No. 92-1345

In The

Supreme Court of the United States

October Term, 1992

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Petitioners,

vs.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

When medical research funded by the United States Government at a nonprofit institution results in a critical new drug producing sales of over $600 million annually and generating enormous royalties for the institution, and when the funding agreements between the government agency and the institution fail to contain provisions that such royalties be shared with the inventors despite the requirement of 35 U.S.C. § 202(c) that:

> "Each funding agreement . . . shall contain appropriate provisions to effectuate . . . a requirement that the contractor share royalties with the inventor",

must the institution share such royalties with inventors on an appropriate and reasonable basis, or, as the lower courts held, may the institution adopt any policy it chooses to minimize the inventors' share, however unreasonable, and impose such policy upon inventors who did not agree to it and were not informed of it?

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The University and Small Business Patent Procedures Act of 1980, (the "Bayh-Dole Act") Pub. L. 96-517, 94 Stat. 3020, as amended Pub. L. 98-620, 98 Stat. 3364-3366 ..... passim

35 U.S.C. § 200 11

35 U.S.C. § 202(c)(7)(B) 2, 3, 5, 9, 10, 13

35 U.S.C. § 202(c)(7)(C) 2, 3, 11

Legislative History Cited:

H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt. 1 (1980), *reprinted in* 1980 U.S. Code Cong. & Admin. News 6460 (1980) 4, 4 n.2

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OPINIONS BELOW

The opinion of the United States District Court, Southern District of New York, dismissing Petitioners' complaint, is reported at 787 F. Supp. 360 (S.D.N.Y. 1992). (A.3-20).[1]

1. References to the Appendix to this Petition are referred to herein as (A.__).

> (C) . . . a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of any expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education.

STATEMENT OF THE CASE

A. The Statute

This case focuses on major legislation enacted by Congress to stimulate the economy by promoting scientific advancement and technological innovation. At this critical time when our economy is faltering, the lower courts have completely misconstrued and undermined the Bayh-Dole Act of 1980, which was intended to use government-funded research to provide incentives necessary to enhance our free-market economy. The decisions below eviscerate the explicit statutory requirement that inventors — the progenitors of technological advancement — must be appropriately compensated for their achievements.

After twelve years of congressional study, the Bayh-Dole Act was passed to effectuate major changes in the patent laws applicable to government-funded research. The dimension of the problem sought to be remedied by the legislation is described in the congressional reports accompanying the Act:

> The crisis in U.S. productivity and the governmental role in it has not gone unnoticed, ... In May of 1978 the President called for a major policy review of industrial innovation as

inventors, that the Bayh-Dole Act was passed, and incorporated into the patent laws. Inventors' rights are explicitly contained in the statute; 35 U.S.C. § 202(c) provides, in pertinent part:

> Each funding agreement ... shall contain appropriate provisions to effectuate the following:
>
> * * *
>
> (7) In the case of a nonprofit organization,
>
> * * *
>
> (B) a requirement that the contractor share royalties with the inventor;

In keeping with this provision, the Senate Report accompanying the legislation states that the statute "gives special recognition to the equity of inventors, and requires that nonprofit organizations share royalties with them." S. Rep. No. 480 at p. 33.

The statute mandates that the inventors' share must be "appropriate," and government agencies funding research are required to ensure compliance; each government funding agreement with a private institution must contain a royalty-sharing provision which must be "appropriate ... to effectuate" the legislative purpose.

Nothing in the legislative history suggests that Congress intended what has occurred in this case — that a government-funded private institution could evade the statute by omitting the required royalty-sharing provision from its funding agreements, pay its inventors any amount it unilaterally chooses, and avoid administrative or judicial review. Such conduct, approved by the lower courts, does violence to the statutory scheme.

This critical drug is now, for the first time, available and regularly prescribed for use with chemotherapy for virtually all cancer patients. It materially reduces the deleterious side effects of such treatment and enables patients to tolerate larger therapeutic dosages. It will have many other significant medical applications for the prevention and treatment of neutropenia, including bone marrow transplants, burn treatment and concomitant AIDS therapy.

