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The Special Regime of Intellectual Property for the Pharmaceutical Industry



The Special Regime of Intellectual Property for the Pharmaceutical Industry

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I. Introduction

The pharmaceutical industry is distinct from most other sectors in its reliance on intellectual property rights (IPRs) – and the full duration of patent protection in particular. There are a number of reasons for this which distinguishes the pharmaceutical industry from other industries where a product can enter the market soon after a patent application is made and where innovation and technological development can make patented technology obsolete long before the expiry of the patent.

First, there are significant regulatory and scientific requirements that must be fulfilled before any new drug can be placed on the market. The drug must complete a rigorous testing process to establish that it is both safe and effective. It can easily take 15 years from the discovery of - and the filing of a patent application on - a new molecule to the date that it enters the market in the EU. This delay has been steadily increasing. Today this process can take up to 15 years.

Second, is the relative speed with which generic producers can enter the market once the patent has expired given that they do not need to repeat the regulatory process. This means that the pharmaceutical company which developed the drug must plan to recoup the cost of its R&D investment before patent protection expires.

Third, the very significant cost of developing a new drug, which today is estimated at around a billion dollars.² This compares to approximately \$230 million at the end of the 1980s. This cost includes the thousands of drugs that fail to make it through the R&D process – the thousands of potential molecules which are found to be unsuitable and the promising new molecules which fail to clear the final hurdle after a decade's worth of work.

This article explores the unique regulatory environment of the pharmaceutical industry, with a focus on the regime in Europe. It examines two sector-specific IP rights, which are granted in the EU to compensate pharmaceutical companies for the delays inherent in the regulatory system, namely Supplementary Protection Certificates (SPC) and regulatory data protection, and discusses some recent cases involving SPCs. Finally, it briefly reviews the current plans to address delays in the regulatory regime, which could, if successful, reduce the long-term need for special IP rules for pharmaceuticals.

II. The regulatory hurdles for new drugs

Before any drug can be put on the market in Europe it must obtain a marketing authorisation. There are two different procedures for obtaining a marketing authorisation in Europe – the centralised and the mutual recognition procedure.

² According to a 2003 study by Bain & Company, when the costs of failed prospective drugs are factored in, the actual cost of discovering, developing and launching a single new drug has risen to nearly \$1.7 billion. This represented a 55% increase over the average commercialization cost for the five years from 1995 to 2000. See http://www.bain.com/bainweb/publications/in_the_news_detail.asp?id=14243&menu_url=for%5Fthe%5Fmedia%2Easp. Other studies report figures of the same order of magnitude.

Under the centralised procedure, the European Medicines Agency (EMA) grants a single marketing authorisation for a product which is valid throughout the EU. The centralised procedure is compulsory for certain medicinal products, notably high-technology products and those containing an entirely new active substance.

Under the mutual recognition procedure, which is still widely used where the centralised procedure is not obligatory, a pharmaceutical company obtains a marketing authorisation from one EU Member State, and then applies to other Member States for recognition of the authorisation, in accordance with the mutual recognition principle.

To obtain a marketing authorisation, new molecules must undergo extensive and highly regulated testing before they are approved nationally or at the European level and allowed to enter the market. The same testing is required under the centralized and mutual recognition procedures; the only difference being the authority to which the test results are to be presented. There are two stages of testing: pre-clinical testing and clinical testing.

Pre-clinical testing consists of laboratory and animal studies to assess the chemical, biological and toxicological properties of the compound against the targeted disease. Tens of thousands of molecules may be screened to see if they have a potential pharmacological effect. Over a period of two to three years, only a handful may move forward for detailed pre-clinical evaluation. On average, compounds spend around four years in the pre-clinical stage.

Potential drugs that pass the pre-clinical testing stage will then undergo three phases of clinical trials, i.e. experiments conducted on human beings under very strict ethical and technical rules.³

In Phase I, the substance is tested on a limited number (between 20 and 100) of healthy volunteers, under strict hospital supervision. These trials typically account for less than 10% of total R&D spending. Usually around 80-90% of candidate drugs fail to make it past phase I.

