Patents on living organisms

Selection of the most important decisions of American courts

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Introduction

There are three different patent types under U.S. law. One of them, called – "utility patent" – protects new and innovative objects. The second one – "design patent" – provides for patent on new and inventive ornamental designs for articles of manufacture. And finally there is one called "plant patent", that allows to protect new and inventive plant varieties.

Congress passed the first national patent statute in 1790. The act was revised in 1793 and since then only one change was made in the act, in 1952. Section 101 of the **Patent Act** (in Title 35 of the U.S. Code) states as follows: *"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*." In 1952 the word "process" was replaced by a word "art".

In most cases the content of sec. 101 of the Patent Act was easily applicable. Nevertheless, the biggest controversies concerned biotechnology (including living, genetically-modified organisms) and computer programs[1].

The code said nothing about patenting life, but a key precedent discouraging it was established in 1889, when the U.S. Commissioner of Patents rejected an application for a patent covering a fiber identified in the needles of a pine tree. He noted that ascertaining the composition of the trees in the forest was "not a patentable invention, recognized by statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found." The commissioner added that it would be "unreasonable and impossible" to allow patents upon the trees of the forest and the plants of the earth[2].

The ruling became later the basis for a doctrine called "product of nature", according to which processes devised to extract what is found in nature can be patented, while objects discovered there can not.

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[1] When talking about patenting software one should look up the so-called patent-eligibility-trilogy that consists of three important decisions of United States Supreme Court. First one is *Parker v. Flook*, 437 U.S. 584 (1978), second one is *Gottschalk v. Benson*, 409 U.S. 63 (1972), and the last one is *Diamond v. Diehr*, 450 U.S. 175 (1981).

[2] D.J. Kevles, *A history of patenting life in the United States with comparative attention to Europe and Canada*, Luxembourg 2002, p. 1-2.

It has to be noticed though, that courts all over U.S. held for a very long time that patents are not available for laws of nature, natural phenomena, or abstract ideas. These basic pieces of innovation are our common heritage, and everyone should have access to them.

The Patent Office in U.S. represented almost the same attitude - viewed plants, even newly invented varieties that would not exist without human intervention, as unpatentable products of nature. Moreover, the inventors (plant breeders) used to have some serious trouble with filling out the patent application form, as it was too detailed.

A solution to this problem came from Congress, which in 1930 created a new kind of patent called a "plant patent," different from a utility patent. Congress expressly made new plant varieties patentable, in language now codified at 35 U.S.C. § 161: "*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, subject to the conditions and requirements of this title*." Congress also ensured that the disclosure requirement for a plant patent would not be so demanding as to prevent protection. Title 35 U.S.C. § 162 states: "*No plant patent shall be declared invalid for noncompliance with [the disclosure requirement for utility patents] if the description is as complete as is reasonably possible*."

A plant patent gives its owner the "*the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States*." (Title 35 U.S.C. § 163). To sum up a new plant patent covers a single plant and its asexually reproduced (that is by pollination and seeds) progeny.

As you can read in ***Imazio Nursery, Inc. v. Dania Greenhouses*** case, the American **Plant Patent Act (PPA)** was the pioneer legislation in the world that allowed to grant patent rights to plant breeders. Nonetheless, the PPA protection did not give the patentee the right to prevent someone from cultivating a similar variety on his or her own. Nor did it pertain to plants reproduced by seeds, or seeds themselves.

In response to these problems in 1970 Congress created a patent-like system for seed-reproduced plants, with the enactment of the **Plant Variety Protection Act (PVPA)**. The

PVPA created a Plant Variety Protection Office within the Department of Agriculture, which is an independent unit, different from the Patent Office.

Under the PVPA the applicant receives a plant variety protection certificate, not a patent. According to Title 7 U.S.C. the breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety, or the successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is:

1) new,
2) distinct,
3) uniform, and
4) stable.

The certificate gives its owner the right "*to exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom*." (Title 7 U.S.C. § 2483(a)(1)). It is worth noticing, that although the PVPA excludes others from reproducing the protected variety of seed, it allows a farmer to save seed from one crop and plant it at a later time. Paragraph 2543 states, that "(…) *it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section*". This is a significant exception in the breeder's scope of protection.

The other exception allows to conduct a research on a PVPA-protected variety: "*The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter*." (Title 7 U.S.C. § 2544).

None of the before mentioned exceptions would be allowed under the Patent Act, which means that the utility patent is still more desirable to the seed companies than the certificate under the Plant Variety Protection Act. Nonetheless, since 1970, as a result of the Plant Variety Protection Act, the number of seed companies had increased, especially in wheat, cereal grains, and soybeans (before that year, six companies had been engaged in the development of soybean varieties; now the number was twenty-five). Also since 1970, almost

1,000 applications had been submitted for plant variety protection certificates on 57 distinct crops. About ten percent of these had come from agricultural experiment stations at colleges and universities; about twenty percent, from the six largest U.S. seed companies; and almost 70%, from private breeders of all sizes[3].

But there was still more than one question to answer. The most important one was: could one get a utility patent on a living organism such as a genetically modified bacterium? Answer to that questions can be found by careful studying of the ***Diamond v. Chakrabarty*** case…

The other question that remained unanswered is: what is the relationship between utility patent under the Patent Act and certificate under the PVPA? Can one obtain both of the means of protection or obtaining one of them excludes obtaining the other?

Genetic engineering and consent to patenting living organisms had also raised issues of ethics (the creation of new life forms, including human ones) and safety (recombinant organisms polluting the environment). One could ask: if we open the door and allow for patenting lower life forms (like the bacteria from Chakrabarty case), it might raise a question of the patentability of higher life forms one day. But the courts could only resolve the scope of the patentability of life if and when that question came concretely before them, not prospectively.

The opportunity appeared when Philip Leder and his postdoctoral collaborator Tim Stewart from Harvard University developed a transgenic mouse that was highly susceptible to breast cancer because it contained an oncogene - a tumor-causing gene. On June 22, 1984, on behalf of Harvard University, Clark filed an application for a patent on Leder and Stewart's invention. The same year that Harvard filed the patent application on Leder and Stewart'smouse, three marine biologists applied for a patent on an improved version of *Crassostrea gigas*, a variety of the Pacific oyster[4]. The examiners in the U.S. Patent Office denied all the claims. The scientists appealed the examiners' decision to the Board of Patent Appeals and Interferences, of the U.S. Patent and Trademark Office. The Board of Patent Appeals and Interferences granted the patent to Leder and Stewart but denied the patent to modified oyster as "obviousness of art disqualified the oyster for a patent". The Board also

[3] D.J. Kevles, *A history of patenting life in the United States with comparative attention to Europe and Canada*, Luxembourg 2002, p. 34-35.

[4] D.J. Kevles, *A history of patenting…,* p. 45.

declared that that patents could in principle be granted on living animals, but not on human beings. The Board held that human beings fell outside the scope of patentability by reason of the 13th Amendment to the U.S. Constitution[5].

The grant of patents on animals provoked another flood of ethical and economic objections to the patenting of life. But the biggest controversy was yet to come… In 1991 J. Craig Venter, a biologist at the National Institutes of Health (NIH), in Bethesda, Maryland, raised the both the economic and ethical stakes in the patenting of life or its parts by proposing the wholesale patenting of human gene fragments. Venter's lab, using automated machines, had sequenced not whole genes but random fragments of cDNA -- that is, DNA complementary to the coding regions in genomic DNA -- derived from part of the brain[6]. Such a fragment was called an "expressed sequence tag," or EST[7]. Although just 150 to 400 base pairs long, each was unique and served to identify the gene of which it was a part[8]. In June 1991, Venter and NIH filed for patents on 315 ESTs and the human genes from which they came[9]. The patent was denied mainly because ESTs did not fully characterized genes but that did not end the discussion. To find out more about that matter we encourage readers to explore the ***Mayo v. Prometheus case*** and ***the Association for Molecular Pathology v. Myriad Genetics case***.

The patent law and the possibility to grant a protection on a living organism is not only extremely controversial but also very interesting matter. The collection of cases decided by American courts is obviously not complete and the choice is strictly subjective. Nonetheless we hope that exploring the presented cases will bring the Readers as much satisfaction as it brought to the Authors when preparing this compilation.

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[5] D.J. Kevles, *A history of patenting…,* p. 47.

[6] Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, *Complementary DNA sequencing: expressed sequence tags and Human Genome Project*, Science, 252 (June 21, 1991), pp. 1651-1656.

[7] Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, *Complementary DNA sequencing*…, pp. 1651-1656.

[8] Mark D. Adams, Jenny M. Kelley, Jeannine D. Gocayne, Mark Dubnick, Mihael H. Polymeropoulos, Hong Xiao, Carl R. Merril, Andrew Wu, Bjorn Olde, Ruben F. Moreno, Anthony R. Kerlavage, W. Richard McCombie, and J. Craig Venter, *Complementary DNA sequencing*…, pp. 1651-1656.

[9] D.J. Kevles, *A history of patenting…,* p. 47.

SUPREME COURT OF THE UNITED STATES

SIDNEY A. DIAMOND, COMMISSIONER OF PATENTS AND TRADEMARKS, PETITIONER, v. ANANDA M. CHAKRABARTY ET AL.

No. 79-136. 447 U.S. 303 (1980)

Mr. Chief Justice BURGER delivered the opinion of the Court. We granted certiorari to determine whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.

I

In 1972, respondent Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Co. The application asserted 36 claims related to Chakrabarty's invention of "a bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway."[10] This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.[11]

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria

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[10] Plasmids are hereditary units physically separate from the chromosomes of the cell. In prior research, Chakrabarty and an associate discovered that plasmids control the oil degradation abilities of certain bacteria. In particular, the two researchers discovered plasmids capable of degrading camphor and octane, two components of crude oil. In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single Pseudomonas bacterium, which itself has no capacity for degrading oil.

[11] At present, biological control of oil spills requires the use of a mixture of naturally occurring bacteria, each capable of degrading one component of the oil complex. In this way, oil is decomposed into simpler substances which can serve as food for aquatic life. However, for various reasons, only a portion of any such mixed culture survives to attack the oil spill. By breaking down multiple components of oil, Chakrabarty's microorganism promises more efficient and rapid oil-spill control.

themselves. The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that micro-organisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.

Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and the Board affirmed the Examiner on the second ground.[12] Relying on the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants, the Board concluded that § 101 was not intended to cover living things such as these laboratory created micro-organisms.

The Court of Customs and Patent Appeals, by a divided vote, reversed on the authority of its prior decision in In re Bergy, 563 F.2d 1031, 1038 (1977), which held that "the fact that microorganisms . . . are alive . . . [is] without legal significance" for purposes of the patent law.[13] Subsequently, we granted the Acting Commissioner of Patents and Trademarks' petition for certiorari in Bergy, vacated the judgment, and remanded the case "for further consideration in light of Parker v. Flook, 437 U.S. 584, [98 S.Ct. 2522, 57 L.Ed.2d 451] (1978)." 438 U.S. 902, 98 S. Ct. 3119, 57 L.Ed.2d 1145 (1978). The Court of Customs and Patent Appeals then vacated its judgment in Chakrabarty and consolidated the case with Bergy for reconsideration. After re-examining both cases in the light of our holding in Flook, that court, with one dissent, reaffirmed its earlier judgments. 596 F.2d 952 (1979).

The Commissioner of Patents and Trademarks again sought certiorari, and we granted the writ as to both Bergy and Chakrabarty. 444 U.S. 924, 100 S.Ct. 261, 62 L.Ed.2d 180 (1979). Since then, Bergy has been dismissed as moot, 444 U.S. 1028, 100 S.Ct. 696, 62 L.Ed.2d 664 (1980), leaving only Chakrabarty for decision.

II

The Constitution grants Congress broad power to legislate to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive

[12] The Board concluded that the new bacteria were not "products of nature," because Pseudomonas bacteria containing two or more different energy-generating plasmids are not naturally occurring.

[13] Bergy involved a patent application for a pure culture of the micro-organism Streptomyces vellosus found to be useful in the production of lincomycin, an antibiotic.

Right to their respective Writings and Discoveries." Art. I, § 8, cl. 8. The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. Kewanee Oil Co. v. Bicron Corp., 416 U. S. 470, 480-481, 94 S.Ct. 1879, 1885-1886, 40 L.Ed.2d 315 (1974); Universal Oil Co. v. Globe Co., 322 U.S. 471, 484, 64 S.Ct. 1110, 1116, 88 L.Ed. 1399 (1944). The authority of Congress is exercised in the hope that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." Kewanee, supra, 416 U.S., at 480, 94 S.Ct., at 1885-86.

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101, which 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."

Specifically, we must determine whether respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the meaning of the statute.[14]

III

In cases of statutory construction we begin, of course, with the language of the statute. Southeastern Community College v. Davis, 442 U.S. 397, 405, 99 S.Ct. 2361, 2366, 60 L.Ed.2d 980 (1979). And "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." Perrin v. United States, 444 U. S. 37, 42, 100 S.Ct. 311, 314, 62 L.Ed.2d 199 (1979). We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." United States v. Dubilier Condenser Corp., 289 U.S. 178, 199, 53 S.Ct. 554, 561, 77 L.Ed. 1114 (1933).

Guided by these canons of construction, this Court has read the term "manufacture" in § 101

[14] This case does not involve the other "conditions and requirements" of the patent laws, such as novelty and nonobviousness. 35 U.S.C. § § 102, 103.

in accordance with its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 51 S.Ct. 328, 330, 75 L.Ed. 801 (1931). Similarly, "composition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F.Supp. 279, 280 (D. C.1957) (citing 1 A. Deller, Walker on Patents § 14, p. 55 (1st ed. 1937)). In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, § 1, 1 Stat. 319. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871). See Graham v. John Deere Co., 383 U.S. 1, 7-10, 86 S.Ct. 684, 688-690, 15 L.Ed.2d 545 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S.Rep.No.1979, 82d Cong., 2d Sess., 5 (1952); H.R.Rep.No.1923, 82d Cong., 2d Sess., 6 (1952).[15]

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. See Parker v. Flook, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978); Gottschalk v. Benson, 409 U.S. 63, 67, 93 S.Ct. 253, 255, 34 L.Ed.2d 273 (1972); Funk Brothers Seed Co. v. Kalo

[15] This same language was employed by P. J. Federico, a principal draftsman of the 1952 recodification, in his testimony regarding that legislation: "[U]nder section 101 a person may have invented a machine or a manufacture, which may include anything under the sun that is made by man. . . . " Hearings on H.R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess., 37 (1951).

Inoculant Co., 333 U.S. 127, 130, 68 S.Ct. 440, 441, 92 L.Ed. 588 (1948); O'Reilly v. Morse, 15 How. 62, 112-121, 14 L.Ed. 601 (1854); Le Roy v. Tatham, 14 How. 156, 175, 14 L.Ed. 367 (1853).

Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc 2; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none." Funk, supra, 333 U.S., at 130, 68 S.Ct., at 441.

Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter--a product of human ingenuity "having a distinctive name, character [and] use." Hartranft v. Wiegmann, 121 U.S. 609, 615, 7 S.Ct. 1240, 1243, 30 L.Ed. 1012 (1887). The point is underscored dramatically by comparison of the invention here with that in Funk. There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered "only some of the handiwork of nature," the Court ruled the product nonpatentable:

"Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee." 333 U.S., at 131, 68 S.Ct., at 442.

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

IV

Two contrary arguments are advanced, neither of which we find persuasive.

(A)

The petitioner's first argument rests on the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection.[16] In the petitioner's view, the passage of these Acts evidences congressional understanding that the terms "manufacture" or "composition of matter" do not include living things; if they did, the petitioner argues, neither Act would have been necessary.

We reject this argument.

(B)

The petitioner's second argument is that microorganisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. His position rests on the fact that genetic technology was unforeseen when Congress enacted § 101. From this it is argued that resolution of the patentability of inventions such as respondent's should be left to Congress. The legislative process, the petitioner argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. In support of this position, the petitioner relies on our recent holding in Parker v. Flook, 437 U.S. 584, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978), and the statement that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." Id., at 596, 98 S.Ct. at 2529.

[16] 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 propogated plant or a plant found in an uncultivated state, may obtain a patent therefor . . . ." The Plant Variety Protection Act of 1970, 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 . . . ." 84 Stat. 1547, 7 U.S.C. § 2402(a). See generally, 3 A. Deller, Walker on Patents, ch. IX (2d ed. 1964); R. Allyn, The First Plant Patents (1934).

It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is "the province and duty of the judicial department to say what the law is." Marbury v. Madison, 1 Cranch 137, 177, 2 L.Ed. 60 (1803). Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.

Nothing in Flook is to the contrary. That case applied our prior precedents to determine that a "claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101." 437 U.S., at 595, n. 18, 98 S.Ct., at 2528, n. 18. The Court carefully scrutinized the claim at issue to determine whether it was precluded from patent protection under "the principles underlying the prohibition against patents for 'ideas' or phenomena of nature." Id., at 593, 98 S.Ct. at 2527. We have done that here. Flook did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable per se.

