into force on June 12, 2001, its provisions relating to data exclusivity will only take effect on the presumed date of Hungary's EU accession, which is, according to the Government's expectations, January 1, 2003.

- Even if EU accession takes place later than January 1, 2003, the provisions on data exclusivity will take effect on January 1, 2003. They will only apply to marketing approval procedures initiated after that date, however.

- The relevant part of the Decree providing for data exclusivity will, as soon as it enters into force, apply to all applications for marketing approval of original products submitted after the date of publication of the Decree (i. e. after April 12, 2001).

- The term of data exclusivity will, as a general rule, be six years counted from the first marketing authorization in the EU and Hungary, taken together. The reference in the Decree to the first marketing authorization in the EU is needed for full compliance with the EU Directive. If Hungary succeeds in acceding to the EU on January 1, 2003, in accordance with the Hungarian Government's present working hypothesis, such a reference will no longer be a reference to "third country marketing approval" (as those criticizing the Decree have called it). Should EU accession take place later than expected, the reference to EU marketing authorizations would not constitute a breach of TRIPS Agreement obligations, because there is nothing in Article 39.3 of the Agreement that would preclude such a reference. The critics' claim that this arrangement can considerably shorten the data exclusivity period does not seem justified. Even if it occurred exceptionally, it could not be described as a breach of TRIPS Agreement obligations, as there is no specific provision in Article 39.3 defining the minimum term of data exclusivity.

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12 Decree of the Minister of Health No 12/2001 (IV. 12) EÜM on the regulatory approval and marketing authorization of medicinal products for human use.

- In the case of medicinal products for which the EU's so-called centralized procedure is followed, the duration of data exclusivity will be ten years. The reference in the Decree to the first marketing authorization is inevitable with regard to these products.

- The six-year period will not apply beyond the expiry date of the patent with the earliest priority date protecting the original product. Article 39.3 of the TRIPS Agreement does not exclude a linkage of data exclusivity to a patent. This sort of linkage is expressly permitted by the EU Directive. Even if data exclusivity ends on the patent expiry date, it has certain effects that can be felt after that date. It has the effect that producers of generic products can only apply for marketing authorizations after the expiry date of the patent protecting the original product at the earliest. As a consequence, although under patent law rules they are no longer prevented from the economic exploitation of the invention because the patent has expired, they are still unable to start manufacturing and marketing the medicinal product for want of the necessary authorization. Therefore, data exclusivity does continue to have effects after the expiry of the patent term; it does result in a *de facto* prolongation or extension of the exclusivity arising from patent protection. In addition, attention should be drawn to two other aspects. Firstly, it has to be stressed that the ten-year period is not linked to the patent term. Secondly, it has further to be emphasized that Article 39.3 of the TRIPS Agreement does not set any requirement as to the duration of data exclusivity.

SUPPLEMENTARY PROTECTION CERTIFICATES (SPCS) FOR MEDICINAL PRODUCTS

28. At the negotiations on EU accession, Hungary originally requested a transitional period of five years for the application of Council Regulation (EEC) No 1768/92 of June 18, 1992, concerning the creation of a supplementary protection certificate for medicinal products.

29. The reasons underlying this request have been the following: the capacity for producing generic pharmaceutical products is important to the Hungarian pharmaceutical industry, to national healthcare funds and to patients; there is a considerable difference in the price level of generic and original (protected) pharmaceutical products; the immediate introduction, on 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 healthcare, which in view of the general health situation would have to be avoided. According to the estimations, the immediate introduction of supplementary protection, with full retroactivity, would concern a high number of medicinal products and would substantially increase the expenditure and the deficit of the national healthcare fund.

30. Hungary has, nevertheless, stated that its request for a transitional period is related to, and greatly dependent on, the way in which Article 19 of the Regulation is applied (if it is applied at all) to Hungary on its accession to the European Union. It is worth recalling that, by virtue of Article 21, the transitional provisions of Article 19, which had a kind of retroactive effect, were not applicable in Greece, Portugal and Spain. Those Member States were, in addition, granted a five-year transitional period for the application of the whole SPC Regulation.

31. The Hungarian request was therefore quite modest. And during the negotiations we have made it even more modest, as we have expressed our conditional readiness and willingness to reassess our request for a transitional period of five years for the application of the SPC Regulation if Article 19 is not applied to Hungary (even though it was applied in a modified form on Austria's, Finland's and Sweden's accession). The non-application of Article 19 would mean that, in accordance with Article 7 of the Regulation, only those medicinal products would be granted supplementary protection certificates that received their first marketing approval from the relevant health authorities not earlier than six months prior to accession to the EU, provided that, at the time of filing an application for an SPC, there was still a Hungarian patent in force protecting that product. It needs to be stressed that, in this respect, Hungary has only requested the application of the *acquis communautaire* as it stands now. It is in fact the EU that has asked for a derogation from the general rules of the SPC Regulation by claiming that SPCs should be granted in Hungary after accession on the basis of all marketing authorizations issued in the EU prior to the date of accession, regardless of the expiry of the regular six-month period to be counted from the first authorization.

32. At the end of March this year, on the occasion of the 11th meeting of the Intergovernmental Conference at Deputy Level, we managed to reach an agreement with the European Union on the conditions for introducing SPCs in Hungary on accession to the EU.

