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Do rules experience culture shock?

– Interpreting Article 3(a) of the Supplementary Protection Certificate Regulation: is the donor rule faulty or is the transplanted rule incompatible with its new legal environment?

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TERMINOLOGY IN THIS ARTICLE

"Patent term extension" is used generically to refer to an additional time of protection in relation to a pharmaceutical product which is the subject of protection by a patent. "Patent term restoration" is the term used when referencing the U.S. extension, while the "Supplementary Protection Certificate", or SPC, refers specifically to the EU instrument.

ABSTRACT

In order to stimulate product development and innovation in the pharmaceutical industry, the United States Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), also known as the Hatch-Waxman Act. One goal of the Hatch-Waxman Act was to extend patent life to compensate patent holders for a portion of the patent term lost while awaiting review of the safety and efficacy of the product by the Federal Drug Administration.

Influenced by the United States, the European Union (EU) introduced legislation in 1992 offering the possibility for a patent holder to apply for an additional time of protection as compensation for the regulatory delays caused by marketing authorization procedures. This additional time period of protection is granted in the form of a Supplementary Protection Certificate (SPC), governed by an EU Regulation.[1]

As the subject matter protected by the SPC, the product is defined as "the active ingredient or combination of active ingredients of a medicinal product."[2] The term product within the context of the SPC Regulation is an independent term which cannot be equated with the patented invention or marketing authorization.[3] The product for which the SPC is sought must be protected by a basic patent in force,[4] which is also a condition for patent term extension in the United States.[5]

The interpretation of product and its relation to the patent in force is a central condition to determine if a certificate may be granted.[6] There has been divergence in the application of this condition by the national courts and a stream of requests for preliminary rulings. Legal uncertainty in interpretation remains due to the lack of clear guidance from the Court of Justice of the European Union (hereinafter "CJEU").

This article examines the material condition of the SPC Regulation requiring that a product be protected by a basic patent, from its origin in the United States to the legislation and institutions of the European Union, in order to investigate rules as an institutional phenomenon. Do the issues of interpretation with Article 3(a) of the SPC Regulation arise at the fault of the borrowed material legal solution itself, or do they occur from transplanting the solution from its native environment into a new legal system? The answer as the reader will discover is both.

1.0 INTRODUCTION

The process of bringing a medicinal product to market is time-consuming, expensive and subject to failure. The testing and regulatory process to receive approval to market medicinal products erodes the time a product has exclusive rights under the protection of a patent. In some cases, patents expire even before a medicinal product is approved to be placed on the market. Upon the expiration of a patent, sales of the formerly patented product drop significantly as instant competition opens up to its generic version by competitors, generating a loss of revenue for the firm whom once held the patent.[8]

The pharmaceutical sector performs a crucial role in our society through their research and production of new medicinal products.[9] The interest of society rests in between the competing interest of the large pharmaceutical firms (to ensure the on-going development of new medicinal products) and the generic manufacturers (to bring down the cost). The generic manufacturers of pharmaceutical drugs have an interest themselves in patents being pursued by and granted to large pharmaceutical firms so the "know-how" behind the new product is disclosed, allowing for eventual generic reproduction.[10] Government holds an interest in ensuring that expenditure in the public health sector is not artificially increased due to patent term extension of products containing old active ingredients which are simply modified without innovation and marketed as a new product.[11]

Adequate regulatory measures are required to balance all interests at stake in this complex environment and to promote an innovation culture. Patent term extension

can encourage the development of new drugs through the incentives it provides to patent owners, addressing the decline in the rate of return to R&D investments attributed to the reduction in the effective patent term.[12]

To stimulate product development and innovation, the United States (U.S.) Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), also known as the Hatch-Waxman Act. The goal of the Act was to extend patent life to compensate patent holders for a portion of the patent term that is lost while the patent holder is awaiting regulatory review of the safety and efficacy of the product. The restoration period cannot exceed five years and the total patent term including the restoration period cannot exceed 14 years following marketing approval.

In 1990 the European Commission expressed concern over a drop in the number of "molecules of European origin that have reached the research and development stage" and the "(...) slow erosion of the European market shares as compared with those of the USA and Japan(...)" who "(...) since 1984 and 1988 respectively, benefitted from patent term restoration for pharmaceutical products on their national markets."[13]

The European Supplementary Protection Certificate (SPC) Regulation[14] was first established in 1992,[15] introducing a European Union (EU) legal instrument of patent term extension borrowed from a foreign legal system in order to provide EU law reformers an efficient solution to an identified problem.

An SPC comes into force only after the corresponding patent expires and relates to a specific product. It has a maximum lifetime of five years and the total combined duration of market exclusivity of a patent and SPC cannot exceed 15 years.[16]

Certain criteria must be fulfilled prior to the successful grant of a patent term extension. The commercial importance of the products that it protects has meant that the SPC regime is challenged by conflicting interests. A pivotal issue in the grant of an SPC is the interpretation of Article 3(a) of the SPC Regulation which, similarly to the award of a period of patent term restoration in the U.S., requires a basic patent in force protecting the *product* in question.[17]

This article will draw conclusions to which extent the jurisprudence of the transplanted rule has undergone transformation due to the difference in law-making institutional structure in its new environment.

2.0 U.S. DONOR LEGISLATION AND ITS INSTITUTIONAL ENVIRONMENT

2.1 U.S. Patents

United States (U.S.) patent law is codified in Title 35 of the United States Code (35 U.S.C.) and authorized by the United States Constitution which declares: "The Congress shall have power...To promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writing and discoveries."[18]

Under U.S. law, a patent is a right granted to an inventor of a process, machine, article of manufacture, or composition of matter that is new, useful and non-obvious.[19] A patent is an intellectual property right to exclude others from making, using, selling, offering for sale, importing, inducing others to infringe, and/or offering a product specially adapted for practice of the patent.[20] After the patent term expires, the invention, along with the know-how contained within the patent filing, enters the public domain and competition ensues.

