OVERLAPPING INTELLECTUAL PROPERTY RIGHTS

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*Duncan Curley and Marleen H.J. van den Horst*

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PATENTS AND REGULATORY DATA
EXCLUSIVITY FOR MEDICINAL PRODUCTS


A. Hypothetical

Following the synthesis of compound Z in its laboratories in the mid-1980s, BigPharma Inc. discovered that Z had useful biological properties. It patented compound Z and subsequently carried out extensive clinical trials on a medicine containing compound Z as the active substance. The medicine was approved for use in humans in Europe. The clinical trials data package for the medicine containing compound Z was the subject of a period of data exclusivity, but this ran out long before the patent to compound Z expired. In the meantime, BigPharma Inc. had discovered that Z existed in a form comprised of two chemically similar but structurally different isomers. When the individual isomers were separated, it was found that one was much more biologically active than the other. BigPharma filed for a separate patent on the active isomer, which it called iso-Z. It also developed a new medicine containing iso-Z as the active substance and submitted to the relevant European authority an application for a marketing authorization. The regulatory authority was content for BigPharma to rely on much of the clinical data that it had already obtained on the medicine containing the original compound (Z) and granted the marketing authorization. Nevertheless, iso-Z was treated as a new active substance, thereby attracting a further period of data exclusivity. Whilst both patents and data exclusivity may be available to protect such investments in the field of medicines, do these rights overlap and do they always offer bullet-proof protection?

1 The authors gratefully acknowledge the assistance of Annemieke Kooy of BarentsKrans NV in the preparation of this chapter.
B. Introduction

6.02 The focus of this chapter is an examination of the laws prevailing in the European Union (the EU) which relate to data exclusivity and patent protection for medicinal products for human use. We will describe the European system for the grant of supplementary protection certificates (SPCs) for medicinal products, which provides a link between the regulatory and patent frameworks. We will then address the question of any overlap between data exclusivity and patent protection (including SPCs) and compare this to the US position, before concluding with three examples from the EU which illustrate the various topics discussed.

6.03 Maintenance of exclusivity in the market by means of patent protection has historically been the way in which companies operating in sectors that depend on research and innovation have survived and thrived. The importance of patents for the protection of new medicinal products (both small molecules and biologicals) cannot be over-stated, but the time spent on invention and discovery may represent only a proportion of the time that it actually takes to bring such products to market. In the healthcare field, extensive preclinical and clinical trials must be undertaken to demonstrate a drug product’s quality, safety, and efficacy. A dossier containing the results of these trials is then submitted to the relevant regulatory authority, in order to gain governmental approval to place the drug product on the market. The authority assesses the data for compliance with the regulatory standards in force, before considering whether to grant a marketing authorization that would allow the new medicine to be prescribed by physicians and used to treat illnesses.

6.04 The mailing of active substances for the purposes of regulatory approval will often lead to the accumulation of valuable data on their biological effects. PhRMA, the Pharmaceutical Research and Manufacturers of America, an industry association of originator companies, states that (on average) $1.2 billion is invested in preclinical and clinical testing of new medicines. This is an average figure and clearly the cost of obtaining data on an experimental medicine will vary considerably.

6.05 Clinical trials are by no means restricted only to new active substances that have never been used before in marketed drug products. Known substances may be re-examined in studies that involve testing a new dosage regime or that seek to discover other biological effects, such as second or further medical uses. For example, in the 1980s, it was discovered that the bisphosphonate compound, alendronate, could be used in the treatment of osteoporosis. This use of alendronate was patented in 1982 by the Istituto Gentili research laboratories in Pisa, Italy, which were subsequently acquired by the American pharmaceutical company Merck & Co. Inc. Following clinical trials, Merck launched an approved drug product containing alendronate in 1993. However, patents that claim only uses of a known compound (as opposed to compounds per se) can be weak and may be liable to challenge. Merck discovered this to its cost in relation to alendronate in a number of European countries. In declaring two

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2 See PhRMA’s website at: <http://www.phrma.org/issues/intellectual-property> last visited 20 February 2012.

of Merck's UK alendronate 'use' patents to be invalid in 2003, Jacob, J (as he then was) said,

I .,. hold both patents invalid. I do so with some regret. Merck have only had a few years' exclusive exploitation of alendronate. They must surely have had to make a very considerable investment and incurred considerable risk in bringing it to market. And mankind is better off as a result. But the patent system does not confer monopolies on those who develop obvious or old products, even if they have never been exploited.\(^4\)

It is clear from the alendronate example (above) that patents cannot always guarantee a period of market exclusivity, after regulatory approval of a drug product has been obtained. What about the data that was derived from the clinical trials that must be provided to the relevant regulatory authority in support of the proposed medicinal use of the product? Some degree of legal protection is required, in order to ensure that it cannot immediately be used by others, given the size of the financial commitment that is usually associated with trials and obtaining the data. The concept of data exclusivity—a period of time after the initial registration of a new drug product during which only the entity that developed the data may use it to support additional marketing authorizations—has thus evolved.

Data exclusivity is not like other intellectual property rights, such as patents or copyright. The latter rights may be enforced privately against infringers in the courts. Data exclusivity is better characterized as a governmental or administrative obligation not to allow data that has been provided to support a registration dossier for a medicine to be used by third parties. Article 39(3) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), states as follows,

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

The protection of data against disclosure as mandated by TRIPS is achieved by means of regulatory data exclusivity in the legal frameworks governing the authorization of medicinal products in the EU, the USA, and in many other countries.

