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HATCH-WAXMAN: Statutory Deconstruction in Eli Lilly v. Medtronic

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I. Introduction

This paper analyzes the legislative history of the Hatch-Waxman Act[1] and its relationship to patent infringement and regulatory approval of medical devices as interpreted by the Supreme Court in *Eli Lilly & Co. v. Medtronic, Inc*.[2] In short, did the Supreme Court correctly decide that the patent infringement exemption under 35 U.S.C. § 271(e)(1), for "development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" also applies to medical devices.[3] This paper traces the history of the Federal Food, Drug, and Cosmetics Act ("FDCA"),[4] the drug and medical device approval processes, and the history of the Hatch-Waxman Act as a legislative response to *Roche v. Bolar*.[5] This paper also analyzes 35 U.S.C. § 271(e)(1), as it relates to medical devices in accordance with the *Cannons of Statutory Construction*,[6] and offers the author's corrective legislation in accordance with the original legislative intent. The author also proposes corrective legislation to repeal special purpose patent term extension and restoration provisions[7] that are no longer effective.

The Hatch-Waxman Act, officially entitled "The Drug Price Competition and Patent Term Restoration Act of 1984,"[8] is a complicated piece of legislation that sought to "make available more low cost generic drugs by establishing a generic drug approval procedure."[9] A

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[1]The Drug Price Competition and Patent Term Restoration ("Hatch-Waxman") Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2002); 21 U.S.C. §§ 301 note, 355, 360cc (2002); 28 U.S.C. § 2201 (2002); 35 U.S.C. §§ 156, 271, 282 (2002)).

[2]496 U.S. 661 (1990).

[3]*Id.* The phrase "a Federal law which regulates . . . drugs," 35 U.S.C. § 271(e)(1), could have alternatively been interpreted to only cover those specific statute sections regulating drugs, rather than as an entire Act of law regulating, and thereby exempting from patent infringement, multiple products including drugs.

[4]21 U.S.C. §§ 301-399 (2002).

[5]Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

[6]*See infra* Part VIII.

[7]35 U.S.C. § 155 (2002); 35 U.S.C. § 155A (2002).

[8]Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2002); 21 U.S.C. §§ 301 note, 355, 360cc (2002); 28 U.S.C. § 2201 (2002); 35 U.S.C. §§ 156, 271, 282 (2002)).

[9]H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

second purpose of the Hatch-Waxman Act was to "create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval."[10] In a single act, Congress drastically changed the effective term of exclusive rights for patented inventions that are subject to regulation by the Food and Drug Administration.

The patent laws encourage disclosure of trade secrets by granting exclusive rights in exchange for such disclosure.[11] This furthers the intent of the Constitution "to promote the progress of . . . useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries."[12] Congress established the U.S. Patent and Trademark Office as an agency within the Department of Commerce[13] to provide patents to inventors ex parte,[14] and established private enforcement of patent rights through United States district court action.[15]

On the other hand, the Federal Food, Drug, and Cosmetics Act[16] seeks to ensure that human drugs are safe and effective and that there is a reasonable assurance of safety and effectiveness for devices intended for human life.[17] The Food and Drug Administration ("FDA"), established within the Department of Health and Human Services,[18] controls the application and approval process of pharmaceutical drugs and medical devices. Any drug "not

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[10]*Id.* at 15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

[11]Martin J. Adelman et al., *Cases and Materials on Patent Law*, § 1.6[d] (West Group 1988) ("[I]nventors seeking legal protection must ultimately opt to either maintain the technology as a trade secret, or to obtain a patent from the United States Patent and Trademark Office.").

[12]U.S. Const. art. I, § 8, cl. 8.

[13]Act of July 19, 1952, ch. 950, § 1, 66 Stat. 792, 792 (codified as amended at 35 U.S.C. § 1(a) (2002)).

[14]*See* 35 U.S.C. § 122(a) (2002) ("[A]pplications for patents shall be kept in confidence by the Patent and Trademark Office."); 37 C.F.R. § 1.14(a) (2002) ("Patent applications that have not been published . . . are generally preserved in confidence." (citations omitted)).

[15]35 U.S.C. § 281 (2002) ("A patentee shall have remedy by civil action for infringement of his [or her] patent.").

[16]FDCA, 21 U.S.C. §§ 301-399 (2002).

[17]*Id.* § 903(b)(2)(B), 21 U.S.C. § 393(b)(2)(B) (defining mission of FDA to ensure that, *inter alia*, human drugs are safe and effective).

[18]*Id.* § 903(a), 21 U.S.C. § 393(a) (establishing Food and Drug Administration within Department of Health and Human Services).

generally recognized among experts . . . as safe and effective" is deemed a new drug,[19] and no person shall "introduce . . . into interstate commerce any new drug, unless an approval of the application . . . is effective."[20] Likewise, any device "intended for use in the diagnosis . . . [or] treatment . . . of disease," is a regulated medical device,[21] and cannot be sold without approval if not reasonably safe absent general or special controls.[22] The Federal Food, Drug and Cosmetics Act requires the FDA to refuse approval of a new drug and to withdraw any prior approval if substantial evidence of effectiveness is lacking.[23] Medical devices to support human life[24] also require FDA approval[25] and may be recalled[26] by the FDA if they present an unreasonable risk of harm to public health. A decision by the FDA will not be set aside unless found by a court to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[27]

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[19]*Id.* § 201(p), 21 U.S.C. § 321(p) (defining *new drug* as one not generally recognized among experts as safe and effective).

[20]*Id.* § 505(a), 21 U.S.C. § 355(a) (prohibiting introduction of new drug into interstate commerce absent effective approval of application); *id.* § 301(d), 21 U.S.C. § 331(d) (redundantly prohibiting introduction of any article into interstate commerce in violation of section 505).

[21]*Id.* § 201(h), 21 U.S.C. § 321(h) (defining a *device* as, *inter alia*, an instrument, apparatus, machine, or implant intended for the diagnosis or treatment of disease).

[22]*Id.* § 515(b)(1), 21 U.S.C. § 360e(b)(1) (requiring premarket approval for new class III device); *id.* § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C) (defining class III device as, *inter alia*, supporting or sustaining human life, or preventing impairment of health, and which is not reasonably safe with general or specific controls); 21 C.F.R. § 807.20 (2002) (requiring all medical device manufacturers to register and submit device listing information to FDA).

[23]FDCA, § 505. 21 U.S.C. § 355 (d) and (e) (2002) (refusing approval of new drugs and withdrawing approval of existing drugs absent substantial evidence of effectiveness).

[24]Class III devices require premarket approval because insufficient information exists to assure safety and effectiveness with general or specific controls, and because they are used to support or sustain human life or prevent impairment to human health. *Id.* § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C) (2002) (defining Class III medical device).

[25]*Id.* 515(b), 21 U.S.C. § 360e(b) (2002) (requiring premarket approval of Class III medical device).

[26]*Id.* § 518(a), 21 U.S.C. § 360h(a) (2002) (permitting order of recall by FDA for medical device presenting an unreasonable risk of substantial harm to public health).

[27]5 U.S.C. § 706(2)(A) (2002). *See also* Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 216 (D.D.C. 1996) (according FDA deference but requiring showing that relevant factors as basis for decision is supported by some evidence).

The Hatch-Waxman Act[28] legislatively created the abbreviated new drug application for generic drugs,[29] and substantively modified two separate areas of United States patent law.[30] Without adequate definitions, the Hatch-Waxman Act has appeared to the Supreme Court as not plainly comprehensible[31] or unclear.[32] However, analysis under the *Cannons of Statutory Construction*[33] indicates that application of the Hatch-Waxman Act to exempt medical devices from infringement during the premarket approval process is misplaced. The author's proposed legislation, set forth at the end of this paper, should provide clarification in accordance with the *Cannons*.

II. Milestones in the History of Food, Drug and Medical Device Regulation

A century before codification of the Hatch-Waxman Act, the United States saw the emergence of its first food and drug laws. The history of food quality regulation is easily traced to the appointment in 1882 of Harvey Washington Wiley as the Chief Chemist, Bureau of Chemistry, in the Department of Agriculture.[34] By 1902, Wiley had conducted a number of well publicized "poison squad" studies, which consisted of feeding various preservatives, such as formaldehyde and sulphate of copper, to healthy young men employed by the Department of

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[28]Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2002); 21 U.S.C. §§ 301 note, 355, 360cc (2002); 28 U.S.C. § 2201 (2002); 35 U.S.C. §§ 156, 271, 282 (2002)).

[29]Hatch-Waxman Act, sec. 101, § 505(j), 21 U.S.C. § 355(j) (2002) (defining contents of abbreviated new drug application).

[30]*Id*., § 201, 35 U.S.C. § 156(a)(4) (extending patent term for products subject to regulatory approval before commercial marketing or use); *id*., § 202, 35 U.S.C. § 271(e)(1) (exempting from infringement use of patented invention reasonably related to submission of information under a Federal law which regulates drugs).

[31]Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669 (1990) ("As far as the text is concerned, therefore, we conclude that we have before us a provision that somewhat more naturally reads as the Court of Appeals determined, but that it is not plainly comprehensible on anyone's view.").

[32]*Id*. at 680 (Kennedy, J., dissenting) ("The Court asserts that Congress could have specified this result in a clearer manner . . . that is all too true.").

[33]*See infra* Part VIII.

[34]U.S. Food and Drug Administration, *FDA History, FDA Commissioners and Their Predecessors*, *at* http://www.fda.gov/opacom/morechoices/comm1.html#wiley (last visited Nov. 14, 2002).

Agriculture.[35] The 1906 novel, *The Jungle*,[36] intensified public concern by detailing the filthy conditions of a Chicago meat packing plant. Public response led to the passage of the Federal Food and Drugs Act of 1906.[37] The 1906 Act deemed it unlawful to manufacture adulterated or misbranded food or drugs.[38] Drugs were defined with reference to the U.S. Pharmacopoeia[39] or National Formulary,[40] or as substances intended to cure disease. While violations of the 1906 Act were reportable to the proper United States district attorney,[41] the manufacturer was not required to test for product safety.[42] Further, prosecutions under the 1906 Act were difficult because the state was required to prove intent.[43] In 1927, the Bureau of Chemistry within the Department of Agriculture was renamed the Food, Drug and Insecticide Administration,[44] and was shortened in 1931 to the Food and Drug Administration.[45]

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[35]Harvey W. Wiley, M.D., *The History of a Crime Against the Food Law*, ch. 2 (Harvey W. Wiley, M.D., pub., 1929). *See also* Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 Law & Contemp. Prob. 3, 6 (1933).

[36]Upton Sinclair, *The Jungle* (1906) (depicting experiences of a Slavic immigrant working in the Chicago meat-packing industry).

[37]Ch. 3915, 34 Stat. 768 (repealed 1938).

[38]*Id.* § 1.

[39]The United States Pharmacopeia ("USP") is a non-government organization that publishes the standards publication, *United States Pharmacopeia*, for drug identity, strength, and quality. USP, *News Release, The USP 25-NF . . . Becomes Official*, http://www.onlinepressroom.net/uspharm/ (last modified Jan. 2, 2002). The U.S. Pharmacopeia is "known as the 'bible' of the pharmaceutical industry." United States v. Bhutani, 175 F.3d 572, 575 (7th Cir. 1999).

[40]In 1975, USP purchased the standards publication, *National Formulary,* for excipients, botanicals, and similar products. The two publications remain separate, but are currently published under the same cover. *News Release,* supra note 39.

[41]Federal Food and Drugs Act of 1906, ch. 3915, § 4, 34 Stat. 768, 769 (repealed 1938).

[42]S. Doc. No. 75-124, at 1 (1937) ("[T]he Federal Food and Drugs Act contains no provision against dangerous drugs.").

[43]Federal Food and Drugs Act of 1906, ch. 3915, §§ 1-2, 34 Stat. 768, 768 (repealed 1938) (defining manufacture or shipping of adulterated food or drugs as a misdemeanor). *See generally* 1 Toulmin, *The Law of Foods, Drugs and Cosmetics* § 2.3 (W.H. Anderson Co. 1963) (outlining chief differences between the Acts of 1906 and 1938, notably that intent is required for a conviction of false therapeutic claims under the 1906 Act).

[44]Act of Jan. 18, 1927, ch. 39, 44 Stat. 976, 1002 (referring to Food, Drug and Insecticide Administration by name). *See generally* 1 James T. O'Reilly, *Food and Drug Administration*, § 3.03 (2d ed. 1993).

[45]Act of May 27, 1930, ch. 341, 46 Stat. 392, 422 (referring to Food and Drug Administration by name).

In 1932, German biochemist Gerhard Johannes Paul Domagk slightly changed the chemical makeup of a red dye Prontosil, created Sulfanilamide,[46] and changed the world. Mr. Domagk gave his newly created drug to his daughter and saved her from near death by streptococcal bacterial infection.[47] Sulfanilamide is the grandparent of the Sulfonamide family of drugs, popularly known today as "sulfa drugs."[48] However, in 1937 the S.E. Massengill company directed its chief chemist, Harold Cole Watkins, to create a liquid form of Sulfanilamide that would be more acceptable to children.[49] Mr. Watkins diluted Sulfanilamide with 72 percent[50] diethylene glycol ("DEG"), a poison currently used in the manufacture of polyurethanes[51] and as a tobacco humectant.[52] As a result, over a hundred people, mostly children, suffered a severe and painful death.[53] The 1906 Act[54] did not require new drugs to be tested for safety, and the FDA technically lacked statutory authority to recall individual medicine bottles.[55] The S.E. Massengill Company was merely fined $26,100 for misbranding violations

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[46]David Steinert, *World War II Combat Medic, The History of WWII Medicine*, *at* http://home.att.net/~steinert/wwii.htm (last updated Apr. 5, 2002).

