chapter 21

Hatch-Waxman Practice in the Supreme Court of the United States

As the U.S. judiciary's ultimate arbiter of "what the law is,"[1] the Supreme Court has addressed issues involving the Hatch-Waxman Amendments to the Food, Drug, and Cosmetics Act (FDCA) on six occasions. Two of these cases involved the scope of the FDCA's experimental-use exception to patent infringement; one involved the act's counterclaim provision, which authorizes the courts to require brand-name drug makers to correct inaccurate patent information filed with the Food and Drug Administration (FDA); two involved "preemption" issues involving the effect of Hatch-Waxman's requirements on conflicting state tort law; and one involved the potential antitrust implications of cases settled under the Hatch-Waxman framework. The Supreme Court also will occasionally use pharmaceutical cases to delve into general patent law issues, as in 2015's *Teva v. Sandoz* decision. This chapter summarizes these cases.

I. *Eli Lilly & Co. v. Medtronic, Inc.* (1990)

The first Hatch-Waxman case to reach the Supreme Court was *Eli Lilly & Co. v. Medtronic, Inc.*[2] The Court there considered the "safe harbor" provision of 35 U.S.C. § 271(e)(1), which says it is *not* "an act of infringement" to use "a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[3]

All agreed that this provision protected generic drug companies conducting the research necessary to submit Abbreviated New Drug Applications (ANDAs) to the FDA from infringement claims brought by brand-name drug makers.[4] The question was whether the safe harbor also extended to medical devices. The answer would be no, of course, if "a Federal law" referred only "to those individual provisions of federal law that regulate drugs."[5] But devices would be covered if "a Federal law" referred to "the

[1]David S. Bloch, Steffen N. Johnson, and Charles B. Klein, Winston & Strawn LLP. The authors thank Matthew J. Mezger for helpful research assistance.

. Marbury v. Madison, 5 U.S. (1 Cranch) 137, 177(1803).

[2]. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

[3]. 35 U.S.C. § 271(e)(1) (2012); *Eli Lilly*, 496 U.S. at 663.

[4] . *See* 21 U.S.C. § 360(e) (2012); *see also, e.g.*, Eugene Trogan, *Balancing the Need for Innovative Drugs While Providing Lower Cost Alternatives to Consumers: Hatch-Waxman Reviewed*, 24 MED. & L. 355, 358–59 (2005).

[5] . *Eli Lilly*, 496 U.S. at 665.

entirety of any Act . . . at least some of whose provisions regulate drugs."[6] Advocating the first of these possible interpretations of Hatch-Waxman, Eli Lilly argued that Medtronic's testing of an allegedly infringing device—an implantable cardiac defibrillator—was not covered. But the Supreme Court disagreed, holding instead that the experimental-use exception applies to any product subject to FDA approval under the FDCA.[7]

Faced with the conflicting textual signals in § 271(e)(1)—indeed, the Court candidly described that provision as "not plainly comprehensible on anyone's view"[8]—the Court found its answer in "the structure of the 1984 Act taken as a whole."[9] As the Court explained, Congress enacted the relevant Hatch-Waxman's provisions to cure twin patent-term "distortions."[10] On the one hand, during the infancy of a patent, a manufacturer might spend years developing a device and waiting for FDA approval.[11] On the other hand, as the patent aged, competitors were forced to wait for the patent's expiration even to begin research and development.[12] To correct these "dual distorting effects," the Court observed that Hatch-Waxman established, on the front end, a term extension for patents relating to products that are subject to lengthy regulatory delays and, on the back end, a safe harbor for experimentation.[13] Since these provisions were "meant generally to be complementary," the Court found that "[a]ll of the products eligible for a patent term extension," including medical devices, were "subject to [the safe harbor]."[14]

Because makers of devices were expressly entitled to the benefit of a term extension on the front end, the Court held that competitors were implicitly covered by the safe harbor on the back end.[15] That is, the Court chose the reading of the safe harbor provision that "appears to create a perfect 'product' fit between the two sections."[16] To do otherwise, the Court explained, would "leave in place an anticompetitive restriction at the end of the monopoly term" and "simultaneously expand the monopoly term itself."[17] "It would take strong evidence to persuade us that this is what Congress wrought, and there is no such evidence

---

[6] . *Id.* at 665–66.

