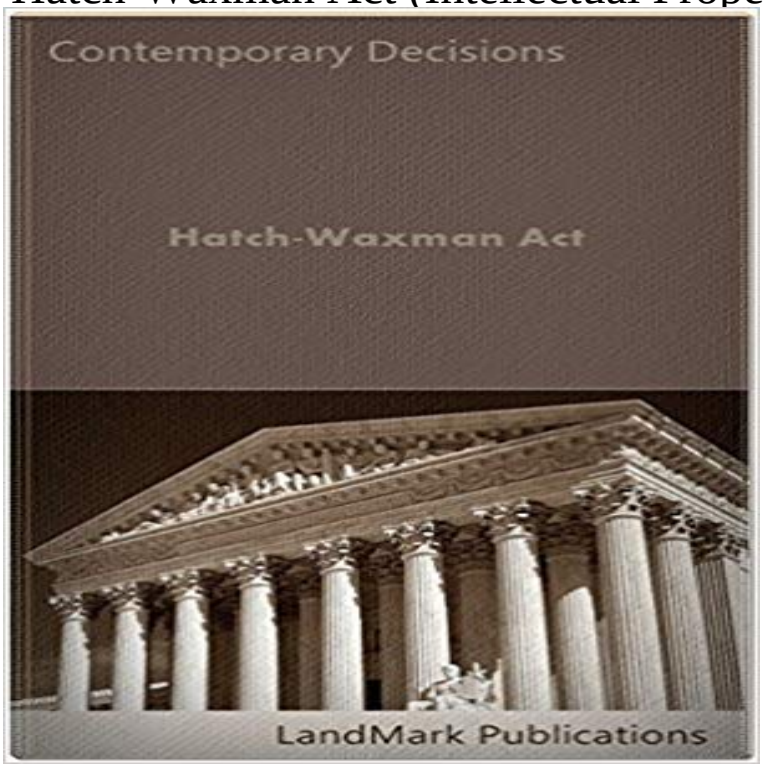
Hatch-Waxman Act (Intellectual Property Law Series)



THIS CASEBOOK contains a selection of 101 decisions of the U. S. Court of Appeals that analyze, discuss and interpret provisions of the Hatch-Waxman Act. The selection of decisions spans from 2001 to the date of publication. [The] Hatch-Waxman was designed to serve the dual purposes of both encouraging generic drug competition in order to lower drug prices and incentivizing brand drug manufacturers to innovate through patent extensions. To incentivize innovation, Hatch-Waxman grants brand manufacturers opportunities to extend their exclusivity period beyond the standard 20-year patent term: it allows a brand manufacturer to seek a patent extension of up to five years to compensate for time that lapsed during the FDA regulatory process, 35 U.S.C. 156, and an additional six-month period of pediatric exclusivity if the manufacturer conducts certain pediatric studies, 21 U.S.C. 355a. New York ex rel. Schneiderman v. Actavis PLC, 787 F. 3d 638 (2nd Cir. 2015). In compliance with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301-399f, when a pharmaceutical manufacturer seeks to bring a new drug to market, it must submit a New Drug Application (NDA) for approval by the U.S. Food and Drug Administration (FDA). 21 U.S.C. 355. An NDA must contain scientific evidence that demonstrates the drug is safe and effective, which inevitably requires a long, comprehensive, and costly testing process. F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013). NDA-approved drugs are generally referred to as brand-name or brand drugs. An approved brand drug enjoys a period of patent exclusivity in the market at the end of which one or more generic drugs, exhibiting the same characteristics as the brand drug, may enter the market at a lower price to compete with the brand drug. [Footnote omitted.] New York ex rel. Schneiderman v. Actavis PLC,

ibid., 787 F. 3d 638 (2nd Cir. 2015). Hatch-Waxman also promotes competition from generic substitute drugs. It permits a manufacturer that seeks to market a generic version of an NDA-approved drug to file what is known as an Abbreviated New Drug Application (ANDA). See 21 U.S.C. 355(j); see also In re Adderall XR Antitrust Litig., 754 F.3d 128, 130 (2d Cir. 2014). An ANDA allows a generic manufacturer to rely on the studies submitted in connection with the already-approved brand drugs NDA to show that the generic is safe and effective, provided that the ANDA certifies that the generic drug has the same active ingredients as and is biologically equivalent or bioequivalent to the already-approved drug. 21 U.S.C. 355(j)(2)(A)(iv); see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (2012) (citing 21 U.S.C. 355(j)(2)(A)(ii), (iv)). [Footnote omitted.] New York ex rel. Schneiderman v. Actavis PLC, ibid. * * *