To read that concept into Flook would frustrate the purposes of the patent law. This Court frequently has observed that a statute is not to be confined to the "particular application[s] . . . contemplated by the legislators." Barr v. United States, 324 U.S. 83, 90, 65 S.Ct. 522, 525, 89 L.Ed. 765 (1945). Accord, Browder v. United States, 312 U.S. 335, 339, 61 S.Ct. 599, 601, 85 L.Ed. 862 (1941); Puerto Rico v. Shell Co., 302 U.S. 253, 257, 58 S.Ct. 167, 169, 82 L.Ed. 235 (1937). This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. See Graham v. John Deere Co., 383 U.S., at 12-17, 86 S.Ct., at 691-693. Mr. Justice Douglas reminded that the inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like." Great A. & P. Tea Co. v. Supermarket Corp., 340 U.S. 147, 154, 71 S.Ct. 127, 131, 95 L.Ed. 162 (1950) (concurring opinion). Congress employed broad general language in drafting §

101 precisely because such inventions are often unforeseeable.[17]

To buttress his argument, the petitioner, with the support of amicus, points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates--that with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."

It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under § 101. We disagree. The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

What is more important is that we are without competence to entertain these arguments--either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot.

[17] Even an abbreviated list of patented inventions underscores the point: telegraph (Morse, No. 1,647); telephone (Bell, No. 174,465); electric lamp (Edison, No. 223,898); airplane (the Wrights, No. 821,393); transistor (Bardeen & Brattain, No. 2,524,035); neutronic reactor (Fermi & Szilard, No. 2,708,656); laser (Schawlow & Townes, No. 2,929,922). See generally Revolutionary Ideas, Patents & Progress in America, United States Patent and Trademark Office (1976).

That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[18]

We have emphasized in the recent past that "[o]ur individual appraisal of the wisdom or unwisdom of a particular [legislative] course . . . is to be put aside in the process of interpreting a statute." TVA v. Hill, 437 U.S., at 194, 98 S. Ct., at 2302. Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Cf. 42 U.S.C. § 2181(a), exempting from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Or it may chose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is. The language of that section fairly embraces respondent's invention.

Accordingly, the judgment of the Court of Customs and Patent Appeals is

Affirmed.

Mr. Justice BRENNAN, with whom Mr. Justice WHITE, Mr. Justice MARSHALL, and Mr. Justice POWELL join, dissenting. [on the effect of the Plant Patent Act]

[18] We are not to be understood as suggesting that the political branches have been laggard in the consideration of the problems related to genetic research and technology. They have already taken action. In 1976, for example, the National Institutes of Health released guidelines for NIH-sponsored genetic research which established conditions under which such research could be performed. 41 Fed.Reg. 27902. In 1978 those guidelines were revised and relaxed. 43 Fed.Reg. 60080, 60108, 60134. And Committees of the Congress have held extensive hearings on these matters. See, e. g., Hearings on Genetic Engineering before the Subcommittee on Health of the Senate Committee on Labor and Public Welfare, 94th Cong., 1st Sess. (1975); Hearings before the Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation, 95th Cong., 1st Sess. (1977); Hearings on H.R. 4759 et al. before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, 95th Cong., 1st Sess. (1977).

SUPREME COURT OF THE UNITED STATES

No. 92-2038

ASGROW SEED COMPANY, PETITIONER *v.* DENNY WINTERBOER and BECKY WINTERBOER, DEEBEES

on writ of certiorari to the United States Court of Appeals for the Federal Circuit

[January 18, 1995]

Justice Scalia delivered the opinion of the Court.

In 1970, Congress passed the Plant Variety Protection Act (PVPA) 84 Stat. 1542, 7 U.S.C. § 2321*et seq.*, in order to provide developers of novel plant varieties with "*adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties,"* §2581. The PVPA extends patent like protection to novel varieties of sexually reproduced plants (that is, plants grown from seed) which parallels the protection afforded asexually reproduced plant varieties (that is, varieties reproduced by propagation orgrafting) under Chapter 15 of the Patent Act. See 35 U.S.C. §§ 161-164.

The developer of a novel variety obtains PVPA coverage by acquiring a certificate of protection from the Plant Variety Protection Office. See 7 U.S.C. §§ 2421 2422, 2481-2483. This confers on the owner the exclusive right for 18 years to "*exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing (as distinguished from developing) a hybrid or different variety therefrom*." §2483.

Petitioner, Asgrow Seed Company is the holder of PVPA certificates protecting two novel varieties of soybean seed, which it calls A1937 and A2234. Respondents, Dennis and Becky Winterboer, are Iowa farmers whose farm spans 800 acres of Clay County, in the northwest corner of the state. The Winterboers have incorporated under the name "D Double U Corporation" and do business under the name "DeeBee's Feed and Seed." In addition to growing crops for sale as food and livestock feed, since 1987 the Winterboers have derived a

sizable portion of their income from "brown bag" sales of their crops to other farmers to use as seed. A brown bag sale occurs when a farmer purchases seed from a seed company, such as Asgrow, plants the seed in his own fields, harvests the crop, cleans it, and then sells the reproduced seed to other farmers (usually in nondescript brown bags) for them to plant as crop seed on their own farms. During 1990, the Winterboers planted 265 acres of A1937 and A2234, and sold the entire saleable crop, 10,529 bushels, to others for use as seed--enough to plant 10,000 acres. The average sale price was $8.70 per bushel, compared with a then current price of $16.20 to $16.80 per bushel to obtain varieties A1937 and A2234 directly from Asgrow.

Concerned that the Winterboers were making a business out of selling its protected seed, Asgrow sent a local farmer, Robert Ness, to the Winterboer farm to make a purchase. Mr. Winterboer informed Ness that he could sell him soybean seed that was "just like" Asgrow varieties A1937 and A2234. Ness purchased 20 bags of each; a plant biologist for Asgrow tested the seeds and determined that they were indeed A1937 and A2234.

Asgrow brought suit against the Winterboers in Federal District Court for the Northern District of Iowa, seeking damages and a permanent injunction against sale of seed harvested from crops grown from A1937 and A2234. The complaint alleged infringement under 7 U.S.C. § 2541(1), for selling or offering to sell Asgrow's protected soybean varieties; under §2541(3), for sexually multiplying Asgrow's novel varieties as a step in marketing those varieties for growing purposes; and under §2541(6), for dispensing the novel varieties to others in a form that could be propagated without providing notice that the seeds were of a protected variety[19].

[19] At the time of the infringement action was filed, §2541 provided in full:
"Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 2567 of this title:
"(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;
"(2) import the novel variety into, or export it from, the United States;
"(3) sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or
"(4) use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or
"(5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the novel variety; or

The Winterboers did not deny that Asgrow held valid certificates of protection covering A1937 and A2243, and that they had sold seed produced from those varieties for others to use as seed. Their defense, at least to the §§2541(1) and (3) charges, rested upon the contention that their sales fell within the statutory exemption from infringement liability found in 7 U.S.C. § 2543. That section, entitled "Right to save seed; crop exemption," reads in relevant part as follows:

"*Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: Provided, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable. A bona fide sale for other than reproductive purposes, made in channels usual for such other purposes, of seed produced on a farm either from seed obtained by authority of the owner for seeding purposes or from seed produced by descent on such farm from seed obtained by authority of the owner for seeding purposes shall not constitute an infringement. . . .*".[20]

The Winterboers argued that this language gave them the right to sell an unlimited

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"(6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received; or

"(7) perform any of the foregoing acts even in instances in which the novel variety is multiplied other than sexually, except in pursuance of a valid United States plant patent; or

"(8) instigate or actively induce performance of any of the foregoing acts."

In October, 1992, Congress amended §2541, designating the prior text as subsection (a) and adding a subsection (b), the provisions of which are not relevant here. Curiously, however, the references in §2543 to the infringement provisions of §2541 were not amended to reflect this change. For clarity's sake, therefore, we will continue to refer to the infringement provisions under their prior designations, e.g., §§2541(1)(8), rather than their current designations, e.g., §§2541(a)(1)(8).

[20]Congress has recently amended this section by striking from the first sentence the words " `section: Provided, That' and all that follows through the period and inserting `section.' " Plant Variety Protection Act Amendments of 1994, Pub. L. 103-349, 108 Stat. 3136, 3142. That amendment has the effect of eliminating the exemption from infringement liability for farmers who sell PVPA protected seed to other farmers for reproductive purposes. That action, however, has no bearing on the resolution of the present case, since the amendments affect only those certificates issued after April 4, 1995, that were not pending on or before that date. See id., §§14(a), 15, 108 Stat. 3144, 3145.

amount of seed produced from a protected variety, subject only to the conditions that both buyer and seller be farmers "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes," and that all sales comply with state law. Asgrow maintained that the exemption allows a farmer to save and resell to other farmers only the amount of seed the seller would need to replant his own fields--a limitation that the Winterboers' sales greatly exceeded. The District Court agreed with Asgrow and granted summary judgment in its favor. 795 F. Supp. 915 (1991).

The United States Court of Appeals for the Federal Circuit reversed. 982 F. 2d 486 (1992). Although "*recogniz[ing] that, without meaningful limitations, the crop exemption [of §2543] could undercut much of the PVPA's incentives," id.*, at 491, the Court of Appeals saw nothing in §2543 that would limit the sale of protected seed (for reproductive purposes) to the amount necessary to plant the seller's own acreage. Rather, as the Court of Appeals read the statute, §2543 permits a farmer to sell up to half of every crop he produces from PVPA protected seed to another farmer for use as seed, so long as he sells the other 50 percent of the crop grown from that specific variety for non reproductive purposes, *e.g.*, for food or feed. The Federal Circuit denied Asgrow's petition for rehearing and suggestion for rehearing en banc by a vote of six judges to five. 989 F. 2d 478 (1993). We granted certiorari. 511 U. S. ___ (1994).

It may be well to acknowledge at the outset that it is quite impossible to make complete sense of the provision at issue here. One need go no further than the very first words of its title to establish that. Section 2543 does *not*, as that title claims and the ensuing text says, reserve any "[r]ight to save seed"--since nothing elsewhere in the Act remotely prohibits the saving of seed. Nor, under any possible analysis, is the proviso in the first sentence of §2543 ("*Provided*, That") really a proviso.

With this advance warning that not all mysteries will be solved, we enter the verbal maze of §2543. The entrance, we discover, is actually an exit, since the provision begins by excepting certain activities from its operation: "*Except to the extent that such action may constitute an infringement under subsections (3) and (4) of section 2541 of this title, it shall not infringe any right hereunder for a person to save seed produced by him . . . and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section* . . . ." (emphasis added). Thus, a farmer does not qualify for the exemption from

infringement liability if he has

"*(3) sexually multipl[ied] the novel variety as a step in marketing (for growing purposes) the variety; or*

(4) use[d] the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom." 7 U.S.C. §§ 2541(3)%(4).

In 1990, the Winterboers planted 265 bushels of Asgrow protected variety seed and collected a harvest of 12,037 bushels of soybeans. The parties do not dispute that this act of planting and harvesting constituted "sexual multiplication" of the novel varieties. See 7 U.S.C. § 2401(f) (defining "sexually reproduced" seed to include "any production of a variety by seed"). The Winterboers sold almost all of these beans for use as seed (*i.e.*, "for growing purposes"), without Asgrow's consent. The central question in this case, then, is whether the Winterboers' planting and harvesting were conducted "as a step in marketing" Asgrow's protected seed varieties for growing purposes. If they were, the Winterboers were not eligible for the §2543 exemption, and the District Court was right to grant summary judgment to Asgrow.

The PVPA does not define "marketing." When terms used in a statute are undefined, we give them their ordinary meaning. *FDIC* v. *Meyer,* 510 U. S. ___, ___ (1994) (slip op., at 5-6). The Federal Circuit believed that the word "marketing" requires "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities." 982 F. 2d, at 492. We disagree. Marketing ordinarily refers to the act of holding forth property for sale, together with the activities preparatory thereto (in the present case, cleaning, drying, bagging and pricing the seeds). The word does not require that the promotional or merchandising activities connected with the selling be extensive. One can market apples by simply displaying them on a cart with a price tag; or market a stock by simply listing it on a stock exchange; or market a house (we would normally say "place it on the market") by simply setting a "for sale" sign on the front lawn. Indeed, some dictionaries give as one meaning of "market" simply "to sell." See, *e.g.*, Oxford Universal Dictionary 1208 (3d ed. 1955); Webster's New International Dictionary 1504 (2d ed. 1950). Of course effective selling often involves extensive promotional activities, and when they occur they are all part of the "marketing." But even when the holding forth for sale relies

upon no more than word of mouth advertising, a marketing of goods is in process. Moreover, even if the word "marketing" could, in one of its meanings, demand extensive promotion, we see no reason why the law at issue here would intend that meaning. That would have the effect of preserving PVPA protection for less valuable plant varieties, but eliminating it for varieties so desirable that they can be marketed by word of mouth; as well as the effect of requiring courts to ponder the difficult question of how much promotion is necessary to constitute marketing. We think that when the statute refers to sexually multiplying a variety "as a step in marketing," it means growing seed of the variety for the purpose of putting the crop up for sale.[21] Under the exception set out in the first clause of §2543, then, a farmer is not eligible for the §2543 exemption if he plants and saves seeds for the purpose of selling the seeds that they produce for replanting.

Section 2543 next provides that, so long as a person is not violating either § 2541(3) or (4),

"*it shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section* . . . ." (Emphasis added.)

Farmers generally grow crops to sell. A harvested soybean crop is typically removed from the farmer's premises in short order and taken to a grain elevator or processor. Sometimes, however, in the case of a plant such as the soybean, in which the crop is the seed, the farmer will have a portion of his crop cleaned and stored as seed for replanting his fields next season. We think it clear that this seed *saved for replanting* is what the provision under discussion means by "saved seed"--not merely regular uncleaned crop that is stored for later market sale or use as fodder.

There are two ways to read the provision, depending upon which words the phrase "for

[21]The dissent asserts that the Federal Circuit's more demanding interpretation of "marketing" is supported by the ancient doctrine disfavoring restraints on alienation of property, see post, at 2-3. The wellspring of that doctrine, of course, is concern for property rights, and in the context of the PVPA it is the dissent's interpretation, rather than ours, which belittles that concern. The whole purpose of the statute is to create a valuable property in the product of botanical research by giving the developer the right to "exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it," etc. 7 U.S.C. § 2483. Applying the rule disfavoring restraints on alienation to interpretation of the PVPA is rather like applying the rule disfavoring restraints upon freedom of contract to interpretation of the Sherman Act.

sale as provided in this section" is taken to modify. It can be read "*production of a crop . . . for sale as provided in this section*"; or alternatively "*use such saved seed . . . for sale as provided in this section*." The parallelism created by the phrase "*for* use on his farm" followed immediately by "or *for* sale as provided in this section, suggests the former reading. But the placement of the comma, separating "use [of] such saved seed in the production of a crop for use on his farm," from "or for sale" favors the latter reading. So does the fact that the alternative reading requires the reader to skip the lengthy "*Provided*, That" clause in order to find out what sales are "provided [for] in this section"--despite the parallelism between "provided" and "*Provided*," and despite the presence of a colon, which ordinarily indicates specification of what has preceded. It is surely easier to think that at least some of the sales "provided for" are those that are "Provided" after the colon. (It is of course not unusual, however deplorable it may be, for "Provided, That" to be used as prologue to an addition rather than an exception. See *Springer* v. *Philippine Islands*, 277 U.S. 189, 206 (1928); 1A N. Singer, Sutherland on Statutory Construction §20.22 (5th ed. 1992).)

We think the latter reading is also to be preferred because it lends greater meaning to all the provisions. Under the former reading, ("*production of a crop . . . for sale as provided in this section*") the only later text that could be referred to is the provision for "bona fide sale[s] for other than reproductive purposes" set out in the second sentence of § 2543--the so called "crop exemption". (The proviso could *not* be referred to, since it does not provide for sale of *crops* grown from saved seed, but only for sale of saved seed itself.) But if the "or for sale" provision has such a limited referent, the opening clause's ("*Except to the extent that . . .*") reservation of § 2541(3) infringement liability (*i.e.*, liability for growing as a step in marketing for reproductive purposes) would be devoid of content, since the provision to which it is attached would *permit* no sales for reproductive purposes. Under the latter reading, by contrast, the farmer may not "use [his] saved seed . . . for sale" as the proviso allows *if* the seed was intentionally grown for the purpose of such sale--*i.e.*, "*sexually multipl[ied] . . . as a step in marketing (for growing purposes) the variety.*"[22] A second respect in which our favored reading gives greater meaning to the provision is this: The other reading ("*crop . . . for sale as*

[22]This reading also gives meaning to the proviso's statement that "without regard to the provisions of section 2541(3) . . . it shall not infringe any right hereunder" for a person to engage in certain sales of saved seed for reproductive purposes (emphasis added). This serves to eliminate the technical argument that a production of seed which was originally in compliance with §2541(3) (because it was not done as a step in marketing for reproductive purposes) could retroactively be rendered unlawful by the later sale permitted in the proviso, because such sale causes the earlier production to have been "a step in the marketing" for reproductive purposes.

provided in this section") causes the "permission" given in the opening sentence to extend only to sales for non reproductive purposes of the *crops grown* from saved seed, as opposed to sales of the saved seed itself. But no separate permission would have been required for this, since it is already contained within the crop exemption itself; it serves only as a *reminder* that crop from saved seed can be sold under that exemption--a peculiarly incomplete reminder, since the saved seed *itself* can also be sold under that exemption.

