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BNA's PATENT, TRADEMARK & COPYRIGHT JOURNAL

In The Supreme Court of the United States

OCTOBER TERM, 1978

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LUTRELLE F. PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS, PETITIONER

MALCOLM E. BERGY, ET AL

LUTRELLE F. PARKER, ACTING COMMISSIONER OF PATENTS AND TRADEMARKS, PETITIONER

Ananda M. Chakrabarty

i (<u>1918) - Andrean</u> Sanighter (1918) - Antre A. 1919 - Antre and Antre Sanit (1918) - Antre Angel (1918) PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS

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, diteller och <u>en som hende</u> fördet och på hande. Som genera och som en en som en so The Solicitor General, on behalf of the Acting Commissioner of Patents and Trademarks, petitions for a writ of certiorari to review the judgments of the United States Court of Customs and Patent Appeals in these cases. 1, the know we want of the set there is not set

OPINIONS BELOW

The most recent opinion of the Court of Customs and Patent Appeals (App. A, infra, 1a-103a) in these cases is reported at 596 F.2d 952. The deviation of the second states of the second states of the second states and the second states are second states and the second states are se

The opinion of this Court remanding Parker v. Bergy to the Court of Customs and Patent Appeals is reported at 438 U.S. 902. The prior opinion of the Court of Customs and Patent Appeals in that case (App. C, infra, 106a-128a) is reported at 563 F.2d 1031. The opinion of the Patent and Trademark Office Board of Appeals (App. D, infra, 129a-139a), is reported at 197 U.S.P.Q. 78. The opinion of the patent examiner (App. E, infra, 140a-141a) is not reported.

The prior opinion of the Court of Customs and Patent Appeals (In The Matter of the Application of Ananda M. Chakrabarty) (App. F, infra, 142a-158a) is reported at 571 F. 2d 40. The opinions of the Patent and Trademark Office Board of Appeals (App. G, infra, 159a-164a) and of the patent examiner (App. H, infra, 165a-167a) are not reported. and dista

JURISDICTION The set of the set of

The judgments of the Court of Customs and Patent Appeals were entered on March 29, 1979 (App. B, infra, 104a-105a). On June 13, 1979, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including July 27, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1256. Gottschalk v, Benson, 409 U.S. 63 (1972); Dann v. Johnston, 425 U.S. 219 (1976).

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Whether a living organism is patentable subject matter under 35 U.S.C. 101.

STATUTES INVOLVED

.35 U.S.C. 101 provides: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Plant Patent Act of 1930, 35 U.S.C. 161, provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor * * *.

Section 42(a) of the Plant Variety Protection Act of 1970, Pub. L. No. 91-577 84 Stat. 1547, 7 U.S.C. 2402(a), provides in relevant part:

The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor * * *.

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In 1974, Malcolm E. Bergy and two other scientists applied for a patent (B.R. 6-27),² assigned to the Up-

²"B.R." refers to the Bergy record; "C.R." refers to the Chakrabarty record.

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¹The two cases present a common legal issue and were decided by the Court of Customs and Patent Appeals in one opinion; we are therefore filing one petition to seek review of both judgments. See Rule 23.5 of the Rules of this Court.

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john Company (App. A, infra, 4a), with four claims to a process for preparing the antibiotic lincomycin using a newly isolated microorganism, Streptomyces vellosus ("S. vellosus") (App. D, infra, 129a)³ and a fifth claim for a culture of S. vellosus itself, as follows (ibid.):

A biologically pure culture of the microorganism Streptomyces vellosus, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

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The examiner allowed claims 1-4, and his decision on those claims is not in dispute (App. E, infra, 140a; App. A, infra, 27a). He rejected claim 5, however, on the basis that S. vellosus was a product of nature and thus not patentable (App. E. infra, 140a) if each robustice

The Board of Appeals, with one member dissenting, sustained the rejection of claim 5 on the ground that a living organism is not patentable subject matter under 35 U.S.C. 101 (App. D, infra, 129a-139a). The Board found support for this view in the Plant Patent Act of 1930, 35 U.S.C. 161 et seq: It reasoned that Congress would not have specifically given patent protection under the 1930 Act to certain kinds of plants if it had believed that patents could already be obtained for these plants, as living organisms, under the general patent laws, R.S. 4886, now 35 U.S.C. 101 (App. D, infra, 130a-132a).4

The Court of Customs and Patent Appeals reversed, with two judges dissenting (App. C, infra, 106a). The court reasoned that, since patents are available for processes using a strain of living bacteria (e.g., in septic systems or to produce alcohol), it would be "illogical" to insist that the living bacteria in a biologically pure culture are not themselves statutory subject matter (App. C. infra, 118a).

