PABST PATENT GROUP

# How to Extend Exclusivity and Thereby Royalty Income

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# Overview

There is a tendency to over-emphasize patent rights in licensing agreements, as if there were no other rights having value, and as if the duration of exclusivity is limited only to patent term.

These are major misconceptions.  One may derive a royalty based on Know How, which exists even if a patent never issues, or the exclusivity derived by the requirements for regulatory approval, which may extend far beyond patent term. These are all contingent upon these provisions being defined in the agreement, and licensed as a part of, not subsumed within, the patent rights.

# Know How

## Examples Definitions of Know How

**“Know How”** shall mean any and all confidential or proprietary information and materials, including discoveries, improvements, processes, methods, protocols, formulas, molecular constructs, reagents, assays, data, results, inventions, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise, and including any copyrights therein.

# Know How

**Example Definitions**

**“Licensed Know How”** shall mean all Know How that (a) is Controlled by Pfizer or any of its Affiliates as of the effective date of the Pfizer-MPP Agreement, (b) directly relates to the use of the Compound, Product or Licensed Product in the Field, and (c) is not in the public domain or otherwise generally known. For the avoidance of doubt, (i) Licensed Know How shall not include any Know How to the extent solely and directly related to any other Pfizer compound or to the extent related to the use of the Compound, Product or Licensed Product outside the Field and (ii) Licensed Know How includes only that Know How, designated by Pfizer in its sole discretion, necessary for the manufacture, registration and commercialization of the Compound and/or Licensed Product for use in the Field. For the avoidance of doubt, Licensed Know How excludes any Know How related to ritonavir that has been (either as of the Effective Date or at any time during the term of this Agreement) in-licensed by Pfizer from any Third Party.

# Know How

**Example Definitions**

**“Licensed Know How”** means any Know How that is necessary or useful for the Development, Manufacture or Commercialization of Product in the Field of Use in the Territory and that is Controlled by Licensor or any of its Affiliates as of the Effective Date or during the Term.

# Know How

## License Terms and Duration of Licenses to Know How

Patents and Know How are usually licensed together. Typically, there is a royalty for the license to the patent(s), which may be dependent in part on whether the patent(s) is pending, issued, or expired. In all cases, however, the Licensee will want associated Know How: where to obtain components, how to make the licensed product using the most recent methods and materials to maximize yield, efficacy, regulatory approval, etc. This Know How has typically taken much time, resources and effort, not just before the "invention" was made, but afterwards. Patent applications, by necessity, are filed early in development, but development rarely stops upon filing of a patent application. The Licensee will want the benefit of the subsequent knowledge.

# Know How



In exchange, the licensee should be required to pay royalties on Know How and products that are not covered by a licensed patent in the country of manufacture or sale, but whose manufacture or development benefitted from the licensed Know How, and that on-going Know How.

Licensees argue that, unless the Know How provides a clear competitive advantage for the licensee's product over other products, it should not attract a royalty. This argument is particularly acute where the product can be easily reverse-engineered by a competitor; for example, the chemical composition of many pharmaceutical drugs can be established by a competent chemist once the product is on the market. An additional argument, sometimes, is that the upfront payment is, in effect, a payment for access to the licensed Know How, and that a royalty on the use of Know How is inappropriate.

# Know How



Licensors point out the head start and reduction in subsequent development costs that the Know How provides to the licensee. Often, patents have only been obtained in key markets (countries or regions such as the European Patent convention countries), and it is appropriate (says the licensor) for a royalty to be paid throughout the licensed territory, given the protection of the patents in the key markets. However, the royalty rate may be reduced if there is no patent, either in a jurisdiction where no patent was filed, or where the patent has been permanently rejected, invalidated or expired.

Ultimately, these issues are for commercial negotiation.

License negotiations involve many detailed issues of this kind, which are difficult to reduce to a “high level” summary document such as a term sheet. Commercial negotiators who know their way around these points and do not leave negotiating them to the last minute can significantly reduce the costs of legal advice on the transaction.

# Know How



**Some examples of compromises that were reached:**

- royalty of X% on products covered by licensed patents
- royalty of X/2% on products that are only protected by licensed Know How, where “the manufacture of the Licensed Product used all or part of Licensed Know How”, and for as long as the licensed Know How remains confidential (See, for example, Article 1(1)(i) of the EU Technology Transfer Regulation for Know How to be “secret, substantial and identified”)
- a re-negotiation of the X/2% royalty, where the licensed product is subject to “significant competition” (as defined) in the country of sale

This compromise is fairly conventional.

