



Authorized Generics: Antitrust Issues and the Hatch-Waxman Act

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An authorized generic (AG) is a pharmaceutical product that was originally marketed and sold by a brand company, but is relabeled and marketed under a generic product name. One problem with AGs is that they do not have to abide by the 180-day market exclusivity provision granted by the Hatch-Waxman Act to the first generic on the market. AGs could thus undercut the public policy rationale underlying the Hatch-Waxman Act, and have the potential of threatening the generic industry as a whole.

An AG, also known as “authorized copy” or “brand-in-bottle,” may be marketed by the brand company itself or through a subsidiary, or the brand company may license the product to another company for marketing in return for royalties. The AG is sold at a lower cost, and as an alternative, to the branded product. The brand companies may choose to launch an authorized generic for a variety of reasons, including to settle patent litigation with a generic company by partnering with it, to participate in the generic market once generic competition starts, or to maintain manufacturing capacity for the drug substance or the drug product. For example, of the 57 largest selling drugs in the United States, more than 30 are scheduled to lose patent protection by 2008, representing total sales of more than \$60 billion. The launching of AGs allows the branded companies to maintain cash flow, albeit at a lowered rate, once generic competition starts. Similarly, generic companies may choose to partner with the brand company to launch an AG to settle litigation, to market a product they otherwise might not have been able to enter, or to increase their product portfolio.

HATCH-WAXMAN ACT

In 1984, Congress enacted Hatch-Waxman with the intent, *inter alia*, to open up the market for products that were previously patent protected. Between 1962 and 1984, approximately 150 drugs went off-patent. However, there were no generic drugs, and the off-patent drugs continued to be sold at high prices. This resulted in a *de jure* and *de facto* ability to exclude beyond the exclusivity provided by the patent term. Generics cost less than the branded drugs. For example, in 2001, the generic prescription drugs totaled 45% of all prescriptions filled at a cost of about \$11.1 billion, while branded drugs totaled 55% of the prescriptions filled at a cost of about \$121 billion, or approximately 91.6% of cost of drugs. The legislative intent of Hatch-Waxman was to balance the competing policy interests of manufacturers of brand-name drugs and those of the generic trade group. The intention was to maintain inducements necessary for the brand companies to research and develop new therapies, and enable lower cost generic products to reach the market.

Hatch-Waxman allowed generic manufacturers to file an Abbreviated New Drug Application (ANDA). The ANDA requires the generic company to demonstrate that its product is “*bioequivalent*” to a referenced NDA’s brand name product. Proof of bio-equivalence for a drug is much easier to establish than the requirements for an NDA: *i.e.*, the *active* (not inactive) ingredients must be proven “bioequivalent” by performing tests on twenty-four people exhibiting blood absorption rates within twenty percent of such rates exhibited for a “pioneer”

brand named drug. Thus, ANDA is a far less expensive process than filing an NDA.

In addition, Hatch-Waxman was a legislative reaction to *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.1984). In *Roche*, the Federal Circuit, on appeal from the United States District Court for the Eastern District of New York, (572 F. Supp 255 (E.D.N.Y. 1983)), held that:

“Bolar’s intended ‘experimental’ use is solely for business reasons... Bolar’s intended use of [the drug is], to derive FDA required test data, is thus an infringement of the ‘053 patent. Bolar may intend to perform experiments but unlicensed experiments conducted with a view to the adoption of the patented invention to the experimenter’s business was a violation of the rights of the patentee to exclude others from using his patented invention.”

The Federal Circuit refused to construe the experimental use exception to cover activities required for submission to regulatory agencies. Thus, a generic company could not begin the experiments to obtain data required for FDA drug approval until after the expiration of the patents protecting the marketed product. As a result, the protection provided by patents extended beyond the statutory time.

In response to *Roche*, Hatch-Waxman defined the use by a generic manufacturer with the intention to file an ANDA of clinical information already in an NDA as a non-infringing use. The ANDA must reference the NDA of the patented drug listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is generally known as the “Orange Book.” The Orange Book provides a list of the applicable patents to licensed drugs. In order to reference an NDA, the generic manufacturer must file one of four alternative certifications provided for under Hatch-Waxman:

- **“Paragraph I Certification”- No patent in the NDA.** This certification pertains to a drug listed in the “Orange Book” that does not have an accompanying patent as part of the NDA. *The FDA shall approve any ANDA making this certification.*
- **“Paragraph II Certification”- Term of patent(s) in NDA has expired.** The certification covers an NDA that contains one or more expired patents. *Again, FDA shall approve any ANDA making this certification.*
- **“Paragraph III Certification”- Patent(s) in NDA remains extant.** This certification indicates that the generic manufacturer seeks ANDA approval after the applicable patent(s) expires. *The FDA can only approve an ANDA with a Paragraph III Certification after all patent(s) in the NDA have expired.*
- **“Paragraph IV Certification”- Patent in NDA is alleged to be invalid or the generic equivalent product does not infringe.** By using this certification a generic manufacturer can either challenge the validity of applicable patents in the NDA or certify that the generic equivalent product will not infringe any patent held by the pioneer drug company whose patent(s) is part of the NDA. The generic manufacturer contemporaneously with its Paragraph IV Certification must notify the innovator manufacturer that it is filing a Paragraph IV certification with its ANDA.

