

INTELLECTUAL PROPERTY ISSUES AND EU ACCESSION

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Introduction

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. These exceptions that 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 submitted its application for EU membership in 1994 and accession talks began in the framework of an intergovernmental conference in 1998. At these negotiations the following main intellectual property issues for substantive talks have been identified:

- comparison of levels of protection with special regard to pharmaceutical products,
- pre-patent expiry development work,
- addition of product claims to process patent applications,
- supplementary protection certificates,
- data exclusivity,
- parallel imports.

I would like to provide an overview of these issues.

Comparison of levels of protection: implementing the Europe Agreement

In terms of international law, Hungary’s European integration has commenced with the conclusion of the Europe Agreement¹. It is a so-called Association Agreement, because it has established a special relationship, i.e. an association between the European Communities and their Member States, of the one part, and Hungary, of the other part. It was signed in late 1991 and it entered into force on 1 February 1994. Article 65 of, and Annex XIII to, the Europe Agreement provide for Hungary’s obligations concerning the protection of intellectual, industrial and commercial property rights. The deadline set for meeting those obligations

¹ Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part (OJ No. L 347, 31.12.1993, p.1.)

expired on 31 December 1996, as it had to be counted from 1 January 1992, under Article 124 of the Europe Agreement. It is worth mentioning that intellectual property-related provisions formed part of the Interim Agreement² on trade and trade-related matters, which showed the commercial importance the EC attached to the protection of intellectual property rights even at that time.

Under Article 65(1) of the Europe Agreement Hungary had to continue to improve the protection of intellectual, industrial and commercial property rights in order to provide, by the end of 1996, a level of protection similar to that existing in the Community, including comparable means of enforcing such rights.

In order to properly assess the fulfilment of Hungary's obligations stemming from this provision one has to clarify some points of interpretation.

In general, it needs to be stressed that Hungary has only undertaken to provide a level of protection similar to that existing in the Community. The difference between similar and equal level has already been acknowledged by the European Union's Common Position on Company Law³ where it has been clearly stated that it is only upon accession that Hungary should attain "a level of protection equal to that in the EU". It is obvious both from the wording of Article 65 and the statement in the Common Position that differences of minor importance, without a considerable impact on the level of protection, cannot be seen as breaches of Hungary's obligations under the Europe Agreement.

In addition, 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 assessing whether the level of protection is similar to that existing in the Community.

It should also be pointed out that Article 65 cannot be extended to those rules that are only applied by some of the Member States. Furthermore, there are provisions of Community law with which a non-Member State's legislation cannot sensibly or reasonably be brought into line because they concern such legal concepts that exist only in the context of the internal market (e.g. Community trade marks or, in the future, patents, Community-wide exhaustion of rights). It is, in general, questionable whether the provisions of Article 65(1) can be construed in a way as to extend their scope to EC Regulations, which are directly applicable in all Member States and need not be transposed into national legislation.

Since Article 65(1) refers to the level of protection existing in the Community, this provision can only be applied to Community legislation that is in fact implemented throughout the whole Community.

Furthermore, Hungary's obligation under Article 65(1) covers the *acquis communautaire* existing at the time of the entry into force of the Agreement (in this case: the Interim Agreement), i. e. on 1 January 1992, and not the new elements of the *acquis* adopted later. New pieces of legislation fall under the general obligation of approximation of laws (Articles 67 and 68) where no specific deadline is set.

² Interim Agreement on trade and trade-related matters between the European Economic Community and the European Coal and Steel Community, of the one part, and the Republic of Hungary, of the other part (OJ No. L 116, 30.04.1992, p.1., see Article 35 (1) of that Agreement)

³ Chapter 5, CONF-H 17/99

It is the Hungarian Government's firm view that Hungary has complied with Article 65(1) of the Europe Agreement. Since the entry into force of that Article Hungary has made considerable progress in renewing its intellectual and industrial property legislation⁴.

