Pharmaceutical Pricing: Lack of Competition in the Pharmaceutical Market

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1. **Introduction**

Rising healthcare expenditures have been a source of concern for many years, but more recently, the concern has begun to focus specifically on prices and spending on prescription drugs, and for good reason. In 2015, expenditures on prescription drugs rose faster than overall healthcare spending.[1] According to a report issued by the Department of Health and Human Services (DHS), while overall healthcare spending has risen at a consistent rate, pharmaceutical spending sharply rose from 2010 to 2014. The high prices of prescription drugs are more frequently being felt by individuals in the form of out-of-pocket costs, which has made prescription drug prices a key public issue. Despite this momentum to address the ever-increasing cost of drugs, reforming the pharmaceutical pricing system is no easy task. There are many aspects of the pharmaceutical and healthcare system to blame for high prices.

This issue brief addresses one factor of pharmaceutical pricing – lack of competition in the pharmaceutical market. In the upcoming year, The Source will also cover other pharmaceutical pricing issues, including lack of price transparency and the pharmaceutical distribution market. In this issue brief on competition, we first discusses why the pharmaceutical market

lacks competition, including (1) inherent characteristics of the market for pharmaceutical products|(2) laws and regulations inhibiting competition|and (3) generic delay tactics by pharmaceutical companies. We then discusses possible strategies for promoting competition in pharmaceutical markets.

1. Factors Affecting Competition in Pharmaceutical Markets

The key factor driving high pharmaceutical prices is that the pharmaceutical industry does not function like a normal market, as it lacks competition. The lack of competition between pharmaceutical manufactures is due to (1) the inherent characteristics of the market for pharmaceuticals|(2) laws restricting competition in order to protect consumers and incentivize new drug development|and (3) tactics employed by the pharmaceutical industry to avoid competition by generic drugs.

1. Characteristics of Pharmaceutical Markets

The market for pharmaceutical products exhibits several inherent characteristics that inhibit strong competition.[2] These characteristics include the existence of an innovation market and low elasticity of demand.[3]

Innovative markets, such as the pharmaceutical industry, are characterized by high fixed costs for research and development of innovative products.[4] It is extremely expensive to develop

new drugs. The estimated cost to get one drug to market successfully is now more than $2.8 billion.[5] These high fixed costs create barriers to entry, making it a challenging and time consuming for competitors to enter the market. Because of these barriers to entry, existing pharmaceutical companies have the ability set and maintain high prices for their products,[6] because it will take time for another competitor to enter the market, compete, and drive down prices.

The pharmaceutical market also is characterized by a low elasticity of demand, which means that changes in price or quantity of a drug in the market has little effect on demand for that drug. The low elasticity in the drug market inhibits competition by giving drug manufacturers a significant amount of power over how to price their products.[7] By nature, demand for pharmaceutical drugs is inelastic because these products are medically necessary, and often there is no substitute for a pharmaceutical available on the market.[8] Thus, drug manufacturers may increase prices because consumers have no substitute for the good and must accept higher prices because the product is needed to maintain good health.

High research and development costs and low elasticity of demand are inherent to the nature of pharmaceutical products. Simply put, producing safe and effective pharmaceuticals costs enormous amounts of money, and the output or out-of-pocket costs do not have a large affect on demand because individuals rely on pharmaceutical products to maintain health. In addition to these inherent challenges to competition, the Untied States has also adopted laws and regulations that purposefully inhibit

competition in the pharmaceutical market in order to protect other interests.

2. **Laws Restricting Competition**

Strict regulatory systems, such as the Food and Drug Administration (FDA) and the patent system also make the pharmaceutical market anticompetitive. These two systems can be though of as facilitating a trade-off, hindering competition in order promote some other important interest. For the patent system, that interest is promoting innovation through new drug development and for FDA, that interest is protecting consumers by promoting drug safety and efficacy.

1. **Patent Protection**

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The main function of the patent laws is to provide the incentive to innovate,[9] particularly in industries where innovation is key for growth such as the pharmaceutical industry.[10] To provide such incentive the Patent and Trademark Office (PTO) awards a property right known as a patent in exchange for an inventor publicly disclosing his or her invention. A patent gives the patent holder a limited monopoly on the invention, during which no one other than the patent holder or a person with a license may make, use, or sell the invention.[11] A patent term is generally 20 years, and begins at the time the inventor files a patent application with the PTO.

