Legal Backgrounder

Washington Legal Foundation
effective advocate of free enterprise®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

Vol. 17 No. 24 June 7, 2002

"HATCH-WAXMAN" LAW HAS PLAYED CRITICAL ROLE IN MEDICAL ADVANCES

by

Dr. Gregory J. Glover

The U.S. pharmaceutical market is robust, competitive, and working to the benefit of consumers, exactly as Congress intended when it passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act). Recently, there have been calls to reform the Hatch-Waxman system. Those advocating reforms must overcome a heavy burden to show that change is both needed and would not upset the delicate balance achieved nearly twenty years ago by Congress. As this LEGAL BACKGROUNDER will argue, advocates of reform have not met that burden.

The U.S. pharmaceutical industry continues to lead the world in innovation. Over the past 100 years, pharmaceutical research has helped transform health care. Medical products developed here have conquered infection, made mental illness highly treatable, enhanced independence in old age, and made impressive inroads against cancer, heart disease, stroke, and many other previously unmanageable diseases.

The Hatch-Waxman Act has played a critical role in this. On the one hand, the generic industry has flourished since the law eliminated major barriers to market entry and made it much easier, far less costly, and quicker for low-cost generic drug manufacturers to get their copies of innovator medicines to market following patent expiration. On the other hand, the Hatch-Waxman Act provided the research-based pharmaceutical industry — the source of virtually all new drugs in the U.S. — incentives to innovate. The law restored part of the patent life lost by pioneer medicines as a result of regulatory review by the Food and Drug Administration (FDA), and provided litigation procedures to decrease the likelihood of patent infringement when generic drug products entered the market. As a result, consumers are receiving the benefits of both an expanding stream of ever more effective, precise, and sophisticated medicines, as well as early access to low-cost generic copies.

To encourage competition, the Act, in effect, revoked the trade-secret status of innovators' safety and effectiveness information. Instead of proving safety and effectiveness, a generic manufacturer was allowed to show only that its copy is bioequivalent to a pioneer product and that FDA could, therefore, rely on the pioneer's safety and efficacy data to approve the copy. As a result of the Hatch-

---

Dr. Gregory J. Glover is a partner in the Washington, D.C. office of the law firm Ropes & Gray. Dr. Glover is a licensed physician and registered patent attorney with experience in food and drug law, intellectual property law, and technology licensing. He frequently testifies before Congress on these issues, most recently in April 2002 before the U.S. Senate Committee on Commerce, Science and Transportation. ***The views expressed here are those of the author and do not necessarily reflect those of the Washington Legal Foundation. They should not be construed as an attempt to aid or hinder the passage of legislation.***

Waxman Act, generic manufacturers are able to avoid the huge cost (estimated at over $800 million on average) of discovering and developing a new drug. The Act retains only a very limited vestige of the pioneer companies' former, complete proprietary rights in this extremely valuable data. For example, under the Act, FDA is prohibited from approving generic copies of a pioneer drug for five years after approval of an innovator product using new chemical entities, and for three years after approval of other pioneer drugs and innovations in existing drugs.

The Hatch-Waxman Act also assisted generic manufacturers by overruling the patent infringement standard articulated in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (D.C. Cir. 1984). In line with prior judicial patent law decisions, the court had held that it constituted patent infringement for a generic company to manufacture and test a medicine before its patent expired, including for the purpose of preparing a marketing application to submit to FDA. In a unique exception to patent law, the Hatch-Waxman Act compromise allowed generic manufacturers to use innovator medicines still under patent to obtain bioequivalency data for their FDA applications so they would be ready to market their copies as soon as the pioneer patents expired.

In addition, the Hatch-Waxman Act also sought to increase the number of generic copies by providing an incentive for generic manufacturers to challenge pioneer patents. The first generic manufacturer to certify to FDA that a patent on an innovator medicine is invalid or is not infringed by its product obtains 180 days of exclusive marketing rights if the copy is approved before the patent expires. During that 180-day period, FDA cannot approve any other copies.

In an attempt to balance the generic provisions, the Hatch-Waxman Act provided limited incentives to pioneer companies to help spur innovation. The law restores part of the patent life — but not all — lost by innovator products as a result of FDA review. The provisions include giving a pioneer drug a half-day in restored patent life for every day the product is in clinical trials prior to FDA review. In addition, a pioneer drug receives day-for-day restoration of patent life for the time it is under FDA review. However, the effective patent life of a drug cannot exceed 14 years, regardless of how much time is lost in clinical testing and review, and the total time restored is limited to no more than five years.

In addition to partial patent restoration, the law also creates procedures to facilitate the efficient resolution of patent disputes before FDA approves an allegedly infringing generic copy. Failure to resolve patent issues prior to generic product approval presents problems for pioneer and generic manufacturers alike. The marketing of a product that is later determined to be infringing will severely and irreparably injure the pioneer's market at a magnitude that generally cannot be compensated by the infringing generic manufacturer. At the same time, the generic manufacturer is faced with the risk of having to pay crippling actual and enhanced damages for intentional infringement if it decides to market the approved product before the resolution of the patent infringement claim.