2.2 U.S. Patent Term Restoration

In 1978, U.S. President Jimmy Carter called for a domestic policy review of industrial innovation. One outcome of the policy review was a recommendation by two sub-committees to lengthen the term of pharmaceutical patents to compensate for the time consumed in meeting government regulatory requirements.[21] President Reagan's Cabinet Council on Commerce and Trade supported the proposal and set up an intellectual property committee. The committee recommended, and the Cabinet Council supported, the introduction of patent term restoration.[22]

1 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (hereinafter "SPC Regulation").
2 SPC Regulation, article 1(b).
3 The German Association for the Protection of Intellectual Property, Journal of Intellectual Property Law & Practice, 2013, vol 8, no. 9, p. 723, citing German Federal Court of Justice (BGH), GRUR 2002, p. 415 Sumatriptan.
4 SPC Regulation, article 3(a).
5 Title 35 United States Code §156(a)(1).
6 SPC Regulation, article 3(a).
7 Adams, John N., "Supplementary Protection Certificates: The challenge to EC Regulation 1768/92", European Patent Convention Article 83 (1994) EIPR 16(8), p. 323.
8 Opinion of Advocate General Trstenjak delivered 13 July 2011 on C-322/10 Medeva BV and C-422/10 Georgetown University v Comptroller General of Patents, Design and Trademark, ECLI:EU:C:2011:476, para 77. (Hereinafter AG Opinion Medeva).
9 SPC Regulation, articles 2-3.
10 Commission of the European Communities, "Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products" COM (90) 101 final – SYN 255 (April 1990), p 14. (Hereinafter "Explanatory memorandum").
11 AG Opinion on Medeva, supra n 8, para 77.
12 Patent-Term Extension and the Pharmaceutical Industry, August 1981, NTIS #PB82-100918.
13 Explanatory Memorandum supra n 10, § 6.
14 SPC Regulation, supra n 9.
15 Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.
16 The maximum time of 15 years is not including any possible paediatric extension.
17 SPC Regulation, supra n 9, article 3(a) and Title 35 United States Code § 156(a)(1).
18 United States Constitution, Article One, section 8, clause 8.
19 Title 35 of the United States Code §§ 101-103.
20 Title 35 of the United States Code § 154(a)(2).
21 See Advisory Committee on Industrial Innovation, Final Report, iii at 70 (recommendation no 8 of the Health and Safety Industrial Subcommittee) and at 157 (proposal VI of the Industrial Subcommittee for Patent & Information Policy).
22 Mossinghoff, G., Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, Food and Drug Law Journal, 1999, volume 54, p. 188.

In 1984, the U.S. Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, which amended the Federal Food, Drug and Cosmetic Act[23] and the Patent Act.[24] The goal was to strike a balance between incentivizing brand pharmaceutical companies to invest in research and encouraging generic entry to reduce market prices.

The patent restoration provisions are just one part of the intricate and complex compromise embodied in the Hatch-Waxman Act of 1984 intended to positively impact the pharmaceutical business in the United States.[25] It is worth noting that an earlier Act addressing solely patent term restoration was defeated in 1982, partly through the efforts of Representative Henry Waxman of California who made clear that any future legislation would have to deal with his concerns relating to the approval of generic drugs.

The Hatch-Waxman Act[26] was a major revision to U.S. law governing the regulation of pharmaceuticals. It provided a mechanism for approving generic drugs without the need to duplicate the expensive safety and efficacy studies required of the originally approved brand medicinal product. The Hatch-Waxman Act also provided several protections for the innovator companies, including several non-patent data exclusivities that limit, for specific periods of time, the ability to file an application for approval of a generic equivalent or to obtain final approval of the generic application. A particular benefit to the brand pharmaceutical companies in the Hatch-Waxman Act is the ability, under specific circumstances, to obtain restoration for part of the term of a patent that claims a new drug.[27]

The types of products permitted to receive an extension are restricted to those drug products subjected to a regulatory review period.[28] The legislation works to prevent any one patent holder from obtaining an extension on multiple patents related to the same product as only the earliest issued patent is eligible for an extension.[29]

The contents of the application for patent term restoration are laid out in detail in the U.S. Patent and Trademark Office (PTO) Guidelines.[30] To qualify for patent extension, there are five conditions which must be satisfied. First, the applicant must show that the patent for the product has not expired. Second, the application must establish that the patent has not previously been extended under the Hatch-Waxman Act.[31] Third, the applicant must establish that the product was subject to a regulatory review period prior to its marketing approval. Fourth, the applicant must show the product either represents the first permitted marketing of the product or, in the case of a process patent, the first permitted marketing of the product manufactured under the process claimed in the patent. Finally, the applicant must submit a complete application for patent term restoration to the PTO within 60 days of marketing approval by the Federal Drug Administration (FDA).[32]

Based on the information submitted, the Secretary of Health and Human Services determines the length of the regulatory review period, and the Commissioner of Patents then decides whether the patent is eligible for extension and what length of time is granted. A Certificate of Extension, which becomes a part of the Letters Patent, is then issued by the PTO.[33] The restoration period cannot exceed five years and the total patent term including the restoration period cannot exceed 14 years following marketing approval.

The FDA is responsible to assist the PTO in determining the eligibility of a product for patent term restoration and provides information regarding the regulatory review period of such product. The FDA also has the responsibility for due diligence petitions and hearings, for which the PTO is responsible for determining the period of patent extension. The FDA defers to the PTO on all matters involving the construction and validity of patent claims. The scope of rights extended are limited – for a patented product, the rights are limited to any use approved for the product.[34]

The patent term restoration provisions are codified in Title 35 of the United States Code §156 (35 U.S.C. § 156). The U.S. PTO has promulgated rules in Title 37 of the Code of Federal Regulations in sections 1.710 to 1.791 (37 CFR 1.710-1.791), and the FDA has promulgated rules in Title 21 of the Code of Federal Regulations in sections 60.1 to 60.49 (21 CFR 60.1-60.46).[35]

3. EU RECIPIENT LEGISLATION AND ITS INSTITUTIONAL ENVIRONMENT

3.1 European Patents

A European patent is a form of national intellectual property granted by a national patent authority conferring exclusive rights on a patentee.[36] Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of 1994 states that the term of protection available for patents shall not end before the expiration of a period of twenty years counted from the date of filing. Article 28 of TRIPS describes the right a patent confers upon its owner: the exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing.

The EPC, amended in 2000, regulates the legal framework for granting a patent; however, it is not a European Union instrument.[37] The EPC established the European

Patent Organization, which carries the task of granting European patents, and is made up of the European Patent Office (hereinafter "EPO") and an Administrative Council.[38]

Under the EPC, a European patent can be granted for any invention in all fields of technology provided it is susceptible to industrial application, novel and involves an inventive step.[39] The invention must also be disclosed in a sufficiently clear and complete manner.[40] Article 69 of the EPC stipulates that the extent of protection conferred by a patent is to be determined by its claims.