# Marketing Data Exclusivity

## Definitions of Market Data Exclusivity

Market Data Exclusivity ("MDE") is a key incentive for drug developers. MDE is a form of intellectual property protection that applies specifically to data from pharmaceutical clinical trials. It is granted by the Regulatory Agency that reviews clinical trial data and approves a new drug for ***marketing within a jurisdiction. MDE extends for a fixed period of time following drug approval during which the Sponsor of the clinical trial can market its drug without direct competition from manufacturers of duplicate or reformulated products, even if regulatory approval has been obtained.***

# Marketing Data Exclusivity



In the US, MDE extends to medical devices (21 USC §360j) (six years of data exclusivity for medical devices approved pursuant to a pre-marketing approval "PMA") and to biological drug products. This varies by jurisdiction.  As with SPCs, the European provisions regarding regulatory exclusivity do not extend to medical devices. "Hybrid" devices including biological or therapeutic agents may have MDE in jurisdictions other than the US.

MDE is independent of, and distinct from, patents. Patents can be issued or expire at any time regardless of a drug's regulatory approval status, and, assuming the patent is not successfully challenged and is maintained, will typically provide exclusivity for a period of 20 years from the first non-provisional filing date, which may be extended for a period of time if the patent has not expired at the time regulatory approval is obtained, and the appropriate submission is timely filed.

# Marketing Data Exclusivity



In contrast, MDE attaches upon regulatory approval of a drug product if the statutory requirements in the jurisdiction are met, regardless of whether or not there is patent protection. Test data exclusivity refers to protection of clinical trial data required to be submitted to a regulatory agency to prove safety and efficacy of a new drug, and prevention of generic drug manufacturers from relying on this data in their own applications.

Licenses that provide for a royalty (or a higher royalty) in jurisdictions that have a valid patent can be significantly expanded in favor of the licensing party by requiring the same royalty in countries with Market Data Exclusivity, since the higher royalty rate is in recognition of having exclusive rights to market.

# Marketing Data Exclusivity



## Exemplary MDE License and Term Language

Royalties. Subject to Section 7.3 of this Agreement, Licensee will pay to Licensor an earned royalty at the rate of:

a) five percent (5%) of aggregate Net Sales of Licensed Products sold by Licensee or its Affiliates to a Governmental Authority or Public Purchaser in each country in the Territory, other than the LIC Territory, during the Royalty Term, to the extent

(i) a Valid Claim of Patent exists in the country of manufacture and/or sale of such Licensed Product; or

(ii) regulatory exclusivity exists for such Licensed Product in such country of sale

and

# Marketing Data Exclusivity

**License and Term Language**

b) ten percent (10%) of aggregate Net Sales of Licensed Products sold by Licensee or its Affiliates to a commercial entity in a country in the Territory, other than the LIC Territory, during the Royalty Term, to the extent

(i) a Valid Claim of Patent exists in the country of manufacture and/or sale of such Licensed Product; or

(ii) regulatory exclusivity exists for such Licensed Product in such country of sale.

# Patent Term Extension or Supplemental Protection Certificates (“SPCS”)

These provisions must be filed for prior to a patent expiring and after obtaining regulatory approval.  Short time frames and no flexibility. These extend exclusivity of the patent for the approved product only beyond the expiration of the patent.

## Patent Term Extension Under US Law

The right to a patent term extension based upon premarket regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984; 35 U.S.C. 156, 271, 282)(Hatch-Waxman Act). The act sought to eliminate the loss in patent term produced by the requirement that certain products must receive premarket regulatory approval.

# Patent Term Extension

**Under US Law**

The statute enables the owners of patents on certain human drugs, food or color additives, medical devices, animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting premarket government approval from a regulatory agency. The rights derived from extension of the patent term under ) are defined in **35 U.S.C. 156(b)** but are not limited to a claim-by-claim basis. Rather, **subsection(a) of 156** indicates that "[t]he term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended." *See Genetics Institute LLC v. Novartis Vaccines and Diagnostics Inc.,* 655 F.3d 1291, 99 USPQ2d 1713 (Fed. Cir. 2011). However, pursuant to 35 U.S.C. 156(b), if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent. See *Biogen Int'l GmbH v. Banner Life Scis. LLC*, 956 F.3d 1351 (Fed. Cir. 2020). 35 U.S.C. 156 was amended by Public Law 100-670, to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products which are primarily manufactured through biotechnology are excluded from the provisions of patent term extension.