Once the therapeutic and financial benefits from Petitioners' discovery became apparent, SKI granted an exclusive license for commercial production of the drug to Amgen, Inc., a California-based pharmaceutical company which now markets it throughout the United States (under the brand name "Neupogen") and throughout much of the world.

The financial impact of Petitioners' invention is unprecedented. SKI did not dispute below that sales of G-CSF will be at least $600 million annually. As reported in a detailed Washington Post report discussing Petitioners' invention and the significance of this case, Neupogen "appears to be the richest royalty-producing invention ever to come out of a nonprofit institution." *Washington Post*, "Dividing The Royalty Pie," Health News p. 9 (Nov. 17, 1992).

In November 1990, SKI received from its exclusive licensee, Amgen, an initial payment of U.S. royalties of $50 million, and

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he hypothesized that, by working in collaboration with Petitioner Dr. Karl Welte, he might be able to purify G-CSF for amino-acid sequencing. For the next two years, Dr. Platzer and Dr. Welte pursued their research together at SKI, often working in collaboration with Petitioner Dr. Roland Mertelsmann, and with Dr. Malcolm A.S. Moore and Dr. Janice Gabrilove. Drs. Moore and Gabrilove remain employed at SKI and have not joined in this lawsuit.

C. Prior Proceedings

Petitioners filed suit on September 30, 1991, in United States District Court, Southern District of New York. The complaint alleges three federal claims, all derived from and dependent on the proper construction of the royalty-sharing requirement contained in 35 U.S.C. § 202(c) of the Bayh-Dole Act. Federal question jurisdiction is asserted under 28 U.S.C. § 1331, and patent law jurisdiction is invoked under 28 U.S.C. § 1338(a).

In their first claim, Petitioners asserted an implied private right of action under the statute, alleging that SKI had breached its statutorily-imposed obligation to share royalties with Petitioners.

In their second claim, Petitioners alleged that they are third-party beneficiaries of the congressionally-mandated contractual provision requiring SKI to share royalties reasonably with inventors. Petitioners argued, and SKI agreed, that although no royalty-sharing provision was actually included in the funding agreements, the requirement is incorporated by operation of law. Petitioners further argue that since the percentage of royalties to be paid to inventors was not included in the funding agreements or approved by a government agency to determine that it is "appropriate", the "appropriate" share must now be judicially determined. SKI argued that in the absence of a specific mandated ratio it was free to pay inventors any amount it chose, even if the share is unreasonable, inappropriate in light of the invention and not comparable to that paid by other institutions. Under SKI's contention, it could have satisfied the statutory requirement to share royalties with the inventors by giving each of the plaintiffs one dollar. The lower courts adopted SKI's argument.

In their third claim, Petitioners alleged that the required royalty-sharing provision is also incorporated by operation of law in their employment agreements with SKI. Again, SKI agreed that

REASONS FOR GRANTING THE WRIT

This is the first case to arise in any court requiring judicial interpretation of the Bayh-Dole Act. The Act was a major revision of the laws applicable to government-financed research. Its purpose was to promote and encourage technological advancement and economic development by creating significant financial incentives for inventors and private institutions. The lower courts' misreading of the Act obliterates the requirement that inventors, whose ingenuity furthers humanity and enriches their institutions, are entitled to share significantly in monetary rewards flowing from their work.

The lower courts' erroneous decisions were based upon 35 U.S.C. § 202(c)(7)(C) of the Act which requires that the institution's share of royalties must be used for scientific research or education. On the basis of this section the district court held: "Clearly Congress' concern was with the reinvesting of funds to further research, not with furthering the private interests of individual inventors." (A.18).

Nothing in the legislative history of the Bayh-Dole Act or the statute itself supports the lower courts' finding that the congressional "concern" behind the Act was to generate funds for further research and education. Although obviously desirable, this goal is quite incidental to, and much less important than, the clearly expressed purpose of promoting commercial technology and enhancing the economy. 35 U.S.C. § 200.

The advancement of technology is the goal of both the Act and the Patent Clause pursuant to which it was passed. Similarly, the means to this end, under both the Constitution and the Bayh-Dole Act, is the allowance of significant rewards to inventors.

The district court's conclusion that providing reasonable

inventor to demand 50% of the royalties" would not further that purpose.[8] (A.13).