[7] . Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. §§ 301–399 (2012)).

[8] . *Eli Lilly*, 496 U.S. at 669.

[9] . *Id.*

[10]. *Id.* at 672.

[11]. *See id.* at 669–70.

[12]. *See id.* at 670.

[13]. *Id.*

[14]. *Id.* at 673–74.

[15]. *See id.* at 678–79.

[16]. *Id.* at 674.

[17]. *Id.* at 672.

here."[18]

Along the way, the Court noted that "[t]he function of the paragraphs in question is to define a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications."[19] Thus, in addition to its core holding, *Eli Lilly* is notable for being the first case to acknowledge "the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification"—the "paragraph IV certification" discussed later.[20]

II. *Merck KGaA v. Integra Lifesciences I, Ltd.* (2005)

The Court was again called upon to determine the scope of § 271(e)(1)'s experimental-use exception in *Merck KGaA v. Integra Lifesciences I, Ltd.*[21] There, Merck contracted with researchers at the Scripps Research Institute to develop a cancer therapy based on chemicals that block integrin receptors.[22] This research, however, necessarily used research tools and intermediate compounds protected by Integra's patents.[23] Noting that these research tools were not themselves part of Merck's investigational new drug application, Integra asserted that their use was not covered by the § 271(e)(1) exception to patent infringement.[24]

The Supreme Court disagreed. It held that experimental-use immunity "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA."[25] As the Court explained, this exception to infringement liability "necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process," whether or not a generic drug applicant ultimately seeks approval to market that particular drug product.[26]

---

[18]. *Id.* at 673.

[19]. *Id.* at 676.

[20]. *Id.* at 678.

[21]. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 195 (2005).

[22]. *Id.* at 197.

[23]. *Id.* at 200.

[24]. *See id.* at 203.

[25]. *Id.* at 202 (citing *Eli Lilly*, 496 U.S. at 665–69).

[26]. *Id.*

III. *PLIVA, Inc. v. Mensing* (2011)

The Court's decisions in *PLIVA, Inc. v. Mensing*[27] and *Actavis, Inc. v. Demahy*,[28] consolidated cases issued in 2011, marked the second time in two years that the Court had addressed preemption of state tort claims against drug makers. Two years earlier in *Wyeth v. Levine*, the Court had addressed state failure-to-warn claims against *brand-name* manufacturers.[29] By a vote of 6–3, the Court there ruled against preemption, reasoning that there was no conflict between federal and state law because federal law allowed brand-name drug makers to initiate changes to their labels.[30] In *PLIVA*, the Court faced the same issue as it relates to *generic* drug manufacturers.[31] This time, however, the Court reached a different result based on the provisions of Hatch-Waxman.[32]

As the Court's 5–4 majority explained, Congress has not allowed generics (unlike brands) to initiate label changes.[33] Rather, with limited exceptions not relevant to that case, generic labels must be "the same as" the brand's, making it impossible for generic drug makers to comply with both federal law and conflicting labeling requirements imposed by state juries and seeking stronger warnings.[34]

The plaintiffs in these cases developed tardive dyskinesia, a neurological disorder, after long-term use of generic versions of the drug metoclopramide.[35] At the time, the FDA-approved label for the brand-name product, Reglan, warned of that very risk. And, as required by federal law, the generic products used by the plaintiffs carried an identical warning. (The warning has since been further strengthened. In 2009, the FDA ordered that Reglan and generic metoclopramide products carry a "black box" warning about the risk of tardive dyskinesia and long-term use of metoclopramide.) The plaintiffs nonetheless filed suit, claiming that the generic manufacturers violated Louisiana and Minnesota law because they knew or should have known that their labels provided an inadequate warning of the risks of metoclopramide.

The generic manufacturers responded that the claims were preempted because federal law precluded them from providing any warning that was not "the same as" the label that the FDA had approved for the brand-name product. The Supreme Court agreed.

Writing for a five-justice majority, Justice Thomas first agreed with the FDA's position that federal law does *not* allow these generic manufacturers to make unilateral label changes. That is, generic manufacturers cannot add or change warnings provided with the product. Nor can they send "Dear Doctor" letters, which constitute "labeling" under federal law and thus must

---

[27]. In the interest of full disclosure, Winston & Strawn filed an amicus brief on behalf of two generic drug manufacturers in these cases.