On June 26, 1978 this Court granted a petition for a writ of certiorari filed by the Solicitor General seeking review of the Court of Customs and Patent Appeals' decision, vacated the judgment and remanded the case to the Court of Customs and Patent Appeals "for further consideration in light of Parker v. Flook, 437 U.S. 584" (438 U.S. 902).

B. Chakrabarty

On June 7, 1972, Ananda M. Chakrabarty filed a patent application, assigned to the General Electric Company, with 36 claims to, inter alia, a strain of bacteria from the genus *Pseudomonas*, and an inoculum consisting essentially of these bacteria (C.R. 6-53, 118).

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Certain strains of Pseudomonas bacteria existing in nature are capable of degrading by enzymatic reactions a particular component of a complex hydrocarbon, such as crude oil, but no known, naturally-occurring bacterium can degrade more than one such component. Chakrabarty employed so-called "genetic engineering" to develop a *Pseudomonas* bacterium capable of degrading more than one component of crude oil (App. F, infra, 142a-143a).5 ATEL HERE'E SPROTOO

Although the examiner allowed claims for the process by which incompatible plasmids present in a Pseudomonas bacterium are fused to render them compatible,⁶ he rejected those claims for the genetically engineered Pseudomonas bacteria themselves on two grounds; (1) the microorganisms are "products of nature"; and (2) as living organisms they are not patentable subject matter under 35 U.S.C. 101 (App. H, infra, 165a-167a; C. R. 117).

The Board of Appeals affirmed the examiner on the second ground (App. G, infra, 160a-163a).7 Relying on the legislative history of the Plant Patent Act, the Board reasoned that the terms "manufacture" or "composition of matter" in 35 U.S.C. 101 were not intended to cover living organisms (App. G, infra, 161a-162a). The Board also observed that if 35 U.S.C. 101 were interpreted to encompass genetically-modified bacteria, it could also be read to encompass modified living multicellular organisms (ibid.).

The Court of Customs and Patent Appeals reversed, with two judges again dissenting (App. F, infra). The majority found the case indistinguishable from its recent decision in Bergy (App. F, infra, 147a-148a).

On July 26, 1978, the Solicitor General filed a petition for a writ of certiorari seeking review of the Court of Customs and Patent Appeals' decision (No. 78-145). Shortly thereafter, however, that court vacated its earlier judgment, recalled its mandate and restored the appeal to the calendar. On August 25, 1978, pursuant to the parties' stipulation, the petition for a writ of cer-3 tiorari was dismissed (App. A, infra, 5a-6a).

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⁵Plasmids, which are hereditary units separate from the chromosomes, carry the hydrocarbon-degrading capacity of the cell. Chakrabarty utilized a process of natural conjugation (C.R. 8) to effectuate the transfer to a single cell of plasmids from various known strains of bacteria, each known to have a specific capacity to degrade a particular component of crude oil (C.R. 13, 25-33). The resulting organism, which Chakrabarty seeks to patent, is a bacterium with separate hydrocarbon-degrading path-ways representative of each kind of plasmid so incorporated (App. F, infra, 143a). A second second

"The examiner also allowed claims 30-32 and 35-36, which were for an inoculum comprised of a carrier material able to float on water and of Pseudomonus bacteria containing at least two stable energy-generating plasmids, each providing a separate hydrocarbon-degrading pathway (C.R. 118).

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³This microorganism was found in Arizona soil samples (B.R. 11) and a subculture, supplied by Upjohn, is permanently maintained by the Department of Agriculture at its research facilities. It is identified by its accession number, NRRL 8037 (App. D, infra, 129a).

[&]quot;It did not reach the "product of nature" issue upon which the examiner's decision rested. The dissenting Board member concluded that claim 5 involved a "composition" or "manufacture" and was accordingly patentable under 35 U.S.C. 101 (App. D, infra, 132a).

The Board rejected the product-of-nature theory partially relied upon by the examiner, noting that Pseudomonas bacteria containing two or more energy-generating plasmids are not naturally occurring (App. G, infra, 163a).