Attention should also be drawn to the Union's own assessment of the fulfilment of Hungary's obligations in this field. It is in this context that reference should be made to the Commission's opinion on Hungary's application for membership. It has stated that "significant progress in the protection of intellectual and industrial property has already been achieved", and that in the field of intellectual property "the legislative foundation is almost completely in place". In the latest Progress Report the following has been stated by the Commission: "The framework legislation in the field of intellectual property is to a large extent in line with the *acquis*". Furthermore, it can clearly be seen as an indirect acknowledgement of Hungary's achievements in this field that in the new Council Decision [1999/850/EC] on the Accession Partnership with Hungary neither short-term, nor medium-term priorities have been set for Hungary concerning the protection of intellectual and industrial property rights.

It is also to be noted that Article 65(1) of the Europe Agreement lacks any form of mutuality. It is only Hungary that has to make its intellectual property laws and their enforcement similar to those of the Community. The Community has not undertaken any obligation in this respect⁵, and, of course, the whole provision has been based on the assumption that the level of protection is always, at any time and concerning all intellectual property rights, higher in the Community than in Hungary.

⁴ The following, in particular, need to be highlighted (in the brackets a reference is included to those pieces of Community law with which alignment has been achieved):

a) Act XXXIX of 1991 on the Protection of Topographies of Microelectronic Semiconductor Products (Council Directive 87/54/EEC of 16 December 1986 on the legal protection of topographies of semiconductor products);

b) Act XXXIII of 1995 on the Protection of Inventions by Patents (European Patent Convention, Community Patent Convention, although the latter is not yet in force);

c) Act XI of 1997 on the Protection of Trade Marks and Geographical Indications (First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, Council Regulation (EEC) No. 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs);

d) Government Decree No. 128/1997. (VII. 24.) Korm. on Measures in Customs Administration Proceedings against Infringements of Intellectual Property Rights (Council Regulation (EC) No. 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods);

e) Act LXXVI of 1999 on Copyright (all the copyright-related Directives, i.e. Directives 91/250/EEC, 92/100/EEC, 93/83/EEC, 93/98/EEC and 96/9/EC).

Further legislative steps are also planned concerning biotechnological inventions and industrial designs (Directives 98/44/EC and 98/71/EC).

⁵ Except for those following from Annex XIII where, under point 3, the Contracting Parties (i.e. not only Hungary but also the EC and its Member States) have "*confirmed the importance they attach to the obligations*" arising from the multilateral conventions listed therein.

Comparison of levels of protection: implementing the Europe Agreement

During the accession negotiations, the EU has noted that the level of industrial property protection for pharmaceutical products in Hungary is unlikely to be comparable as from the date of accession with that existing in the Union.

The Hungarian Government is committed to grant an adequate level of protection for intellectual and industrial property rights. As it has already been pointed out, this level is already similar to that existing in the Community.

It is the Hungarian Government's firm intention to continue to improve the protection of intellectual and industrial property rights with a view to attaining upon accession a level of protection that will not cause any unjustifiable disturbance to the functioning of the internal market. It should also be taken into consideration that the establishment of a real internal market for medicinal products has been a slow, gradual process within the Community and, despite the considerable efforts of the Community and its Member States, it has not yet been completed. In addition, when comparing levels of protection to each other a reliable and exact measure should be found so that the Central and Eastern European applicant countries are placed on an equal footing with those having acceded to the Union in the past.

The Union has pointed out that patent protection for pharmaceutical products as such was introduced in the Central and Eastern European applicant countries in the early 1990's. It has also been noted that those new patent laws have no generalised retroactive effects.