The EPC simplifies the process of filing for patents, however, it does not create a centralized European judiciary. A grant does not result in a unified European patent as its name would suggest, but instead provides for an independent patent under the national jurisdiction of the member state(s) in which an application is sought.[41] Article 64 of the EPC provides that the rights of the basic patent are those prescribed by the national state and its domestic law, under which the patent was granted.

It is worth noting that although both U.S. and EU patent term extensions require a "basic patent in force," the patents themselves are of different nature – a U.S. patent is enforceable throughout the entire U.S. territory, while an EU patent is only valid in the specific countries for which the applicant applied for protection.

3.2 EU Supplementary Protection Certificate

Similarly to the patent term extensions available in the U.S., EU law offers since 1992 the possibility to compensate European patent holders for the regulatory delays caused by marketing authorization procedures.

In 1988, the European Federation of the Pharmaceutical Industry Associations published a "Memorandum on the necessity to restore the effective duration of patents for pharmaceutical products." Shortly thereafter, the European Commission expressed concern over a "fall in the number of molecules of European origin that have reached the research and development stage" and the "(...) slow erosion of the European market shares as compared with those of the USA and Japan"who "(...)since 1984 and 1988 respectively, benefitted from patent term restoration for pharmaceutical products on their national markets."[42]

Thus, the proposal for a European patent term extension in the form of the Supplementary Protection Certificate (hereinafter "SPC"), was to "close some of the gap which has arisen between Europe and its major competitors in the international market – specifically in the USA, with the Hatch-Waxman Act."[43] In 1991, France introduced the Certificate of Complementary Protection (hereinafter "CCP") as a new intellectual property right, followed closely by a proposal for similar legislation in Italy. The Commission understood the need to create a unified solution in the community in order to support the free movement of pharmaceutical goods.[44]

The European SPC system was established in 1992 with the introduction of EC Regulation 1768/92[45] which following subsequent amendments was consolidated into Regulation 469/2009 (SPC Regulation) binding all member states of the EU.[46]

The aim of the SPC Regulation is to improve innovation in the pharmaceutical sector by providing favorable rules to ensure protection and encourage research.[47] The objectives behind the SPC Regulation outlined in the Explanatory Memorandum of the Regulation are: to provide favorable rules for sufficient protection encouraging research for medicinal products;[48] to create a uniform solution at the Community level to prevent disparities likely to create obstacles to the free movement of medicinal products;[49] to grant "adequate" protection;[50] and to take into account all the interests at stake, including the public health sector and the pharmaceutical sector.[51]

[23] FDCA Pub. L. No. 75-717, chapter 675, 52 Stat. 1040 (June 25, 1983) codified as amended at 21 United States Code §§ 301-399 (2002); at 21 United States Code § 355 (2006).
[24] Title 35 of the United States Code §§ 156 and 271 (2006).
[25] Goldstein, Steven J., The Drug Price Competition and Patent Term Restoration Act of 1984 Title II – Patent Extension Provisions, Food Drug Cosmetic Law Journal, 1985, volume 40, p 367.
[26] Public Law No. 98-417, 98 Stat. 1585 (1984), codified in 21 USC 355, 360cc (2000), 35 USC 156, 271, 282 (2000), as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law No. 108-173, 117 Stat. 2066 (2003).
[27] Boone, Jeffrey S., Patent term extensions for human drugs under the U.S. Hatch-Waxman Act, Journal of Intellectual Property Law & Practice, 2009, volume 4, no 9.
[28] Title 35 of the United States Code § 156(g).
[29] Ibid, § 156(c)(4).
[30] Guidelines for Extension of Patent Term Under 35 USC 156, U.S. Patent and Trademark Office Official Gazette (1984), 1047 O.G. 17.
[31] Patent term adjustments under 35 USC 154(b) dealing with delays in the PTO do not limit the availability of patent term restoration under the Hatch-Waxman Act.
[32] Title 35 of the United States Code 156(a)(3) and 156(d)(1).
[33] Goldstein, Steven J., The Drug Price Competition and Patent Term Restoration Act of 1984 Title II – Patent Extension Provisions, Food Drug Cosmetic Law Journal, 1985, volume 40, p 366.
[34] Title 35 United States Code § 156(b).
[35] Boone, Jeffrey S., Patent term extensions for human drugs under the U.S. Hatch-Waxman Act, Journal of Intellectual Property Law & Practice, 2009, volume 4, no 9.
[36] The Convention of the Grant of European Patents of 5 October 1973 (as amended), article 63(1) (hereinafter "EPC"); Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) articles 28 and 33 (hereinafter "TRIPS").
[37] MacQueen, Hector et al., Contemporary Intellectual Property Law and Politics, 2nd edition, 2011, Oxford University Press, p. 372.
[38] EPC, article 4.
[39] Ibid, articles 52–55 and 56.
[40] Ibid, article 83.
[41] EPC, articles 2-3.
[42] Explanatory Memorandum, supra n 10, § 6.
[43] Ibid, § 15.
[44] SPC Regulation, supra n 9, recital 7.
[45] Council Regulation (EEC) No 1768/92, supra n 15.
[46] SPC Regulation, supra n 9.
[47] Ibid, recitals 3-6.
[48] Explanatory Memorandum, supra n 10, recital 3.
[49] Ibid, recital 7.
[50] Ibid, recital 9.
[51] Ibid, recital 10.

The SPC is a *sui generis* right granted through an application process as a successor to a patent. The extension via a Supplementary Protection Certificate is governed by an EU Regulation and is intertwined with both patent and regulatory law. The legislative basis is harmonized under European law, however since patent law has not yet been harmonized on a European level, the SPC confers national protection – hence, it is the national patent law which must be applied within the context of the SPC Regulation.