[47]*Id.*

[48]*Id.*

[49]GMP Institute, *Food and Drug Legislation - The Story Behind the Law*, *at* http://www.gmp1st.com/histlaw.htm (last modified Apr. 5, 2002).

[50]Drug Store News 2 (June 16, 1997).

[51]Shell Chemicals, *Diethylene Glycol: What is diethylene glycol?*, *at* http://www.shellchemicals.com/diethylene_glycol/1,1098,611,00.html (last visited Nov. 24, 2002) (linking to closely related chemical ethylene glycol, popularly used as antifreeze).

[52]Philip Morris USA, *Our Products: Ingredients in Cigarettes*, *at* http://www.philipmorrisusa.com/our_products/ingredients/non_tobacco_ingredients.asp (last visited Nov. 11, 2002) (indicating by percentage amount of diethylene glycol in cigarette paper).

[53]Drug Store News, *supra* note 50.

[54]Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 (repealed 1938).

[55]O'Reilly, *supra* note 44, § 13.02, at 13-5. In fact, at the height of the effort, Massengill salesmen were uncooperative and at least one was jailed until he disclosed recipients of the elixir. S. Doc. No. 75-124, at 6 (1937).

under the 1906 Act[56] and Harold Watkins committed suicide.[57] In 1938, Congress passed the Federal Food, Drug and Cosmetics Act.[58] While excepting existing drugs subject to the 1906 Act, the 1938 Act prohibited delivery of any new drug unless shown to the Secretary of Agriculture to be safe for use.[59] In 1940, the FDA was transferred to the Federal Security Agency,[60] and in 1953 was merged into the Department of Health, Education, and Welfare.[61]

In 1958, the drug thalidomide was popular in Europe for treating sleep disorders and morning sickness in pregnant women.[62] Thalidomide was available in Germany without a prescription, and the William S. Merrill Company submitted a U.S. application to the FDA for U.S. marketing.[63] Concerned about reports of tingling nerve inflammation in long time users, Ms. Frances Kelsey of the FDA did not approve the application and requested additional information from Merrill.[64] By 1961, reportedly 5,000 German babies were born with severe birth defects as a result of thalidomide and at least 3,000 United States women had received thalidomide experimentally.[65] In fact, during pendency of the thalidomide new drug application with the FDA, the Merrill Co. had distributed over 2,500,000 tablets for investigational use by

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[56]Linda Bren, *Frances Oldham Kelsey: FDA Medical Reviewer Leaves Her Mark on History, at* http://www.fda.gov/fdac/features/2001/201_kelsey.html (last modified Feb. 28, 2001). Had the product been called a "solution," rather than an "elixir," no charge of violating the law could have been brought. S. Doc. No. 75-124, at 9 (1937).

[57]Bren, *supra* note 56.

[58]Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399 (2002)).

[59]FDCA, § 505(a), 21 U.S.C. § 355(a) (2002).

[60]Reorg. Plan No. 4 of 1940, § 12, 5 Fed. Reg. 2,431 (1940), *reprinted in* 54 Stat. 1234 (1940) (approved by Act of June 4, 1940, ch. 231, § 4, 54 Stat. 231 (1940)).

[61]Reorg. Plan No. 1 of 1953, § 5, 18 Fed. Reg. 2,053 (1953), *reprinted in* 67 Stat. 631 (1953).

[62]GMP Institute, *supra* note 49.

[63]*Id.*

[64]Bren, *supra* note 56.

[65]*Id*. Public concern was enhanced by press reports of a woman having taken thalidomide during a trip abroad and being denied a U.S. abortion during her first trimester of pregnancy. *See generally* Taussig, *A Study of the German Outbreak of Phocomelia*, 80 J. Am. Med. Assoc. 1106 (1962).

1,270 physicians in the United States, who in turn dispensed thalidomide to 20,771 patients.[66] In response to the thalidomide tragedy of the late 1950's,[67] Congress passed the Drug Amendments of 1962,[68] thereby requiring new drugs to also be proven effective, as well as safe. For her efforts in minimizing the effects of thalidomide in the United States, President John F. Kennedy subsequently presented Ms. Frances Kelsey with the President's Award for Distinguished Federal Civilian Service.[69]

Before passage of the Drug Amendments of 1962, there were thousands of generic drugs, often called "me-too" drugs, being marketed without FDA approval in reliance on prior "pioneer" drug applications.[70] According to the Drug Amendments of 1962, *all* drugs were now required to show effectiveness, and the generic drugs were given a two year grace period to present such evidence to the FDA.[71] To handle the considerable burden of reviewing all marketed drugs for efficacy, the FDA retained the National Academy of Sciences-National Research Council ("NAS-NRC") to create expert review panels.[72] This procedure was known as the Drug Efficacy Study Implementation ("DESI").[73] The DESI review of drug products

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[66]77 Pub. Health Rep. 946 (1962). *See also* Comment, *The Food and Drug Administration: Law, Science and Politics in the Evaluation and Control of New Drug Technology*, 67 Nw. U. L. Rev. 858, 867-68 (1973).

[67]Critics argue that the Congressional action was not a direct response because the efficacy proposals had been pending a number of years, and the problem with Thalidomide was safety -- not efficacy.

[68]Drug Amendments of 1962, § 102, Pub. L. No. 87-781, 76 Stat. 780, 781-82 (codified as amended in scattered sections of 21 U.S.C.) (adding "and effectiveness" after "safety" throughout statute).

[69]Remarks Upon Presenting the President's Awards for Distinguished Federal Civilian Service, 1962 Pub. Papers § 323 (Aug. 7, 1962). The President's Award for Distinguished Federal Civilian Service is often confused with the Presidential Medal of Freedom, authority for both deriving from the same statute. 5 U.S.C. § 4504 (2002).

[70]Weinberger v. Hynson, Estcott & Dunning, Inc., 412 U.S. 609, 614 (1973) ("'[M]e-toos,' are similar to or identical with drugs with effective NDA's and are marketed in reliance on the 'pioneer' drug application approved by FDA.").

[71]Drug Amendments of 1962, § 107(c)(2), Pub. L. No. 87-781, 76 Stat. 780, 788 (proclaiming approval of drug applications that were effective before passage of 1962 Act); *id*. § 107(c)(3)(B)(i), at 789 (withdrawing approval of drug applications two years after passage of 1962 Act if not shown effective).

[72]*See generally Hynson* at 614 (confirming NAS-NRC expert panels to review efficacy of every approved drug).

[73]*See generally* National Academy of Sciences, *Drug Efficacy Study: Final Report to the Commissioner of Food and Drugs* (1969).

produced monographs[74] responding to approximately 16,500 claims made for approximately 4000 pre-1962 drugs.[75]

During the DESI review process 1962-69, the FDA concluded that each drug product was in fact a *new drug* that required an approved new drug application ("NDA") before it could be legally marketed.[76] In 1968, the FDA revoked earlier advisory opinions that drugs could be marketed without prior FDA clearance.[77] By 1969, the FDA created an abbreviated new drug application ("ANDA") to provide for regulatory approval of generic drugs marketed before the 1962 Act.[78] The FDA initially permitted marketing by generic drug manufacturers while the ANDA was pending, however this practice was enjoined in 1975 as a violation of the Drug Amendments of 1962.[79] The FDA has not permitted the filing of 1962 ANDAs for generic drugs corresponding to pioneer drugs approved on or after October 10, 1962.[80]

In 1969, Dr. Theodore Cooper, Director of the National Heart and Lung Institute, headed a panel to review the need for additional medical device legislation.[81] The Cooper Committee searched the scientific literature for accounts of injuries from medical devices and discovered

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[74]A monograph is a scientific report describing a class of drugs and making certain findings regarding safety and effectiveness. O'Reilly, *supra* note 44, § 13.07.

[75]*Id.*

[76]United States v. Generix Drug Corp., 460 U.S. 453 (1983) (holding a generic drug product is a *drug* within the meaning of section 201(g)(1) of the Federal Food, Drug, and Cosmetics Act, thereby requiring the filing of a new drug application under section 505 of the Act).

[77]33 Fed. Reg. 7,758 (May 28, 1968) (codified as amended at 21 C.F.R. § 310.100(d) (2002)) (revoking all previous opinions by the FDA that an article is "not a new drug" or is "no longer a new drug").

[78]34 Fed. Reg. 2,673 (Feb. 27, 1969) (defining regulations for filing and content of abbreviated new drug applications); 35 Fed. Reg. 11,273 (July 14, 1970) (requiring generic drug manufacturer without approved NDA to submit full or abbreviated NDA).

[79]Hoffmann-LaRouche, Inc. v. Weinberger, 425 F. Supp. 890 (D.D.C. 1975) (requiring FDA to prohibit marketing of generic drugs during NDA approval phase); FDA/ORA *Compliance Policy Guide Manual*, § 448.100 (implementing Hoffmann-LaRouche court order through FDA Compliance Program 7332.26.), *at* http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg448-100.html (revised Mar. 1995)).

[80]54 Fed. Reg. 28,872, 28,873 (July 10, 1989).

[81]Study Group on Medical Devices, Department of Health, Education & Welfare, *Medical Devices: A Legislative Plan* (1970) [hereinafter Cooper Committee Report]. *See also* Cooper, *Device Legislation*, 26 Food Drug Cosm. L.J. 165 (1971).

some 10,000 recorded injuries, of which 731 resulted in death.[82] For example, 186 injuries were related to heart pacemakers, while 10 deaths and 8,000 injuries were related to intrauterine devices, most notably the Dalkon Shield.[83] In 1976, Congress passed the Medical Device Amendments of 1976[84] to further distinguish medical devices from drugs, solidify FDA authority over medical devices, establish different classes of medical devices, and mandate premarket approval for devices in need of additional information.[85] Prior to passage of the 1976 Amendments, the FDA bore the burden of proving that a medical device in the stream of commerce was unsafe or misbranded.[86] Now, for the first time, the 1976 Amendments gave the FDA comprehensive regulatory authority over medical devices.[87] In general, the medical device applicant must submit to a complicated and lengthy premarket approval process,[88] or show that the device is substantially equivalent to a device existing prior to enactment of the 1976 Amendments.[89]

By way of a 1978 memorandum, Dr. Marion Finkel, FDA Associate Director for New Drug Evaluation, instructed her staff to accept published reports as the main supporting documentation for the safety and effectiveness of post-1962 drugs, thereby creating the *paper*

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[82]S. Rep. No. 94-33, at 6 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1076.

[83]H.R. Rep. No. 94-853, at 8 (1976), *reprinted in An Analytical Legislative History Of The Medical Device Amendments Of 1976*, app. III (Daniel F. O'Keefe & Robert Spiegel eds., The Food and Drug Law Institute, Inc., 1976). House Report 853 is considered by scholars to be "the best source of legislative history on the Medical Device Amendments of 1976." Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J. Law & Tec. 1, 84, n.11 (1989).

[84]Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

[85]*See generally* Jennifer Salvatore O'Connor, *The Impact of Lohr v. Medtronic on the First Circuit's Application of the Medical Device Amendments*, 3 Suffolk J. Trial & App. Adv. 157 (1998).

[86]*See generally* Leflar, *supra* note 83, at 2.

[87]Slater v. Optical Radiation Corp., 961 F.2d 1330, 1331 (7th Cir. 1992) (quoting H.R. Rep. No. 94-853, at 6-13 (1976)).

[88]FDCA, § 515(b)(1), 21 U.S.C. § 360e(b)(1) (2002) (requiring premarket approval for Class III devices); 21 C.F.R. pt. 814 (2002) (providing procedures for the premarket approval of medical devices intended for human use).

[89]*Id.* § 513(f)(1), 21 U.S.C. § 360c(f)(1) (designating device as Class III device unless substantially equivalent to class I or II device).

NDA.[90] Accordingly, evidence of safety and effectiveness for generic drugs could be derived from published reports.[91] However, the *paper NDA* procedure did not effectively enhance the generic drug approval process because many of the essential studies on safety and efficacy were conducted by, and hence only available to, the pioneer drug company.[92]

The next major legislative change[93] was the Drug Price Competition and Patent Term Restoration Act of 1984,[94] also known as the Hatch-Waxman Act. The Hatch-Waxman Act primarily sought to quicken the approval process for generic drugs and extend patent life of pioneer drugs to compensate for regulatory delay. The Hatch-Waxman Act had a number of effects, notably: to establish a statutory abbreviated new drug application ("ANDA") for generic drugs,[95] to establish patent term extensions for delays in the approval of products regulated by the FDA,[96] to exempt submission of information under a Federal law which regulates drugs from patent infringement,[97] and to provide for a number of technical clarifications relating to patent infringement and regulatory approval. For example, constructive patent infringement was

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[90]Burroughs Wellcome Co. v. Schweiker, 649 F.2d 221, 223 (4th Cir. 1981) (quoting memorandum that FDA "will not interpret the full reports of investigations' phrase of (21 U.S.C. § 355(b)) as requiring either case reports or an exhaustive review of all published reports on the drug.").

[91]*Id.* at n.1 ("For duplicate NDAs for already approved post-62 drugs, the Agency will accept published reports as the main supporting documentation for safety and effectiveness.").

[92]H.R. Rep. No. 98-857, pt. 1, at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649 (receiving unsatisfactory reports for 85% of post-1962 generic drugs). *See also Burroughs Wellcome* at 223, n.1 ("Present interpretation of the law [by the FDA] is that no data in an NDA can be utilized to support another NDA without express permission of the original NDA holder."); 45 Fed. Reg. 82,052 (Dec. 12, 1980) (explaining that the requirement for submission of raw data in paper NDAs serves as an entry barrier to competitors because raw data is only available to the originator of the new drug).