In this respect it should be recalled that patent protection for pharmaceutical products was only introduced a few years ago in some Member States as well (Austria: 1987; Greece: 1992; Portugal: 1992; Spain: 1992; Finland: 1995). This also means that those countries - with the exception of Austria - were allowed to join the European Communities or the Union without providing in their patent law for the patentability of pharmaceutical products as such. It can also be seen that one of the Member States introduced patent protection of those products even later than any of the Central and Eastern European applicant countries. Furthermore, the aforementioned Member States did not provide for any retroactive effects let alone generalised ones. As in the corresponding Acts of Accession those differences in the level of protection were overcome by appropriate legal means, the obviously smaller differences in the protection level that might occur in the present accession process could have been accepted without the need to resort to unprecedented exceptional mechanisms⁶.

Although patent protection of pharmaceutical products was introduced in Hungary in 1994, this does not mean that such protection would become "industrial reality" in the Hungarian market only in the long run. Firstly, because even prior to that date, process patents had been available in the pharmaceutical field, and the protection of such patented processes extended, and still extends, to the products directly obtained through those processes. Secondly, introduction of patent protection for pharmaceutical products was accompanied by establishing certain rules on transitional patent protection of pharmaceutical products patented abroad prior to 1 July, 1995, with a priority date from 1 January, 1987. As many as 304 patent

⁶ In its Common Position on Chapter 5, Company Law (CONF-H 7/00 of 8 March 2000) the EU has, nevertheless, suggested that a specific mechanism be provided for in the Accession Treaty according to which, the holder, or his beneficiary, of a patent or Supplementary Protection Certificate (SPC) for a pharmaceutical product filed in a Member State at a time when a product patent or SPC could not be obtained in Hungary for that product, may rely on the rights granted by that 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". The Hungarian Government has already indicated its conditional willingness to accept, in principle, the introduction of this specific mechanism despite that it departs from the *acquis communautaire*.

applications from EU Member States benefited from this transitional form of protection, the term of which expires at the same date as the original term of the foreign patent.

In addition, the overall number of “ordinary” pharmaceutical patents owned by EU nationals and being in force in Hungary exceeds 2400.

Hence it follows that the presumption of the EU, namely that many medicinal products introduced on the market in the applicant countries after the introduction of product patent protection will not benefit from the new law, is not applicable to Hungary because of the provisions on transitional (“pipeline”) patent protection. In order to benefit from this exceptional form of patent protection in Hungary, the owner of a foreign patent (e.g. a patent in an EU Member State) had to file an application to this effect with the Hungarian Patent Office, within the prescribed period of time (i.e. until 1 July, 1995). No failure in meeting that deadline can be remedied through re-negotiating the legislative terms of introducing product patent protection in Hungary.

It is for these reasons that the Hungarian Government takes the view that patent protection for pharmaceutical products in Hungary is not worse, not weaker than that of at least four Member States. The impact of the still existing discrepancies is diminishing, and, after accession, it is not expected to have significant effects on the internal market.

Pre-patent expiry development work (“Roche-Bolar”)

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”.

The Hungarian Government has maintained that this provision of the Patent Act is in compliance with 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 accession negotiations, there seems to be no “system among the EU Member States” which 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.

Article 19(2) of the Patent Act does provide for all the exclusive rights that are listed by Article 28 of the TRIPS Agreement, i.e. 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 qualify 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 (i.e. the individual users of the health care system and the public and private sector entities that pay for them) and would-be competitor producers of those products. The use of generic medicinal products results in considerable savings for the public health care system, and thereby it contributes to its viability and the promotion of public health. Thus, society at large and, in particular, consumers of the health care system have an undeniably legitimate interest in assuring the availability of competitively priced generic medicines as soon after the patent expiry as possible.

Obviously, the regulatory approval of the medicinal product is entirely irrelevant in the patent law context, that is, such a marketing authorisation cannot replace the consent or licence of the patentee during the term of protection. However, after the term of protection expires, there is nothing that would or should prevent the economic exploitation of the invention. If proceedings for granting marketing authorisation were permitted to be initiated only after the expiration of the period of protection, the length of regulatory approval proceedings would entail a *de facto* prolongation or extension of the term of patent protection. Such a *de facto* extension of the patent term would have a detrimental financial impact on the social security system and would adversely affect the patients’ ability to cover the expenses of health care, since there is a considerable difference between the price of generic products and that of original (protected) ones.