Data exclusivity does not last in perpetuity. After a prescribed period of time (the data exclusivity period), another company may seek marketing approval for a 'generic' product, by submitting an abbreviated application for registration that relies on the original data that has already been collected and submitted by the originator company. In the USA, a direct link is made between the regulatory approval of generic medicines and the patent protection status of drug products in the Hatch-Waxman Act of 1984 (the Hatch-Waxman Act).\(^5\) This link has been said to blur the rewards available through the patent system and drug approval regulation.\(^6\) As we shall see, in the EU, the system conferring regulatory data exclusivity and the patent framework are effectively distinct. A legal link between the regulatory approval process


Chapter 6: Patents and Regulatory Data Exclusivity for Medicinal Products

and the patent system is established in the mechanism for the grant of patent extensions for authorized medicinal products in the EU (supplementary protection certificates), but this link is purely functional and it does not produce any ambiguity about overlapping rewards.

C. The EU Battleground: Data Exclusivity, Patents, and Supplementary Protection Certificates

(1) Data exclusivity

6.10 Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use ('the Directive') lays down rules relating to the marketing of medicinal products with which the member states in the EU must comply. The core provision is Article 6, which states that,

No medicinal product may be placed on the market of a Member State unless a Marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive . . .

6.11 There are several routes that a company may follow in order to obtain a marketing authorization in accordance with Article 6: the Centralized Procedure, the National Procedure (which may be followed by the Mutual Recognition Procedure), and the Decentralized Procedure. The choice depends on the type of product and whether a company wishes to obtain a marketing authorization in one, some, or all of the member states, which in turn may depend on timing and strategy considerations.

6.12 An application for marketing authorization may be made on the basis of one of the following articles in the Directive:

- Article 8 (3): ordinary procedure
- Article 10
  - 10(1): abridged procedure
  - 10(3): hybrid abridged procedure
  - 10(4): procedure for biosimilar products

8 Following the Centralized Procedure (CP) will, if all the requirements have been met, result in one marketing authorization valid throughout the EU (in contrast to the other routes described, which result in marketing authorizations valid in one or more member states). An application is made to the European Medicines Agency. For certain specific types of medicinal product (such as those that have been made using biotechnological methods), obtaining a marketing authorization via the CP is mandatory.
9 A National Procedure results in a marketing authorization for one member state only. The application is filed at the national Marketing Authorization Authority in the relevant member state. In the event that the applicant subsequently wishes to obtain marketing authorizations for the same medicinal product in other member states, the national application offers the basis for the first stage of the Mutual Recognition Procedure (MRP). The applicant may ask for the authorization to be recognized by one or more other member states by following the MRP. This procedure is described in Article 28(2) of the Directive and is substantively similar to the Decentralized Procedure.
10 The Decentralized Procedure (DCP) is followed if the applicant decides, from the outset, to obtain marketing authorizations in several member states at the same time. The procedure is described in Article 28(1) of the Directive. The applicant asks the authority of one member state to act as a so-called Reference Member State (RMS). The application is submitted with this authority and the applicant will indicate the other member states in which it wishes to obtain a marketing authorization for the same medicinal product. These other member states are called the Concerned Member States (CMS).
C. The EU Battleground: Data Exclusivity, Patents, and SPCs

- Article 10 (bis): bibliographic procedure
- Article 10 (ter): procedure for new combinations of active substances
- Article 10 (quater): approved procedure (where the dossier holder of a previous authorization gives permission for references to studies from this dossier).

The distinction between an ordinary procedure (Article 8(3)), an abridged procedure (Article 10(1)), and a hybrid abridged procedure (Article 10(3)) pertains to the nature and scope of the data to be submitted (the dossier). An application for a marketing authorization must, in principle, contain all of the data as stated in Article 8(3) of the Directive, namely (inter alia) the results of pharmacological, toxicological, and clinical trials. An application containing all data is called a 'full' or 'complete' application, or full dossier. This is regardless of the question of whether all of the data are in fact new. A full application can also comprise data that are already part of a different application dossier, for example, if the application relates to a new formulation of a known substance, or a second medical use, or a different dosage regime.

As already stated, preclinical and clinical trials are expensive and time consuming and often require significant investment from the originator companies. Conducting such trials also implies extensive testing on animals and humans. One of the objectives of the European legislation is to ensure that such trials are not repeated unnecessarily. Thus, under certain defined conditions, third parties (ie, generic companies) may refrain from repeating such studies and may refer to the results of the relevant tests in the dossier of the earlier, original registration (the so-called spécialité).

Under Article 10(1) of the Directive, an applicant does not have to submit a full dossier, but is allowed to refer to the data in a marketing authorization dossier for a reference medicinal product. This option exists if the medicinal product for which a marketing authorization is being requested is a 'pure' generic (see below) with respect to the reference medicinal product and if a marketing authorization was granted for the latter medicinal product at least eight years before the application date. An application based on Article 10(1) is referred to as an abridged application.

Article 10(2) of the Directive defines a generic medicinal product as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. Article 10(2) specifies that different salts, esters, ethers, isomers (including enantiomers), mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same substance, unless they differ significantly in properties with regard to safety and/or efficacy.

Article 10(3) of the Directive describes the so-called 'abridged hybrid procedure'. An application under Article 10(3) is made for a marketing authorization for a medicinal product that does not satisfy the definition of generic medicinal product in Article 10(2) (see above) or whose biological equivalence cannot be demonstrated by studies or where the active substance(s), the therapeutic indication, the strength, the pharmaceutical form, or the manner of administration are changed, compared to the reference medicine. The abridged

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11 See Recital 10 to the Directive.
hybrid procedure opens up the possibility of referring to data which have already been submitted in the dossier for a reference medicinal product, but requires the submission of additional data that serve to bridge the differences to that reference medicinal product ('bridging data'). The bridging data may consist of (for example) bioequivalence studies and tests demonstrating the safety and efficacy of the product for which the application is made.