C. The Decision After Remand

The Court of Customs and Patent Appeals reaffirmed its earlier judgments in both cases (App. A, infra, 40a, 70a).⁸ The majority discussed Parker v. Flook, supra, which it distinguished as being "concerned only with the question of what is a 'process' under § 101", an issue unrelated to the appeals before it (App. A, infra, 22a). It nevertheless asserted that Flook contained "an unfortunate and apparently unconscious, though clear. commingling of distinct statutory provisions which are conceptually unrelated" (id. at 10a), and adopted a "novel * * * doctrine" with "potential for great harm to the incentives of the patent system" (id. at 23a-24a)⁹. The Court of Customs and Patent Appeals summarized: "[t]o conclude on the light Flook sheds on these cases, very simply * * * we find none" (id. at 26a). It therefore adhered both to the analysis and the conclusion in its earlier decisions, emphasizing that the plain language of Section 101 does not distinguish between living and inanimate matter (id. at 44a-45a, 64a-65a, 69a), and that considerations of novelty are unrelated to the determination of coverage under Section 101 (id. at 13a).10

Judge Miller, dissenting, stated that the majority had read Parker v. Flook, supra, too narrowly. He interpreted the decision in Flook as requiring a clear and certain signal from Congress where there is substantial doubt over Congress' intent to include a particular development as patentable subject matter under Section 101. From his reading of the legislative history of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970, Judge Miller found that at least a substantial doubt existed about Congress' intent to include living things within the scope of patentable subject matter in Section 101 (App. A, infra, 96a).

REASONS FOR GRANTING THE WRIT

In concluding that living things are patentable subject matter under 35 U.S.C. 101, the Court of Customs and Patent Appeals significantly extended the coverage of the patent laws without legislative authorization, and rejected the principles of construction of the patent law recently restated in *Parker* v. *Flook*, 437 U.S. 584 (1978).

1. As the court below recognized, this decision is the first to hold that living things may themselves be patentable under 35 U.S.C. 101 (App. A, *infra*, 25a,

⁸The court, though not formally consolidating the cases, heard and decided them together because they involved "the same single question of law" (App. A, *infra*, 2a).

⁹The Court of Customs and Patent Appeals implied that the reason for the errors it perceived in *Flook* was that the briefs filed by the Solicitor General "badly, and with a seeming sense of purpose, confuse" the analysis of the Patent Act (*id.* at 17a).

¹⁰In a separate concurrence, Judge Baldwin found that the precedents cited in *Parker v. Flook* defined an area where patents were not possible because "the inventor attempted to preclude others from using those bare [natural] phenomena" (App. A, *infra*, 88a). He observed that in the instant cases the inventions did not "reach out to encompass natural phenomena *.**, but rather recite only non-naturally occurring compositions of matter that are but single tools for utilizing natural phenomena in producing new and useful end results" (App. A, *infra*, 91a). 68a).¹¹ The economic implications of that holding are very significant, given the vast area that it opens to patentability. Even if the holding applies only to microorganisms (compare App. A, *infra*, 45a with 48a-49a, 64a-67a), such basic life forms are among the most important areas of current research in the life sciences.¹² The decision below thus involves issues that clearly merit consideration by this Court. Moreover, review at this time is appropriate in order to avoid further complicating the already highly controversial policy problems surrounding genetic engineering¹³ with questions concerning the patentability of specific life forms.¹⁴

Only last Term this Court in Parker v. Flook, supra, held that the courts "must proceed cautiously when * * asked to extend patent rights into areas wholly unforeseen by Congress." 437 U.S. at 596. The Court warned that when the expansion of patent rights is based on inference from ambiguous statutory language, it would "require a clear and certain signal from Congress * * * before approving the [patent]." Ibid. (quoting from Deep South Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972)).¹⁵ This emphasis on caution

¹¹ Dicta in earlier cases, which the court below disapproved (App. A. *infra.*, 45a-48a), suggest that living things are not patentable. See e.g. *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F. 2d 400, 410 (D. Del. 1931), aff'd, 61 F. 2d 1041 (3d Cir. 1932), cert. denied, 288 U.S. 614 (1933); Application of Mancy, et al., 499 F. 2d 1289, 1294 (C.C.P.A. 1974).

¹² Moreover, the nature of living things—especially microorganisms—creates a substantial risk that a patent monopoly will exceed its lawful limits. The difficulty of describing and understanding microorganisms creates serious problems in determining whether competitive developments are lawful or infringing. Cf. Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F. 2d 1347, 1379–1383 (5th Cir. 1976), cert. denied, 429 U.S. 1094 (1977); Jeffery, The Patentability and Infringement of Sport Varieties: Chaos or Clarity?, 59 J. Pat. Off. Soc'y 645, 654-657 (1977).

¹³See "Recombinant DNA Research: Revised Guidelines," released by the National Institutes of Health, 43 Fed. Reg. 60080, 60108, 60134 (1978). See also "Recombinant DNA: Accelerated Processing of Patent Applications for Inventions," 42 Fed. Reg. 2712-2713 (1977), suspended in part by "Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions," 42 Fed. Reg. 13147 (1977).