Under Hatch-Waxman, as originally enacted, the first generic company that filed an ANDA obtained a period of 180 days during which it could exclude any other prospective generic market entrant from marketing the same generic product based upon the same pioneer drug. The 180-day exclusivity commenced upon a generic manufacturer’s first sale of the generic after receiving the FDA’s approval of its ANDA. However, under the original Hatch-Waxman provision, if the generic company holding the exclusivity period never

put the drug up for sale, all other generic manufacturers who have filed an ANDA for the same drug would be precluded from marketing another generic version of the same pioneer drug.

The 30-month stay ordered by the FDA upon the filing of a Paragraph IV Certification lawsuit could result in substantially delaying the marketing of a generic drug. The filing of the infringement suit triggered the “30 month stay” period. During this period the FDA cannot approve the ANDA until the earlier of: (1) the date the patent expires; (2) a court determination of non-infringement or patent invalidity; or (3) 30-months after notification to the patent holder of the Paragraph IV Certification. The 30-month stay results from the filing of an infringement suit by the original patentee within 45 days of the prospective generic manufacturer filing a Paragraph IV Certification. While Hatch-Waxman requires all NDA applicants to list all patents that are part of an NDA for a branded drug in the “Orange Book”, it does not provide a mechanism for ascertaining the accuracy of the listing. There is no way for an ANDA filer to challenge an improper listing of a patent in the Orange Book. The Federal Circuit held in *Mylan Pharmaceuticals, Inc. v. Thompson* 268 F.3d 1323, 60 USPQ 2d 1576 (Fed. Cir. 2001), and affirmed in *Andrx Pharmaceuticas, Inc. v. Biovial Corp.* 276 F.3d 1368, 61 USPQ 2d 1414 (Fed. Cir. 2002) and in *Minnesoat Minin and Manufacturing and Riker Labs, Inc. and Alpharpharm, Ltd. v. Varr Laboratories, Inc.* 303 F.3d 1294, 64 USPQ 2d 1270 (Fed. Cir. 2002) that there is no private cause of action for delisting a patent from the FDA’s Orange Book under the FFDCA. Some companies developed a strategy for unlimited consecutive 30-month stays, thereby keeping generics from ever receiving ANDA approval.

MEDICARE ACT OF 2003

The Medicare Act of 2003 amended Hatch-Waxman in order to address some of these deficiencies and to further reduce the barriers to more generic drugs

entering the marketplace. The new law eliminates multiple 30 month stay periods by providing that ANDA applicants can only provide Paragraph IV Certification in respect of patents listed in the Orange Book at the precise time the ANDA was filed. The new law also prohibits the patent holders from obtaining more than one 30-month stay by including a different patent for a drug that is the subject matter of the ANDA.

The new law requires the company submitting a Paragraph IV Certification to provide notice of the ANDA application to the NDA holder and patent owners within 20 days of the receipt of notice from the FDA that its application has been filed. Previously, the law was silent as to when the ANDA applicant was required to give such notice so that the applicant could file its ANDA without immediately risking patent litigation.

The new law also requires that the NDA holder bring an infringement suit within 45 days against the ANDA applicant. If an infringement action is not commenced, then the ANDA applicant may bring its own declaratory judgment action against the NDA holder. A precondition is that the ANDA applicant must allow the NDA holder to review the confidential ANDA to determine if a patent infringement suite should commence. The ability of the generic company to bring a declaratory judgment action avoids it from going through the regulatory process, receive an approval, and then upon the first sale of the generic product, get embroiled in an infringement suit initiated by the brand company. Thus, the ANDA applicant can better manage the risk of future uncertainties, such as litigation, while seeking FDA approval, prior to its scale-up to manufacture and incurring expenses of marketing a product.

Under the new law, the 180 day exclusivity period does not begin until the first commercial marketing, thereby allowing an ANDA applicant to scale-up its manufacture of an approved drug without sacrificing part of the exclusivity period. Further, the exclusivity period begins upon the applicant’s commercial marketing of either the

NDA product or the ANDA product. This is a subtle point in the new law, and addresses the situation in which a first ANDA applicant agrees to market the brand-name drug instead of its own ANDA product.

The exclusivity period is forfeited under the Medicare Act of 2003 if the first ANDA applicant does not market its drug within 75 days after of the ANDA approval, or if the first applicant's ANDA is withdrawn or deemed withdrawn by the FDA for substantive reasons such as (i) the first applicant amends or withdraws its Paragraph IV Certification, (ii) the Orange Book listed patents expire, or (iii) the ANDA applicant is found to have entered into an agreement that violates the antitrust laws.

The new law further clarifies that if more than one applicant files a "substantially complete" ANDA for a previously unchallenged drug on the same day each shares the same 180 day exclusivity period, and it begins on the first day of marketing by one of the two applicants. This provision moots any question of which application was filed first on any particular day. Further, agreements among ANDA applicants and brand-name drug companies or other ANDA applicants as to the exclusivity period, or the manufacturing, marketing, or sale of the brand-name or generic drug must be filed with the Federal Trade Commission and the Department of Justice within 10 days of execution.