To summarize: By reason of its proviso the first sentence of §2543 allows seed that has been preserved for reproductive purposes ("saved seed") to be sold for such purposes. The structure of the sentence is such, however, that this authorization does *not* extend to saved seed that was grown *fortheverypurpose* of sale ("marketing") for replanting--because in that case, §2541(3) would be violated, and the above discussed exception to the exemption would apply. As a practical matter, since §2541(1) prohibits all unauthorized transfer of title to or possession of the protected variety, this means that the only seed that can be sold under the proviso is seed that has been saved by the farmer to replant his own acreage.[23] (We think that limitation is also apparent from the text of the crop exemption, which permits a farm crop from saved seeds to be sold--for non reproductive purposes--only if those saved seeds were "produced by descent *on such farm*" (emphasis added). It is in our view the proviso in §2543, and not the crop exemption, which authorizes the permitted buyers of saved seeds to sell the crops they produce.) Thus, if a farmer saves seeds to replant his acreage, but for some reason changes his plans, he may instead sell those seeds for replanting under the terms set forth in the proviso (or of course sell them for non reproductive purposes under the crop exemption).

It remains to discuss one final feature of the proviso authorizing limited sales for reproductive purposes. The proviso allows sales of saved seed for replanting purposes only between persons "whose primary farming occupation is the growing of crops for sale for other than reproductive purposes." The Federal Circuit, which rejected the proposition that the only

[23]For crops such as soybeans, in which the seed and the harvest are one and the same, this will mean enough seeds for one year's crop on that acreage. Since the germination rate of a batch of seed declines over time, the soybean farmer will get the year after next's seeds from next year's harvest. That is not so for some vegetable crops, in which the seed is not the harvest, and a portion of the crop must be permitted to overripen ("go to seed") in order to obtain seeds. One of the amici in the Court of Appeals asserted (and the parties before us did not dispute) that it is the practice of vegetable farmers to "grow" seeds only every four or five years, and to "brown bag" enough seed for four or five future crops. A vegetable farmer who sets aside protected seed with subsequent replantings in mind, but who later abandons his plan (because he has sold his farm, for example), would under our analysis be able to sell all his saved seed, even though it would plant (in a single year) four or five times his current acreage.

seed sellable under the exemption is seed saved for the farmer's own replanting, sought to achieve some limitation upon the quantity of seed that can be sold for reproductive purposes by adopting a "crop by crop" approach to the "primary farming occupation" requirement of the proviso. "*[B]uyers or sellers of brown bag seed qualify for the crop exemption,"* it concluded, "*only if they produce a larger crop from a protected seed for consumption (or other non reproductive purposes) than for sale as seed."* 982 F. 2d, at 490. That is to say, the brown bag seller can sell no more than half of his protected crop for seed. The words of the statute, however, stand in the way of this creative (if somewhat insubstantial) limitation. To ask what is a farmer's "primary farming occupation" is to ask what constitutes the bulk of his total farming business. Selling crops for other than reproductive purposes must constitute the preponderance of the farmer's business, not just the preponderance of his business in the protected seed. There is simply no way to derive from this text the narrower focus that the Federal Circuit applied. Thus, if the quantity of seed that can be sold is not limited as we have described--by reference to the original purpose for which the seed is saved--then it is barely limited at all (*i.e.*, limited only by the volume or worth of the selling farmer's total crop sales for other than reproductive purposes). This seems to us a most unlikely result.

* * *

We hold that a farmer who meets the requirements set forth in the proviso to § 2543 may sell for reproductive purposes only such seed as he has saved for the purpose of replanting his own acreage. While the meaning of the text is by no means clear, this is in our view the only reading that comports with the statutory purpose of affording "adequate encouragement for research, and for marketing when appropriate, to yield for the public the benefits of new varieties." 7 U.S.C. § 2581. Because we find the sales here were unlawful, we do not reach the second question on which we granted certiorari--whether sales authorized under §2543 remain subject to the notice requirement of § 2541(6).

The judgment of the Court of Appeals for the Federal Circuit is

Reversed

IMAZIO NURSERY, INC. v. DANIA GREENHOUSES

IMAZIO NURSERY, INC., Plaintiff-Appellee, v. DANIA GREENHOUSES, Defendant, Coastal Nursery, Jess Rodrigues, and Donna Rodrigues, Defendants-Appellants

No. 94-1450. Decided: November 3, 1995.

Before RICH, MAYER, and LOURIE, Circuit Judges. David A. Dillard, Christie, Parker & Hale, Pasadena, California, argued for plaintiff-appellee. With him on the brief were Vincent G. Gioia and John D. Carpenter. Philip C. Swain, Kirkland & Ellis, Los Angeles, California, argued for defendants-appellants. With him on the brief was Jay I. Alexander, Kirkland & Ellis, Washington, D.C. William L. LaFuze, Vinson & Elkins, L.L.P., Houston, Texas, was on the brief for Amicus Curiae, Greenleaf Nursery Company.

Coastal Nursery, Jess Rodrigues, and Donna Rodrigues (collectively, Coastal) appeal from the judgment of the United States District Court for the Northern District of California granting summary judgment of infringement of U.S. Plant Patent No. 5,336 (the '336 patent). Imazio Nursery, Inc. v. Dania Greenhouse, No. 92-20755 (SW) (N.D.Cal. September 2, 1993). We reverse the holding of infringement, vacate the finding of willfulness and the award of attorney fees, and remand.

I. BACKGROUND

A. The Patent

Bruno Imazio, the owner of Imazio Nursery, Inc. (Imazio), is the inventor of the '336 patent which is entitled "Heather Named Erica Sunset." According to the '336 patent, Mr. Imazio discovered Erica Sunset heather in 1978 "as a seedling of unknown pollen parentage growing in a cultivated field of Erica persoluta, the variety believed to be the seed parent, where it was noticed because of its early blooming and particularly because of its reaching

full bloom, from base to tip, more than a month before the parent plant begins to bloom." It was the early blooming of the Erica Sunset, during the Christmas and Valentine's Day seasons, that distinguished the Erica Sunset from other known varieties.

The sole claim of the '336 patent recites: A new variety of Heather persoluta, substantially as herein shown and described, particularly characterized by its profuse production of blooms over the entire length of the stem beginning in early December.

B. The Litigation

In April 1992, Imazio sued Coastal for patent infringement alleging that Coastal's "Holiday Heather" infringed the '336 patent. In December 1992, the trial court entered an order granting Imazio's motion for preliminary injunction. Imazio Nursery, Inc. v. Dania Greenhouse, 29 USPQ2d 1217, 1992 WL 551670 (N.D.Cal.1992). The trial court enjoined Coastal from "*selling, shipping, giving away, trading or otherwise disposing of potted heather plants of the variety sold by [Coastal] as Holiday Heather."* Coastal was not enjoined from selling cut flowers. Id. at 1222, 1992 WL 551670. Coastal appealed the entry of the preliminary injunction to this court. However, in an order dated April 22, 1993, the appeal was dismissed for failure to file a brief. Imazio Nursery, Inc. v. Dania Greenhouses, No. 93-1193 (Fed.Cir. Apr. 22, 1993).

On September 2, 1993 the district court granted Imazio's motion for summary judgment of infringement, denied its summary judgment motion on the issue of validity, and denied its motion for a permanent injunction.

The issues of patent validity, willful infringement, and damages were subsequently tried to a jury. The jury found the '336 patent not to have been proven invalid, found Coastal's infringement to have been willful, and determined actual damages of $101,279.20. The district court entered final judgment on June 29, 1994, finding the case to be exceptional within the meaning of 35 U.S.C. § 285 (1988) and awarding attorney fees of $363,140.59 to Imazio for a total award of $464,419.79 plus pre-judgment interest. Coastal appealed to this court from the grant of summary judgment of plant patent infringement. We have jurisdiction under 28 U.S.C. § 1295(a)(1) (1988).

II. SUMMARY JUDGMENT

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Fed. R. Civ. P. 56(c).

"*In ruling on a motion for summary judgment, the district court is required to view the evidence in a light most favorable to the nonmoving party and draw all reasonable inferences in favor of the nonmoving party*." C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 672, 15 USPQ2d 1540, 1542 (Fed.Cir.1990).

We review de novo a district court's grant of summary judgment. Conroy v. Reebok Int'l Ltd., 14 F.3d 1570, 1575, 29 USPQ2d 1373, 1377 (Fed.Cir.1994). A district court's decision on summary judgment "*must be overturned if the court engaged in a faulty analysis in applying the law to the facts and a correct application of the law to those facts might bring a different result.*" Litton Indus. Prods., Inc. v. Solid State Sys. Corp., 755 F.2d 158, 164, 225 USPQ 34, 38 (Fed.Cir.1985).

III. PLANT PATENTS

At least as early as 1892, legislation was proposed to grant patent rights for plant-related inventions. H.R.Rep. No. 5435, 52d Cong., 1st Sess. (1892). Plant patent legislation was supported by such prominent individuals as Thomas Edison who stated that "*nothing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now have through the law."* S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930) (Senate Report). It was also supported by Luther Burbank, a leading plant breeder of the day, [24] whose widow stated that her late husband "*said repeatedly that until Government made some such provision [for plant patent protection] the incentive to create work with plants was slight and independent research and breeding would be discouraged to the great detriment of horticulture."* H. R.

[24] Luther Burbank experimented with thousands of plant varieties and developed many new ones, including new varieties of prunes, plums, raspberries, blackberries, apples, peaches, and nectarines. Besides the Burbank potato, he produced new tomato, corn, squash, pea, and asparagus forms, a spineless cactus useful in cattle feeding, and many new flowers, especially lilies and the famous Shasta daisy. The New Columbia Encyclopedia 396 (1975).

Rep. No. 1129, 71st Cong., 2d Sess. 4 (1930) (House Report).

The Townsend-Purnell Plant Patent Act was passed by Congress on May 13, 1930 and was signed by President Hoover on May 23, 1930. It was the first legislation anywhere in the world to grant patent rights to plant breeders [25] and was enacted to "*afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given to industry, and thus assist in placing agriculture on a basis of economic equality with industry."*

Senate Report at 3. Before enactment of the Plant Patent Act, two factors were thought to prevent plants from being patentable subject matter. The first was the belief that plants, even those bred by man, were products of nature and therefore not subject to patent protection. The second factor was that plants were not considered amenable to the "written description" requirement of the predecessor of 35 U.S.C. § 112, first paragraph.[26]In promulgating the Plant Patent Act, Congress addressed both concerns. It explained that the work of the plant breeder "in aid of nature" was subject to patent protection. Additionally, the written description requirement, applicable to utility patents, was relaxed in favor of a "*description as complete as is reasonably possible."* 35 U.S.C. § 162 (1988); see also Diamond v. Chakrabarty, 447 U.S. 303, 312, 100 S.Ct. 2204, 2209, 65 L.Ed.2d 144 (1980); Ex Parte Hibberd, 227 USPQ 443 (PTO Bd.App. & Int.1985).

As originally enacted, the provisions for plant patent protection were made as amendments to the general patent law. Specifically, section 4884 of the Revised Statutes was amended to recite:

Every patent shall contain a grant to the patentee of the exclusive right to make, use, and vend the invention or discovery (including in the case of a plant patent the exclusive right to asexually reproduce the plant).

Rev.Stat. § 4884, as amended by Act of May 23, 1930, ch. 312, § 1, 46 Stat. 376 (current version at 35 U.S.C. § 163 (1988)) (emphasis added).

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[25] Robert S. Allyn, The First Plant Patents 10 (1934).

[26] Section 112 states in part that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112 (1988).

Similarly, section 4886 of the Revised Statutes was amended to recite: Any person who has invented or discovered any new and useful art, machine or who has invented or discovered and asexually reproduced any distinct and new variety of plant other than a tuber-propagated plant, may obtain a patent therefore.

Rev. Stat. § 4884, as amended by Act of May 23, 1930, ch. 312, § 1, 46 Stat. 376 (current version split between 35 U.S.C. §§ 101 and 161 (1988)) (emphasis added).

With the promulgation of the 1952 Patent Act, the plant patent provisions were included as a separate chapter of the statute. Act of July 19, 1952, ch. 950, 66 Stat. 804 (current plant patent provisions at 35 U.S.C. §§ 161-164 (1988)). Additionally, as was done for utility patents in 35 U.S.C. § 154(a)(1) (1988), the plant patent grant was changed from the "exclusive right" to the "right to exclude" following court decisions explaining the nature of the right conferred by a patent. 35 U.S.C. § 163 (1988); see Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 34, 43 S.Ct. 254, 256, 67 L.Ed. 516 (1923) ("All that the Government grants and protects is the power to exclude others from making, using or vending during the grant."); P.J. Federico, Commentary on the New Patent Act, 35 U.S.C.A. 1, 40-41 (1954), reprinted in 75 J.Pat. & Trademark Off. Soc'y 161, 202 (1993); Giles S. Rich, Address to the New York Patent Law Association Meeting of Nov. 6, 1952, 14-15 ("*A change was made, however, in Section 163, where the plant patent right is expressed as the right to exclude.")*.

It should be noted that although the plant patent provisions were separated from the utility patent provisions with the enactment of the 1952 Patent Act, the statute explicitly states that "*[t]he provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided."* 35 U.S.C. § 161. Thus, section 161 "*engrafts the Plant Patent Act onto the basic patent law, which requires us to apply thereto all the rules, regulations, and provisions of the basic patent law*," except as otherwise provided.[27] In re LeGrice, 301 F.2d 929, 933, 133 USPQ 365, 369 (CCPA 1962); 37 C.F.R. § 1.161 (1994).

The specification of a plant patent application must contain as full and complete a

[27] For instance, by the express provision of 35 U.S.C. § 162 (1988), a plant patent cannot be declared invalid for noncompliance with 35 U.S.C. § 112 if its description "is as complete as is reasonably possible."

disclosure as possible of the plant and the characteristics thereof that distinguish it from related known varieties and must particularly point out where and in what manner the variety of plant has been asexually reproduced. 37 C.F.R. § 1.163(a). Only a single claim is permitted in a plant patent. 37 C.F.R. § 1.164; Manual of Patent Examining Procedure (MPEP) § 1605 (Rev. 14, Nov. 1992) ("*A plant patent is granted only on the entire plant. It therefore follows that only one claim is necessary and only one is permitted.");* Kim Bros. v. Hagler, 167 F.Supp. 665, 120 USPQ 210 (S.D.Cal.1958).

The only amendment to the plant patent provisions since enactment of the 1952 Patent Act came in 1954 when section 161 was amended to preclude patent protection for plants found in an uncultivated state, thereby broadening the statute to include plants found in a cultivated state and subsequently asexually reproduced. Act of Sept. 3, 1954, Pub.L. No. 83-775, 68 Stat. 1190.

Currently, chapter 15 of title 35 of the United States Code includes the following provisions: 35 U.S.C. § 161, entitled "Patents for Plants," states: Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

35 U.S.C. § 163, entitled "Grant," states: In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.

IV. STATUTORY CONSTRUCTION

A. Standard of Review

We review issues of statutory interpretation under a de novo standard of review. Kane v. United States, 43 F.3d 1446, 1448 (Fed.Cir.1994). We need not defer to the trial court. Chaparral Steel Co. v. United States, 901 F.2d 1097, 1100, 8 Fed.Cir. (T) 101, 105 (1990). When interpreting statutes, a court looks to the language of the statute and construes it

according to the traditional tools of statutory construction, including certain well-known canons of statutory construction. Markman v. Westview, 52 F.3d 967, 987, 34 USPQ2d 1321, 1336 (Fed.Cir.1995) (in banc) (citing United States v. Grimberg, 702 F.2d 1362, 1365 (Fed.Cir.1983) (in banc)), cert. granted, --- U.S. ----, 116 S.Ct. 40, 132 L.Ed.2d 921 (1995).

B. Scope of a Plant Patent

We first consider the scope of protection of plant patents. We begin by interpreting the relevant statutory provisions. Statutes in pari materia are to be construed together. Selfway, Inc. v. Travelers Petroleum, Inc., 579 F.2d 75, 80, 198 USPQ 271, 275 (CCPA 1978); see 2 Sutherland & Lewis, Statutory Construction § 344 (1904) ("*It is an elementary rule of construction that all the parts of an act relating to the same subject should be considered together, and not each by itself.")*.

1. The meaning of the term "variety"

The parties dispute the meaning of the term "variety" in section 161. The meaning of that term may inform the scope of protection of plant patents inasmuch as such patents are granted to "*[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant."* 35 U.S.C. § 161 (emphasis added). Imazio argues that in providing plant patent protection for "*any distinct and new variety of plant*," it was intended that a plant patent cover "*all plants of that new and distinct variety, i.e., all plants having the same essential and distinctive characteristics*." Thus, argues Imazio, "variety" should be construed in its technical, taxonomical sense and should be interpreted to encompass more than just clones of a single plant. Coastal, on the other hand, contends that "variety" should be construed in the vernacular sense as "*something different from others of the same general kind*." Coastal maintains that by use of the term "variety" Congress did not intend to afford plant patent protection to a range of plants but intended only to protect a single plant.

The Plant Patent Act does not define "variety." However, the legislative history of the Plant Patent Act states: new and distinct varieties fall into three classes-sports, mutants, and hybrids. In the first class of cases, the sports, the new and distinct variety results from bud variation and not seed variation. A plant or portion of a plant may suddenly assume an appearance or character distinct from that which normally characterizes the variety or species. In the second class of cases, the mutants, the new and distinct variety results from seedling variation by self pollenization of species. In the third class of cases, the hybrids, the new

and distinct variety results from seedlings of cross pollenization of two species, two varieties, or a species and a variety.

Senate Report at 3. Thus, upon passage of the Plant Patent Act, a patentable variety could be either a sport, mutant, or hybrid. In addition, by amendment in 1954, Congress added another class of plants, newly found seedlings, subject to the exception that such seedlings found in an uncultivated state cannot be patented. Act of Sept. 3, 1954, Pub.L. No. 83-775, 68 Stat. 1190; see Ex parte Moore, 115 USPQ 145 (Pat.Off.Bd.App.1957) (Section 161, as amended September 3, 1954, was intended to include "cultivated sports, mutants, hybrids, and newly found seedlings.").