[93]The Orphan Drug Act of 1983 provided a limited exclusive license and tax incentives to manufacturers of drugs for rare diseases. FDCA, § 526, 21 U.S.C. 360(bb) (2002).

[94]The Drug Price Competition and Patent Term Restoration ("Hatch-Waxman") Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 15 U.S.C. §§ 68b-68c, 70b (2002); 21 U.S.C. §§ 301 note, 355, 360cc (2002); 28 U.S.C. § 2201 (2002); 35 U.S.C. §§ 156, 271, 282 (2002)).

[95]Hatch-Waxman Act sec. 101, 21 U.S.C. § 355(j) (2002) (defining contents of abbreviated new drug application).

[96]*Id.* sec. 201, 35 U.S.C. § 156(a) (extending patent term of product subject to regulatory review).

[97]*Id.* sec. 202, 35 U.S.C. § 271(e) (exempting from infringement making, using or selling a patented invention solely for uses reasonably related to the development and submission of information under a Federal law which regulates drugs).

established for the manufacture and sale of generic drug copies prior to patent expiration,[98] while the drug approval process itself was removed from infringement.[99] Moreover, in 1990 the Supreme Court excepted from patent infringement the FDA regulatory approval process for all products, including medical devices.[100]

III. Overview of the Modern Drug Approval Process

The definition of a "drug," and hence, the range of pharmaceutical articles requiring FDA approval, is set by statute.[101] A drug is:

1. An article recognized by the U.S. Pharmacopeia[102] and other formularies;[103]
2. An Article intended to be used in diagnosis, cure, . . . or treatment of disease in man or animals -- by chemical action rather than by the merely physical or mechanical action that characterizes medical devices;[104]
3. An Article intended to affect the structure or any function of the body of man or animals . . . by chemical . . . action;[105]

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[98] *Id.* sec. 102, 21 U.S.C. § 355(b) (requiring the applicant to file patent number and expiration date of patent claiming drug).

[99] *Id.* sec. 201, 35 U.S.C. § 271(e)(1) (exempting from infringement activities reasonably related to development and submission of information under a federal law which regulates drugs).

[100] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

[101] FDCA, § 201(g), 21 U.S.C. § 321(g) (2002).

[102] *See* notes 39-40 *supra*. Recognition of an item in the USP is not absolute, but constitutes prima facie evidence that the item is a "drug," thereby calling on an opposing party to come forward with contrary evidence or else risk an adverse ruling. United States v. Article of Drug . . . OVA II, 414 F. Supp. 660, 665 (D.N.J. 1975) *aff'd mem.*, 535 F.2d 1244 (2nd Cir. 1975) (rejecting FDA attempt to categorize home pregnancy kit as a drug).

[103] FDCA, § 201(g)(1)(A), 21 U.S.C. § 321(g)(1)(A) (2002).

[104] *Id*. at (g)(1)(B), 21 U.S.C. § 321(g)(1)(B).

[105] *Id*. at (g)(1)(C), 21 U.S.C. § 321(g)(1)(C).

4. An Article intended to become an active or inactive[106] component of the three above types.[107]

The drugs-verses-devices, chemical-verses-mechanical distinction was created by Congress so that a close parallel definition could be used to describe medical devices.[108]

Truly new drugs are prohibited from introduction or delivery for introduction into interstate commerce unless an FDA application is effective for the new drug.[109] The approval process for new drugs is closely regulated, and therefore subjects applicants to exceptional costs and delay related to, *inter alia,* research, clinical trials, and government submission.[110] This begs to question when FDA approval is required and under what standards the FDA may take action.

The FDA may pursue enforcement and injunctive remedies against a manufacturer that has not obtained approval for a new drug through action in United States district courts.[111] To maintain a United States district court action, the FDA is required to show probable cause that the drug in question is either a new drug or is misbranded.[112] The government is not required to provide a hearing prior to exercising its discretion to seize articles.[113] However, the United States district courts lack jurisdiction to determine whether in fact a drug is a "new drug" under

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[106]United States v. Generix Drug Corp., 460 U.S. 453, 461 (1983) (holding mere change of inactive "excipients" may make generic drug product less safe and effective, thereby requiring a new drug application).

[107]FDCA, 201(g)(1)(D), 21 U.S.C. § 321(g)(1)(D) (2002).

[108]O'Reilly, *supra* note 44, § 13.03. Drugs are likewise expressly excluded from the medical device definition. FDCA, § 201(g), 21 U.S.C. § 321(g) (2002).

[109]FDCA, § 505(a), 35 U.S.C. § 355(a) (2002) ("No person shall introduce or deliver . . . any new drug, unless an approval . . . [by the FDA] is effective.").

[110]Edmund Polubinski III, *Closing the Channels of Communication: A First Amendment Analysis of the FDA's Policy on Manufacturer Promotion of "Off-Label" Use*, 83 Va. L. Rev. 991, 1006 (1994) ("Approval for a new drug can cost a pharmaceutical company many millions of dollars.").

[111]*Id.* § 302(a), 21 U.S.C. § 332(a) ("The district courts . . . shall have jurisdiction . . . to restrain violations of section 301, except paragraphs (h), (i), and (j) [of the Federal Food, Drug, and Cosmetics Act]").

[112]Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 598 (1950) ("The administrative finding of probable cause required by § 304(a) is merely the statutory prerequisite to the bringing of the lawsuit.").

[113]*Id.* (explaining that a subsequent hearing by a claimant in front of the court satisfies due process).

section 505 of the Federal Food, Drug and Cosmetics Act,[114] and should defer to an agency determination.[115] Of course, by its very definition, a new drug is not a drug that has already been generally recognized as safe and effective.[116]

Generally Recognized as Safe and Effective

Drugs that are generally recognized as safe and effective ("GRASE") are outside the statutory authority of a new drug.[117] While a general recognition of safety and effectiveness avoids preclearance approval by the FDA, it is neither a determination that the drug is safe nor is it a determination that the drug is effective.[118] Historical GRASE status for a drug is not based simply on history of use; there must also be evidence of its safety and recognition by experts.[119] In fact, the FDA is required to withdraw any prior approval if evidence shows the drug to be unsafe or if substantial evidence shows that the drug is lacking effectiveness for its intended use.[120]

The FDA rarely loses GRASE disputes.[121] As a general rule, a general recognition requires a two-step showing: first, expert consensus that the product is effective; and second,

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[114]FDCA, § 505(a), 21 U.S.C. § 355(a) (2002) (prohibiting introduction or delivery of new drug into interstate commerce absent FDA approval).

[115]CIBA Corp. v. Weinberger, 412 U.S. 640, 644 (1973); Weinberger v. Bentex Pharm., Inc., 412 U.S. 645, 652 (1973); Weinberger v. Hynson, Wescott and Dunning, Inc., 412 U.S. 609 (1973). *But see*, United States v. Western Serum Co., 498 F. Supp. 863, 865 (D. Ariz. 1980) (holding in animal drug case that the Supreme Court did not establish FDA jurisdiction as *exclusive*).

[116]FDCA, § 201(p), 21 U.S.C. § 321(p) (2002) (defining new drug).

[117]*Id. See also* O'Reilly, *supra* note 44, § 13.05 (discussing "generally recognized as safe and effective").

[118]O'Reilly, *supra* note 44, § 13.05.

[119]United States v. Undetermined Quantities . . . Wrm-Rid Dog Wormer, 145 F.3d 1335 (6th Cir. 1998).

[120]FDCA, § 505(e)(3), 21 U.S.C. § 355(e)(3) (2002) (withdrawing approval of a drug application for a lack of substantial evidence of effectiveness).

[121]O'Reilly, *supra* note 44, § 13.05.

substantial evidence to support the expert consensus.[122] In fact, mere absence of published peer journal articles about a compound "is proof that the requisite general recognition does not exist."[123] A general recognition of safety and effectiveness is ordinarily based upon published studies that may be corroborated by unpublished studies and other data and information.[124] Moreover, as a result of another infant tragedy, resulting in deaths of at least 38 infants through use of the unapproved drug E-Ferol,[125] the FDA now requires NDAs even when an approved drug merely changes its formulation. Since the mid 1980's, changes in formulation, dosage form, strength, route of administration, or intended population, trigger the NDA process for drugs that had been previously determined as safe and effective through the DESI process.[126] It is now well settled that even a change of inactive excipients, i.e. coatings, binders, and capsules, of a GRASE active ingredient, can constitute the formulation of a new drug.[127]

New Drug Application

The new drug process inevitably begins with the discovery of a compound or experimental testing of know compounds. During preclinical product development, laboratory screening and animal studies are conducted for a pharmacological "new chemical entity" that might intercept and combat disease.[128] Preclinical product development lasts an average of 18

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[122]United States v. An Article of Drug Consisting of 4,680 Pails, More or Less, Each Pail Containing 60 Packets, Etc., 725 F.2d 976, 987 (5th Cir. 1984).

[123]United States v. Undetermined Quantities of Articles of Drug, 145 F. Supp. 2d 692 (D. Md. 2001).

[124]21 C.F.R. § 314.200 (2002).

[125]United States v. Hiland, 909 F.2d 1114, 1135 (8th Cir. 1990) (holding that statement, "E-Ferol had been associated with the deaths of thirty-eight infants," was not unfairly prejudicial to defendant).

[126]FDA/ORA Compliance Policy Guides Manual, ch. 4, § 440.100 *at*, http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg440-100.html (revised Mar. 1995).

[127]United States v. Generix Drug Corp., 460 U.S. 453, 461 (1983).

[128]O'Reilly, *supra* note 44, § 13.11.

months.[129] Although the time period for completion of Phase I to Phase III of the new drug application process is set by statute at 180 days,[130] this has virtually never been met.[131]

Phase I is the first phase of the NDA approval process, which formally begins with the filing of an investigational new drug ("IND") application.[132] The FDA then examines the proposed testing protocols, and if need be, prepares a clinical hold.[133] Phase I trials are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.[134] IND reviews are then conducted by medical officers and clinical research experts at the Center for Drug Evaluation & Research ("CDER").[135] While the regulations require a written determination from the FDA 30 days after receiving the IND,[136] immediate approval is rare, and most determinations result in a clinical hold.[137] During this stage, commercial distribution is not allowed, but the FDA may grant permission for recoupment of manufacturing costs.[138]

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[129]Food and Drug Administration, Department of Health and Human Services, *FDA Almanac Fiscal Year 1992,* at 33 (1992). The 1992 Almanac was the last version published in book form, while a condensed version omitting statistical information is available on the internet. Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, *FDA ALMANAC*, *at* http://vm.cfsan.fda.gov/~lrd/almcfsan.html. (last updated June 15, 1998).

[130]FDCA, § 505(c), 21 U.S.C. § 355(c) (2002).

[131]O'Reilly, *supra* note 44, § 13.11, at 13-74.

[132]21 C.F.R. § 312.20(a) (2002) (requiring IND submission to FDA prior to clinical investigation of new drug).

[133]FDCA, § 505(i)(3)(A), 21 U.S.C. § 355(i)(3)(A) (2002) (prohibiting clinical testing by FDA at any time upon determination of unreasonable risk to safety of clinical participants); *see also* Ken Flieger, *Testing in 'Real People',* FDA Consumer, Nov. 1987, at 11.

[134]21 C.F.R. § 312.21(a) (2002); *See generally* Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services, *Guidance for Industry, M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals* (July 1997), http://www.fda.gov/cder/guidance/1855fnl.pdf.

[135]Center for Drug Evaluation and Research, U.S. Food and Drug Administration, *Investigational New Drug (IND) Application Process*, *Introduction*, *at* http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm (last updated Nov. 7, 2002).

[136]21 C.F.R. § 312.20(c) (2002) (requiring written FDA response 30 days after receiving IND).

[137]21 C.F.R. § 312.42 (2002) (listing grounds for imposition of a clinical hold).

[138]21 C.F.R. § 312.7(d)(1) (2002) (allowing sponsor to explain for FDA approval why charging is necessary in order to undertake or continue clinical trial).

Phase II of the NDA approval process is the development of safety data from all patients having the target disease of the compound under investigation.[139] Phase II tests are designed to evaluate the effectiveness of the drug for particular patients with the disease under study and to determine common short-term side effects and risks associated with the drug.[140] Phase II test generally involve several hundred closely monitored sick patients[141] and usually take two years to complete.[142] Approximately one third of drugs which begin this process will proceed beyond this stage, primarily due to safety issues.[143]

Phase III clinical studies include expanded controlled and uncontrolled trials performed after obtaining preliminary evidence suggesting effectiveness of a drug.[144] The clinical studies are intended to gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.[145] Phase III studies usually involve two large multilocation studies over one to four years, and approximately one quarter of drugs that began Phase I with the filing of an IND survive Phase III.[146] During Phase III clinical trials, hundreds or thousands of patients may receive the drug in double blind studies.[147] The FDA will requires the applicant to prove effectiveness by substantial evidence.[148] The term "substantial evidence" is further defined as consisting of adequate and well controlled investigations,

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[139]O'Reilly, *supra* note 44, § 13.11.

[140]21 C.F.R. § 312.21(b) (2002) (defining Phase II clinical studies to evaluate effectiveness, to determine short term side effects and risks).

[141]*Id.* (explaining further that relatively small number of patients usually involves no more than several hundred subjects).

[142]*FDA Almanac Fiscal Year 1992*, *supra* note 129, at 32.

[143]*Id.*

[144]21 C.F.R. § 312.21(c) (2002) (defining Phase III studies to gather additional safety and effectiveness data).

[145]*Id.*

[146]*FDA Almanac Fiscal Year 1992*, *supra* note 129, at 32.