The PTO determines whether an invention in a patent application

meets the requirements for patentability. In order to be patentable, an invention must be (1) of a subject matter eligible for patent protection|(2) novel|(3) non-obvious|and (4) useful. If an new drug meets the patentability requirements, as well as meeting other various requirements for awarding a patent, then the drug maker will be granted a patent on the drug.

When another company makes, uses, or sells a patented drug, it is known as infringing on the patent, and the patent-holder can sue the infringing party for damages and an injunction to prevent the infringement. The infringing party can challenge the validity of a patent, and if the court findings that a patent was not valid, it is a total defense to the infringement. Patents are particularly important in the pharmaceutical industry because of the high research and development costs of creating new pharmaceuticals. The patent monopoly period often allows the pharmaceutical company to recoup its investment in research and development, and re-invest in developing a new drug. In some cases, however, a patent may be insufficient protection because a patent term may expire before a new drug is brought to market.

Pharmaceutical manufacturers can apply for a patent at any time during the drug development of a drug, and in most cases patents are filed well before a drug enters the market.

In some cases, it takes longer than 20 years for the a drug to be fully tested, approved by the FDA, and ready to enter the market. Thus, in some cases pharmaceutical patents have expired by the time the drug is ready the enter the market. This deprives pharmaceutical companies of the opportunity to use the

exclusion because patents may be filed and awarded before having a final marketable product approved by the FDA. If, for example, a pharmaceutical company files a patent with the USPTO in year one without having a product ready to be consumed by the public and FDA approval took longer than 20 years, then the pharmaceutical company could not recoup the years of costly investment. The inability to use the monopoly power effectively lowered the pharmaceutical companies' incentive to create new products.

As discussed in detail below, Congress sought to fix this problem in 1984 with the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Act"), also known as the Hatch-Waxman Act. [12] The Hatch-Waxman Act gave the FDA the ability to give drugs "exclusivity grants," which begin at the time the FDA approves the drug and can in some cases extend a drug manufacture's monopoly on a drug beyond a patent term.

1. **The Food &amp|Drug Administration**

One of the FDA's main purpose is to oversee the safety and efficacy of pharmaceutical products, under the Federal Food, Drug, and Cosmetic Act in 1938.[13] To carry out its purpose, the FDA approves every drug in the United States, unless exempted, before it is marketed.[14] New brand name drugs seek approval by the FDA by filing a New Drug Application (NDA), which requires costly investment in formal testing to prove the safety and effectiveness of the new drug. Generic companies merely go through an expedited FDA approval process by filing an Abbreviated New Drug Application (ANDA).[15] After approval, the

FDA regulates the production and distribution of the pharmaceutical products.[16] The FDA creates barriers to entry because entrants in the pharmaceutical space face large costs before they can enter the market because they must comply with the FDA regulatory schemes.[17] Even after receiving FDA approval, if production and marketing is not up to FDA standards, the FDA can slow down production, which may give rise to higher prices.[18] These regulatory requirements bar pharmaceutical manufactures from brining new products to compete in the market quickly.

In addition to requiring approval before a drug can enter the market, the FDA also grants exclusive marketing rights to some drugs. The purpose of exclusivity grants, according to the FDA, is to "promote a balance between new drug innovation and generic drug competition."[19] If a drug qualifies for an exclusivity grant, the FDA will prohibits approval of competitor drugs for the time the exclusivity grant runs. In order to receive an FDA exclusivity grant, a drug must either fall under (1) the Orphan Drug Act, as a drug intended to treat a diseases or conditions affecting fewer than 200,000 people in the United states|(2) New Chemical Exclusivity, as a drug containing a chemical that has not been previously approved by the FDA|(3) "Other" Exclusivity, as a drug used in new clinical investigations with results that have not been previously relied on by the FDA|(4) Pediatric Exclusivity, as a drug used in new pediatric studies following a written request from the FDA|or (5) 180-day Generic Drug Exclusivity, as a generic drug that is first to file an ANDA challenging the validity of a brand name drug patent.[20] The length of the exclusivity grant is either seven years, five years, three years, six months, or 180 days, depending on the reason for the grant.[21]

Exclusivity grants are different from patents (which are discussed in detail below) because they are granted by the FDA (not the Patent and Trademark Office), they protect only marketing rights (whereas patents cover a range of rights), and are granted only upon FDA approval of a NDA or ANDA (whereas patents can be granted at anytime during development of a drug). Exclusivity grants may or may not run concurrently with the term of a drug's patent. Like patents, exclusivity grants give pharmaceutical manufacturers a temporary monopoly in order to incentivize new drug development.