Section 161 also requires that a patentable variety be new. Additionally, the variety must be distinct. As to this requirement, the legislative history states that in order for the new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties. The characteristics that may distinguish a new variety would include, among others, those of habit; immunity from disease; resistance to cold, drought, heat, wind, or soil conditions; color of flower, leaf, fruit, or stems; flavor; productivity, including ever-bearing qualities in case of fruits; storage qualities; perfume; form; and ease of asexual reproduction. Within any one of the above or other classes of characteristics the differences which would suffice to make the variety a distinct variety, will necessarily be differences of degree.

Senate Report at 4. The legislative history is clear that Congress intended that distinct and new cultivated sports, mutants, hybrids, and newly found seedlings be entitled to plant patent protection.

Although the legislative history does not answer the question of what "variety" means in terms of whether a single plant or a range of plants is protected by a plant patent, in addition to being distinct and new, a patentable plant must also be asexually reproduced. 35 U.S.C. § 161; see Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1377, 193 USPQ 264, 291 (5th Cir.1976) ("*For plant patents the additional requirement of asexual reproduction is introduced*."), cert. denied, 429 U.S. 1094, 97 S.Ct. 1108, 51 L.Ed.2d 540 (1977); Senate Report at 5 ("*It is not only necessary that the new and distinct variety of plant shall have been invented or discovered, but it is also necessary that it shall have been asexually reproduced prior to the application for patent.")*. As discussed below, this

additional requirement informs the scope of protection of plant patents and hence directs the meaning of "variety" in § 161.

2. The significance of the asexual reproduction requirement

The legislative history defines asexual reproduction as reproduction by "grafting, budding, cuttings, layering, division, and the like, but not by seeds." Senate Report at 1; see MPEP § 1601.

The legislative history further states that whether the new variety is a sport, mutant, or hybrid, the patent right granted is a right to propagate the new variety by asexual reproduction.[28] It does not include the right to propagate by seeds. This limitation in the right granted recognizes a practical situation and greatly narrows the scope of the bill. Whether the new variety is a hybrid, mutant or sport, there is never more than one specimen of it produced except through asexual reproduction. For example, without asexual reproduction there would have been but one true McIntosh or Greening apple tree. These varieties of apples could not have been preserved had it not been through human effort in the asexual reproduction of the two original trees. They could not have been reproduced true to the type by nature through seedlings.

Senate Report at 4 (emphasis added) (footnote added). The legislative history additionally sets forth that plants sought to be patented must be asexually reproduced in order to have their identity preserved. This is necessary since seedlings either of chance or self-pollenization from any of these would not preserve the character of the individual.

Senate Report at 3. It is clear from the legislative history that as a result of the asexual reproduction requirement, only a single plant, i.e., reproduction from one original specimen in the words of Congress, is protected by a plant patent. At the time of enactment, Congress recognized that the asexual reproduction prerequisite greatly narrowed the scope of protection of plant patents but found such a limitation necessary to ensure that the characteristics of the plant to be patented were maintained. Additionally, it has since been recognized that as intimated by Congress, asexual reproduction confirms the existence of a new variety by

[28] As noted above, when the 1952 Patent Act was enacted, the right to asexually reproduce was amended to the right to exclude others from asexually reproducing. No "right to propagate" is granted by the patent. See 35 U.S.C. § 163.

separating variations resulting from fluctuations in environmental conditions from true plant variations. Kenneth J. Burchfiel, Biotechnology and the Federal Circuit 407 (1995); Dunn v. Ragin, 50 USPQ 472, 475 (Pat.Off.Bd.Interf. Ex'rs 1941). The Supreme Court also recognized the significance of the asexual reproduction requirement of the Plant Patent Act. In Diamond v. Chakrabarty, the Court indicated that asexual reproduction was required in the Plant Patent Act because it was believed that new varieties could not be reproduced true-to-type through seed. 447 U.S. at 312, 100 S.Ct. at 2209.

Though there is a paucity of case law on this point,[29] the requirement and effect of asexual reproduction as a prerequisite to plant patent protection has been recognized by the courts and the Patent Office. Yoder, 537 F.2d at 1380, 193 USPQ at 293 ("*Asexual reproduction is the heart of the present plant patent system: the whole key to the 'invention' of a new plant is the discovery of new traits plus the foresight and appreciation to take the step of asexual reproduction.")* (emphasis in original); In re LeGrice, 301 F.2d 929, 937, 133 USPQ 365, 372 (CCPA 1962) ("*In 'asexual propagation,' the plant is propagated by divisions or cuttings to form clones, each of which is identical to the parent plant and to all other cuttings or clones taken from the parent."* (citing Samuel L. Emsweller, Fundamentals in Plant Breeding, Plants and Gardens, Summer 1959)); see also Dunn v. Ragin, 50 USPQ at 474; Ex parte Moore, 115 USPQ 145 (Pat.Off.Bd.App.1957).

The commentators have also identified the importance of the asexual reproduction requirement. 1 Donald S. Chisum, Patents § 1.05[1][b][ii] (1986) ("*Asexual reproduction is of central importance throughout the plant patent act.").* The significance of the asexual reproduction requirement has also been appreciated. Edward A. Hayman, Botanical Plant Patent Law, 11 Cleveland-Marshall L.Rev. 430, 433 (1962) ("*It would seem that a plant patent only protects the clones, or in other words, the asexual progeny of a particular plant.");* Robert S. Allyn, The First Plant Patents 28 (1934) ("*The fact that the Commissioner of Patents has ruled that only a single claim will be permitted in these plant patents indicated that he regards the protection intended by the Statute as limited to the exact variety described.");* Robert S. Allyn, Plant Patents 1934-1943 at 12 (1944) ("*From a study of the plant patents thus far issued I have reached the conclusion that regardless of the intent of the*

[29] "In many areas relating to plant patents, one writes on virtually a clean slate." Kenneth J. Burchfiel, Biotechnology and the Federal Circuit 408 (1995).

law-most plant patents if sustained at all by the Courts will be considered as covering only plants which have been asexually reproduced from the original plant."); Peter F. Langrock, Plant Patents-Biological Necessities in Infringement Suits, 41 J.Pat.Off. Soc'y 787, 787 (1959) ("*What constitutes asexual reproduction, this semi-sacred word in the field of plant patents? There are several specific methods. Each one of these methods consists of the isolation of a group or mass of vegetative cells from the parent plant that are capable of reproducing a plant that is genetically an exact duplication of its parent plant. In asexual reproduction, as the cells are separated from the parent plant without any internal change, they will reproduce an exact replica of the parent.")* (emphasis added).

Due to the asexual reproduction prerequisite, plant patents cover a single plant and its asexually reproduced progeny. See Senate Report at 6 (Plant patent protection encourages "*those who own the single specimen to reproduce it asexually and create an adequate supply.").* Thus, the term "variety" in section 161 must be interpreted consistently with this requirement. Accordingly, "variety" in section 161 cannot be read as affording plant patent protection to a range of plants, as asserted by Imazio.

3. Comparison with the Plant Variety Protection Act

Both parties argue that the provisions of the Plant Variety Protection Act are relevant to a proper interpretation of the scope of protection afforded plant patents under the Plant Patent Act.

The Plant Variety Protection Act of 1970 (PVPA) provides "*patent-like protection to novel varieties of sexually reproduced plants (that is, plants grown from seed), which parallels the protection afforded asexually reproduced plant varieties (that is, varieties reproduced by propagation or grafting) under Chapter 15 of the Patent Act*." Asgrow Seed Co. v. Winterboer, 513 U.S. 179, ----, 115 S.Ct. 788, 790, 130 L.Ed.2d 682 (1995). Under the PVPA, the U.S. Department of Agriculture issues certificates of plant variety protection to the "*breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first-generation hybrids) who has so reproduced the variety."* 7 U.S.C. § 2402(a) (1994).

The term "variety" is defined in the PVPA at 7 U.S.C. § 2401(a)(9) (1994) as follows: The term "variety" means a plant grouping within a single botanical taxon of the lowest known rank, that, without regard to whether the conditions for plant variety protection are fully met, can be defined by the expression of the characteristics resulting from a given genotype or

combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the suitability of the plant grouping for being propagated unchanged. A variety may be protected by seed, transplants, plants, tubers, tissue culture plantlets and other matter.

According to the legislative history, the 1994 amendments to the PVPA were made to conform the statute with the International Convention for the Protection of New Varieties of Plants of March 1991. H.R.Rep. No. 2927, 103d Cong., 1st Sess. 6377 (1994). There is no indication in the legislative history that the addition of a definition of the term "variety" was in any sense intended to change the scope of protection afforded under the PVPA. In fact, both before and after the 1994 amendments, the right to protection under the PVPA is based on a determination of whether the variety is new, distinct, uniform, and stable. 7 U.S.C. § 2402(a).

Imazio argues that because the Plant Patent Act and the PVPA both use the term "variety," that term must be interpreted in the same manner in both statutes. As such, according to Imazio, the term variety can only mean a group of plants that have the same essential and distinctive characteristics under the Plant Patent Act because that is how the term is defined under the PVPA. We disagree.

Where Congress uses the same form of statutory language in different statutes having the same general purpose, courts presume that Congress intended the same interpretation to apply in both instances. Northcross v. Board of Educ., 412 U.S. 427, 428, 93 S.Ct. 2201, 2202, 37 L.Ed.2d 48 (1973). It is true that both the Plant Patent Act and the PVPA use the term "variety" and grant some form of intellectual property protection. However, the two statutes differ significantly in their purposes. The Plant Patent Act grants a plant patent to one who "*invents or discovers and asexually reproduces any distinct and new variety of plant*." 35 U.S.C. § 161. Conversely, one is entitled to plant variety protection under the PVPA if he has sexually reproduced the variety and has otherwise met the requirements of 7 U.S.C. § 2402(a). The term "variety" in both statutes cannot be read divorced from the very different circumstances in which that term is used.

Those circumstances, asexual reproduction in the case of plant patents, and sexual reproduction in the case of plant variety protection, mandate the protection afforded under these different statutory provisions. Asexual reproduction is the cornerstone of plant patent

protection, while sexual reproduction is the distinguishing feature of plant variety protection. Indeed, this is why the PVPA was enacted, to afford protection for sexually reproduced plants. Diamond v. Chakrabarty, 447 U.S. 303, 313, 100 S.Ct. 2204, 2209-10, 65 L.Ed.2d 144 (1980). The result of asexual reproduction is a plant that is genetically identical to its parent. Yoder, 537 F.2d at 1380, 193 USPQ at 293 ("*Asexual reproduction is literally the only way that a breeder can be sure that he has reproduced a plant identical in every respect to the parent.");* LeGrice, 301 F.2d at 937, 133 USPQ at 372. The result of sexual reproduction is a plant that combines the characteristics of the parents, but is a different plant. Id. (In sexual reproduction, "*the parent plants each contribute to the formation of the embryo that will develop in the seed and eventually give rise to a plant that differs from either of the parent plants as well as from other plants produced from other seeds resulting from the cross-pollination.")*[30]

It follows from this that the scope of protection afforded as a result of sexual versus asexual reproduction must be different; in the case of asexual reproduction, the same plant is produced, but in the case of sexual reproduction, a different plant, albeit like the parent plants, is produced. Given this, we reject Imazio's contention that the meaning of variety in the Plant Patent Act and the PVPA must be the same.

4. Conclusion

In view of the statutory language, the legislative history, the case law, the views of the commentators, and a review of relevant provisions of the PVPA, we conclude that the scope of a plant patent is the asexual progeny of the patented plant variety. Variety as used in section 161 encompasses a single plant, the plant shown and described in the specification.

V. INFRINGEMENT

A. The Trial Court's Analysis

In issuing its December 1992 preliminary injunction order, the trial court adopted the

[30] Plants true-to-type, although different in a strict genetic sense, are protectable under the PVPA. Chakrabarty, 447 U.S. at 312, 100 S.Ct. at 2209. RICH, Circuit Judge.

standard set forth in Pan-American Plant Co. v. Matsui, 433 F.Supp. 693, 694 n. 2, 198 USPQ 462, 463 n. 2 (N.D.Cal.1977) that the Plant Patent Act "*bars the asexual reproduction and sale of any plant which is the same variety (i.e., has the same essential characteristics) as the patented plant, whether or not the infringing plant was originally cloned from the patented plant."* Imazio, 29 USPQ2d at 1219, 1992 WL 551670. The district court also addressed whether independent creation could be a defense to plant patent infringement as discussed in Yoder, 537 F.2d 1347, 193 USPQ 264. The district court stated that "*independent creation is [not] a proper defense to patent infringement*" and asserted that "*the courts' recognition of an independent creation defense would inadvertently entice deliberate infringement, with a fraudulent defense of independent creation asserted." Id.*

In granting summary judgment of infringement in September 1993, the trial court reiterated its adoption of the standard for plant patent infringement set forth in Pan-American. The trial court also reiterated its refusal to recognize independent creation as a defense to plant patent infringement concluding that such a defense "*would result in a deluge of litigation without contributing any necessary safeguards."*

On the merits of the infringement charge, the trial court reviewed the testimony of both parties' experts and found that the "*undisputed evidence thus shows that the patented Erica Sunset heather and the Holiday Heather are the same plants both morphologically (internal and external characteristics) and phenologically (blooming cycle)."* The trial court concluded that Imazio had "*successfully demonstrated that the Holiday Heather is an asexual reproduction of the Erica Sunset*."

B. The Law of Infringement

Determining infringement is a two-step process. The first step is to determine the meaning and scope of the patent claim asserted to be infringed. Markman, 52 F.3d at 976, 34 USPQ2d at 1326. The second step is to compare the properly construed claim to that which is asserted to infringe. *Id.* We review claim construction, a question of law, de novo. *Id.* 52 F.3d at 979, 34 USPQ2d at 1329.

C. Infringement of a Plant Patent

As to the first step, consistent with our analysis above, the scope of the claim of the '336 patent is the asexual progeny of the Heather persoluta shown and described in the '336 patent

specification. To perform the second step of the infringement analysis, we first look to the language of the statute.

Section 163 grants to plant patentees the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced. 35 U.S.C. § 163. As stated above, the trial court held that asexual reproduction is shown if the patentee can prove that the alleged infringing plant has the same essential characteristics as the patented plant. We disagree.

We note that the trial court based its infringement analysis on a footnote in Pan-American which is dictum because in that case infringement was denied on other grounds. Additionally, the Pan-American court expressly stated that "*there [was] no need to discuss the asexual reproduction question in detail." Id.*

The "asexual reproduction question," however, is critical to the infringement analysis. In construing section 161, we held above that the scope of a plant patent is the asexual reproduction of the plant shown and described in the specification. Asexual reproduction, in terms of section 161, means the progeny of the patented plant via "*grafting, budding, cuttings, layering, division and the like, but not by seeds."* Senate Report at 1; see MPEP § 1601.

We must construe the term "asexual reproduction" in section 163 in the same way as we did in section 161. Thus, for purposes of plant patent infringement, the patentee must prove that the alleged infringing plant is an asexual reproduction, that is, that it is the progeny of the patented plant. Yoder, 537 F.2d at 1380, 193 USPQ at 293 ("*It is quite possible that infringement of a plant patent would occur only if stock obtained is used, given the extreme unlikelihood that any other plant could actually infringe*.").

Our interpretation of section 163 is in accord with the majority of the commentators who have considered this issue. 1 Donald S. Chisum, Patents § 1.05[1][d] (1994). ("*It is generally assumed that one infringes only if the accused plant is a direct or indirect asexual reproduction of the patentee's original parent plant.");* Peter F. Langrock, Plant Patents-Biological Necessities in Infringement Suits, 41 J.Pat.Off. Soc'y 787, 788-89 (1959) ("*What test is to be used in [plant patent] infringement proceedings? It is necessary that there be some sort of physical appropriation from one of the patent plants. It is only when there is such a physical appropriation that the rights of the patentee are invaded. The test set out by [another] calling for only a showing of an asexual reproduction of 'substantially the same*

plant' misses the narrow confinement of the protection afforded to plant patents." (footnotes omitted)); David B. Bernstein, Is a Plant Patent a Form of Copyright?, 27 IDEA 31, 35 (1986) ("*The relevant court holdings have suggested that no infringement of a plant patent can occur without an actual, physical taking from the plant discovered by the patentee.").*

1. Independent creation as a defense to plant patent infringement

Below, the parties disputed whether independent creation is a proper defense to plant patent infringement. The trial court refused to recognize such a defense stating that the "*patent holder would have great difficulties enforcing his patent rights if a defendant were allowed to raise independent creation as an affirmative defense."* The trial court reasoned that it would be hard for the patentee to refute evidence of independent creation because all such evidence would be in the defendant's control.

We must reject the trial court's analysis of the independent creation defense because it is contrary to the plain meaning of the statute. See Wilner v. United States, 24 F.3d 1397, 1402 (Fed.Cir.1994) (in banc) (court's approach constituted legal error because it was contrary to the plain meaning of the statute). The statute requires asexual reproduction of the patented plant for there to be infringement. It is necessarily a defense to plant patent infringement that the alleged infringing plant is not an asexual reproduction of the patented plant. Part of this proof could be, thus, that the defendant independently developed the allegedly infringing plant. However, the sine qua non is asexual reproduction. That is what the patentee must prove and what the defendant will seek to disprove.