The SPC regime in the EU does not strictly speaking extend patent term. Instead, it confers a separate right which is meant to be open to the same challenges of validity as an already granted patent ("the basic patent") and to be capable of enforcement in the same way as the basic patent, except that its scope is limited to the particular product that is protected by that basic patent and which has also received its first marketing authorization.[52]

One reason for this approach lies in the fact that the SPC regime is a creature of EU law, in contrast to patents which are subject to the European Patent Convention, which is not an EU instrument, and which did not at the time of the SPC Regulation admit the possibility of patent term extension. The amendment to the EPC to permit patent terms of more than 20 years from the date of filing first came into effect on 4 July 1997.[53]

Any medicinal product protected by a patent in force in the territory of a member state may be the subject of an SPC.[54] Article 3 of the SPC Regulation sets out the conditions which must be fulfilled in respect of the product in order to obtain an SPC including that a basic patent is in force, a valid marketing authorization exists and is the first such authorization, and that the product has not already been awarded an SPC. An application for an SPC must be lodged within six months of obtaining the marketing authorization to place the product on the market.[55]

An SPC is a "national document harmonized at the Community level and is essentially different from the basic patent."[56] Therefore, the national industrial property office in each member state is responsible for assessing and granting SPCs.[57] It provides for the same rights that are conferred by the basic patent for which the SPC is based upon, and is subject to the same limitations and obligations.[58]

According to EU Law, national courts must interpret the SPC Regulation in the same manner as the CJEU.[59] Faced with a dilemma, the national court must pause the national proceedings in order to refer for a preliminary ruling to the CJEU under Article 267 of the Treaty of the Functioning of the European Union (hereinafter "TFEU").

The interpretation of the law governing an additional period of protection after the expiration of the patent term attained through an SPC is complex. The issue that is often raised in case law has been centered on Article 3(a) of the SPC Regulation, one rule transplanted from the Hatch-Waxman Act, which requires that the product be protected by a basic patent in force.

4.0 INTERPRETATION OF A "PRODUCT PROTECTED BY A PATENT"

4.1 U.S. Case Law

The restoration of a patent term in the U.S. is available for a new product, meaning the active ingredient of a new drug.[60] However, a new drug application does not always qualify for patent term restoration.

An early case clarifying the scope of the term *product* in this context was *Fisions plc v Quigg*,[61] where an application for an extension covering a new dosage formula was rejected and the Court of Appeals for the Federal Circuit (hereinafter "CAFC") ruled that product refers to the active ingredient. Another case, *Arnold Partnership v Dudas*[62], stipulated that a new combination of old drugs, or a new use of old drugs, failed to qualify as a new product.

The U.S. Patent and Trademark Office (PTO) initially interpreted the term *product* in Section 156(a)(5)(A) to mean "active moiety," meaning the molecule in a medicinal product responsible for the pharmacological action (regardless of whether the active moiety is formulated as a salt, ester, or other noncovalent derivative), as opposed to an "active ingredient", which is physically found in the medicinal product.[63]

However, in 1990 the Court of Appeals ruled in the case of *Glaxo Operations UK Ltd v Quigg* that an ester of a previously approved salt was in fact a new product and entitled to an extension.[64] In *PhotoCure ASA v Kappos*,[65] the Federal Circuit rejected the "active moiety" argument by the PTO and held that the term product means the active ingredient present in the drug for which the marketing approval was obtained. The court noted that the patent term restoration statute was enacted to restore a portion of the patent life lost during the lengthy procedures associated with the FDA's regulatory review, with the goal to preserve the economic incentive for development of new therapeutic products.

52 Cook, Trevor, The Court of Justice Recasts the EU Patent Term Extension System, Journal of Intellectual Property Rights, March 2014, volume 19, p. 141.

53 The Act Revision Article 63 EPC of 17 December 1991 (OJ EPO 1992), p. 1.

54 SPC Regulation, supra n 9, article 2.

55 Ibid, article 7. Note that if the MA is obtained prior to the patent, then the application for an SPC must be lodged within 6 months of the grant of the patent.

56 Explanatory memorandum, supra n 10, p. 12.

57 SPC Regulation, supra n 9, article 9.

58 SPC Regulation, supra n 9, article 5.

59 See cases C-6/64 Costa v. Enel ECLI:EU:C:1964:66, Case C-106/77 Simmenthal ECLI:EU:C:1978:49, Case 26/62 Van Geht en Loos ECLI:EU:C:1963:1, Case C-399/11 Melloni, ECLI:EU:C:2013:107 and Case C-617/10 Aker Fransson ECLI:EU:C:2013:105.

60 Title 35 of the United States Code § 156(f).

61 10 USPQ2d 1869 (CAFC 1989).

62 362 F.3d 1338 (Fed. Cir. 2004).

63 See Glaxo Operations UK Ltd. v Quigg, 894 F.2d 392 (Fed. Cir 1990).

64 13 USPQ2d 1628 (CAFC 1990).

65 603 F.3d 1372 (Fed. Cir. 2010).

66 Title 35 United States Code 156(f)(1)(A) and 156(f)(2)(A).

67 www.fda.gov/cder/about/smallbiz/patent_term.htm, 14 February 2018.

In the current revision of the Hatch-Waxman Act, the term product is defined as a new drug "...including any salt or ester of the active ingredient, as a single entity or in combination with any other active ingredient."[66] The FDA now also clearly states that a new ester or salt of a previously approved acid is eligible for patent extension, while a new acid of a previously approved salt or ester is ineligible.[67]

The Federal Circuit court ruled in *Hoechst-Roussel Pharm., v Lehman*[68] that at least one claim of the patent must claim the approved product, method of using the approved product, or method of manufacturing the approved product. In *Merck v Teva*,[69] an extension was granted for a salt of an acid, as the definition of product in Section 156(a)(5)(A) includes salt or ester.[70]

For a medicinal product that contains more than one active ingredient, the Federal Circuit has held that at least one of the claimed active ingredients (including any salt or ester of that active ingredient) must be new to the marketplace as a medicinal product for a patent covering the medicinal product to be eligible for patent term extension.[71]

4.2 EU Case Law

The SPC Regulation operates at the interface between two different ecosystems - the laws and practices of the patent system to protect inventions, and the marketing authorization procedures of the pharmaceutical regulatory system to protect the consumer. The subject matter of protection under an SPC, the *product*, is linked to both the patent and marketing authorization, extending only to the product as covered by the marketing authorization within the limits of the protection conferred by the basic patent.[72]

The interpretation of Article 3(a) of the SPC Regulation requires a statutory definition of a "product" in the context of Article 1(b) of the SPC Regulation.