3. **Generic Delay**

In addition to the inherent characteristics of pharmaceutical markets and the legal systems inhibiting competition, in recent years pharmaceutical manufactures have sought to prevent competition between brand name and generic drugs through tactics grouped together under the umbrella term "generic delay." In order to understand generic delay, it is first important to outline the differences between generics and brand name drugs.

Brand name drugs are pioneer drugs that are the first of its kind in the market. These drugs typically cost more than generic drugs because pharmaceutical companies participate in years of research and development to invent their drugs.[22] Brand name drug companies are also burdened with costly investment in formal testing to prove the safety and effectiveness of the new drug. Generic drugs are nearly identical versions of their brand name drug counterparts. They contain identical active

ingredients as the brand name drug, but they may not include the same inactive ingredients.[23] Generic drugs are much cheaper than brand name drugs, but are not lower in quality.[24][25] Generic drug companies sell their drugs at lower prices because they do not have to invest in costly research, development, and marketing, as do brand name drugs.

Brand name drug companies have attempted to prevent competition from generic drugs through generic delay tactics. Generic delay is a set of anticompetitive practices by brand name drug companies that prevent generic drug companies from entering the market to keep drug prices high.[27] By delaying the entry of generic drugs, brand name drug companies hold onto their patents or FDA exclusivities longer than intended by law. [28] As a result, they reap monopoly profits by maintaining high drug prices.[29] Brand name drug companies engage in generic delay because once a drug no longer has patent or FDA exclusivity protection, generic drug competition quickly eroded their monopoly profits.[30] Generic delay may come in many forms. Here, we focus on the following three generic delay tactics: (1) product hopping, (2) pay-for-delay, and (3) Risk Evaluation &amp|Mitigation Strategies (REMS) based restrictive distribution.

1. **Product hopping**

Product hopping occurs when a brand name drug company makes minor new modifications to a product with an expiring patent, while also taking actions to decrease or destroy the market for the original version of the product.[31] When a brand name drug

company makes minor modifications to an existing product with an expiring patent, it receives a new 20-year patent on the modified version of the product. After creating the modified version, brand name drug companies discontinue the older version from the market and encourage physicians to shift patients to the modified version.[32]

The success of a generic drug depends heavily on state's generic substitution laws, which allow or require a generic drug to be automatically substituted for brand name drugs at the pharmacy.[33] Because modified versions of brand name drugs are not be the pharmaceutical equivalent of the original version, pharmacists are not be able to substitute the generic equivalent for the original version of the brand name drug for the modified version. If a brand name drug manufacturer can introduce a modified version of a brand name drug and push doctors and patients to switch to modified version, through discontinuing or delisting the original version, they can prevent loss of sales to generics one the original brand name drug patent expires. The new patent on the modified drug allows the brand name drug manufacturers to maintain their monopoly profits for another patent term, during which generics are not allowed to enter the market, with very limited R&D expense or risk.[34] Product hopping claims are particularly disconcerting because, while companies are modifying their products, there is often suspicion that these modifications lack meaningful therapeutic benefit to patients.[35] Consumer thus end up paying higher prices for a drug with only minor modifications under the guise of a new and better product.

This generic delay strategy was brought to light in *New York v.*

Actavis PLC, an antitrust suit filed by the New York Attorney General, in which the Second Circuit Court of Appeal ultimately held that product hopping may violate federal antitrust law.[36] In the case, Actavis sold a twice-daily Alzheimer drug, Namenda IR.[37] As Namenda IR was nearing the end of its patent, Actavis introduced a slightly modified version of Namenda IR, releasing a once-daily extended release version of the drug called Namenda XR.[38] Eventually, Actavis made a complete switch to the once-daily Namenda XR by notifying the FDA that it would discontinue Namenda IR and requesting that the Centers for Medicare &amp|Medicaid Services remove Namenda IR from their formularies.[39] The Second Circuit concluded Actavis' conduct "forc[ed] patients to switch to the new version [of Namenda] and imped[ed] generic competition, without a legitimate business justification, violat[ing] § 2 of the Sherman Act."[40] Thus, as the Second Circuit aptly recognized in this case, product hopping artificially inflates drug prices by preventing generics from coming in to the market, without providing any meaningful benefit to patients.