¹⁴The decision of the court below, if unreviewed, means that the claimed patents will issue. But they may be held invalid if they are later challenged in a patent infringement suit in a district court. See 35 U.S.C. 281 *et seq.*, 28 U.S.C. 1338. The decision below thus does not finally resolve the issue of the patentability of living organisms. In light of the substantial economic interests involved, that issue can be expected to trouble the courts until resolved by this Court.

¹⁵The lower court found the quoted language inapplicable because the Court in *Deep South* was refusing a request that it modify prior cases interpreting the patent laws, and the requirement of a clear congressional signal was only applicable in those circumstances (App. A, *infra*, 24a-25a, 64a; but see 406 U.S. at 532). But the context of the quotation in *Flook* refutes that narrow reading; the Court used the quotation to summarize its concern over expanding patent protection into the "modern business of developing programs for computers," and concluded that whether or not such expansion was appropriate was for Congress, not the Court (437 U.S. at 595). The same reasoning applies to the even newer field of genetic engineering (see App. A, *infra*, 29a-30a).

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was not new. Flook followed Gottschalk v. Benson, 409 U.S. 63, 72–73 (1972), where the Court emphasized that policy decisions concerning the extension of the patent laws to new fields are for Congress, not the courts. Thus, where such extensions are involved it is particularly important for the courts to interpret the patent laws so that "the prerequisities to obtaining a patent are strictly observed." Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 230 (1964).¹⁶

This Court's directive to reconsider Bergy in light of Parker v. Flook strongly underscored the lower court's obligation to be very careful before authorizing the grant of a patent. That court, however, concluded that the holding of Parker v. Flook was limited to the patentability of a "method of calculation," obviously not at issue here, and that its language "very simply" shed no light on the issues in these cases (App. A, infra, 26a). Accordingly, the Court of Customs and Patent Appeals reasserted its earlier interpretation of Section 101, emphasizing that the plain language of Section 101 is "broad and general," and requires no showing of novelty or inventiveness (App. A, infra, 12a-13a, 17a, 41a-42a, 69a). Its approach is inconsistent with that of the Court in Flook, and mirrors the analysis of the dissenting opinion in that case (437 U.S. at 600), which, like the court below, criticizes the majority for "importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness."17

In contrast, the Court in Flook noted that "a purely literal reading of" Section 101 is inconsistent with this Court's cases (437 U.S. at 588-589), and rejected the argument that its approach "improperly imports into § 101 the considerations of 'inventiveness' which are the proper concerns of §§ 102 and 103" (id. at 592). Instead, the Court emphasized, "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kinds of 'discoveries' that the statute was enacted to protect" (id. at 592-593). Living things-whether naturally occurring, isolated, or genetically engineered-are no more "discoveries" of the kind the statute was enacted to protect than are the mathematical principles involved in Flook. And, as the Court's analysis in Flook makes clear, it is unnecessary to consider whether such "discoveries" meet the novelty and inventiveness requirements of Sections 102 and 103 in order to deny them patentability-they are simply outside the scope of the general patent laws.

2. The question is thus whether Congress intended to include living things within the scope of the general patent laws. We submit that it did not. Instead, when it believed that it was appropriate to extend patent protection to particular types of living things, it developed special statutory provisions to do so, and imposed the particular requirements it considered appropriate in the circumstances.

In 1930, Congress enacted the Plant Patent Act, 35 U.S.C. 161 *et seq.*, to afford patent protection to certain kinds of asexually-reproduced plants. Congress evidently believed that existing patent law did not extend to living things, for if plants, as living things, already were patentable under Section 101, there would have been no need to provide specifically for plant patents. The legislative history of the 1930 Act confirms that Congress intended for the first time to extend patent protection beyond its previous limits. Both the House and Senate committees considering the bill reported that:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry * * *. The bill will remove the existing discrimination between plant developers and industrial inventors. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930)].¹⁸

Forty years later, Congress again evidenced its belief that living organisms were not covered by 35 U.S.C. 101, and that to afford them protection separate legislation was needed. The Plant Variety Protection Act of 1970, Pub. L. No. 91–577, 84 Stat. 1542, 7 U.S.C. 2321 et. seq., gave the Secretary of Agriculture authority to issue certificates of Plant Variety Protection, similar to patents, for new varieties of sexually-reproduced plants (Section 51, 7 U.S.C. 2421). Significantly, the statute expressly provides that bacteria and fungi are not entitled to protection (Section 42, 7 U.S.C. 2402).¹⁹