[147]21 C.F.R. § 312.21(c) (2002).

[148]FDCA, § 505(d)(5), 21 U.S.C. § 355(d)(5) (2002) (requiring FDA to issue order refusing approval because of a lack of substantial evidence of effectiveness). *See also* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629 (1973).

including clinical investigations by qualified experts.[149] A common point of contention is the effective "end point," i.e. a point in time when a determination is made whether the drug has been effective.[150]

Phase III leads to formal acceptance of the proposed NDA. Several groups within the FDA produce recommendations, which are then publically available upon final agency action on the NDA.[151] Once a product is approved, the FDA evaluates the methods associated with product manufacture, labeling, and validation testing.[152] Next, the official and proprietary name of the drug is published by the FDA[153] along with submitted safety and effectiveness data.[154]

Factual internal memoranda of FDA reviewers was historically available under the Freedom of Information Act.[155] This information particularly includes reviews by pharmacologists, physicians and statisticians routinely prepared in connection with an NDA, such as investigative and scientific reports.[156] However, trade secret information will not be disclosed.[157] In particular, any commercially valuable plan, formula, process, or device that is

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[149]FDCA, § 505, 21 U.S.C. § 355(d) (2002) (providing definition for "substantial evidence").

[150]*Id.* For example, because an effective end point for an AIDS drug would not be the cure of the AIDS condition, but rather a statistically significant improvement in white blood cell count.

[151]21 C.F.R. § 314.430 (2002) (criteria for public disclosure of information from applications and abbreviated applications).

[152]The FDA will duplicate the manufacturer's testing method to assure quality and purity in future validation testing. GAO Report, Speeding Up the Drug Review Process, HRD-82-16, at 17 (Nov. 23, 1981).

[153]FDCA, § 505(j)(7)(A), 21 U.S.C. § 355(j)(7)(A) (2002) (requiring FDA to publish list of approved drugs and to update list monthly).

[154]21 C.F.R. § 314.430 (2002) (indicating availability of data in approved drug application or abbreviated drug application).

[155]Sterling Drug, Inc. v. Harris, 488 F. Supp. 1019, 1024 (S.D.N.Y. 1980) (requiring FDA disclosure under FOIA of purely factual, investigative matters inextricably intertwined with agency policy-making recommendations).

[156]*See id.* at 1028 (confirming that investigative and scientific reports do not reflect deliberative process of policy-making and are therefore recoverable under FOIA).

[157]FDCA, § 301(j), 21 U.S.C. § 331(j) (2002) (prohibiting disclosure of trade secret information except within FDA or to the courts). *See generally* O'Reilly, *Knowledge is Power: Legislative Control of Drug Industry Trade Secrets,* 54 U. Cin. L. Rev. 1 (1985).

the end product of innovation or substantial effort qualifies as a trade secret,[158] and is therefore not available for public disclosure.[159]

Fast Track Review of New Drugs

The Food and Drug Administration will hasten product research, testing and approval, also known as "the fast track" to expedite delivery to patients.[160] The FDA may grant marketing approval for a new drug based on clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival.[161] Approval is subject to the requirement for additional drug study to verify and describe the clinical benefit.[162]

The fast track protocol was primarily an administrative response to the AIDS lobby.[163] Congress specifically directed the FDA to act promptly for the evaluation of AIDS drug development needs of patients.[164] FDA authority for fast tracking was expanded by Congress in the 1997 Amendments.[165] Under this standard, the sponsor must show that the drug is intended for treating a serious or life-threatening condition and that it demonstrates potential to address unmet medical needs for that condition.[166] In this case, FDA approval can be based on an

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[158]21 C.F.R. § 20.61(a) (2002) (defining trade secret).

[159]21 C.F.R. § 20.61(c) (2002) (prohibiting public disclosure of trade secret information).

[160]21 C.F.R. § 314.500 (2002) (defining scope of accelerated approval of drugs for serious or life threatening illnesses).

[161]21 C.F.R. § 314.510 (2002) (defining approval based on surrogate endpoint other than survival or irreversible morbidity).

[162]*Id.*

[163]*See* Sheila R. Shulman & Jeffrey S. Brown, *The Food and Drug Administration's Early Access and Fast Tract Approval Initiatives: How Have They Worked?*, 50 Food & Drug L.J. 503, 516 (1995).

[164]Health Omnibus Programs Extension of 1988, § 2312, 42 U.S.C. § 300cc-12 (2002).

[165]Food and Drug Administration Modernization Act of 1997, tit. 1, sec. 112, § 506, Pub. L. No. 105-15, 111 Stat. 2296 (codified as amended at 21 U.S.C. § 356 (2002)).

[166]FDCA, § 506(a)(1), 21 U.S.C. § 356(a)(1) (2002).

endpoint that is reasonably likely to predict clinical benefit.[167] However, the FDA also has the power to withdraw such a drug in rapid withdrawal and to require a 30 day pre-submission approval of all promotional materials.[168] Individual patient access to IND drugs is now allowed under individualized testing protocols as a form of compassionate patient care. Congressionally set preconditions include a showing that the patient has no comparable or satisfactory alternative therapy available to diagnose or treat the disease.[169]

Hatch-Waxman ANDA

The Hatch-Waxman Act created an abbreviated new drug application ("ANDA") for approval of generic equivalents to FDA approved drugs. An ANDA is defined as an application submitted under section 505(j) of the Federal Food, Drug, and Cosmetics Act for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy.[170] The ANDA also includes any supplement to the approved pioneer drug application that may be required for a new or additional use.[171] The ANDA must show:[172]

(i) previous approval of a drug listed[173] by the FDA as safe and effective,

(ii) the active ingredient of the generic drug to be the same as the listed drug,

(iii) the route of administration, dosage, and strength of the generic drug to be the same as the listed drug,

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[167] *Id.* § 506(b)(2), 21 U.S.C. § 356(b)(2).

[168] *Id.* § 506(b)(2), (3), 21 U.S.C. § 356(b)(2), (3).

[169] *Id.* § 561(b), 21 U.S.C. § 360bbb(b).

[170] *Id.* § 201(aa), 21 U.S.C. § 321(aa) (defining abbreviated new drug application).

[171] *Id.*

[172] *Id.* § 505(j)(2)(a), 21 U.S.C. § 355(j)(2)(a) (listing contents of an Abbreviated New Drug Application).

[173] *Id.* § 505(j)(7)(A), 21 U.S.C. § 355(j)(7)(A) (requiring Secretary of Commerce to publish alphabetical list of drugs approved for safety and effectiveness).

(iv) bioequivalence[174] of the generic drug to the listed drug,

(v) labeling of the generic drug to be the same as the listed drug,

(vi) information provided by the listed drug in its New Drug Application, and

(vii) a certificate of the listed drug's patent status.

In practice, the sponsor of a generic drug tests a sample of the pioneer drug and the copy made in the generic facility.[175] The list of approved drugs is published[176] by the FDA in *Approved Drug Products With Therapeutic Equivalence Evaluations*,[177] popularly known as *The Orange Book* due to its orange cover. Next, the generic manufacturer must prepare technical data to show bio-equivalence to the pioneer drug. The generic manufacturer is not required to engage in its own clinical testing, rather, bio-equivalence can be shown by in vitro (test tube) testing, in vivo (human living) testing or both. Bio-equivalence can be shown by showing the same bio-availability (rate and extent of absorption of the active ingredient available at the drug action sites).

The generic drug sponsor's certificate of patent status[178] for each patent covering the drug or use of the drug, is as follows:

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed.

If not barred by patent, the FDA begins the evaluation process for the Abbreviated New Drug Application. The first decision is whether the generic drug is an identical copy of the

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[174]The FDA has the discretion to waive the requirement of bioequivalency. Fisons Corp. v. Shalala, 860 F. Supp. 859 (D.D.C. 1994).

[175]21 C.F.R. § 320.25(c) (2002).

[176]21 C.F.R. § 314.430(e) (2002) (indicating monthly publication of data in approved drug applications).

[177]Federal Food and Drug Administration, Approved Drug Products with Therapeutic Equivalence Evaluations [hereinafter The Orange Book], *available at* http://www.fda.gov/cder/ob/default.htm (current through Oct. 2002); 21 C.F.R. § 314.3(b) (2002) (defining "listed drug" by inclusion in The Orange Book).

[178]FDCA, § 505(b)(2)(A), 21 U.S.C. § 355(b)(2)(A) (2002).

pioneer drug. The FDA has the discretion to accept a similar, albeit not identical drug, however a petition must be filed.[179] The petition, also known as a suitability petition, can cover differences in the active ingredient, combination of ingredients, dosage form, strength, or route of administration.[180] However, a petition cannot be used if a new indication for the drug is described. In that case, a full NDA must be filed. If the petition is denied, the generic sponsor may request an evidentiary hearing under section 505(c) of the Act.[181] However, such hearings are routinely denied.[182]

The test for bioequivalence was added to the FDCA by the Hatch-Waxman Act,[183] and is implemented by the FDA regulations.[184] *Equivalence* means the delivery of a similar amount of active drug ingredient to the bloodstream around the liver, stomach, or other intended internal organ.[185] The term *active ingredient* refers to that active found in the final dosage form and does not reach broadly to any resultant form the drug may take in the body following administration. Furthermore, the ANDA sponsor must file chemistry and manufacturing data which satisfy the FDA that the product can be properly made and analyzed.[186] However, the Hatch-Waxman Act

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[179]21 C.F.R. § 314.93 (2002).

[180]*Id.*

[181]21 C.F.R. § 314.200(b) (2002).

[182]O'Reilly, *supra* note 44, § 13.15. *See also* 21 C.F.R. § 314.200(g)(1) (2002).

[183]FDCA, § 505(j)(2)(A)(iv), 21 U.S.C. § 355(j)(2)(A)(iv) (2002) (requiring information of bioequivalence to be submitted in abbreviated new drug application).

[184]*Id.* § 505(j)(7), 21 U.S.C. § 355(j)(7) (requiring the FDA to publish listing of approved drugs denoting whether in vitro or in vivo bioequivalence studies are required); 21 C.F.R. § 320.1(e) (2002) (defining bioequivalence in terms of rate and extent of drug availability at site of drug action).

[185]*Id.*

[186]21 C.F.R. § 314.94 (1993) (defining content and format of abbreviated new drug application).

retained the preexisting method of decision by the FDA.[187] Furthermore, the FDA must deny an ANDA if interaction with inactive ingredients makes the product unsafe.[188]

IV. Overview of the Medical Device Approval Process

The first step in the medical device approval process is to determine if approval is actually needed. As set by statute,[189] a medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar article, which is --

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or animals, or
3. intended to affect the structure or any function of the body of man or other animals, and

which does not operate through chemical or metabolic action.[190] As indicated in the Congressional Record, this definition covers "well nigh everything in Creation,"[191] or as alternatively stated in a House Subcommittee report, everything "from bedpans to brain scans."[192]

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[187]Schering Corp. v. Sullivan, Food Drug Cosm. L. Rep. (CCH) ¶38,262 (D. D.C. 1992).

[188]FDCA, § 505(j)(4)(H), 21 U.S.C. § 355(j)(4)(H) (2002) (requiring FDA to approve application unless inactive ingredients or the composition of the drug is unsafe).

[189]*Id.* § 201(h), 21 U.S.C. § 321(h) (The term "device" is defined for purposes of FDA regulation. The term "medical device" is a term of art not defined by statute.).

[190]*Id.*

[191]122 Cong. Rec. H1,721 (Mar. 9, 1976) (remarks of Rep. Collins), *reprinted in* An Analytical Legislative History Of The Medical Device Amendments Of 1976, app. III (Daniel F. O'Keefe & Robert Spiegel eds., The Food and Drug Law Institute, Inc., 1976).

[192]Staff of Subcomm. on Oversight & Investigations, House Comm. on Energy & Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* (Comm. Print 98-F, 1983), *microformed on* CIS No. 83-H362-13 (Cong. Info. Serv.).

Absent FDA approval, the introduction or delivery for introduction of a medical device into interstate commerce is prohibited.[193] However, unlike drugs, the widely different uses and risks associated with different types of medical devices led to the development of different standards of approval for different types of devices.[194] Accordingly, Congress established three classes of medical devices,[195] namely:

1. Class I devices, wherein safety and efficacy are reasonably assured by general controls;

2. Class II devices, wherein safety and efficacy are reasonably assured by imposition of performance standards in addition to general controls; and

3. Class III devices, wherein

(1) safety and efficacy can not be reasonably assured by any combination of general controls and performance standards, and

(2) whose purported purpose is to aid in supporting or sustaining human life or preventing its impairment, or whose availability presents a potential unreasonable risk of illness or injury.

The FDA currently sponsors a website to assist manufactures in identifying classifications for their medical devices.[196]

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[193]FDCA, § 301(a), 21 U.S.C. § 331(a) (2002) (prohibiting introduction or introduction for delivery of medical device that is adulterated); *id.* § 501(f)(1), 21 U.S.C. § 351(f)(1) (deeming a class III device adulterated absent approval of application for premarket approval).

[194]Cooper Committee Report, *supra* note 81, at 11 (recommending Secretary [of Health, Education and Welfare] to enlist assistance to develop classification of medical devices).

[195]FDCA, § 513(a)(1), 21 U.S.C. § 360c(a)(1) (2002) (establishing three classes of medical devices). *See also* Center for Devices and Radiological Health, U.S. Food and Drug Administration, *Device Advice, Device Classes*, *at* http://www.fda.gov/cdrh/devadvice/3132.html (last updated Nov. 21, 2002) (delineating differences between Class I, Class II, and Class III devices).