[28]. PLIVA, Inc. v. Mensing, 564 U.S. ___, 131 S. Ct. 2567 (2011).

[29]. Wyeth v. Levine, 555 U.S. 555 (2009).

[30]. *Id.* at 581.

[31]. *PLIVA*, 131 S. Ct. at 2574.

[32]. *Id.* at 2579.

[33]. *Id.* at 2574 (citing 21 U.S.C. § 335(b)(1), (d) (2012)).

[34]. *Id.* at 2574.

[35]. *Id.* at 2573.

at all times match that of the name-brand equivalent.[36] As the majority explained, this was the critical difference between the cases and the Court's earlier decision in *Wyeth*: FDA regulations permit brand-name drug manufacturers to *unilaterally* strengthen a warning; the FDA has authority to rescind such changes, but preapproval is not necessary.[37] Generic manufacturers, by contrast, have an "ongoing federal duty of 'sameness' " that precludes any unilateral label change.[38]

Second, assuming without deciding that federal law requires generic manufacturers to ask the FDA for a "safer label" if they become aware of a new safety issue, the majority concluded that any such duty does not defeat preemption: "State law demanded a safer label; it did not instruct the [generic] Manufacturers to communicate with the FDA about the possibility of a safer label."[39] This is the heart of the decision—that conflict preemption does not take into account actions third parties might or could be asked to take. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it."[40]

The plaintiffs in these cases argued that the generic manufacturers should be required to prove that they tried and failed to get FDA approval for a warning that would have complied with state law.[41] The Court disagreed. "In these cases," the Court explained, "it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label."[42] It is also "*possible*" that the manufacturers could have convinced the FDA to reinterpret its regulations to allow unilateral label changes, or that, "by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments."[43] But such "conjectures," the Court concluded, cannot be sufficient or else the Supremacy Clause would have no effect outside of express preemption—rendering "conflict preemption all but meaningless."[44]

The majority and dissenting opinions both remarked on the different treatment for generic and name-brand drugs under *Wyeth* and *PLIVA*.[45] But as the majority concluded, federal law governing generic drug makers is "meaningfully different" from that governing brand-name manufacturers, and "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire."[46]

---

[36]. *Id.* at 2585.

[37]. *Id.* (citing *Wyeth*, 555 U.S. at 570–71).

[38]. *Id.* at 2575.

[39]. *Id.* at 2578.

[40]. *Id.* at 2579.

[41]. *See id.* at 2574.

[42]. *Id.*

[43]. *Id.*

[44]. *Id.*

[45]. *Id.* at 2574 (noting "brand-name and general drug manufacturers have different federal drug labeling duties") (citing *Wyeth*, 555 U.S. at 570–71); *see also PLIVA, Inc.*, 131 S. Ct. at 2585 (Sotomayor, J., dissenting) (citing *Wyeth*, 555 U.S. 570–71).

[46]. *PLIVA*, 131 S. Ct. at 2582.

IV. *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S* (2012)

The Supreme Court's first decision elaborating on the patent-dispute provisions of Hatch-Waxman came just four years ago, in *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*.[47] That decision involved the meaning of Hatch-Waxman's counterclaim provision, which permits generic drug makers defending pharmaceutical patent cases to obtain an order requiring the patent holder "to correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim . . . an approved method of using the drug."[48]

Before turning to the details of the Court's decision, one must understand the relevant provisions of Hatch-Waxman and the surrounding regulatory framework. Naturally, patents are at the core of the Hatch-Waxman's regulatory architecture.[49] And when the FDA evaluates when to approve an application to market a generic drug, it considers whether the proposed drug would infringe a patent held by the maker of the brand-name version of the drug.[50] To assess that matter under the statute, the FDA requires brand manufacturers to submit descriptions of the scope of their patents.[51]

Specifically, Hatch-Waxman directs brand-name drug makers that hold a new drug application (NDA) to provide a list of their pertinent product and method patents for submission in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the Orange Book) whenever "a claim of patent infringement could reasonably be asserted" against those who, without a license, manufacture, use, or sell the drug.[52] If the listed patent claims a particular method of using the drug, the brand-name drug maker must also submit a patent use code description explaining what is covered by the patented method of use.[53]