6.18 Whilst the purpose of the abridged procedures laid down in Article 10 is to avoid unnecessary repetition of clinical trials, a balance must be found between this imperative and the need to stimulate the originator companies to continue to invest in the development of new medicinal products and accordingly to contribute to human health and well-being. This balance is found in the form of data exclusivity. During the period of data exclusivity, only the marketing authorization holder (that conducted the pharmacological, toxicological, and clinical trials) is allowed to use the data in order to apply for a marketing authorization and/or to use such authorization, once obtained. Thus, it is only after the expiration of this period that third parties (such as those seeking to bring generic medicines to market) are allowed to refer to the original data in the context of the abridged procedures.

6.19 The data exclusivity rules are contained in Article 10(1) of the Directive. In the EU, the current data exclusivity regime is often referred to by the shorthand '8+2+1', the figures referring to the years that have to elapse before an abridged marketing authorization can be applied for by third parties (eight years) and another two or three years before the marketing authorization can be used by those third parties to market their product. In other words, once (after eight years) a third party has applied for and subsequently obtained a marketing authorization on the basis of an abridged procedure in Article 10, the generic medicinal product may not be marketed before ten years have elapsed, counted from the date when the marketing authorization for the reference product was granted. In some cases, this can be increased to eleven years, if,

during the first eight years of those ten years, the marketing authorization holder [of the reference product] obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.\textsuperscript{12}

The '8+2+1' data exclusivity rules (outlined above) apply to those products that have been authorized in the EU after 30 October 2005.\textsuperscript{13}

6.20 Apart from being used to support applications for marketing authorizations, the results of clinical trials are often published in the scientific literature. The fact that such data are in the public domain does not necessarily mean that they fall outside the ambit of the protection conferred by data exclusivity. It is important to distinguish between the availability of data in the public domain on the one hand and the exclusive right to use such data on the

\textsuperscript{12} See the last sub-paragraph of Article 10(1).

\textsuperscript{13} However, data submitted in support of marketing authorizations applied for before this date continue to benefit from the previous (non-harmonized) data exclusivity rules. A good summary of the previous European data exclusivity rules may be found in R.F. Kingham and G.H. Castle, (2000) 55 FOOD AND DRUG LAW JOURNAL 209–223.
other hand. The concept of data exclusivity ordinarily entails (as the word 'exclusivity' implies) that the company that acquired the data by conducting relevant trials can, to the exclusion of other parties, use such data for the purpose of marketing the medicinal product involved. Hence, data which is in the public domain can still be protected by a period of data exclusivity. This specific issue arose in both the clopidogrel and the escitalopram cases, which will be discussed further, below.

An important concept in the EU regulatory framework when discussing data exclusivity is the global marketing authorization. This concept is found in Article 6(1) (second paragraph) of the Directive:

... When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1) (emphasis added).

The concept of a global marketing authorization thus entails that there is a marketing authorization with greater scope, based on the first authorization that was granted for the original active substance in the medicinal product. In consequence, all authorizations granted subsequently with regard to the same substance, for instance as a consequence of variations in the active substance, form part of the same, initial marketing authorization. The words 'variations and extensions' in Article 6 are taken from the successive variation regulations, the currently valid one being Commission Regulation (EC) No 1234/2008 ('the Variation Regulation').

Variations to medicinal products are classified in different categories, depending on the level of risk to public health and the impact on the quality, safety, and efficacy of the medicinal product concerned. Certain changes, namely those which have the highest potential impact on the quality, safety, or efficacy of medicinal products, require a complete scientific assessment, in the same way as for the evaluation of new marketing authorization applications. Other changes to medicinal products do not require an extensive scientific assessment. According to the Variation Regulation, an extension of a marketing authorization (or simply an 'extension') means a variation which is listed in Annex I to the Variation Regulation and which fulfils the conditions specified therein. Every change listed in Annex I of the Variation Regulation is thus an extension, which is also often called a 'line-extension'. Every authorization granted for an extension thus forms part of the same global marketing authorization as the first authorized version of the active substance(s) in a medicinal product, regardless of whether it is in the form of a new, separate marketing authorization or as an amendment to an existing marketing authorization.

The global marketing authorization concept has special significance for the application of Article 10 of the Directive and accordingly for the calculation of the period in which data exclusivity can be claimed. The period of data exclusivity is calculated as beginning on the date that the first of all of the authorizations in the group that forms the global marketing authorization was granted. An applicant wishing to base its application on Article 10 of the Directive may refer to each authorization that forms part of the global marketing authorization.
Chapter 6: Patents and Regulatory Data Exclusivity for Medicinal Products

to serve as reference medicinal product in abridged (hybrid) proceedings.\textsuperscript{14} Therefore, even when an applicant for a marketing authorization based on Article 10(1) or 10(3) refers to the dossier of a specific reference medicinal product (which is for instance another pharmaceutical form than the first authorized version of the reference product), the period of data exclusivity will still be calculated by using the date of the grant of the first, initial version of that medicinal product.

6.25 To summarize, the grant of a marketing authorization by a regulatory authority is an administrative decision that follows, once the authority has established legal and scientific compliance with all relevant requirements. It does not explicitly include the grant of data exclusivity as such, nor can the decision of the authority be seen as the 'vesting' of a right. Whether or not data are protected by data exclusivity is, in practice, something that is assessed and determined at a later moment in time, mostly when third parties apply for a marketing authorization via an abridged procedure, referring to the data in the dossier of the reference product (spécialité).\textsuperscript{15} The regulatory authority in the member state where the application is filed has to assess whether the data can or cannot be referred to and thus to determine whether data exclusivity (still) exists in relation to the original dossier. Given the fact that the concept of data exclusivity is laid down in Article 10 of the Directive (prescribing the requirements for generic applications), it is clear that the issue of entitlement to data exclusivity for specific data only comes into contention when a generic company starts an abridged procedure based on Article 10.

