GENERIC DRUGS POST *NOVO NORDISK*

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Generic pharmaceuticals provide the public with the opportunity to purchase low cost medications after these medications' patents have expired. This system is created through the Hatch Waxman Act which strikes an important balance between providing developmental entities an opportunity to recoup their research and development costs through a patent monopoly and allowing generic alternatives to be developed and FDA approved as a low cost alternative. This balance creates an innovative engine that powers both economic improvement and public health. This balance is at risk after the Federal Circuit's 2010 decision in Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Inc. *The outcome of this case allows developmental entities to use the FDA regulation system to lengthen their pharmaceutical monopolies. This paper will discuss the interaction between the patent system and FDA regulation, the policies that are at issue, the effects of* Novo Nordisk, *and potential solutions to this unique problem.*

I. INTRODUCTION

Entrepreneurship is the engine that powers innovation. Professor Greg Watson of the University of Pennsylvania defines entrepreneurship as "a process through which individuals identify opportunities, allocate resources, and create value."[1] He elaborates on this point by stating that value is often created "through the identification of unmet needs or through the identification of opportunities for change."[2] The scope of the entrepreneurial spirit is broader than just a small start-up or a sole proprietorship, it encompasses innovation at all levels of business.

Innovation is powered by entrepreneurship and the United States Patent System provides a policy structure which allows innovation to move with continuous acceleration. This system is so paramount to improvements in technology that in 1858 Abraham Lincoln stated that the discovery of America, the perfection of printing and the introduction of patent laws were

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[1] Greg Watson, *Definition of Entrepreneurship*, ENTREPRENEURSHIP, EDUC., & ETHICS, http://www.gregwatson.com/entrepreneurship-definition/ (last visited Mar. 28, 2012).

[2] *Id.*

the three most important developments in the world's history.[3] A patent accelerates innovation as a dual-engine system. A patent is ostensibly a contract between an inventive entity and the government, or, put differently, an inventive entity and the American people. The inventor receives a twenty-year monopoly on the sale and use of the invention in exchange for releasing the invention to the public in a manner in which one skilled in the art of the particular invention will be able to use the invention without undue experimentation.[4]

This creates an incentive for innovation in two ways. The first incentive is the obvious monetary incentive that an inventive entity will hold a monopoly over the technology for twenty years offering the inventive entity an opportunity to recoup upfront research and development costs and profit from the investment.[5] The second incentive is the expiration of the patent.[6] The expiration of patent protection allows any entity in the public domain to copy and use the invention without first acquiring a license from the patent holder and without the risk of infringement.[7] At first blush this may seem to weaken the incentive for invention because of the risk that the invention's economic success will not be enough to recover the initial research and development costs, as well as the production and marketing costs of selling a new product or a product with novel aspects. There are certainly instances where obtaining patent protection was not, in retrospect, an economically sound decision, but this is a case-by-case analysis and patent protection is often crucial to securing economic protection of an invention and ensuring the invention becomes profitable for the inventive entity.[8]

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[3] *Points to Ponder: A Patent for a President*, U.S. PATENT AND TRADEMARK OFFICE KIDS' PAGES, http://www.uspto.gov/web/offices/ac/ahrpa/opa/kids/ponder/ponder1.htm (last visited Mar. 28, 2012). Another historical anecdote comes from the War of 1812 when the British burned every government building in Washington D.C. except the U.S. Patent and Trademark Office. *Great Patent Fire of1836*, U.S. PATENT AND TRADEMARK OFFICE KIDS' PAGES, http://www.uspto.gov/web/offices/ac/ahrpa/opa/kids/special/1836fire.htm (last visited Mar. 28, 2012).

[4] 35 U.S.C. § 112 (2006).

[5] *Patent Economics: Part 4—Incentives*, PAT. PROSPECTOR (Apr. 17, 2005), http://www.patenthawk.com/blog/2005/04/patent_economics_part_4_incent.html.

[6] *Id.*

[7] *Id.*

[8] Guriqbal Singh Jaiya & Christopher M. Kalanje, *Managing Patent Costs: An Overview*, WORLD INTELL. PROP. ORG., http://www.wipo.int/export/sites/www/sme/en/documents/pdf/managing_patent_costs.pdf (last visited Mar. 28, 2012).

> Merely because an invention meets the criteria of patentability, one should not rush to file a patent application. As a rule of thumb, an enterprise, big or small, should obtain and maintain patent protection over inventions that are or will be used for developing commercially useful technologies and products.

The limited number of years of a patent furthers the policy of innovation originally formulated by the Founders during the drafting of the Constitution. Article 1, Section 8, Clause 8 of the Constitution states: "To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . ."[9] This clause is often referred to as the Patent and Copyright Clause, Intellectual Property Clause, or just the Progress Clause.[10] The name "Progress Clause" highlights the focus on innovation.[11] The original constitutional policy of the Patent and Copyright Clause and the patent laws promulgated by this clause was the promotion of progress and innovation.[12] Without an end to the twenty-year monopoly granted in a patent there would be less incentive for the inventive entity to improve on its technology or invent new technologies because it would be able to perpetually profit from their original idea. It would still be incentivized to improve on its technologies to create more monopolies, but a certainty that the monopoly will end increases the incentive to continue improving on existing technologies. This would limit the "Progress" that the Founders wanted to facilitate in the Constitution. In a more general scope, progress, innovation, and entrepreneurship are intertwining concepts and are pervasive themes of the American experience starting from the county's inception.

This promotion of progress and innovation through the expiration of patents and the incentive that creates for research and development in new technologies is threatened by the recent holding in *Novo Nordisk A/S v.*

> While the cost of acquiring and maintaining patent protection may be significant, it should be noted that patent costs are generally only a small component of the total cost incurred in turning an invention into a commercially useful technology or product, and of marketing and selling it in the domestic or export markets. However, if there is good reason to believe that the profits from an invention will not justify the investment in obtaining patent protection, then, by all means, one should not patent it.

Id.

[9] U.S. CONST. art. VIII, § 8.

[10] *Article 1, Section 8, Clause 8*, THE FOUNDERS' CONSTITUTION, http://press-pubs.uchicago.edu/founders/tocs/a1_8_8.html (last visited Mar. 28, 2012).

[11] Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution*, 2 J. INTELL. PROP. L. 1, 52 (1994) (explainings that the Intellectual Property Clause of the Constitution's goal to promote progress equates to innovation in today's society, "to promote the progress of useful arts presupposed an intent to advance or forward the course or procession of such trades.").

[12] *Id.*

Caraco Pharmaceutical Laboratories[13] (*Novo Nordisk*) from the U.S. Court of Appeals for the Federal Circuit. The holding of *Novo Nordisk* created new developments in patent law with respect to the pharmaceutical industry, which will allow a pharmaceutical company to lengthen its monopoly on a drug by amending the use code required by the FDA to box out generic competitors who are trying to gain approval for a generic version of a drug before the patent expires.[14] Pharmaceutical companies have always been able to obtain a patent on a new use or new combination of a drug, but based on the holding in *Novo Nordisk*, a new use or new combination patent could be used in the FDA process to block any generic competitors from reaching the shelves. While the patent will have expired, the monopoly will remain.[15] The effect of this will be detrimental to the generic pharmaceutical industry and to pharmaceutical innovation.

The ability for generic pharmaceutical companies to compete with name brand pharmaceutical companies creates a competitive market that benefits economic growth and the public at large. Generic pharmaceutical companies provide many important checks and pressures on the pharmaceutical industry.[16] They are able to offer medicine to the general public at a greatly reduced price once the patent covering the drug has expired.[17] More importantly, their competition drives the name brand, or developmental drug companies to continuously create new and improved drugs in order to stay competitive. This balance creates an economic powerhouse of front-end innovation driven by back-end competition. This allows the developmental drug companies to make huge profits through their patented drugs, creates a secondary market of generics, and provides the consumer a continuously healthier life at a reduced price.[18]

The recent ruling in *Novo Nordisk* has made it easier for developmental pharmaceutical companies to lengthen their patents and effectively box out the generic competitors by manipulating the FDA approval process.[19] This holding will have major effects on the pharmaceutical industry in the short and long run. In order to maintain the balance and drive of innovation furthered by the current generic pharmaceutical system, the Supreme Court should overturn this holding or Congress should amend the law to remove this statutory outcome.