[196]Center for Devices and Radiological Health, U.S. Food and Drug Administration, *Search Classification Database, at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (last updated Dec. 10, 2002).

Class I medical devices are generally simple devices, such as tongue depressors,[197] bedpans,[198] or crutches,[199] posing little or no threat to public health and safety.[200] Class I devices may be sold without FDA premarket approval,[201] subject to general controls of product registration, listing, good manufacturing practices, labeling, and submission of a pre-market notification (also known as a 510(k)). In fact, most Class I devices are exempt from the requirements of pre-market notification.[202]

Class II medical devices are more complex than Class I devices, and may be subject to product specific recommendation, guidelines, post-marketing surveillance, and specific performance standards.[203] Examples of Class II devices include tampons,[204] syringes,[205] and neonatal incubators.[206] A large number of Class II medical devices have been exempted from the requirements of pre-market notification in accordance with the Food and Drug Administration Modernization Act of 1997.[207] While regulated medical devices are generally codified in Title

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[197]21 C.F.R. § 880.6230 (2002) (defining tongue depressor as Class I medical device).

[198]21 C.F.R. § 880.6730 (2002) (defining bedpan as Class I medical device).

[199]21 C.F.R. § 890.3150 (2002) (defining crutch as Class I medical device).

[200]Ginochio v. Surgikos, Inc., 864 F. Supp. 948, 950 (N.D. Cal. 1994) (discussing examples of Class I medical devices).

[201]FDCA, § 301(a), 21 U.S.C. § 331(a) (2002) (requiring premarket approval *only* for Class III devices).

[202]*Device Advice*, *supra* note 195. *See also* Center for Devices and Radiological Health, U.S. Food and Drug Administration, *Device Advice, Class I/II Exemptions, at* http://www.fda.gov/cdrh/devadvice/3133.html (last updated Sept. 1, 1000 [sic]).

[203]Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 42 (D. Mass. 1994) (describing Class II devices and providing examples).

[204]21 C.F.R. § 884.5470 (2002) (defining unscented menstrual tampon as Class II medical device).

[205]21 C.F.R. § 870.1670 (2002) (defining syringe actuator for an injector as Class II medical device).

[206]21 C.F.R. § 880.5400 (2002) (defining neonatal incubator as Class II medical device).

[207]Pub. L. No. 105-115, 111 Stat. 2296 (1997).

21 of the Code of Federal Regulations[208] exempted devices are particularly listed on the FDA website.[209]

In general, Class III devices are all devices that cannot be deemed safe or effective through general or specific controls. Examples of Class III devices requiring premarket approval include replacement heart valves,[210] silicone gel-filled breast prosthetics,[211] and implantable pacemakers.[212] Because all Class III medical devices are required to undergo premarket approval,[213] identification of a product as Class III device will significantly delay entry into the market.[214] In general, there are four ways that a device can attain Class III status:

1. devices marketed prior to the 1976 Amendments, and subsequently classified as Class III devices in response to recommendations from expert review panels;[215]

2. devices marketed after the 1976 Amendments and substantially equivalent to Class I or Class II devices are classified as Class III devices until actual grant of applicant petition;[216]

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[208]*See generally* 21 C.F.R. sub. ch. H (2002).

[209]Center for Devices and Radiological Health, U.S. Food and Drug Administration, *Medical Device Exemptions 510(k) and GMP Requirements*, *at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm (last updated Dec. 10, 2002).

[210]21 C.F.R. § 870.3925 (2002) (defining replacement heart valve as Class III medical device).

[211]21 C.F.R. § 878.3540 (2002) (defining silicone gel-filled breast prosthesis as Class III medical device).

[212]21 C.F.R. § 870.3610 (2002) (defining implantable pacemaker pulse generator as Class III medical device).

[213]FDCA, § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C) (2002) (requiring premarket approval for products meeting statutory test of Class III device); *id.* § 515(a), 21 U.S.C. § 360e(a) (requiring premarket approval for Class III devices until reclassification as Class I or II device in accordance with § 515(f)); *id. §* 515(b), 21 U.S.C. § 360e(b) (requiring premarket approval for pre 1976 Amendment Class III devices and their post 1976 Amendment substantial equivalents).

[214]See Robert Adler, *The 1976 Medical Device Amendment: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 519-20 (1988).

[215]FDCA, § 513(b)-(d), 21 U.S.C. § 360c(b)-(d) (2002) (requiring FDA to establish and organize expert review panels to recommend classification of all medical devices, publish their results, and if need be change or revoke regulatory approval). *See also Medical Device Classification Procedures, Notice to Manufacturers*, 40 Fed. Reg. 21,848 (May 19, 1975) (providing notice to manufacturers of expert review panels).

[216]FDCA, § 513(f)(1), 21 U.S.C. § 360c(f)(1) (2002) (classifying new device as Class III until reclassification by FDA into Class I or II in response to applicants petition).

3. devices marketed after the 1976 Amendments and not substantially equivalent to Class I or Class II devices;[217]

4. transitional devices regulated as new drugs prior to the 1976 Amendments.[218] Recognizing the costly effect of Class III status, the 1976 Amendments provided for reclassification[219] of each type of Class III status device.[220]

Premarket Approval of Medical Devices: the PMA Application

All Class III medical devices are required to obtain premarket approval.[221] Like its counterpart new drug application,[222] premarket approval of Class III medical devices is concerned with safety and effectiveness.[223] However, while a new drug application is required to prove safety and effectiveness by substantial evidence,[224] a premarket approval application (PMA) is required to provide a "reasonable assurance . . . of safety and effectiveness."[225] Nevertheless, the PMA is considered the most stringent type of device marketing application required by the FDA.[226] The FDA approved 43 PMAs and 474 PMA supplements in fiscal year

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[217]*Id.*

[218]*Id*. § 520(*l*)(1), 21 U.S.C. § 360j(*l*)(1) (classifying transitional devices, previously approved new drugs, as Class III medical devices).

[219]*See generally* Kahan, *Medical Device Reclassification: The Evolution of FDA Policy*, 42 Food Drug Cosm. L.J. 288 (1987).

[220]FDCA, § 513(e), 21 U.S.C. 360c(e) (2002) (permitting FDA to change device classification upon own initiative or in response to petition); *id*. § 513(f)(2)(A), 21 U.S.C. § 360c(f)(2)(A) (permitting request for non-Class III status for type of device previously unclassified upon submission of 510(k) pre-market notification report); *id.* § 520(*l*)(2) (permitting petition to reclassify transitional drug now designated as a Class III device to be Class I or Class II).

[221]*See supra* note 216 and accompanying text. *See also* H.R. Rep. No. 94-853, at 30-32 (1976).

[222]*See generally* FDCA, § 505, 21 U.S.C. § 355 (2002).

[223]FDCA, § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C) (2002) (stating intent of premarket approval to provide reasonable assurances of device safety and effectiveness).

[224]*See supra* note 148 and accompanying text.

[225]FDCA, § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C) (2002).

[226]Center for Device and Radiological Health, U.S. Food and Drug Administration, *Device Advice, Premarket Approval (PMA)*, *at* http://www.fda.gov/cdrh/devadvice/pma/ (last updated Nov. 1, 2002).

2000.[227] Device applicants may submit reports of clinical investigations by qualified experts,[228] or other valid scientific evidence sufficient to determine effectiveness and from which the effects may be determined by qualified experts.[229] Device applicants are permitted to submit data from other PMAs that they have prepared to avoid duplication.[230] There is reasonable assurance that a device is effective when a significant portion of the target population receives clinically significant results.[231]

Unlike the new drug application process, the PMA process relies upon quasi-public non-governmental review. Upon receipt of the device application, the FDA refers the application to an advisory panel for study and recommendation.[232] The advisory panel is composed of non-government experts in fields such as medicine, engineering, and the physical sciences.[233] Transcripts of advisory panel meetings are made public after deletion of confidential information.[234] Upon review of the panel recommendations, the FDA may issue an order effectively approving or denying the application along with a detailed summary of safety and effectiveness information.[235] The approval process also allows the applicant to amend or supplement the application.[236]

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[227]Center for Device and Radiological Health, U.S. Food and Drug Administration, *CDRH Annual Report Fiscal Year 2000*, *available at* http://www.fda.gov/cdrh/annual/fy2000/annualreport-2000.pdf.

[228]FDCA § 513(a)(3)(A), 21 U.S.C. § 360c(a)(3)(A) (2002).

[229]*Id.* § 513(a)(3)(B), 21 U.S.C. § 360c(a)(3)(B).

[230]*Id.* § 520(h)(3), 21 U.S.C. § 360j(h)(3) (permitting use of PMA effectiveness data from another device only by same applicant).

[231]21 C.F.R. § 860.7 (2002) (defining safety and effectiveness for medical devices).

[232]FDCA, § 515(c)(2), 21 U.S.C. § 360e(c)(2) (2002).

[233]*Id.* § 513(b)(2), 21 U.S.C. § 360c(b)(2).

[234]*Id.* § 520(i), 21 U.S.C. § 360j(i).

[235]*Id.* § 520(h)(1), 21 U.S.C. § 360j(h)(1); 21 C.F.R. §§ 814.44-47 (2002) (detailing possible FDA action in response to PMA).

[236]21 C.F.R. § 814.37 (2002) (amending and resubmitting PMA application); 21 C.F.R. § 814.39 (2002) (supplementing information to PMA application).

However, many Class III devices find approval through an alternate pre-market notification process, also known as a 510(k). A regulation number for Class III devices marketed prior to the 1976 Medical Device Amendments is provided in the Code of Federal Regulations. The regulation for these Class III devices that require a PMA states that the device is Class III and will provide an effective date of the requirement for PMA. If the regulation states that "No effective date has been established of the requirement for premarket approval," a Class III 510(k) should be submitted.[237]

Premarket Notification: the 510(k) Application

Most medical devices receive premarket review through the 510(k) process.[238] In fiscal year 2000, the FDA reviewed 4,397 510(k) submissions.[239] All classes of medical devices, namely Class I, Class II and Class III are required to register with the FDA in accordance with section 510(k) of the Federal Food, Drug and Cosmetics Act.[240] A 510(k) is not a "form," but rather a package of information containing many different parts or elements.[241] For non-exempt Class I and Class II devices, a 510(k) is the way to provide pre-market notification to the FDA. For Class III devices, a 510(k) presents sufficient information for the FDA to determine whether the device is substantially equivalent (SE) to other, similar, legally marketed devices *predicate devices*, thereby receiving market authorization.[242] A predicate device is: 1. a device legally marketed device prior to Medical Device Amendments of 1976; 2. a device reclassified from Class III to Class II or I; or 3. a device which has already been found to be substantially

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[237]Center for Device and Radiological Health, U.S. Food and Drug Administration, *Device Advice, Premarket Approval (PMA) Introduction*, *at* http://www.fda.gov/cdrh/devadvice/pma/index.html#introduction (last updated Nov. 1, 2002).

[238]*CDRH Annual Report Fiscal Year 2000, supra* note 227.

[239]*Id.*

[240]FDCA, § 510(k), 21 U.S.C. § 360(k) (2002).

[241]21 C.F.R. § 807.92 (2002) (defining content for 510(k) summary).

[242]21 C.F.R. § 807.92(b) (2002) (defining predicate device for 510(k) application).

equivalent through the 510(k) premarket notification process.[243] A predicate device therefore cannot be a Class III device that has gone through the PMA process. The FDA has recently implemented Special 510(k): Device Modification" option, which utilizes certain aspects of the Quality System Regulation, and the "Abbreviated 510(k)"

Product Development Protocol

Another avenue for regulatory approval of Class III devices is the Product Development Protocol ("PDP").[244] The intention of the Product Development Protocol was to ease the regulatory requirements for devices that are subject to modification during development.[245] The PDP application merges device investigation and development of approval information into a single procedure.[246] In 1998 4 PDP were approved,[247] and in 1999 only 2.[248] Thus, the PDP application does not present a commercially significant avenue for device approval.

V. Call for Legislative Action in Roche v. Bolar

In 1984, the newly formed United States Court of Appeals for the Federal Circuit[249] decided the case of Roche v. Bolar.[250] For the first time, exclusive jurisdiction over appeals in patent cases were vested in a single, national, article III court.[251] At issue, Roche Products, Inc.

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[243] *Id*.

[244] FDCA, § 515(f), 21 U.S.C. § 360e(f) (2002) (defining Product Development Protocol for Class III medical devices).

[245] H.R. Rep. No. 94-853, at 32-34 (1976).

[246] *Id.*

[247] Center for Device and Radiological Health, U.S. Food and Drug Administration, *CDRH Annual Report Fiscal Year 1998*, at 3, *available at* http://www.fda.gov/cdrh/annual/fy2000/annualreport-2000.pdf.

[248] Center for Device and Radiological Health, U.S. Food and Drug Administration, *CDRH Annual Report Fiscal Year 1999*, at 6, *available at* http://www.fda.gov/cdrh/annual/fy99rpt.pdf.

[249] *See generally* Hon. Randall R. Rader, *Introduction: Specialized Courts: The Legislative Response*, 40 Am UL Rev. 1003 (1991).