6.26 The ten (possibly eleven) years of data exclusivity that are now available in the EU for new active substances offers a relatively high level of protection, compared to equivalent regimes elsewhere in the world. The USA offers only an initial five years of data exclusivity for conventional small molecule drug products.\textsuperscript{16} A recent paper suggests that there are benefits to be gained from giving small molecule drugs a longer period of data protection in the USA.

\textsuperscript{14} This is stated in Volume 2A, Chapter I Section 5.3.1 of the Notice to Applicants, which is a document to be used as guidance by applicants for marketing authorizations. The Notice to Applicants says:
Besides, Article 6(1) contains the notion of global marketing authorisation as the initial marketing authorisation and any additional strengths, pharmaceutical forms, administration routes or presentations, as well as any variations and extensions. Each product within the global marketing authorisation may be chosen as the reference product.

The Notice to Applicants determines (on page 35) that the requirement to observe a period of eight years before an abridged application for a marketing authorization for a generic medicinal product can be made does not apply to (line-) extensions:

\ldots Even if they are authorised in accordance with the procedure for granting a new marketing authorisation, according to Article 6(1) of Directive 2001/83/EC, when a medicinal product has been granted an initial marketing authorisation, any extension shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the rules on data and market protection. This means that for an original medicinal product, the start of the data exclusivity period is the date when the first marketing authorisation was granted in the Community. Extensions do not restart or prolong this period; they will have the same end point of the data exclusivity period.

\textsuperscript{15} We suggest that a generic company is not 'time-barred' from objecting to a period of data exclusivity allegedly attaching to a dossier for a medicinal product, several years after the grant of the marketing authorization for the product in question. Generic companies applying for marketing authorizations under the abridged procedure usually do not object to the grant of the (initial) marketing authorization for the reference medicinal product, but rather seek to contest the consequence of data exclusivity that is attached to it by the regulatory authority.

\textsuperscript{16} Under the Hatch-Waxman Act. Applications for approval of new indications (for uses other than the one for which the drug was originally approved) receive three extra years of data exclusivity.
C. The EU Battleground: Data Exclusivity, Patents, and SPCs

in terms of spurring innovation and ultimately consumer welfare.\(^{17}\) Although there has on occasion been some suggestion that the number of years of protection for clinical trials data in the USA should be raised,\(^{18}\) these proposals have not gained traction in the US legislature. In contrast however, biologics have now been granted a 12 year data exclusivity period in the Patient Protection and Affordable Care Act of 2010, implemented as part of President Obama’s reforms to the US healthcare system.\(^{19}\)

(2) Patents

Traditionally, the pharmaceutical industry has operated by synthesizing new chemical substances in the laboratory, testing them for biological activity and patenting them. Patent protection is usually sought at an early stage in the life of a product, often long before it is known whether the compound will actually prove useful as an active substance in a marketed drug product. This simple model served the originator companies well for many years, but today, looming patent expirations (the so-called ‘patent cliff’) on a number of big-selling products based on small molecule active ingredients and an increased intensity of competition from the manufacturers of generic products afflict many of the companies that are active in this sector.\(^{20}\) In the 1980s, small molecule drug discovery programmes were supplemented by rapid advances in the manipulation of biological material, leading to the patenting of biotechnology-derived products. Today, biological products are a boon to the life sciences sector, although the manufacturers of so-called follow-on biologics (or similar biological products, or biosimilars) pose a threat to some of the blockbuster biopharmaceutical products, in some markets, in the near to medium term.

(3) Supplementary protection certificates

It is often—but not always—the case in the EU that patents will protect the market exclusivity for both small molecule-based drug products and biologicals for longer than the data exclusivity period,\(^{21}\) by virtue of the European system for the grant of extensions to patent rights, which are called supplementary protection certificates (SPCs) in Europe.\(^{22}\) SPCs sit in a class of their own (as sui generis legal instruments) between the regulatory and the patent systems. SPCs extend certain rights conferred by a patent after its expiry, for a

\(^{17}\) D.P. Goldman, D.N. Lakdawalla, J.D. Malkin, J. Romley and T. Philipson, ‘The Benefits from giving makers of conventional ‘small molecule’ drugs longer exclusivity over clinical trials data’, (2011) 30(1) HEALTH AFFAIRS 84-90. The article reports on the results of research funded (in part) by INTERPAT, an association of originator pharmaceutical companies.

\(^{18}\) For example, from GlaxoSmithKline, who have proposed that new drugs should receive 14 years of data exclusivity.

\(^{19}\) Part of the quid pro quo for this concession to the originator companies was to pave the way for a regulatory framework for the speedier authorization by the FDA of follow-on biologics, although at the time of writing, this framework has not been implemented and the EU remains well ahead of the game, with a regulatory pathway for biosimilars that is being used successfully and a number of biosimilar products already having been launched successfully on to EU markets.


\(^{22}\) For an overview of the European system for the grant of supplementary protection certificates for medicinal products, see D. Curley, ‘Extending Rewards for Innovative Drug Development’, (2007) INTELLECTUAL PROPERTY INSTITUTE.
period of up to five years.\textsuperscript{23} The European regime for the grant of SPCs for medicinal products for human and veterinary use was first proposed in a European Commission Explanatory Memorandum in 1990, in response to patent extension legislation in the USA and Japan.\textsuperscript{24} The original regulation subsequently came into force on 2 January 1993\textsuperscript{25} and was followed in February 1997 by a similar regulation for plant protection products.\textsuperscript{26}

6.30 The jurisprudence on SPCs is still evolving, but from the Explanatory Memorandum and the preamble to the medicinal products regulation,\textsuperscript{27} it seems clear that the original purpose of SPCs was to compensate those who obtained patents for novel and inventive research and development for the period of delay that usually occurs between the filing of a patent application and the subsequent grant of a marketing authorization. It may not be until the latter point in time—perhaps a decade or so after the filing of the original patent application—that the patentee is able to start marketing the product and to earn money from exclusive sales of that product. SPCs are thus intended to address the cutting down of the twenty year patent monopoly that affects in particular those in regulated industries that cannot market patented products without first conducting trials on those products and obtaining regulatory approval.