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[13] Novo Nordisk A/S v. Caraco Pharm. Labs., 601 F.3d 1359, 95 U.S.P.Q.2d 1031 (Fed. Cir. 2010), *cert. granted*, Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 131 S. Ct. 3057, 180 L. Ed. 2d 884 (2011).
[14] *Novo Nordisk A/S* , 601 F.3d 1359.
[15] *Id.*
[16] David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics,* FED. TRADE COMM'N (Feb. 2002), *available at* http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf.
[17] *Id.*
[18] *Id.*
[19] *Novo Nordisk A/S*, 601 F.3d 1359.

II. OVERVIEW AND BACKGROUND OF PATENT LAW

The current patent law is based on the Patent Act of 1952, codified in Title 35 of the United States Code.[20] This statute allows inventors to obtain patents on processes, machines, manufactures, and compositions of matter that are useful, new, and non-obvious.[21] Granted patents confer the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[22] A patent is a quid pro quo with the U.S. government that the inventive entity will receive a monopoly (generally of twenty years from the date of application) in exchange for the divulgence of all the necessary information for the invention to be replicated by someone who is skilled in the area of the invention.[23] This way when the patent expires, the public at large is free to replicate the invention.[24] This fosters the spread of ideas and gives an economic incentive to innovate.

The primary requirements for patentability are novelty, usefulness and non-obviousness.[25] Novelty means that an invention must be new to be patentable.[26] A person is not entitled to a patent if the invention was known or used by others in this country or patented or described in this or a foreign country before the invention by the applicant for the patent.[27] This prior knowledge, description, or existence of the widget trying to be patented is called prior art.[28]

United States patent law is statutory, and while Title 35 of the U.S. Code contains many provisions, four sections of the patent law carry particular importance with respect to patentability of inventions (101, 102 and 103)[29] and the specification of a patent (112).[30] Section 101 discusses

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[20] The law is currently changing under the America Invents Act of 2011, which is slowly being implemented. This will change some of the statutory language, and an understanding of these changes will come over time as much of the new language will still need to be litigated for practitioners to truly get a handle on their breadth.
[21] 35 U.S.C. § 101 (2006).
[22] Wendy H. Schacht & John R. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act")*, CRS REPORT OF CONGRESS 15–16 (Jan. 10, 2005), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf [hereinafter *Patent Law*] (discussing 35 U.S.C. § 271(g) (2006)).
[23] AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003) ("[A]s part of the quid pro quo of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention.").
[24] 35 U.S.C. § 154 (2006).
[25] 35 U.S.C. §§ 102–103.
[26] 35 U.S.C. § 102.
[27] 35 U.S.C. §§ 102–104.
[28] *Id.*
[29] 35 U.S.C. §§ 101–103.
[30] 35 U.S.C. § 112.

which inventions are patentable.[31] Not every new idea is patentable. The statute states that "[w]hoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."[32] Pure ideas and natural phenomenon cannot be patented because they do not meet this patentability requirement of section 101. Section 102 discusses the conditions required for patentability including novelty and the loss of right to patent.[33] The section lists instances when a person is not entitled to a patent even though the invention passed muster under section 101.[34] An invention is not patentable if it was known, used, patented or described in a publication, in the U.S or a foreign country before the invention by the applicant.[35] An invention is also not patentable if the inventor has abandoned the invention or the inventor did not actually invent the subject matter sought to be patented.[36]

Section 103 also discusses the conditions required for patentability, focusing on the requirement of non-obvious subject matter.[37] The requirement for non-obvious subject matter is found in part (a) of section 103:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.[38]

The section 103 requirement for patentability is that the invention must be non-obvious to someone skilled in the art of the invention.[39] The term "art" in the patent context means the area or field of the invention.[40] For example, a patent for a new strain of drug would be in the "art" of pharmaceuticals, pharmacology, or biochemistry.

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[31] 35 U.S.C. § 101.
[32] *Id.*
[33] 35 U.S.C. § 102.
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] 35 U.S.C. § 103.
[38] *Id.*
[39] *Id.*
[40] U.S. CONST. art. VIII, § 8. "To promote the Progress of Science and useful Arts . . . ."

The phrase "person having ordinary skill in the art" (sometimes shortened PHOSITA) is a legally significant phrase that has been judicially defined.[41] The Federal Circuit in *Environmental Designs, Ltd. v. Union Oil Co.*[42] created a six-factor test to determine whether someone is a PHOSITA. These factors included "[1] the education level of the inventor; [2] type of problems encountered in the art; [3] prior art solutions to those problems; [4] rapidity with which innovations are made; [5] sophistication of the technology; and [6] educational level of active workers in the field."[43] The Supreme Court refined the capabilities of a PHOSITA in the 2007 case *KSR International Co. v. Teleflex Inc.*[44] stating that "[a] person of ordinary skill in the art is also a person of ordinary creativity, not an automaton."[45] Even if there is not a reference that anticipates the patent, the claim is not patentable if the differences between the claim and the prior art at the time of the invention are obvious to someone of ordinary skill in the art.

Obviousness is determined by looking at four factors laid out by the Supreme Court in *Graham v. John Deere Co. of Kansas City*.[46] These factors are the Supreme Court's statutory interpretation of section 103.[47] The four factors are the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed invention and the prior art and objective evidence of non-obviousness (this objective evidence is called secondary concerns).[48]

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[41] *Ordinary Skill in the Art*, THE PAT. PROSPECTOR, (May 9, 2007), http://www.patenthawk.com/blog/2007/05/ordinary_skill_in_the_art_1.html.
[42] Envtl. Designs, Ltd. v. Union Oil Co., 713 F.2d 693 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).
[43] *Id.*
[44] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).
[45] *Id.* at 421 (emphasizing that this definition was more of a refinement and did not necessarily overturn all other Federal Circuit precedent, i.e. Envtl. Designs, Ltd. v. Union Oil Co.).
[46] Graham v. John Deer Co. of Kansas City, 383 U.S. 1 (1966).
[47] *Id.*
[48] *Id. KSR Int'l* added to these factors by laying out an additional set of factors. Existence of any of these factors would support a conclusion of obviousness and include: (1) combining prior art elements according to known methods to yield predictable results, (2) simple substitution of one known element for another to obtain predictable results, (3) use of a known technique to improve similar devices, methods, or products in the same way, (4) applying a known technique to a known device, method, or product ready for improvement to yield predictable results, (5) obvious to try (i.e. there are a limited number of solutions to a known problem), (6) known work in one field may prompt variations of it for use in the same field or a different one based on design incentive or market forces, (7) some teaching, suggestion, or motivation in the prior art that would have lead one of ordinary skill in the art to use the prior art to create the claimed invention). *KSR Int'l*, 550 U.S. 398.