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 by 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 Agreement⁷. However, in Hungary, some legislative refinement might be necessary to make the relevant provision of the Patent Act neutral from the viewpoint of technological fields.

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 patent⁸. 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 such tests also advance the state of the art in some way⁹. 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 patent¹⁰.

⁷ Case WT/DS 114

⁸ COM(2000) 412 final, Art. 9(b)

⁹ BGH Urt. vom 17. April 1997 - X ZR 68/94[OLG. Düsseldorf], [1998] RPC 423

¹⁰ E.R. Squibb & Sons Inc. v. Giovannia Aguggini, 12 June 1995, 1996 *Giur. annot. di Dir. Industriale* 13

At Community level, a recent ruling of the Court of Justice of the European Communities¹¹ has confirmed the competence of the Member States to decide whether, and on what conditions, they allow patent owners to oppose the submission by third persons of samples of medicinal products manufactured in accordance with the patented process to the authority competent for issuing marketing authorisations¹².

Until this issue is completely clarified and settled within the Community and among the Member States, Hungary does not intend to take any legislative action in this regard, because it would certainly be premature.

Addition of product claims to process patent applications

It is Act No VII of 1994 that has introduced patent protection of pharmaceutical products, chemical products and foodstuffs in Hungary. Article 70.7 of the TRIPS Agreement is not applicable to those applications pending on the date of entry into force of Act No VII of 1994, as the Act took effect on 1 July 1994, i. e. one and a half year before the date of application of the TRIPS Agreement. Therefore, patent protection for pharmaceutical products cannot, in the case of Hungary, be qualified as enhanced protection provided under the provisions of the TRIPS Agreement.

Furthermore, as a result of lengthy negotiations on the transitional arrangements for the introduction of the product patent system, an agreement was reached, by the Governments of the United States of America and Hungary, in 1993 on the transitional patent protection of pharmaceutical products patented abroad prior to the entry into force of the provisions introducing such protection in Hungary. Should there have been any possibility of applying any transitional provision of the TRIPS Agreement, which was still in the making at that time, Hungary would not have had to negotiate the terms and conditions of introducing patent protection for pharmaceutical products.

A great number of countries - e.g. Japan, Switzerland, Sweden, Austria, Norway, Finland, Poland - have introduced product patent protection without the possibility of product protection in pending applications.

It is, however, to be noted that, in Hungary, the Metropolitan Court issued in late 1998 a ruling allowing, on the basis of a new, different interpretation of the relevant transitional provisions (contained in Article 20 of Act No VII of 1994), the addition of product claims to process patent applications pending on the date of entry into force of the 1994 Act, without questioning the novelty of such claims because of their dictated modification priority. Given this ruling and the fact that in the Hungarian Patent Office an internal administrative decision has been taken to follow the Court's ruling concerning all pending applications, there seems

¹¹ Case C-316/95, Generics BV v. Smith Kline & French Laboratories Ltd, [1997] ECR I-3929

¹² 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. "

to be no legal obstacle to adding product claims to pending process patent applications. However, it should be noted that, in the case before the Metropolitan Court, the TRIPS Agreement has not been invoked and the ruling has not referred to that Agreement. Therefore, the change in the legal practice is unrelated to Article 70.7 of the TRIPS Agreement and the former interpretation of Article 20 of Act No VII of 1994 cannot be considered to have been in breach of the TRIPS Agreement.

The latest development in this matter is that Hungarian Pharmaceutical Manufacturers Association has challenged the Court's interpretation of Article 20 of Act No VII of 1994 before the Constitutional Court claiming that such an interpretation results in an unconstitutional conflict with acquired rights and legitimate expectations. The Hungarian Patent Office is of the firm view that there is no ground for claiming a breach of Constitutional rules in this respect. The case is still pending before the Constitutional Court.