4.2.1 Definition of Product

The definition of *product* is central to the operation of the provision of the SPC Regulation and has proven to present difficulties when attempting to apply the substantive provisions of the regulation. A *product* is defined in Article 1(b) of the SPC Regulation as "the active ingredient or combination of active ingredients of a medicinal product[73] and the term should be subject to a narrow interpretation.[74]

The CJEU has determined that the following are not active ingredients, and therefore not "products":

- An inert excipient which has no therapeutic effect on its own used to obtain a certain pharmaceutical form yet is required to make the active ingredient therapeutically effective.[75]
- An inactive carrier.[76]
- An adjuvant.[77]
- An active ingredient which acts only as an adjuvant when in combination with another active ingredient to which it is covalently bound, meaning it does not in the given situation produce a pharmacological immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorization.[78]

The CJEU has also held that the following are not different active ingredients in relation to the question of multiple SPCs and therefore not different "products":

- The product, as a medicinal product, in any of the forms enjoying protection of the basic patent. Specifically, salts and esters of a product are not separate active ingredients.[79]
- A purer form or different concentration of the active.[80]

4.2.2 Article 3(a) of the SPC Regulation

The interpretation of Article 3(a) of the SPC Regulation of whether or not a product is protected by a basic patent in force has elicited a substantive number of disputes and jurisprudence at the CJEU.

Prior to the landmark *Medeva*[81] case (along with a rapid succession of related case rulings building upon its reasoning which came to be known as the Medeva quintet[82]) national courts of EU member states pursued one of two methods in interpreting Article 3(a) - the "infringement test" or the "identification or disclosure test."

[68] 109 F.3d 756 (Fed. Cir. 1997).
[69] 347 F.3d 1367 (Fed. Cir. 2003).
[70] See Glaxo Operations UK Ltd v Quigg 894 F.2d 392 (Fed. Cir 1990).
[71] See Arnold Partnership v. Dudas, 362 F.3d 1338 (Fed. Cir. 2004).
[72] SPC Regulation, supra n 9, article 4.
[73] SPC Regulation, supra n 9, article 1(b).
[74] Explanatory Memorandum, supra n 10, p. 16.
[75] C-431/04 MIT ECLI:EU:C:2006:291.
[76] C-202/05 Yissum ECLI:EU:C:2007:214.
[77] C-210/13 Glaxosmithkline ECLI:EU:C:2013:762.
[78] C-631/13 Forsgren ECLI:EU:C:2015:13.
[79] C-392/97 Farmitalia ECLI:EU:C:1999:416.
[80] C-258/99 BASF ECLI:EU:C:2001:261.
[81] Case C-322/10 Medeva BV v Comptroller General of Patents, designs and Trade Marks, ECLI:EU:C:2011:773. (hereinafter Medeva).
[82] C-322/10 Medeva BV ECLI:EU:C:2011:773, C-422/10 Georgetown University ECLI:EU:C:2011:776, C-518/10 Yeda Company Ltd and Aventis Holdings Inc. ECLI:EU:C:2011:779, C-630/10 University of Queensland and CSL Ltd ECLI:EU:C:2011:780 and C-6/11 Daiichi Sankyo Company ECLI:EU:C:2011:781.

The "infringement test" is a relatively wide test interpreting Article 3(a) as extending to anything under which an action for infringement could be successfully brought under the national court by looking at whether the product under the SPC would infringe upon the basic patent. The "identification or disclosure test" applies a narrower interpretation of the provision in which a patent claim must sufficiently disclose the relevant product in order for the patent protection to cover it.[83]

The decision of the CJEU in *Medeva* held that an SPC could be granted if the active ingredient or ingredients are specified in the wording of the claims of the basic patent and furthermore explicitly rejected the infringement test.

The Medeva case, referred to the CJEU by the United Kingdom (UK), concerned a patent owned by Medeva for two active ingredients in a whooping cough vaccine, pertactin and filamentous heamagglutinin (Hg). The patent was filed in 1990, granted in 2009 and expired in 2010. The first commercial vaccine using their active ingredients was given marketing authorization in 1996 in combination with other ingredients.

In 2009, Medeva applied for five SPCs to seek protection for a new combinatory vaccine holding a marketing authorization and covering respectively diphtheria (D), tetanus (T), Bordetella pertussis (Pa), poliomyelitis (IPV) and/or haemophilus influenza (HIB). The respective vaccines all contained the combination of Medeva's patented active ingredients pertactin and Hg, together with 8 to 11 other active ingredients.

All five SPC applications were rejected because although the respective vaccines included pertactin and Hg as specified in the basic patent, they were included in combination with other active ingredients not covered by the claims of the basic patent. The court found that the products did not fall under the protection of the basic patent according to Article 3(a), as they covered more active ingredients than were referred to in the subject matter of the basic patent.[84] An appeal was lodged and because the High Court had doubts with regard to the interpretation of Article 3(a), it referred a number of questions to the CJEU for a preliminary ruling under Article 267 TFEU.

The key question referred by the Court of Appeal was:

> *What is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?*

The Opinion of the Advocate General[85] (hereinafter "AG") delivered on 13 July 2011 became an important platform for the interpretation of Article 3(a) of the SPC Regulation.

The first step in the interpretation by the AG was a literal approach based on the wording and scheme of the Regulation, which led the AG to conclude that the definition of a product in Article 1(b) must be interpreted to mean the entire combination of active ingredients as such, not just the patented parts.[86] The AG reasoned that on a literal interpretation of the wording "only the combination of active ingredients of that medicinal product in its entirety, and not the patented part of that combination, can be described as a product within the meaning of Article 1(b)."[87] The opinion continued with the notion that a literal interpretation ..."leads to the conclusion that, in the case of medicinal products with multiple active ingredients, that an SPC may be granted only in the relation to the entire (patented) combination of the active ingredients."[88]

The AG concluded that a literal interpretation of Articles 1(b) and 3(a) was therefore not compatible with the aim of the Regulation to extend the term of patent protection for active ingredients used in medicinal products, as it would create a situation where it would never be possible to extend a term of patent protection when a manufacturer is obliged to combine their patented active ingredient with others to market it as a medicinal product.[89]

The AG then applied a teleological interpretation "proceeding with great caution" in consideration of the goal to achieve a balance between the various interests at stake in the pharmaceutical sector - a complex situation.[90] After, AG undertook an exercise in teleological reasoning, with the result that a combination of patented and non-patented active ingredients would in fact fall within the scope of Article 3(a) of the SPC Regulation.[91] The AG acknowledged that this would introduce a risk that a manufacturer could abuse the system by combining different active ingredients on the basis of one patented active ingredient, and therefore concluded that only one SPC could be granted on the basis of a product that is the subject matter of the basic patent.[92]

The question of whether the product is the subject matter of the basic patent is then to be determined by the national laws governing the patent. However, the AG stated that it was incompatible for a national court to "invoke the protective effect of the patent granted for a specific ingredi-