Finally, section 112 describes the specification requirement in a patent.[49] The specification is a written description of the invention and is part of the patent application.[50]

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[51]

Section 112 continues by describing what is required of the claims, the language in the patent application that is written immediately after the specification.[52]

The claims of a patent are the operative language that defines the scope and contours of the property right granted in the patent.[53] The property right granted in a patent through the patent claims is a right to exclude.[54] In the classic bundle-of-sticks model of property rights, the patent holder holds a "right to exclude" stick for the scope of the patent claims for the 20-year patent term. Section 112 of Title 35 contains the statutory language describing the general structure of claims. "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[55] A claim can be written in independent or dependent form.[56] Independent claims are claims that, as a whole, describe the invention or an independent feature of the invention.[57] A dependent claim is a claim that adds at least one additional element to an independent claim.[58] Dependent claims can depend on other dependent claims, with each claim adding an additional feature or features to the original independent claim.[59] Claims are always one sentence

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[49] 35 U.S.C. § 112 (2006).
[50] *Id.*
[51] *Id.*
[52] *Id.*
[53] David V. Radack, *Reading and Understanding Patent Claims*, 47 JOM 69 (1995), *available* at http://www.tms.org/pubs/journals/jom/matters/matters-9511.html.
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] 35 U.S.C. § 112 (2006). Theexact language of the part of § 112 which explains "claims" states that:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or, if the nature of the case admits, in

and are broken into three distinct parts; the preamble,[60] the transitional phrase,[61] and the set of limitations.[62]

> dependent or multiple dependent form. Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers. A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered. An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Id.

[60] *2111.02 Effect of Preamble [R-3]–2100 Patentability*, U.S. PATENT & TRADEMARK OFFICE (Dec. 18, 2008, 11:40 AM), http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2111_02.htm. The claim preamble either creates a limiting structure or a recitation of purpose of intended use. Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. *See, e.g.*, Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257, 9 U.S.P.Q.2d 1962, 1966 (Fed. Cir. 1989) (determining whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim").

> The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.

Corning Glass Works, 868 U.S. at 1257.

[61] *2111.03 Transitional Phrases [R-3]–2100 Patentability*, U.S. PATENT & TRADEMARK OFFICE (Dec. 18, 2008, 11:40 AM), http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2111_03.htm.

> The transitional phrases "comprising," "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim . . . . The transitional term "comprising," which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Id.

See, e.g., Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended"); *In re* Gray, 53 F.2d 520 (C.C.P.A. 1931) ("The transitional phrase 'consisting of'

The United States is currently on a first-to-invent system, meaning that someone can still receive a patent even if they lose the race to file in the patent office.[63] This will change with the implementation of the America Invents Act of 2011, which changes the United States from a first-to-invent patent system into a first-to-file system.[64] This change becomes effective in late 2012 and from that point on the first person to file the patent with the office (assuming it is a patentable invention) will receive the rights to the invention.[65]

Part of the patent agreement between the inventor and the government is that the inventor receives a monopoly for twenty years from the date of filing for the patent on the invention.

> For patents resulting from publications filed after June 8, 1995, the patent term is ordinarily twenty years from the date the patent application was filed. For patents issued prior to June 8, 1995, as well as for patents resulting from applications pending at the U.S. Patent and Trademark Office as of that date, the patent endures for the greater of twenty years from filing or seventeen years from grant.[66]

This is a major issue in pharmaceuticals because there is an extended period of time after filing but before the first sale of the drug can be made in which the drug has to go through extensive testing from the Food and Drug Administration before approval for sale. This is a lengthy and expensive process that is only required of the developmental drug companies.[67]

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excludes any element, step, or ingredient not specified in the claim"); Ex parte Davis, 80 U.S.P.Q. 448, 450 (Bd. App. 1948) ("consisting of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith"). The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re* Herz, 537 F.2d 549, 551–52 (C.C.P.A. 1976). (emphasis in original).

[62] The set of limitations together describe the invention and define the scope of property rights the inventive entity has in the invention.

[63] *First-to-File vs. First-to-Invent: Who Really Benefits from Changing the U.S. Patent System?*, WEALTH OF IDEAS NEWSL. (Oct. 2007), *available at* http://www.generalpatent.com/first-file-vs-first-invent-who-really-benefits-changing-u-s-patent-system.

[64] *Id.* (discussing the America Invents Act of 2011).

[65] *Id.*

[66] *Patent Law*, *supra* note 22.

[67] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Aug. 17, 2011), http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm. (explaining the FDA drug approval process).

III. THE FOOD AND DRUG ADMINISTRATION'S NEW DRUG APPLICATION PROCESS

The process a drug undergoes between initial laboratory discoveries and store shelves is a long process, with most drugs going the way of the lowly Bill on Capitol Hill who is still "just a bill."[68] Most drugs that go through preclinical testing (animal testing) never reach the human testing stage or undergo Food and Drug Administration (FDA) review.[69] Sometimes drugs are initially researched for a particular purpose and are later discovered to be effective for another use.[70] For example, Retrovir (zidovudine) was originally studied in the 1960s as an anti-cancer drug without success.[71] In the 1980s, it was realized that the drug could be used to treat AIDS and was finally approved by the FDA to treat AIDS in 1987.[72]

This is the lengthy process that generic pharmaceuticals are able to mostly circumvent by showing that their drug is effectively identical to the developmental drug company's product. The process through which the generic companies essentially "piggyback" off the developmental company's research and testing will be discussed in greater detail below. This is a major advantage for generic companies.

A. *The New Drug Application Process*

FDA drug review for approval of a new drug is a twelve-step process. Step one is preclinical trials, which consist primarily of animal testing.[73] Step two is an investigational new drug application (INDA).[74] Sponsors, who include companies, research institutions and other organizations, who are responsible for the development of the drug, have to show the FDA the results of the preclinical testing and explain what their plans are for human testing in clinical trials.[75]

The next three steps are the three phases of clinical trials. Clinical trials are drug studies in humans and can only start once the INDA is reviewed by the FDA through a local institutional review board. This board is a panel of scientists and non-scientists employed by hospitals and research faculties that oversee clinical research.[76] The local institutional review board also

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[68] *I'm Just a Bill*, SCHOOLHOUSE ROCK, *available at* http://www.schoolhouserock.tv/Bill.html.
[69] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[76] *Id.*

approves the clinical trial "protocols."[77] The first phase of clinical trials (step three) is typically done with twenty to eighty healthy volunteers and the emphasis is the safety of the new drug.[78] The goal is to determine the most common side effects, and how the drug is metabolized and excreted.[79] The second phase of clinical studies (step four) begins if the toxicity measurements from the first phase are at an acceptable level.[80] Up to three hundred volunteers are studied in phase two and the emphasis of this phase is on the effectiveness of the new drug.[81] The goal is to figure out whether the drug works to treat certain diseases or conditions.[82] This is usually done by giving the drug to one patient and a placebo or a different drug to a similar patient.[83] After this stage, the sponsors and the FDA reconvene to discuss how the large-scale studies of phase three will be performed.[84] Phase three of clinical trials will only begin if effectiveness is shown in phase two.[85] Phase three is a larger-scale study with up to 3000 volunteers.[86] The purpose is to measure the effectiveness and safety of the new drug on a larger scale, using a variety of populations and dosages.[87]

The next step of the new drug review process is the pre-NDA (New Drug Application) period.[88] During this time, the sponsor fulfills post-market and commitment study requirements, which are used by the FDA to gather more information about a drug's safety, efficacy or optimal use.[89] Once the pre-NDA period is completed, the review process continues to the NDA stage.[90] This is the formal step in which the sponsor discloses all their animal and human testing data to the FDA and requests that the FDA consider approving the new drug for marketing in the United States.[91] The Drug Price Competition and Patent Term Restoration Act of 1984[92]

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[77] *Id.*
[78] *Id.*
[79] *Id.*
[80] *Id.*
[81] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Patent Law*, *supra* note 22. This is often called the Hatch-Waxman Act and creates the modern drug approval system with respect to patents. This system lays out the requirements for a new drug to be approved patents and sets up the modern system of generic drugs. This will be discussed in greater detail *infra*.

explained that as part of the NDA process, the sponsor must also identify all patents that claim the drug or a method of its use.[93]

> The applicant shall file with the application *the patent number* and the *expiration date* of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, of the drug.[94]

