

U. S. Department of Justice

Office of the Solicitor General

Solicitor General

Washington, D.C. 20530

October 25, 1999

Patricia Mack Bryan, Esq. Senate Legal Counsel 642 Hart Office Building Washington, D.C. 20510

Dear Ms. Bryan:

Re: Genentech v. Regents of the University of Cal.,

No. 97-1099 (Fed. Cir.); 35 U.S.C. 271 and 296

I am writing to inform you that the Department of Justice has decided to withdraw the United States' intervention as a party in the above-captioned case, which was undertaken to defend the constitutionality of 35 U.S.C. 271 and 296, as added by the Patent and Plant Variety Remedy Clarification Act, Pub. L. No. 102-560, § 2(a)(2), 106 Stat. 4230. Those provisions abrogate the immunity of States and state entities to private lawsuits for violations of the patent laws. The Department's decision to withdraw its intervention in this case is undertaken in light of the Supreme Court's decisions in Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 119 S. Ct. 2199 (1999), and College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board, 119 S. Ct. 2219 (1999), which indicate that the arguments that the United States has made to defend the constitutionality of the provisions at issue are no longer available.

The above-captioned case is a private lawsuit challenging the validity of a patent awarded to the University of California, an entity of the State of California, in December 1982. In 1990, the plaintiff, Genentech, brought this lawsuit against the University in federal district court, contending that the University had accused Genentech of infringing its patent and that the patent was invalid. Genentech's lawsuit also named Eli Lilly & Co., which has certain license rights under the University's patent, as a defendant. One day later, the University filed a patent infringement suit against Genentech in another federal district court; that lawsuit continues, and the two cases were consolidated for pretrial proceedings.

In 1991, the district court granted the University's motion to dismiss Genentech's suit on the ground, among others, that the University was immune from suit under the Eleventh Amendment. Genentech appealed, and during the appeal, Congress enacted the Patent and

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Plant Variety Protection Act, abrogating the States' Eleventh Amendment immunity from patent suits. In 1993, the Court of Appeals for the Federal Circuit therefore reversed, and remanded for further proceedings. The Supreme Court denied the University's petition for certiorari. See Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931 (Fed. Cir. 1993), cert. denied, 510 U.S. 1140 (1994).

Subsequently, the Supreme Court decided <u>Seminole Tribe of Florida</u> v. <u>Florida</u>, 517 U.S. 44 (1996), which held that Congress may not abrogate a State's Eleventh Amendment immunity under its Article I powers. The University then moved again to dismiss on Eleventh Amendment grounds. The district court granted that motion. The district court held that Section 5 of the Fourteenth Amendment (which grants Congress authority to enforce the provisions of Section 1 of the Amendment, including the Due Process Clause, which protects property against deprivation without due process of law) did not provide Congress with a basis to abrogate the University's Eleventh Amendment immunity to this patent suit, because Genentech was not suing to protect its own property from vindication; it was suing rather to obtain a declaratory judgment that the University's patent was invalid. The district court also held that the University had not waived its immunity from suit, concluding that the University's procurement of a patent, its grant of a license to Eli Lilly, and its accusations of infringement against Genentech and threats of litigation did not constitute an unambiguous expression of consent to suit in federal court. See <u>Genentech, Inc.</u> v. <u>Regents of the Univ. of Cal.</u>, 939 F. Supp. 639 (S.D. Ind. 1996).

Genentech appealed, and in May 1997, the United States intervened in the Federal Circuit to defend the constitutionality of the challenged provisions abrogating the States' Eleventh Amendment immunity. The United States argued principally that the University of California had waived its Eleventh Amendment immunity under the doctrine of Parden v. Terminal Railway, 377 U.S. 184 (1964), by engaging in commercial activity related to a patent after Congress had abrogated the States' Eleventh Amendment immunity to suit under the patent laws. The Federal Circuit reversed. The court of appeals held that the University had voluntarily waived its Eleventh Amendment immunity by voluntarily participating in the patent system and actively invoking federal judicial power to protect its patent rights against Genentech's allegedly infringing conduct. The court did not reach any issues regarding Congress's abrogation of the States' immunity from suit. Genentech, Inc. v. Regents of the Univ. of Cal., 143 F.3d 1446 (Fed. Cir. 1998).

