India Enters “Pay-for-Delay” Fray: CCI Investigating Pharmaceutical Patent Settlements

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India’s competition authority, the Competition Commission of India (CCI), has begun scrutinizing and investigating pharmaceutical patent settlement agreements between brand and generic firms for potential anticompetitive effects. It has been reported that the CCI is examining two sets of settlements resolving patent litigation in India. These investigations involve U.S. and Indian companies engaged in litigation in India.

Patent settlements have been investigated, scrutinized, and challenged by the competition authorities in the United States and other countries for more than a decade. India, however, is just now becoming more proactive with competition law enforcement as its competition law was just recently established. India adopted its competition law in 2002, the main provisions of which only became effective in 2009 and 2011. Similarly, India’s modern patent law was passed within the last decade (in 2005). Since the CCI became a fully functioning agency in May 2009, it has aggressively enforced its competition law—over the past year, the CCI has investigated more than 60 cases, including some that involve the pharmaceutical industry. In recent years, the CCI has been particularly aggressive in cases where competition law and intellectual property law intersect. Now, it appears that the CCI is turning to patent settlement agreements, and companies should anticipate that the agency generally will become more active in exercising its enforcement authority under the competition law.

In the United States, investigating and litigating “reverse payment” pharmaceutical patent settlements as a potential violation of the antitrust laws has been a Federal Trade Commission (FTC) priority since the late 1990s. Under U.S. law, nearly all patent settlements between brand and generic firms resolving pharmaceutical patent litigation must be reported to the FTC. The FTC then reviews these settlement agreements and may challenge what are referred to as “pay-for-delay” or “reverse payment” agreements, in which the settlement allegedly includes a payment from the brand to the generic in exchange for the generic’s agreement to delay its entry date.

In 2013, the U.S. Supreme Court’s decision in FTC v. Actavis emboldened the FTC’s enforcement initiative by holding that these “reverse payment” patent settlement agreements sometimes can violate the antitrust laws and should be examined under the “rule of reason.” Prior to this ruling, courts were divided as to whether reverse payment patent settlement agreements could be deemed illegal under antitrust law—some holding the agreements to be presumptively unlawful and others holding that such agreements are a legal exercise of a patent holder’s right to exclude (as long as they were within the “scope of the patent”).

Since Actavis was handed down, courts have grappled with the scope of the holding—specifically, whether the opinion is limited to agreements that involve large cash payments to the generic company, as in Actavis, or whether antitrust liability may also extend to agreements that include non-monetary consideration, such as an agreement by the brand to not launch a competing generic product, or what is referred to as an “authorized generic.” In the District of New Jersey, for example, two judges have ruled on opposite sides of this issue. The FTC advocates for a broad application of Actavis that would include non-monetary consideration and has filed amicus curiae briefs asserting this position in pending cases.

2 Id.
6 Prior to the ruling in FTC v. Actavis, the precedent in the Third Circuit was at odds with precedent in the Federal, Second, and Eleventh Circuits. See, e.g. In re K-Dur Antitrust Litig., 886 F. 3d 197, 218 (3d Cir. 2013) (holding that reverse payment settlement agreement are presumptively unlawful, applying a quick-look rule of reason analysis); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1223,1303-34 (Fed. Cir. 2008) (affirming the ruling that “any adverse anti-competitive effects within the scope of the [patent] could not be redressed by antitrust law”).
7 Compare In re Lamictal Direct Purchaser Antitrust Litig., 2014 U.S. Dist. LEXIS 9257, at *22 (holding that Actavis only applies to agreements involving “an exchange of money”); In re Lipitor Antitrust Litig., 2013 U.S. Dist. LEXIS 126468, at *95 (holding that “nothing in Actavis strictly requires that the payment be in the form of money.”)
8 See, e.g. In re Effexor XR Antitrust Litigation, No. 3:11-cv-05479, Brief of the Federal Trade Commission as Amicus Curiae (D.N.J. August 14, 2013), at 5–8 (involving a settlement in which the brand agreed to not launch an authorized generic in exchange for a delayed generic market entry).
In Europe, competition officials do not have as long of a history of enforcement against pharmaceutical patent settlements, but the European Commission (EC) has been very active in recent years, issuing hundreds of millions of dollars in fines. Earlier this summer, the EC issued the largest penalty to date in a reverse payment case, fining French drug manufacturer Les Laboratoires Servier and five generic companies more than €427 million for reverse payment patent settlement agreements that the EC asserts kept generic versions of blood pressure medication Perindopril off the market. Unlike the previous fines issued for patent settlements in which the violations were limited to the law against agreements that restrict competition (similar to U.S. Sherman Act Section 1), the EC found in this most recent case that Servier had also violated the law against abuse of a dominant position (similar to U.S. Sherman Act Section 2).

In India, the CCI analysis of patent settlement agreements is likely to parallel the enforcement policies that the FTC has pursued in the United States. The competition authorities from the two countries have had a strong working relationship over many years. FTC competition staff has visited and served as advisors to the CCI in an effort to assist the country in developing competition policy and enforcement procedure.

In 2012, the CCI and the United States competition agencies (FTC and DOJ) codified this relationship by signing a Memorandum of Understanding in order to promote increased cooperation and communication between the agencies. The memorandum provides, among other things, that (1) the agencies will cooperate as agreed and work to keep each other informed of significant competition policy and enforcement developments, and (2) that the agencies will consult on competition matters and communicate through regular meetings to exchange information on policy and enforcement priorities.

Given the FTC’s substantial history in investigating and challenging patent settlements, and the degree of coordination between U.S. and Indian competition authorities, it is likely that the FTC’s experience and actions in this area should provide guidance as to how the CCI will investigate and pursue pharmaceutical patent settlements. Accordingly, pharmaceutical companies—both Indian and U.S. companies active in the India market and courts—should look to the current treatment of patent settlement agreements by US courts and the enforcement policies of the FTC in analyzing potential liability under Indian competition law.

For More Information

For more information on any issues relating to reverse payments or pharmaceutical antitrust law, please contact Seth Silber at 202-973-8824 or Jonathan Lutinski at 202-973-8818. Seth is a partner in Wilson Sonsini Goodrich & Rosati’s Washington, D.C., office, previously served at the FTC as an advisor to former Chairman Jon Leibowitz, and investigated and litigated pharmaceutical patent settlement challenges while at the FTC. Jon is a senior associate in the firm’s Washington, D.C., office, and also previously served at the FTC as a staff attorney in the agency’s Health Care Division reviewing, investigating, and litigating pharmaceutical patent settlement challenges.

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9 Melissa Lipman, “3 Key Facts from the EU’s Latest Pay-For-Delay Case,” Law360, July 15, 2014, available at https://www.law360.com/articles/557309/3-key-facts-from-the-eu-s-latest-pay-for-delay-case. The EC has yet to release any of its “reverse payment” decisions to the public, however reports from those companies involved and public comments from EC commissioners indicate that the agency is applying the strict anticompetitive “by object” standard (similar to a per se standard in the US).