

Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664 (2017)

Under the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), a biological product may be licensed by two routes: first, the FDA may license a biologic product if the product has been demonstrated to be safe, pure, and potent; and second, the FDA may approve an abbreviated biologic license application (“aBLA”) if the applied for product is shown to be a “biosimilar” of a previously approved biologic product (a “reference product”).

Under the BPCIA’s patent dispute resolution process, an aBLA applicant seeking FDA approval of a biosimilar is supposed to provide its application and manufacturing information to the sponsor within 20 days of the date the FDA notifies the applicant that it has accepted the application for review. 42 U.S.C. § 262(l)(2)(A). This triggers an exchange of information designed to create lists of relevant patents. *Id.* at § 262(l)(3). Two phases of litigation may then occur. In the first, the parties collaborate to identify patents on the lists for immediate litigation. The second phase—triggered when the applicant gives 180 days notice of commercial marketing pursuant to § 262(l)(8)(A)—involves any listed patents not litigated in the first phase.

Sandoz submitted an aBLA for a biological product that Amgen markets. A day after the FDA informed Sandoz that its aBLA had been accepted for review (to eventually determine licensure), Sandoz notified Amgen that it had submitted an aBLA and notice of intent to market immediately upon receiving future FDA licensure. Sandoz later informed Amgen that it did not intend to provide its aBLA and manufacturing information and that Amgen could sue immediately for patent infringement under § 262(l)(9)(C). Amgen sued, and also asserted that Sandoz’s refusal to exchange information violated California’s unfair competition law. Sandoz counterclaimed for declaratory judgments that, *inter alia*, it had not violated the BPCIA. While the case was pending, the FDA licensed Sandoz’s product and Sandoz provided a second notice of commercial marketing.

The district court granted partial judgment on the pleadings to Sandoz on its BPCIA counterclaims and dismissed Amgen’s state-law claim. The Federal Circuit affirmed the dismissal of Amgen’s state-law claim, holding that Sandoz’s failure to disclose its application and manufacturing information did not violate the BPCIA and that the BPCIA provides the exclusive remedies for failure to comply with this requirement. The Federal Circuit also held that under § 262(l)(8)(A) an applicant must provide the 180 day notice of commercial marketing after obtaining licensure, and enjoined Sandoz from marketing until 180 days from its second notice.

The Supreme Court affirmed the Federal Circuit’s ruling that injunctive relief is not available to force the information exchange, explaining that the declaratory remedies of § 262(l)(9)(C) are the exclusive federal remedies for a violation of § 262(l)(2)(A). However, the Supreme Court remanded to the Federal Circuit to consider whether an injunction could be available under state law. The Supreme Court then reversed the Federal Circuit on the issue of notice timing, holding that the applicant’s notice of commercial marketing may be given prior to FDA licensure. In interpreting the language of § 262(l)(8)(A), the Court rationalized that the phrase “the biological product licensed under subsection (k)” modifies “commercial marketing” rather than “notice,” thus “commercial marketing” is the point in time by which the biosimilar must be “licensed.” Therefore, the applicant may provide notice either before or after receiving FDA licensure.

Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017)

In *Lexmark*, the Supreme Court addressed two important issues concerning the reach of patent exhaustion.¹ First, whether a patentee that imposes contractual limitations on the sale of a product can enforce these limitations by means of an infringement lawsuit. And second, whether an authorized sale of a patented product abroad exhausts a patentee's patent rights in the United States. The Supreme Court held that exhaustion applies in both circumstances finding that "a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale."²

The dispute between Lexmark and Impression Products concerned refillable printer cartridges sold pursuant to a "Return Program," which provided consumers a 20% discount in return for agreeing not to transfer the used cartridges to anyone but Lexmark. Impression Products nonetheless bought used cartridges from consumers, both domestically and abroad, refilled them, and even exchanged microchips to circumvent Lexmark's digital rights management software. Lexmark then sued Impression Products for patent infringement.

Patentees Cannot Enforce Restrictions on an Authorized Sale Through the Patent Act

The Supreme Court reasoned that an authorized sale of a patented product exhausts a patentee's patent rights because of the "common law's refusal to permit restraints on the alienation of chattels."³ Using a used car dealership as an example, Chief Justice Roberts explained that, absent patent exhaustion, the dealership could not be sure it will be free to resell a car purchased from its former owner because of potentially-retained patent rights. Concerned the "smooth flow of commerce would sputter," the Court thus rejected a patentee's ability to retain sticks in the bundle of patent rights once an authorized sale has taken place. In contrast, the Federal Circuit had reached the opposite result by reasoning that 35 U.S.C. § 271 trumped the common law doctrine and allowed patent owners to retain rights under § 271 as long as these conditions were imposed as part of the authorized sale.

Sales Outside the United States Similarly Exhaust Patent Rights

The Supreme Court further held that "[a]n authorized sale outside the United States, just as one within the United States, exhausts all rights under the Patent Act," because the common law doctrine of patent exhaustion is not limited in its geographical reach.⁴ The Court's decision parallels its reasoning in *Kirtsaeng*, which involved a similar question under copyright law.⁵ Justice Ginsburg dissented and would have found no international exhaustion because patent laws are country specific. In her view, because a sale occurring abroad is beyond the reach of U.S. patent law, "it makes little sense to say that such a sale exhausts an inventor's U.S. patent rights."⁶

¹ *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523 (2017).

² *Id.* at 1529.

³ *Id.* at 1532.

⁴ *Id.* at 1535–36.

⁵ *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519 (2013).

⁶ *Id.* at 1539 (Ginsburg, J., dissenting).

Samsung Elecs. Co. v. Apple, Inc., 137 S. Ct. 429 (2016)

Apple secured many design patents in connection with its iPhone. Among those patents were the D618,677 patent, covering a black rectangular front face with rounded corners, the D593,087 patent, covering a rectangular front face with rounded corners and a raised rim, and the D604,305 patent, covering a grid of 16 colorful icons on a black screen.

When Samsung released a series of smartphones that resembled the iPhone, Apple sued Samsung alleging that Samsung smartphones infringed Apple's D593,087, D618,677, and D604,305 design patents. A jury found infringement and awarded Apple \$399 million in damages for Samsung's design patent infringement, the entire profit Samsung made from its sales of the infringing smartphones.

The Federal Circuit affirmed the design patent infringement damages award. In doing so, it rejected Samsung's argument "that the profits awarded should have been limited to the infringing 'article of manufacture'"—for example, the screen or case of the smartphone—"not the entire infringing product"—the smartphone. The Supreme Court granted *certiorari*, and reversed and remanded.

The Supreme Court's opinion concerned the meaning of "article of manufacture" with respect to damage calculations arising from design patent infringement. The Federal Circuit identified the entire smartphone as the only permissible "article of manufacture" for the purpose of calculating §289 damages because consumers could not separately purchase components of the smartphones. The question before Court was whether that reading is consistent with §289, and Court held that it was not.

Section 289 of the Patent Act makes it unlawful to manufacture or sell an "*article of manufacture*" to which a patented design or a colorable imitation thereof has been applied and makes an infringer liable to the patent holder "to the extent of his total profit." 35 U. S. C. §289.

Court held that the term "article of manufacture" should be interpreted as encompassing both a product sold to a consumer and a component of that product. Court reasoned that this is consistent with the Court's reading of the other statutory language, such as the term "design[s] for an article of manufacture" in §171(a) or "manufacture" in §101 of the Patent Act.

Because the term "article of manufacture" is broad enough to embrace both a product sold to a consumer and a component of that product, Court held that Federal Circuit's narrower reading cannot be squared with §289's text.

Court, however, declined to resolve whether the relevant article of manufacture for each design patent at issue here is the smartphone or a particular smartphone component because parties did not adequately brief this issue. Court directed the Federal Circuit to address any remaining issues on remand.

SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC, 137 S. Ct. 954 (2017)

In *SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954 (2017), the Supreme Court held in a 7–1 decision¹ that the equitable defense of laches does not bar recovery of damages in the six-year period provided by 35 U.S.C. § 286.

Section 286 states: “Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action.” 35 U.S.C. § 286. In deciding whether laches could nonetheless bar recovery of damages within this statutorily prescribed six-year period, the Court analogized to its decision in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962 (2014), which addressed a similar issue: whether laches could bar recovery of damages incurred within the Copyright Act’s three-year limitations period. The Court held in *Petrella* that, “in face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief.” *Id.* at 1974.

Writing for the majority in *SCA Hygiene*, Justice Alito followed *Petrella*’s logic and “infer[red] that [Section 286] represents a judgment by Congress that a patentee may recover damages for any infringement committed within six years of the filing of the claim.” *SCA Hygiene*, 137 S. Ct. at 961. The majority rejected the proposed distinction between the forward-looking statute-of-limitations at issue in *Petrella* and the backward-looking limitations period in Section 286. *Id.*

The majority next analyzed whether, because of older patent-infringement cases applying laches, Congress had effectively codified a laches defense in the 1952 Patent Act. The majority began its analysis by noting that the “most prominent feature of the relevant legal landscape” at the time of the Patent Act’s enactment was the “well-established general rule . . . that laches cannot be invoked to bar a claim for damages incurred within a limitations period specified by Congress.” *Id.* at 963. In light of this general rule, the majority required “nothing less than a broad and unambiguous consensus of lower court decisions” to support the inference that Congress codified a “very different patent-law-specific rule.” *Id.* at 964. The majority did not find such a consensus. It therefore adhered to its reasoning in *Petrella* and found laches inapplicable to bar a claim for damages within Congress’s prescribed six-year limitations period.

¹ The opinion issued in the period between Justice Scalia’s passing and Justice Gorsuch’s appointment.

Issue: In March 2017, the U.S. Supreme Court handed down a decision clarifying federal copyright law surrounding whether features incorporated into the design of a useful article are eligible for copyright protection. The case involves cheerleader uniforms designed by market leader Varsity Brands (“Varsity”) and copied by Star Athletica. The legal problem is whether copyright protection, which extends naturally not only to works of music and literature, but also to “pictorial, graphic, or sculptural” works, protects the particular combination of chevrons, zigzags and stripes that characterizes Varsity’s uniforms. Star Athletica argued that this kind of “industrial” design largely influenced by utilitarian considerations does not warrant copyright protection.

Holding: A feature incorporated into the design of a useful article is eligible for copyright protection under the Copyright Act of 1976 only if the feature (1) can be perceived as a two- or three-dimensional work of art separate from the useful article, and (2) would qualify as a protectable pictorial, graphic or sculptural work -- either on its own or fixed in some other tangible medium of expression -- if it were imagined separately from the useful article into which it is incorporated; that test is satisfied here.

Judgment: Affirmed, 6-2. Mar. 22, 2017. Opinion by Justice Thomas. Justice Ginsburg filed a concurrence. Justice Breyer filed a dissenting opinion and Justice Kennedy joined.

Reasoning: The majority addresses the topic wholly as a matter of statutory interpretation. Working in that vein, it reads the statute as giving broad protection to industrial designs, emphasizing that key language of the statute does not protect useful articles but instead “the design of a useful article,” and it protects that only if the design “incorporates pictorial, graphic, or sculptural features that can be identified separately from, and are capable of existing independently of, the utilitarian aspects of the article.” The key question is that of “separability,” or when the design’s expressive aspects are sufficiently “separable” from the utilitarian design. Instead of the various separability tests that the 6th Circuit noted and that other courts have used to determine a design’s copyrightability under Section 101, the Court set forth a simple test.

“Applying this test to the surface decorations on the cheerleading uniforms is straightforward. First, one can identify the decorations as features having pictorial, graphic, or sculptural qualities. Second, if the arrangement of colors, stripes, and chevrons ... were separated from the uniform and applied in another medium – for example, on a painter’s canvas—they would qualify as ‘two-dimensional ... works of ... art.’ And imaginatively removing the surface decorations from the uniform and applying them in another medium would not replicate the uniform itself.”

TC Heartland LLC v. Kraft Foods Group Brands LLC, 518 U.S. ____ (2017)

In *TC Heartland*, the Supreme Court clarified where venue is proper for patent infringement suits, holding that, under the patent venue statute (28 U.S.C. § 1400(b)), a domestic corporation “resides” only in its state of incorporation. The decision upended nearly 30 years of Federal Circuit precedent holding that a corporation “resides” in any jurisdiction in which it is subject to personal jurisdiction.

Section 1400(b) provides that a plaintiff may bring a patent infringement action either in (1) “the judicial district where the defendant resides”; or (2) “where the defendant has committed acts of infringement and has a regular and established place of business.” In 1957, the Supreme Court interpreted § 1400(b) to mean that a domestic corporation “resides” only in its state of incorporation.¹ In so holding, the Court rejected the argument that § 1400(b) incorporated the broader definition of corporate “residence” contained in the general venue statute, § 1391(c).

In 1988, Congress amended § 1391(c) to provide that, “[f]or purposes of venue under this chapter, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced” Soon thereafter, the Federal Circuit held in *VE Holding Corp. v. Johnson Gas Appliance Co.* that the amendment to § 1391(c) defined corporate “residence” for all provisions under the same “chapter,” including § 1400(b).² The Federal Circuit consistently applied that interpretation for about 30 years. Thus, both the district court and the Federal Circuit rejected *TC Heartland*’s challenge to venue when it was sued by Kraft Foods in Delaware.

In 2017, the Supreme Court revisited this issue by granting *certiorari* in *TC Heartlands* and, ultimately, reversing the Federal Circuit’s holding in an 8-0 decision. The Court noted that it had already interpreted § 1400(b) in *Fourco* and found that Congress had not changed the meaning of § 1400(b) when it amended § 1391(c) in 1988. The Court explained that the version of the statute at issue in *Fourco* included language (“for venue purposes”) similar to the language of the 1988 amendment (“purposes of venue under this chapter”). Moreover, the Court noted that § 1391(c) does not apply when “otherwise provided by law,” which is the case for patent infringement suits that are governed by the specific provisions of § 1400(b).

In the wake of *TC Heartland*, a domestic corporation can no longer be sued for patent infringement in any jurisdiction where it is subject to personal jurisdiction. Rather, a domestic corporation may only be sued (i) in its state of incorporation, or (ii) where it has committed acts of infringement and has a “regular and established place of business.”³

¹ *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222 (1957).

² *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990).

³ In the wake of *TC Heartlands*, courts have grappled with a number of subsidiary venue issues. <http://www.friedfrank.com/siteFiles/Publications/092217IPHeartlandFederalCircuitVacatesRatheonOrder.pdf>, *See also* <http://www.friedfrank.com/siteFiles/Publications/102017IPHeartlandASubsidiarysOperationsetc.pdf>, <http://www.friedfrank.com/siteFiles/Publications/09282017IPHeartlandTalskvEvernote.pdf>.

35 U.S.C. § 101 Legislative Proposals

Current Statute	AIPLA Proposal	IPO Proposal	ABA-IP Proposal
<p>Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement and useful thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.</p>	<p>(a) Eligible Subject Matter.—Whoever invents or discovers any useful process, machine, manufacture, composition of matter, or any useful improvement thereof, shall be entitled to a patent therefor, subject only to the conditions and requirements set forth in this title.</p> <p>(b) Sole Exceptions to Subject Matter Eligibility.—A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.</p> <p>(c) Sole Eligibility Standard.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept.</p>	<p>(a) Eligible Subject Matter—Whoever invents or discovers, and claims as an invention, any useful process, machine, manufacture, composition of matter, or any useful improvement thereto, shall be entitled to a patent for a claimed invention thereof, subject only to the exceptions, conditions, and requirements set forth in this Title.</p> <p>(b) Sole Exception To Subject Matter Eligibility—A claimed invention is ineligible under subsection (a) if and only if the claimed invention as a whole, as understood by a person having ordinary skill in the art to which the claimed invention pertains, exists in nature independently of and prior to any human activity, or exists solely in the human mind.</p> <p>(c) Sole Eligibility Standard—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard as to the requirements or conditions of sections 102, 103, and 112 of this Title, the manner in which the claimed invention was made or discovered, or the claimed invention’s inventive concept.</p>	<p>(a) Eligible Subject Matter.—Whoever invents or discovers any useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, shall be entitled to obtain a patent on such invention or discovery, absent a finding that one or more conditions or requirements under this title have not been met.</p> <p>(b) Exception.—A claim for a useful process, machine, manufacture, or composition of matter, or any useful improvement thereof, may be denied eligibility under this section 101 on the ground that the scope of the exclusive rights under such a claim would preempt the use by others of all practical applications of a law of nature, natural phenomenon, or abstract idea. Patent eligibility under this section shall not be negated when a practical application of a law of nature, natural phenomenon, or abstract idea is the subject matter of the claims upon consideration of those claims as a whole, whereby each and every limitation of the claims shall be fully considered and none ignored. Eligibility under this section 101 shall not be negated based on considerations of patentability as defined in Sections 102, 103 and 112, including whether the claims in whole or in part define an inventive concept.</p>