# Patent Term Extension

**Under US Law**

An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of record of the patent or its agent within the sixty-day period beginning on the date the product received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use. (c)The term of a patent eligible for extension under subsection (a) shall be extended by the time equal to the regulatory review period for the approved  product which period occurs after the date the patent is issued, except that (1) each period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period; (2) after any reduction required by paragraph (1), the period of extension shall include only one-half of the time remaining in the periods described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g);

# Patent Term Extension

**Under US Law**

(3) if the period remaining in the term of a patent after the date of the approval of the approved product under the provision of law under which such regulatory review occurred when added to the regulatory review period as revised under paragraphs (1) and (2) exceeds fourteen years, the period of extension shall be reduced so that the total of both such periods does not exceed fourteen years; and (4) in no event shall more than one patent be extended under subsection (e)(1) for the same regulatory review period for any product.

# Patent Term Extension



## European Supplemental Protection Certificates

Regulation (EC) 469/2009 of 6 May 2009, provides for supplementary protection certificates (SPC) for medicinal products in individual member states of the European Community (EC). These certificates allow an extension of the duration of the granted patent for a period of, at the most, 5 years, insofar as the patent concerns an authorized medicinal product. The application for such an SPC shall be lodged within a non-extendable period of 6 months starting either from:

(i) the issuance date of the authorization to place the medicinal product on the market ("marketing authorization") in the respective EC member state where the patent has previously been granted, or

(ii) the date on which the patent is granted, in the event that the marketing authorization has issued prior to patent grant.

# Patent Term Extension

**European Supplemental Protection Certificates**

The current SPC Regulation (EC) No 469/2009 (“SPC Regulation”) provides patent holders the ability to enjoy additional patent protection with respect to a medicinal product under an SPC for up to five years where there is a delay between the date of filing of the patent and the grant of the marketing authorization (“MA”). An SPC takes effect at the end of the patent term and remains in force for the period between the date of patent filings and the date that the first MA for the medicinal product covered by such patent was granted, minus five years (and subject to a maximum duration of five years). However, the period may also subject to a possible six-month extension under the Pediatric Regulation 1901/2006/EC upon the successful completion of an agreed pediatric investigation plan (currently only for non-orphan products).

Currently patent holders must lodge separate SPC applications with national patent offices in order to obtain SPC protection in each Member State where such protection is available. On April 27, 2023 the European Commission (“Commission”) released its proposal to introduce a single procedure for the granting of Supplementary Protection Certificates (“SPCs”) throughout the EU.

# Patent Term Extension

**European Supplemental Protection Certificates**

The changes are intended to complement the new unitary patent procedure that entered into force on June 1, 2023. The unitary patent is a single, uniform patent right that will have effect in all Member States participating in the unitary patent system, and the corresponding Unified Patent Court ("UPC") will provide a forum for uniform patent litigation in participating countries. Unitary SPC rights will attach to the underlying unitary patent and will therefore take effect in the (currently) 17 Member States that will recognize unitary patents from June 1, 2023. For medicinal products, unitary SPCs will only be available for products approved via the centralized procedure. The European Union Intellectual Property Office ("EUIPO") will be the body responsible for examining and issuing unitary SPCs. Unitary SPC applicants who receive a negative opinion from the EUIPO will be able to appeal the decision before the Boards of Appeal of the EUIPO, with further appeals possible to the Court of Justice of the European Union. The EUIPO will also handle third party opposition proceedings and will have jurisdiction to hear revocation actions.

# Patent Term Extension

**European Supplemental Protection Certificates**

In addition to the new unitary SPC, companies that satisfy the relevant SPC requirements will be able to file a “combined application” to obtain both a unitary SPC and a bundle of national SPCs for any Member States not included under the protection of the corresponding unitary patent. Double protection by both a unitary SPC and a national SPC in any given Member State is prohibited. Any product that is covered by a patent and that is a (human or veterinary) medicinal product, or a plant protection product, and thus falls under the scope of the SPC regulations, can benefit from the new centralized procedure that will be implemented by the EUIPO.

The new SPC regulations foresee the possibility to apply for a “combined application” for the same product to obtain a unitary and national SPCs, for those cases where the product is protected by a European patent having unitary effect. Since a unitary SPC can only cover those Member States where the basic patent has unitary effect, national SPCs would be needed to ensure protection in additional Member States. That said, a given product cannot be protected by both a national SPC and a unitary SPC in the same Member State.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

How patents, data exclusivity and SPCs interact to extend market exclusivity of medicines: the example of Truvada

## Patent Exclusivity

Patents usually confer 20-year exclusive rights on inventions. Data exclusivity laws confer, depending on the country, 5 to 10 years' exclusive rights over safety and efficacy data submitted for the registration of new medicines by regulatory agencies. Supplementary protection certificates, or SPCs, are a form of patent term extension, granted at the expiry of the patent term to compensate for time lags due to the medicine's registration process, during which the exclusive rights on the medicine could not be exploited commercially.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

The delay to generic entry these additional protections can create is best illustrated by an example: Gilead's well-known antiretroviral medicine tenofovir disoproxil fumarate (TDF), available in fixed-dose combination with emtricitabine (FTC) under the brand name Truvada, is recommended by the World Health Organization as an essential part of first line treatment for HIV/AIDS and for HIV pre-exposure prophylaxis or PrEP, to prevent the acquisition of HIV infection by uninfected persons.
Gilead filed four categories of patents at the European Patent Office (EPO) which protect various aspects of TDF/FTC.

