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OUTLOOK 2016: Busy Year Expected in Drug Patent, Antitrust Law

In 2016, patent and antitrust issues will be key for the pharmaceutical industry.

Bloomberg BNA talked with attorneys, other policy experts and stakeholders in late 2015 and early 2016 about antitrust and patent-related issues expected to affect the pharmaceutical industry this year.

On the patent side, increasing use of inter partes review at the Patent and Trademark Office to challenge pharmaceutical patents, possible changes for the Patent Trial and Appeal Board's rules and heightened standards for pleading patent infringement are all expected to affect the pharmaceutical industry in 2016.

On the antitrust front, further consolidation in the drug industry is predicted and legal developments are expected on the issues of patent litigation ''reverse payment'' deals and the practice of product hopping to thwart generic competition.

Inter Partes Review. 2016 will bring continued developments in the use of inter partes review proceedings at the PTO's Patent Trial and Appeal Board, attorneys tell Bloomberg BNA.

IPRs, a type of post-grant review proceeding, were established under the America Invents Act of 2011 to allow third-party challenges of patents at the PTO, and they're increasingly being used in the pharmaceutical patent world as an alternative to more costly district court patent litigation.

''As far as important topics for 2016, I think a key one will be the increasing use of IPRs by generic manufacturers,'' Steven H. Sklar of Leydig, Voit & Mayer Ltd. in Chicago said. ''This is a growing strategy by second or later-filers who don't want to incur the expense of actively participating in the district court litigation but still want to be able to make arguments with respect to invalidity.''

But Sklar said, ''It remains to be seen whether IPRs will lead to higher invalidation rates than district court and how the IPR impacts the 'traditional' model of the first ANDA [abbreviated new drug application]-filer taking the lead in the district court litigation.''

''It could very well lead to strategic behavior between the various generics,'' he said.

Despite the popularity of the IPR process, there is some industry concern that the process is stacked against patent holders.

''An interesting dynamic is that while IPRs have made it easier for anyone to attack the validity of a U.S. patent, the requirements for asserting a U.S. patent against an alleged infringer has become more difficult,'' Robert E. Colletti, of Frommer Lawrence & Haug LLP in New York, said. ''It is now settled by the Federal Circuit that IPRs are constitutional and challenges to standing by third parties have been unsuccessful,'' he said. ''So, without a change in legislation, third parties can continue to attack the validity of U.S. patents.''

Indeed, as Deborah Lu, of Vedder Price in New York, noted, ''There have been complaints from patent owners, that if your patent is challenged through an IPR it stands a good chance of being partly or completely invalidated.''

Stakeholders including the Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization are pushing for legislation to revamp the IPR process, including tightening standing requirements regarding who can challenge pharmaceutical patents through IPRs, an issue brought about by Kyle Bass.

Hedge-fund manager Kyle Bass's Coalition for Affordable Drugs has filed almost three dozen petitions challenging drug patents since February 2015. The drug industry accuses Bass of abusing the system. PhRMA and the BIO are urging Congress to exempt patents on federally approved drugs from PTAB review altogether.

Meanwhile, there may be changes in the offing that could stem the growth of these types of post-grant proceedings before the PTAB by making them less attractive to challengers than they are now.

The PTO has proposed changes to the rules for PTAB proceedings, including a pilot program that changes the number of judges making board decisions, and Congress is also proposing changes, with multiple bills pending in both houses. But it's far from certain that either the House or the Senate will act any time soon on any of the bills, especially as the 2016 presidential election draws closer.

The Supreme Court also may wind up weighing in on how the America Invents Act of 2011's post-grant proceedings are supposed to be run, if it decides to take up a petition filed by Cuozzo Speed Technologies LLC that seeks review of a decision that the PTO made in interpreting the AIA.

District Court Litigation: Pleading Standards. In the realm of district court patent litigation, Colletti said that litigants are likely to see the effects of 2015's amendments to the Federal Rules of Civil Procedure play out. Those amendments abolished so-called ''bare bones'' Form 18, a pleading for patent infringement that al-

lowed an infringement charge without any identification of specific patent claims allegedly infringed or even the purportedly infringing products. The new rules require patent owners to provide sufficient factual detail to show that the claim is ''plausible''—instead of the bare minimum complaint allowed in Form 18 complaints.