When a generic drug maker submits an ANDA to the FDA, that ANDA must specifically address patents listed in the Orange Book that relate to the drug for which the generic seeks marketing approval.[54] The generic drug maker submitting an ANDA may choose from four different patent certification options: (I) no relevant patent information has been submitted to the FDA; (II) the relevant patent has expired; (III) the applicant will await patent expiry before marketing its product; or (IV) the applicant seeks to market the product before patent expiry based on contentions that the patent is invalid, unenforceable, or will not be infringed.[55] These options are called paragraph I, II, III and IV certifications, respectively. Paragraph IV certifications require the applicant to notify the brand-name drug maker of the application, and such notice often leads to immediate patent

---

[47]. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. ___, 132 S. Ct. 1670 (2012). Winston & Strawn represented Caraco in this litigation.

[48]. 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2012); *Caraco*, 132 S. Ct. at 1675.

[49]. *See Caraco*, 132 S. Ct. at 1675–76.

[50]. *Id.* at 1676.

[51]. *Id.*

[52]. 21 C.F.R. § 314.53(b)(1) (2014); *Caraco*, 132 S. Ct. at 1675.

[53]. 21 C.F.R. § 314.53(c)(2)(i)(O)(1).

[54]. 21 U.S.C. § 355(j)(7)(A)(i).

[55]. *Id.* § 355(j)(2)(A)(vii).

infringement.[56]

In some instances, however, the generic drug maker can avoid waiting until patent expiry (under a paragraph III certification) and also avoid patent litigation (under a paragraph IV certification) by filing a so-called "section viii statement."[57] This statement is an option only when the FDA has approved multiple uses for the listed product (say, to treat cancer or, alternatively, to treat epilepsy), the listed method patent covers fewer than all of these uses (say, only to treat cancer), and the generic applicant seeks approval solely for the nonpatented use (say, only to treat epilepsy). The section viii statement specifies that the ANDA does not seek approval for the patented method of use.

The FDA does not evaluate patents.[58] Thus, when assessing the viability of a generic applicant's section viii statement, the agency relies on the patent description (or "use code" description) submitted by the brand-name drug maker.[59] The FDA will reject a section viii statement if the generic is seeking approval for a use that overlaps, even in part, with the patent (or use code) description submitted by the brand-name drug maker. If that description is overbroad or otherwise inaccurate, it could inappropriately block a generic applicant from using the section viii process to expedite generic competition.[60]

If an ANDA applicant believes a patent use code description is improper, its first remedy is to object to the listing.[61] In response, the FDA will ask the NDA holder to affirm or correct the challenged listing. But again, the FDA is not a patent agency. Thus, "[u]nless the application holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the [Orange Book] list"—it essentially defers to the brand-name drug company's description of the scope of its patent.[62]

Caraco v. Novo Nordisk involved patent litigation asserted by brand-name drug maker (and NDA holder) Novo against generic drug maker Caraco in connection with a diabetes drug branded as Prandin (repaglinide).[63] The FDA had approved Prandin for three uses—as a monotherapy, as a combination therapy with metformin, and as a combination therapy with a third drug. Novo's patent-in-suit, however, covered only the second use, that is, combination therapy with metformin.[64]

Caraco thus attempted to avoid the infringement allegation by limiting its application to the other two nonpatented uses and submitting a section viii statement. In response, however, Novo Nordisk changed its use code description for its patent from "use of repaglinide in combination with metformin to lower blood glucose" to the more general description a method of using

---

[56]. *Id.* § 355(j)(2)(A)(vii)(IV).

[57]. *Id.* § 355(j)(2)(A)(viii).

[58]. Application for FDA Approval to Market a New Drug, 68 Fed. Reg. 36,676, 36,683 (June 18, 2003) (noting that the FDA "has long observed that [it] lack[s] expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that our outside both [FDA's] expertise and [FDA's] authority.").

[59]. *Caraco*, 132 S. Ct. at 1677.

[60]. *See id.*

[61]. 21 C.F.R. § 314.53(f).

[62]. *Id.*

[63]. *Caraco*, 132 S. Ct. at 1678.

[64]. *Id.* at 1679.

the drug repaglinide "for improving glycemic control in adults with type 2 diabetes."[65] In light of this broad patent description, the FDA rejected Caraco's section viii statement—thus forcing Caraco to include an infringing label in its application and defend the litigation by alleging patent invalidity and unenforceability.