6.31 A common objective in both the medicinal and plant protection products SPC regimes is to provide a period of exclusivity (by virtue of both patent and SPC) of an overall maximum of 15 years from the time that a product first receives regulatory approval for marketing in the EU,\textsuperscript{28} thus providing a link between the patent and the relevant regulatory systems.

6.32 As stated above, in the field of human medicines, the combination of granted patent rights and the protection offered by a SPC will usually provide longer effective market exclusivity in the EU than the period of data exclusivity, although sometimes experimental medicines in the cancer or CNS therapy areas may need to be studied in the clinic over a protracted period of time. Relevant patents may therefore have expired by the time marketing authorization is granted and a drug product is launched, or alternatively, they may expire only a few years after such launch. Data exclusivity may be vital in such circumstances, in order for the originator company to earn a return on its financial investment in the product.

(4) Overlapping protection?

6.33 For the manufacturers of generic medicines, an important one-off revenue generating opportunity is to be derived by being the first to gain marketing approval and launch a generic drug product on to the market. Data exclusivity, patents, and SPCs preserve incentives for the


\textsuperscript{24} European Commission's Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM(90) 101 final.


\textsuperscript{27} In particular Recital (4) of Regulation (EC) No 469/2009.

\textsuperscript{28} See Recital (9) of Regulation (EC) No 469/2009 and Recital (11) of Regulation (EC) No 1610/96.
originator firms by acting as a bar to generic competition. To that limited extent, data exclusivity and patent rights (including SPCs) may be considered to be overlapping, but the purpose underlying the exclusivity that is conferred by each of them is different. Data exclusivity is intended to stimulate and protect investment in expensive and time-consuming clinical trials. Patents are intended to stimulate and protect inventive activity, but not necessarily labour and investment. The essential rationale behind SPCs is to compensate for time lost during the twenty year patent term (patent term erosion), whilst clinical trials are undertaken and regulatory approval is obtained.

In both the EU and the USA, data exclusivity is specifically linked to the investment in clinical studies that has been made. Only investments that have been made in substantial new studies on the safety and efficacy of new active substances (and not trials on products that involve simple variations to existing drugs, or line extensions) are entitled to the protection. So, in general, clinical research that is intended only to demonstrate the safety and efficacy of variations to existing medicines is not intended to be rewarded with a new extended period of data exclusivity. We will analyse in detail how the limits on data exclusivity play out in practice in the EU, as this is an important and evolving area of the law.

In the EU, it is possible to draw a clear distinction between the patent system on the one hand and the drug approval system (including the data exclusivity framework) on the other hand. Indeed, the European Commission has actively discouraged the regulatory authorities in the member states from making their consideration of the compliance of generic medicines with regulatory approval standards conditional upon clearance of the patent protected status of active ingredients.

By contrast, in the USA, the patent regime and the generic drug approval process are intertwined, in certain respects at least, by virtue of the Hatch-Waxman Act. A detailed description of the complex legal machinery of Hatch-Waxman is outside the scope of this article, but in brief, it permits generic manufacturers to file an abbreviated new drug application (ANDA) before the patents of the originator companies have expired. A generic manufacturer must certify either that their product does not infringe any relevant patents listed in the Orange Book—a list of approved drug products that is maintained by the US Food and Drug Administration (FDA)—or that the patents in question are invalid or unenforceable. This certification usually triggers a lawsuit for patent infringement by the originator company. A 180-day period of marketing exclusivity may be granted to the first generic manufacturer to file an ANDA with an appropriate certification, provided that it wins the subsequent patent dispute, for example by successfully invalidating a relevant patent or by proving non-infringement. The 180-day period of exclusivity is an extremely valuable right for the first generic manufacturer to file an ANDA with an appropriate certification, provided that it wins the subsequent patent dispute, for example by successfully invalidating a relevant patent or by proving non-infringement.
to secure and it has made the US market an attractive one for those seeking to market generic drug products. No such right exists in the EU.

6.37 The balance of incentives conferred by patents and data exclusivity continues to be the subject of debate in the USA and has been the subject of discussion in the literature, but in the EU, less so. One of the reasons for this may be the lack of a legislative framework (like Hatch-Waxman) that links the patent and regulatory systems with a reward for generics of a fixed period of exclusivity (although this may be a topic of future debate, bearing in mind current pricing and reimbursement pressures on generic medicines in a number of EU member states).

6.38 A financial opportunity for the generic firms presently only exists in national EU markets between the first launch of a generic product, which may bear a price close to that of the originator product, and the subsequent genericization of the market for that product, caused by the entry of a number of other generic competitors and leading eventually to commodity pricing. In order to secure this first mover advantage, generic firms often adopt the dual tactic of an early regulatory filing, coupled with patent litigation. There is however at present no statutory, fixed reward in the EU for being the first generic to market. Some examples from the case law illustrate the use of the dual strategy that is often necessary to carve out a first-to-market generic product opportunity in the EU and demonstrate the fact that data exclusivity and patents have to be addressed as separate issues by the generic firms.