Supplementary protection certificates

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

The capacity of producing generic pharmaceutical products is important for the Hungarian pharmaceutical industry, for the national health-care funds and for the patients. There is a considerable difference in the price level of generic and original (protected) 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 the patients' ability to cover the expenses of health care, which, in view of the general health situation, should be avoided. According to the 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 care fund. The functioning of the Single Market of the Community would not be affected by this transition since the owner of the patent/SPC would be able to prevent marketing of the product in Member States other than Hungary. Hungary has, nevertheless, indicated that its request for a transitional period is related to, and greatly dependent on, the way Article 19 of the Regulation is applied (if it is applied at all) to Hungary upon its accession to the European Union. It is worth recalling that by virtue of Article 21, the transitional, and preferential, provisions of Article 19 were not applicable in Greece, Portugal and Spain. Those Member States were, in addition, granted a five-year long transitional period for the application of the whole SPC Regulation. The Hungarian request is therefore quite modest as we have already expressed our 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 (despite that it was applied upon Austria's, Finland's and Sweden's accession in a modified form). The non-application of Article 19 would mean that, in accordance with Article 7 of the Regulation, only those medicinal products will be granted supplementary protection certificates which will have received the 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 will be still a Hungarian patent in force protecting that product.

Data exclusivity

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”. This provision should not be construed in isolation from other parts of Article 39 of the TRIPS Agreement. It has to be taken into account 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 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 by relying on Article 4 of the Hungarian Competition Act (Act No LVII of 1996 on the Prohibition of Unfair Market Practices and the Restriction of Competition). The provisions of that Article comply, in full, with all the requirements following from Article 39 of the TRIPS Agreement.

There is nothing in Article 39.3 of the TRIPS Agreement that would support the allegation of, for example, PhRMA that “as long as Hungary does not have a specific regime in place to guarantee the protection of original filing data, it is in violation of TRIPS”. PhRMA argues that government action is required by Article 39.3 of the TRIPS Agreement to prevent breaches of confidentiality. The wording of that Article, however, contradicts this argument because it refers to “protection”, that is, to private rights to be exercised and enforced primarily by the right holders themselves (see the preamble of the TRIPS Agreement and the note to Article 3).

Moreover, there are grounds under Hungarian legislation for preventing breaches of confidentiality. Under Article 84 (4) of the Hungarian Civil Code and Article 156 of the Code on Civil Procedure the court may issue provisional measures to prevent breaches of confidentiality. The application of these general provisions is not excluded by the Competition Act.

In summary, 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. It is also to be noted that the Hungarian interpretation of Article 39.3 of the TRIPS Agreement is somewhat different from that of e.g. PhRMA. It should, however, be stressed that this is still a matter of interpretation. This is not an outright and willful breach of Hungary’s TRIPS Agreement obligations and is certainly not a case where intellectual property protection is “denied”. Such a difference in the interpretation of a single provision of the TRIPS Agreement by no means warrants any action in the dispute settlement framework of WTO.

Furthermore, the current Hungarian practice in this regard is also in line with paragraph 4. of Article VI of the US-Hungary Agreement on Intellectual Property and its Protocol concerning regulatory approval of products. Paragraph 4. of that 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 an application for 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.”

It should also be pointed out that the special legal regime for data exclusivity which, among others, PhRMA urges Hungary to introduce has the effect that producers of generic products can only apply for marketing authorizations after the date of expiry 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 of the expiration of the patent term, they are still unable to start manufacturing and marketing the medicinal product, because of the lack of the necessary authorization. Therefore, data exclusivity may, and in most cases does, result in a *de facto* prolongation or extension of the term of protection because it usually takes several months to get a marketing authorization for a medicinal product.

The capacity of producing generic pharmaceutical products is of vital importance to the Hungarian pharmaceutical industry, to the national healthcare funds, and to patients. There is a considerable difference between the price of generic products and that of original ones. It is obvious that the longer the exclusivity period, the longer the delay before generics can enter the market, in other words, the longer the delay before patients may obtain medicines they need at a lower, affordable price.

In Hungary, the health insurance fund spends approximately one fifth of its whole expenditure on subsidizing the consumption of medicinal products. The proportion of such costs has sharply increased since 1990 mainly due to the rising prices of medicines. This, of course, has the effect that less money can be spent on other healthcare activities such as disease prevention or health promotion. The co-payment rate of Hungarian patients is already higher than the EU average.

Therefore, the introduction of any “special legal regime” for data exclusivity that would extend the term of exclusivity of original products beyond the term of patent protection would reduce the availability of generic pharmaceutical products on the market and would have a detrimental impact on the national healthcare system in Hungary. It would increase the costs of healthcare creating an additional burden on the State, the society and, particularly, on patients.

This is, of course, without prejudice to the application of general competition and civil law rules against unfair commercial use and unauthorized disclosure of data submitted for regulatory approval of pharmaceutical products, as described above. What the Hungarian healthcare fund and patients cannot cope with is the extension of the period of exclusivity beyond the patent term.

The regulatory approval of the medicinal product is of course, entirely irrelevant in the patent law context, that is, such a marketing authorization cannot replace the consent or licence of the patentee during the term of protection. However, after the term of protection expires, there is nothing that would or should prevent the economic exploitation of the invention.

The Hungarian Government is, of course, aware that rules on data exclusivity have been harmonized in the European Union by a Council Directive. Although it is still a substantive issue at the negotiations on Hungary's accession to the EU upon what conditions that Directive will have to be applied in Hungary after accession, our Office has reached an inter-agency preliminary agreement with the Ministry of Health and the Ministry of Economy on the introduction of data exclusivity provisions into Hungarian pharmaceutical legislation. This common decision has, however, been taken not to remedy any alleged breach of TRIPS obligations but rather with a view to preparing for EU accession.

The core elements of our plans for the new data exclusivity provisions are the following:

a) the relevant Decree is to be adopted by the end of this year; however, the provisions relating to data exclusivity would only take effect on the presumed date of Hungary's EU accession, which is, according to the Government's expectations, January 1, 2003;

b) the new provisions would be modelled on the EC Directive, making use of those options that are the most preferential or favourable to the Hungarian health care system;

c) the term of data exclusivity would, as a general rule, be six years, counted from the first marketing authorization in the EU and Hungary, taken together; in the case of some high-technology medicinal products it would be extended to 10 years; on the other hand, the six-year period would not apply beyond the date of expiry of a patent protecting the original product;

d) the new provision would not have any retroactive effects, because such effects could lead to certain constitutional concerns.

Parallel imports

In its Common Position on Chapter 5, Company Law (CONF-H 7/00 of 8 March 2000) the EU has suggested that "a specific mechanism be provided for in the Accession Treaty according to which the holder, or his beneficiary, of a patent or Supplementary Protection Certificate (SPC) for a pharmaceutical product filed in a Member State at a time when a product patent or SPC could not be obtained in Hungary for that product, may rely on the rights granted by that 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 in the market in Hungary for the first time by him or with his consent."

The Hungarian Government would be willing to accept the specific mechanism in the accession Treaty suggested by the European Union provided that with respect to SPCs for medicinal products only the general provisions contained in Article 7 of Council Regulation (EEC) No 1768/92 were applicable to Hungary upon accession and no transitional arrangements were required similar to Article 19 of the Regulation or to the solution proposed in the EU Common Position on Chapter 5, Company Law.

As regards the specific mechanism relating to the limitation of parallel imports it should be specified that the provisions in question are not applicable where the holder, or his beneficiary, of a patent or a supplementary protection certificate in a present Member State could have filed for a product patent in Hungary under the transitional provisions of Act VII of 1994, but did not use this opportunity.