The first one, EP0915894, expired in July 2017, claimed essentially tenofovir disoproxil (TD).
A second one, EP0998480, due to expire on 23rd July 2018, claims specifically the fumarate salt of tenofovir disoproxil.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

A third one, EP1583542, originally due to expire in 2024, claimed combinations of TDF and FTC but was revoked in March 2017 by the EPO for lack of inventive step.

A fourth one, EP2386294, due to expire in 2026, claims the triple combination TDF/FTC/EFV, known under the brand name Atripla, which includes efavirenz as a third component. This is nine years after the first related patent (TD) expires.

This practice of applying for subsequent patents related to a single medicine, known as evergreening, is a common practice of pharmaceutical companies to extend patent protection for as long as possible, thereby keeping generic competition at bay.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

In 2017, generic companies found a way around Gilead's second, third and fourth TDF patents to bypass Gilead's evergreening strategy for TDF and to market more affordable versions of the medicine. Generic manufacturers demonstrated that other salts of tenofovir disoproxil, e.g. tenofovir disoproxil phosphate or maleate were bio-equivalent to Gilead's TDF. As a result, the European Medicines Agency (EMA) approved several generic tenofovir products (now called TDX) as standalone products or in combination with FTC and EFV for sale in the EU as soon as Gilead's rights on TD expired in July 2017. Had generic companies not developed TDX and the EPO not rejected the patent on TDF/FTC, evergreening might have extended patent protection of TDF/FTC until 2024 and of TDF/FTC/EFV until 2026.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

**What about data and market exclusivity?**

In Europe, original drug manufacturers enjoy 8 years of data exclusivity plus 2 years of market exclusivity as of the date of approval of their medicine. This means that generic manufacturers can:

- start to apply for the approval of a generic version only 8 years after the original medicine was approved, and
- launch their approved generic in the European market only 10 years after the original medicine was approved, assuming that the patent has also expired by this time.

Gilead's market exclusivity on TDF, TDF/FTC and TDF/FTC/EFV expired in 2012, 2015 and 2017, retrospectively, because these products were approved in 2002, 2005 and 2007. Generic companies could apply for registration of generic TDX, TDX/FTC and TDX/FTC/EFV at EMA but Gilead's patent on TD prevented any marketing until it expired in July 2017.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

**SPC Extension of Exclusivity**

What about patent extension in the form of supplementary protection certificate (SPCs)? Like data exclusivity, SPCs are subject to EU regulation but the decision to grant an SPC is made by national patent offices. SPCs extend the monopoly period for a medicinal "product" (active ingredient or a combination of active ingredients) that is protected by a patent to an 'effective patent life' of a maximum of 15 years.

Gilead could not obtain an SPC for TD because the time lapse between the patent filing date (July 1997) and the market approval (February 2002) was less than 5 years, and the company still had more than 15 years to enjoy the exclusivity conferred by the patent.

Gilead requested SPCs in several European countries, based on the approval of TDF/FTC, to extend its patent claiming tenofovir disoproxil EP0915894, which expired on 31 July 2017 in most European countries.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

Gilead requested SPCs in several European countries, based on the marketing approval of TDF/FTC, to extend its patent claiming tenofovir disoproxil EP0915894, which expired on 31 July 2017 in most European countries. Several countries refused to grant such SPCs (including the Netherlands and Greece), but others (e.g. France, Ireland, Switzerland) did extend the monopoly until February 2020 (e.g., 15 years from the date of approval of TDF/FTC).

The UK Patent Office had initially rejected Gilead's request for an SPC to extend its TD patent, based on TDF/FTC (Truvada)'s marketing approval in 2005, but Gilead appealed and obtained the grant of the SPC until 23 February 2020. Generic manufacturers (Teva, Accord Healthcare, Lupin and Mylan) challenged this decision, asserting that Gilead's TD patent does not claim Truvada specifically and therefore Gilead cannot obtain an SPC to extend its TD patent based on Truvada market approval.

# Example of How to Combine Patent, MDE and SPCS to Extend Exclusivity

The UK High Court deferred the case to the Court of Justice of the European Union (CJEU) to clarify if Gilead's marketing authorization for Truvada could form the basis for an SPC on Gilead's TD patent. The CJEU affirmed it was not eligible for an SPC.

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