After Novo refused to correct its use code description, Caraco invoked the counterclaim provision—21 U.S.C. § 355(j)—asking the court to order Novo to limit the description of its patent to the one patented use actually covered by the patent. As noted, § 355(j) allows courts to enjoin the brand "to correct or delete the patent information submitted by the [NDA] holder . . . on the ground that the patent does not claim either—the drug for which the application was approved; or an approved method of using the drug."[66] The sole remedy for a § 355(j) counterclaim is an order to "correct or delete" the erroneous patent use code information.

Novo contended that the counterclaim provision did not apply, because its patent *did* cover "an approved method of using the drug."[67] Caraco countered that the same patent "does not claim" two *other* approved methods.[68] In other words, the question before the Supreme Court was whether a counterclaim may be brought only if the patent claims *no* method of using the drug (as Novo asserted), or also if it does not claim the particular method of using the drug for which the generic seeks FDA marketing approval (as Caraco asserted).[69]

The Supreme Court unanimously sided with Caraco, explaining that its reading of the statute "sees, raises, and bests Novo's."[70] As the Court explained, the counterclaim provision was designed to avoid the problem of overbroad use code descriptions, which "throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates."[71] Specifically, "a single drug may have multiple methods of use, only one or some of which a patent covers," and Congress "contemplate[d] that one patented use will not foreclose marketing a generic drug for other unpatented ones."[72] Against that backdrop, the Court explained, "[t]he availability of the counterclaim thus matches the availability of FDA approval under the statute: A company may bring a counterclaim to show that a method of use is unpatented because establishing that fact allows the FDA to authorize a generic drug via section viii."[73]

The Court thus rejected Novo's argument that "the counterclaim disappears because it has a patent for a method of use in which neither Caraco nor the FDA is interested at all."[74] In this context, the phrase "not an" meant "not a particular one" rather

---

[65]. *Id.*

[66]. 21 U.S.C. § 355(j)(5)(C)(ii)(I).

[67]. *Caraco*, 132 S. Ct. at 1679.

[68]. *Id.*

[69]. *See id.* at 1680–81.

[70]. *Id.* at 1682.

[71]. *Id.* at 1684.

[72]. *Id.* at 1681–82.

[73]. *Id.* at 1682.

[74]. *Id.*

than "not any." That reading best "fit within the statutory scheme . . . by facilitating the approval of non-infringing generic drugs under section viii."[75]

In light of this decision, the counterclaim to correct an inaccurate patent description submitted to the FDA is available to a defendant in a Hatch-Waxman case even in the situation where the listed patent does in fact cover some uses of the reference listed drug.[76]

V. *Federal Trade Commission v. Actavis, Inc.* (2013)

Federal Trade Commission v. Actavis, Inc.[77] does not address Hatch-Waxman litigation per se, but rather the antitrust implications of certain settlements under the Hatch-Waxman framework.[78] Generic and brand drug companies sometimes settle Hatch-Waxman cases by entering into "reverse payment" settlements, in which the brand-name drug maker (the plaintiff) pays the generic drug maker (the defendant).[79] In general, the payment is tied to particular marketing activities, drug supply, or other services. The Federal Trade Commission (FTC) argued, however, that such arrangements were pretexts and, in reality, the plaintiff was paying the defendant to delay generic competition.[80]

How to treat such settlements under the antitrust laws was and remains the subject of hot debate.[81] The FTC had long contended that so-called pay for delay settlements are per se illegal, while both brand and generic drug companies have defended the settlements as procompetitive and proper so long as they stay within the scope of the patents-in-suit.[82] In 2013, this dispute finally reached the Supreme Court, which agreed that reverse-payment settlements are potentially anticompetitive but declined to impose a per se prohibition.[83]

FTC v. Actavis, Inc. involved a reverse-payment situation in which brand company Solvay paid generics Actavis, Paddock, and Par for "marketing considerations" and, as part of the settlement, the generics agreed to stay off the market even after their generic versions of AndroGel testosterone gel were approved by the FDA.[84] When all four settling parties submitted their set-

---

[75]. *Id.* at 1683.

[76]. *See id.* at 1688.

[77]. Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. ___, 133 S. Ct. 2223 (2013).

[78]. *Id.* at 2227.