In fact, awarding Petitioners a reasonable share of royalties, which could be as much as the 50% share paid by many other institutions if the court so determines would indeed further the basic purpose of the statute. Consistent with congressional intent, such an award would attract talented young people to consider careers as research scientists. The once-in-a-lifetime sums Petitioners would receive, though considerably smaller than even the annual earnings of major athletes, entertainers and businessmen, would fairly compensate them for the benefit which their creativity has bestowed upon the world, and would induce others to follow their lead.[9]

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8. Petitioners have never argued that any specific percentage of royalties must be shared with inventors under the Act, only that the share must be reasonable, or to use the equivalent word contained in the statute, "appropriate", and that the percentage should be judicially established, after considering the circumstances of the case.

9. This purpose was expressed to the United States Court of Appeals for the Federal Circuit by the Leukemia Society of America, Inc., in its motion for leave to file a brief as *amicus curiae* supporting Petitioners, as follows:

> The interest of The Leukemia Society in this appeal is to ensure that the royalty sharing provision of 35 U.S.C. § 202(c)(7)(B) is properly construed so that medical researchers are adequately financially compensated and thus optimally stimulated to continue to make medical breakthroughs, such as plaintiffs' invention, leading to more effective treatment of cancer and other diseases.

The Leukemia Society was denied leave to file its brief.

APPENDIX A — JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT FILED NOVEMBER 10, 1992

Note: Pursuant to Fed. Cir. R. 47.8, this disposition is not citable as precedent. It is a public record. The disposition will appear in tables published periodically.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

92-1280

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs-Appellants,

v.

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant-Appellee.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

in CASE NO(S). 91-6578

This CAUSE having been considered, it is

APPENDIX B — MEMORANDUM OPINION AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK FILED MARCH 4, 1992

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

91 Civ. 6578 (JSM)

DR. ERICH PLATZER, DR. KARL WELTE and DR. ROLAND MERTELSMANN,

Plaintiffs,

-against-

SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,

Defendant.

MEMORANDUM OPINION AND ORDER

JOHN S. MARTIN, JR., District Judge:

Doctors Erich Platzer, Karl Welte and Roland Mertelsmann commenced this action to recover a share of the royalties stemming from a discovery they made while in the employment of Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering). Sloan-Kettering now moves to dismiss the complaint pursuant to Fed.R.Civ.P. 12(b)(1) and 12(b)(6). For the reasons contained herein, the motion to dismiss is granted in its entirety.

FACTUAL BACKGROUND

Sloan-Kettering is a not-for-profit corporation engaged in scientific research largely funded by the federal government.

Appendix B

Patent Policy expressly disclaims any obligation to share royalties with employees where the Patent office has denied a patent application.[2] However, the Patent Policy does allow for discretionary awards to inventors of unpatented inventions.

The second relevant agreement is the funding agreement entered into between Sloan-Kettering and the federal government. This Institutional Patent Agreement Governing Grants and Awards between Sloan-Kettering and the Department of Health, Education, and Welfare (the "IPA") applies to inventions arising out of government-funded research which are or may be patentable. The IPA as originally drafted allowed for the sharing of royalties with inventors up to a maximum of 15% of gross royalties. However, the terms of the IPA were modified by the 1980 Bayh-Dole Act. (Act of Dec. 12, 1980, Pub. L. 96-517, § 6(a), 94 Stat. 3019, codified at 35 U.S.C. § 200 *et seq.*). The Bayh-Dole Act grants non-profit organizations exclusive title to inventions developed through federal funding, and allows them to freely license such inventions for profit so long as such profit is used to

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Annual Gross Proceeds	Inventor(s) Share %
$0 - $50,000	25%
$50,000 - $150,000	15%
$150,000 - $300,000	10%
Over $300,000	5%

2. The Patent Policy states:

> **In the event that a patent application is denied, whether or not [Sloan-Kettering] intends to continue prosecution of the patent application or appeal the adverse decision, [Sloan-Kettering] shall not be obligated to pay a share of royalties received after the date of denial to the inventor(s).**

Appendix B

The Complaint sets forth five causes of action, the first three of which are based on the statute.

