Anti-Competitive Behaviors: Examples from the Pharmaceutical Industry

Introduction

Competition in the form of generic, biosimilar, and interchangeable biologics in pharmaceutical market is key to bringing down prescription drug prices. In fact, multiple generics on the market can lower prices by as much as 85 percent.[1] But some brand-name manufacturers engage in anti-competitive behaviors to block or delay generics from being approved by the FDA and marketed to patients. The summary below provides some notable examples of these tactics, though a comprehensive list would span many more pages.

BLOCKING THE APPROVAL OF A GENERIC: SAMPLES FOR BIOEQUIVALENCE TESTING

To receive FDA approval for a generic, a generic manufacturer must demonstrate that it is equivalent to the brand-name in terms of safety and efficacy through bioequivalence testing. An initial step for this process is for the generic manufacturer to obtain samples of the brand-name drug from the manufacturer and then compare its product to that sample. In order to delay the generic approval process, brand-name manufacturers sometimes work to keep these samples from being obtained.

One notable way some brand-name companies block generic manufacturers' access to samples is to abuse what is known as the Risk Evaluation and Mitigation Strategy (REMS) process at the FDA. A REMS is a drug safety requirement that the FDA imposes for drugs with high toxicity or other risk factors that present safety concerns that was first authorized as part of the Food and Drug Administration Amendments Act of 2007.[2] A REMS can include a variety of measures to ensure patient safety, including a limited distribution system to control who can purchase and access prescription drug—known as "Elements to Assure Safe Use" (ETASU).[3]

Certain brand-name manufacturers have cited REMS as a reason to refuse the sale of their product to a generic manufacturer, claiming doing so would violate the safety requirements. The FDA has denied this to be the case, claiming that REMS should have no effect on sample distribution[4] and there are ongoing legal challenges that seek to keep brand-name manufacturers from limiting samples in this way.[5] However, despite these actions—in addition to long-standing Congressional proposals to end the practice and independent efforts by the FDA to expose and discourage its use—the REMS misuse continues.[6]

BLOCKING THE APPROVAL OF A GENERIC: SHARED DISTRIBUTION SYSTEMS

Some brand-name manufacturers have used a REMS in a different way to block or delay competition even after a generic is developed from a sample. Any generic version of a brand-name drug that is subject to a REMS must itself also adhere to the REMS.

A REMS for a generic version of a drug must incorporate any additional safety information in the labeling and packaging of the drug as well as incorporate any distribution restrictions from the ETASU for the brand-name drug.[7] While the packaging requirements are not usually a challenge for generics, the REMS presents an opportunity for brand-name manufacturers to delay a generic's REMS from being approved because the expectation is that the generic manufacturer will use the same limited distribution system set up by the brand-name manufacturer for the REMS. This requires a negotiation between the brand-name and generic manufacturers regarding how the generic will be included.

The FDA assists in this negotiation, which can be extremely sensitive as the process is likely to invoke the disclosure of cost-sharing data, confidentiality matters, product liability, antitrust concerns, and patent information.[8] As a result, the brand-name manufacturers can typically stretch out the negotiations for significant time-periods, allowing them to protect their market.

Some brand-name manufacturers have defended shared REMS and claim that given the important safety concerns, the negotiations must take time.[9] Generic manufacturers argue, however, that the nature of these negotiations can make it extremely difficult to come to agreement.[10] While the FDA has authority to waive the shared REMS if negotiations are not feasible, it is only considered as an "option of last resort." Reflecting this, the FDA has only issued three such waivers.[11] However, because of rising concern about this issue, in June 2018 the FDA published guidance clarifying how and when the agency will waive the requirements in the future to avoid abuse.[12]

DELAYING THE APPROVAL OF A GENERIC: CITIZEN'S PETITIONS

Some brand-name manufacturers also try to use the FDA's citizen petition process to slow down the review of generic drug applications. The citizen petition process is designed to allow individuals, organizations, and other entities to submit information and urge a particular action in regard to a product (including prescription drugs) that the FDA oversees.[13] While these petitions can serve a valuable function, especially in regards to raising or highlighting safety information, brand-name manufacturers have submitted citizens petitions that are without merit in order to prevent or delay the approval of a generic.[14]

The FDA has stated that generic applications are rarely blocked by specific citizen petitions, but the agency indicates that the volume of these petitions strains the FDA resources and burdens the entire generic review process.[15] In October 2018, the FDA issued updated guidance describing how they will more quickly reject citizen petitions designed to delay competition, as well as refer those petitions to the Federal Trade Commission (FTC) and include them in future Reports to Congress.[16] This process, however, will still require staff time and agency resources to carry out.[17]

BLOCKING A GENERIC FROM COMING TO MARKET: REVERSE PAYMENT PATENT SETTLEMENTS

Even after the development and approval process, a brand-name manufacturer has the ability to block generics from coming to market—at times in agreement with the generic manufacturer itself.

Some brand-name manufacturers enter agreements with generic manufacturers to suppress competition through a "reverse-payment patent settlement"—sometimes known as "pay-for-delay." These settlements result in a generic agreeing not to bring their approved generic product to market for a period of time in exchange for a significant payout, royalty, or other arrangement. The agreements also include a date—typically many years in the future—in which the generic can come to market without fear of litigation from the brand-name manufacturer.[18]

These settlements benefit the brand-name manufacturer by extending a product's monopoly for a longer period and benefit the generic manufacturer by ensuring the company can be profitable without going through costly litigation. Patients, however, enjoy no such benefits. Before the Supreme Court in 2013, the FTC challenged the practice as a violation of anti-trust laws. The Court agreed, ruling that the pay-for-delay agreements could violate anti-trust laws and should be subject to oversight.[19] Following that ruling the number such agreements have dropped[20] but still remains a significant tool that can be used to lower competition.

While the FTC has authority to investigate these settlements, it has chosen only to take on the most egregious cases, citing to the complexity of doing so, while continuing to urge Congress to pass legislation to eliminate reverse payment patent settlements.[21] And while bipartisan legislation has been introduced to address the practice for years, it has not yet been passed into law.[22]

BLOCKING A GENERIC FROM COMING TO MARKET: PARKING EXCLUSIVITIES

Brand-name manufacturers also enter into agreements with generic manufacturers under which the brand-name manufacturer agrees not to sue the generic manufacturer before the FDA has approved a generic application.

A distinct subset of patent settlements, the practice takes advantage of a provision in law that grants a 180-day exclusivity period to the first generic company that submits an application for a generic drug—otherwise known as a "first-filer."[23] Under these types of agreements with brand-name manufacturers, the first-filer agrees not to enter the market during the 180-day period ("parking" their exclusivity), giving the brand-name drug more time to enjoy a monopoly and allowing the generic to avoid incur legal fees to defend their product in court. As with pay-for-delay, Congressional proposals have been advanced to end this practice but have not yet been passed into law.[24]

CONCLUSION

The above is meant to sample the breadth of strategies that some brand-name manufacturers deploy in the drug approval process to restrict competition and keep drug prices high—there are many more types of anti-competitive behaviors that also operate to prop up monopolies, for example, through the patent system. Unfortunately, as noted above, while both Congress and regulators have attempted to address some of these tactics, much remains to be done. American families benefit greatly from drug price competition. Preventing pharmaceutical manufacturers from engaging in anti-competitive behaviors will strongly assist in driving down costs.

ENDNOTES

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