[79]. *See id.* at 2229.

[80]. *See id.* at 2229–30.

[81]. 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3a1 (2d ed. 2010).

[82]. Kenneth Glazer & Jeneé Desmond-Harris, *Reverse Payments: Hard Cases Even under Good Law*, ANTITRUST, Spring 2010, at 14, 14.

[83]. *See Actavis, Inc.*, 133 S. Ct. at 2237–38.

[84]. *Id.* at 2229–30.

tlement agreements to the FTC and the Department of Justice for approval (as required under Hatch-Waxman),[85] the FTC sued, claiming that the settlement violated antitrust law.[86]

The Supreme Court did not reach the question whether the particular settlement at issue was unlawful.[87] In a 5–3 decision authored by Justice Breyer,[88] the Court rejected the per se illegality position advanced by FTC, but also rejected the scope-of-the-patent test advanced by the pharmaceutical industry.[89] Instead, the Court adopted a "rule of reason" analysis, holding that "what the holder of a valid patent could do does not by itself answer the antitrust question" because "[t]he patent here may or may not be valid, and may or may not be infringed."[90]

The Court noted that even though "the agreement's 'anticompetitive effects fall within the scope of the exclusionary potential of the patent' " is relevant, if not dispositive.[91] That is because "[a] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects" and "one who makes such a payment may be unable to explain and to justify it."[92] The Court thus reasoned that "[i]t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy and not against procompetitive antitrust policies as well."[93]

After *Actavis*, the key issue in assessing the legality of these "reverse payment" settlements is whether anticompetitive effects outweigh procompetitive effects in the relevant markets.[94] Instead of establishing a bright-line test, the Court noted that "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification"—in other words, "the FTC must prove its case as in other rule-of-reason cases."[95]

In the wake of this decision, the parties to Hatch-Waxman disputes have been less likely to settle patent litigation under terms where the plaintiff pays cash to the defendant in return for a delayed generic product launch. But this has not ended the disputes as to such settlements. Among other issues, the lower courts are grappling with whether *Actavis* extends to noncash "payments," such as where the brand agrees not to launch its own generic during the initial term of the generic product launch

---

[85]. As required by Pub. L. No. 108-173, § 1112, 117 Stat. 2066, 2461–63 (2003) (codified as amended at 21 U.S.C. § 355 (2012)).

[86]. *Actavis, Inc.*, 133 S. Ct. at 2230.

[87]. *See id.* at 2234–39.

[88]. Justice Alito did not participate.

[89]. *See id.* at 2231, 2237–38.

[90]. *Id.* at 2230–31.

[91]. *Id.* at 2230.

[92]. *Id.* at 2237.

[93]. *Id.* at 2231.

[94]. Daniel A. Crane, Actavis, *the Reverse Payment Fallacy, and the Continuing Need for Regulatory Solutions*, 15 MINN. J. L. SCI. & TECH. 51, 53 (2014).

[95]. *Id.* at 2237.

if, in return, the generic agrees to delay its product launch.[96]

The *Actavis* decision also impacts the evaluation of reverse-payment settlements under state law. State courts typically view reverse-payment pharmaceutical settlements through the lens of state antitrust laws asserted in class-action cases. In 2015, the Supreme Court of the State of California held in a pair of consolidated cases (*In re Cipro Cases I & II*)[97] that, just as reverse-payment settlements lacking legitimate justifications are unlawful under the Sherman Act, they too are illegal under California's Cartwright Act.[98] Guided by *Actavis*, the California Supreme Court explained that "[u]nder federal antitrust law, these [reverse-payment] settlements are not immune from scrutiny, even if they limit competition no more than a valid patent would have. . . . We conclude the same is true under state antitrust law."[99] Thus, California will now apply a "rule of reason" when analyzing pharmaceutical settlements. *In re Cipro Cases I & II* is the first state supreme court case to apply *Actavis* in the context of its domestic antitrust laws, but it is reasonable to expect that other states will follow suit.

