

Supreme Court's Dismissal of Invalidity Counterclaim Based on Covenant Not to Sue Raises New Potential Avenues for Argument in Hatch-Waxman Act Cases

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In a trademark decision that may have implications on other intellectual property cases, last week, the United States Supreme Court issued a unanimous opinion affirming the dismissal of an alleged infringer's counterclaim for trademark invalidity after the trademark owner provided a covenant not to sue. See *Already, LLC v. Nike, Inc.*, 568 U.S. ---, No. 11-982 (2013) (Slip Op.), available [here](#). The Court found that Already's counterclaim challenging the validity of Nike's trademark was mooted after Nike issued a broadly worded covenant not to sue to Already and voluntarily dismissed its claims of trademark infringement with prejudice. While the end result in this case may not be remarkable, it provides insight on the current thinking of the Supreme Court Justices and provides potential new arguments for use in the context of patent cases, particularly in Hatch-Waxman ANDA litigation, where this issue has frequently arisen in recent years.

Proceedings In *Already*

Nike sued Already for infringement of its trademark on its Air Force 1 line of shoes, and Already filed a counterclaim alleging that the trademark was invalid. In an attempt to end the litigation without jeopardizing the validity of its Air Force 1 trademark, Nike provided a broad covenant not to sue Already, its distributors, and its customers for infringement of this trademark based on any of the shoes at issue in the suit and any "colorable imitations" thereof. Nike then moved to dismiss its infringement claims with prejudice and also moved to dismiss as moot Already's invalidity counterclaim without prejudice. Already opposed dismissal. In support, Already presented affidavits from its president stating that Already had plans to introduce new versions of its current shoe line into the marketplace and from three potential investors stating that they would not consider investing in Already until Nike's trademark was invalidated. The district court granted Nike's motion to dismiss for failure to meet the Article III "case or controversy" requirement. The Second Circuit affirmed and the Supreme Court granted *certiorari*.

The Supreme Court's Opinion

In a unanimous opinion, the Supreme Court found that no controversy existed and declared Already's counterclaims to be moot. The Court held that the "voluntary cessation doctrine" applied to this case, requiring that "a defendant claiming that its voluntary compliance moots a case bears the formidable

burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur.” *Id.* at 4 (citing *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000)). The parties and the Court did not seem to question that the covenant would cover any of Already’s existing products, but were more concerned about whether the covenant would cover Already’s future products. The Court held that the “breadth of the covenant suffices to meet the burden imposed by the voluntary cessation test.” *Id.* at 6. Though Already attempted to create a “case or controversy” by focusing on its intent to introduce a new shoe line, the Court found the covenant so broad that it could not find evidence of any shoes Already might manufacture that would not be covered by the covenant. *Id.* at 7 (“If such a [potentially infringing] shoe exists, the parties have not pointed to it, there is no evidence that Already has dreamt of it, and we cannot conceive of it. It sits, as far as we can tell, on a shelf between Dorothy’s ruby slippers and Perseus’s winged sandals.”).

The Court rejected Already’s alternative theories of injury giving rise to Article III standing. One of these rejected theories was that the continued validity of Nike’s trademark “gives false color to state and federal trademark claims which expose [Already’s] business to substantial and unpredictable risks, deterring investors.” *Id.* at 10 (internal quotation marks omitted, substitution original). In support of this argument, Already offered affidavits from potential investors stating that they would consider investing in the company only if Nike’s trademark was declared invalid. Already argued that the mere existence of the trademark was hampering its ability to attract capital and tried to analogize this to “a present invasion of [Already’s] property rights” similar to the reductions of property value that gave rise to standing in *Village of Euclid v. Amber Realty Co.*, 272 U.S. 365, 386 (1926). Slip Op. at 10. The Court, however, rejected Already’s reliance on this theory after finding that “[h]ere there was no such present invasion,” and held that “the fact that some individuals may base decisions on ‘conjectural or hypothetical’ speculation does not give rise to the sort of ‘concrete’ and ‘actual’ injury necessary to establish Article III standing.” *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)).