''We will likely see a rise in motions to dismiss at least certain patent infringement complaints,'' given the amendments, Colletti said. ''Now that the bare bones Form 18 patent complaint is abolished, it may result in challenges to patent complaints that do not plead the particulars of the infringement allegations.''

''It will be interesting to see how high of a burden courts set for asserting patent claims, especially given the many proposed patent reform bills which, if passed, require detailed explanation of any infringement allegations,'' Colletti said.

Antitrust Issues. Antitrust issues are also expected to be a top issue for pharmaceutical companies in 2016.

''Drug company mergers are likely to increase in 2016, and with greater consolidation, the level of Federal Trade Commission scrutiny of these proposed deals will also likely increase,'' James M. Burns, of Baker Donelson PC in Washington, said.

One issue that gained attention in 2015 was New York-based Pfizer Inc.'s announcement that it would merge with Dublin-based Allergan Plc and move its tax address to Ireland as part of the $160 billion combination.

The proposed Pfizer-Allergan transaction will be the largest so-called corporate inversion, in which U.S. companies use a merger to take a foreign address and cut their tax rates.

The new company—with products including Viagra and Botox—will be able to take advantage of Ireland's 12.5 percent corporate tax rate. The U.S. rate is 35 percent.

The Federal Trade Commission is likely to scrutinize the deal heavily, especially given that it's the largest such deal to date in the pharmaceutical world, eclipsing Pfizer's purchase of Warner-Lambert Co. in 2000 for $116 billion.

''While the Pfizer-Allergan transaction does not appear to present significant competitive issues,'' Burns said, ''given the size of the transaction, it can be expected that the FTC will carefully review the deal to ensure that this is the case.''

Some in Congress, including Sen. Richard J. Durbin (D-Ill.), are ''pushing the FTC to go outside their box to look at the Pfizer-Allergan merger,'' David A. Balto, of the Law Offices of David A. Balto in Washington, said. Balto formerly served as assistant director for policy and evaluation in the FTC's Bureau of Competition.

''There's fierce lobbying going on right now,'' he said. ''The key is going to be Comcast/Time Warner,'' Balto said, referring to the ''unconventional'' approach government regulators took in scrutinizing that deal last year.

In April 2015, Comcast Corp. and Time Warner Cable Inc. dropped their plans for a proposed $45.2 billion merger after they were unable to win support from the Justice Department, the FTC and the Federal Communications Commission. The government was uncomfortable with the proposed Internet giant's ability to ensure innovation and fair competition.

''The issue is whether the FTC is going to be willing to use the same kind of unconventional approach to the Pfizer-Allergan deal,'' Balto said.

Burns said that the transaction's size alone ''has the potential to reshape the entire pharmaceutical industry.''

''With greater consolidation, drug companies will likely be required to choose sides—branded versus generic—and to divest those portions of their current business that don't fit within their chosen path,'' Burns said.

Indeed, he said, ''The days where a drug company has both branded and generic divisions may be coming to an end.''

'Reverse Payments' Still An Issue. Courts are expected to continue to deal with another antitrust issue in 2016— reverse payments in drug patent litigation settlements. Reverse payment or pay-for-delay patent litigation settlements generally involve payments from branded drug companies to generic drug companies in exchange for keeping the generic off the market.

''I expect 2016 to produce decisions in many of the district court actions considering the legality of reverse payments,'' Colletti said. ''There are a dozen or more cases working through the district courts, and we will likely see clarification on what does or does not constitute a reverse payment.''

In *FTC v. Actavis*, the Supreme Court held in 2013 that large and unjustified payments made by the brand-name drug patent holder to the alleged generic patent infringer to settle litigation will subject the settlement to antitrust scrutiny under the rule of reason. But the *Actavis* opinion left open many questions, including whether the reverse payment must be in cash, the degree of importance that should be attached to the size of the payment and whether the strength of the underlying patent is relevant to the antitrust analysis.

Eric M. Grannon, of White & Case in Washington, said he hoped 2016 might bring a little more clarity to all the issues.

''In 2016, there are likely to be several important grants of summary judgment to defendants in reverse payment cases,'' Grannon said. ''The hope is that these grants of summary judgment will coalesce into a jurisprudence that provides guidance and potential safe harbors for settling parties going forward,'' Grannon said.