When the FDA receives an NDA, they have sixty days to decide whether to file the application for review.[95] Once the FDA approves the file for review the NDA undergoes a much more rigorous evaluation to determine whether the drug is safe for use in the United States.[96] The FDA puts together a review team which consists of doctors, statisticians, scientists, and other experts, who evaluate whether the drug is safe and effective for the proposed use.[97] When determining safety, the review team acknowledges that no drugs are completely safe, so the main inquiry is whether the benefits of the drug outweigh the risks. These risks are colloquially known as the side effects of the drug. The review team also analyzes the tests that the sponsor used to determine the safety and effectiveness of the drug to determine whether these were effective and whether there were any flaws in the studies.[98] The reviewers determine whether they agree with the results of the sponsor's studies.[99] The reviewers then create a written evaluation of their conclusions and recommendations with respect to the drug.[100]

When the FDA would like a more thorough review of the new drug they will occasionally use advisory committees. Mark Goldberger, a former director of the FDA's Center for Drug Evaluation and Research (CDER), indicates certain situations when the FDA would decide this is a necessary step. His analysis includes looking at whether "it's a drug that has significant questions, [] it's the first in its class, or the first for a given

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[93] Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1360 (Fed. Cir. 2010). *See also* 21 U.S.C. § 355(b)(1) (2006).
[94] *Novo Nordisk A/S*, 601 F.3d at 1360–61. *See* 21 U.S.C. § 355 (b)(1)(G) (emphasis added by *Novo Nordisk*).
[95] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[96] *Id.*
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*

indication."[101] Generally, when these situations are presented, the FDA will take the advice of its advisory committees, but this is not always the case.

The final three steps for approval start with an FDA review of the information that goes on the drugs professional labeling, which describes how to use the drug.[102] Next, the FDA evaluates the facilities where the drug will be manufactured to ensure they meet FDA standards.[103] Finally, the FDA reviewers will either approve the application or issue a complete response letter explaining any flaws or issues with the application or the drug testing process.[104]

Once a new drug is approved for use by the FDA, the developmental entity is required to register any patents which claim one or more methods of using this drug in the FDA Orange Book through the "use code narrative."[105] This narrative is a description of each of these claimed processes.[106] The use code is a unique number assigned to each of these descriptions. The effect this use code has on the generic drug process is central to the issue in *Novo Nordisk* and will be discussed further *infra*.

B. *Policy Considerations of the New Drug Application Process*

This expensive and extensive process is a major argument for increasing the protection of developmental pharmaceutical companies. Developmental pharmaceutical companies already have the high research and development costs that any inventive entity must pay to develop a new invention, and they also have the unique extra testing that is required by the FDA's new drug application review process.[107] Because of this, developmental drug companies are taking on larger risks when they acquire a patent.[108] This highlights the reasoning behind arguments to lengthen the patent term for pharmaceutical inventions or to provide avenues for certain pharmaceutical patents to gain term extensions.

But there are flaws and criticisms to this argument and to the current pharmaceutical industry model as a whole. These include the financial

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[101] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] Novo Nordisk A/S v. Caraco Pharm. Labs., 601 F.3d 1359, 1361 (Fed. Cir. 2010) Tthe Orange Book is the colloquial name for the Approved Drug Products with Therapeutic Equivalence Evaluations; it is essentially the FDA directory of all approved drugs and their respective patents. *Id.*
[106] *Id.*
[107] Erica Westly, *The Price of Winning FDA Approval*, FAST CO. (Dec. 1, 2009), http://www.fastcompany.com/magazine/141/the-price-of-approval.html (stating that the average out-of-pocket cost for developing a new drug, from inception to approval is $494 million dollars).
[108] *Id.*

barriers that prevent many people in both the developing and developed world from accessing medications, in light of the industry's high profits, and the amount of spending on advertising and marketing, among other issues.[109] The National Institute of Health, Department of Clinical Studies cited six major problems with the patent based drug development system.[110] These include:

> (1) recovery of research costs by patent monopoly reduces access to drugs; (2) market demand rather than health needs determines research priorities; (3) resources between research and marketing are misallocated; (4) the market for drugs has inherent market failures; (5) overall investment in drug research and development is too low, compared with profits; and (6) the existing system discriminates against U.S. patients.[111]

These problems were all cited in 2005, before the *Novo Nordisk* decision. *Novo Nordisk* further adds to the power developmental drug companies have over the process and the profits of the pharmaceutical industry. This power is often to the detriment of the health of society and to the detriment of a system of generic medications, which provide an engine for pharmaceutical innovation.

Typically someone receives a patent for an entirely new invention, but one can also get an improvement patent for an innovation that provides a new use for an existing invention. The Supreme Court first allowed new use patents in 1892 through the holding of *Ansonia Brass & Co. v. Electric Supply Co.*[112] The Court stated:

> [I]f an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability.[113]

New-use inventions are typically done by finding a new and useful process for a known substance or composition.[114] The 1952 Patent Act defined process and included the phrase "includ[ing] a new use of a known

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[109] J.H. Barton, and E.J. Emanuel, *The Patents-Based Pharmaceutical Process: Rationale, Problems, and Potential Reforms*, JAMA, NAT'L INST. OF HEALTH, DEP'T OF CLINICAL BIOETHICS (Oct. 26, 2005), http://www.ncbi.nlm.nih.gov/pubmed/16249422.
[110] *Id.*
[111] *Id.*
[112] Ansonia Brass & Co. v. Elec. Supply Co., 144 U.S. 11 (1892).
[113] *Id.* at 17.
[114] 35 U.S.C. § 100(b) (2006).

process, machine, manufacture, composition of matter, or material."[115] An example of a new-use patent came in 2000 when the Federal Circuit Court of Appeals allowed a patent for the idea of using Bag Balm—an ointment normally used to soothe irritated cow udders—to treat human baldness. The court found it patentable because it was a new use of a known composition.[116] This type of patent is similar to the issue found in *Novo Nordisk,* in which Novo Nordisk patented a new method of using Prandin. The court held that this not only created a new patent, but based on interpretation of the Hatch-Waxman Act, the generic manufactured was unable to receive FDA approval on the original Prandin formula, effectively increasing the length of the original patent.

IV. THE DRUG COMPETITION AND PATENT TERM RESTORATION ACT (HATCH-WAXMAN ACT)

The modern system of generic drugs was created by the Drug Competition and Patent Term Restoration Act, otherwise known as the Hatch-Waxman Act. The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act.[117] This act set up a process in which generic drug companies can file Abbreviated New Drug Applications (ANDAs) to expedite the FDA approval process.[118] A generic drug company can use an ADNA to receive FDA approval of a U.S. generic drug for an existing licensed medication that has been previously approved by the FDA through the twelve-step New Drug Application (NDA) process.[119] The Hatch-Waxman Act also grants a 180-day exclusivity window to generic companies that are the "first-to-file" an ANDA with respect to the developmental holders of the patent's NDA.[120] This 180-day exclusivity allows the first generic to prove bioequivalence and be granted an ANDA. When the developmental drug patent expires, the first generic equivalent will be given 180 days to exclude any other generic versions of this drug.[121] This allows the first generic the profits from being the only alternative to the name brand version and offers them the opportunity to create brand recognition in consumers.

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[115] *Id.*
[116] Kirk Teska, *What Are Improvement Patents and New Use Patents?*, NOLO LAW FOR ALL, http://www.nolo.com/legal-encyclopedia/improvement-patents-new-use-patents-30250.html (last visited Mar. 28, 2012).
[117] *Patent Law*, *supra* note 22.
[118] *Id.*
[119] *Id.*
[120] *Id.*
[121] *Id.*

A. *The Abbreviated New Drug Application Process*

The basis of the Abbreviated New Drug Application is bioequivalence.

> Two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards.[122]

This allows generic drug companies to piggyback off the testing efforts of the developmental pharmaceutical companies by allowing the generic companies to use previous FDA approval of the drug as long as they prove bioequivalence.