(5) Clopidogrel

6.39 The blockbuster anticoagulant medicines Plavix® (Sanofi-aventis) and Iscover® (Bristol-Myers Squibb) contain the active pharmaceutical ingredient (API) clopidogrel hydrogen sulphate. These products were granted marketing authorizations in the EU under the centralized procedure on 15 July 1998. Data exclusivity was expected to continue until July 2008.

6.40 As far as the patent position was concerned, the patent that originally disclosed the clopidogrel molecule had expired, but in the EU, Sanofi-aventis had obtained a further patent on the specific hydrogen sulphate salt form of clopidogrel with SPCs expiring in 2013. This patent could be avoided by generic competitors by employing a different salt of clopidogrel, but it was generally assumed that no application for a generic form of clopidogrel could be considered by any competent regulatory authority until after the relevant data exclusivity period had expired.

6.41 On 21 May 2008, the German regulatory authority (BfArM) then granted marketing authorizations to a company called Yes Pharmaceutical Development Services GmbH for an alternative salt of clopidogrel (the besylate) on the basis of a mixed bibliographical application (under Article 10bis of the Directive). In bibliographic applications, preclinical and clinical trial data can be replaced by scientific literature references, provided that the applicant can demonstrate well-established medicinal use within the EU for at least ten years. The ten years of systematic and documented use of clopidogrel were calculated by Yes Pharmaceutical from the date of publication of the results of a pivotal clinical trial. Furthermore, the data required to support the application included the use of information

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32 European patent no 0281459 B1.
33 This German company was the agent for Cimex AG, which could not file the application itself because it was based outside the EU.
referred to in the European Public Assessment Report (EPAR) that was obtained by Yes Pharmaceutical by means of a Freedom of Information request.34

The EPAR is a document that contains an official scientific assessment by the European Medicines Agency (the EMA) of the clinical and other data submitted by an originator when making an application for marketing authorization for a new active substance. Its content is therefore drawn up by reference to the underlying data to which data exclusivity attaches. As indicated above, it would seem that data exclusivity should also attach to the summary of the assessment of the underlying data in the EPAR, even if that summary has been published by the relevant authority (EPARs are in fact now published on the EMA's website). This was the view of Sanofi-aventis,35 who applied to the Cologne Administrative Court to have the decisions of BfArM reviewed. On 25 July 2008, the court decided—in a preliminary hearing—that the objections to the Yes Pharmaceutical authorizations made by Sanofi-aventis were unfounded. It further decided that the EPAR was not part of Sanofi-aventis' protected data. The court also decided that a bibliographic application relying on 10 years' documented use could be submitted prior to the end of the relevant 10 year data exclusivity period and then granted with effect on the first day after the expiry of that 10 year period. The rejection of the arguments of Sanofi-aventis and BMS were upheld on appeal on 26 September 2008.

It should be noted that these decisions were only made on a preliminary basis and although they seem to be potentially far-reaching in a number of respects, it is probably inadvisable to draw any firm conclusions about the correctness of the actions of BfArM. Nevertheless, the German clopidogrel decisions came as a shock to both sides of the pharmaceutical industry, many of whom had assumed that the term of data exclusivity for new active substances was sacrosanct.

(6) Galanthamine

Case C-527/07 (Generics [UK] Limited) was referred to the Court of Justice in Luxembourg in 2009. It concerned a product called Nivalin containing the API galanthamine that was first authorized to a company called Waldheim in 1963 in Austria for the treatment of polio. The original dossier for Nivalin was never updated in accordance with the requirements of Community law upon the accession of Austria in 1995. Waldheim subsequently withdrew Nivalin from the market, but galanthamine was then resurrected as a drug for the treatment of Alzheimer's disease. Extensive testing was carried out between 1995 and 1999. This eventually resulted in the submission on 30 March 1999 of a full application for marketing authorization36 for galanthamine. The submission was made to the Swedish competent authority by Janssen-Cilag AB. A Swedish marketing authorization for galanthamine (subsequently sold under the brand name Reminyl®) was granted on 1 March 2000 and its
Galanthamine is an example of a molecule for which 10 year periods of data exclusivity (in some countries) and a period of patent protection were achieved in Europe in respect of the new Alzheimer’s indication, despite the fact that the compound was both old and already known to have anti-cholinesterase properties. The relevant patent expired in January 2007, but SPCs for galanthamine were granted, including one that was obtained in the UK, which was set to expire on 15 January 2012.

6.45 Generics [UK] Limited ("Generics [UK]") sought to enter the EU market early with a generic version of Reminyl®. For the regulatory limb of their early market entry strategy, on 14 December 2005, Generics [UK] submitted an application to the relevant UK authority (the MHRA) for a marketing authorization for a generic form of galanthamine, using as the basis of its application Article 10(1) of the Directive and specifying Nivalin as the reference medicinal product. The MHRA rejected the application, stating that Nivalin could not be used as the reference medicinal product for the purposes of Article 10(1), since its dossier had not been updated so as to bring it into compliance with the requirements of Community legislation upon the accession of Austria. Generics [UK] challenged this rejection by means of judicial review of the MHRA’s decision. The administrative court decided to stay the proceedings whilst clarification was sought from the Court of Justice on whether a product such as Nivalin could be a reference medicinal product for the purposes of an abridged application under Article 10(1).

6.46 In a relatively short judgment issued on 18 June 2009, the Court of Justice emphasized that the purpose of the Community medicines legislation in requiring the results of toxicological and pharmacological tests and clinical trials to be submitted in support of a marketing authorization is to ensure that medicines are safe and efficacious. The abridged procedure in Article 10 has as its objective the avoidance of unnecessary tests on humans and animals, but the essential aim of the rules is to safeguard public health. Only when the competent authority has been provided with all relevant particulars and documents relating to the reference medicinal product and has been satisfied that the generic product in relation to which approval is sought is so similar to the reference product that it does not differ significantly with respect to safety and efficacy may a marketing authorization be granted under the abridged procedure.