[250] Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

[251] *Id.* at 1008.

owned the patent[252] on an active ingredient for the prescription sleeping pill "Dalmeny."[253] Roche sought to enjoin generic drug manufacturer, Bolar Products, Inc., from taking regulatory steps necessary to obtain premarket approval of a generic equivalent drug. Bolar did not wait for the patent to expire, but rather purchased the active ingredient from a foreign manufacturer for the purpose of obtaining necessary data in support of a new drug application before the FDA.[254] Tracing the doctrine of experimental use, and noting that Congress has never defined the term "use" as a predicate for patent infringement under 35 U.S.C. § 271(a), the United States Court of Appeals for the Federal Circuit held that pre-made activity in anticipation for regulatory approval was infringement. Further, the court pointed to pending legislation before Congress, namely the Drug Price Competition Act of 1983,[255] while inviting Congress to change the rule with explicit and even shameless language.[256] Congress answered with the Hatch-Waxman Act, confirming that "section 202 of the bill [will] have the net effect of reversing the court in Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc."[257] Thus, 35 U.S.C. § 271(e)(1) is known as the Bolar exemption to patent infringement.[258]

VI. Non Hatch-Waxman Patent Term Extensions of FDA Regulated Products

Title 35 of the United States Code sets forth three codified public laws for extending patent terms of articles regulated by the Food and Drug Administration, namely §§ 155, 155A,

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[252]U.S. Patent No. 3,299,053 (issued Jan. 17, 1967, expired Jan. 17, 1984).

[253]*Roche Prods.* at 860.

[254]*Id.*

[255]H.R. 3605, 98th Cong. (1983).

[256]*Roche Prods.* at 867.

[257]H.R. Rep. No. 98-857, pt. 2, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711.

[258]*See generally* Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 J.L. & Tech. 389, 410 (1999) (defining 35 U.S.C. § 271(e)(1) as the Bolar exception to patent infringement).

and 156.[259] Moreover, a number of private laws[260] and at least one non-codified public law have extended patent terms of selected drug patents. These particular patent extensions were enacted prior to or during the same legislative session as the Hatch-Waxman Act. In order to avoid confusion, the codified non-Hatch-Waxman patent term extensions (§§ 155 & 155A) and non-codified patent term extensions are presented to distinguish from the Hatch-Waxman Patent Term Extension (§ 156) discussed below.

Patent Term Extension under 35 U.S.C. § 155

Title 35, section 155 of the United States Code is a public law[261] that extends the term of a patent which encompasses a composition of matter subject to regulatory review by the Federal Food and Drug Administration, and for which there has been a stay of regulation of approval imposed pursuant to section 409 of the Federal Food, Drug, and Cosmetics Act, which stay was in effect on January 1, 1981. The United States Patent and Trademark Office ("USPTO") publishes a listing of all patents, 22 in total, that have been subject to extension under 35 U.S.C. § 155.[262] According to the USPTO, all published patent term extensions under section 155 relate to the FDA regulated product Aspartame.[263] A stay of effectiveness for aspartame was granted by the FDA on December 5, 1975[264] and was lifted on October 22, 1981.[265]

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[259]35 U.S.C. §§ 155 - 156 (2002). 35 U.S.C. § 154(b) adjusts patent term for delays resulting from the administrative patent acquisition process. Patent Term Guarantee Act of 1999, Pub. L. No. 106-113, §§ 4401-4405, 113 Stat. 1501, app. 557-561 (9th of 9 bills in appendix) (codified at 35 U.S.C. § 154(b) (2002)).

[260]Priv. L. No. 98-34, 98 Stat. 3430 (*approved* Oct. 19, 1984), Priv. L. No. 98-46, 98 Stat. 3434 (*approved* Oct. 19, 1984).

[261]Act of Jan. 4, 1983, Pub. L. No. 97-414, § 11(a), 96 Stat. 2065-2066 (codified as amended at 35 U.S.C. § 155 (2002)).

[262]United States Patent and Trademark Office ("USPTO"), *PATENT TERMS EXTENDED UNDER 35 USC § 155*, *at* http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html (last modified Nov. 15, 1996).

[263]*Id.*

[264]40 Fed. Reg. 56,907 (Dec. 5, 1975).

[265]46 Fed. Reg. 50,947 (Oct. 16, 1981).

The most recently issued patent from the USPTO listing, U.S. Patent No. 4,277,464, was issued on July 7, 1981, and had a corresponding issue date originally set to expire on July 7, 1998.[266] The patent term of U.S. Patent No. 4,277,464 was extended five years, ten months, and 17 days[267] in accordance with 35 U.S.C. § 155, and therefore will expire on May 24, 2004.

The USPTO published listing of patents extended under section 155 only lists issued patents.[268] To determine if additional patent term extensions are possible under 35 U.S.C. § 155, a two-fold analysis is required. First, a determination must be made whether any possible pending patents may be issued claiming priority from the original aspartame patent application. Although pending patent applications are generally kept in confidence by the USPTO,[269] a patent now issuing from such an application would be limited in its original term to twenty years from application priority date.[270] Further, because the latest in time priority date of all aspartame patents is March 28, 1979,[271] corresponding to a maximum patent ending March 28, 1999,[272] no other aspartame patents may be granted.

Next, a determination must be made whether 35 U.S.C. § 155 applies to any other regulated compositions of matter other than aspartame.[273] The authority to "stay [a] regulation of approval," and thereby invoke the patent term extension provision 35 U.S.C. § 155, at first blush

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[266]35 U.S.C. § 154(a)(2) (1981) (patent term ending 17 years from issue date) (amended 1994, patent term ending 20 years from filing date).

[267]*PATENT TERMS EXTENDED UNDER 35 USC § 155*, *supra* note 262.

[268]Id.

[269]35 U.S.C. § 122(a) (2002) (U.S. patents generally published eighteen months from filing, but USPTO may withhold publication upon request of applicant. 35 U.S.C. § 122(b)(2)(B)(i) (2002).)

[270]35 U.S.C. § 154(a)(2) (2002).

[271]United States Patent No. 4,277,464 (filed Mar. 28, 1979 as a Continuation of Ser. No. 614,995 filed Sept. 19, 1975, and issued July 7, 1981).

[272]U.S. Patent No. 4,277,464 only has a term date ending May 24, 2004 because the patent issued with an original term determined from the date of issue. New patents would issue with an original term determined from the date of filing, and therefore could not be extended under 35 U.S.C. § 155.

[273]The regulation for Aspartame is Title 21, Code of Federal Regulations, section 172.804. 21 C.F.R. § 172.804 (2002).

seems confusing. However, section 409(c)[274] of the FDCA requires the establishment of a "regulation" to prescribe the conditions of use for a food additive.[275] In other words, each food additive is given its own regulation section in Title 21 of the Code of Federal Regulations, namely section 172.[276] Thus, section 409(e) of the Federal Food, Drug, and Cosmetics Act permits the Commissioner of Food and Drugs[277] to stay the effectiveness of any "regulation."[278] A stayed regulation is retained within Title 21 of the Code of Federal Regulations, but a notation is made next the affected regulation.

Finally, to determine possible regulatory stays under section 409 of the Federal Food, Drug, and Cosmetics Act that were pending as of January 1, 1981 (the effective date of 35 U.S.C. § 155), a review of all regulations under Title 21, Code of Federal Regulations, section 172 was made. Of the one hundred and twenty-two food additive regulations listed in the 1981 edition of Title 21 Code of Federal Regulations, only aspartame, section 172.804[279] was stayed. A review of the Federal Register Annual Index, January - December 1980[280] indicates that no other regulatory stays for food additives were issued in 1980.[281]

Title 35, section 155 of the United States Code is no longer possibly effective to grant extensions of patent term. There is a considerable burden placed on the government, the publishers, and private attorneys when this section is amended, such as in accordance with

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[274]FDCA, § 409(c), 21 U.S.C. § 348(c) (2002).

[275]*Id.*

[276]21 C.F.R. § 172 (2002).

[277]The Commissioner of the FDA regulates under delegated authority from the Secretary of Health and Human Services. 21 C.F.R. § 5.10 (2002).

[278]FDCA, § 409(e), 21 U.S.C. § 348(e) (2002).

[279]21 C.F.R. § 172.804 (Apr. 1, 1980) (amended to remove stay 46 Fed. Reg. 50,947 (Oct. 16, 1981)).

[280]45 Fed. Reg. Index 114 (Jan. - Dec. 1980 Annual) (indexing volume 45 - numbers 1-252, pages 1-87012 of the Federal Register).

[281]As a check, I confirmed that the stay of effectiveness for aspartame was listed in the 1975 Annual Index of the Federal Register. 40 Fed. Reg. Index 80 (Jan. - Dec. 1975 Annual) (indexing volume 40 of the Federal Register).

technical corrections to the United States Patent Laws.[282] Further, this section presents considerable confusion to practitioners, scholars, and adjudicators when trying to determine possible applicability to a subject patent. Thus, 35 U.S.C. § 155 should be repealed.

Patent Term Extension under 35 U.S.C. § 155A

Title 35, section 155A, United States Code is a pubic law that extends the term for patents defined therein by reference to correspondence between the Federal Food and Drug Administration and the patentee.[283] By its terms, section 155A extends the term of patents that encompasses a composition of matter which is a new drug product, if during regulatory review: (A) the FDA sent the patentee a letter dated February 20, 1976; (B) in 1977 the patentee submitted health effects results to the FDA; (C) the FDA approved the drug in a letter dated December 18, 1979; and (D) the FDA approved a supplementary application by a letter dated May 26, 1981.[284] The history of Title 35, section 155A[285] indicates that this legislation was particularly drafted to extend the patent life of Forane(R).[286] The Amendment was introduced on the senate floor to extend the patent life of a "new life-sustaining anesthetic called Forane."[287]

According to the United States Patent and Trademark Office, only one product and two patents were subject to the provisions of Title 35, section 155A, namely Forane(R), embodied in U.S. Patent Nos. 3,535,388 and 3,535,425.[288] Forane(R) is the proprietary name of Isoflurane,

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[282]Intellectual Property and Communications Omnibus Reform Act of 1999, § 4732(a)(6), Pub. L. No. 106-113, 113 Stat. 1536, 4732 (appearing as the 9th of 9 bills in an appendix to Pub. L. No. 106-113) (codified at 35 U.S.C. § 155 (2002)) ("Section 155 of Title 35, United States Code, is amended by striking 'Commissioner of Patents and Trademarks' and inserting 'Director'.").

[283]35 U.S.C. § 155A (2002).

[284]Id.

[285]129 Cong. Rec. 11,509 (1983).

[286]U.S. Trademark Reg. No. 978,040 (registered Feb. 5, 1974) (status LIVE).

[287]Id.

[288]United States Patent and Trademark Office ("USPTO"), *PATENT TERMS EXTENDED UNDER 35 USC § 155A*, *at* http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html (last modified Nov. 15, 1996).

which is a liquid inhalation anesthetic, listed as an approved drug[289] in application number 017624 in the FDA Orange Book.[290] New drug applicants are required to provide patent information to the FDA along with a new drug application or within 30 of receiving the patent.[291] This information is then listed in the FDA Orange Book.[292] There are no patents listed in *Approved Drug Products with Therapeutic Equivalence Evaluations ("The Orange Book")*[293] for Forane(R).[294]

Title 35, section 155A, United States Code is no longer effective to grant extensions of patent term. As with section 155, there is a considerable burden placed on the government, the publishers, and private attorneys when this section is amended, such as in accordance with technical corrections to the United States Patent Laws.[295] As with section 155, this section presents considerable confusion to practitioners, scholars, and adjudicators when trying to determine possible applicability to a subject patent. Thus, 35 U.S.C. § 155A should be repealed.

Patent Term Extensions under Non-codified Public Laws

The term of one patent, U.S. Patent No. 3,674,836 (issued Jan. 18, 1977), was extended under a non-codified portion of the Omnibus Trade and Competitiveness Act of 1988.[296] No legislative history was evident from the Congressional Record, although the public law itself

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[289]21 C.F.R. § 314.3 (2002).

[290]The Orange Book, *supra* note 177, App. No. 017624 (Oct. 2002).

[291]FDCA, § 505(b)(1), (c)(2), 21 U.S.C. § 355(b)(1), (c)(2) (2002); 21 C.F.R. § 314.53 (2002).

[292]FDCA, § 505(b)(1), 21 U.S.C. § 355(b)(1) (2002).

[293]The Orange Book, *supra* note 177.

[294]*Id.*

[295]Intellectual Property and Communications Omnibus Reform Act of 1999, § 4732(a)(7), Pub. L. No. 106-113, 113 Stat. 1536, 4732 appearing as the 9th of 9 bills in an appendix to Pub. L. No. 106-113) (codified at 35 U.S.C. § 155A (2002)) ("Section 155A(c) of Title 35, United States Code, is amended by striking 'Commissioner of Patents and Trademarks' and inserting 'Director'.").

[296]Pub. L. No. 100-418, 102 Stat. 1107, 1569-1570 (1988).

cites the patent number.[297] U.S. Patent No. 3,674,836 corresponds to the drug Lopid(R).[298] The original term was set to expire on July 4, 1989 and was extended by three years, six months, to January 4, 1992. Lopid(R) is currently listed in The Official Listing of Therapeutic Equivalence (Orange Book) under application number 018422 without listing of any enforceable patents.[299]

Patent Term Extension under Non-codified Private Laws

Five patents[300] were each extended in term until April 21, 1992 by a private law.[301] The patents related to oral hypoglycemic drugs of the sulfonylurea class.[302] Extension of patent term for each of these patents was published on the USPTO website.[303]

A private law[304] also extended the patent term for U.S. Patent No. 3,376,198 (issued Apr. 2, 1968) for fifteen years. Thus, the original term was extended from April 2, 1985 until April 2, 2000. However, the subject matter of U.S. Patent No. 3,376,198 is currently subject to Investigational New Drug Application No. 546 and is banned from licensing as set forth in the FDA/ORA Compliance Policy Guides Manual.[305]

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[297] *Id.*

[298] United States Patent and Trademark Office ("USPTO"), *PATENT TERMS EXTENDED UNDER PRIVATE LAWS (NOT CODIFIED INTO TITLE 35*, *at* http://www.uspto.gov/web/offices/pac/dapp/opla/term/155.html (last modified Nov. 15, 1996) (incorrectly listing U.S. Patent No. 3,674,836 as extended under a private law rather than a non-codified public law).