> The Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 Act)—commonly known as the 'Hatch-Waxman Act'—made several significant changes to the patent laws designed to encourage innovation in the pharmaceutical industry while facilitating the speedy introduction of lower-cost generic drugs.[123] These changes include: provisions for extending the term of a patent to reflect regulatory delays encountered in obtaining marketing approval by the FDA, a statutory exemption from patent infringement for activities associated with regulatory marketing approval, establishment of mechanisms to challenge the validity of a pharmaceutical patent, and a reward for disputing the validity, enforceability, or infringement of a patented and approved drug. The 1984 Act also provides the FDA with authority to offer periods of marketing exclusivity for a pharmaceutical company, independent of the rights conferred by patents.[124] This means the generic companies can be ready to put their version of the drug on shelves the day the patent expires. This also means that the process of

[122] Donald J. Birkett, *Generics—Equal or Not?*, 26 AUSTRALIAN PRESCRIBER 4, 85–87 (2003), *available at* http://www.australianprescriber.com/upload/pdf/articles/712.pdf.
[123] *Patent Law*, *supra* note 22.
[124] *Id.*

> developing and testing the generic will not be actionable patent infringement because it is protected activity.[125]

Once the generic gains the approved bioequivalence it must assert to the FDA, that sale of the generic will not infringe on any patents. The first step in this process is outlined in a provision of the Hatch-Waxman Act.

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.[126]

Basically, the applicant must state to the FDA which patents are related to this proposed generic drug.

The Hatch-Waxman Act discusses ADNAs and states that the FDA is prohibited from asking a generic drug manufacturer for more than bioavailability studies.[127] The Act lays out conditions for a generic manufacturer to file an ADNA and at least one of these conditions must be met.[128] One of the conditions is met if the drug the generic manufacturer is attempting to emulate is not patented, the patent for the original version has expired, the generic drug will not go to market until after the original patent has expired, or it is proven that the development drug patent is not infringed by the generic version.[129] These four conditions are referred to as paragraph 1–4 certifications.[130]

There is also a focus on patent term restoration for developmental entities in the Hatch-Waxman Act. The bill states that the developmental drug can receive a patent extension term equal to 50% of the time of the investigational new drug (IND) period and the NDA process. These are the three phases of human testing discussed in the previous section.[131] This entire period runs from the start of human testing to the end of the NDA review process.[132] These extensions come with a few limitations. The

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[125] *Id.*
[126] Novo Nordisk A/S v. Caraco Pharm. Labs., 601 F.3d 1359, 1360–61 (Fed. Cir. 2010). *See also* 21 U.S.C. § 355(b)(1) (2012).
[127] Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L. J. 187, 194 (1999), *available at* http://www.regulatorypro.com/FDLI%20-%20Overview%20of%20Hatch-Waxman%20Act%201984.pdf.
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.*
[132] *Id.*

extension is limited to up to five years.[133] This means that the patent will not recuperate any time greater than five years, even if the IND and NDA process exceeds ten years. This is further limited in the Hatch-Waxman Act, which states that the time the drug can receive protection while on the market, after it has received FDA approval, cannot exceed fourteen years.[134] This means that a drug which was initially developed relatively quickly in its pre-clinical trial stages may not receive a full five-year recoupment of FDA approval delays if it would still enjoy fourteen protected years on the market. Also the Hatch-Waxman Act states that if the developmental entity does not exercise due diligence when seeking a patent term restoration, the delay caused by the lack of due diligence will be subtracted from the final patent term extension.[135]

B. *Policy Considerations of the New Drug Application Process*

The Hatch-Waxman Act and the entire generic drug system are premised under two assumptions. The first is that the generic drug is the same as the developmental drug.[136] This is done through a measure of bioequivalence. The FDA requirement states that if the proposed generic has to be within plus-or-minus 20% of the bioavailability of the developmental drug.[137] This means the drug must be 80% or more the same amount of active ingredient in the blood over time.[138] The margin is generally a safe one, but there are instances where this could lead to some dangerous, or at least undesirable, results. One scenario would be a patient taking a medication that is on the "plus 20%" bioavailability range and switching to a similar medication that is on the "minus 20%" bioavailability range.[139] The drugs would technically be bioequivalent, but this would be a 40% shift and could potentially have much different effects on the patient. Some scientists and medical professionals believe that pharmaceutical technology has advanced enough since the Hatch-Waxman Act was passed to tighten this bioavailability range in the interest of safety and effectiveness.[140] These scientists believe this would not be overly

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[133] Mossinghoff, *supra* note 127.
[134] *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 67.
[135] *Id.*
[136] Wendy Schacht & John R. Thomas, *The "Hatch-Waxman" Act: Selected Patent-Related Issues*, CONG. RES. SERVICE, THE LIBR. OF CONGRESS, RES., SCI., AND INDUS. DIV. (April 1, 2002), http://congressionalresearch.com/RL31379/document.php?study=The+Hatch-Waxman+Act.http://congressionalresearch.com/RL31379/document.php?study=The+Hatch-Waxman+Act (hereinafter *The "Hatch-Waxman" Act). See also Patent Law*, *supra* note 22.
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*

detrimental to the generic pharmaceuticals and would benefit the public at large.[141]

The second assumption under which the Hatch-Waxman Act operates is that establishing similarity between two drugs using bioequivalence is an effectual replacement for the safety and effectiveness measures used in the FDA testing process.[142] Can a simple measure of bioequivalence replace the different phases of testing and years of research and development undertaken by the developmental drug companies? This may be a concern, but generic drugs that undergo an ANDA process meet the same FDA regulatory standards as the original developmental drugs, so these fears seem somewhat unfounded.[143]

The Hatch-Waxman Act strikes a balance between two potentially competing policy interests: inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term.[144] This policy balance highlights the competing policy arguments behind a patent system that favors generic drug companies, and one that favors developmental drug companies.

The first argument for a system in favor of generic companies is the public interest in cheap yet safe and effective medicines. A system that allows generic producers to develop generic drugs at a much lower cost allows a larger segment of the public to access these medicines. Medication is unique in the patent world because it is a rare class of patented products that provide direct care to the public at large. This public interest incentive of low cost medication allows access to the market by more individuals. The generic system also allows more business entrance into the pharmaceutical industry. Generic pharmaceutical companies require less research and development capital, and research and development is an expensive investment with a long waiting period on return.[145] This allows a broader base of entrepreneurial firms to enter the market, employing more individuals and creating more competition. Increased competition forces all industry participants to remain price competitive while simultaneously helping the consumer and the producer.

Another advantage of the generic system and a patent policy favoring generic pharmaceuticals is the incentive it places on developmental drug companies to continuously develop new medications. This would still be

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[141] *Id.*
[142] *See* Barton and Emanuel, *supra* note 109.
[143] *See id.*
[144] *See* Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). *See also* Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1365–66 (Fed. Cir. 2010).
[145] *Why Generics Prescription Drugs Cost Less*, HUMANA, http://www.staysmart stayhealthy.com/generic_drug_costs (last visited Mar. 28, 2012).

the case if the generic system did not exist and pharmaceutical patents were treated like any other patents, but the incentive for continuous development would not be as strong. With only a few years of profit between successful FDA approval and the expiration of the patent, a developmental drug company must constantly innovate in order to have a consistent stream of revenue from patented drugs on the market. Without the strong and immediate competition from generics, developmental drug companies would have more time to rest on their laurels and reap the benefits of older drugs. This drives innovation to more effective medication for the public and more profits by a broad base of generic and developmental pharmaceutical companies. The public at large benefits from better and cheaper drugs, creating an entire industry of generic pharmaceuticals, thus adding jobs and economic growth. The principle drawback is the lost marginal profits of the developmental pharmaceutical industry. This does not mean the developmental pharmaceutical industry is limited in the amount of money it can make; it just requires them to continue to innovate in order to maintain their share of the market. Considering innovation and progress are the original policies stated in the Patent and Copyright Clause of the U.S. Constitution,[146] the positives of the generic drug system outweigh the negative from (nearly) every vantage point.