D. Conclusion as to Infringement

In this case, therefore, in order for there to be infringement of the '336 patent, the infringing plant must be an asexual reproduction of the plant claimed, i.e., the Heather persoluta shown and described in the '336 patent. The trial court erred as a matter of law when it held that infringement of the '336 patent was shown by proof merely of asexual reproduction of a plant having the same essential characteristics as the patented plant. Accordingly, we reverse the holding of infringement. We also therefore vacate the finding of willfulness and the award of attorney fees.

"*We recognize that, in some cases, it may be proper for an appellate court which disagrees with a district court's decision granting summary judgment in favor of the moving party, to*

reverse and remand with instructions to award summary judgment in favor of the nonmoving party." Litton, 755 F.2d at 164, 225 USPQ at 38. However, in certain circumstances it is more appropriate to remand to the trial court for further proceedings. *Id.* at 164, 225 USPQ at 38-39 (citations omitted). We believe such circumstances exist here because the trial court did not consider the proper standard for plant patent infringement and, therefore, may not have considered all evidence relevant to the infringement issue. Therefore, we remand to the district court for an infringement determination consistent with this opinion.

VI. CONCLUSION

The judgment of infringement of the '336 patent is reversed. The finding of willfulness and the award of attorney fees are vacated. The case is remanded for further proceedings consistent with this opinion.

VII. COSTS

No costs.

United States Court of Appeals,

Federal Circuit.

AMGEN, INC., ORTHO BIOTECH, INC., OMJ PHARMACEUTICAL, INC. AND ORTHO PHARMACEUTICAL CORP., V. GENETICS INSTITUTE, INC.

No. 95-1247. Decided: October 25, 1996

Before NEWMAN, LOURIE and BRYSON, Circuit Judges. D. Dennis Allegretti, Banner & Allegretti, Boston, MA, argued, for plaintiff-appellee. With him on the brief, were Dale A. Malone and John P. Iwanicki. Also on the brief, were Lloyd R. Day, Jr., David M. Madrid, and Robert M. Galvin, Cooley Godward Castro Huddleson & Tatum, Palo Alto, CA, and Steven M. Odre and Stuart L. Watt, Amgen, Inc., Thousand Oaks, California. David F. Dobbins, Patterson, Belknap, Webb & Tyler, L.L.P., New York City, argued, for plaintiffs-appellees. With him on the brief, were Gregory L. Diskant, Jeffrey I.D. Lewis, and Richard S. Eisert. Paul H. Heller, Kenyon & Kenyon, New York City, argued, for defendant-appellant. With him on the brief, were Paul Lempel and John R. Moore. Also on the brief, were William F. Lee and David B. Bassett, Hale & Dorr, Boston, MA, and Scott A. Brown and Bruce M. Eisen, Genetics Institute, Inc., Cambridge, MA. Of counsel, was Lawrence V. Stein, Genetics Institute, Inc.

At issue in this declaratory action is United States Patent No. 5,322,837 (the '837 patent) entitled "*Homogeneous Erythropoietin Compositions and Methods of Using Same.*" The patentee is Genetics Institute, Inc.; the accused infringers are Amgen, Inc. and its distributors or licensees Ortho Biotech, Inc., OMJ Pharmaceuticals, Inc. and Ortho Pharmaceutical Corp. (collectively herein Amgen).

The '837 patent is a continuation of United States Patent No. 4,677,195 (the '195 patent), having the same specification. In a previous suit involving the same parties in interest,

styled Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 18 USPQ2d 1016 (Fed.Cir.), cert. denied, 502 U.S. 856, 112 S.Ct. 169, 116 L.Ed.2d 132 (1991) (Amgen II), the claims of the '195 patent were held to be invalid under 35 U.S.C. § 112 for lack of enablement. In the case now before us the district court held[31], upon summary judgment, that this suit for infringement of the claims of the '837 patent is precluded by the ruling of non-enablement in Amgen II. We affirm.

SUMMARY JUDGMENT

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 106 S.Ct. 2505, 2509-10, 91 L.Ed.2d 202 (1986). The appellate court must independently determine whether the standards for summary judgment have been met. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 72 F.3d 857, 860, 37 USPQ2d 1161, 1162 (Fed.Cir.1995). On motion for summary judgment, the court views the evidence and any disputed factual issues in the light most favorable to the party opposing the motion. Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986); Allied Colloids, Inc. v. American Cyanamid Co., 64 F.3d 1570, 1573, 35 USPQ2d 1840, 1841 (Fed.Cir.1995). When a party moves for summary judgment of res judicata or other basis of preclusion, it must be shown that the claim or issue would be precluded even on the non-movant's version of the case. See generally Festo Corp., 72 F.3d at 860, 37 USPQ2d at 1162; Kearns v. General Motors Corp., 94 F.3d 1553, 1555-56, 39 USPQ2d 1949, 1951 (Fed.Cir.1996).

BACKGROUND

Erythropoietin (EPO) is a hormone that is used in treatment of anemia, renal failure,

[31] Amgen, Inc. v. Genetics Institute, Inc., No. 94-Civ-1818 (D. Mass. March 29, 1995) (Memorandum and Order).

and other conditions associated with low levels of production of red blood cells. It is produced in minute quantities in the human body, and was obtained by Genetics Institute from the urine of persons with aplastic anemia. This product is called uEPO. Amgen synthetically produced EPO using recombinant DNA technology. This product is called rEPO. The separation and purification of uEPO as well as the production of rEPO are complex and difficult procedures, evolving over many years of scientific research. This history is summarized in Amgen II and in somewhat greater detail by the district court in Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 13 USPQ2d 1737 (D.Mass.1989) (Amgen I).

The purity of a complex protein is described by its homogeneity, that is, the degree to which the desired protein is free of undesired proteins and other contaminants. Homogeneity may be measured by reverse phase high performance liquid chromatography (RP-HPLC), wherein movement of the composition as a single peak is an indicator of a substantially pure product.

Another indicator of purity is the specific activity of the protein composition. Specific activity measures the biological potency of the protein, and is expressed as international units (IU) of potency per absorbance unit (AU) of the composition. The AU for EPO has been established as the amount of light that is absorbed by the composition under designated conditions at a wavelength of 280 nanometers. The higher the specific activity of the sample, the fewer impurities in the composition. See Amgen I, 13 USPQ2d at 1754-58.

Amgen I and Amgen II were concerned with Genetics Institute's '195 patent, which claimed homogeneous EPO characterized by its molecular weight, RP-HPLC performance, and specific activity.

The relevant '195 patent claims were as follows:

1. Homogeneous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least 160,000 IU per absorbance unit at 280 nanometers.

3. A pharmaceutical composition for the treatment of anemia comprising a therapeutically effective amount of the homogeneous erythropoietin of claim 1 in a pharmaceutically acceptable vehicle.

This court concluded in Amgen II that the '195 specification did not enable EPO having a specific activity of at least 160,000 IU/AU. The court held, reversing Amgen I, that the patent "*fails to enable purification of either rEPO or uEPO*." Amgen II, 927 F.2d at 1217, 18 USPQ2d at 1030.

Genetics Institute had initially sought to claim homogeneous EPO without limitation to the specific activity of the product. After the decision in Amgen II Genetics Institute proceeded with prosecution of a continuation of the '195 patent, presenting for examination claims without a specific activity limitation, duly directing the examiner's attention to the decision in Amgen II. This continuation application led to grant of the '837 patent. Genetics Institute states that it always viewed its invention as homogeneous EPO unlimited by any numerical specific activity, and that the '837 specification and claims are to this effect. Claim 1 is representative:

1. A pharmaceutical composition for stimulating production of red blood cells comprising a therapeutically effective amount of homogeneous human EPO protein characterized by a molecular weight of about 34,000 daltons in a single band on SDS PAGE and movement as a single peak in reverse phase high performance liquid chromatography and a pharmaceutically acceptable vehicle.

After the '837 patent issued, Genetics Institute again sued Amgen for infringement.

Amgen moved for summary judgment on the ground that Genetics Institute is barred by the doctrine of res judicata, claim preclusion, or issue preclusion, from bringing this infringement action against Amgen or its privies. The district court agreed, holding that "*Genetics is bound by the prior determination that the '195 patent specification does not enable the making of homogeneous EPO, and thus may not assert the virtually identical claims of the '837 patent against Amgen's homogeneous rEPO product.*" This appeal followed.

DISCUSSION

A final judgment on the merits bars relitigation of the same cause between the same parties. Brown v. Felsen, 442 U.S. 127, 131, 99 S.Ct. 2205, 2209, 60 L.Ed.2d 767 (1979); Parklane Hosiery Co. v. Shore, 439 U.S. 322, 326 n. 5, 99 S.Ct. 645, 649 n. 5, 58 L.Ed.2d

552 (1979). Thus, a claim that was litigated and decided on its merits can not be presented in a second suit. The doctrine of issue preclusion is of similar effect; it requires that the identical issue was fully litigated in a prior suit between the same parties or their privies, and that resolution of the issue was essential to the judgment in the prior suit. Montana v. United States, 440 U.S. 147, 153-54, 99 S.Ct. 970, 973-74, 59 L.Ed.2d 210 (1979); see 1B James Wm. Moore et al., Moore's Federal Practice 0.401, 0.405, 0.441 (2d ed. 1992).

Amgen states that whether on a theory of res judicata, claim preclusion, or issue preclusion, see Moore et al., supra, Genetics Institute's suit for infringement of the '837 patent is barred by the Amgen II decision of non-enablement of purified EPO. In Amgen II this court held that EPO having a specific activity of at least 160,000 IU/AU was not enabled by the description in the '195 specification. In the case now before us the district court held that since the '195 specification did not enable EPO having a specific activity of at least 160,000 IU/AU, enablement of that product could not be relitigated for the identical '837 specification. The district court observed that the '837 claims are of a scope that includes EPO having a specific activity of at least 160,000 IU/AU, and that claims of that scope were finally held to be not enabled in Amgen II.

Genetics Institute states that since no specific activity is required by the '837 claims, enablement of the 160,000 IU/AU specific activity explicitly stated in the '195 claims is not dispositive of enablement of the broader '837 claims. Genetics Institute argues that the decision in Amgen II was limited to whether the specification enabled EPO having a specific activity of at least 160,000 IU/AU, and that the invention claimed in the '837 patent is a different, broader invention directed to homogeneous EPO generally. Genetics Institute states that since none of the '837 claims requires EPO of at least 160,000 IU/AU, the Amgen II decision of non-enablement of the '195 claims does not affect the enablement of the '837 claims.

Genetics Institute is correct that it was not decided in Amgen II whether the '195 specification enables any EPO compositions having a specific activity below 160,000 IU/AU. However, as the district court discussed, it was at issue in Amgen II whether purified EPO as required by the specification and prosecution history, was enabled.

Accepting for purposes of Amgen's motion for summary judgment that the '195/'837 specification enables the EPO compositions having the specific activities exemplified therein,

all of which are well below 160,000 IU/AU, the district court correctly held that Genetics Institute is precluded by Amgen II from asserting that the '195/'837 specification enables claims that include EPO compositions having a specific activity of at least 160,000 IU/AU. See In re Szwarc, 50 C.C.P.A. 1571, 319 F.2d 277, 284, 138 USPQ 208, 214 (1963) (later claims broader in scope than the previously deficient claim were precluded because the later claims included the unenabled product of the previously rejected claim); see also In re Katz, 58 C.C.P.A. 713, 467 F.2d 939, 167 USPQ 487 (1970) (claims were precluded which described the structural equivalent of claims already adjudicated).

In its charge of infringement, Genetics Institute states that claim 1 of the '837 patent encompasses Amgen's products having a specific activity of at least 160,000 IU/AU. On Genetics Institute's necessary interpretation of the scope of the '837 claims in order to pursue this infringement action, the same issue of enablement arises as was decided in Amgen II. The district court correctly held that this issue is precluded.

Genetics Institute argues that the district court's holding violates the rule that each patent and each patent claim is a separate invention and must be considered separately. Genetics Institute points out that the '837 patent could not have been litigated in Amgen I and Amgen II, for the '837 patent was not issued until after the litigation of the '195 patent was concluded. We have recently reaffirmed that each patent constitutes a distinct property right, see Kearns, 94 F.3d at 1555, 39 USPQ2d at 1950, and of course suit can not be brought for infringement of a patent that has not issued. However, in Amgen II enablement was fully litigated for the identical product on the identical specification. That issue can not be relitigated, although it could not be raised until the continuation patent was granted. Cf. In re Freeman, 30 F.3d 1459, 1466, 31 USPQ2d 1444, 1448-50 (Fed.Cir.1994) (district court decision of issue in infringement suit precluded different interpretation in subsequent reexamination proceeding).

Genetics Institute argues that it has yet to be litigated whether homogeneous EPO can have a specific activity below 160,000 IU/AU. In Amgen II this court accepted and relied on Genetics Institute's representations, in prosecution of the '195 patent, that homogeneous EPO has a specific activity of at least 160,000 IU/AU. Questions of lower specific activities were not necessary to the decision in Amgen II. Nor is this aspect of relevance to the decision herein, for the basis of Genetics Institute's complaint is that the '837 patent claims encompass

Amgen's EPO having a specific activity of at least 160,000 IU/AU. Non-enablement of that claim scope was finally decided in Amgen II. Consequently, summary judgment that Genetics Institute may not assert the '837 patent claims against the Amgen EPO was properly granted.

COSTS

Costs to Amgen.

AFFIRMED.

PAULINE NEWMAN, Circuit Judge.

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA v. ELI LILLY AND COMPANY

119 F.3d 1559 (1997)

Annotate this Case

U.S. Court of Appeals for the Federal Circuit - 119 F.3d 1559 (1997) July 22, 1997.Rehearing Denied; Suggestion for Rehearing In Banc Declined Oct. 24, 1997

Harold J. McElhinny, Morrison &Foerster LLP, San Francisco, CA, argued for plaintiff-appellant. With him on the brief were Donald S. Chisum, Alan K. Palmer, Rachel Krevans, and Debra A. Shetka. Also with him on the brief were Arthur I. Neustadt, Jean-Paul Lavalleye, Marc R. Labgold, and William J. Healey, Oblon, Spivak, McClelland, Maier &Neustadt, P.C., Arlington, VA. Of counsel was Gladys H. Monroy, Morrison &Foerster LLP, San Francisco, CA.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett &Dunner, L.L.P., Washington, DC, argued for defendant-appellee. With him on the brief were Donald R. Dunner, Howard W. Levine, and John R. Alison. Of counsel on the brief was Amy E. Hamilton, Eli Lilly and Company, Indianapolis, IN.

Before NEWMAN, LOURIE, and BRYSON, Circuit Judges.

LOURIE, Circuit Judge.

The Regents of the University of California (UC) appeal from the judgment of the District Court for the Southern District of Indiana, holding that Eli Lilly & Company (Lilly) does not infringe U.S. Patent 4,652,525 or U.S. Patent 4,431,740 in its manufacture of human insulin; that the asserted claims of the '525 patent are invalid; and that both patents are

unenforceable. Regents of the Univ. of Cal. v. Eli Lilly and Co., 39 USPQ2d 1225 (S.D.Ind.1995). We hold that the district court (1) properly exercised jurisdiction over this case for trial on the merits, (2) did not err in concluding that the asserted claims of the '525 patent are invalid for failure to provide an adequate written description of the subject matter of the asserted claims, and (3) did not clearly err in finding that Lilly did not infringe the '740 patent. We further hold that the district court (4) abused its discretion in holding that the '525 and '740 patents are unenforceable. We therefore affirm-in-part and reverse-in-part.

BACKGROUND

In 1990, UC brought this action in the Northern District of California, alleging that Lilly was infringing claims 1, 2, and 4-7 of the '525 patent under the doctrine of equivalents and infringing claims 2-3, 5-6, 8-10, and 13-14 of the '740 patent, either literally or under the doctrine of equivalents. Lilly responded that it does not infringe any of the asserted claims, that the asserted claims are invalid, and that the patents are unenforceable. Lilly did not assert any counterclaims against UC.

The patents in suit relate to recombinant DNA technology[32] and, more specifically, to recombinant plasmids and microorganisms that produce human insulin, a protein involved in the regulation of sugar metabolism. A person unable to produce insulin is afflicted with diabetes. Prior to the development of recombinant techniques for the production of human insulin, diabetic patients were treated with injections of animal insulin, which often caused allergic reactions. Human insulin produced by recombinant methods is less likely to produce such reactions. It consists of two separate amino acid chains, a 21-amino acid A chain and a 30-amino acid B chain, which are linked only by disulfide bonds. Healthy people produce insulin in vivo via the terminal enzymatic cleavage of preproinsulin (PPI) to yield proinsulin (PI), a single amino acid chain consisting of the A and B chains, linked by a sequence of additional amino acids that positions the A and B chains so that the disulfide bonds are readily formed. The PI is then further cleaved to liberate the linking sequence and yield insulin.

[32] For a detailed discussion of recombinant DNA technology, see Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207-08 n. 4, 18 USPQ2d 1016, 1022 n. 4 (Fed.Cir.1991) and In re O'Farrell, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed.Cir.1988) and references therein.