> (i) Plaintiffs assert an implied private right of action under the Statute, alleging that Sloan-Kettering has breached its statutorily imposed obligation to share royalties equally or equitably with inventors.
> (ii) Plaintiffs claim that they are entitled to a larger share on the ground that they are third-party beneficiaries of the IPA which, by operation of law, contains the mandated clause to share royalties with inventors.
> (iii) Plaintiffs claim that they are entitled to a larger share on the ground that the Statute created an implicit term of their employment agreement.
> (iv) and (v) Plaintiffs assert two state law claims, one under a contract theory and the other under an unjust enrichment theory.

Sloan-Kettering moves to dismiss the first three claims on the ground that the Court lacks subject matter jurisdiction over the claims in that they do not "arise under" the laws of the United States as required by 28 U.S.C. §§ 1331 and 1338(a). Additionally, Sloan-Kettering seeks dismissal of these claims on the ground that they do not state a cause of action in that no private right of action exists under 35 U.S.C. § 202(c)(7)(B). Once these claims are dismissed, Sloan-Kettering argues that the Court should decline to exercise its supplemental jurisdiction over the state law claims, or in the alternative should dismiss these claims for also failing to state a claim for which relief can be granted.

Appendix B

Sloan-Kettering cites *Merrell Dow Pharmaceuticals, Inc. v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229 (1986) for the proposition that where Congress has determined that there should be no private right of action for the violation of a federal statute, a claim based on that statute does not state a claim "arising under the Constitution, laws, or treaties of the United States" within the meaning of 28 U.S.C. § 1331. Sloan-Kettering reads this case too broadly. Specifically, Sloan-Kettering fails to take into consideration that *Merrell Dow* did not involve a direct implied right of action, but rather involved a state law action which required interpretation of a federal statute. The importance in this distinction can not be overemphasized. The Supreme Court stated, "This case does not pose a [direct] federal question . . . respondents do not allege that federal law creates any of the causes of action that they have

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(Cont'd)

> as to determine issues of fact arising in the controversy. Jurisdiction, therefore, is not defeated as respondents seem to contend, by the possibility that the averments might fail to state a cause of action on which petitioners could actually recover. For it is well settled that the failure to state a proper cause of action calls for a judgment on the merits and not for a dismissal for want of jurisdiction. Whether the complaint states a cause of action for which relief could be granted is a question of law and just as issues of fact it must be decided after and not before the court has assumed jurisdiction over the controversy. If the court does later exercise its jurisdiction to determine that the allegations in the complaint do not state a ground for relief, then dismissal of the case would be on the merits, not for want of jurisdiction.

Bell v. Hood, 327 U.S. 678, 682, 66 S.Ct. 773, 776 (1946).

be granted. Thus, if Congress did not intend for a private cause of action to exist under the statute, the claim will be dismissed.[6]

In ascertaining whether a private cause of action exists under a federal statute, courts are to consider four factors: (l) whether plaintiff is part of the class for whose especial benefit the statute was passed; (2) whether the legislative history indicates a Congressional intent to confer a private right of action; (3) whether a federal cause of action would further the underlying purpose of the legislative scheme; and (4) whether the plaintiff's cause of action is a subject traditionally relegated to state law. *See Merrell Dow*, 478 U.S. at 810-11, 106 S.Ct at 3233; *California v. Sierra Club*, 451 U.S. 287, 293, 101 S.Ct. 1775, 1778 (1981); *Cannon v. University of Chicago*, 441 U.S. 677, 689-709, 99 S.Ct. 1946, 1953-64 (1979); *Cort v. Ash*, 422 U.S. 66, 78, 95 S.Ct. 2080, 2087 (1975).

The first factor to be considered is whether the plaintiff is a member of the class for whose "especial" benefit the statute was enacted. A review of the legislative history does not suggest that the Bayh-Dole Act was enacted for the benefit of research scientists. The Bayh-Dole Act was intended "to promote the utilization and commercialization of inventions made with Government support, to encourage the participation of smaller firms in the Government research and development process, and to promote increased cooperation and collaboration between the nonprofit and commercial sectors." 35 U.S.C. § 200 ("Policy and Objectives"). To such end, the intended beneficiaries of the Bayh-Dole Act are the institutions themselves and the government.