The University filed a petition for certiorari, which was held pending the Supreme Court's decisions in <u>Florida Prepaid</u> and <u>College Savings Bank</u>, noted above. In the <u>Florida Prepaid</u> case, the Supreme Court held invalid Congress's abrogation of the States' Eleventh Amendment immunity to private lawsuits for damages under the patent laws in 35 U.S.C. 271 and 296. The Court held that, in light of the legislative record, the abrogation could not be defended as an exercise of Congress's authority under Section 5 of the Fourteenth Amendment

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to enforce the Due Process Clause of Section 1 of the Amendment, which protects "property" from "deprivation" without due process. See 119 S. Ct. at 2209-2210. In the College Savings Bank case, the Supreme Court concluded that a private trademark lawsuit for damages brought against a state entity based on the allegation that the state entity had misrepresented its own product must be dismissed under the Eleventh Amendment. As relevant here, the Court there overruled the Parden doctrine, and held that the Eleventh Amendment immunity of a State to a private lawsuit for damages may not be waived impliedly by a State's participation in commercial conduct subject to federal regulation, including a provision subjecting the States to suit. See 119 S. Ct. at 2228-2229. The Court in that case did not reach whether Congress might permissibly rely on its power under the Fourteenth Amendment to protect property from deprivation without due process to abrogate a State's Eleventh Amendment immunity to a private trademark suit for damages, because the Court there concluded that the particular trademark claim in that case (which did not involve injury to the plaintiffs' own trademark) did not allege any deprivation of "property." See 119 S. Ct. at 2224-2225.

After those decisions were issued, the Supreme Court remanded this case to the Federal Circuit for further proceedings. Regents of the Univ. of Cal. v. Genentech, Inc., 119 S. Ct. 2388 (1999). The Federal Circuit has now directed the parties to file briefs addressing the impact of the Supreme Court's decisions in Florida Prepaid and College Savings Bank, and has stated that the government may file a further brief as intervenor.

The Department of Justice has determined that, in light of the Supreme Court's <u>Florida Prepaid</u> and <u>College Savings Bank</u> decisions, the United States should not continue its intervention in this case to defend the constitutionality of 35 U.S.C. 271 and 296, which authorizes patent suits against States and state entities in federal court. As noted above, in the <u>College Savings Bank</u> case, the Supreme Court overruled the <u>Parden</u> doctrine, which was the principal basis for the United States' defense of the constitutionality of the provisions at issue in this case. Also, although the University has invoked the jurisdiction of the federal courts in another suit by bringing a patent infringement case against Genentech, that action does not waive the University's immunity to this suit (although it is possible that Genentech might continue to be able to raise a defense of invalidity to the University's infringement action). In an analogous situation, the courts have uniformly held that the federal government's institution of one lawsuit does not waive the United States' sovereign immunity from a different lawsuit.

In addition, in light of the Supreme Court's decisions, it does not appear that the United States can argue that 47 U.S.C. 271 and 296 validly abrogate the University's immunity from Genentech's suit. As noted above, those abrogations were held invalid by the Court in Florida Prepaid. Also, the College Savings Bank decision holds that Congress may not act under Section 5 of the Fourteenth Amendment to abrogate a State's Eleventh Amendment immunity from a private trademark action when no "property" is at risk of deprivation. That decision would appear to govern here, because Genentech has not argued that its own patent (which

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would be "property") has been infringed; rather it has argued that the University's patent is invalid. Although Genentech claims harm to its commercial interests from the University's allegedly unlawful patent, the <u>College Savings Bank</u> decision makes clear that the activity of doing business by itself is not "property" in the constitutional sense. 119 S. Ct. at 2225.

We note, however, that neither <u>College Savings Bank</u> nor <u>Florida Prepaid</u> casts doubt on a private plaintiff's ability to invoke the doctrine of <u>Ex parte Young</u>, 209 U.S. 123 (1908), to enjoin state officers from engaging in continued violations of the patent laws, and the patent laws expressly authorize suits against state officers, see 35 U.S.C. 271(h), 296(a). It is therefore possible that in the future plaintiffs similarly situated to Genentech might be able to bring an action against state officers for declaratory and injunctive relief based on a claim of patent invalidity, without the need to name the State or a state entity as a defendant.

For your information, I have enclosed copies of the pertinent decisions of the lower courts in this case as well as the most recent filing of the Department of Justice withdrawing the United States' intervention. We have informed the court of appeals that we are notifying the House and Senate of the withdrawal of our intervention and that the House and Senate may wish to consider participation in the further proceedings in this case. It is our understanding that, under a schedule established by the Federal Circuit, the University's brief is due December 9, 1999.

Sincerely,

Seth P. Waxman

Enclosure