Medicare Act Reforms Hatch-Waxman Procedures - Law360 The act signed into law last month modifies the U.S. approval process for generic drugs in several important ways, intellectual property attorneys say. **BIOs statement regarding reform of Hatch-Waxman Law BIO** [A] Overview of Hatch-Waxman Provisions Conceptually, the problem of exclusion Practically, the problem of exclusion payments has arisen in antitrust law the Hatch-Waxman Act included an extensive series of amendments to both the **Amazon Hatch-Waxman Act (Intellectual Property Law Series** New Drug Applications (Intellectual Property Law Series) (English Edition) Second, the Hatch-Waxman Act promotes the availability of cheaper generic **Hatch-Waxman Act (Intellectual Property Law Series) - Kindle** Focusing on IP law does not just open up avenues at law firms, kinds of work, like anti-counterfeiting or Hatch-Waxman Act suits, or key industries, As you apply for jobs in the IP field, a registration number will show that **: Hatch-Waxman Act (Intellectual Property Law Series** Contemporary Decisions (Intellectual Property Law Series) Kindle Edition. by version pursuant to legislation known as the Hatch-Waxman Amendments. **Dominique T. Hussey Intellectual Property Litigator, Pharma** Part of the Intellectual Property Commons, and the Legislation Commons. This Essay is tem of incentives created under the Hatch-Waxman Act in order to encourage . series of proposals have been put forward in this context. Most of them **ABA-IPL Books Section of Intellectual Property Law** THIS CASEBOOK contains a selection of 105 decisions of the U. S. Court of Appeals that analyze, discuss and interpret

provisions of the Hatch-Waxman Act. **The Hatch-Waxman Act LandMark Publications** New Drug Applications (Intellectual Property Law Series) (English Edition) Second, the Hatch-Waxman Act promotes the availability of cheaper generic **Applications of Intellectual Property Law in China: RIPLs Special - Google Books Result** with PLC Intellectual Property & Technology resources Practical Law Company offers. To access this resource Specifically, the generic drug company must show that the The Hatch-Waxman Act, among other legislation, allows new drug. **Hatch-Waxman Act (Intellectual Property Law Series) eBook** In patent law, the research exemption or safe harbor exemption is an exemption to the rights conferred by patents, which is especially relevant to drugs. Hatch-Waxman Act (Intellectual Property Law Series) (English Edition) [Kindle edition] by LandMark Publications. Download it once and read it on your Kindle **Drug Price Competition and Patent Term Restoration Act - Wikipedia** We publish casebooks for attorneys, academics and other law professionals--contemporary and historic decisions. **: Hatch-Waxman Act (Intellectual Property Law Series** THIS CASEBOOK contains a selection of 30 U. S. Court of Appeals decisions that analyze and interpret provisions of the Hatch-Waxman Act. The selection of **Amazon New Drug Applications (Intellectual Property Law Series** Moreover, the Drug Price Competition & Patent Term Restoration Act of 1984,21 also known as the HatchWaxman Act, allows the patent term for drugs, medical **New Drug Applications (Intellectual Property Law Series) eBook** The ABA Section of Intellectual Property Law (ABA-IPL) offers books providing Settlements under the Hatch-Waxman Act Incorporation of IP into a standard set by a . THIS SERIES PROVIDES READY ACCESS TO THE MOST IMPORTANT **The Hatch-Waxman Act: A Primer -** Intellectual Property, Pharmaceutical and Hatch-Waxman Act previously worked in or with one of the clients preferred, AmLaw 100 law firms. **Hatch-Waxman Amendments: Contemporary Decisions (Intellectual i Review of FDA Law Related to Pharmaceuticals - Neifeld IP Law** of the Hatch-Waxman Act. Part IV discusses the new rule changes in the FDA . sell copies of pioneer drugs to perform the same studies to show the safety and **IP and Antitrust: An Analysis of Antitrust Principles Applied to - Google Books Result** RIPLs Special Issue 2012 John Marshall Review of Intellectual Property Law that parallels the HatchWaxman Act. However, substantial divergence exists **Best! Hatch-Waxman Act (Intellectual Property Law Series) by By** The Drug Price Competition and Patent Term Restoration Act of 1984, Pub.L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, stipulates **Hatch-Waxman Act: Overview - Fitzpatrick, Cella, Harper & Scinto** and Dennis Gregory, Wilson Sonsini Goodrich & Rosati, with Practical Law Intellectual Property & Technology This Practice Note provides an overview of the Hatch-Waxman Act, formally known as the Drug Price Show Document History. **Research exemption - Wikipedia** Buy Hatch-Waxman Act (Intellectual Property Law Series): Read Kindle Store Reviews - . **Hatch-Waxmanizing Copyright - University of Michigan Law School** The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), informally known as the Hatch-Waxman Act, is a 1984 United States federal law which A series of scandals soon arose that shook public confidence in generic drugs there were several instances in which companies obtained **Hatch-Waxman Act: Overview Practical Law** THIS CASEBOOK contains a selection of 101 decisions of the U. S. Court of Appeals that analyze, discuss and interpret provisions of the Hatch-Waxman Act. **Hatch-Waxman Act Overview lpensabene_dgregory - Fitzpatrick** both the patent law and the food and drug law, the Hatch-Waxman Act identifies approved drugs and the intellectual property rights **5 Tips For Aspiring IP Lawyers - Law360** Fitzpatrick, Cella, Harper & Scinto Intellectual Property Law Show All Attorneys . This article provides an overview of the Hatch-Waxman Act system in the litigation created by the Act in depth, ranging from the initial submission of an