ANTITRUST ISSUES

The law gives a 180-day exclusivity to paragraph IV ANDA filer. The argument for the 180-day exclusivity grant is that companies need an incentive in order to develop generic products and to reward them for taking the risk of an infringement suit. Further, it provides an incentive to the generics to challenge potentially invalid patents. Aside from greater revenues and profits generated during the 180-day exclusivity period, the generic company can also establish itself with a larger customer base thereby retaining a greater market share after the exclusivity ends. Further, it helps the

company develop a brand, enhance reputation in the industry, and increase customer good will. Thus, the 180-day exclusivity period is very important to the generic companies.

The economic and other tangible benefits of the six-month exclusivity are significantly reduced by the introduction of the authorized generic products. The entry of a second generic reduces the revenues of the first generic company by about 80%. The introduction of AG during the 180-day exclusivity period is similar to two generic companies competing for the same market, and reduces the benefit to the paragraph IV ANDA filer. Mylan Pharmaceuticals reportedly lost an estimated \$30 million in revenues when Proctor & Gamble licensed Watson to sell the authorized generic version of nitrofurantoin for urinary tract infection treatment just as Mylan was about to bring its own generic version to the market.

The position of the FDA is that the AGs do not have to abide by the 180-day market exclusivity to the first generic. The FDA reached the conclusion because it lacks the authority to regulate changes in approved products that do not potentially affect the safety or the effectiveness of the product, as in AGs. Moreover, the FDA stated that AGs appeared to promote rather than impede competition. Therefore, the FDA's current policy is to deny petitions to prohibit the sale of AG during the 180-day exclusivity period. (see denial of petition by Mylan Pharmaceuticals, Docket No. 2004P-0075/CP1, and by Teva Pharmaceuticals, U.S.A., Docket No. 2004P-0261/CP1).

The fact that authorized generics may compete with ANDA generic products, even during the 180-day exclusivity period was affirmed by the U.S. District Court for the District of Columbia in *Teva Pharmaceuticals v. FDA* (D.D.C. December 23, 2004), and by the U.S. Court of Appeal for the District of Columbia Circuit (June 3, 2005). The court held that Pfizer may market

its own authorized generic version of its epilepsy drug Neurontin (gabapentin) during the 180-day exclusivity period granted to Teva Pharmaceuticals.

Judge Keeley in *Mylan Pharmaceuticals Inc. v. Food and Drug Administration*, Civ. No. 1:04cv174 (N.D. W. Va.) (filed August 5, 2004; withdrawn without prejudice Aug. 30, 2004), reportedly suggested that there might be antitrust issues with AGs. For one, the introduction of the AGs during the 180-day exclusivity period could be an attempt to remove the economic incentive for paragraph IV certification for other drugs thereby maintaining market share in other brand markets. Secondly, selling the branded product at generic prices could be predatory pricing. However, it could be difficult to prove these antitrust issues.

The generic company will have to show that the introduction of AG is a willful anti-competitive conduct that prevents the generic from fairly competing in the relevant market for the drug. Factually, AGs do not prevent a generic version from being introduced into the market; AGs decrease the revenues and the profits of a generic during the exclusivity period. The generic company is thus able to enter the market, but will likely not reap the economic and non-tangible benefits of being a paragraph IV filer. This will likely not meet the legal test under the Sherman Act.

The second theory of predatory pricing may not be of help to the generic companies either. A predatory pricing claim under §2 of the Sherman Act alleges that the brand company priced its AG in an unfair manner with an object to eliminate or retard generic competition and thereby gain and exercise control over the price. Proving predatory pricing is a two pronged test. The generic must prove that the prices complained of are below an appropriate measure of the brands costs and that the brand had a reasonable prospect of recouping its investments in below cost prices. Thus, even assuming that the generic could show that the price of the AG was below cost, it must also show that

by pursuing this scheme, the brand company had a reasonable prospect of recovering its losses by slowing the growth of the generics. The second prong of the test is hard to meet.

For the particular product for which the exclusivity was granted, additional generic companies will come in after 6 months, thereby further decreasing the price of the drugs. Therefore, the brand company is not likely to be able to increase the price after the 180-day exclusivity period ends. Although the AG causes severe loss to the first generic company, it will be very difficult to show that eventually there will be a rise in prices sufficient for the brand to recoup the costs.

The launch of every paragraph-IV generic expected to be a blockbuster has been met with the availability of an AG since the fall of 2003. This has financially hurt the generic companies, and could work against the public policy of the Hatch-Waxman Act by removing the economic incentive from challenging the validity and enforceability of weak patents. However, the courts have upheld the rights of the brand companies to introduce AGs, and challenging AGs on antitrust issues is likely to fail as well. Congressman Waxman has publicly stated that AG's violate the purpose of the 180-day exclusivity period. Therefore, the best cause for the generic companies might be to work with the government to amend the laws specifically prohibiting AGs during the exclusivity period.

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