The '525 patent, the application for which was filed in May 1977, was based upon the determination of the PI and PPI cDNA sequences found in rats. Claim 1 of that patent reads as follows: "A recombinant plasmid replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin." (emphasis added). Claim 2 relates to a recombinant procaryotic microorganism containing vertebrate insulin-encoding cDNA. Claims 4 and 5 depend from claim 2, and are limited, respectively, to mammalian and human insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain "at least one genetic determinant of the plasmid col E1." Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

The '740 patent, the application for which was filed in September 1979, was based upon the determination of human PPI and PI cDNA sequences and the development of "tailoring" techniques for the incorporation of human PI cDNA into a recombinant plasmid. Using these techniques, a specific semi-synthetic DNA may be incorporated into a suitable transfer vector. Using one such tailoring technique, the human PI cDNA and the plasmid into which it is incorporated may be modified so that they contain complimentary oligo-dC and oligo-dG ends, which facilitate the formation of the recombinant plasmid. Independent claim 2 of the '740 patent reads: "A DNA transfer vector comprising an inserted cDNA consisting essentially of a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide of the sequence coding for said proinsulin." (emphasis added). Dependent claim 3 is directed, inter alia, to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector comprising a deoxynucleotide sequence coding for human proinsulin consisting essentially of a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." (emphasis added). Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

Lilly makes human PI using a semi-synthetic DNA to yield a cleavable fusion protein[33] that consists of a bacterial protein, a "cleavable linkage" consisting of a single methionine residue, and human PI. After the fusion protein is produced, the desired human PI is obtained by cleaving it from the remainder of the fusion protein.

In 1992, pursuant to 28 U.S.C. § 1407 (1994), the Judicial Panel on Multidistrict Litigation (JPML) consolidated this case with five other related cases for pre-trial proceedings in the District Court for the Southern District of Indiana. In re Recombinant DNA Tech. Patent and Contract Litig., No. 912 (J.P.M.L. Feb. 19, 1992). UC petitioned this court for a writ of mandamus, seeking to vacate the transfer order as barred by the Eleventh Amendment and inconsistent with various prior decisions in the consolidated cases, including two decisions of the District Court for the Northern District of California in this case. See In re Regents of the Univ. of Cal., 964 F.2d 1128, 1131-32, 22 USPQ2d 1748, 1751-52 (Fed.Cir.1992). We denied UC's petition, holding that the transfer did not force unconsented suit upon UC and thus was permissible for purposes of pretrial discovery. Id., at 1134, 964 F.2d 1128, 22 USPQ2d at 1754.

In 1994, responding to Lilly's pretrial motion, the District Court for the Southern District of Indiana transferred venue to itself for trial on the merits pursuant to 28 U.S.C. § 1404(a) (1994). After conducting a bench trial, the court issued a memorandum opinion in which it ruled, inter alia, that (1) Lilly does not infringe the asserted claims of either patent, 39 USPQ2d at 1228-39, (2) the asserted claims of the '525 patent, those directed to mammalian, vertebrate, and human cDNA, are invalid for lack of an adequate written description, id. at 1239-41, and (3) both patents are unenforceable due to inequitable conduct on the part of UC, id. at 1247-58. UC appeals from these rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

[33] For a detailed discussion of fusion proteins, see Schendel v. Curtis, 83 F.3d 1399, 1400 & n. 3, 38 USPQ2d 1743, 1744 & n. 3 (Fed.Cir.1996).

DISCUSSION

As a preliminary matter, UC argues that the District Court for the Southern District of Indiana lacked jurisdiction to hear this case on the merits and was an inappropriate venue for trial. UC first argues that the Eleventh Amendment deprives the Indiana court of jurisdiction. Specifically, UC asserts that by choosing to bring suit in the District Court for the Northern District of California, it waived its Eleventh Amendment immunity only in California federal courts. Relying on Port Authority Trans-Hudson Corp. v. Feeney, 495 U.S. 299, 307, 110 S.Ct. 1868, 1873-74, 109 L.Ed.2d 264 (1990), UC argues that the Eleventh Amendment bars the transfer of this case for trial on the merits. Lilly responds that the Eleventh Amendment is inapplicable where, as here, a state asserts a claim and no counterclaim against the state is involved. We agree with Lilly that the Eleventh Amendment does not preclude trial in Indiana.

The Eleventh Amendment provides that: "*The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.*" U.S. Const. amend. XI. The Supreme Court has recently confirmed that "*the reference to actions 'against one of the United States' encompasses not only actions in which a State is named as a defendant, but also certain actions against state agents and state instrumentalities,"* such as UC. Regents of the Univ. of Cal. v. Doe, --- U.S. ----, ----, 117 S.Ct. 900, 903, 137 L.Ed.2d 55 (1997); see also BV Eng'g v. Univ. of Cal., 858 F.2d 1394, 1395, 8 USPQ2d 1421, 1422 (9th Cir.1988).

The question raised by this case is whether it is one that has been brought "against" UC. In deciding this question, we are aided by the Supreme Court's guidance in its opinion in United States v. Peters, 9 U.S. (5 Cranch) 115, 3 L.Ed. 53 (1809) (Marshall, C.J.). In that case, the Court declined to apply the Eleventh Amendment to bar a suit instituted against the heirs of a deceased state treasurer. The Court stated:

The right of a state to assert, as plaintiff, any interest it may have in a subject, which forms the matter in controversy between individuals, in one of the courts of the United States, is not affected by [the Eleventh] amendment; nor can [the amendment] be so construed as to

oust the court of its jurisdiction, should such claim be suggested. The amendment simply provides, that no suit shall be commenced or prosecuted against a state. The state cannot be made a defendant to a suit brought by an individual; but it remains the duty of the courts of the United States to decide all cases brought before them by citizens of one state against citizens of a different state, where a state is not necessarily a defendant. Id. at 139. This case involves a state's assertion of a claim rather than a state being a defendant.

In the Feeney case relied on by UC, the Court applied the Eleventh Amendment because a claim for damages was asserted "against" a state instrumentality. The Feeney Court noted that "*a State's Constitutional immunity encompasses not merely whether it may be sued, but where it may be sued"* 495 U.S. 299, 307, 110 S.Ct. 1868, 1873-74, 109 L.Ed.2d 264 (quoting Pennhurst State Sch. & Hosp. v. Halderman, 465 U.S. 89, 99, 104 S.Ct. 900, 907, 79 L.Ed.2d 67 (1984)), but the Court did not construe the Eleventh Amendment to apply to suits in which a state is solely a plaintiff, as UC is here. In fact, we do not believe that the Court has ever so construed the Eleventh Amendment. This is because the Eleventh Amendment applies to suits "against" a state, not suits by a state. Thus, we need not determine whether UC waived its immunity only in California, because this case does not create an Eleventh Amendment jurisdictional issue concerning which the question of waiver even arises. This case only involves UC's patent infringement claims and Lilly's defenses; it does not involve any claim or counterclaim against UC that places UC in the position of a defendant. Accordingly, we conclude that the Eleventh Amendment does not deprive the Indiana district court of jurisdiction in this case.

UC next argues that, under the law of the regional circuit to which appeal from the trial court would normally lie, the Indiana court abused its discretion by, as the court stated, transferring venue for trial on the merits from the California court to itself. See Heller Fin., Inc. v. Midwhey Powder Co., 883 F.2d 1286, 1293 (7th Cir.1989) (applying the abuse of discretion standard of review); Lou v. Belzberg, 834 F.2d 730, 739 (9th Cir.1987) (same). Specifically, UC argues that the Indiana court abused its discretion by, inter alia, affording too much weight to the element of judicial economy in granting Lilly's motion to transfer the case

to Indiana.[34] Lilly responds that the court acted within its discretion by retaining the case for trial and that it properly considered and weighed the relevant factors before deciding to do so.

We agree with Lilly that the court did not err on this point. A federal district court may *"[f]or the convenience of parties and witnesses, in the interest of justice, ... transfer any civil action to any other district court or division where it might have been brought.*" 28 U.S.C. § 1404(a) (1994). The Indiana court based its decision to retain the case for trial on the merits on its finding that, although the convenience of the parties and witnesses did not favor either the Indiana or the California court, the interests of judicial economy would be served by trial in the Indiana court. Consideration of the interest of justice, which includes judicial economy, "*may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result.*" Coffey v. Van Dorn Iron Works, 796 F.2d 217, 220-21 (7th Cir.1986); Allen v. Scribner, 812 F.2d 426, 436-37 (9th Cir.1987) ("*Because the transfer of this case undoubtedly would have led to delay, the district court did not abuse its discretion in denying Allen's motion notwithstanding possible inconvenience to the witnesses.*"); Commodity Futures Trading Comm'n v. Savage, 611 F.2d 270, 279 (9th Cir.1979) (affirming denial of transfer motion because "*[t]he district court was familiar with the case and transfer may have led to delay*"). Thus, the fact that the district court ultimately afforded little or no weight to the other factors does not, standing alone, indicate that the district court abused its discretion. On the contrary, in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial economy may favor transfer to a court that has become familiar with the issues. Accordingly, the court did not abuse its discretion by transferring the case after affording determinative weight to the consideration of judicial economy.

In its reply brief, UC first raises another basis for determining that Indiana was an improper venue for trial. UC argues that 28 U.S.C § 1407(a) (1994) requires that a case transferred by the JPML for consolidated pretrial proceedings be returned for trial on the merits to the court from which it was transferred. Aware that it failed to address this issue in its opening brief in this appeal, UC contends that it adequately raised this argument when it filed its petition for mandamus seeking to vacate the transfer order for consolidation of

[34] UC also argues that the Indiana court abused its discretion by erroneously determining that UC could have brought this suit in Indiana without the state of California's consent, by overruling inconsistent decisions of the California district court, and by failing to give special weight to UC's choice of forum. We have considered these arguments and do not find them to be persuasive.

discovery in Indiana. See In re Regents, 964 F.2d 1128, 22 USPQ2d 1748. Lilly first responds that UC waived this argument by failing to raise it in its opening brief in this appeal, regardless of the argument it made in its earlier petition. Lilly also maintains that the transfer was lawful, citing In re American Continental Corp./Lincoln Savings & Loan Securities Litigation, 102 F.3d 1524 (9th Cir.1996), cert. granted sub nom., Lexecon Inc. v. Milberg Weiss Bershad Hynes &Lerach, --- U.S. ----, 117 S.Ct. 1818, 137 L.Ed.2d 1026, 65 U.S.L.W. 3761 (1997) (No. 96-1482), for the proposition that § 1407(a) does not prohibit a discovery transferee court from transferring a case to itself for trial if an adequate reason for that transfer exists under 28 U.S.C. § 1404(a) (1994).

We agree with Lilly insofar as it argues that UC waived its argument regarding § 1407 by failing to raise it in its opening brief in this appeal. See Fed. R.App. P. 28(a)(6), 28(c); Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 800, 17 USPQ2d 1097, 1103 (Fed.Cir.1990) *("[A]n issue not raised by an appellant in its opening brief ... is waived.*"). UC's assertion that it adequately raised this argument when it filed its petition for mandamus is not persuasive. In denying that petition, we noted that UC expressed concern that, inter alia, "*Lilly will maneuver to try the merits of the California actions in Indiana ... thus defeating [UC's] expectation and entitlement that the merits of the California actions will be tried in California."* In re Regents, 964 F.2d at 1133, 22 USPQ2d at 1753. However, we declined to address UC's concern then because *"[t]hese possibilities can not be evaluated in the abstract." Id*. An assertion that the district court had actually erred was required, not the mere assertion that UC feared a potential error. We thus told UC that if it desired to contest the Indiana court's self-transfer, it would be required to raise that issue if and when the Indiana court actually transferred the case to itself. Because UC failed to do so by asserting error in a writ of mandamus or in its opening brief in this appeal, we decline to address the merits of its argument. Having determined that the Indiana court had jurisdiction and that its transfer of venue to itself under § 1404 was not, given the arguments properly before us, an abuse of that court's discretion, we address the remaining issues in UC's appeal.

The district court ruled that all of the claims of the '525 patent that UC asserted against Lilly, viz., claims 1, 2, and 4-7, are invalid under § 112, p 1, because the specification, although it provided an adequate written description of rat cDNA, did not provide an adequate written description of the cDNA required by the asserted claims. 39 USPQ2d at 1239-41.

Whether a specification complies with the written description requirement of § 112, p 1, is a question of fact, which we review for clear error on appeal from a bench trial. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed.Cir.1991); Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed.Cir.1985). To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "*the inventor invented the claimed invention.*" Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed.Cir.1989) *("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.*"). Thus, an applicant complies with the written description requirement "*by describing the invention, with all its claimed limitations, not that which makes it obvious,*" and by using "*such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention."* Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "*requires a precise definition, such as by structure, formula, chemical name, or physical properties,"* not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir.1993). Accordingly, "*an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id*. at 1170, 25 USPQ2d at 1606.

We first consider claim 5, which is specific to a microorganism containing a human insulin cDNA. UC argues that the district court clearly erred in finding that claim 5 is invalid under § 112, p 1. Specifically, UC argues that a constructive or prophetic example in the '525 specification describes in sufficient detail how to prepare the claimed organism. Lilly responds that the district court properly applied the written description requirement, as this court applied it in Fiers, 984 F.2d at 1170-71, 25 USPQ2d at 1605-06, and thus did not clearly err in finding that the cDNA encoding human insulin required by claim 5 is not adequately described in the '525 patent.

Claim 5 is directed to a recombinant procaryotic microorganism modified so that it

contains "*a nucleotide sequence having the structure of the reverse transcript of an mRNA of a [human], which mRNA encodes insulin*." Thus, the definition of the claimed microorganism is one that requires human insulin-encoding cDNA. The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

As indicated, Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA. Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. See, e.g., In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("*A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein.*"); In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed.Cir.1993). Thus, a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, p 1. Because the '525 specification provides only a general method of producing human insulin cDNA and a description of the human

insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA. Accordingly, the district court did not err in concluding that claim 5 is invalid for failure to provide an adequate written description.

UC also argues that the district court erred in holding claims 1 and 2, which generically recite cDNA encoding vertebrate insulin, and claim 4, which is directed generically to cDNA encoding mammalian insulin, invalid. Dependent claims 6 and 7 similarly recite cDNA encoding vertebrate insulin. In support of this argument, UC cites the disclosure of a species (the rat insulin-encoding cDNA) within the scope of those generic claims. UC argues, citing In re Angstadt, 537 F.2d 498, 190 USPQ 214 (Cust. & Pat.App.1976) and Utter v. Hiraga, 845 F.2d 993, 6 USPQ2d 1709 (Fed.Cir.1988), that because the '525 specification meets the requirements of § 112, p 1, for a species within both of these genera, the specification necessarily also describes these genera. Lilly responds that the district court did not clearly err in finding that cDNA encoding mammalian and vertebrate insulin were not adequately described in the '525 patent, because description of one species of a genus is not necessarily a description of the genus.

We agree with Lilly that the claims are invalid. Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (Cust. & Pat.App.1973) ("*In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus....").*

The cases UC cites in support of its argument do not lead to the result it seeks. These cases do not compel the conclusion that a description of a species always constitutes a description of a genus of which it is a part. These cases only establish that every species in a genus need not be described in order that a genus meet the written description requirement. See Utter, 845 F.2d at 998-99, 6 USPQ2d at 1714 ("*A specification may, within the meaning of § 112 p 1, contain a written description of a broadly claimed invention without describing*

all species that claim encompasses.") (affirming board's finding that an application that "*describes in detail the geometry and components that make its internal pivot embodiment work" also sufficiently describes an interference count that is "silent as to the location of the pivot*"). In addition, Angstadt is an enablement case and Utter involves machinery of limited scope bearing no relation to the complex biochemical claims before us.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed.Cir.1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that

make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.[35] This is analogous to enablement of a genus under § 112, p 1, by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "*are not required to disclose every species encompassed by their claims even in an unpredictable art*" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); In re Robins, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (Cust. & Pat.App.1970) ("*Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification ... mention of representative compounds may provide an implicit description upon which to base generic claim language.");* Cf. Gosteli, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); In re Grimme, 274 F.2d 949, 952, 124 USPQ 499, 501 (Cust. & Pat.App.1960) ("*[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'* ") (citations omitted). We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Accordingly, we reject UC's argument that the district court clearly erred in finding claims 1, 2, 4, 6, and 7 invalid for failure to provide an adequate written description. Because we affirm the district court's ruling that all of the claims of the '525 patent asserted against Lilly are invalid, we need not consider whether Lilly infringed those claims. See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319

[35] We note that in claims 4, 5, and 12-14 of the '740 patent, genera of DNA sequences encoding human PI or PPI are described by reference to the structure of the claimed DNA sequences rather than by reference to their function.

(Fed.Cir.1996).

The district court also ruled the '525 patent unenforceable on the ground of inequitable conduct. The court based this ruling on its findings that UC had violated National Institutes of Health (NIH) guidelines in order to develop the patented invention as soon as possible and had falsified material in its patent application in an effort to disguise its violation. The court noted that at the time the application that became the '525 patent was filed, NIH had certified only three plasmids for use with mammalian DNA: pSC101, pCR1, and pMB9. 39 USPQ2d at 1249. It then found that UC researchers knowingly used the uncertified pBR322 plasmid to hasten their determination of the rat PI and PPI cDNA sequences, and misrepresented that they had used pMB9, a certified plasmid, in the actual examples of their patent application. The court also found that a reasonable patent examiner would have viewed this misrepresentation as material to patentability.