[83] Miller, Richard, et al., Terrell on the Laws of Patents, 17th edition 2011, p. 144.
[84] Medeva BV v The Comptroller General of Patents (2010) EWHC 68 (Pat) (Medeva EWHC); AG Opinion in Medeva, supra n 8, para. 15–17.
[85] AG Opinion Medeva, supra n 8.
[86] Ibid, para. 63.
[87] AG Opinion Medeva, supra n 8, para. 67.
[88] Ibid, para. 63.
[89] Ibid, paras. 75 and 80.
[90] Ibid, paras. 77–78.
[91] Ibid, paras. 89–90.
[92] Ibid, para. 100.
[93] AG Opinion Medeva, supra n 8, para. 72.
[94] Medeva, supra n 84, para. 28.
[95] Cook, supra n 52, p. 143.
[96] C-493/12 Eli Lilly v Human Genome Sciences ECLI:EU:C:2013:835.
[97] Ibid, para. 39.
[98] Ibid, para 43.
[99] C-322/10 Medeva ECLI:EU:C:2011:773.
[100] C-518/10 Yeda ECLI:EU:C:2011:779.
[101] C-630/10 Queensland ECLI:EU:C:2011:780.
[102] C-518/10 Yeda ECLI:EU:C:2011:779.
[103] C-493/12 Eli Lilly ECLI:EU:C:2013:835.
[104] Ibid.
[105] C-392/97 Farmitalia ECLI:EU:C:1999:416.
[106] C-493/12 Eli Lilly ECLI:EU:C:2013:835.
[107] C-518/10 Yeda ECLI:EU:C:2011:779, C-630/10 Queensland ECLI:EU:C:2011:780, C-6/11 Daiichi ECLI:EU:C:2011:781.

ent in order to declare that patent to be the basic patent for all combinations of active ingredients in which the patented active ingredient was to be used."[93] In this interpretation the AG distinguishes between the subject matter of a basic patent and its protection.

The AG cited that the reason for rejecting the infringement test under Article 3(a) was the fact that the patent claim scope is not harmonized at an EU level, and so the concept should be given an autonomous meaning. Thus, the AG held that for an active ingredient to be "protected by a patent" that such active ingredient must be "specified" or "identified" in the wording of the claims of the basic patent.

In its judgment, the CJEU followed the opinion of the AG by stating that to assess whether or not Article 3(a) was fulfilled, the patent claims should be examined to see if the active ingredients are specified in the wording of the claims. It also emphasized that Article 3(a) of the SPC Regulation must be interpreted as precluding the competent industrial property office of a member state from granting an SPC relating to active ingredients which are not specified in the wording of the claim of the basic patent relied on in support of the SPC application.[94]

Critics have claimed this approach to Article 3(a) may reflect ignorance on the part of the CJEU which has little experience of the variety of different ways in which patent claims to pharmaceuticals may be formulated, and that the judgment immediately put into question the issue of whether SPCs could be secured for single active products where there are not relevant claims of the basic patent that list specific chemicals, but only that the relevant claims are expressed functionally as a "Markush" form.[95]

This issue was addressed by the CJEU two years later in *Eli Lilly v Human Genome Sciences*[96] which held that to be treated as protected it was not necessary for the active ingredient to be identified in the claims of the patent by a structural formula, but that it had to be possible for someone skilled in the art "to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention (...) that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question."[97] The CJEU suggested that Article 3(a) would not be met in circumstances "where the patent holder has failed to take steps to carry out more in-depth research and identify his invention specifically" – meaning that specific indication in the claims of all ingredients is a prerequisite for protection.[98]

There have been a number of CJEU decisions discussing the meaning of a "product protected by a basic patent" yet these decisions have not provided a generally applicable test for meeting the condition of Article 3(a).

The guidance given by the CJEU on the relationship between the product and the patent to date can be summarized as follows:

- All active ingredients in the product must be specified[99] or identified[100] in the wording of the claims of the basic patent for a product claim patent. In the case of a process claim, all active ingredients in the product must be identified in the wording of the claims of that patent as the product deriving from the process in question.[101]
- An active ingredient (A) which is identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination with another active ingredient (A+B), but which is not the subject of any claim relating to the active ingredient alone, is not protected by the basic patent.[102]
- It is not necessary for the active ingredient in the SPC to be identified in the claims of the patent by a structural formula. However, where the active ingredient is covered by a functional formula, the claims need to relate "implicitly but necessarily and specifically "to the active ingredients in question. The application of that test to the facts is a matter for the national courts.[103]
- The claims are of central importance when determining whether a product is protected by a basic patent. An active ingredient which is not identified in the claims of a basic patent by means of a structural or a functional definition cannot be protected within the meaning of Article 3(a).[104]
- The question of whether or not the product is protected by a basic patent must ultimately be determined by reference to the national rules governing the patent in question[105] but note that recourse should not be given to national infringement rules when considering Article 3(a).[106]

The word "identified" was used instead of the word "specified" in several cases.[107] The difference in wording was not addressed by the CJEU and it is unclear whether it was deliberate, and whether or not it is significant.

5. MATERIAL WEAKNESS OR INSTITUTIONAL INEFFICIENCY?

5.1 The Donor Rule

The legislative intent of the Hatch-Waxman Act was to achieve a delicate balance of innovation and competition. Many conclude that the Hatch-Waxman Act did encourage growth in the generic sector and provided brand companies with incentives. However, these incentives led to gaming of the system. Both brand name and generic companies evolved in their strategy towards patent term extensions.[108] Brand companies discovered loopholes and generic companies developed their own anticompetitive strategies to level the playing field.[109]

Early on, litigation ensued to resolve the ambiguity and construe the statutory meaning of terms such as "active ingredient" and "product."[110] Despite attempts to clarify this issue, conditions for patent term restoration remained the subject of controversy and as a result, the Hatch-Waxman Act was amended.[111]

An analysis in the Berkeley Technology Law Journal claims patent term restoration is unpredictable – "fluctuating from product to product, over time, and based on the type of treatment and illness."[112] Furthermore, the article claims that patent term restoration has failed to align the incentives of the pharmaceutical industry with public health, as the brand names have responded to the incentives by increasing their reliance on improvement patents which represent an "inefficient run-around" to the system.[113]

That same article claimed the history and structure of the Hatch-Waxman Act as being plagued with contradictory and extraneous provisions that resulted in an unpredictable, biased, and innovation-suppressing patent-term restoration system.[114] The article goes so far as to draw the conclusion that "major structural reforms are needed" due to the fact that "the life of a pharmaceutical patent continues to be highly unpredictable and subject to numerous biases and inefficiencies."[115]