More recently, in September 2016 thirty-four states and the District of Columbia filed an antitrust suit involving product hopping in the Eastern District of Pennsylvania.[41] The complaint in *State of Wisconsin v. Indivior Inc.* alleges that Indivor tried to force patients to switch from a tablet version of their brand name drug Suboxone to a modified dissolvable oral strip version Suboxone. The modification to the oral strip version of the drug occurred just before the patent on the tablet version of Suboxone was set to expire. The states argue that Indivor engaged in anticompetitive business practices to maintain Indivior's monopoly over Suboxone and prevent generic competition, including attempting to delay approval of the generic Indivor tablet by raising "unfounded pediatric safety

concerns" about the tablet. It will be interesting to see whether the states involved in this lawsuit are able to follow the success of the New York Attorney General in *Actavis* in showing that the pharmaceutical manufacture acted to unreasonably restrain competition in violation of federal antitrust law.

1. **Pay for delay**

Pay-for-delay is an agreement between the brand name and generic drug companies[42] to diminish competition through a settlement in which the brand name manufacture pays a generic manufacturer to stay out of the market. In a pay-for-delay scenario, first a generic drug manufacturer files an ANDA with the FDA, and then the brand name drug manufacturer sues the generic manufacturer for patent infringement.[43] Eventually, the brand name and the generic drug company come to an agreement, in which the generic drug company agrees to not challenge the brand name drug company's patent or sell a generic version of the drug for certain period of time.[44] In return, the brand name drug company pays the generic drug company for staying out of the market.[45] The brand name drug company pays the generic drug company more than what the generic company would have earned if it entered the market.

In some cases, the brand name drug company bringing the infringement suit does not even have a valid claim against the generic drug company for patent infringement, because the brand name drug's patent is not valid.[46] Both the brand name and generic companies agree to the settlement rather than continuing

the cases through to a decision on the patent infringement and validity because both companies face significant risks if the cases goes to trial.[47] If a court strikes the brand name drug company's patent as invalid, it results in a sharp decline in profit for the brand-name drug company because the generic drug company can enter the market and compete against the brand name.[48] Alternatively, if a court finds the brand-name drug company's patent valid and infringed, the generic drug company loses its FDA exclusivity.[49] When the brand name drug company's patent is in fact invalid, the pay-for-delay settlement gives a legal monopoly to the brand name drug company which the brand name company should not have even initially received.[50]

The Federal Trade Commission (FTC) brought the anticompetitive harms of pay-for-delay settlements to light in *FTC v. Actavis, Inc*.. In that case, generic drug manufacturer Actavis designed a generic version of AndroGel, a brand name testosterone replacement therapy,[51] and filed an ANDA with the FDA.[52] Solvay Pharmaceuticals, who owned the patent for AndroGel, sued Actavis for patent infringement. The two parties ended the case by engaging in a pay-for-delay settlement.[53] The terms of the settlement required Actavis to agree to stay out of the market until the patent expired in nine years, and in return Solvay paid Actavis millions of dollars from its profits from the sale of AndroGel.[54] The FTC sued Actavis and Solvay, arguing that the agreement to abandon the patent challenges in exchange for payment to Actavis to prevent generic competition violated federal antitrust law. In 2013, the United States Supreme Court heard the case and held Actavis' pay-for-delay settlement indeed violated federal antitrust law.[55] The Supreme Court did, however, reject the FTC's argument that pay-for-delay settlements are presumptively illegal. The decision still

established a strong precedent for bringing antitrust lawsuits against brand-name manufacturers to challenge settlement payments to generic competitors to keep the generic substitutes out of the market. In 2015, the FTC filed a similar suit against Cephalon, Inc. for its pay-to-delay settlement blocking a generic version of its blockbuster brand name sleep disorder drug. The FTC reached a settlement with Cephalon, which required Cephalon to agree to end pay-for-delay agreements and to pay $1.2 billion in compensation for its conduct. As these cases demonstrate, both brand name and generic drug manufactures have engaged in concerted action to prevent competition in the pharmaceutical market, giving brand name manufactures enormous power over the pricing of their products for long periods of time.