Congress recognized that it would be preferable to resolve patent infringement disputes prior to FDA product approval. Accordingly, the Act establishes patent litigation provisions to benefit both pioneer and generic manufacturers. These provisions provide for: (1) patent listing to notify generics of patents that claim the pioneer's product; (2) patent certification to inform pioneers of proposed generic products that may infringe their patents; (3) up to a 30-month stay of product approval to allow for resolution of patent infringement claims; and (4) the grant of a 180-day period of market exclusivity to the first generic that successfully challenges a listed patent. These provisions facilitate efficient

Copyright © 2002 Washington Legal Foundation

ISBN 1056 3059

resolution to patent infringement claims.

Although the Hatch-Waxman Act compromise stimulates competition and provides only limited incentives for the innovation upon which pioneer and generic pharmaceutical companies alike depend, generic manufacturers are the most forceful advocates for reform. While these reform ideas are, ostensibly, intended to speed approval of generic drugs and enhance pharmaceutical competition, they are unlikely to promote either of these objectives, and, if adopted, would substantially undermine the Hatch-Waxman compromise that has proven so successful. The ideas reform proponents are putting forward would: (1) deny effective remedies to holders of patents infringed by generic drugs; (2) change the standards to allow FDA to approve generic drugs that could not be approved under current law because they are not, in fact, the same as the innovator drugs for which FDA has the data necessary to assess safety and efficacy; and (3) create new requirements designed to deter outside parties from submitting scientific information to FDA that could be adverse to generic drugs. In addition, the reforms would revise the current system for rewarding generic companies that challenge patents on innovator drugs in a way that would result in unnecessary litigation and keep many generic drugs off the market for a six-month period.

These reform ideas would severely impair, if not eliminate, effective remedies for patent infringement. As explained above, under current law, FDA is barred for up to thirty months from approving a generic drug that is involved in timely-initiated patent litigation. Under Hatch-Waxman it is no longer an act of patent infringement for a generic company to use a pioneer company's patented product in preparing the marketing application for its generic copy of that product. Patent holders are not permitted to assert their rights against generic applicants during this period. Now, a claim for patent infringement cannot be brought until the generic company actually files its application. The 30-month stay increases the likelihood that a pioneer company will still be able to defend its patent rights before FDA approval enables an allegedly infringing generic product to come onto the market.

The generics' proposal would simply abolish the innovator's right to litigate patent disputes prior to FDA approval. Although an innovator could still theoretically seek a preliminary injunction from the court against the generic product, courts rarely grant preliminary injunctions in patent litigation, and such injunctions are especially difficult to obtain in the pharmaceutical patent context due to the highly complex and technical, fact-intensive claim analysis required. As a result, even though generic companies would continue to enjoy the benefits of the Hatch-Waxman Act which were created at the expense of innovator companies, the innovator industry would be denied the corresponding, necessary means provided in the Act to protect against patent infringement because of this unique privilege granted to generic companies.

The proposals would also permit the approval of generic drugs that do not, in fact, duplicate their reference drugs. Present law prohibits the use of studies, other than bioequivalence data, to support an abbreviated new drug application for a generic drug. The premise of the law is that the generic drug must be the same as the innovator drug in all material respects, and therefore all that must be shown is that the generic is absorbed by the body at the same rate and to the same extent as the innovator drug. The reform would allow the standard to be loosened, permitting FDA to approve generic drugs that are not the same as the reference innovator drugs.

In addition, the reforms would inhibit the submission of citizen petitions offered in good faith to inform the Agency of legitimate concerns regarding a proposed drug product. They would impose

Copyright © 2002 Washington Legal Foundation

ISBN 1056 3059

new burdens on use of the citizen petition, which is the mechanism by which an outside party can request an official FDA decision on a scientific or other issue. Under the proposals, it appears that the Federal Trade Commission (FTC) may be *required* to open an investigation of any person submitting a citizen petition to FDA if anyone alleges that the citizen petition has been submitted for an improper purpose. Congress and FDA should welcome a process for airing scientific issues, rather than trying to inhibit discussion. If a party were to submit a baseless citizen petition to achieve an anti-competitive effect, the existing antitrust laws would provide ample bases for the FTC, or a private party, to bring an enforcement action. The reforms would serve only to chill legitimate petitioning, to the detriment of the FDA approval process, undermining the legitimate economic interests of competitors, and, potentially, putting consumers at risk.

The generics' reform ideas would also revise the requirements for obtaining generic drug exclusivity in a manner that would keep more rival generic products off the market longer and promote unnecessary litigation. In an apparent inconsistency with its stated objective of speeding generic drug approvals, the reforms would enhance the ability of the first generic drug company that challenges an innovator patent to keep all other generic products off the market for six months. A provision for six months of exclusivity exists in current law but has been made less capable of keeping other generics off the market. The proposed reforms would overrule those decisions.

The Hatch-Waxman Act is one of the most successful pieces of consumer legislation in history. The law works. Contrary to the assertions of others, the reforms would not close loopholes. It would instead undermine the Act's few, critical protections for innovators' intellectual property rights. Without these protections, there will be less innovation, fewer new drugs for generics to copy and, more importantly, fewer new drugs to enhance treatment for patients.

Copyright © 2002 Washington Legal Foundation

ISBN 1056 3059