Bloomberg BNA

Pharmaceutical Law & Industry Report®

Antitrust

Briefs Criticize Branded Company Stance On Denying Drug Samples to Generic Firms

A company's freedom to transact business with whomever it wants does not necessarily mean that branded drug companies can refuse to deal with generic firms requesting drug samples for bioequivalence studies, the Federal Trade Commission said in an amicus brief filed in the U.S. District Court for the District of New Jersey March 11 (*Actelion Pharmaceuticals Ltd. v. Apotex*, D.N.J., No. 12-cv-05743-NLH-AMD, *amicus briefs filed* 3/11/13).

The Generic Pharmaceutical Association (GPhA), the lobbying arm for the generics industry, also submitted an amicus brief in the case March 11, arguing that if drugmakers are allowed to refuse to sell drug samples to generic companies, the entire balance of the Hatch-Waxman Act could be in peril.

''The resolution of lawsuits such as this will help to determine whether the prescription drug industry of the future will resemble the one consumers have enjoyed for the past quarter century—one characterized by widespread generic drug availability and reduced prices . . . or the drug industry before Hatch-Waxman, with less competition, fewer choices, and higher prices,'' GPhA's amicus brief said.

FTC and GPhA submitted their amicus briefs in a declaratory judgment action in which branded drug company Actelion Pharmaceuticals Ltd. is seeking a court ruling that it is not required to sell samples of its branded products to generic drug companies so that the generic firms can conduct bioequivalence testing required by the Food and Drug Administration.

In the suit, Actelion argues that it has a fundamental right to ''choose for itself with whom to deal and to whom to supply its products.''

''The right to choose with whom one does business is subject to only a few narrow exceptions,'' Actelion said in its complaint, adding that none of the exceptions applied in this instance.

In its amicus brief, FTC argued that the right is not absolute, especially when it has the effect of blocking market entry of cheaper, generic drugs. ''Under certain circumstances . . . a monopolist's refusal to sell to its rivals may violate Sherman Act Section 2,'' FTC said. In addition, it said, restricted distribution agreements for drugs may violate Sherman Act Section 1.

FTC's brief urged the court to ''carefully consider the unique regulatory framework governing the pharmaceutical industry and the potential ramifications for consumers of prescription drugs.''

Antitrust expert James M. Burns, of Dickinson Wright's Washington office, told BNA March 13 that FTC's amicus filing is in line with FTC's strong interest in competition in the generic drug market.

''Given the importance that the FTC has placed on trying to preserve competition between branded and generic drugs, it is not surprising that the FTC has filed an amicus brief in the Actelion case,'' Burns said. ''Moreover, it is not surprising that the FTC would take the position that efforts by a branded manufacturer to delay or impede the ability of a generic to enter the market and compete with a branded drug may be challenged under the antitrust laws in some circumstances,'' he said.

Branded company Actelion argues that it has a fundamental right to choose for itself with whom to deal and to whom to supply its products.

Indeed, Burns said, ''That view is very much in line with the FTC's approach in the pay-for-delay and 'product hopping' areas—that conduct by a branded manufacturer that delays generic competition should be subject to potential challenge if the branded manufacturer cannot demonstrate some justification for its action that has nothing to do with restraining generic competition.''

Case is 'One to Watch.' Burns said that ''the case is likely to be 'one to watch' over the next year or two, and [is not] likely not to end without first enjoying appellate review, if not Supreme Court review.''

''While the right of a business to 'choose for itself with whom to deal' has long been acknowledged in antitrust law, that right has never been absolute, and the Actelion case presents the opportunity for the outer limits of that maxim to be explored,'' he said.

According to John P. Elwood, of Vinson & Elkins LLP's Washington office, the Actelion suit is the first suit of its kind initiated by a branded drug manufacturer. Elwood represents GPhA in its amicus filing in the Actelion case.

''To our knowledge, Actelion's suit is the first time a branded drug manufacturer has sought declaratory judgment saying that it has no obligation to sell neces-

 ISSN 1542-9547

sary reference samples to potential generic competitors,'' Elwood told BNA March 13.