33. In its so-called "supplementary negotiating position[13]," the Hungarian Government put forward the following proposal:

> *"The Hungarian Government maintains its readiness to withdraw its request for transitional period and to accept the specific mechanism [proposed by the EU in respect of parallel trade] … provided that the SPC regime to be introduced by Hungary by the time of accession would be applicable only to those patented pharmaceutical products for which the first marketing authorisation in the Community or in Hungary (or in the other acceding countries) was obtained after 1 January 2000. This means that the Hungarian Government is ready to accept a provision to be included in paragraph 1 of Article 19 of Council Regulation (EEC) No 1768/92 according to which in the case of certificates to be granted in Hungary the date of 1 January 1985 shall be replaced by that of 1 January 2000. It is understood that the 6-month period referred to in paragraph 2 of Article 19 will start on the date of accession in the case of Hungary."*

34. In its Common Position[14], the EU accepted this proposal by confirming the following:

> *"In this context, the EU notes that the SPC regime, which will be applicable in Hungary by the time of accession, will contain a provision according to which the SPC regime will be applicable to any product which, on the date of Hungary's accession, is protected by a valid basic patent and for which the first marketing authorisation was obtained after 1 January 2000. An application for a certificate, as referred to above, will have to be submitted within six months from the date of Hungary's accession."*

35. As can be seen, this agreement is based on a cut-off date for those marketing authorizations to which Article 19, in its modified form, will have to be applied. It provides for an exceptional and transitional opportunity for departing from the general rules contained in Article 7. It is a transitional arrangement, as applications for SPCs to be granted in

13 CONF-H 10/01.

accordance with these exceptional provisions will have to submitted within six months of the date on which Hungary's Accession Treaty enters into force. Following the expiry of this six-month period, it is exclusively Article 7 that will apply in Hungary too.

36. With regard to the agreement reached in respect of SPCs, the following might be worth mentioning:

- Both position papers have referred to the SPC regime that has to be introduced in Hungary or will be applicable in Hungary by the time of accession. Obviously, the SPC regime to which these references are made is the one established by the Regulation. The Regulation is directly applicable in all Member States, including, of course, those acceding to the EU after its entry into force. Therefore, there is no need to enact national provisions on SPCs except those called for, or permitted, by the Regulation itself.[15]

- The agreement relating to the cut-off date is based on the assumption that Hungary will accede to the European Union in 2004 at the latest.

- The agreement reached on SPCs is linked to the application of the "specific mechanism," as the latter covers not only product patents and the like but also SPCs.

- Applications under both Article 7 and Article 19 will have to be filed with the Hungarian Patent Office.[16]

- Only those products may be granted SPCs (under either Article 7 or Article 19) that are protected by a valid basic patent in Hungary. A basic patent can be a patent that protects a product, a process for obtaining a product or an application of a product.[17]

PARALLEL TRADE

37. The European Union and Hungary have agreed on a specific mechanism to be provided for in Hungary's Accession Treaty. Under this mechanism

> *"the holder of a patent or Supplementary Protection Certificate (SPC) for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in Hungary for that product, or his beneficiary, may rely on the rights granted by the patent or SPC in order to prevent the import and marketing of that product in the Member State or States where the product in question enjoys patent or SPC protection, even if this product was put on the market in Hungary for the first time by him or with his consent."*

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15 See, e.g., Articles 8(2), 12 and 18 of the Regulation.

16 See Article 9(1) of the Regulation.

17 See Article 1(b) of the Regulation.

38. The following comments need to be made on this specific mechanism:

- Hungary has accepted the establishment of the specific mechanism as part of a package solution to IPR-related problems of pharmaceutical products, and, in particular, in return for a fair and reasonable cut-off date with respect to SPCs. It is not an indirect acknowledgement that the EU is right in assuming that the level of industrial property protection for pharmaceutical products in Hungary is unlikely to be comparable with that existing in the Union as from the date of accession. We continue to believe that a comparison between the levels of protection should not be made on a provision-by-provision basis. It is the overall legislation on, and enforcement of, intellectual property rights that should be taken into account when the level of protection is assessed for similarity to that existing in the Community.
- Patent protection of pharmaceutical products was introduced in Hungary in 1994 by Act No VII of 1994. The introduction of the protection was accompanied by the establishment of certain rules on transitional patent protection of pharmaceutical products patented abroad prior to July 1, 1995, with a priority date from January 1, 1987. As many as 304 patent applications from EU Member States benefited from this transitional form of protection, the term of which expires on the same date as the original term of the foreign patent. It is clear from the wording of the EU's Common Position that the specific mechanism covers not only product patents *per se*, i.e. patents obtained under the ordinary grant procedure, but also patents obtained under transitional provisions provided that those transitional patents also directly protect the product itself. So the acquisition of such transitional patents in Hungary precludes the application of the specific mechanism. It has also to be stressed that the specific mechanism will not be applicable where the holder of a product patent granted in, or for, a Member State, or his beneficiary, could have filed an application for a transitional (i.e. product) patent in Hungary under the relevant provisions of Act No VII of 1994 but failed to do so.

- A similar specific mechanism was established in the Acts of Accession of Spain and Portugal. The main difference is that, in the case of Spain and Portugal, the specific mechanism applied only for a period of fixed, limited duration, while in the case of Hungary it applies as long as there is a product falling within its scope of application.

- The specific mechanism will apply in normal litigation for patent infringement. Hungary is not required to take any administrative action to implement the provisions on the specific mechanism, as they will be enforced by the national courts of that Member State in which the right holder wants to prevent the import or marketing of the product in question. The general rules of evidence will also have to be applied. It will be up to the plaintiff, therefore, to prove that the conditions for invoking the specific mechanism have been met.

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