The Hatch-Waxman Act has been referred to by the court as "an ambitious piece of legislation (...) by no means a model of legislative clarity."[116] The U.S. lawmaking institutions and the pharmaceutical industries' "race for patents" has resulted in considerable litigation as the courts and the FDA have sought to interpret the Hatch-Waxman Act in a way that is consistent with both the statutory and legislative intent. While some maintain that the federal court system has adequate authority to challenge litigation settlements that may be anticompetitive, others believe the judicial system is not the appropriate venue to resolve these issues.[117]

5.2 The Recipient Legal System

The EU adopted provisions for the SPC Regulation following the initial enactment of the Hatch-Waxman Act, transplanting the discourse over the conditions under which an SPC may be granted. Article 3(a) has been a disputed issue in granting an SPC, *a sui generis* right that "lies at the interface between two systems."[118]

The AG in *Medeva* points out an internal conflict of the wording itself due to the definitions of "medicinal product", "product" and "active ingredient" attempting to bridge the gap between the spheres of pharmaceutical law and intellectual property law. The AG highlights a number of inconsistencies and ambiguities in the definitions, which require a clear interpretation and yet it is not always clear to what extent these terms are intended to co-exist in content.[119]

One of the most controversial questions in the dispute has long been how to define whether a product is protected by a basic patent in force.

On 24 November 2011, the CJEU delivered its judgments in *Medeva*[120] and *Georgetown I*,[121] and only one day later, the *Queensland*,[122] *Yeda*,[123] and *Daiichi Sankyo*[124] decisions were delivered, all of which followed the court's reasoning in *Medeva* and *Georgetown*.

The decisions in the "Medeva Quintet" established a precedent, however it did not clarify what level of identification or specification is required for the product to be considered the subject matter of a basic patent. This was later addressed in a series of judgments delivered two years later in the cases of *Actavis*,[125] *Georgetown II*[126] and *Eli Lilly*[127] which are often referred to as the "Lilly Trio".

Although the judgments in the Lilly Trio attempted to build upon the Medeva Quintet,[128] the clarification

brought by the CJEU in the Lilly Trio did not address all the controversial issues in the interpretation of Article 3(a)[129] and introduced yet another test difficult for national patent offices to apply to cases having different material facts.

The "one SPC for one patent" restriction in the *Medeva* opinion[130] has been the topic of contention as it is deemed inconsistent with practice. In the AG Opinion of the earlier Biogen case[131] from 1996, the AG stated that "it is nowhere stated that a patent can be the subject of only one certificate, or of a certificate in respect of one medicinal product, as the same patent may be used for widely differing medicinal products."[132]

The Commission specifically states in their Explanatory Memorandum that the Regulation concerns only new products and only one certificate may be granted for any one product - a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product will not lead to the issue of a new certificate.[133] The Commission does not state "one SPC for one patent" instead "one SPC for one product."

Although the main principles are embedded at the Community level in the SPC Regulation, the national industrial property office in each member state is responsible for assessing if the product in question is protected by a patent. This means that when the courts attempt to interpret the SPC Regulation, significant weight is given to the purposes and rationales set out in the recitals and the general principles of the SPC Regulation.[134] Adding to the complexity of the SPC Regulation is that the national interpretation is made in the same tribunals as patents, which must also employ concepts drawn from other institutions competence areas such as regulatory law and the marketing authorization regime.

In the recent UK case of *Teva v Gilead*,[135] the Judge said in paragraph 81:

> *I am bound to say that...the Court of Justice has once again failed to give national authorities clear guidance as to the proper interpretation of Article 3(a).*

The judge then stated in paragraph 91:

> *In my judgment the test to be applied in order to determine whether a product is "protected" by a basic patent within the meaning of Article 3(a) remains unclear. It is clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. But it is not clear whether that is sufficient. It appears from the case law of the CJEU that it is not sufficient, and that more is required; but it is not clear what more is required. Accordingly, it is necessary to refer the question once more to the Court of Justice in the hope that finally a clear answer will be given.*

The Judge concluded by stating:

> *I shall therefore ask (question 1 in Actavis v Sanofi) again: What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of the SPC Regulation?*

6. CONCLUSIONS

It seems reasonable to conclude that the SPC Regulation fails to meet one of its fundamental objectives to provide a "simple, transparent system which can easily be applied by the parties concerned."[136]

It is clear that the evolution of medicinal products and the intense competition of the pharmaceutical industry bring challenges to the application of the SPC Regulation, in particular with regards to the definition of the subject matter of an SPC[137] – a product protected by a patent. The means by which an SPC is achieved is a matter of EU law and must ultimately be interpreted by the national courts in the manner of the CJEU, and consequences of any preliminary rulings must be implemented by national courts.[138]

[108] Rumore, Martha M., The Hatch-Waxman Act – 25 years later: Keeping the Pharmaceutical Scales Balanced (2009).
[109] Bajefsky RD, Chopskie G., Biting the Hand that Feeds? Generic Drugs and Abuse of the Hatch-Waxman Law, Washington Legal Foundation, 2002, 17:1.
[110] McGough KJ., Preserving the Compromise: The Plain Meaning of Hatch-Waxman Market Exclusivity, Food Drug Cosmetic Law Journal, volume 45, pp. 487-504.
[111] Medicare Prescription Drug Improvement and Modernization Act of 2003. Publ L. No. 108-173, 117 Stat. 2066 (2003).
[112] Cárdenas-Navia, James F., Thirty Years of Flawed Incentives, Berkeley Technology Law Review, 2014, volume 29, p. 1373.
[113] Ibid, p. 1374.
[114] Cárdenas-Navia, supra n 112, p. 1373.
[115] Ibid, p. 1301.
[116] Eli Lilly v. Medtronic, Inc. 496 U.S. 661, at 649 (1990).
[117] Rumore, Martha M., The Hatch-Waxman Act – 25 years later: Keeping the Pharmaceutical Scales Balanced (2009).
[118] Explanatory Memorandum, supra n 10, para. 20.
[119] AG Opinion Medeva, supra n 8, para. 58.
[120] C-322/10 Medeva ECLI:EU:C:2011:773.
[121] C-422/10 Georgetown ECLI:EU:C:2011:776.
[122] C-630/10 University of Queensland ECLI:EU:C:2011:780.
[123] C-518/10 Yeda ECLI:EU:C:2011:779.
[124] C-6/11Daiichi ECLI:EU:C:2011:781.
[125] C-443/12 Actavis ECLI:EU:C:2013:883.
[126] C-484/12 Georgetown ECLI:EU:C:2013:828.
[127] C-493/12 Eli Lilly ECLI:EU:C:2013:835.
[128] Gassner, U.M., Recent development in the area of supplementary protection certificates, Pharmaceutical Policy and Law, 2016, volume 16, p. 58.
[129] Papadopoulou, Frantzeska, Supplementary protection certificates: still a grey area?, Journal of Intellectual Property Law & Practice, 2016, volume 11, no 5, p. 376.
[130] Opinion Medeva, supra n 8, paras. 98–101.
[131] C-181/95 Biogen v Smithkline Beecham ECLI:EU:C:1996:370.
[132] Opinion on Case C-181/95 Biogen Inc v SmithKline Beecham Biological S.A. (1996) ECLI:EU:C:1996:370, para. 53.
[133] Explanatory Memorandum, supra n 10, p. 8.
[134] Richard Miller, et al., Terrell on the Laws of Patents, 17th ed. (2011) p. 144.
[135] Teva UK Ltd and Ors v Gilead Sciences Inc (2017) EWHC 13 (Pat).
[136] Explanatory Memorandum, supra n 10, para 16.
[137] Papadopoulou, supra n 129, p 373.
[138] Cook, supra n 52, p. 141.