UC argues that we should reverse the district court's ruling because it is based on a misinterpretation of the applicable law on inequitable conduct. Specifically, UC argues that the district court improperly considered alleged misrepresentations made to the NIH and Congress, and failed to properly consider whether the alleged misrepresentation in the patent application regarding the use of pMB9 was material to patentability. UC also argues that the district court clearly erred in finding that UC actually used pBR322 and then misrepresented that it used pMB9. In response, Lilly argues that under General Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 30 USPQ2d 1149 (Fed.Cir.1994), UC's misrepresentation was sufficient to support a finding of inequitable conduct, and that such a misrepresentation need not bear directly on patentability as long as that misrepresentation was made in an effort to obtain a patent more quickly than otherwise. Lilly also argues that the district court properly found that UC's alleged pattern of deceit before a variety of governmental bodies was sufficient to render the patent unenforceable under the broad doctrine of "unclean hands." See, e.g., Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 54 S.Ct. 146, 78 L.Ed. 293, 19 USPQ 228 (1933).

"A *determination of inequitable conduct is committed to a district court's discretion. Accordingly, we review the district court's judgment for an abuse of discretion.*" Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541, 41 USPQ2d 1829, 1834 (Fed.Cir.1997) (citing Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 USPQ2d 1384,

1392 (Fed.Cir.1988)). To overturn a discretionary ruling of a district court, "*the appellant must establish that the ruling is based on clearly erroneous findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court."* Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1827 (Fed.Cir.1995).

We conclude that the district court abused its discretion in holding the '525 patent to be unenforceable. An infringer asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney either failed to disclose material information or submitted false material information to the Patent and Trademark Office (PTO) and that the applicant or his attorney did so with an intent to deceive the PTO. See Kingsdown, 863 F.2d at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed.Cir.1984).

The alleged misinformation submitted to the PTO in this case consists of statements in Examples 4 and 5 of the specification that the pMB9 plasmid was used as the cloning vector for the rat cDNA when pBR322 appears to have been used. Lilly does not argue that the pMB9 plasmid was inoperable in the stated examples, only that Examples 4 and 5 should not have been stated as actual examples (even though they presumably could have been stated as constructive, i.e., hypothetical, examples). Accordingly, Lilly must demonstrate that this distinction would have been considered material by a reasonable patent examiner. We conclude that it has not done so by clear and convincing evidence.

There is no reason to believe that a reasonable examiner would have made any different decision if UC had framed Examples 4 and 5 as constructive examples. See Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1578, 224 USPQ 409, 415 (Fed.Cir.1984) ("*Even if intent could be inferred, and if the examples were constructive but not disclosed to the examiner as such, [the alleged infringer] has not shown the nondisclosure to have been material, i.e., important to an examiner in allowing the patent to issue.*"); Manual of Patenting Examining Procedure (MPEP) § 707.07(l) (5th ed. 1993) ("*The results of the tests and examples should not normally be questioned by the examiner unless there is a reasonable basis for questioning the results.");* cf. Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808-09, 15 USPQ2d 1481, 1484 (Fed.Cir.1990) (affirming a finding of inequitable

conduct based on an applicant's intentional disclosure of a "fictitious, inoperable" example and withholding of a best mode.). Moreover, the examiner would not have made any different decision if pBR322, the plasmid the district court found was actually used, was recited in the examples, because, as the record shows, the procedures described in Examples 4 and 5 for rat insulin cDNA worked to yield the intended results irrespective of whether pMB9 or pBR322 was used. The misidentification of the plasmid was therefore not material to patentability. Thus, no inequitable conduct occurred in the procurement of the patent.

In addition, contrary to the findings of the district court, a reasonable patent examiner would not have considered non-compliance with the NIH guidelines to be material to patentability. The district court based its finding of materiality on the theory that if the applicant had complied with the guidelines, the application might have been delayed and the applicants might not have been the first to apply for a patent on the claimed subject matter. However, such unfounded speculation is not clear and convincing evidence of materiality.

General Electro Music does not support Lilly's argument that UC's failure to have actually used pMB9 would have been material to patentability. In General Electro Music, we concluded that "*a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent."* 19 F.3d at 1411, 30 USPQ2d at 1154. We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." *Id.* As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. UC got no advantage in the patent examining process. Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability

We also reject Lilly's alternative argument that the patent is unenforceable under the doctrine of "unclean hands." This court has previously refused to afford equitable relief in that guise in the absence of proof of materiality. In J.P. Stevens, 747 F.2d at 1560 n. 7, 223 USPQ at 1093 n. 7, we rejected the argument that "unclean hands" could render a patent unenforceable without proof of materiality because such a "*categorization is inconsistent with this court's view that materiality is a necessary ingredient of any inequitable conduct*." Accordingly, there is no legal basis for the conclusion that inequitable conduct occurred in the procurement of the patent and the district court therefore abused its discretion in its

conclusion that the patent was unenforceable.

The district court ruled that Lilly did not infringe claims 5-6 and 8-10 of the '740 patent either literally or under the doctrine of equivalents, 39 USPQ2d at 1231-38, and did not infringe claims 2-3 and 13-14 of the '740 patent under the doctrine of equivalents, *id*. at 1238. After evaluating the specification and the prosecution history, and receiving extrinsic evidence, the court construed these claims to be limited to genetic constructs (i.e., "plasmids" and "transfer vectors") and microorganisms from which human PI is directly expressed. Accordingly, the court found that Lilly, which does not make or use such constructs or microorganisms, but expresses a recombinant fusion protein that is later cleaved to yield human PI, did not literally infringe the asserted claims. The court further determined that Lilly did not infringe the claims under the doctrine of equivalents because claim amendments made during the prosecution of the patent application bar UC from successfully asserting that the materials Lilly uses for expressing a recombinant fusion protein are equivalent to the claims of the '740 patent.

Challenging the district court's finding of a lack of literal infringement, UC argues that the district court incorrectly interpreted the claims. Specifically, UC argues that the use of the term "comprising" in the claims indicates that a transfer vector such as that used by Lilly will infringe the claims as long as it includes the inserted cDNA encoding human PI, irrespective of the presence of other elements such as the DNA encoding the remainder of Lilly's fusion protein. Lilly responds that the district court correctly interpreted the claims in light of the prosecution history. Lilly argues that a prior art rejection was based on the examiner's conclusion that the prior art taught how to make recombinant insulin as part of a fusion protein and that UC therefore obtained allowance of the claims by specifically disclaiming transfer vectors that encode fusion proteins.

A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576, 27 USPQ2d 1836, 1839 (Fed.Cir.1993). The first step, claim construction, is a question of law which we review de novo; the proper construction of the claims is based upon the claim language, the specification, the prosecution history, and if necessary to aid the court's understanding of the patent, extrinsic evidence. See

Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81, 34 USPQ2d 1321, 1329-31 (Fed.Cir.1995) (in banc), aff'd, --- U.S. ----, 116 S.Ct. 1384, 134 L.Ed.2d 577, 38 USPQ2d 1461 (1996). The second step, determining whether a particular device infringes a properly construed claim, is a question of fact which we review for clear error on appeal from a bench trial. See Fed.R.Civ.P. 52(a); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed.Cir.1983). In order to prove infringement, a patentee must show that "*the accused device includes every limitation of the [asserted] claim or an equivalent of each limitation."* Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397, 29 USPQ2d 1767, 1769 (Fed.Cir.1994).

We agree with Lilly that UC surrendered coverage of DNA that encodes a fusion protein. The district court correctly interpreted the asserted claims to be limited to genetic constructs and microorganisms that do not include DNA coding for a fusion protein. UC argues that the direct expression of human PI and the expression of human PI via a fusion protein are both described in the patent as part of the invention of the '740 patent, but that fact doesn't change the prosecution history which indicates that UC surrendered coverage of the latter in order to overcome prior art.

This surrender is best exemplified by the prosecution history relating to the claims that ultimately issued as claims 2 and 5. These claims as originally filed were directed, with varying degrees of specificity, to a DNA transfer vector comprising a DNA sequence coding for human PI. The word "comprising," as UC argues and as is well-established, permits inclusion of other moieties.

However, during the prosecution of the patent, the examiner rejected these claims as unpatentable based on, inter alia, Ullrich et al., 196 Science 1313 (June 17, 1977) and Villa-Komaroff et al., 75 PNAS 3727 (August 1978).[36] The district court, essentially repeating the statements made by the patent examiner during the prosecution of the patent, found that these references taught,[37] respectively, the need "*to combine the genetic information for the*

[36] Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in the production of human PI. See 39 USPQ2d at 1231 n. 12. For the sake of brevity, we do not discuss them here.

[37] UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be revisited in an infringement

eukaryotic insulin gene with prokaryotic regulatory sequences, to obtain expression of insulin in bacteria," and "*a general method for the expression and secretion of any eukaryotic protein [such as human PI] provided another protein ... will serve as a carrier [as part of a fusion protein], by virtue of its leader sequence.*" 39 USPQ2d at 1232. The examiner thus rejected the claims because he believed that the prior art taught the use of recombinant eukaryotic/procaryotic fusion proteins for the production of a eukaryotic protein, including insulin, in a recombinant bacterium.

In an effort to overcome the rejection based on these references, UC first amended claim 2 to read, in pertinent part: "*A DNA transfer vector comprising an inserted cDNA having a[DNA] sequence coding for human [PI]...."* The word "having" still permitted inclusion of other moieties. When again confronted by a rejection based upon the same references and a later requirement that the word "having" be changed to "consisting essentially of," a narrower term, UC ultimately complied by amending claim 2 to its present form, viz., "*A DNA transfer vector comprising an inserted cDNA consisting essentially of a[DNA] sequence coding for human [PI]*." Similarly, UC amended claim 5 to its present form, which reads, in pertinent part: "*A DNA transfer vector comprising a[DNA] sequence coding for human [PI] consisting essentially of a plus strand having the sequence ...."* (emphasis added). The examiner allowed these claims, noting that the required "consisting essentially of" language "*excludes from the cDNA the presence of sequences other than [those coding for PI]*." We agree with the district court that UC thus narrowed its claims in response to a prior art rejection to exclude the materials producing a fusion protein, as Lilly now does. UC urges us to read the examiner's statement on allowance of the claims narrowly as pertaining only to claim 2 and to exclude only DNA other than naturally-occurring human cDNA. However, that statement is not so limited; it expressly applies to claim 5 and, moreover, reflects the examiner's consistent requirement, acquiesced in by UC, that the DNA inserted in the claimed vectors code only for PI, not for a PI-containing fusion protein.[38]

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action." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., --- U.S. ----, ---- n. 7, 117 S.Ct. 1040, 1051 n. 7, 137 L.Ed.2d 146, 41 USPQ2d 1865, 1872-73 n. 7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." Id. Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history.

[38] *UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends*

We have considered all of the other arguments made by UC, including its assertion that the examiner's rejections were based on a distinction between tailored and non-tailored cDNA, but find them to be unpersuasive. In light of the prosecution history, we agree with the district court that claims 5 and 6, which contain the language added during prosecution, cannot be construed to literally cover Lilly's expression of human PI via a fusion protein. Furthermore, UC has stated in its appeal brief that, for purposes of the analysis of literal infringement, the scope of claims 8-10 is no broader than that of claims 5 and 6, and that it does not appeal the court's finding with respect to claims 8-10. Accordingly, we affirm the district court's construction of claims 5-6 and 8-10; its factual finding that Lilly does not literally infringe claims 5-6 is not clearly erroneous and is therefore also affirmed.

Regarding the district court's application of the doctrine of equivalents, UC argues that the district court improperly interpreted the prosecution history to indicate that UC had disclaimed vectors encoding fusion proteins instead of to indicate, as properly interpreted, that the claims were limited to "tailored" cDNA inserts. However, as indicated above, we find no error in the district court's interpretation of the claims and the prosecution history and hence its conclusion that Lilly does not infringe the asserted claims under the doctrine of equivalents.

When a claim has been narrowed by amendment for a "substantial reason related to patentability," such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., U.S. 117 S.Ct. 1040, 1049-51, 137 L.Ed.2d 146, 41 USPQ2d 1865, 1871-73 (1997); Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1107, 40 USPQ2d 1602, 1609 (Fed.Cir.1996), cert. denied, U.S. 117 S.Ct. 1555, 137 L.Ed.2d 703 (1997); ("*Prosecution history estoppel bars the patentee from recapturing subject matter that was surrendered by the patentee during prosecution in order to promote allowance of the claims.").* "*The application of prosecution history estoppel is a question of law subject to de novo review." Id*.; see also Warner-Jenkinson, U.S. at 117 S.Ct. at 1049-51, 137 L.Ed.2d 146, 41 USPQ2d at 1871-73.

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actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement.

As the district court properly concluded, the above-described prosecution history estops UC's '740 patent from dominating Lilly's expression of its fusion protein. As a matter of law, the material used by Lilly for expressing its fusion protein is not equivalent to that of the above-analyzed claims, or to the materials of the other asserted claims, i.e., claims 2-3 and 13-14, for such an application of the doctrine of equivalents would allow UC to recapture subject matter it surrendered during the prosecution of the '740 patent. Accordingly, UC cannot meet its burden of establishing infringement under the doctrine of equivalents. The district court did not clearly err in determining that Lilly did not infringe the '740 patent, either literally or under the doctrine of equivalents.

The district court ruled that the '740 patent was unenforceable for inequitable conduct. 39 USPQ2d at 1255-58. The court based this ruling in part on its finding that UC failed to disclose to the PTO a highly-material reference, European Patent Application No. 1929 (EPA-1929), entitled "Plasmid for Transforming Bacterial Host to Render It Capable of Polypeptide Expression" in which the expression of human somatostatin and insulin are used as examples.[39] The court also based its ruling on its finding that UC was made aware of the materiality of EPA-1929 when it was cited as prior art by the European Patent Office (EPO) during the prosecution of the European counterpart of the application that led to the '740 patent. The court found that under these facts, it would "*draw an inference of intent to mislead," id*. at 1257, and accordingly, found that UC had engaged in inequitable conduct.

UC argues that it did not have a duty to disclose EPA-1929 to the PTO because it was merely cumulative of the references it had submitted to the PTO. Specifically, UC argues that EPA-1929 was cumulative of the two references on which EPA-1929 was based, which were already before the examiner when UC became aware of EPA-1929: Goeddel et al., 76 PNAS 3727 (1979) and Itakura et al., 198 Science 1056 (1977).[40] UC also argues that the district court misapplied the law on inequitable conduct by inferring an intent to deceive when the uncited reference was merely cumulative. Lilly responds that EPA-1929 was not cumulative because, unlike the reference before the examiner, it described a specific, enabling technique for making "tailored" DNA that would encode for a fusion protein including human PI. Lilly argues that UC's assertions of subjective good faith amount to no more than a mere denial of

[39] This application was filed by Genentech, Inc. and named Drs. Itakura and Riggs as inventors.

[40] Drs. Itakura and Riggs, inventors of the EPA-1929 subject matter, are noted as authors on both of these articles.

bad faith and accordingly that the district court properly disregarded those assertions. We agree with UC that the district court clearly erred in finding that EPA-1929 was not cumulative and, accordingly, in inferring an intent to deceive.

As stated above, we review a district court's ruling that a patent is unenforceable for inequitable conduct under an abuse of discretion standard. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed.Cir.1988). An infringer asserting an inequitable conduct defense must prove by clear and convincing evidence that the applicant or his attorney failed to disclose material information or submitted false material information to the PTO, with an intent to deceive the PTO. See id. at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed.Cir.1984). However, even where an applicant fails to disclose an otherwise material prior art reference, that failure will not support a finding of inequitable conduct if the reference is "simply cumulative to other references," i.e., if the reference teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014 (Fed.Cir.1991).

The district court correctly found that UC knew of the materiality of EPA-1929 because the EPO considered EPA-1929 to be material to the examination of the European counterpart of the '740 patent. However, if EPA-1929 was merely cumulative of other references already before the examiner, UC's failure to cite it will not support a finding of inequitable conduct because one is justified in not submitting cumulative prior art. The record indicates that EPA-1929 was cumulative. The examiner had already noted the relevance of both the Itakura article, entitled "Expression in Escherichia coli of Chemically Synthesized Gene for the Hormone Somatostatin," and the Goeddel article, entitled "*Expression in Escherichia coli of Chemically Synthesized Genes for Human Insulin."* As is suggested by their respective titles and their dates of publication and submission, the work described in the two articles is essentially the same as that described in EPA-1929. In fact, the record indicates that the European patent examiner cited EPA-1929 against the European counterpart of the '740 patent, but cited the Goeddel article merely to demonstrate the state of the art and did not cite the Itakura article at all.

Lilly argues that these articles are distinguishable from EPA-1929 based on the fact that EPA-1929 also includes a claim (claim 6) directed, in part, to a plasmid encoding human proinsulin. But the inclusion of a claim is not controlling in a determination whether EPA-1929 is cumulative. What is relevant is whether EPA-1929 discloses subject matter relevant to the examination of the '740 patent application that is not taught by the Goeddel and Itakura articles. Plainly it does not. The Goeddel article and EPA-1929 describe in similar detail the same experiments which led to the production of a recombinant human insulin/J-galactosidase fusion protein. That Genentech attempted to claim a plasmid encoding human proinsulin in EPA-1929 does not add to its disclosure compared with the Goeddel article. We therefore conclude that the district court clearly erred in finding that EPA-1929 was not cumulative.

Because we conclude that the district court's finding of materiality was clearly erroneous, we also necessarily conclude that the district court clearly erred in inferring deceptive intent from the mere fact that UC did not cite EPA-1929. UC's failure to disclose the EPA-1929 reference, given its cumulative nature, is not clear and convincing evidence of inequitable conduct. Because the district court's conclusion that the '740 patent is unenforceable for inequitable conduct is based on clearly erroneous findings of materiality and intent, that conclusion is reversed.