Again, the legislative history of the Act unmistakably indicates that Congress was extending protection to materials not previously covered under the patent laws—*i.e.*, materials that were not within the terms of either the 1930 Act or 35 U.S.C. 101. Thus, the House Report states (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)):

Under patent law, protection is presently limited

¹⁹ In *In re Arzberger*, 112 F.2d 834, 837 (C.C.P.A. 1940), the court had earlier recognized that "the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants." The court nevertheless affirmed the Board's refusal to issue a plant patent for certain bacteria. Nothing in *Arzberger* implies that the bacteria could have been patented under the general patent laws. Instead, the court quoted with approval the examiner's statement that the Plant Patent Act was not designed "to afford patent protection for bacteria used in the production of butyl alcohol, ethyl alcohol, and acetone" (112 F.2d at 836), suggesting that no such protection was otherwise available.

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¹⁶In *Stiffel*, this Court held that even a State's concern with unfair competition could not prevail over the exclusive responsibility of Congress to determine the extent of the patent laws.

¹⁷This inconsistency between the analysis of the scope of Section 101 in *Flook* and in the decision below, which can only create uncertainty in the administration of the patent laws, is an additional reason why review by the Court is warranted.

¹⁸Appended to both the House and Senate Reports were letters from then Secretary of Agriculture Hyde, referring more specifically to the coverage of the pre-existing patent law:

The evident purpose of the bill is to encourage the improvement of some kinds of cultivated plants ***. This purpose is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st cong., 2d Sess. 9 (Appendix A) (1930).]

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to those varieties of plants which reproduce asexually * * *. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

The Court of Customs and Patent Appeals strained to avoid the force of this legislative history. Its principal argument was that the history should be ignored as a matter of law, for it "ascribe[s] to a preceding Congress an intent that the members of that Congress did not themselves state" (App. A, infra, 51a). It hardly advances the careful search for congressional intent, however, to make rote application of general maxims, and no useful source of legislative history should be reflexively cast aside. Cf. Train v. Colorado Public Interest Research Group, 426 U.S. 1, 10 (1976). The views of the Congress that passed the Plant Patent Act concerning Section 101's applicability to living things deserve especially serious consideration where, as here, the terms of the general statute hardly define themselves. Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 380-381 (1969); NLRB y. Bell Aerospace Co., 416 U.S. 267, 274-275 (1974). In any event, Congress in revising and codifying the patent code in 1952 chose to maintain explicitly the distinction among living things that the Plant Patent Act effects.

The lower court also contended that the Plant Patent Act itself shows that Congress did not consider it important that plants are living things. It read the Act as intended primarily to extend the patent system to a nonindustrial area, plant breeding, and secondarily to reject the judicial interpretation of the patent code that plants of the sort created by plant breeders like Luther Burbank were nonetheless "products of nature" and, as such, non-statutory subject matter (App. A, infra, 56a-59a). The first stated objective, however, necessarily assumes that Congress believed that Section 101 would not, without special amendment, apply to living things.²⁰ The second stated objective is not supported aan barga ay

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²⁰Because the general patent statute has from the beginning been applied to agricultural as well as industrial uses, it is exceedingly unlikely that Congress believed that Section 101 provided for only industrial patents, and that the new Act was necessary to provide patent protection simply because of the agricultural character of the discoveries involved.

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(No. 439) D - 5 by the legislative history of the Act. There is nothing in that history to indicate that Congress viewed plants developed by breeders like Burbank as already patentable subject matter but for decisions holding them outside the patent statutes as "products of nature."21

Finally, the Court of Customs and Patent Appeals evidently thought that it is illogical not to allow patents on living things themselves while allowing patents on processes that use living things (App. A, infra, 44a-45a, 49a, 67a-68a). This is not so, however. This Court has long recognized that an entity not itself patentable subject matter may nonetheless be used in a patentable process. See Parker v. Flook, supra, 437 U.S. at 588-592. Just as there is nothing illogical in holding that Congress did not give patent protection to a mathematical formula itself but allowed it on certain processes which exploit that formula, there is nothing illogical in a congressional intent to deny patents on living things themselves yet to allow patents on processes which use them, or, in appropriate circumstances, on processes to isolate or produce them.

CONCLUSION

The petition for a writ of certiorari should be 10000 granted. Respectfully submitted.

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²¹ The legislative history of the Plant Patent Act contains no evidence of congressional awareness of Ex Parte Latimer, 1889. C.D. 123, cited by the court below as the interpretation of the general patent law that the Act was designed to overcome (App. A, infra, 59a-61a). 1. 10-20-22

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