Another notable theory of injury rejected by the Court was “that dismissing this case allows Nike to bully small innovators lawfully operating in the public domain.” *Id.* at 13. The Court dismissed this argument as an overly broad theory of standing, noting that “granting covenants not to sue may be a risky long-term strategy for a trademark holder,” and moreover, the Lanham Act separately protects against “abusive litigation practices by providing for an award of attorney’s fees in ‘exceptional cases.’” *Id.* (citations omitted). And although allowing standing based on “bullying” from a larger competitor may benefit Already, the smaller entity in this case, the Court observed that “lowering the gates for one party lowers the gates for all” and expressed concerns that such a rule would also convey standing to larger companies wishing “to challenge the intellectual property portfolios of their more humble rivals.” *Id.*

Justice Kennedy filed a concurring opinion, joined by Justices Thomas, Alito, and Sotomayor. The concurring opinion was “written to underscore that covenants like the one Nike filed here ought not to be taken as an automatic means for the party who first charged a competitor with trademark infringement suddenly to abandon the suit without incurring the risk of an ensuing adverse adjudication.” Concurring Slip Op. at 2 (emphasis added). That is, the concurrence envisions instances where a covenant not to sue after filing a litigation does not render the counterclaim for invalidity moot such as where there is “demonstrated reluctance by investors, distributors, and retailers to maintain good relations with the alleged infringer.” *Id.* Justice Kennedy emphasized that courts should exercise caution when “using a covenant not to sue as the basis for a motion to dismiss as moot,” and proposed that “[t]he formidable burden to show the case is moot ought to require the

trademark holder, at the outset, to make a substantial showing that the business of the competitor and its supply network will not be disrupted or weakened by satellite litigation over mootness or by any threat latent in the terms of the covenant itself.” *Id.* at 3.

The Potential Impact of *Already v. Nike* on Patent Declaratory Judgments

Although this case dealt with an invalidity counterclaim in the trademark context, all federal court litigation is subject to the requirements of Article III of the Constitution. Thus, the Supreme Court’s ruling may potentially be applied in the context of patent litigation. In recent years, some courts, including the Supreme Court, have indicated a willingness to share principles, where appropriate, among patent, trademark, and copyright cases.¹ Further, none of the policy reasons cited by the Court for denying *Already*’s theories of injury were specific to trademark law.

The Court’s opinion provided hints that its principles could be applicable to patent litigation. For example, when discussing the policy implications of allowing standing in this case, the Court referred broadly to the ability of companies to challenge “intellectual property portfolios” when they are not “threatened by any particular patent or trademark”. Slip Op. at 13 (emphasis added).

This raises the important question of what effect the Supreme Court’s opinion in *Already* may have on the Federal Circuit’s jurisprudence on declaratory judgment jurisdiction in patent cases, which is discussed in more detail below.

A. Declaratory Judgment Jurisdiction in Non-Hatch-Waxman Patent Declaratory Judgment

The opinion of the Court is consistent with the Federal Circuit’s longstanding general approach that a covenant not to sue or a promise not to assert a patent against an alleged infringer renders a patent invalidity counterclaim moot where the covenant or promise covers past, present, and future acts. *See, e.g., Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995). Nothing in the Court’s opinion or the concurrence offers any indication that there is any significant change to the *Super Sack* rule with respect to non-Hatch-Waxman patent cases. Beyond making clear that generalized economic harms are not sufficient to confer jurisdiction, *Already* will likely have little impact on jurisdictional issues in patent declaratory judgments in non-Hatch-Waxman cases.