6.47 An interpretation of the requirements of the abridged procedure which in effect amounted to a relaxation of the standards of safety and efficacy prescribed by the rules was therefore inconsistent with one of the main objectives of the Directive. The Court concluded that in order to get the benefit of the abridged procedure, the applicant had to show that the reference medicinal product was authorized on the basis of Community law in force at the time of the application for the reference medicinal product. Nivalin was not such a product and

37 Janssen-Cilag have an exclusive licence to market Reminyl® in the EU, apart from the UK and Ireland. Shire Pharmaceuticals have the exclusive rights to the product for the UK and Ireland.
38 European patent no 0236684 B1 claims the use of galanthamine in second medical use form: ‘Use of galanthamine or an analogue or a pharmaceutically acceptable acid addition salt thereof for preparing a medicament for the treatment of Alzheimer’s disease or related dementias’.
39 SPC/GBOO/033.
40 Now trading as Mylan.
41 See the description of the abridged procedures under Article 10 of the Directive.
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so it could not be a reference medicinal product within the meaning of Article 10(2) of the Directive. 42

This case highlights an important issue for applicants seeking abridged (generic) authorizations in Europe. Upon accession to the EU, some member states (such as Austria, in this case) did not require the dossiers of existing medicinal products that were already authorized and on the market to be updated, in order to meet the rigorous standards of European pharmaceutical law. It is therefore necessary carefully to examine nationally authorized reference medicinal products to assess their suitability to be a reference medicinal product in an abridged application. Only those products that have been assessed and authorized by the relevant authorities in accordance with the standards specified in the Directive will satisfy the requirement. 43

Under the patent limb of their market penetration strategy, Generics [UK] challenged both the validity and the term of the UK SPC. 44 The case was referred by the English Court of Appeal to the Court of Justice. 45 Because of the outcome of the regulatory limb of the strategy, the result of the patent limb became somewhat moot. However, the Court of Justice subsequently held in Generics [UK]'s favour. In a decision issued on 28 July 2011, the Court of Justice decided that the previous authorization of galanthamine (as Nivalin, in Austria) was fatal to the grant of a SPC based on the subsequent Reminyl® authorization. 46 Active ingredients (such as galanthamine) that had been marketed in old drug products in the EU that had not gone through the administrative procedures laid down in Community law (ie without having undergone safety and efficacy testing to Community law standards) were not within the scope of Regulation (EC) No 469/2009 for the grant of SPCs.

The galanthamine case serves to emphasize the need for generic firms to address separately both the data exclusivity and patent regimes within the EU, whilst maintaining an overarching strategy that encompasses both. It also illustrates the necessity for both limbs of the strategy to succeed, in order for the generic firm to achieve a significant first mover advantage over its competitors.

(7) Escitalopram

A final example of a case in which companies sought to deploy the dual strategy of an early regulatory filing and patent nullity proceedings concerns the API escitalopram. Escitalopram is another name for the S-enantiomer of citalopram. Citalopram is a racemate, which means that it exists as a mixture of two enantiomers present in equal proportions, being the R-enantiomer of citalopram and the S-enantiomer of citalopram (escitalopram). Enantiomers differ in one structural aspect only: they mirror each other, like a left hand and a right hand. Yet this difference can have a profound effect on the respective biological activity of each enantiomer. In this case, escitalopram proved to be the biologically active molecule.

42 Paragraph 37 of the judgment.
43 For example, it has been observed that dossiers and authorizations in Germany that underwent the process of 'Nachzulassung' according to the relevant provision of the German Medicines Act should be capable of being reference medicinal products in the sense of Directive 2001/83/EC. See the article by B. Friese, (2009) 71(8) PHARM IND 1335–1337.
44 Case HC 08 CO 0231: Generics (UK) Ltd v Synaptech Inc, relating to SPC/GBOO/033.
46 Case C-427/09: Generics (UK) Ltd v Synaptech Inc.
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6.52 The Danish originator company H. Lundbeck A/S ('Lundbeck') was granted a European patent to escitalopram in 1995. SPCs have been granted in a number of countries that extend Lundbeck's exclusive rights under this patent until May 2014. In 2001, the relevant Swedish regulatory authority granted to Lundbeck a marketing authorization for the drug product Cipralex—containing escitalopram—following an application for regulatory approval 11 months earlier.

6.53 Before the data exclusivity period for escitalopram had expired and in advance of both patent and SPC expiry, a number of companies managed to obtain approvals for generic escitalopram products, with a view to bringing these to market. This resulted in a number of legal cases in several European countries, on the validity of the Lundbeck patent to escitalopram and separately on the regulatory and data exclusivity issues arising out of the generic marketing authorizations.

6.54 In the Netherlands, the Dutch part of the European patent for escitalopram was revoked by the first instance court. Lundbeck appealed. Despite the revocation of the patent in first instance, the generic companies have not yet been able to sell their products on the Dutch market, because Lundbeck has in the meantime successfully objected to the grant of their marketing authorizations. The main thrust of Lundbeck's objection was that the generic companies should not have been allowed to refer to data in the dossier of Lundbeck's 2001 marketing authorization for escitalopram. Because the regulatory proceedings have reached an end in the Netherlands, we will confine ourselves here to a discussion of the main issues in the Dutch regulatory proceedings.

6.55 The generic companies argued that in granting the marketing authorization for escitalopram in 2001, the Swedish authority had simply assumed—and not substantively investigated—the question of whether escitalopram was a new active substance. They contended that escitalopram should be regarded as a line extension of citalopram; the data that Lundbeck had filed in order to obtain its marketing authorization for escitalopram did not relate to research on a new active substance, because a significant portion of that research had already been carried out in support of an earlier application for authorization of the racemate, citalopram, as the drug product Cipramil.