Phase II consists of controlled trials on approximately 100 to 500 volunteers to gather information on the substance's efficacy (relation between dose and effect) and safety (identification of possible adverse side effects). Phase II trials typically account for around 10-15% of a pharmaceutical company's R&D budget. Statistically, fewer than 40% of Phase II candidates will progress to Phase III.

In Phase III, the remaining compounds undergo more comprehensive studies, usually involving 1,000 to 5,000 voluntary patients in clinics and hospitals. Phase III investigates long-term effects and also compares the proposed new treatment with other treatments already in use. Phase III trials are often described as pivotal trials and usually form the major part of the submission to the regulatory authorities. They could typically account for 30-35% of a company's R&D spending.

³ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, O.J. L 121, 1/5/2001 pp. 34 – 44; Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products O.J. L91, 09/04/2005 pp. 13-19

Even after a product has successfully completed at least two pivotal trials and received the approval of the relevant regulatory authority, the clinical process has not ended. Pharmaceutical companies must continue to monitor a product for adverse reactions throughout its lifetime on the market. An adverse reaction may occur only rarely, meaning it was not detected in the trials, even though up to 5,000 patients may have been involved. Such reactions may be detected only when the product has been used by a substantial number of patients. A number of products have had to be withdrawn from the market due to safety concerns, despite passing all three phases of clinical trials.

So it would be fair to say that the pharmaceutical industry operates in a strict regulatory regime, which differentiates it from most other industry sectors, notably because of the lengthy delay before a patented new drug can be placed on the market. In no other industry does it take up to 15 years from the day the patent application is made until the product is actually marketed.

III. The SPC: A special intellectual property right for the pharmaceutical industry

Given the situation described above, the pharmaceutical industry argued for a special IP regime, pointing out that the period of effective patent protection was insufficient to allow the developer of a new drug to recover its investment in R&D. Specifically, it argued that regulatory authorisation to place the product on the market was granted only many years after the date on which a patent application was made. In other words, much or most of the monopoly granted by the patent had been used up before the product could be placed on the market.

The EU responded in 1992 by adopting the Supplementary Protection Certificate (SPC) Regulation,⁴ which grants pharmaceutical products up to five years' extra patent protection to compensate research-based companies for the delays inherent in the regulatory system. The aim of the regulation is to allow pharmaceutical manufacturers sufficient time to recover their investments in developing new products and make a reasonable profit which they can re-invest in future R&D.

It is relevant to note that current earnings are particularly important for the funding of R&D in the pharmaceutical sector. Due to the high risk that a new drug will fail to pass successfully through clinical trials, external R&D financing is very expensive. This leads to an extremely low gearing ratio (i.e. loan capital as a percentage of total capital employed) in the pharmaceutical industry. The gearing ratio is about 5%, compared to typical ratios in excess of 35% in sectors such as telecoms or household goods.

⁴ Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, O.J. L 182, 2/7/1992 pp. 1-5

The SPC rules are also used to promote innovation by encouraging the industry to develop new indications for certain drugs. For example, the recently adopted paediatrics regulation⁵ extends SPC protection of an active substance by six months if the manufacturer performs clinical studies on the product's paediatric uses.

To obtain an SPC on the date of application in the territory concerned, three conditions must be met. Firstly, a medicinal product must be covered by a basic patent in force. If it was not originally patented or the patent has expired, it cannot qualify for an SPC. Secondly, the manufacturer must have been granted a valid authorisation⁶ to place the product on the market as a medicinal product and it must have been the first manufacturer to obtain an authorisation for that particular product. Thirdly, the product may not already have been the subject of an SPC: a product may only obtain a single SPC for a maximum of five years.

The SPC has a different scope of protection from a patent. An SPC attaches to a particular medicinal product. Different products require different SPCs, even if covered by the same basic patent. However, while the SPC Regulation defines the notion of a product as “the active ingredient or combination of active ingredients of a medicinal product”, it gives no definition of what constitutes an “active ingredient”. An SPC can only cover a single product, i.e. a single active ingredient or combination of active ingredients.

The divergence between the SPC Regulation and the patent system was highlighted in a recent case involving MIT.