The aim of preventing a heterogeneous development of national laws to ensure a uniform solution within the Community carries significant weight when interpreting the Regulation.[139] However the AG states in the *Novartis* case that an analysis of the recitals in the SPC Regulation indicate that the main objective of the legislature was not to guarantee the free movement of medicinal products within the Community, but to ensure that conditions exist for profitable pharmaceutical research and to deter firms from relocating outside the union.[140]

The CJEU is forced to maneuver within the complex linkage between the EU SPC Regulation, the national patent law and courts of the member states, as well as the market authorization process of the European Medicines Agency – interpreting terminology that is uncoordinated across the three systems.[141]

During the literal interpretation exercise in the *Medeva Opinion*, the AG discussed internal conflicts of the wording of the SPC Regulation.[142] The provisions of the SPC Regulation adopted from the Hatch-Waxman Act brought with it the same basic flaws. Notwithstanding the material law itself, the institutional law-making system in the EU introduces new weaknesses, creating legal uncertainty in the application of the SPC Regulation.

In the EU legal environment, patent law is not (yet) harmonized and the law-making court (CJEU) is unable to rule on the interpretation of the EPC, as the EU is not party to the EPC.[143] Lacking jurisdiction to interpret the provisions of the EPC, the Court cannot provide further guidance to the referring court concerning the manner in which it is to determine the extent of the claims of a patent issued by the EPO.[144]

As a result, the CJEU with its limited competence to interpret patent law is faced with the challenge of interpreting the SPC Regulation in a manner consistent with its objectives, without jeopardizing the balance between the various interests at stake.[145] In 2014 it was written: "When a national court makes a referral because there is a particular area of uncertainty, a judgment from the CJEU follows that fails to clarify the original uncertainty, and creates a new one."[146] An unequivocal ruling by the CJEU is needed to allow national courts to avoid divergence in their conclusions. However, The CJEU may be correct in their reluctance, as the court does not have the jurisdiction to interpret EPC provisions.[147]

In the end, the final conclusion of whether a product is protected by a patent is left to the national courts, armed solely with the CJEU reference to Article 69 EPC in combination with the conclusion that the claims should relate "implicitly but necessarily and specifically" to the active ingredient in question. The determination of whether the subject matter falls within the scope of the patent turns out to be a rather complicated task.[148]

The lack of EU harmonization on substantive patent law contributes to the fragmented application of the SPC Regulation.[149] The interdependence between three systems in the EU introduces complexity beyond the material application of the rule in comparison with the U.S. where patent and patent term extensions are processed within the same courts, and where both patent extensions and marketing authorization are part of the same body of legislation. This arrangement presents advantages, including consistent use of technical terminology and coherence in the system as a whole.[150]

[139] Teva UK Ltd and Ors v Gilead Sciences Inc (2017) EWHC 13 (Pat), p. 145.
[140] AG Opinion in joined cases C-207/03 and C-252/03 Novartis AG, University College London and Institute of Microbiology and Epidemiology v Comptroller, ECLI:EU:C:2004:491, para. 42.
[141] Papadopoulou, supra n 129, p. 380.
[142] AG Opinion Medeva, supra n 8, paras. 57 – 62.
[143] According to the European Patent Convention, adopted by the Administrative Council or the European Patent Organization by decision of 28 June 2001.
[144] C-493/12 Eli Lilly ECLI:EU:C:2013:835, para. 40.
[145] Cook, supra n 52, p. 141.
[146] Smyth, Darren, Two gaps instead of one: the CJEU's effect on Supplementary Product Certificate jurisprudence, Journal of Intellectual Property Law & Practice, 2014, volume 9, no 6, p. 445.
[147] C- 493/12 Eli Lilly ECLI:EU:C:2013:835, paras. 39–44.
[148] Papadopoulou, supra n 129, p. 376.
[149] Ibid, p. 373.
[150] Ibid, p. 381.
[151] Cárdenas-Navia, supra n 112, p. 1375.
[152] Ibid, p. 1377.

The potential of the Unitary Patent Package (UPP) may improve the system coherence, however it may create yet another fissure in an already fragmented system as current European patent holders are given the option to "opt out" of the UPP system. The EU legislature may consider amending the wording of the Regulation to support a homogenous interpretation by the national courts and fulfill the purpose of the SPC Regulation.

One alternative to an amendment of the rule would be to automatically restore any patent time lost during regulatory approval up to the limit. It is argued that guaranteeing a minimum term of exclusivity for new products would provide the predictability to effectively promote pharmaceutical research and "allow brand names to focus on competing against one another instead of against their patent term clocks, eliminating inefficiencies."[151]

Another solution would be to eliminate patent term extensions, focusing instead on terms of market exclusivity. Market exclusivity would ensure that generic manufacturers could not enter the market until a certain number of years have passed after the brand-name product entered the market. A major advantage of market exclusivity compared to patent term extensions is its ease of enforcement, taking away the requirement of a case-by-case analysis on the patent claim construction.[152]

The EU legal system, with the CJEU lacking the competence to rule on patent law, will suffer from incoherence while national courts continue to face legal uncertainty when determining whether the product implicitly but necessarily and specifically is identified or specified in the patent claim.

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