The arguments in favor of a pro-generic system are opposed by policy arguments aimed at protecting the developmental pharmaceuticals and the products they create (the one vantage point which might disagree with the proposition that the positives of the generic drug system outweigh the negatives). Developmental drug companies are the innovative entities in the pharmaceutical industry and they should be protected in order to promote progress and innovation. Without strong patent protection there would be less incentive for developmental drug companies to spend a large amount of money on research and development. Patent policies aimed at furthering the public interest must not overburden the developmental drug company's incentive to innovate. Otherwise, the steady stream of new medicine developed by these companies will slow. Developmental companies put all the investment into the products and they should be rewarded for that investment. Protection of developmental pharmaceuticals is necessary to maintain continuous development of new medicines and investment in research and development.[147]

These competing policy arguments are at the center of the current issue regarding the holding of *Novo Nordisk*. The question in *Novo Nordisk*

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[146] U.S. CONST. art. I, § 8.

[147] Frank Pasquale, JD, *Pharmaceutical Research Expenditures and Industrial Policy*, HEALTH CARE BLOG (Jan. 3, 2011), http://thehealthcareblog.com/blog/2011/01/03/pharmaceutical-research-expenditures-and-industrial-policy/ (discussing the policies behind developmental pharmaceutical spending).

centers around the interpretation of language from the Hatch-Waxman Act which states in part that:

> [T]he ANDA applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either- (aa) the drug for which the application was approved; or (bb) an approved method of using the drug.[148]

Caraco, the generic manufacturer, is trying to manufacture a generic version of Prandin (a drug designed to treat Type 2 Diabetes). Novo Nordisk holds a patent for repaglinide (the patented ingredient in Prandin) in combination with metformin, which expires in 2018.[149] Caraco asks the court to read "an approved method" in the counterclaim statute as "any approved method" and Novo Nordisk asks the court to read it as "all approved methods".[150]

The argument made by Novo Nordisk will allow developmental pharmaceutical companies to essentially extend original drug patents through new-use patents related to a method or combination of the originally patented drug which are part of the NDA use code.[151] This isn't a patent extension but the use code can block the generic from approval through the ANDA process. Without the ability for generic competitors to gain FDA approval, developmental pharmaceuticals can retain their monopoly on a particular drug well past the expiration of the patent.[152] This statutory interpretation dampens the dual-engine of innovation that the patent system creates. Without a change in the language or the interpretation of the statute, developmental pharmaceutical companies will slowly be able to box out generic competitors. This outcome will harm the industry and slow the development of new medication.

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[148] Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1362 (2010) (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2006) (also known as the "Greater Access to Affordable Pharmaceuticals Act" or "Gregg-Schumer Bill")).

[149] *Novo Nordisk A/S*, 601 F.3d at 1362.

[150] *See id.* at 1365–66.

[151] *Id.* at 1364.

[152] With this outcome the generic would not be infringing the patent per se, but they would not be able to gain FDA approval, eliminating the opportunity to put a competing product on the shelves. This effectively extends the monopoly held by the developmental entity past the expiration of the patent.

V. NOVO NORDISK A/S V. CARACO PHARMACEUTICAL LABORATORIES, LTD

The crux of *Novo Nordisk* is the statutory interpretation of the Hatch-Waxman Act's counterclaim language and a generic entity's ability to challenge the accuracy of the patent information submitted to the FDA through the NDA process. The holding that Caraco (the generic entity) has no statutory basis to assert a counterclaim requesting a change to the patent information in Novo Nordisk's use code creates a scenario where the generic entity is effectively barred from marketing, distributing, and selling the drug which perpetuates the developmental drug company's monopoly.[153] It is important to note that this case was granted certiorari by the Supreme Court and was argued in late 2011.[154] The forthcoming Supreme Court decision could change the outcome of this case and further alter the patent law with respect to generic pharmaceuticals.

Novo Nordisk markets and distributes a drug called repaglinide under the brand name Prandin.[155] Prandin is a drug to treat Type 2 Diabetes by increasing glycemic control in adults.[156] The FDA approved three uses relating to repaglinide: repaglinide alone, repaglinide in combination with metformin, and repaglinide in combination with thiazolidinediones.[157] The FDA Orange Book lists two patents for Prandin: the chemical composition of repaglinide (the "035 patent", set to expire on March 14, 2009) and repaglinide in combination with metformin (the "358 patent", set to expire June 12, 2018).[158] Novo Nordisk owns the 358 patent, but does not own the other two patents relating to the use of repaglinide.[159] The FDA initially gave the 358 patent a use code titled "U-546—Use of repaglinide in combination with metformin to lower blood glucose".[160] In 2005, Caraco filed an Abbreviated New Drug Application in an effort to gain FDA approval to market and distribute a generic version of repaglinide.[161] This ANDA initially contained a Paragraph III certification (stating that the patent is set to expire on a certain date) for the 035 patent and a Paragraph IV certification (stating that the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug) for the 358 patent.[162] This prompted Novo Nordisk to bring an infringement suit in 2005 against Caraco based on Caraco's attempt to create a generic version of repaglinide

[153] *Novo Nordisk A/S*, 601 F.3d. at 1367–68 (Clevenger, J., concurring).
[154] Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 601 F.3d 1359 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3057 (2011).
[155] *Novo Nordisk A/S*, 601 F.3d. at 1362.
[156] *Id.*
[157] *Id.*
[158] *Id.*
[159] *Id.*
[160] *Id.* at 1362–63.
[161] *Novo Nordisk A/S*, 601 F.3d at 1363.
[162] *Id.*

patented in the 358 patent.[163] In 2008, Caraco stipulated that its ANDA would infringe if the label included a combination of repaglinide and metformin (the 358 patent, which expires in 2018), and moved to amend their ANDA, stating that they were not seeking approval for the repaglinide-metformin combination, just repaglinide by itself.[164]

On May 6, 2009, Novo Nordisk submitted amended information regarding Prandin to the FDA and updated its use code narrative for the 358 patent.[165] This prompted the FDA to remove the use code U-546 from the Orange Book and replace it with a new code, "U-968—A method for improving glycemic control in adults with Type 2 Diabetes Mellitus."[166] Once the FDA approved this new use code, they subsequently denied Caraco's attempt at an ANDA carve out, and stated that the carve-out label overlapped with this new U-968 use code. This prompted Caraco to counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii) (the language of Hatch-Waxman discussing counterclaims), requesting that Novo Nordisk change the use code for Prandin back to the U-546 code.[167] "Caraco claimed that the use code U-968 was overbroad because it incorrectly suggested that the 358 patent covered all three approved methods of using repaglinide even though it claimed only one approved method."[168] If Caraco cannot use this counterclaim action to compel Novo Nordisk to change this new FDA use code, they will not be able to gain FDA approval of repaglinide. This means they will not be able to sell repaglinide even after the drug's patent has expired. This effectively extends the Novo Nordisk patent past its expiration date, at least with respect to Caraco, and extends against everyone else by the amount that this new use code is broader than the original patent.

The Hatch-Waxman Act enables the ANDA applicant to assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder to the FDA, under subsection (b) or (c) of this section on the ground that the patent does not claim either- (aa) the drug for which the application was approved; or (bb) an approved method of using the drug.[169]

The two parties disagree over the proper reading of "an approved method" in the Hatch-Waxman Act. "Novo reads 'an approved method' in the counterclaim statute as 'any approved method' while Caraco reads it as

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[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] *Id.* at 1363.
[167] *Novo Nordisk A/S*, 601 F.3d at 1363.
[168] *Id.*
[169] *Id.* (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2006) (also known as the "Greater Access to Affordable Pharmaceuticals Act" or "Gregg-Schumer Bill")).