''Suits where the court set a low bar at the dismissal stage for assessing the plausibility of plaintiffs' allegations will be ripe for determinations that the facts don't support a finding of a 'large and unjustified' payment or that other circumstances demonstrate that the parties would not have reached any earlier settlement entry date even without the contemporaneous business transaction,'' he said.

''For example, a manufacturing deal that saves the innovator money or meets a pre-existing need could be readily justified and thereby pass muster under *Actavis*.''

Plaintiffs who ''hang their hat on the allegation that the innovator had cheaper alternatives than the business deal at issue are likely to be disappointed,'' Grannon said. ''Judges will be reluctant to send cases to juries to second-guess justifiable business decisions.''

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Authorized Generics. In 2016, the high court may wind up weighing in on at least one issue left unanswered by *Actavis*: whether noncash features of drug patent settlement agreements can be subject to antitrust scrutiny.

Richard A. Samp, chief counsel of the Washington Legal Foundation, a Washington-based pro-business group, said it's likely that the Supreme Court will grant review this spring on whether a patent litigation settlement between branded and generic drug companies that includes a commitment by the branded maker not to launch an authorized generic can violate the antitrust laws.

Authorized generics are generic drugs sold under a license from the patent holder. Patent litigation settlements between brand-name and generic manufacturers may include an agreement by a branded drugmaker not to launch an authorized generic version of its brand-name drug during the 180-day period of generic exclusivity granted to the first generic challenger under the Hatch-Waxman Act. Such agreements not to launch authorized generics are informally referred to as ''no-AG'' agreements.

In 2015, the U.S. Court of Appeals for the Third Circuit decided that issue in favor of the antitrust plaintiffs in the *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.* case. The defendants, GlaxoSmithKline and Teva Pharmaceutical Industries Ltd., are expected to file a review petition with the U.S. Supreme Court in February, Samp said.

''I expect that the petition will be granted in May or June, and that the case will be argued in the fall,'' Samp said.

''That issue is a close one and could go either way,'' he said.

But others weren't quite as hopeful that 2016 would provide additional guidance on questions *Actavis* left unanswered.

''Conflict in the lower courts regarding how to interpret *Actavis* remains the most significant pharma antitrust issue as we go into the new year,'' Burns said. ''Given the number of 'open issues' that the Supreme Court created in its opinion, this uncertainty was predictable and unavoidable.''

And he said, ''With all of the uncertainty surrounding the reverse payment issue, it seems quite clear that either the Supreme Court will be required to revisit its *Actavis* decision or Congress will need to create a legislative solution; the status quo is not unpalatable for all concerned—pharma, plaintiffs, consumers and the courts,'' Burns said.

''There are so many permutations to the post-*Actavis* antitrust fights that I don't see this issue being resolved for many years,'' Samp said.

But, according to Balto, reverse payments isn't even much of an issue any more. ''Reverse payments are a problem from the past, not an ongoing problem,'' he said. ''Most companies know how to settle litigation without raising those issues.''

''The reverse payments issue is the distraction,'' Balto said. ''That's not where the serious issues are.''

Product Hopping, State Officials. According to Balto, the critical pharmaceutical antitrust issues involve instances of individual company conduct that artificially inflate drug costs and delay generic drug entry. Balto pointed to the practice of ''product hopping'' as an example of such conduct.

Product hopping or ''forced switching'' occurs when brand-name drugmakers make small formulation changes to their products just before patents are about to run out and as generics are about to enter the market.

Because product changes tend to be viewed as procompetitive, Balto said, and because the conduct is by an individual company, it's a hard area for antitrust law to grapple with.

The antitrust laws tend to be much more harsh on collective conduct, he said, and it's harder to challenge individual conduct by an individual company. ''There's a huge black line between collective conduct and individual firm conduct. The law is much more willing to condemn collective conduct as 'pernicious,' '' Balto said.

There's zero enforcement by the FTC in this area, Balto said. ''The FTC takes a monk-like vow of silence with these type of cases and wasn't prosecuting them,'' Balto said. But, he said, a ''game-changer'' ruling from the U.S. Court of Appeals for the Second Circuit in 2015—in which the appeals court found that a drug company's product-hopping scheme could violate the antitrust laws—has the potential to usher in an entirely new era of antitrust enforcement.

