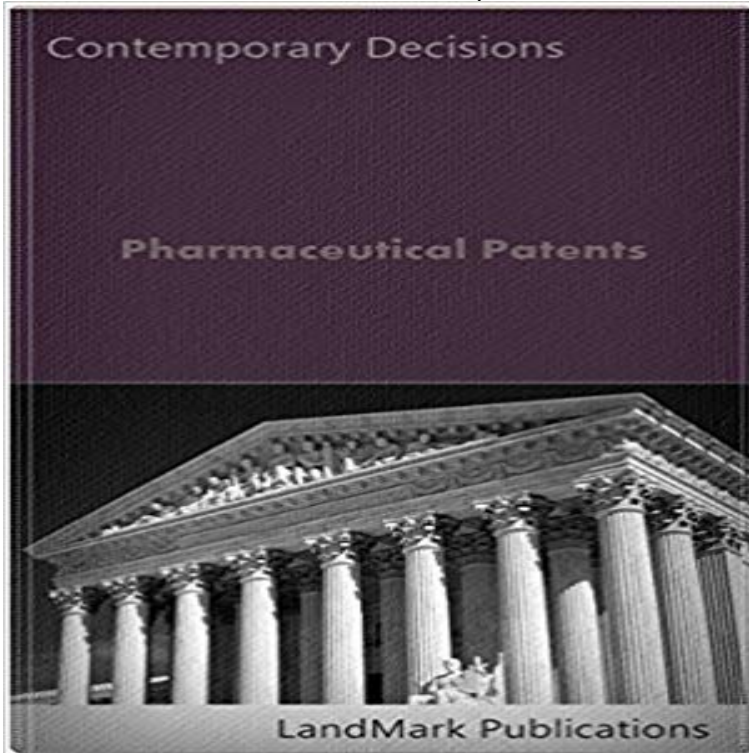


Pharmaceutical Patents (Intellectual Property Law Series)



THIS CASEBOOK contains a selection of 158 decisions of the U. S. Court of Appeals that discuss and analyze patent law issues related to the pharmaceutical industry. The selection of decisions spans from 2005 to the date of publication. Section 271(a) of the patent statute provides that [e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent. 35 U.S.C. 271(a). In 1984, as part of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Congress created an exemption from the general rule of infringement for certain uses of a patented invention in the federal regulatory process. Pub. L. No. 98-417, 202, 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. 271(e)(1)). The safe harbor provision of 271(e)(1) provides in relevant part that: It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs 35 U.S.C. 271(e)(1) (emphasis added). *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, (Fed. Cir. 2015). Under 271(e)(1), the exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the FDCA. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (emphasis in original). The statute does not exclude certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included. *Id.* Nor does

the statute limit the safe harbor only to those activities necessary for seeking approval of a generic version of a brand-name drug product. *Id.* at 206. *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, *ibid.* Although in the post-approval context it may be less straightforward to determine whether an accused infringers use of a patented invention was solely for uses reasonably related to the development and submission of information under the FDCA, 35 U.S.C. 271(e)(1) (emphasis added), the statutory language does not categorically exclude post-approval activities from the ambit of the safe harbor, *Momenta*, 686 F.3d at 1359. Indeed, under the FDCA, drug manufacturers may voluntarily, or sometimes may be required to, conduct post-approval studies on their products for purposes of developing and submitting information to the FDA. See 21 U.S.C. 355(e), (o); *id.* 356(c)(2)(A); 21 C.F.R. 314.70. *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, *ibid.* ...

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