A. The MIT Case

It was not clear until recently whether an SPC could also be granted for formulation patents or combinations, where a substance only exercises its pharmacological effect when combined with another substance which provides no pharmacological effect as such. This issue was the subject of recent litigation before the German courts, which referred this question to the European Court of Justice (ECJ).⁷

The case concerned Gliadel, a product patented by the Massachusetts Institute of Technology (MIT) which is used to treat recurrent brain tumours. Its action mechanism consists in the slow release of the active substance, carmustine, controlled by polifeprosan, in order to delay the recurrence of the tumour. The combined use of carmustine and polifeprosan is said to extend the life expectancy of patients by several months, by permitting the delivery of a much higher but still constant dose of the active substance onto the tumour.

MIT applied to the German Patent and Trade Mark Office for an SPC for Gliadel, requesting a certificate for carmustine in combination with polifeprosan or, alternatively, an SPC for carmustine. Its application was

⁵ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, O.J. L 378, 27.12.2006, pp. 1–19

⁶ Under either Directives 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, O.J. L 311, 28/11/2001 pp. 67–128, 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, O.J. L 311, 28/11/2001 pp. 1–66 or Regulation 726/2004/EC of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency O.J. L 136, 30/4/2004 pp. 1–33

⁷ Case C-431/04 *Massachusetts Institute of Technology*, [2006] ECR I-4089

rejected by on the ground that polifeprosan could not be considered an active ingredient within the meaning of the SPC Regulation, and that no certificate could be granted for carmustine on its own because it had been an authorised active substance for many years. However, on appeal, the Bundesgerichtshof (Federal Court of Justice) referred to the ECJ the question of whether there can be a “combination of active ingredients of a medicinal product” within the meaning of Article 1(b) of the SPC Regulation where a medicinal combination of two substances, one of which is a known substance with pharmacological properties of its own and the other makes it possible to increase significantly the therapeutic effects of the first substance”.

In his Opinion,⁸ Advocate General Léger argued for a liberal interpretation of Article 1(b) and an extension of the scope of the SPC to include such combinations. “A restrictive interpretation of the provision at issue would not be consistent either with the broad logic of the regulation of which it forms part or, above all, with the objectives pursued by the Community legislature.”⁹ Consequently, while recognising that an SPC should not be granted every time the characteristics of a medicinal combination are only slightly modified, as this would be disproportionate and would frustrate the objectives of the SPC Regulation, the Advocate General concluded that “where the effective treatment of certain illnesses requires an active ingredient to be combined with a substance which, whilst not having any pharmacological properties of its own, allows the biologically active substance effectively to release its therapeutic effects, such a combination must fall within the scope of ‘combination of active ingredients of a medicinal product’ within the meaning of Article 1(b) of Regulation No 1768/92.”¹⁰ The Advocate General therefore favoured broadening the scope of the definition of a “product” under the Regulation, and consequently extending the products which could potentially qualify for SPC protection.

However, in its judgment, the ECJ took the opposite view, rejecting the notion that the combination of a substance which has no therapeutic effect of its own with a medicinal product which does have therapeutic effects of its own could qualify as a “combination of active ingredients” within the meaning of the SPC Regulation. The Court justified its reasoning as follows. Firstly, the Court held that a broad interpretation of Article 1(b) to cover such combinations might create legal uncertainty, as evaluating whether “a substance without any therapeutic effect of its own is necessary for the therapeutic efficacy of the active ingredient cannot, in this case, be regarded as a sufficiently precise test.”¹¹ Secondly, the adoption of such a broad interpretation might actually go against the Regulation’s objective of “preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market.”¹² The Court therefore refused to interpret the scope of the SPC Regulation as covering formulation patents or novel indications.¹³

This case highlights a divergence between the SPC regime and the patent regime. MIT held a patent on its drug, which appears to have produced a useful effect, namely extending the patients’ life expectancy. Yet the

⁸ Opinion delivered on 24 November 2005

⁹ *Ibid*, paragraph 39 of the opinion

¹⁰ *Ibid*, paragraph 62 of the opinion

¹¹ Paragraph 29 of the judgment

¹² Paragraph 30 of the judgment

¹³ The ECJ followed the same approach in its Order in case C-202/05 *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents*, Order of the Court of 17 April 2007

drug did not qualify for SPC protection because the grant of an SPC is based on different criteria to patents, being linked to particular products and marketing authorisations. This case perhaps highlights why the SPC regime is not always a remedy for the length of the regulatory process.