But, Elwood noted, branded manufacturers have advanced the same general theory before in a case filed in 2008 in the U.S. District Court for the Eastern District of Pennsylvania (*Lannett Co. v. Celgene Corp.*, E.D. Pa., No. 2:08-cv-3920). In that case, generic drug company Lannett Co. sued branded company Celgene Corp., alleging that Celgene refused to give it access to samples of Thalomid that it needed to conduct bioequivalence testing for its proposed generic product. Lannett claimed that Celgene's refusal made it impossible for it to bring a generic version of Thalomid to market and thus caused consumers to pay supracompetitive prices for the drug. In that case, Elwood said, Celgene moved to dismiss, arguing, like Actelion, that it had an absolute right to decide with whom it transacts business. But the case was eventually settled, so the court never ruled on the issues (9 PLIR 1545, 12/16/11).

Generics File Antitrust Counterclaims. After Actelion filed its declaratory judgment action in September 2012, generic companies Apotex Inc., Roxane Laboratories Inc., and Actavis Elizabeth LLC, which seek to market copies of Actelion's brand drug products, Tracleer (bosentan) tablets and Zavesca (miglustat) capsules, filed counterclaims in the suit alleging that Actelion's refusal to provide them with the drug samples constitutes monopolistic conduct in violation of the Sherman Act and the New Jersey Antitrust Act.

Actelion subsequently moved for judgment on the pleadings and to dismiss the antitrust counterclaims.

Restricted Distribution Plans. Adding to the complexity of the issues in the case, Tracleer and Zavesca are subject to restricted distribution programs.

Generic companies seek access to two of Actelion's drugs, Tracleer and Zavesca.

Tracleer is distributed under a risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU). The 2007 FDA Amendments Act (FDAAA) created the REMS to ensure safe distribution of drugs with high-risk profiles. Tracleer can cause serious liver damage, including in rare cases liver failure, as well as serious birth defects if taken during pregnancy.

Zavesca also is distributed under a restricted distribution program that Actelion itself developed for the product.

Tracleer is used to treat high blood pressure in the lungs (pulmonary arterial hypertension). Zavesca capsules are approved to treat mild to moderate Type I Gaucher disease in adults for whom enzyme replacement therapy is not a therapeutic option.

Actelion's suit also claims that the generic companies' demands that it sell Tracleer samples to them is ''inconsistent with the restrictions in the REMS for Tracleer.''

''There is no provision in the REMS statute that the owner of a drug subject to a REMS program is required to provide samples of its drug upon the request of a potential competitor,'' Actelion said in its suit. And it added, ''Actelion has no affirmative obligation to assist Apotex or Roxane with their efforts to develop generic drugs, particularly where the generics' testing may create risk for Actelion and the Tracleer brand.''

FTC, GPhA Briefs Warn of Consequences. In its amicus brief, FTC warned that adopting Actelion's legal position in the case ''potentially preserve[s] a brand firm's monopoly indefinitely'' and ''threatens to undermine the careful balance created by the Hatch-Waxman Act.''

''While the evidence may not ultimately support any of the Sherman Act claims in this case, the FTC respectfully submits that they are not barred as a matter of law,'' the agency added.

Meanwhile, GPhA's brief warned the court that a ruling in the lawsuit in favor of Actelion could force potential generic competitors to repeat the costly and lengthy clinical testing already performed by the branded drugmaker.

''[S]uch a result would strike at the heart of the 1984 Hatch-Waxman Act that jump-started the robust generic competition in today's pharmaceutical market by creating the simpler and more-efficient ANDA [abbreviated new drug application] process,'' Elwood told BNA.

Moreover, Elwood said, even a narrower ruling that gave branded manufacturers the authority to refuse to provide drug samples only with regard to drugs subject to REMS, still would have a major impact on the prescription drug industry because of the widespread and increasing use of REMS.

''That would have the perverse result that the measure Congress enacted in 2007 to promote consumer safety would be used to harm consumers by eliminating generic competition for REMS drugs,'' he said.