VI. *Mutual Pharmaceutical Co. v. Bartlett* (2013)

Mutual Pharmaceutical Co. v. Bartlett[100] was the Court's third case in four years involving state tort claims against drug makers. As noted previously, *Wyeth v. Levine* held that failure-to-warn claims against *brand-name* manufacturers were not preempted, since federal law allowed such manufacturers to initiate changes to their labels.[101] Then, in *PLIVA, Inc. v. Mensing* and *Actavis, Inc. v. Demahy*, the Court ruled that Congress *did* preempt failure-to-warn claims against *generic* manufacturers, reasoning that federal law does not permit generics to initiate label changes—making it impossible to comply with more stringent labeling rules imposed by state juries.[102]

Bartlett arose when the First Circuit held that the rule of *PLIVA* preempted only *failure-to-warn* claims against generics, not *defective design* claims—even though federal law likewise requires generic drugs to share the same design as their branded counterparts.[103] The court reasoned that generic drug makers could avoid the tension between conflicting federal and state duties by taking their products off the market.[104]

---

[96]. Brenna E. Jenny, *Information Costs and Reverse Payment Settlements: Bridging the Gap between the Antitrust Agencies*, 30 SANTA CLARA COMPUTER & HIGH TECH. L.J. 231, 300 (2014).

[97]. *In re* Cipro Cases I & II, 61 Cal. 4th 116 (2015).

[98]. CAL. BUS. & PROF'L CODE §§ 16700 *et seq.*

[99]. *Cipro*, 61 Cal. 4th at 130.

[100]. Mut. Pharm Co. v. Bartlett, 570 U.S. ___, 133 S. Ct. 2466 (2013). Winston & Strawn filed an amicus brief on behalf of eight generic drug manufacturers in this case.

[101]. Wyeth v. Levine, 555 U.S. 555, 581 (2009).

[102]. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011).

[103]. *Mut. Pharm. Co.*, 133 S. Ct. at 1270.

[104]. *See id.* at 2476–77.

The Supreme Court reversed—again, as in *PLIVA*—by a 5–4 vote.[105] As Justice Alito's opinion for the Court explained, the relevant provisions of Hatch-Waxman "require[] a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based," making it "impossible" for "manufacturers to comply with both state and federal law."[106] As in *PLIVA*, therefore, the Court's decision rested on the doctrine of "impossibility" preemption—which governs when complying with both federal and state law is impossible.[107] As the Court concluded, "state-law design-defect claims . . . that place a duty on manufacturers to render a drug safer *by either altering its composition or altering its labeling* are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling."[108]

Bartlett had argued that Mutual could avoid any conflict by taking its product off the market, and that state law was simply "compensatory"—it did not create a "regulatory" duty to redesign the drug, just an obligation to pay plaintiffs.[109] But the Court rejected both arguments. Unlike an "absolute liability" regime "in which liability does not reflect the breach of any duties at all, but merely serves to spread risk," the Court explained, the "strict liability" regime at issue turned on a "breach of duty."[110] Thus, any finding of liability necessarily presumed that the generic manufacturer had the authority to change its product's design—contrary to federal law.[111] Moreover, the Court reasoned that a "'stop selling' rationale [is] incompatible with [its] pre-emption jurisprudence," which "presume[s] that a manufacturer's ability to stop selling does not turn impossibility into possibility."[112]

VII. *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* (2015)

The Supreme Court's decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*,[113] does not turn on the Hatch-Waxman Amendments or issues unique to pharmaceuticals. Rather, it announced an important change to the way *all* patents are interpreted by the courts: namely, the deference given by the Federal Circuit to district court interpretations of patent claim terms.

Teva was a Hatch-Waxman dispute concerning Sandoz's ANDA for a generic version of Teva's drug product branded as Copaxone (copolymer-1), which treats multiple sclerosis. Sandoz argued that Teva's Copaxone patent was indefinite because it failed to define one of three distinct methods for calculating "molecular weights"—a key claim term. The U.S. District Court for

---

[105]. *See id.* at 2480.

[106]. *Id.* at 2475, 2477.

[107]. *See id.* at 2477.

[108]. *Id.* at 2479 (emphasis added).

[109]. *See id.* at 2473.

[110]. *Id.*

[111]. *See id.* at 2475–76.

[112]. *Id.* at 2477 & n.3.

[113]. Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. ___, 135 S. Ct. 831 (2015). For a more detailed discussion of this case, see Steffen N. Johnson, *What the Supreme Court's 2014 Term Means for Business*, NAT'L (July 15, 2015).

the Southern District of New York took evidence from various experts on the meaning of "molecular weight," ultimately concluding that the patent was valid because persons of skill in the art would understand from the context of Teva's patent which method should be used to calculate molecular weights.