B. The AstraZeneca Decision

The difficulties inherent in the SPC system - and its importance to pharmaceutical companies – are also illustrated by the recent decision in the AstraZeneca (AZ) case.¹⁴

In the first case of this kind, the Commission fined AZ €60 million for abusing its dominant position notably by misusing the SPC system. The Commission found that by giving misleading information to national patent offices and deliberately concealing the correct date of the first market authorisation, AstraZeneca was able to receive SPCs for Losec when either it should not have been entitled to an SPC at all, or for a longer period of time than if it had provided the national patent offices with the correct dates. The Commission held that AZ's misleading conduct amounted to an abuse of a dominant position in Belgium, Denmark, Germany, the Netherlands, Norway and the UK.

It is important to note the Commission concluded that AZ deliberately stated the wrong date of first market authorisation in order to obtain protection to which it was not entitled. The implication is that a company which does not intentionally supply incorrect information in its applications should have nothing to fear.

Another factor in this case is that for a long time, the interpretation of “first authorisation” in the relevant article of the SPC Regulation was unclear. The ECJ clarified only in April 2005 that AZ's interpretation was not correct.¹⁵ This raises the issue of whether a company in a dominant position which interprets a provision of EC legislation in a way which is later decided to be incorrect risks being accused of infringing Article 82. In its decision the Commission specifically rejects this argument, stating that its objections are to AZ's misleading representations, and not to its incorrect interpretation of the SPC Regulation. *“Any lack of clarity in the SPC Regulation (...) cannot justify AZ's misleading representations and concealments as part of its SPC strategy”*.¹⁶

The reasons given by the Commission for why it prosecuted this case are interesting - it considered that AstraZeneca had prevented competition from generic producers and hence kept Losec prices artificially high. The Commission noted that health care systems throughout Europe rely on generic drugs to keep costs down.¹⁷ There is an obvious tension between these reasons and the purpose of the SPC Regulation, which was to extend patent life to ensure the developer of the drug could ensure a return on its R&D investment.

¹⁴ COMP/A. 37.507/F3 – AstraZeneca, decision of 15 June 2005, C(2005)1757 final <http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/en.pdf>. For a critical comment, see Gunter and Breuvert, “Misuse of patent and drug regulatory approval systems in the pharmaceutical industry: An analysis of US and EU converging approaches” ECLR 2005, 26(12), pp. 669-684

¹⁵ Joined Cases C-207/03 *Novartis AG, University College London, Institute of Microbiology and Epidemiology v Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom* and C-252/03 *Ministre de l'Économie v Millennium Pharmaceuticals Inc, formerly Cor Therapeutics Inc* [2005] ECR I-3209

¹⁶ Recital 666 of the Decision

¹⁷ Recital 116 of the Decision

The Commission did accept that there was a need for strong IP protection so companies could recoup their R&D expenditure¹⁸ and it limited the case to its facts (the alleged misleading of the regulators). But it also added a more questionable statement that “competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals.”¹⁹ This is only true if the effective duration of the patent is sufficiently long to allow research-based companies to recover their investment and to fund future investments.

The case does highlight the tension between the need to allow companies to recoup the extensive R&D needed to develop a new drug and the desire to enable cheaper generic products to enter the market. AstraZeneca’s appeal to the Court of First Instance may cast light on whether the Commission adopted the right balance in this instance.²⁰

IV. Regulatory data protection

In addition to patents and SPC, pharmaceutical products also benefit from another form of sector-specific intellectual property protection, in the form of protection of the data generated by the research conducted by pharmaceutical companies to demonstrate the efficacy and safety of new medicines. This form of IP protection, similar to trade secret protection and known as “regulatory data protection” or “data exclusivity”, refers to the period of time during which a company enjoys proprietary rights over the clinical data relating to a given medical product - meaning that generic manufacturers cannot use the data when applying for authorisation to market a competing generic product.

The EU, following the example of the US,²¹ first introduced regulatory data protection provisions in 1987. There was initially a distinction in the period of data exclusivity according to whether a product had been registered through the centralised system or the mutual recognition procedure.²² This disparity was abolished by the new Medicines Package of legislation adopted in 2004,²³ which created a harmonised EU “8+2+1” data exclusivity period.