''As we mention in . . . our proposed amicus brief, the number of drugs subject to REMS has been increasing for years to the point where the FDA requires almost half of all new molecular entities and nearly 40 percent of all new drug applications to have a REMS,'' he said.

Potential Impact of Ruling in Case. Lawyers interviewed by BNA agree that a decision in the case could have far-reaching impacts.

Burns said that if the court accepts Actelion's position, the ruling could significantly damage the current balance in the Hatch-Waxman Act between respecting a branded manufacturer's patent rights and the objective of increasing generic competition.

Moreover, he said, ''If Actelion's position prevails, it would not be surprising to see proposed legislation introduced in Congress seeking to amend the Hatch-Waxman Act to make clear whether the act was intended to provide an entity like Actelion with the rights it claims.''

Philip Katz, of Hogan Lovells US LLP, in Washington, predicted that a ruling against Actelion could have multiple negative repercussions. ''First,'' he said, ''it would fundamentally change the long-standing notion that you can't be forced to sell your product to others. In that regard, I think such a decision could have ramifications beyond pharmaceuticals, particularly because it likely would be rooted in antitrust law.''

In addition, he said, a ruling in favor of the generic companies could expose innovator companies to liability risks over which they have no control.

''In essence, the generics want the drugs, but want the liability to stay with the innovator. I think compa-

  PLIR ISSN 1542-9547

nies like Actelion are rightly concerned that having to provide drugs with real risks associated with them . . . may lead to harm, for which the innovator company may be left as the responsible party.''

Last, he said, ''a decision against Actelion would give the statute a meaning that Congress clearly didn't intend, because Congress had before it, and rejected, a provision requiring companies to provide drugs to competitors seeking to conduct BE [bioequivalence] studies.''

Actelion Pharmaceuticals Ltd. is based in Switzerland and co-plaintiff Actelion Clinical Research Inc. is based in Cherry Hill, N.J. Apotex Inc. is based in Toronto, Canada, and Roxane Laboratories Inc. is based in Columbus, Ohio. Actavis Elizabeth LLC is based in Elizabeth, N.J.

Michelle Hart Yeary and Ezra D. Rosenberg, of Dechert LLP, in Princeton, N.J.; George G. Gordon, Carolyn E. Budzinski, and David S. Caroline, of Dechert LLP, in Philadelphia; and Paul H. Friedman, of Dechert LLP, in Washington, represent Actelion.

A. Richard Feldman, of Bazelon Less & Feldman PC, in Philadelphia; Michael A. Shapiro, of Bazelon Less & Feldman PC, in Marlton, N.J.; and Aitan Goelman and Paul B. Hynes Jr., of Zuckerman Spaeder LLP, in Washington, represent Apotex.

Charles J. Falletta and Beth S. Rose, of Sills Cummis & Gross, in Newark, N.J., and Eunnice H. Eun, of Kirkland & Ellis LLP, in Washington, represent Roxane.

Jason B. Lattimore, of the Law Office of Jason B. Lattimore, in Morristown, N.J., and Abbott B. Lipsky Jr. and Amanda P. Reeves, of Latham & Watkins LLP, in Washington, represent Actavis Elizabeth LLC.

Richard A. Feinstein, director of the FTC's Bureau of Competition; Peter J. Levitas, deputy director, Bureau of Competition; David C. Shonka, FTC acting general counsel and FTC attorneys Markus H. Meier, Bradley S. Albert, Michael J. Perry, James E. Rhilinger, Daniel W. Butrymowicz, and Timothy John Slattery, in Washington, submitted the amicus brief for the FTC .

Dennis Schmelzer, John P. Elwood, Jeremy C. Marwell, and Eric A. White, of Vinson & Elkins LLP, in Washington, submitted the amicus for GPhA.

BY DANA A. ELFIN

GPhA's amicus brief is at http://op.bna.com/hl.nsf/r?Open=deln-95rmhm. FTC's amicus is at http://op.bna.com/hl.nsf/r?Open=deln-95rmjn.