On appeal, the Federal Circuit conducted a de novo review of the Southern District of New York's findings, including an independent analysis of the expert testimony submitted by both parties, as required by the Supreme Court's seminal decision in *Markman v. Westview Instruments*.[114] *Markman* held that patent claim construction was "exclusively" a matter for "the court" rather than the fact-finder, and the Federal Circuit reasoned that this rule applied not only to the patent's claim language, specification, and prosecution history (the intrinsic record), but also to subsidiary factual matters resolved during claim construction (the extrinsic record). Based on its de novo review, the Federal Circuit reversed the trial court's determination and held that Teva's patent was invalid for indefiniteness.

The Supreme Court disagreed. By a 7–2 vote, it reversed the Federal Circuit, holding that trial court findings concerning extrinsic evidence are reviewed for "clear error." Although the "ultimate question of the proper construction of [a] patent [is] a question of law," the "clear command" of Federal Rule of Civil Procedure 52(a)(6) permits appellate courts to set aside "findings of fact" only if "clearly erroneous."[115] Thus, the Court's prior decision in *Markman* "did not . . . create an exception from the ordinary rule governing appellate review of factual matters" for "subsidiary factual matters" resolved during the district court's "construction of a patent claim."[116] Given that extrinsic evidence (in the form of expert testimony, dictionaries, and the like) can help lay courts understand scientific or technical patent claim terms that use "technical words or phrases not commonly understood," the evaluation of extrinsic evidence is properly the domain of the trial court and hence trial court decisions turning on extrinsic evidence should only be reversed for clear error. The Federal Circuit's decision was thus remanded for reconsideration under the "clear error" standard.[117]

Teva thus represents a check on appellate review of trial court patent determinations. In future cases, the Federal Circuit will apply de novo review to findings based on "evidence intrinsic to the patent," but clear-error review to questions on which "the district court needs to consult extrinsic evidence in order to understand, for example, the background science."[118] Trial court patent-interpretation decisions that turn on extrinsic evidence are thus less vulnerable to reversal on appeal.

VIII. Conclusion

Although more than 30 years have passed since Congress passed Hatch-Waxman in 1984, the Supreme Court has yet to take up Hatch-Waxman cases involving some of the key aspects of the law, such as the requirements for generic drug approval, the first filer's 180-day exclusivity, the provisions addressing the forfeiture of such exclusivity, or the paragraph IV certification process leading to patent litigation. This may reflect the fact that the Supreme Court endeavors not only to limit its review to cases raising critical issues of national importance, but to do so in cases that are suitable "vehicles"—cases that involve recurring fact patterns and present the issues cleanly. Moreover, many pharmaceutical patent cases are somewhat technical and fact-

[114]. Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996).

[115]. *Teva*, 135 S. Ct. at 837.

[116]. *Id.* at 838.

[117]. *Id.* at 837–38, 841–42.

[118]. *Id.* at 841.

dependent, and the Court—aware that its decision will establish "the law of the land"[119]—is appropriately cautious about wading into issues that may require specialized expertise in the chemical arts and the life sciences.

At the same time, the Court has recently taken an increased interest in patent cases in general,[120] and the pharmaceutical industry is vitally important to American economic life. Also, Hatch-Waxman cases can raise issues of general patent law, as in 2015's *Teva* decision. Thus, it seems likely that the high Court will have occasion to take up more of the recurring issues that arise in pharmaceutical patent cases—and to address other key Hatch-Waxman issues—in the not distant future. Where an issue has national implications for the development of patent law under Hatch-Waxman—and particularly where that issue has produced conflicting outcomes in similar Federal Circuit cases—pharmaceutical practitioners should consider asking the Supreme Court to declare "what the law is."[121]

---

[119]. Marbury v. Madison, 5 U.S. (1 Cranch) 137, 176 (1803).

[120]. *See* Steffen N. Johnson, *The Roberts Court Gets Intellectual (Property)*, NAT'L (Aug. 27, 2014) (noting that, during the Court's 2013 term, it "heard ten IP cases—six patent, two copyright, and two Lanham Act—more than in any term since 1946").

[121]. *Marbury*, 5 U.S. at 177.