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6. This two part approach to subject matter jurisdiction and claim sufficiency for implied right of actions is consistent with the approach suggested in *Bell v. Hood*. *See* Note 4 *supra*.

completely silent with regard to a private cause of action. As such, it is safe to assume that Congress did not intend for a private right of action to exist. *Touche Ross & Co. v. Redington,* 442 U.S. 560, 576, 99 S.Ct. 2479, 2489 (where legislative history is silent, "[t]he question whether Congress . . . intended to create a private right of action, has been definitely answered in the negative"). This conclusion is supported by the fact that elsewhere in the patent statutes, Congress did explicitly grant private causes of action. *See, e.g.,* 35 U.S.C § 281 (1988) (a "patentee shall have remedy by civil action for infringement of his patent"); 35 U.S.C. §§ 141-145 (1988) (applicant whose patent is rejected by the Patent Office on appeal may pursue his claim in the federal courts). The fact that elsewhere in the patent statutes private rights were expressly provided indicates that "when Congress wished to provide a private damage remedy, it knew how to do so and did so expressly." *Touche Ross,* 442 U.S. at 573, 99 S.Ct. at 2487. Likewise, that such a right was not created under § 202(c)(7)(B) suggests that no right was intended.

Nor would implication of such a right further the purpose of the statute. The Bayh-Dole Act was enacted to foster commercial development of government funded research. As such, the statute requires that royalties be funneled back into scientific research. See H.R. Rep. No. 1307, 96th Cong., 2d Sess., pt.1, at 5, 2 (1980), reprinted in 1980 U.S. Code Cong. & Adm. News 6460, 6464, 6461. A private right of action allowing an inventor to demand 50% of the royalties, as is the case here, would clearly frustrate this purpose rather than further it.

In light of the foregoing, the Court concludes that no private cause of action exists under § 202(c)(7)(B) of the Bayh-Dole Act. Accordingly, the first cause of action asserting an implied right must be dismissed for failing to state a claim for which relief can be granted.

Merrell Dow, which involved a state law claim in which the alleged federal violation was peripheral,[8] to cases where the alleged violation is essential to the existence of the state-law claim.

That *Merrell Dow's* reach should not be so extended is suggested in the language of the opinion itself. The Court left undisturbed the holding of *Franchise Tax Board*, that federal question jurisdiction is "appropriate when 'it appears that some substantial, disputed question of federal law is a necessary element of the well-pleaded state claims.' " *Merrell Dow*, 478 U.S. at 813, 106 S.Ct. at 3234 (quoting *Franchise Tax Board*, 463 U.S. at 13, 103 S.Ct. at 2848). Leaving intact "arising under" jurisdiction to determine substantial questions of federal law, the Court held that the "*mere presence* of a federal issue in a state cause of action does not automatically confer federal question jurisdiction." *Merrell Dow*, 478 U.S. at 813, 106 S.Ct. at 3234 (emphasis added). As such, the Court emphasized the need to evaluate "the nature of the federal issue, *Merrell Dow*, 478 U.S. at 814 n.12, 106 S.Ct. 3235 n.12, and the "need for careful judgments about the exercise of federal judicial power in . . . area[s] of uncertain jurisdiction." *Merrell Dow*, 478 U.S. at 814, 106 S.Ct. at 3235.[9]

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8. *Merrell Dow* involved a products liability claim that children were born with deformities as a result of the injection of Bendectin. Of the six counts in the complaint, only one implicated federal law. That claim asserted, in part, that the drug was misbranded in violation of the Federal Food, Drug and Cosmetic Act ("FDCA") and that the violation of the FDCA constituted "a rebuttable presumption of negligence." *Merrell Dow*, 478 U.S. at 805-06, 106 S.Ct. at 3230-31.

9. Emphasizing the nature of the federal issue within the state-law claim, the Court went on to cite with approval *Textile Workers Union v. Lincoln Mills of Alabama*, 353 U.S. 448, 470, 77 S.Ct. 912, 928 (1957) (Frankfurter, J., dissenting) (defining the inquiry as "the degree to which federal law must be in the forefront of the case and not collateral, peripheral or remote"). *Merrell Dow*, 478 U.S. at 813 n. 11, 106 S.Ct. at 3234 n. 11.