B. Declaratory Judgment Jurisdiction of Subsequent ANDA Filers After *Already*

Beginning in 2008, the Federal Circuit began allowing jurisdiction for a subsequent ANDA filer to seek a noninfringement or invalidity declaratory judgment even after receiving a covenant not to sue covering all past, present, and future activities had been given. *See, e.g., Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008); *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158 (Fed. Cir. 2012); *Teva Pharms. USA v. Eisai Co., Ltd.*, 620 F.3d 1341 (Fed. Cir. 2010), *vacated*, 426 F. App’x 904 (Fed. Cir. 2011).²

Whether *Already* provides an argument around these cases will likely be the subject of future litigation. Subsequent ANDA filers may look to distinguish *Already* by arguing that the existence of the patent listed in the Orange Book affects their business in not allowing the immediate commercial activity they seek whereas the *Already* Court concluded that *Already* was freely able to sell all the products it was currently marketing and those it planned to market in the future due to the covenant. Alternatively, subsequent ANDA filers may claim to hold a present property right in their ability to potentially hasten a first-filer’s 180-day exclusivity period or trigger a forfeiture event. There are, however, several counterarguments available to the patent holder in this situation. First, the harm

alleged by the subsequent ANDA filer is not a harm but rather it is a benefit to the first-filer and “a result envisioned by the Hatch-Waxman Act.” *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008). The patent rights at issue are not creating the harm; it is the regulatory scheme created by Congress that creates the temporary block on the subsequent filer’s ability to enter the market. Second, the patent holder can seek to analogize the ANDA filer’s inability to challenge a patent’s validity and thereby expedite forfeiture or the start date of the first-filer’s 180-day exclusivity period – if successful – to the generalized economic harms found to not constitute an injury in *Already* as discussed above.

The *Already* decision may also impact jurisdiction in Hatch-Waxman cases where it is an actual or near impossibility for a subsequent ANDA filer to obtain all the necessary final, non-appealable decisions in time to have any effect on when the subsequent ANDA filer can market its product. The Federal Circuit has relied on this impossibility to find no jurisdiction in the past. *See, e.g., id.* at 1361 (Janssen could not obtain the necessary court decisions because it had stipulated to the validity of one of the patents). A similar situation would be where an ANDA filer loses its case on infringement and validity at the trial court on at least one of the Orange Book patents, which would make it “absolutely clear” that the ANDA filer could not obtain a final, non-appealable judgment of invalidity or noninfringement on all of the Orange Book patents within a timeframe that would matter.

The four-Justice concurrence noted the Federal Circuit’s decision in *Caraco*, as among the few cases addressing a covenant rendered in ongoing litigation and generally cautioned courts to proceed with caution before ruling that a covenant not to sue can be used to terminate litigation. Concurring Slip Op. at 3. The concurrence further suggested that “[a]n insistence on the proper allocation of the formidable burden on the party asserting mootness is one way to ensure that covenants are not automatic mechanisms for [intellectual property] holders to use courts to intimidate competitors without, at the same time, assuming the risk that their [intellectual property] will be found invalid and unenforceable.” *Id.* at 3-4. This cautionary language may not apply, however, to a situation in which the patent holder issues a covenant not to sue on the patent before litigation is brought. The patentee could then seek to argue that it is not using a covenant to terminate a litigation that it began. We also note that *Caraco* and the related cautionary discussion was absent from the majority opinion discussion.

Although litigants would be wise at this point to assume for business planning purposes that a generic would have a significant chance of maintaining a declaratory judgment action, we foresee this to be a remaining area for legal development.



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- ¹ See, e.g., *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006) (noting that the approach adopted for injunctions in patent cases is “consistent with our treatment of injunctions under the Copyright Act” and analogizing copyright law to patent law); *Windsurfing Int’l, Inc. v. AMF, Inc.*, 828 F.2d 755, 757 (Fed. Cir. 1987) (“Because declaratory judgment actions involving trademarks are analogous to those involving patents, . . . we may also, when necessary, find guidance in the precedents of this court.”).
- ² Under the Hatch-Waxman Act’s statutory scheme, the first filer of a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV certification”) is awarded a 180-day exclusivity period during which no other ANDA applications may be approved by the FDA. *Caraco*, 527 F.3d at 1283. This exclusivity period is triggered by the date the first filer begins commercial marketing of the generic drug product, and may be forfeited in certain circumstances by a failure to market within a certain time period after a final court decision finding the patent invalid, unenforceable, or not infringed. See 21 U.S.C. § 355(j)(5). Therefore, subsequent Paragraph IV filers are incentivized to seek a judgment to force the first filer to market earlier and/or to cause a forfeiture event so that they are able to enter the market sooner.

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