[299] The Official Listing of Therapeutic Equivalence (Orange Book), App. No. 018422 (2002).

[300] U.S. Patent Nos. 3,426,067 (issued Feb. 4, 1969), 3,454,635 (issued July 8, 1969). 3,507, 954 (issued Apr. 21, 1970), 3,507,961 (issued Apr. 21, 1970), 3,669,966 (issued June 13, 1972).

[301] Law of Oct. 19, 1984, Priv. L. No. 98-46, 98 Stat. 3434.

[302] *Id.*

[303] United States Patent and Trademark Office ("USPTO"), *PATENT TERMS EXTENDED UNDER PRIVATE LAWS (NOT CODIFIED INTO TITLE 35)*, *at* http://www.uspto.gov/web/offices/pac/dapp/opla/term/law.html (last modified Nov. 15, 1996).

[304] Law of Oct. 19, 1984, Priv. L. No. 98-34, 98 Stat. 3430.

[305] FDA/ORA, *Compliance Policy Guides Manual August 2000 at*, http://www.fda.gov/ora/compliance_ref/cpg/cpgbio/cpg275-100.html (revised Mar. 1995).

The United States Patent and Trademark Office website lists U.S. Patent No. 4,004,039 (issued Jan. 18, 1977) as being subject to extension under private law.[306] This would place the patent term extension date at January 18, 2009. However the USPTO website incorrectly copies data from the Impro product into the '039 product and the file history is currently being pulled.

VII. Patent Term Extension under the Hatch-Waxman Act

The patent term restoration provisions are set forth in section 201 of the Hatch Waxman Act.[307] The Hatch-Waxman Act is intended to restore a portion of the time lost by a patentee during the pre-market regulatory clearance process.[308] However, section 201 of the Act imposes a number of conditions to achieve successful patent term extension, as follows:

1. the patent must be in force at time of application for extension;[309]

2. the patent term is subject to only a one time extension;[310]

3. the patent term extension must be submitted by the patent owner or representative;[311]

4. the approved product cannot be claimed in an earlier issued product patent or a patent previously extended, and the approved product and use cannot be identically disclosed in an earlier issued product patent or a patent previously extended;[312]

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[306] *PATENT TERMS EXTENDED UNDER PRIVATE LAWS* , *supra* note 303 (incorrectly listing patent as "Impro" and copying other data from U.S. Patent No. 3,376,198 listing).

[307] Hatch-Waxman Act, sec. 201, Pub. L. No. 98-417, 98 Stat. 1585, 1598 (codified as amended at 35 U.S.C. § 156 (2002)).

[308] H.R. Rep. No. 98-857, pt. 2, at 21 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2707; Merck & Co. v. Kessler, 80 F.3d 1543, 1547 (Fed. Cir. 1996). *See generally* Bristol-Myers Squibb Co., v. Royce Labs., Inc., 69 F.2d 1130 (Fed. Cir. 1995).

[309] 35 U.S.C. § 156(a) (2002).

[310] *Id.* § 156(b).

[311] *Id*. § 156(c).

[312] *Id. § 156(d).*

5. for non-recombinant DNA method patents, no other issued method patent exists for any therapeutic purpose, and for recombinant DNA method patents, no related use patents are owned;[313]

6. the claimed product has been subject to premarket regulatory review;[314]

7. the regulatory approval is the first approval, or at a minimum a second approval for recombinant DNA technology;[315] and

8. if two approved products are covered by a patent, extension only for the first approved product.[316]

The patent restoration period for a patent issued after the effective date of the Hatch-Waxman Act, may not exceed five years.[317] Further, to calculate the patent restoration period, only one half of the actual regulatory review period may be used.[318] Moreover, if the patent restoration period added to the remaining patent term exceeds 14 years, the restoration period is reduced so that the resulting patent term is 14 years.[319]

VIII. Statutory Construction and Interpretation of the Hatch-Waxman Act

The case of Eli Lilly v. Medtronic[320] required the Supreme Court to provide interpretation to section 202 of the Hatch-Waxman Act, codified at 35 U.S.C. § 271(e)(1). That portion provides, in pertinent part:

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[313] *Id.* § 156(e).

[314] *Id.* § 156(f).

[315] *Id.* § 156(g).

[316] *Id.* § 156(h).

[317] 35 U.S.C. § 156(g)(6)(A) (2002).

[318] 35 U.S.C. § 156(c)(2) (2002) (specifying patent extension to be one half of time periods calculated in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g)).

[319] 35 U.S.C. § 156(c)(3) (2002).

[320] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

> "It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) 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) (2002).

The Supreme Court was left to determine specifically whether "a Federal law which regulates the manufacture, use, or sale of drugs" should be applied narrowly to only cover those specific statute sections regulating drugs, or broadly to cover an entire Act of law (such as the entire Federal Food, Drug, and Cosmetics Act) that regulates multiple products, including drugs.

The factual predicate, for purposes of statutory construction is brief. Eli Lilly owned critical patents[321] for implantable cardiac defibrillators, which are medical devices used in the treatment of heart disease. Medtronic, with full knowledge of the Eli Lilly patents,[322] undertook activities to develop and submit information necessary to obtain premaket device approval from the FDA. Eli Lilly brought suit alleging that the premarket testing by Medtronic constituted patent infringement, and won a judgement totaling $26,666,000.[323] On appeal to the United States Court of Appeals for the Federal Circuit, and before the Supreme Court, Medtronic defended on the grounds that their activity was exempt under 35 U.S.C. § 271(e)(1) as reasonably related to development and submission of information under the FDCA. The Court agreed, reasoning that the purpose of the Hatch-Waxman Act was to remedy distortions at both ends of the patent term for all regulated products, not just drugs. In accordance the *Cannons of Statutory Construction*, the Supreme Court jurisprudence was misplaced.

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[321]U.S. Patent No. Re 27,757 and U.S. Patent No. 3,942,536.

[322]At one time during the 1970s, Medtronic owned rights in those very patents by assignment, but subsequently the project was abandoned and the rights reverted to the inventor. Brief for the Petitioners, *Eli Lilly,* 496 U.S. 661 (citing Pet. App. 24a).

[323]Eli Lilly & Co. v. Medtronic, Inc., 696 F. Supp. 1033, 1041 (E.D. Pa. 1988), *rev'd*, 872 F.2d 402 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

At first it should be emphasized that the phrase *Cannons of Statutory Construction* represents a term of art, and not a rule defined by statute or other authority.[324] The learned treatise *Statutes and Statutory Construction*[325] provides multiple volumes of statutory interpretation while failing to set forth a cohesive set of the *Cannons.* Further, while many scholars and Supreme Court decisions reference and quote from the *Cannons*, a great many writings,[326] including this article, necessarily select for discussion a subset of all possible *Cannons* based on relevance and rhetoric.

1. The Plain Meaning Rule

The *Plain Meaning Rule* is probably the most notorious and often cited *Cannon of Statutory Construction*. Simply put, if the words of the statute are clear, the language must be given effect in the absence of absurdity.[327]

In *Eli Lilly*, Justice Scalia wrote that "[o]n the basis of words alone, [Medtronic's] interpretation seems preferable,"[328] noting that "a bill" becomes "a law" upon presentment to the President of the United States. Thus, Justice Scalia argues that the phrase "a Federal law" may apply to an entire Act of law.[329] However, this analogy strays too far afield from a possible "plain meaning" of the code because every activity regulated by Congress could be included

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[324]This is true even though the term appears throughout the published literature and though Black's Law Dictionary defines *Cannons of Construction* as a "system of fundamental rules and maxims which are recognized as governing the construction or interpretation of written instruments. Black's Law Dictionary 107 (abr. 5th ed. 1983).

[325]Norman J. Singer, *Statutes and Statutory Construction* (6th ed. 2001).

[326]*See generally* Russell L. Weaver, *Some Realism About Chevron*, 58 Mo. L. Rev. 129, 162 (1993) (listing a number of popular *Cannons of Statutory Construction*).

[327]Immigration & Naturalization Serv. v. Cardoza - Fonseca, 480 U.S. 421, 452 (1987) (Scalia, J. concurring) ("Although it is true that the Court in recent times has expressed approval of [the *Expressed Intent Cannon of Statutory Construction*], that is to my mind an ill-advised deviation from the venerable principle that if the language of a statute is clear, that language must be given effect -- at least in the absence of a patent absurdity."). *See generally* 2A Norman J. Singer, *Statutes and Statutory Construction*, § 46:01 (6th ed. 2001) (defining the plain meaning rule with multiple case citations).

[328]*Eli Lilly*, at 666.

[329]*Id*.

within a single "bill," and therefore be referred to as "a law."[330] Even Justice Scalia does not rest his decision on the *Plain Meaning Rule* alone.

2. The Mischief Rule

The *Mischief Rule* looks to the mischief to be corrected by the statute. The *Mischief Rule* was eloquently stated by Judge Learned Hand in *Cabell v. Markham*,[331] to wit:

> [T]he words used, even in their literal sense, are the primary, and ordinarily the most reliable source of interpreting the meaning of any writing: be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

In *Eli Lilly*, Scalia fails to particularly address the *Mischief Rule*, relying more closely on the *Objective Policy Rule* set forth below.

By its terms, *Eli Lilly* relates to the Hatch-Waxman Act. The "mischief," according to most scholarly authorities including the House Report itself, was to "make available more low cost generic drugs by establishing a generic drug approval procedure,"[332] and to "create a new incentive for increased expenditures for research and development of certain products which are subject to premarket approval."[333] The first purpose relates to generic drugs, while the second purpose relates to patent term extension under 35 U.S.C. § 156, not a patent infringement exemption under 35 U.S.C. § 271(e). Accordingly, the *Mischief Rule* favors interpretation of the statute to exclude medical devices from patent infringement exemption.

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[330]*See, e.g.* Intellectual Property and Communications Omnibus Reform Act of 1999, Pub. L. No. 106-113, 113 Stat. 1536 (exemplifying 1 of 9 bills in a separately bound appendix to a public law).

[331]148 F.2d 737, 739 (2d Cir.), *aff'd*, 326 U.S. 404 (1945).

[332]H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[333]*Id.* at 15.

3. The Golden Rule

The *Golden Rule* can be considered a subset of the *Plain Meaning Rule,* or even a contra-positive of the *Mischief Rule,* but is often designed a separate rule for emphasis. According to the *Golden Rule*, a statute should be interpreted to achieve a non-absurd result.[334] To determine whether a result is absurd, reference to the legislative history is usually helpful. However, as observed by at least one scholar, there is a paucity of legislative history on the Hatch-Waxman Act.[335] Nevertheless, a question arises whether it would be absurd to define "a Federal law which regulates the manufacture, use, or sale of drugs"[336] as an entire field of drug law, rather than specific drug regulating sections of the Federal Food, Drug and Cosmetics Act.

As set forth in *United States v. Article of Drug . . . OVA II*,[337] the Federal Food, Drug and Cosmetics Act does not purport to encompass the entire federal field of drug law.[338] Other acts dealing with other aspects of drugs include: the Public Health Service Act;[339] the Controlled Substances Act;[340] the Controlled Substances Import and Export Act;[341] the Narcotic Addict

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[334]United States v. Kirby, 74 U.S. 482, 486-87 (1868) ("All laws should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language, which would avoid results of this character. The reason of the law in such cases should prevail over its letter."). *See generally* Veronica M. Dougherty, *Absurdity and the Limits of Literalism: Defining the Absurd Result Principle in Statutory Interpretation*, 44 Am. U.L. Rev. 127 (1994).

[335]Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food Drug L.J. 187, 187 (1999).

[336]35 U.S.C. § 271(e)(1) (2002).

[337]414 F. Supp. 660 (D.N.J. 1975) *aff'd mem.*, 535 F.2d 1244 (2nd Cir. 1975).

[338]*Id*. at 665 (confirming that the Federal Food, Drug and Cosmetics Act does not encompass the entire federal field of drug law).

[339]42 U.S.C. §§ 262 - 300ff-72 (2002), *available at* http://www.fda.gov/opacom/laws/phsvcact/phsvcact.htm (last updated Nov. 17, 2000).

[340]21 U.S.C. §§ 801 - 889 (2002), *available at* http://www.fda.gov/opacom/laws/cntrlsub/ctlsbtoc.htm (last updated Mar. 20, 2001).

[341]21 U.S.C. §§ 951 - 1105 (2002), *available at* http://www.fda.gov/opacom/laws/csbieact.htm (last updated Mar. 20, 2001).

Rehabilitation Act;[342] the Hazardous Substances Act;[343] the Fair Packaging and Labeling Act;[344] the Poison Prevention Packaging Act;[345] the Caustic Poison Act;[346] and the Federal Trade Commission Act.[347]

Therefore, while it would be absurd to extend the Hatch-Waxman infringement exemption to criminals undergoing rehabilitation in accordance with the Narcotic Addict Rehabilitation Act,[348] a limit must therefore be placed on the reach of the infringement exemption. FDA regulatory activities that were not contemplated and not addressed in the legislative history should simply not be included in the Hatch-Waxman infringement exemption.

4. The Objective Policy Rule

The *Objective Policy Rule*, for lack of a better name,[349] sets forth that statutory construction should be guided not by a single sentence, but rather by provisions of the whole law, while looking its object and policy.[350] The *Objective Policy Rule* is the rule most closely

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[342]42 U.S.C. §§ 3411 - 3426 (repealed 2000).