The marketing authorisation holder benefits from an eight-year data exclusivity period from the date of the first approval in the European Union. Thereafter, there is an additional two-year period of market protection during which the generic producers can use the regulatory data but cannot place competing generic products on the market. This 10-year period can be extended to a maximum of 11 years if, during the first eight years,

¹⁸ Commissioner Kroes said that she supported “the need for innovative products to enjoy strong intellectual property protection so that companies can recoup their R & D expenditure and be rewarded for their innovative efforts.” See Press Release IP/05/737 of 15 June 2005

¹⁹ See Press Release IP/05/737 of 15 June 2005

²⁰ Case T-321/05 *AstraZeneca v Commission* (pending)

²¹ In 1984 the US became the first country to enact data exclusivity legislation. The Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Act”, grants applications for approval of new drugs five years’ data exclusivity. Applications for the approval of new indications for an existing drug receive three years’ data exclusivity.

²² Article 13(4) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (O.J. L 214, 24/8/1993 pp. 1-21 provided that for a 10-year period of protection for medicinal products which were authorised by the Community via the centralised procedure. This Regulation has now been replaced by Regulation 726/2004. By contrast, Directive 2001/83 only provided for a period of protection of exclusivity of six years, which individual EU Member States could extend to ten years if they considered this necessary in the interest of public health.

²³ For the centralised procedure, Article 14(11) of Regulation 726/2004; for the decentralised procedure see Article 1 of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (O.J. L 136, 30/4/2004 pp. 34 - 57, amending Article 10 of Directive 2001/83

the marketing authorisation holder either (a) obtains an authorisation for one or more new therapeutic indications which are found to bring a significant clinical benefit in comparison with existing therapies, or (b) makes an application for a new indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication. Hence the “8+2+1” system.

Data protection is increasingly important for pharmaceutical manufacturers. First, it is a reward for the considerable amount of time and expense involved in the creation of the data required to obtain a marketing authorisation. Secondly, because of the 15-year period it can take to obtain a market authorisation for a new drug, data protection is increasingly becoming an instrument for maintaining market exclusivity after the expiry of a product’s patent. But the data protection does not make up for the limited length of patent coverage – for the simple reason that $8+2+1 \neq 15$.

The importance of data protection to the pharmaceutical industry is reflected in the volume of litigation before the European Courts. To take one example, in the *Generics* case²⁴ the ECJ rejected the possibility that additional data submitted in order to obtain a modified marketing authorisation to include new indications of an existing product could enjoy an autonomous period of data protection, independent from that of the original registration data. The new product was considered to be “essentially similar” to the older product and therefore not able to qualify for an individual data exclusivity period. This is another example of the sort of issues that can arise under the special IP rules applicable to the pharmaceutical sector.

The limitations of the data exclusivity rules are another example of a political compromise, aimed at balancing the need of the innovator to recoup its investment in R&D, including the cost of the clinical trials needed to obtain authorisation, against the desire of public health authorities to allow generic versions of the drug to appear on the market.

V. Proposals to make drug approval faster: Implications for IP protection

Although welcome to the research-based pharmaceutical industry, the extension of IP protection granted by the SPC system and regulatory data protection does not address the fundamental issue, namely the delays in the regulatory system, which effectively lead to patent lifetimes of around 5 years instead of 20 years.

There is a growing consensus that the current regulatory system is struggling to keep pace with breakthroughs in medical science, and that there is a need for new methods of evaluation that will allow an evaluation of whether innovative products are safe and effective to take place as quickly and inexpensively as possible.

Recent proposals for reform have been put forward by the US Food and Drug Administration (FDA) which, in March 2004, issued a report “Challenge and Opportunity on the Critical Path to New Medicinal Products,”²⁵ which explored ways of speeding up drug approval. The Report sets out proposals to overhaul the current drug development process, with the aim of achieving accelerated delivery of innovative, safe mechanism-based and targeted therapies that advance patient healthcare. Its long-term goal is to develop tools which will allow

²⁴ Case C-368/96 *The Queen v The Licensing Authority established by the Medicines Act 1968 (acting by The Medicines Control Agency), ex parte Generics (UK) Ltd, The Wellcome Foundation Ltd and Glaxo Operations UK Ltd and Others* [1998] ECR I-7967

²⁵ <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>

the authorities to proactively predict, explore and understand the safety profile of compounds at all stages of development. This overhaul of the traditional methods to develop and approve new medicines would require regulators and applicants for authorisation to accept model-based evidence, together with clinical results, as sufficient evidence for decision-making.