In the case, the Second Circuit found ''ample evidence'' that Actavis (now Allergan) switched patients to a newer patented version of the Alzheimer's drug Namenda to thwart generic competition, and the court held that the monopolization suit was substantially likely to succeed on the merits. The court thus upheld the district court's injunction and rebuffed Allergan's motion for rehearing. New York Attorney General Eric Schneiderman (D) filed the Namenda case in 2014, alleging that Allergan's product hopping scheme to switch patients from Namenda IR to its new extended release drug was a blunt move to maintain its $1.6 billion Namenda monopoly even after its patent expired.

A 'Game-Changer'? ''The Second Circuit's ruling on Namenda was the game changer of 2015, and it's an even bigger game changer in 2016,'' Balto said.

''This is the case that shows that there's an avenue for attacking this kind of conduct,'' Balto said.

''The successful prosecution of the Namenda case is really a landmark,'' he said.

''Consumers care whether generics make it to the market. The injunction that occurred in the case was a benefit to consumers that paid off in 2015.''

''The most important antitrust enforcers at the moment are the state attorneys general,'' Balto said. ''Probably the most important issue going forward is whether the AG will find new ways of going after strategic conduct by pharmaceutical companies.''

''We're only at the beginning,'' he added.

The Namenda case was the first product-hopping case that made it through the appellate courts. Allergan petitioned the Supreme Court for review, but the parties subsequently settled the case, and the appeal was dismissed.

Allergan also withdrew its petition for Supreme Court review, which means the Supreme Court won't be offering any guidance on the product hopping issue.

FTC Targeting Product Hopping in Doryx Case. However, the product hopping theory isn't going away.

The FTC has filed a brief on the issue in *Mylan Pharmaceuticals, Inc. v. Warner-Chilcott PLC*, urging the

U.S. Court of Appeals for the Third Circuit to reinstate a lawsuit in which Mylan NV claims that the makers of an antibiotic called Doryx, including Warner Chilcott Plc and Mayne Pharmaceuticals, changed the formula to thwart competition. The FTC said that, through drug hopping, a ''brand-name manufacturer's well-timed tweaks to its drugs can thus create an ever-retreating horizon of generic competition at the expense of consumers.''

According to Balto, the Second Circuit's Namenda ruling ''provides a crystal-clear template for the Third Circuit'' in the Doryx case. ''If I were Warner Chilcott, I'd walk to the settlement table as quickly as possible,'' he said.

But Burns doesn't see the future of the product hopping theory as so clear-cut.

''Product hopping currently presents a challenging and controversial issue under the antitrust laws,'' Burns said.

''Product hopping as an antitrust violation reflects the continuing evolution of the antitrust laws generally, where the line between lawful and unlawful conduct continues to blur, with the facts and circumstances in each specific case becoming increasingly critical to the analysis,'' Burns said. ''While advocates of such a theory contend that such conduct can present anticompetitive harm, and thus should be actionable, the theory pushes the boundaries of how Section 2 of the Sherman Act has traditionally been utilized,'' he said.

Implications for Antitrust Law Generally. And Burns said, ''Absent consensus on whether such a claim is permissible under the antitrust laws, product hopping presents the prospect of creating significant uncertainty not only for the pharmaceutical industry, but for antitrust jurisprudence generally.''

''We appear to be approaching a place where 'per se' rules, either of lawfulness or unlawfulness, will cease to exist, with the 'rule of reason' governing all conduct,'' he said.

''Ultimately, the Supreme Court will have to address whether product hopping can violate the antitrust laws, and when it does, the court's ruling is likely to have implications not only for pharma antitrust cases, but for Section 2 antitrust principles generally,'' Burns said.

He also said a legislative response to the issue could be on the horizon in 2016. ''Should the courts rule that product hopping is not conduct that can be addressed by the antitrust laws, it would not be surprising to see an attempt at a legislative response to this conduct in 2016 or 2017,'' he said.

BY DANA A. ELFIN

To contact the reporter on this story: Dana A. Elfin in Washington at delfin@bna.com

To contact the editor responsible for this story: Brian Broderick at bbroderick@bna.com

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