[343]15 U.S.C. §§ 1261 - 1278 (2002), *available at* http://www4.law.cornell.edu/uscode/15/ch30.html (last visited Nov. 24, 2002).

[344]15 U.S.C. §§ 1451 -1461 (2002), *available at* http://www.ftc.gov/os/statutes/fpla/fplact.html (last updated Nov. 20, 2002).

[345]15 U.S.C. §§ 1471 - 1476 (2002), *available at* http://www4.law.cornell.edu/uscode/15/ch39A.html (last visited Nov. 24, 2002).

[346]15 U.S.C. §§ 401 - 411 (repealed 1960).

[347]15 U.S.C. §§ 45 - 58 (2002), *available at* http://www.fda.gov/opacom/laws/ftca.htm (last updated Apr. 16, 2001).

[348]42 U.S.C. §§ 3411 - 3426 (repealed 2000).

[349]The name *Objective Policy Rule* was coined by the author.

[350]"[I]n expounding a statute, we are not . . . guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." Massachusetts v. Morash, 490 U.S. 107, 115 (1989) (Stevens, J., delivering a unanimous Court opinion) (quoting Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987)). *See generally* 2A Norman J. Singer, *Statutes and Statutory Construction*, § 46:05 (6th ed. 2001) (supporting interpretation of statute as a whole with multiple case citations).

followed by Justice Scalia in *Eli Lilly*, to wit "[w]e think the Court of Appeals' interpretation is confirmed, however, by the structure of the 1984 Act taken as a whole."[351]

To support application of the medical device infringement exception under 35 U.S.C. § 271(e), Justice Scalia affirms that the text of sections 201 (extension of patent term) and 202 (exemption of infringement) of the Hatch-Waxman Act are complementary, and that there is a "product fit" between the two sections.[352] However, Justice Scalia fails to address the separate regulatory approval protocols for drugs and devices, which were so exhaustively set forth at the top of this article. For example, the Medical Device Amendments of 1976,[353] while seeking to parallel in some respects the New Drug Application Protocol embodied in the 1962 Amendments, made significant departures in both regulatory review and approval. Accordingly, it is respectfully submitted that the *Objective Policy Rule* should be employed by the Court to interpret the Hatch-Waxman Act within the entire body of FDA regulatory law, not just select provisions of the Hatch-Waxman Act. The separate standards and regulation protocols of drugs and medical devices clearly show an objective policy to treat these products separately.

5. Expressio Unius est Exclusio Alterius

The *Cannon* of *Expressio Unius est Exclusio Alterius* sets forth that expression of one thing is the exclusion of the other.[354] In other words, when Congress includes particular language in one section of a statute but omits it in another section of the same Act, "it is

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[351]*Eli Lilly* at 669.

[352]*Eli Lilly* at 674.

[353]Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

[354]Christensen v. Harris County 529 U.S. 576, 583 (2002) ("We accept the proposition that 'when a statute limits a thing to be done in a particular mode, it includes a negative of any other mode.'") (quoting Raleigh & Gaston R. Co. v. Reid, 80 U.S. 269 (1872)). *See generally* Laurence H. Tribe, *Taking Text and Structure Seriously: Reflections on Free-Form Method in Constitutional Interpretation*, 108 Harv. L. Rev. 1221, 1241-42 (1995) (detailing interpretation of *expressio unius est exclusio* as applied to the Constitution by Alexander Hamilton). The doctrine of "expressed intent" sets forth that the text of the legislation itself is the best evidence of legislative intent or will. 2A Norman J. Singer, *Statutes and Statutory Construction*, § 46:03 (6th ed. 2001) (defining doctrine of expressed intent as a preference for literal statutory construction).

generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."[355]

In accordance with the *Cannon* of *Expressio Unius est Exclusio Alterius*, the phrase "a Federal law which regulates the manufacture, use, or sale of drugs"[356] does not mean the Federal Food, Drug and Cosmetics Act because Congress specifically referred to "the Federal Food, Drug and Cosmetics Act", "the Act" or "such Act" elsewhere in the Hatch-Waxman Act. Moreover, Congress emphasized its intent by specifically referencing the "Act" thirty times within the Hatch-Waxman Act, while only referencing "a Federal law which regulates drugs" once. Thus, while Justice Scalia posits that the phrase "a Federal law which regulates" summons the image of an entire statutory scheme of regulation,[357] this single deviation from thirty other references to "the Act" weighs in favor of a different meaning and construction. Under the *Cannon* of *Expressio Unius est Exclusio Alterius*, the only logical construction is one more narrow in scope, namely individual statutory sections regulating drugs.

5. The Doctrine of Intentionalism

The doctrine of *Intentionalism* is best characterized as a theory of statutory construction[358] rather than a cannon. *Intentionalism* defines the original legislative intent as the touchstone of statutory interpretation.[359] At least one Supreme Court case has limited their role to a determination of Congressional intent when enacting a statute.[360] Intent may be obtained

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[355]INS v. Cardoza-Fonseca, 480 U.S. 421, 432 (1987) (quoting Russello v. United States, 464 U.S. 16, 24 (1983)).

[356]35 U.S.C. § 271(e)(1) (2002).

[357]*Eli Lilly* at 666.

[358]Three competing foundationalist theories of statutory construction include: 1. intentionalism. the actual or presumed intent of the legislature enacting the statute; 2. purposivism, the actual or presumed purpose of the statute (also known as "modified intentionalism"); and 3. textualism, the literal commands of the statutory text. William N. Eskridge, Jr. & Philip P. Frickey, *Statutory Interpretation as Practical Reasoning*, 42 Stan. L. Rev. 321, 324 (1990).

[359]*Id.*

[360]Commissioner v. Engle, 464 U.S. 206, 214 (1984) ("Our sole task in this case is to determine whether Congress, in enacting the § 613A 'limitation,' intended to deny the allowance for percentage depletion on advance royalty or lease bonus income altogether.").

from a review of the legislative history, including House and Senate Reports, as well as Subcommittee Reports and debate in the Congressional Record. *Intentionalism* suffers from critique when applied to an overall theory of Congressional intent, because the views of a legislative subgroup may be in tension with the requirements of bicameralism and presentment inherent in article I of the Constitution.[361] Nevertheless, *Intentionalism* is a powerful tool, especially when analyzing legislative understanding of a particular section of an Act.

The House Report accompanying the Hatch-Waxman Act clearly and unambiguously sets forth the legislative intent:

> In Section 202 Congress would provide that it is not an infringement to make, use, or sell a patented invention, solely for uses reasonably related to the development and submission of information for the purpose of obtaining FDA pre-marketing approval of *a drug*. The purpose of the provision is to overturn the ruling in *Roche* . . . . That case held that Bolar infringed a patent . . . to prepare a submission to the FDA for the purpose of enabling Bolar to market *the drug*.[362]

Furthermore, the understanding of the Committee on the Judiciary was that the Hatch-Waxman Act was limited to drug testing:

> First, the *only* activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute.[363]

Thus, under a theory of *Intentionalism*, interpretation of the patent infringement exception within the Hatch-Waxman Act should be applied narrowly to only cover drugs.

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[361]U.S. Const. art. I, § 7. Absent subsequent judicial review and interpretation of a statute, there is little need for the provision of legislative reports in the first place.

[362]H.R. Rep. No. 98-857, pt. 2, at 27 n.18 (1984) (opinion of the Library of Congress, American Law Division) (emphasis added), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2660.

[363]H.R. Rep. No. 98-857, pt. 2, at 8 (1984) (emphasis added), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2692.

6. The Views of the Draftsmen

The *Views of the Draftsmen* have been criticized as a means of statutory construction.[364] However, when the *Views of the Draftsmen* include a unified interpretation from the both the House of Representatives and the Senate, and when the *Views* are by the principal architect of the legislation, such authority is compelling and should be given weight during in statutory interpretation. The *Views of the Draftsmen* should be given additional weight when they are consistent with objective evidence taken from the legislation itself.

The Hon. Senator Orrin G. Hatch, the name sake of the Hatch-Waxman Act, filed a *Pro Se Brief of Amici Curiae* before the Supreme Court in *Eli Lilly* along with Hon. Representative Carlos J. Moorhead.[365] The *Pro Se Brief* defines Sen. Hatch as "the principal, if not sole, author of the senate bill which ultimately was enacted into law as 35 U.S.C. § 271(e)(1)."[366] Likewise, Rep. Moorhead is defined as "a primary manager of the legislation on the floor of the House of Representatives."[367] The *Pro Se Brief* states that "[c]ongress intended to restrict the infringement exemption exclusively to [the] narrow holding of *Roche* limited to human drugs."[368]

The integral relationship of authors Sen. Hatch and Rep. Moorhead serve as the best evidence of Congressional intent based on consistency with the historical pretext of the Hatch-Waxman Act, namely a response to *Roche v. Bolar*.[369] The *Views of the Draftsmen* weigh in favor of not exempting medical devices from premarket infringement.

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[364]2A Norman J. Singer, *Statutes and Statutory Construction*, § 48:12 (6th ed. 2001) ("In this country, as in England, the views of draftsmen are not generally considered appropriate grounds upon which to base interpretation.").

[365]Pro Se Brief of Amici Curiae, *Eli Lilly,* 496 U.S. 661 (submitted by Hon. Orrin G. Hatch, United States Senator & Hon. Carlos J. Moorhead, United States Representative).

[366]*Id.*

[367]*Id.*

[368]*Id.* at 2.

[369]Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

IX. Corrective Legislation and Conclusion

The totality of statutory interpretation in accordance with the *Cannons of Statutory Construction* (admittedly as defined by the author) weigh in favor of withholding a patent infringement exemption from medical devices during regulatory review. Nevertheless, corrective legislation is offered as follows:

1. Proposed Amendment to 35 U.S.C. § 271(e)

The proposed amendment to 35 U.S.C. § 271(e), along with an affirmation of intent in the Congressional Record should rectify judicial interpretation in accordance with the original legislative intent:

> (e) (1) 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 (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information [under] <u>to comply with specific statutory sections of</u> a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

2. Legislative repeal of 35 U.S.C. §§ 155, 155A

As a further recommendation, 35 U.S.C. §§ 155, and 155A should be repealed because they are confusing, ineffective, and place an undue burden on practicing attorneys, scholars, the judiciary, regulatory agencies, publishers, and legislators.

X. Recent Developments concerning Hatch-Waxman

During the course of writing this paper, there have been a few recent developments that may impact pharmaceuticals and medical devices regulated in accordance with the Hatch-Waxman Act. These recent developments are briefly outlined below.

Medical Device User Fee and Modernization Act of 2002

On October 26, 2002, president George W. Bush signed the Medical Device User Fee and Modernization Act of 2002.[370] The Modernization Act amends the FDCA to require user fees for certain premarket reviews, namely: PMAs, PDPs, BLAs, certain supplements, and 510(k)s. Small businesses having less than $30 million in sales, may be entitled to a reduced fee or a fee waiver.[371] The White House announced the benefits of a "reasonable user fee" to add more expert staff to the FDA.[372] This appears to be a step toward making the FDA completely user fee based, like the USPTO.

In addition, the Modernization Act authorizes inspections of medical device manufacturing facilities by accredited third-parties under prescribed conditions. Further, new regulatory requirements are provided for reprocessing of so-called "single-use" devices.

Greater Access to Affordable Pharmaceuticals ("GAAP") Act

The Greater Access to Affordable Pharmaceuticals ("GAAP") Act[373] passed the Senate on July 31, 2002 with an amendment by Yea-Nay Vote of 78 - 21.[374] At present the GAAP Act is currently on hold at the desk in the House. Due to the popular support received by the GAAP Act in the Senate, a version is likely to eventually pass through the House. GAAP proposes a remedy by civil action for correction or deletion of listed patent information with the FDA. Moreover, applicants failing to list their patent with the FDA in a timely manner are barred from pursuing a claim for patent infringement. GAAP further proposes to remove the 30 month stay regarding certain patent infringement contingencies, and to provide limited exclusivity for accelerated generic drug applicants.

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[370]Pub. L. No. 107-250, 116 Stat. 1588 (2002) (codified in scattered sections of 21 U.S.C.).

[371]*Id.*

[372]The White House President Gworge W. Bush, *President Bush Signs Two Bills to Improve Health Care*, *at* http://www.whitehouse.gov/news/releases/2002/10/print/20021026.html (Oct. 26, 2002).

[373]S. 812, 107th Cong. (2002).

[374]Bill Summary & Status for the 107th Congress, *S.812*, *at* http://thomas.loc.gov/cgi-bin/bdquery/z?d107:SN00812:@@@X (last action Sept. 4, 2002).

Proposed Rule Changes in Federal Register

On October 24, 2002, the FDA announced proposed rules[375] that would implement significant changes in current generic drug policy. The proposed rules intend to implement Federal Trade Commission Regulations by changing the automatic 30 month stays for paragraph iv certifications, as well as the drug patent listing process. The FTC, by way of a study entitled Generic Drug Entry Prior to Expiration,[376] identified seven brand-name drugs that unnecessarily benefitted from repeated 30-month automatic stays, thereby significantly delaying patient access to generic drugs.[377] The study provides recommendations that are embodied in the FDA proposed rule changes.

According to the proposed rule changes, pioneer drug manufacturers would be limited to a single 30 month stay per generic application. Multiple stays would not be permitted. Further, drug manufacturers would no longer be entitled to list patents in the FDA Orange Book for auxiliary items to the drug itself, such as packaging, drug formulations and use. False statements with regard to the Orange Book provide stiff penalties and possible criminal charges.

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[375]67 Fed. Reg. 65,448-65 (2002).

[376]Federal Trade Commission, *Generic Drug Entry Prior to Expiration* (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[377]*Id.*