A similar approach was also launched in 2004 by the European Commission, under the Innovative Medicines Initiative (IMI)²⁶, which is part of the Lisbon Agenda, whose goal is to boost innovation and enhance competitiveness. The IMI aims is to remove the current bottlenecks hampering the efficiency of the development of new medicines, thereby providing faster access to better medicines for European citizens and supporting the European biopharmaceutical industry in its goal of becoming world leader in its area. A Strategic Research Agenda²⁷ has been adopted, which will focus on four main topics:

- Prediction of safety (early safety evaluation and risk assessment, creation of a European Centre for Drug Safety);
- Early indication of efficacy (use of predictive pharmacology and biomarkers in the identification and validation, patient recruitment and risk assessment);
- Knowledge management (development of new technologies to control and analyse enormous quantities of information in an integrative and predictive way); and
- Education and training (bridging of gaps in expertise required to strengthen the biopharmaceutical R&D process and creation of a European Medicines Research Academy).

Moreover, in May 2007, the Commission proposal that the IMI be formalised as a Joint Technology Initiative under the EU's 7th Research Framework Programme was launched.²⁸ Once agreement is reached by the Council of Ministers, something which is hoped for by the beginning of 2008, the IMI will receive an EU contribution of up to €1 billion from the EU's 7th Research Framework Programme. This will be matched by funds from industry, leading to a total budget of up to €2 billion. Decisions on how this money will be spent will then be made by the executive bodies of the IMI Joint Undertaking shall be the Board (composed of the founding members, i.e. European Commission and the industry organisation EFPIA), the Scientific Committee and the Executive Office.

Moreover, in July 2007, the Commission launched a public consultation on the future of pharmaceuticals for human use in Europe to improve the regulatory, non-regulatory and R&D framework for pharmaceuticals.²⁹ Following the public debate, which ended on 12 October, the Commission intends to address a Communication to the Council of the European Union and to the European Parliament on the future of the EU single market in pharmaceuticals for human use, outlining its vision and strategy for the sector, as well as

²⁶ http://ec.europa.eu/research/health/imi/index_en.html

²⁷ <http://www.imi-europe.org/Publications.aspx?viewCategory=Researchx20Agenda>

²⁸ Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking, COM(2007) 241 final

²⁹ http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_07/consultationpaper-2007-07-19_en.pdf

concrete action items. The Communication will build on this consultation and will outline how its outcome was taken into account.

Both the US and the EU have now launched long-term initiatives, aiming to modify and adapt their regulatory systems in an attempt to reduce the current delays in getting pharmaceutical products to market. Both authorities have realised that 15 years to obtain approval for a new drug is too long, not just for the pharmaceutical industry but, more importantly, for patients, who are denied access to innovative new treatments.

If those initiatives are successful, it may be necessary to revisit the special IP protection offered to the pharmaceutical sector. But these initiatives are a long way from fruition, and for the foreseeable future there will be a strong continued need for the special rules on SPC and regulatory data protection in the pharmaceutical sector, to enable the research-based pharmaceutical companies to earn sufficient profits to re-invest in future R&D.

VI. Conclusion

The pharmaceutical industry is in a different situation from other sectors when it comes to intellectual property, because of the strict regulatory regime that applies to pharmaceuticals and the 15-year delay that can elapse before a new medicine may enter the market. Special regimes of IP protection have been developed, which partially address this problem, and which aim to ensure that research-based pharmaceutical companies can continue to earn a return on their investment and thereby remain able to fund the next generation of drugs. These rules are therefore necessary for the continued existence of the innovative pharmaceutical industry today. There is a need to address the length of the regulatory processes, but that is a long-term challenge and the pharmaceutical industry is going to need its own special IP regimes for the foreseeable future.