iii. REMS based delay

Brand name drug companies may also unilaterally prevent generic drugs from entering the market by abusing the FDA's Risk Evaluation &amp|Mitigation Strategies (REMS) or by implementing a similar restrictive distribution scheme. Understanding the basics of the REMS program is key to understanding REMS abuse and delay. The purpose of the FDA's REMS program is to make sure that drugs with significant side effects are properly used and administered.[56] Methods of regulation for those drugs typically go beyond the standard labeling requirements and come in many forms.[57] Elements to Assure Safe Use (ETASA), for example, is the most restrictive type of REMS because it includes requirements such as patient monitoring and testing, certifications for prescribers and pharmacies, and limitations on where the drug can be dispensed, such as limited to only a

hospital or specialty certified pharmacy.[58] Given that FDA may place limitations on the sale, distribution, or marketing of a drug via a REMS, the FDA has made the program "ripe for abuse by branded drug manufactures looking to keep generics out of the market."[59]

When generic drug companies file an ANDA, they must prove that their generic drug is a bioequivalent to (i.e. expected to be the same as) the brand name drug by testing samples of the brand name drug against their generic drug.[60] REMS gives brand name drug manufacturers an alleged excuse to refuse to give out samples of its drug to generic companies for bioequivilance testing. In these circumstances, the brand name drug company implements a restrictive distribution system and only allows its drug to be dispensed by approved hospitals or specially certified pharmacies. This restraint allows the brand name drug to refuses to sell its sample to a generic drug company, making generic companies unable to access samples of the name-brand drugs. The brand name companies claim that they cannot give out samples because the FDA limits the drug's distribution, but in fact, the FDA specifically allows brand name companies to sell samples to generic hopefuls. Despite this, generic drug companies face extra costs and barriers accessing the brand name drugs, and creating hurdles to proving that a generic is a bioequivalent of the brand name drug.[61] Given that REMS abuse makes it more difficult for some generic drugs to get FDA approval and enter the market, REMS abuse leaves the brand name drug company as the sole supplier of the drug. This allows the brand name drug company to maintain its monopoly profits and high prices.[62] REMS abuse is particularly concerning and dangerous for generic competition because the act is "not linked to patent protection and can continue indefinitely, even after the expiration of all exclusivities."[63]

This issue garnered the public's attention in 2015, when Turing Pharmaceuticals acquired pyrimethamine (Daraprim), a drug used to treat a fatal parasitic brain infection, and then raised the price of the drug by 5,000 percent.[64] Prior to being acquired by Turing, Daraprim was widely available and sold through wholesalers and drug stores.[65] Shortly before being sold to Turing, the drug suddenly switch to a restricted distribution through only one specialty pharmacy, without any clear or valid safety justification. This switch made it much more difficult for generic competitors to get the samples needed for bioequivalence testing. REMS abuse and REMS based distribution methods, without a legitimate reason to restricting the dissemination of the drug, facilitates these types of price hikes by preventing other manufactures from entering the market to compete and provide alternative lower-priced options.

III. Conclusion

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[12] Note, the Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetics Act and Title 35 U.S. Code relating to patents. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1325 (Fed. Cir. 2001).

[13] Note, biologic agents are regulated under the Public Health Services Act of 1944.

[14] Bloomberg BNA, Pharmaceutical and Medical Device Law Regulation of Research, Development, and Marketing, 2nd Edition, Chapter 2. Key Federal Agencies Regulating Pharmaceuticals

[15] ANDA applicants must make one of four certifications: ""Paragraph I: no patent information has been submitted to the FDA|Paragraph II: the patent has already expired|Paragraph III: the patent will expire on a certain date, prior to FDA approval of the ANDA|or Paragraph IV (most common): the unexpired patent is not enforce-able, or its claims are invalid or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the generic drug for which the ANDA is submitted." Margo A. Bagely, *Patent term restoration and non-patent exclusivity in the US*, in Pharmaceutical Innovation, Compet