'all approved methods.'"[170] The court holds that the correct reading is "any approved method" based on a simple interpretation of the plain language of the patent.[171] Because the new U-968 use code still contains at least one approved method, repaglinide in combination with metformin, Caraco cannot compel Novo Nordisk to change this use code and they are now effectively shut out of the market for the sale of repaglinide by itself until the expiration of the 358 patent in 2018 (even though the 035 patent expired in 2009). This reverses the lower court and rules in favor of Novo Nordisk.

The concurring opinion agrees that the majority's reading of the statue is correct, but recognizes the problem of creating extended patent terms. The concurrence also disagrees with the dissent, which wants the District Court to create a solution to this interpretation issue. The concurrence does agree with the dissent that the outcome is not good for the patent system and will have a detrimental effect on the pharmaceutical industry. But due to the clear language of the statute, the concurrence states that any fix should lie in the hands of Congress.[172]

The dissent focuses on the purpose of the Hatch-Waxman Act to formulate a way around the majority's interpretation of "an approved method of using the drug."[173] According to the dissent, the majority misinterprets "an approved method" as "any approved method."[174] The dissent's argument is that the majority opinion allows patent manipulation that the Hatch-Waxman Act and the Gregg-Shurmer Bill were written to avoid. They say the purpose of the Hatch-Waxman Act was to prevent manipulative practices by patent holders with respect to Orange Book listings.[175] The majority construes the statutory language directly counter to this purpose.[176] According to the dissent, the majority has misconstrued the term "patent information submitted" in the "Greater Access to Affordable Pharmaceuticals Act."[177] There is no definition of this in the Greater Access to Affordable Pharmaceuticals Act; thus, the majority ignores critical statutory language.[178]

The dissent also expands beyond the purpose of the Hatch-Waxman Act and cites other reasons the majority is wrong. The majority thinks that the overruling of *Mylan Pharmaceuticals v. Shalala*[179] is limited to

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[170] *Novo Nordisk A/S*, 601 F.3d at 1364.
[171] *Id.* at 1365–66.
[172] *Id.* at 1367.
[173] *Id.* (Dyk, J., dissenting).
[174] *Id.* (contrary to Supreme Court opinion stating "ultimately context determines meaning" Johnson v. United States, 130 S. Ct. 1265, 1270 (2010)).
[175] *Novo Nordisk A/S*, 601 F.3d at 1367.
[176] *Id.*
[177] *Id.* at 1370–71.
[178] *Id.*
[179] Mylan Pharms. v. Shalala, 81 F. Supp. 2d 30 (Fed. Dist. D.C. 2000).

Mylan.[180] According to the dissent, this does not take the context of the *Mylan* decision into account and the principles of *Mylan* should apply.[181] In *Mylan*, the infringer challenged the accuracy of the listing in the Orange Book relating the patent with the FDA approved method of use.[182] The dissent elaborated on congressional intent with respect to *Mylan* and *Novo Nordisk*. "Congress acted to provide a counterclaim action to correct such errors. Congress' concern with the proper listing of the patent in the Orange Book does not remotely suggest a myopic congressional focus on situations where the patent belonged nowhere in the Orange Book, as the majority suggests."[183] The dissent states that even the plain language of the Hatch-Waxman Act allows:

> [C]orrection of a misdescription of patent scope that includes a drug not covered by the patent and erroneous information about the relationship between the patent and the drug, even if the patent is properly listed elsewhere in the Orange Book. In other words, the scope of the patent and its relationship to the drug must be 'patent information'.[184]

The dissent states that "[m]ost significantly, viewing the overruling of *Mylan* as limited to complete delisting would be inconsistent with the explicit statutory language, which provides for correction of Orange Book information 'on the ground that the patent does not claim . . . the drug for which the application was approved."[185] The dissent does not see a difference between drug information and method of use information. The dissent summarizes this point by stating: "[e]ither both must be 'patent information' or neither must be 'patent information.' In my view, all Orange Book information is "patent information."

VI. CAN GENERICS SURVIVE IN THE SHORT OR THE LONG TERM?

After the holding in *Novo Nordisk A/S v. Caraco Pharmaceuticals*, the question is whether generic pharmaceutical companies can survive in either the short-term or the long-term. The negative effects on the generic industry are likely to be felt solely in a long-term context but only in circumstances unrelated to the holding in *Novo Nordisk*.

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[180] *Id.*
[181] *Novo Nordisk A/S*, 601 F.3d at 1372–73 (Dyk, J., dissenting) ("The problem in *Mylan* was that the Orange Book improperly described the scope of the patent and improperly related the patent to a drug and method of use not covered by the patent. Reversing the district court, we held that there was no declaratory relief available to correct an erroneous Orange Book listing.").
[182] *Id.* at 1373.
[183] *Id.*
[184] *Id.*
[185] *Id.* (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2006)).

In the short-term, generic drug companies may actually flourish because ten of the current best-selling medicines will lose patent protection in 2011 and 2012.[186] This is being called a "patent cliff" by the pharmaceutical industry.[187] Generic drug companies are able to offer lower prices and this can take almost 90% of sales from developmental drug companies.[188] Because of this, the patents set to expire between 2011 and 2015 put about $250 billion in developmental drug company sales at risk.[189] Patents that expired in 2011 include Lipitor, a cholesterol medication owned by Pfizer that had $5.3 billion in 2010 U.S. sales, Zyprexa, an antipsychotic owned by Eli Lily that had $2.5 billion in 2010 U.S. sales, and Levanquin, an ADHD/ADD medication owned by Johnson & Johnson that had $1.3 billion in 2010 U.S sales.[190] Patents expiring in 2012 include Plavix, an anti-platelet medication owned by Bristol-Myers Squibb/Sanofi-Aventis that had $6 billion in 2010 U.S. sales, Seroquel, an antipsychotic owned by AstraZeneca that had $3.7 billion in 2010 U.S. sales, and Singulair, an antipsychotic medication owned by Merck that had $3.2 billion in 2010 U.S sales.[191] Developmental pharmaceutical companies will lose a large portion of their revenue because of the patent cliff.[192] Michael Hay, an analyst at Sagient Research Systems, explained the expected effect these expirations will have on the industry:

> The patent cliff facing the industry is very real, with billions of dollars being stripped from companies' revenues. Although the vast majority of the drugs losing patent protection are sold by large pharmaceutical companies that are well diversified, the amount of revenue that will be lost is going to be very difficult to make up for.[193]

The actual numbers describing the patent cliff highlight this statement. The patent cliff is expected to erode $78 billion in worldwide sales from developmental drugs on patents expiring between 2010 and 2014.[194] Almost half of this lost revenue is expected to occur because of the patents that expired in 2011.[195]

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[186] Melly Alazraki, *The 10 Biggest-Selling Drugs That Are About to Lose Their Patent*, DAILY FIN. (Feb. 27, 2011, 8:00 AM), http://www.dailyfinance.com/2011/02/27/top-selling-drugs-are-about-to-lose-patent-protection-ready/.
[187] *Id.*
[188] *Id.*
[189] *Id.*
[190] *Id.*
[191] *Id.*
[192] *The Patent Cliff Steepens*, NATURE REV. DRUG DISCOVERY 10, 12–13 (Jan. 2011), http://www.nature.com/nrd/journal/v10/n1/full/nrd3356.html.
[193] *Id.*
[194] *Id.*
[195] *Id.*

This boom in soon-to-expire patents is a short-term bandage on a long-term problem now facing the generic pharmaceutical industry. The holding in *Novo Nordisk* will allow developmental pharmaceutical companies to create situations very similar to the famous patent troll situations by amending their use codes in an effort to perpetuate their monopolies. A troll patent typically carries some of the following characteristics: it is owned by someone that does not practice the invention and it is infringed by, and asserted against, non-copiers exclusively or almost exclusively. Copying is any kind of derivation, not just mindless replication. It has no licensees practicing the particular patented invention except for defendants who took licenses as settlement. It is also asserted against a large industry that is based on and composed of non-copiers.[196] *Novo Nordisk* creates a scenario similar to a patent troll because drug companies would be able to perpetuate their protection in situations where they hold multiple combination or method patents which are listed together in the Orange Book. When a generic files an ANDA, the drug company can amend their use code to add other patented material causing the ANDA to now be in violation of the patented information in the use code. This creates an ability to spring a right to exclude on the generic entity similar to a patent troll springing an exclusory right on a new developer. A hypothetical of this "troll patent" situation would be Johnson & Johnson extending the protection of Tylenol (acetaminophen) by "piggybacking" with Tylenol PM (acetaminophen and diphenhydramine) or Novartis' Excedrin (acetaminophen, aspirin, and caffeine); both drugs that contain acetaminophen, in conjunction with other drugs.

This could slowly shut out generic pharmaceutical companies or at minimum, limit their growth. Generic pharmaceuticals would be limited to only producing older generic drugs, and as these drugs become outdated by newer and more effective drugs, they could be entirely shut out of the market. Established generic drug companies would still be able to compete with developmental drug companies on all medications that have already lost their patent protection. The dilution of the market in favor of developmental companies would happen over time. As new medications slowly replace current generics, developmental companies that are able to extend patent protection through the *Novo Nordisk* rule will be able to slowly take an increasing percentage of the pharmaceutical market share from the generic companies. This hurts the industry because it decreases competition and will likely eliminate jobs in the generic industry while leading to higher priced medications for the public. There will still be competition among developmental companies, but decreases in competition

[196] TJ Chiang, *What is a Troll Patent and Why Are They Bad?*, PATENTLY O (Mar. 6, 2009), http://www.patentlyo.com/patent/2009/03/what-is-a-troll-patent-and-why-are-they-bad.html.

from generic companies will slow the engine of innovation in the pharmaceutical industry.

This will also make it difficult for startup generic drug companies to break into the industry. Since a start-up may only be able to produce the older, pre-*Novo-Nordisk* generic drugs, they would have to compete with established developmental and generic companies. There is the difficulty of initial capital and quality production that presents a challenge to a start-up in any industry. This difficulty would increase greatly because a start-up generic drug company would have to compete with established generic drug companies who have already been forced into perfecting the current crop of generic medication in order to compete with the developmental companies. This would place a start-up at the bottom of a hierarchy in which the gap separating the developmental companies from the generic companies would become increasingly larger. A start-up would face an almost impossible task of competing with the established generic manufacturers who can already price lower based on volume and efficiency. The *Novo Nordisk* ruling effectively eliminates the possibility for start-up generic outfits to broaden the pharmaceutical market with new ventures.

VII. POTENTIAL SOLUTIONS TO THE *NOVO NORDISK* PROBLEM

There are some potential solutions to the issue created by the ruling in *Novo Nordisk*. One positive is the industry now knows how courts are interpreting the language of the particular statute of the Hatch-Waxman Act at issue in *Novo Nordisk*. This knowledge also highlights a flaw in the language, which leads to the current result of an open door for pseudo-perpetual pharmaceutical monopolies. The first solution would be for the Supreme Court to overturn the Federal Circuit's ruling and limit the protection to just the claimed use, not just any use. This would still give the protection bargained for by the drug manufacturer without prolonging the protection on their initial drug development and potentially leading to the patent perpetuation protection. The court would need to lean on the legislative history of the statute and rule in the same spirit as the Federal Circuit dissent. Since the purpose of the legislation was not to allow developmental drug companies to extend the life of their patents, the Supreme Court could rule that the language only protects the new use of the patent.

The major issue with the Supreme Court overruling the Federal Circuit's majority opinion is the statutory language is quite straightforward. A commonly used and generally accepted canon of statutory interpretation is the following:

> When the statutory language is clear on its face, and its words neither create ambiguity nor lead to an entirely unreasonable interpretation, an inquiring court must apply

> the statute as written, and need not consult other aids to statutory construction. However, when the statutory language chosen by Congress is unclear, or capable of more than one reasonable interpretation, it is proper for a court to consult extrinsic sources, such as legislative history, for guidance.[197]

If the language was more ambiguous, legislative history and intent might come into play, but as the statutory language currently stands, that seems unlikely. The interpretive canon that unambiguous statutory language should be applied on its face and by its plain meaning should apply.

Other interpretive canons also do not bode well for the generic drug companies. A more succinct canon in the same vein as the one above, states: "Courts are to presume that a legislature says in a statute what it means and means in a statute what it says."[198] Another negative effect on Caraco and generics everywhere is that courts are supposed to interpret statues without considering the effects of the statute, even if the equity may lie with the losing party. "A court's task of statutory construction does not depend on evaluating whether one side or another is unfairly affected by the plain language of the section."[199]

A more realistic solution lies in the hands of Congress. Congress could amend the Hatch-Waxman Act to avoid the issue of extended patent terms altogether. This is a similar solution to the one expressed by the concurring opinion in *Novo Nordisk*. A simple amendment to the rule could clearly state that:

> [The ANDA] applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either- (aa) the drug for which the application was approved; or (bb) an approved method of using the drug *as long as use of this method does not extend protection of*

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[197] Passa v. Derderian, 308 F. Supp. 2d 43 (D.R.I. 2004). *See* Catherine E. Vance, *Some Canons of Statutory Construction*, COM. L. LEAGUE OF AM. (2005), *available at* http://www.clla.org/new_code_docs/CLLA-canons-of-statutory-construction.pdf.

[198] Connecticut Nat'l Bank v. Germain, 503 U.S. 249 (1992). *See* Vance, *supra* note 197.

[199] Price v. Del. State Police Fed. Credit Union, 370 F.3d 362 (3d Cir. 2004) *See* Vance, *supra* note 197.

> *any use of the drug beyond the twenty year patent term.*"[200] (Italic language is an example of added language to a potential amendment of the rule).

New language could also be introduced to allow the generic ANDA applicant an opportunity to amend their ANDA anytime the patent holder amends their Orange Book Use Code. Another amendment would just be to remove the language "an approved method of using the drug," leaving the only stipulation "the drug for which the application was approved." These are only a few examples of congressional amendments to the Hatch-Waxman Act that can solve the extended patent problem. Hopefully Congress will agree that this is an issue and try to create legislative solutions to continue the policy and general execution of the Hatch-Waxman Act while solving this problem.

Even without any legislative changes or a judicial overturn by the Supreme Court, there may still be room for generics to survive in the pharmaceutical industry without any of these proposed solutions because there are still a large number of generic drugs that generic companies can manufacture and sell. Also, although developmental drug companies will be able to block generic ANDA applicants from gaining the FDA approval required for sale, it will be difficult for these companies to hold the patents in their Use Codes into perpetuity. This means there will still be medication patents that expire allowing the generic companies new streams of revenue. There will continue to be competition between generic pharmaceutical companies and developmental pharmaceutical companies but the ruling in *Novo Nordisk* will limit the ability of generic companies to remain competitive and will likely lead to some losses in revenue, profits, and jobs in the generic industry. It will also weaken the engine of innovation provided by generic competitors and slow improvements in the pharmaceutical industry. This limitation on innovation weakens the entrepreneurial spirit of the pharmaceutical industry and the U.S. patent system. It should be overturned or removed to maximize innovation in an industry with strong ties to the medical and economic health of the American people.

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[200] Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359 (2010) (citing 21 U.S.C. § 355(j)(5)(C)(ii)(I) (206)) (also known as the "Greater Access to Affordable Pharmaceuticals Act" or "Gregg-Schumer Bill")).