6.56 A complicating factor was that part of the data to which Lundbeck claimed exclusivity had already been made public in various literature. The relevant Dutch authority (the CBG) had initially granted the generic authorizations, by allowing reference to this public data, despite the fact (as the CBG initially accepted) that the Lundbeck escitalopram dossier was covered by data exclusivity. Following Lundbeck's objection, the CBG decided that Lundbeck

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47 European patent no 0347066 B1.
48 Decision of the District Court of The Hague of 8 April 2009 in Alfred E. Tiefenbacher GmbH v H. Lundbeck A/S JGR 2009/27. It should be noted that Lundbeck has been successful in a number of other European countries on the related patent validity and SPC issues.
49 Decision of the Court of Appeal of The Hague of 24 January 2012, IEPT 2012 0124. By the time of Lundbeck's appeal, the patent had expired. The case proceeded on the basis of the invalidity of the Dutch SPC to escitalopram, based both on the invalidity of the basic patent and, by way of a stand-alone attack on the validity of the SPC, for failure to comply with certain provisions of Regulation No 469/2009. The Court of Appeal held product claims 1–5 of the patent invalid, but upheld claims 6 and 7. Therefore, the SPC was confined to claims 6 and 7 only.
50 The facts are summarized in an English translation of the CBG's decision of 25 February 2010 that is available on its website at <http://www.cbg-meb.nl/NR/rdonlyres/925652E3-845D-4A28-899E-DF6D0AD050B9/0/2522010escitalopram.pdf> last visited 20 February 2012.

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was correct and refused to allow the generic companies to refer to the published data, thus requiring the generic companies to submit appropriate new bridging data of their own. This decision was appealed.

The Dutch regulatory proceedings then focused on the question of whether escitalopram is a line extension of citalopram, i.e., whether there was a significant difference in safety and efficacy between the single enantiomer escitalopram and the racemate, citalopram. If not, then the marketing authorizations for citalopram and escitalopram are part of the same global marketing authorization. As such, the period of data exclusivity expired when the protection for the citalopram data expired, because the date of the earlier, initial citalopram (Cipramil®) marketing authorization will 'count' as the starting point for data exclusivity for every authorization falling within the global authorization. On the other hand, if the marketing authorization for escitalopram does not form part of the same global authorization as citalopram, escitalopram will have its own regulatory data exclusivity period, starting on the day it was granted, in 2001.

On re-examination, the CBG made its own substantive assessment and reached the conclusion that escitalopram did not differ significantly from citalopram in terms of its safety and efficacy, that escitalopram was a line extension of citalopram and that both marketing authorizations formed part of the same global marketing authorization. However, in a decision issued by the Administrative Division of the Dutch Council of State on 6 July 2011, it was held that the question of whether escitalopram could be regarded as a new active substance had already been decided by the relevant Swedish authority and this decision could not be re-opened, regardless of the CBG's own substantive assessment of the position.

As we conclude this chapter, the escitalopram battle in the EU continues. For present purposes, we again emphasize that in the EU, the generic firms must tackle patents/SPCs and data exclusivity as separate challenges to be overcome. Whilst there is clearly some overlap—in terms of the subject-matter—between the Dutch patent and regulatory cases on escitalopram, these cases demonstrate once again that the patent and data exclusivity regimes in the EU are separate and distinct—procedurally, substantively, and in terms of the protection that they confer.

D. Conclusion

Patents, SPCs, and data exclusivity are the key elements in the EU battleground between the originator and the generic companies. Whilst patents and data exclusivity are not strictly overlapping rights, it is usually necessary for a competitor seeking to market a generic drug product in the EU to check both the patent/SPC position and the expiry of the data exclusivity period, for a particular drug product of interest. The rights conferred by patents and data exclusivity in the EU are separate and distinct, but not necessarily bullet-proof. There are significant financial incentives for the generic firms to use patent litigation to avoid or to revoke patents and to deploy early filing (regulatory) strategies in order to carve out a first-to-market opportunity in the EU. The manufacturers of generic medicines continue to test the protection conferred by data exclusivity using the abridged procedures prescribed by EU regulatory law. The clopidogrel, galanthamine, and escitalopram cases are illustrative of the use by the generic firms of such dual patent and regulatory strategies.

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E. Summary

6.61 Patents and SPCs continue to be the main form of legal protection for new active substances (both small molecules and biologicals) in the field of medicines in the EU.

- Extensive preclinical and clinical trials may need to be undertaken to demonstrate a drug product's quality, safety, and efficacy to the relevant regulatory authorities.
- In the EU, data that is provided in support of the proposed use of a new active substance in a medicine may benefit from a period of data exclusivity.
- Data exclusivity usually lasts for a certain period of time after the initial registration of a new drug product, during which only the entity that developed the data may use it to support additional marketing authorizations.
- After the data exclusivity period, it is possible for a third party to seek marketing approval for a generic product, by submitting an abridged application for registration that relies on the data that has already been submitted in support of the original product.
- Under Article 10 of Directive 2001/83/EC, an abridged marketing authorization can be applied for by third parties after eight years and the generic medicinal product may be marketed after a further two (or three) extra years: the so-called 8+2+1 rules.
- Firms seeking to enter the EU market with generic medicinal products must usually wait until after the relevant data exclusivity period has expired before submitting an abridged application for marketing approval. Even then, there may be patent obstacles to be overcome before the path to market is clear.
- Both data exclusivity and patent protection may provide significant barriers to entry for generic firms seeking to enter the EU market. To the extent that both must usually be overcome in order to enter the EU market with a generic drug product, they may be seen in this limited sense as overlapping rights.