PABST PATENT GROUP

ARTICLE

MARKET DATA EXCLUSIVITY:
Excluding Pharmaceutical Competition Outside of the Patent System

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DO YOU ALSO NEED A PATENT?
No

IS IT CUMULATIVE TO A PATENT?
Yes

IS IT IMPORTANT TO INCLUDE IN YOUR LICENSES?
Yes (royalty based on patent OR MDE)

BENEFITS:
Derived from regulatory process, time runs from date of approval by regulatory agency. Enforced by regulatory agency. Country specific. No deadline to apply since derived from regulatory approval process.

What is 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. 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. 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.

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The Duration of MDE is Determined on a Country By Country Basis.

The following are representative jurisdictions:

CANADA: The data protection period is eight years from the date of issuance of the first NOC for the innovative drug. Where the drug has qualified for a six-month pediatric extension, the period is extended to eight years and six months. https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations.html.

CHINA: *6 years for new chemical entity (not including biologics); 12 months pediatric drug; orphan drugs up to 7 years.* Data exclusivity protection is provided for undisclosed trial data and other data submitted for marketing authorization. MDE commences from the date of marketing authorization ("MA") approval in China.

EUROPE: *European Union: 8 years (+ 2 years market exclusivity + 1 year for new indication).* According to the European Commission: "Data exclusivity" refers to the period during which the data of the original marketing authorization holder relating to (pre-) clinical testing is protected, i.e., "the eight-year protection period during which generic applicant may not refer to the information of the original marketing authorization holder. "Marketing exclusivity" refers to the ten-year period after which generic products can be placed on the market. Clinical test data regulation in the European Union currently prohibits the use of the originator's pre-clinical and clinical test data in the processing of a marketing authorization for a generic medicine for a period of eight years. After the eight years have passed, the regulatory authorities can process the generic company's application for marketing authorization, but the product may not be put on the market until ten years have passed after the initial marketing authorization of the originator product. Under certain circumstances, an additional one year of market exclusivity may be obtained, for example when the originator company is granted a marketing authorization for a significant new indication. See https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-paediatric-rewards-s-ribeiro_en.pdf.

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JAPAN: No data exclusivity system. Instead, the major factors that prevent the entry of generics into the market is a post-marketing surveillance system, "the re-examination period". During the re-examination period, further data is collected and, on expiration, the safety and efficacy of the approved product will be re-examined. If during the re-examination period someone other than the applicant of an approved item intends to apply for marketing approval of another item of which the active ingredients, among other things, are identical to the approved item, that person is required to submit the same level of data and documents as those required for the approved item. Reexamination periods run from four to six years (new indication) and six to ten years (orphan and new drugs).

INDIA: No MDE. However, any subsequent applicant for permission to import or manufacture a new drug must submit fresh clinical data if the application is within four years from the date of original approval of the new drug.

U.S.: 7 years for orphan drug; *5 years for new pharmaceutical chemical entities, 3 years for new indications for pharmaceutical drugs, and 12 years for biologic products.* The US data/marketing exclusivity rule on previously unapproved small molecule drug provides for five years of marketing exclusivity and a generic may not apply for tentative marketing approval until after the fourth year and may do so only if the applicant certifies that the underlying patent is invalid or that the medicine will be non-infringing. Final or tentative approval is not available until at least the end of the fifth year [21 U.S. C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii)]. For a previously approved chemical entity, there is a period of exclusivity for three years based on a new use or new formulation [21 U.S. C. § 355(c)(3)(E)(iii), (j)(5)(F)(iii)]. For biologics, the effective marketing exclusivity term provided by the Biologics Price Competition and Innovation Acts 12 years from the date the reference product was first licensed; there is data exclusivity preventing even applications for tentative approval for the first four years [42 U.S.C. § 262(k)(7)]. There is up to 12 months for a pediatric drug which is the first approved for a new variety, dose form or specification for the use for children, or the addition of a pediatric indication or dosage and administration. See https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity.