NOTES

Biotechnology Industry Organization v. District of Columbia: The Federal Circuit Expands Its Jurisdiction in Order To Extend Preemption Doctrine to State Law Restrictions on Patent Rights

I. OVERVIEW OF THE CASE

Recognizing that its citizens were paying unusually high prices for certain patented pharmaceuticals, and in an attempt to reduce the cost of such drugs, the District of Columbia passed the Excessive Drug Pricing Act on September 20, 2005, stating that it shall be "unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price."[1] The D.C. statute came into effect on December 10, 2005, following a mandatory thirty-day period of review by the United States Congress.[2] The plaintiffs, Pharmaceutical Research and Manufacturers of America and Biotechnology Industry Organization, filed separate anticipatory lawsuits in October 2005 in the United States District Court for the District of Columbia, claiming "realistic and imminent" injuries, that the Excessive Drug Pricing Act was invalid in light of the Commerce Clause of the United States

1. Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 60 (D.D.C. 2005), *aff'd*, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373-74 (Fed. Cir. 2007); D.C. CODE §§ 28-4551 to -4555 (West Supp. 2007), *invalidated by Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 56-73.

2. *Biotechnology Indus. Org.*, 496 F.3d at 1365-66; D.C. Home Rule Act of 1973, Pub. L. 93-198, 87 Stat. 774, 777 (1973).

Constitution, and that federal patent law preempted the Act.[3] The district court consolidated the plaintiffs' actions and declared the Act unconstitutional on December 22, 2005, seven days after the statute came into effect.[4]

In its opinion, the district court held that the plaintiffs had standing, that the Excessive Drug Pricing Act was preempted by federal patent law, and that the Act encroached on the federal government's power to regulate interstate and foreign commerce as granted by the Constitution.[5] The District of Columbia appealed the rulings on preemption and standing to the United States Court of Appeals for the District of Columbia Circuit, which transferred the case at the District's request to the United States Court of Appeals for the Federal Circuit.[6] The Federal Circuit raised the issue of subject matter jurisdiction sua sponte during oral argument, and considered the issues of jurisdiction, standing, and preemption by the patent laws in its opinion.[7] Concluding that federal patent law preempted the Act, the Federal Circuit did not address the district court rulings related to the Commerce Clause.[8] Affirming the district court decision, the Federal Circuit *held* that federal patent law preempted the Excessive Drug Pricing Act of the District of Columbia. *Biotechnology Industry Organization v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007).

II. BACKGROUND

A. Jurisdiction

All federal courts are courts of limited jurisdiction,[9] and "[c]ourts created by statute can have no jurisdiction but such as the statute confers."[10] The Federal Courts Improvement Act of 1982 granted the Federal Circuit "exclusive jurisdiction . . . of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of

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3. *Biotechnology Indus. Org.*, 496 F.3d at 1366.

4. *Id.* at 1364-67.

5. *Pharm. Research & Mfrs. of Am.*, 406 F. Supp. 2d at 63-72. For background on intellectual property law and the Commerce Clause, see Sarah Duran, *A Species of Mutant Copyright Law: An Argument Against Using the Commerce Clause to Protect Databases*, 8 TUL. J. TECH. & INTELL. PROP. 87, 101-10 (2006).

6. *Biotechnology Indus. Org.*, 496 F.3d at 1366.

7. *Id.* at 1365-74.

8. *Id.* at 1374.

9. U.S. CONST. art. III, §§ 1-2.

10. Sheldon v. Sill, 49 U.S. (8 How.) 441, 449 (1850); *see also* Firestone Tire & Rubber Co. v. Risjord, 449 U.S. 368, 379-80 (1981).

that court was based, in whole or in part, on [28 U.S.C. § 1338]."[11] For a party to appeal successfully an issue of patent law to the Federal Circuit, the case or controversy must arise under the patent laws, much as a case or controversy must arise under federal law to qualify for federal jurisdiction under 28 U.S.C. § 1331.[12] Federal Circuit jurisdiction under 28 U.S.C. § 1338 is determined by reference to the plaintiff's original complaint and not to the case actually litigated or the issues appealed.[13] Such jurisdiction "extends over 'only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law,' in that 'federal law is a necessary element of one of the well-pleaded . . . claims.'"[14] However, a lawsuit that includes alternative reasons for relief and that states only one reason requiring a resolution of federal law may not establish federal jurisdiction under 28 U.S.C. § 1331.[15] Thus, a complaint supported by alternative theories may not form the basis for Federal Circuit jurisdiction under 28 U.S.C. § 1338(a) unless a resolution of patent law is essential to each theory.[16]

B. Standing

All federal courts are limited to hearing disputes that meet the established definition of a "case" or "controversy."[17] In a true case or controversy, the plaintiff must have standing, meaning he or she must plead an injury or pending injury in fact, reasonably traceable to an act by the defendant, that is likely redressable by the court.[18] A plaintiff may have standing after a penal statute is enacted either before or after

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11. Federal Courts Improvement Act of 1982, 28 U.S.C. § 1295 (2000).

12. Holmes Group, Inc. v. Vornado Air Circulation Sys., 535 U.S. 826, 828-30 (2002) (citing Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807-08 (1988)).

13. *Christianson*, 486 U.S. at 813-14.

14. *Id.* at 808-09 (quoting Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 27-28 (1983) (citation omitted)).

15. *See Franchise Tax Bd. of Cal.*, 463 U.S. at 26. If "on the face of a well-pleaded complaint there are . . . reasons completely unrelated to the provisions and purposes of [the federal law] why the [plaintiff] may or may not be entitled to the relief it seeks," then the claim does not "arise under" those laws. *Id.*

16. *Christianson*, 486 U.S. at 810. However, the Federal Circuit's "liberal treatment" of the *Christianson* holding has led it to assume jurisdiction over several disputes based only in part on § 1338. *See* Joseph R. Re, *Brief Overview of the Jurisdiction of the U.S. Court of Appeals for the Federal Circuit Under § 1295(a)(1)*, 11 FED. CIR. B.J. 651, 656-59 (2001) (discussing *Christianson*).

17. U.S. CONST. art. III, § 2, cl. 1.

18. Allen v. Wright, 468 U.S. 737, 752 (1984).

authorities seek to enforce it against the plaintiff.[19] A trade organization may file suit as plaintiff "'on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.'"[20]

C. Patent Law

Patent law in the United States derives from Article I, Section 8, Clause 8, of the United States Constitution, commonly known as the Copyright and Patent Clause, which grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[21] Congress passed the most recent Patent Act in 1952, which grants the holder of a patent the right "to exclude others from making, using, offering for sale, or selling" his or her invention.[22] More recently, Congress passed the Hatch-Waxman Act of 1994, which provides pharmaceutical patent holders some unique and specific benefits, including extended periods of patent exclusivity.[23]

A patent is a property right.[24] The U.S. patent system is generally believed to be grounded in utilitarian philosophy, where Congress is said to have "struck a bargain" with the patent holder, granting him a time-limited right to exclude others in exchange for public disclosure of the patented material and its release to the public domain upon expiration of the patent.[25] The patent holder's right is exclusive.[26] Indeed, "the federal patent laws do not create any affirmative right to make, use, or sell anything."[27] Although courts and commentators often describe a patent as a monopoly or an exception to the antitrust laws, some argue that the

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19. Babbit v. United Farm Workers Nat'l Union, 442 U.S. 289, 298 (1979).

20. United Food & Commercial Workers Union v. Brown Group, Inc., 517 U.S. 544, 553 (1996) (quoting Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977)).

21. U.S. CONST. art. I, § 8, cl. 8.

22. Patent Act of 1952, ch. 950, 66 Stat. 804 (1952) (codified as amended at 35 U.S.C. § 154 (2000)).

23. Hatch-Waxman Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in various sections of Titles 21 and 35 of the United States Code).

24. *See* ERNEST BAINBRIDGE LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 28:2 (3d ed. 1989).

25. *See id.*

26. *See* Panduit Corp. v. Stahlin Bros. Fibre Works, 575 F.2d 1152, 1158 n.5 (6th Cir. 1978) (noting that patent rights are like property rights in that they allow the holder to exclude others from free use of the invention).

27. Leatherman Tool Group v. Cooper Indus., 131 F.3d 1011, 1015 (Fed. Cir. 1997).

analogy is flawed and can lead to improper conclusions.[28] That said, the United States Supreme Court has held that the patent "monopoly" is a statutory exception to the antitrust laws, and that the exception is limited to the scope of the patent grant.[29]

Historically, the Supreme Court has held that

> the benefit which the government intended to secure [in the Patent Acts] was not the making or use of the patent for the benefit of the public during the . . . years of the grant, except as the patentee might voluntarily confer it from motives of gain, but only the benefit of its public use after the grant expired.[30]

The Supreme Court now recognizes three purposes of the patent system: (1) to foster and reward invention, (2) to stimulate further innovation, and (3) to ensure free use of ideas in the public domain.[31]

D. Preemption

Where state law is at odds with federal legislation, federal law preempts the state statute.[32] The issue of preemption often leads to issues of federalism and states' rights.[33] While the states are free to regulate the use of intellectual property in any manner not inconsistent with federal law,[34] and while "[t]he grant of a United States patent does not exempt the patented product from limitations imposed by state police statutes,"[35] a

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28. *See* Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367 (Fed. Cir. 1984) ("The patent system, which antedated the Sherman Act by a century, is not an 'exception' to the antitrust laws, and patent rights are not legal monopolies in the antitrust sense of that word."); Carl Schenck, A.G. v. Nortron Corp., 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) ("A patent, under the statute, is property . . . . Nowhere in any statute is a patent described as a monopoly. The patent right is but the right to exclude others, the very definition of 'property' . . . . The antitrust laws, enacted long after the original patent laws, deal with appropriation of what should belong to others . . . . A valid patent gives the public what it did not earlier have . . . . It is but an obfuscation to refer to a patent as 'the patent monopoly' or to describe a patent as an 'exception to the general rule against monopolies.'"); *Panduit Corp.*, 575 F.2d at 1160 n.8 ("The loose application of the pejorative term 'monopoly,' to the property right of exclusion represented by a patent, can be misleading. Unchecked it can destroy the constitutional and statutory scheme [of] the patent system.").

29. United States v. Line Material Co., 333 U.S. 287, 310 (1948) ("It is not the monopoly of the patent that is invalid. It is the use of that monopoly, improperly.").

30. Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 34-35 (1923).

31. Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

32. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 479 (1974).

33. *See generally* S. Candice Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. REV. 685 (1991) (discussing preemption and its relation to federalism).

34. *Aronson*, 440 U.S. at 262.

35. LIPSCOMB, *supra* note 24, § 28:8, at 225 n.10 (citing Patterson v. Kentucky, 97 U.S. 501, 509 (1879) (holding that safety standards apply equally to patented and unpatented lamp oil)).

state law cannot contradict the will of Congress.[36] However, the Supreme Court has stated that "[t]he case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to 'stand by both concepts and to tolerate whatever tension there [is] between them.'"[37] Federal law may preempt state law in either of two general ways: (1) If Congress evidenced an intent to occupy the field of law in question, federal law preempts any state law falling within that field; or (2) in the event that Congress has not entirely displaced state regulation over the matter in question, federal law would still preempt state law to the extent it actually conflicts with federal law, that is, when it is impossible to comply with both state law and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress.[38] Most state statutes preempted by federal intellectual property law had attempted to impose a monopoly cost on society.[39] Outside the field of intellectual property, the Supreme Court has considered the issue of federal preemption where a state attempted to control drug prices in the presence of a federal law.[40] Finally, although the noted case addressed a D.C. statute and not a state statute, the D.C. Circuit determined that the preemption doctrine applies equally to the District of Columbia.[41]

Historically, the Supreme Court allowed some state regulations that reduced the economic benefits of intellectual property.[42] In *Fox Film Corp. v. Doyal*, the Supreme Court overruled its previous ruling and recognized *Long v. Rockwood*; in his dissent in *Long*, Justice Oliver Wendell Holmes noted that "[t]he power to fix rates is the power to destroy, but this court, while it endeavors to prevent confiscation, does not prevent the fixing of rates. Even with regard to patents some laws of

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36. *See* U.S. CONST. art. VI, § 1, cl. 2; *Kewanee*, 416 U.S. at 479.

37. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166-67 (1989) (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 256 (1984)).

38. La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374-76 (1986); *Silkwood*, 464 U.S. at 248.

39. Paul Heald, *Federal Intellectual Property Law and the Economics of Preemption*, 76 IOWA L. REV. 959, 980-81 (1991).

40. Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 667-68 (2003) (holding that a modest impediment to federal Medicaid benefits did not necessarily justify preemption where the state law supported the intent of the Medicaid program). *Walsh* was discussed by the district court in the noted case. *See* Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56, 71 n.15 (D.D.C. 2005).

41. *See* Don't Tear It Down, Inc. v. Pa. Ave. Dev. Corp., 642 F.2d 527, 534 n.65 (D.C. Cir. 1980) ("[S]urely the preemption doctrine effects [sic] District of Columbia legislation no less than state enactments.").

42. *E.g.*, Fox Film Corp. v. Doyal, 286 U.S. 123 (1932).

a kind that might destroy the use of them within the state have been upheld."[43] The Court also maintained that price controls and similar regulations are generally matters best left to state regulators.[44] On the other hand, in matters where states attempted to increase or extend exclusive rights under the guise of intellectual property, the Court has held that federal patent law preempted state laws that extended patent-like protection to unpatentable items in the public domain.[45] On matters of preemption by patent law, the Supreme Court now considers a balancing test involving "a consideration of whether that law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"[46]

The Federal Circuit has considered the issue of patent law and federal preemption, noting that "the essential criteria" for determining whether a state law is preempted are "the objectives of the federal patent laws."[47] In determining whether patent law preempts a state law or statute in a civil dispute, the Federal Circuit has considered the elements of proof required in the applicable state and federal laws; where the elements of proof for the state statute are identical to or are a subset of the elements of proof required by the federal patent laws, the court has found that federal laws preempt the state law.[48] The Federal Circuit has also recognized the long-standing tradition of state autonomy with

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43. Long v. Rockwood, 277 U.S. 142, 150 (1928) (Holmes, J., dissenting), *overruled by Fox Film Corp.*, 286 U.S. 123 (following Justice Holmes's dissent in *Long*, which concluded that copyrights and patents may be taxed by the states, and that the United States has no interest in the patent "monopoly" whatsoever). "The advantage to the public is gained merely from the carrying out of the general policy in making such grants and not from any direct interest which the government has in the use of the property which is the subject of the grants." *Fox Film Corp.*, 286 U.S. at 130.

44. *See, e.g.*, California v. ARC Am. Corp., 490 U.S. 93, 101 (1989) ("Given the long history of state common-law and statutory remedies against monopolies and unfair business practices, it is plain that this is an area traditionally regulated by the States.").

45. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 159-61 (1989); Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 231-33 (1964).

46. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 479 (1974) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

47. Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333-34 (Fed. Cir. 1998), *rev'd on other grounds*, Midwest Indus. v. Karavan Trailers, Inc., 175 F.3d 1356, 1358-60 (Fed. Cir. 1999).

48. Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1382-83 (Fed. Cir. 2000) (holding patent laws preempt state RICO statutes when the state statute requires the same elements of proof as the patent claim); *cf.* Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1306 (Fed. Cir. 1999) (holding that patent law does not preempt where state laws do not attempt to provide patent-like protection to classes of inventions covered by the Patent Act, and where the cause of action requires additional elements of proof beyond the questions of patent law).

respect to its internal affairs,[49] and the court has rejected a preemption argument where a state law claim depended on a resolution of an issue of patent law.[50]

III. THE COURT'S DECISION

In the noted case, the Federal Circuit extended the Supreme Court's preemption doctrine to a case where a statute attempted to place additional restrictions on the rights granted to the holder of a federal patent.[51] The court raised the issue of subject matter jurisdiction sua sponte during oral argument and concluded that it did have appellate jurisdiction over the plaintiffs' claim under 28 U.S.C. § 1295(a)(1).[52] The court also considered whether the pharmaceutical industry faced a likely injury sufficient to establish standing in federal court and concluded the Excessive Drug Pricing Act did in fact represent an imminent threat, thus elevating the dispute to a "case" or "controversy."[53] Addressing the question of whether federal patent law preempted the D.C. statute, the court concluded that the Act affected the policy goals of the patent system as established by Congress, and, therefore, held that the Act was unconstitutional.[54] Concluding that federal patent law preempted the Excessive Drug Pricing Act, the Federal Circuit declined to address the district court conclusion that the Act also violated the Commerce Clause of the United States Constitution.[55]

At oral argument, the Federal Circuit questioned its legal authority to hear the noted case,[56] in part because the D.C. Circuit did not rule on the issue prior to the transfer.[57] The Federal Circuit has exclusive jurisdiction over appeals of cases arising under the federal patent laws.[58]

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49. *Hunter Douglas*, 153 F.3d at 1334 (noting that the Supreme Court's jurisprudence favors a presumption against preemption because of states' long-standing governance of such affairs).

50. Dow Chem. Co. v. Exxon Corp., 139 F.3d 1470, 1475 (Fed. Cir. 1998) (holding that a state law claim based in part on a disputed patent is not preempted by federal law).

51. Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1373-74 (Fed. Cir. 2007).

52. *Id.* at 1367-69.

53. *Id.* at 1369-71.

54. *Id.* at 1371-74.

55. *Id.* at 1374.

56. *Id.* at 1367.

57. Recording of Oral Argument, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (No. 2006-1593), *available at* http://www.cafc.uscourts.gov/oralarguments/mp3/2006-1593_Pt1.mp3. The clerk of court for the D.C. Circuit approved the Appellant's transfer request prior to a court order. *Id.*

58. *Biotechnology Indus. Org.*, 496 F.3d at 1367 (citing Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807-09 (1988)).

The court concluded that resolution of patent law was a "necessary element" of one of the plaintiffs' claims; therefore, the noted case depended on a "substantial question of federal patent law."[59] The court observed:

> If the plaintiffs are able to show that the patent laws preempt the Act, the Act will be declared unenforceable and enjoined, but if they cannot, their preemption claim will fail and their members may be required to defend against suits under the Act. In other words, "some right or privilege will be defeated by one construction, or sustained by the opposite construction of [the patent] laws."[60]

Noting two prior opinions where it concluded subject matter jurisdiction was proper, the Federal Circuit concluded it also had jurisdiction over the noted case.[61]

The Federal Circuit then considered whether the plaintiffs had standing, the first issue raised on appeal.[62] The appellant's argument centered on the issue of whether the plaintiffs actually faced an injury that met the standard for a case or controversy, noting that the plaintiffs had not identified any specific instance where one of its members would be subject to penalties under the Excessive Drug Pricing Act.[63] In its opinion, the Federal Circuit looked to the wording of the statute, noting the Act declared that it is "incumbent on the government of the District of Columbia to take action to restrain the excessive prices of prescription drugs,"[64] and looked to the Act's legislative history, noting that the D.C. legislators identified by name two members of the plaintiffs' organization who were clear violators of the proposed Act.[65] Concluding that the plaintiffs had alleged "an actual and well-founded fear that the law will

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59. *Id.*

60. *Id.* Note that the Commerce Clause arguments sought the same result. *See* Complaint at 18, Pharm. Research & Mfrs. of Am. v. District of Columbia, 406 F. Supp. 2d 56 (D.D.C. 2005) (Nos. Civ. 05-2015(RJL), Civ. 05-2106(RJL)).

61. *Biotechnology Indus. Org.*, 496 F.3d at 1367-68 (citing Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1329-31 (Fed. Cir. 1998) (holding that preemption by patent law met the *Christianson* standard); Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc., 986 F.2d 476, 478 (Fed. Cir. 1993) (holding that recovery in state law tort for business disparagement depended on the resolution of an allegedly false patent infringement claim)). Note that in *Hunter Douglas*, the Federal Circuit stated that "all the theories upon which Hunter could prevail depend[ed] on . . . [a resolution] of federal patent law." 153 F.3d at 1329.

62. *Biotechnology Indus. Org.*, 496 F.3d at 1368-72; Appellant's Brief at 2, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (No. 2006-1593).

63. Appellant's Brief, *supra* note 62, at 15-16.

64. *Biotechnology Indus. Org.*, 496 F.3d at 1370 (citing D.C. CODE § 28-4551(c) (2001)).

65. *Id.* at 1369-71.

be enforced against them," the Federal Circuit concluded that the plaintiffs had standing in federal court.[66]

The Federal Circuit next considered whether federal patent laws preempted the Excessive Drug Pricing Act, the second issue raised on appeal.[67] Looking to both the Supreme Court and its own precedent, the Federal Circuit concluded that "'the essential criteria' for determining whether a state law is preempted are 'the objectives of the federal patent laws.'"[68] The court continued its analysis, stating that "[p]atentees value the right to exclude in part because the ability to foreclose competitors from making, using, and selling the invention may allow them an opportunity to obtain above-market profits during the patent's term."[69] The court then looked to the legislative history of the Hatch-Waxman Act, noting a House Committee statement that "[p]atents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities."[70] Turning to the statute in question, the Federal Circuit observed that the Act penalized high prices, "thus limiting the full exercise of the exclusionary power that derives from a patent . . . . [By doing so] the District has chosen to re-balance the statutory framework of rewards and incentives [set by Congress] insofar as it relates to inventive new drugs."[71] The court noted that, on its face, the Act specifically targeted patented materials, concluded that the District had attempted to modify federal patent policy within its borders, and, therefore, held that federal patent law preempted the Excessive Drug Pricing Act.[72] Once it concluded that the Act was invalid on grounds of federal preemption, the court declined to address the Commerce Clause rulings of the district court.[73]

IV. ANALYSIS

The Federal Circuit's decision in the noted case raises significant questions in the areas of appellate jurisdiction and preemption doctrine,

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66. *Id.* at 1370 (citing Virginia v. Am. Booksellers Ass'n, Inc., 484 U.S. 383, 393 (1988)).

67. *Id.* at 1371-74; Appellant's Brief, *supra* note 62, at 2-3.

68. *Biotechnology Indus. Org.*, 496 F.3d at 1372 (quoting Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333 (Fed. Cir. 1998)).

69. *Id.*

70. *Id.* at 1373 (quoting H.R. REP. No. 98-857, at 17 (1984)).

71. *Id.* at 1374.

72. *Id.*

73. *Id.* The Commerce Clause arguments were not raised on appeal. *See* Appellant's Brief, *supra* note 62, at 4.

with potentially large effects in the fields of patent law and civil procedure. First, by accepting appellate jurisdiction, the court appeared to depart from the Supreme Court's holding in *Christianson v. Colt Industries Operating Group*, possibly extending Federal Circuit jurisdiction to all cases that allege a theory of recovery under patent law.[74] Second, the Federal Circuit's ruling on preemption apparently marks the first instance where patent law preempted a state regulatory statute when the statute did not attempt to extend intellectual property rights beyond the limits established by Congress. Broadly speaking, the Federal Circuit's decision may also affect future pharmaceutical regulation and issues of states' rights.

A. Jurisdiction

In *Christianson*, the Supreme Court held that the Federal Circuit's jurisdiction under 28 U.S.C. § 1295(a)(1) extended only to cases where resolution of an issue of patent law was central to the plaintiff's right to relief.[75] In *Christianson*, the plaintiff articulated several distinct legal theories in his complaint, only one of which was related to patent law.[76] Noting that the plaintiff's complaint listed "'reasons completely unrelated to the provisions and purposes' of federal patent law why petitioners 'may or may not be entitled to the relief [they] see[k],'" the Court held that the plaintiff's claim "[did] not arise under federal patent law," and that the Federal Circuit accordingly lacked jurisdiction.[77] Here, the plaintiffs' lawsuit sought only to strike the statute and alleged several legal theories by which the Excessive Drug Pricing Act might be held unconstitutional: (1) that the Act violated the Dormant Commerce Clause of Article I, Section 8, Clause 3 of the Constitution; (2) that the Act violated the Foreign Commerce Clause of Article I, Section 8, Clause 3 of the Constitution; and (3) that federal patent law preempted the statute.[78] If upheld by the court, any one of the plaintiffs' arguments arguably would have the effect the plaintiffs desired. Only the preemption argument involved an issue of patent law. Accordingly, the holding in *Christianson* suggests that the Commerce Clause allegations in the noted case were "reasons completely unrelated" to the patent laws by which the plaintiff could recover, which arguably should have

74. Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807 (1988).
75. *Id.* at 807-10.
76. *Id.* at 811-12.
77. *Id.* at 812.
78. Complaint, *supra* note 60, at 18-22.

precluded Federal Circuit jurisdiction under § 1295(a)(1).[79] If the Federal Circuit did indeed extend its jurisdiction to all multiple-theory-for-relief cases that include one well-pleaded claim under the patent laws, then the court has sanctioned a mechanism by which a party could forum-shop on appeal.[80] Arguably, in any future lawsuit, a plaintiff need only plead one claim or theory for relief under the patent laws to establish appellate jurisdiction in the Federal Circuit. In such a case, the appellant arguably now has the choice to either appeal the case to the trial court's home circuit court of appeals, or to transfer the case to the Federal Circuit.[81] Given the deference that the Court in *Christianson* stated a circuit court of appeals must give to its sister circuits, the appellant's choice of venue in such cases would arguably be final.[82]

B. Preemption Doctrine

The noted case apparently broke new ground in the field of patent law and preemption doctrine by extending preemption to a regulation that attempted to restrict intellectual property rights.[83] The basis for the Federal Circuit's holding was that the Excessive Drug Pricing Act stood "as an obstacle to the federal patent law's balance of objectives as established by Congress."[84] The court stated that "[b]y penalizing high prices—and thus *limiting the full exercise of the exclusionary power* that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs."[85] Although the court did not state it directly, it impliedly affirmed (or, at least gave significant weight to) the notion that the right to set any

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79. In contradiction with its holding in the noted case, the Federal Circuit followed this analysis from *Christianson* in *Hunter Douglas*. *See* discussion *supra* note 61.

80. *See* Holmes Group, Inc. v. Vornado Air Circulation Sys., 535 U.S. 826, 839 n.3 (2002) (Stevens, J., concurring) ("[T]he Federal Circuit was granted appellate jurisdiction over cases involving patent law claims, not issues."); *id.* at 838-39 ("[W]e have already decided that the Federal Circuit does not have exclusive jurisdiction over all cases raising patent issues, . . . therefore, other circuits will have some role to play in the development of this area of the law."); Re, *supra* note 16, at 657 ("Both the Federal Circuit and the regional circuits have concurrent jurisdiction to determine whether a district court has jurisdiction under 28 U.S.C. § 1338.").

81. Arguably, the trial venue need not be federal court. *See* Dow Chem. Co. v. Exxon Corp., 139 F.3d 1470, 1475 (Fed. Cir. 1998) (observing that state courts may rule on an issue of patent law if the issue is "ancillary" to the court's "central purpose").

82. *See* Re, *supra* note 16, at 657.

83. *See generally* Heald, *supra* note 39. Although quite comprehensive, Mr. Heald's article did not address a case where a state law restricts the monopoly-like effect of a patent.

84. Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

85. *Id.* (emphasis added). Do price controls affect an exclusionary power? If the right of a patent is only a right to exclude others, then perhaps they do not.

sale price is an affirmative right implicit in the exclusive right granted to a patent holder under the Patent Act.[86] Should the right to set a price be included in the patent right, one might expect a flurry of lawsuits seeking to strike all statutes that affect a patent holder's desire to set a high price. However, future courts might also consider that the statute in the noted case directly and specifically targeted patented material, thus limiting the Federal Circuit holding. If so, a general state statute that does not specifically identify a federal law might be more likely to withstand a federal preemption claim.[87]

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86. *Contra* Long v. Rockwood, 277 U.S. 142, 150 (1928) (Holmes, J., dissenting); Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 36 (1923). Historically, the Supreme Court noted the government's disinterest in the patent holder's exclusive right and did not assume any right within the patent "monopoly." *See Long*, 277 U.S. at 150; *Crown Die & Tool Co.*, 261 U.S. at 36.

87. *See* Patterson v. Kentucky, 97 U.S. 501, 509 (1878).

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