CONCLUSION

The district court properly exercised jurisdiction over this case and did not abuse its discretion in transferring the case to itself for a trial on the merits. It did not clearly err in finding that the '525 patent does not provide an adequate written description of the subject matter of the asserted claims and thus properly held that those claims are invalid, nor did it clearly err in finding that Lilly did not infringe the asserted claims of the '740 patent. The court abused its discretion in holding that the '525 and '740 patents are unenforceable. Accordingly, the decision of the district court is

AFFIRMED-IN-PART and REVERSED-IN-PART.

COSTS

Costs to Lilly.

SUPREME COURT OF THE UNITED STATES

MAYO COLLABORATIVE SERVICES, dba MAYO MEDICAL LABORATORIES, et al., PETITION- ERS v. PROMETHEUS LABORATORIES, INC.

on writ of certiorari to the United States Court of Appeals for the Federal Circuit

[March 20, 2012]

No. 10–1150

Justice Breyer delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

"*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.*" 35 U. S. C. §101.

The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. Diamond v. Diehr, 450 U. S. 175, 185 (1981) ; see also Bilski v. Kappos, 561 U. S. (2010) (slip op., at 5); Diamond v. Chakrabarty, 447 U. S. 303, 309 (1980) ; Le Roy v. Tatham, 14 How. 156, 175 (1853); O'Reilly v. Morse, 15 How. 62, 112–120 (1854); cf. Neilson v. Harford, Webster's Patent Cases 295, 371 (1841) (English case discussing same). Thus, the Court has written that "*a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.*' " Chakrabarty, supra, at 309 (quoting Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U. S. 127, 130 (1948)).

"*Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work."* Gottschalk v. Benson, 409 U. S. 63, 67 (1972) . And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in Diehr the Court pointed out that " *'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'* " 450 U. S., at 187 (quoting Parker v. Flook, 437 U. S. 584, 590 (1978)). It added that "*an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.*" Diehr, supra, at 187. And it emphasized Justice Stone's similar observation in Mackay Radio & Telegraph Co. v. Radio Corp. of America, 306 U. S. 86 (1939) :

" *'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'* " 450 U. S., at 188 (quoting Mackay Radio, supra, at 94).

See also Funk Brothers, supra, at 130 (*"If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end*").

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, e.g., Benson, supra, at 71–72.

The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not

patentable.

Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "*principles underlying the prohibition against patents for [natural law*s*]*". Flook, supra, at 593. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. Morse, supra, at 112–120; Benson, supra, at 71–72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. Flook, supra, at 594; see also Bilski, supra, at ___ (slip op., at 14) (*"[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity'* " (quoting Diehr, supra, at 191–192)).

We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

(A)

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already

understood that the levels in a patient's blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6–TG) and 6-methyl-mercaptopurine (6–MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. See U. S. Patent No. 6,355,623, col. 8, ll. 37–40, 2 App. 10. *("Previous studies suggested that measurement of 6–MP metabolite levels can be used to predict clinical efficacy and tol- erance to azathioprine or 6–MP*" (citing Cuffari, Théorêt, Latour, & Seidman, 6-Mercaptopurine Metabolism in Crohn's Disease: Correlation with Efficacy and Toxicity, 39 Gut 401 (1996))). But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.

More specifically, the patents—U. S. Patent No. 6,355,623 ('623 patent) and U. S. Patent No. 6,680,302 ('302 patent)—embody findings that concentrations in a patient's blood of 6–TG or of 6–MMP metabolite beyond a certain level (400 and 7000 picomoles per 8x108 red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6–TG metabolite lower than a certain level (about 230 picomoles per 8x108 red blood cells) indicate that the dosage is likely too low to be effective.

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

> "*A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:*
>
> *"(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and*
>
> *"(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,*
>
> *"wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and*
>
> *"wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood*

cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, ll. 10–20, 2 App. 16.

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

(B)

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the '623 and '302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per 8x108 for 6–TG and 5700 pmol per 8x108 for 6–MMP). Prometheus then brought this action claiming patent infringement.

The District Court found that Mayo's test infringed claim 7 of the '623 patent. App. to Pet. for Cert. 110a–115a. In interpreting the claim, the court accepted Prometheus' view that the toxicity-risk level numbers in Mayo's test and the claim were too similar to render the tests significantly different. The number Mayo used (450) was too close to the number the claim used (400) to matter given appropriate margins of error. Id., at 98a–107a. The District Court also accepted Prometheus' view that a doctor using Mayo's test could violate the patent even if he did not actually alter his treatment decision in the light of the test. In doing so, the court construed the claim's language, "indicates a need to decrease" (or "to increase"), as not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable. *Id*., at 107a–109a; see also Brief for Respondent i (describing claimed processes as methods "*for improving . . . treatment . . . by using individualized metabolite measurements to inform the calibration of . . . dosages of . . . thiopurines*" (emphasis added)).

Court reasoned that the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable. App. to Pet. for Cert. 50a–83a.

On appeal, the Federal Circuit reversed. It pointed out that in addition to these natural

correlations, the claimed processes specify the steps of (1) "administering a [thiopurine] drug" to a patient and (2) "determining the [resulting metabolite] level." These steps, it explained, involve the transformation of the human body or of blood taken from the body. Thus, the patents satisfied the Circuit's "machine or transformation test," which the court thought sufficient to "confine the patent monopoly within rather definite bounds," thereby bringing the claims into compliance with §101. 581 F. 3d 1336, 1345, 1346–1347 (2009) (internal quotation marks omitted).

Mayo filed a petition for certiorari. We granted the petition, vacated the judgment, and remanded the case for reconsideration in light of Bilski, 561 U. S. ___, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, but only an important and useful clue. On remand the Federal Circuit reaffirmed its earlier conclusion. It thought that the "machine-or-transformation test," understood merely as an important and useful clue, nonetheless led to the "clear and compelling conclusion . . . that the . . . claims . . . do not encompass laws of nature or preempt natural correlations." 628 F. 3d 1347, 1355 (2010). Mayo again filed a petition for certiorari, which we granted.

II

Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that if the levels of 6–TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x108 red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this

question is no.

(A)

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the "*prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'* " Bilski, supra, at ___ (slip op., at 14) (quoting Diehr, 450 U. S., at 191–192).

Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decision-making (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).

Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12–65, 2 App. 11. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. '623 patent, col. 8, ll. 37–40, id., at 10. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely "conventional or obvious" "[pre]-solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. Flook, 437 U. S., at 590; see also Bilski, 561 U. S., at ___ (slip op., at 14) ("*[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant post-solution activity'* " (quoting Diehr, supra, at 191–192)).

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See Diehr, supra, at 188 ("*[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made*"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

(B)

(1) A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are Diehr and Flook, two cases in which the

Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. The Diehr process (held patent eligible) set forth a method for molding raw, uncured rubber into various cured, molded products. The process used a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. It consisted in effect of the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal "a device" to open the press. Diehr, 450 U. S., at 177–179.

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "*installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly re- calculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.*" *Id.,* at 187. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "*only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." Ibid*. These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.

The process in Flook (held not patentable) provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons. Certain operating conditions (such as temperature, pressure, and flow rates), which are continuously monitored during the conversion process, signal inefficiency or danger when they exceed certain "alarm limits." The claimed process amounted to an improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, e.g., the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm-limit values. 437 U. S., at 585–587.

The Court, as in Diehr, pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it characterized the claimed process as doing nothing other than "provid[ing] a[n unpatentable] formula for computing an updated alarm limit." Flook, supra, at 586. Unlike the process in Diehr, it did not "explain how the variables used in the formula were to be selected, nor did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit." Diehr, supra, at 192, n. 14; see also Flook, 437 U. S., at 586. And so the other steps in the process did not limit the claim to a particular application. Moreover, *"[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring-alarming'"* were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. *Id.,* at 594. *"[P]ost-solution activity" that is purely "conventional or obvious," the Court wrote, "can[not] transform an unpatentable principle into a patentable process."* Id., at 589, 590.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in Diehr and no stronger than the (unpatentable) claim in Flook. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in Diehr was not so characterized; that in Flook was characterized in roughly this way.

(2) Other cases offer further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable. This Court has previously discussed in detail an English case, Neilson, which involved a patent claim that

posed a legal problem very similar to the problem now before us. The patent applicant there asserted a claim "for the improved application of air to produce heat in fires, forges, and furnaces, where a blowing apparatus is required. [The invention] was to be applied as follows: The blast or current of air produced by the blowing apparatus was to be passed from it into an air-vessel or receptacle made sufficiently strong to endure the blast; and through or from that vessel or receptacle by means of a tube, pipe, or aperture into the fire, the receptacle be kept artificially heated to a considerable temperature by heat externally applied." Morse, 15 How., at 114–115.

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an inventive way. Baron Parke wrote (for the court):

"*It is very difficult to distinguish [Neilson's claim] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace.*" Neilson v. Harford, Webster's Patent Cases, at 371.

Thus, the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.

In Bilski the Court considered claims covering a process for hedging risks of price changes by, for example, contracting to purchase commodities from sellers at a fixed price, reflecting the desire of sellers to hedge against a drop in prices, while selling commodities to consumers at a fixed price, reflecting the desire of consumers to hedge against a price increase. One claim described the process; another reduced the process to a mathematical

formula. 561 U. S., at ___–___ (slip op., at 2–3). The Court held that the described "concept of hedging" was "an unpatentable abstract idea." Id., at ___ (slip op., at 15). The fact that some of the claims limited hedging to use in commodities and energy markets and specified that "*well-known random analysis techniques [could be used] to help establish some of the inputs into the equation*" did not undermine this conclusion, for "*Flook established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." Id*., at ___, ___ (slip op., at 16, 15).

Finally, in Benson the Court considered the patentability of a mathematical process for converting binary-coded decimal numerals into pure binary numbers on a general purpose digital computer. The claims "*purported to cover any use of the claimed method in a general-purpose digital computer of any type*." 409 U. S., at 64, 65. The Court recognized that " *'a novel and useful structure created with the aid of knowledge of scientific truth'* " might be patentable. *Id.,* at 67 (quoting Mackay Radio, 306 U. S., at 94). But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. For the mathematical formula had "*no substantial practical application except in connection with a digital computer*." Benson, supra, at 71. Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said "apply the algorithm."

(3) The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in Morse the Court set aside as unpatentable Samuel Morse's general claim for " 'the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances,' " 15 How., at 86. The Court explained:

"*For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this*

patentee." Id., at 113.

Similarly, in Benson the Court said that the claims before it were "so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]." 409 U. S., at 67, 68. In Bilski the Court pointed out that to allow "*petitioners to patent risk hedging would pre-empt use of this approach in all fields*." 561 U. S., at ___ (slip op., at 15). And in Flook the Court expressed concern that the claimed process was simply "*a formula for computing an updated alarm limit," which might "cover a broad range of potential uses*." 437 U. S., at 586.

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "*the basic tools of scientific and technological work.*" Benson, supra, at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. See generally Lemley, Risch, Sichelman, & Wagner, Life After Bilski, 63 Stan. L. Rev. 1315 (2011) (hereinafter Lemley) (arguing that §101 reflects this kind of concern); see also C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012) ("*One problem with [process] patents is that the more abstractly their claims are stated, the more difficult it is to determine precisely what they cover. They risk being applied to a wide range of situations that were not anticipated by the patentee*"); W. Landes & R. Posner, The Economic Structure of Intellectual Property Law 305–306 (2003) (The exclusion from patent law of basic truths reflects "*both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in them and . . . the enormous transaction costs that would be imposed on would-be users [of those truths]*").

The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of

more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The "determining" step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent.

III

We have considered several further arguments in support of Prometheus' position. But they do not lead us to adopt a different conclusion. First, the Federal Circuit, in upholding the patent eligibility of the claims before us, relied on this Court's determination that "*[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines*." Benson, supra, at 70–71 (emphasis added); see also Bilski, supra, at ___ (slip op., at 6–7); Diehr, 450 U. S., at 184; Flook, supra, at 588, n. 9; Cochrane v. Deener, 94 U. S. 780, 788 (1877). It reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels. 628 F. 3d, at 1356–1357.

The first of these transformations, however, is irrelevant. As we have pointed out, the "administering" step simply helps to pick out the group of individuals who are likely interested in applying the law of nature. See supra, at 9. And the second step could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation. See supra, at 18. Regardless, in stating that the "machine-or-transformation" test is an "important and useful

clue" to patentability, we have neither said nor implied that the test trumps the "law of nature" exclusion. Bilski, supra, at ___ (slip op., at 6–7) (emphasis added). That being so, the test fails here.

Second, Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld. Thus, it encourages us to draw distinctions among laws of nature based on whether or not they will interfere significantly with innovation in other fields now or in the future. Brief for Respondent 42–46; see also Lemley 1342–1344 (making similar argument).

But the underlying functional concern here is a relative one: how much future innovation is foreclosed relative to the contribution of the inventor. See supra, at 17. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research. See supra, at 17–18.

In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. See, e.g., Flook, 437 U. S. 584 (holding narrow mathematical formula unpatentable). And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.

Third, the Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as Amicus Curiae. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. §102, that it not be "obvious in light of prior art," §103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, §112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

This approach, however, would make the "law of nature" exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. Bilski, 561 U. S. ___; Diehr, supra; Flook, supra; Benson, 409 U. S. 63 . See also H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) *("A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled*" (emphasis added)).

We recognize that, in evaluating the significance of additional steps, the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

What role would laws of nature, including newly discovered (and "novel") laws of nature, play in the Government's suggested "novelty" inquiry? Intuitively, one would suppose that a newly discovered law of nature is novel. The Government, however, suggests in effect that the novelty of a component law of nature may be disregarded when evaluating the novelty of the whole. See Brief for United States as Amicus Curiae 27. But §§102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. Diehr, 450 U. S., at 188 (patent claims "must be considered as a whole"). And studiously ignoring all laws of nature when evaluating a patent application under §§102 and 103 would "*make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." Id*., at 189, n. 12. See also Eisenberg, Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After In re Bilski, 3 Case W. Res. J. L. Tech. & Internet 1, ___ (forthcoming, 2012) (manuscript, at 85–86, online at http://www.patentlyo.com/ files/eisenberg.wisdomordeadhand.patentlyo.pdf (as visited Mar. 16, 2012, and available in Clerk of Court's case file)); 2 D. Chisum, Patents §5.03[3] (2005).

Section 112 requires only a "written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." It does not focus on the possibility that a law of nature (or its equivalent) that meets these conditions will nonetheless create the kind of risk that underlies the law of nature

exception, namely the risk that a patent on the law would significantly impede future innovation. See Lemley 1329–1332 (outlining differences between §§101 and 112); Eisenberg, supra, at ___ (manuscript, at 92–96) (similar). Compare Risch, Everything is Patentable, 75 Tenn. L. Rev. 591 (2008) (defending a minimalist approach to §101) with Lemley (reflecting Risch's change of mind).

These considerations lead us to decline the Government's invitation to substitute §§102, 103, and 112 inquiries for the better established inquiry under §101.

Fourth, Prometheus, supported by several amici, argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Brief for Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if "*claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care."* Brief for American College of Medical Genetics et al. as Amici Curiae 7; see also App. to Brief for Association Internationale pour la Protection de la Propriété Intellectuelle et al. as Amici Curiae A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential

users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another. See Bohannan & Hovenkamp, Creation without Restraint, at 98–100.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U. S. C. §§161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

* * *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered

SUPREME COURT OF THE UNITED STATES

VERNON HUGH BOWMAN, PETITIONER v. MONSANTO COMPANY ET AL.

on writ of certiorari to the United States Court of Appeals for the Federal Circuit

[May 13, 2013]

No. 11–796

JUSTICE KAGAN delivered the opinion of the Court.

Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention. The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission. We hold that he may not.

I

Respondent Monsanto invented a genetic modification that enables soybean plants to survive exposure to glyphosate, the active ingredient in many herbicides (including Monsanto's own Roundup). Monsanto markets soybean seed containing this altered genetic material as Roundup Ready seed. Farmers planting that seed can use a glyphosate- based herbicide to kill weeds without damaging their crops. Two patents issued to Monsanto cover various aspects of its Roundup Ready technology, including a seed incorporating the genetic

alteration. See Supp. App. SA1–21 (U. S. Patent Nos. 5,352,605 and RE39, 247E); see also 657 F. 3d 1341, 1343–1344 (CA Fed. 2011). Monsanto sells, and allows other companies to sell, Roundup Ready soybean seeds to growers who assent to a special licensing agreement. See App. 27a. That agreement permits a grower to plant the purchased seeds in one (and only one) season. He can then consume the resulting crop or sell it as a commodity, usually to a grain elevator or agricultural processor. See 657 F. 3d, at 1344–1345. But under the agreement, the farmer may not save any of the harvested soybeans for replanting, nor may he supply them to anyone else for that purpose. These restrictions reflect the ease of producing new generations of Roundup Ready seed. Because glyphosate resistance comes from the seed's genetic material, that trait is passed on from the planted seed to the harvested soybeans: Indeed, a single Roundup Ready seed can grow a plant containing dozens of genetically identical beans, each of which, if replanted, can grow another such plant—and so on and so on. See App. 100a. The agreement's terms prevent the farmer from co-opting that process to produce his own Roundup Ready seeds, forcing him instead to buy from Monsanto each season.

Petitioner Vernon Bowman is a farmer in Indiana who, it is fair to say, appreciates Roundup Ready soybean seed. He purchased Roundup Ready each year, from a company affiliated with Monsanto, for his first crop of the season. In accord with the agreement just described, he used all of that seed for planting, and sold his entire crop to a grain elevator (which typically would resell it to an agricultural processor for human or animal consumption).

Bowman, however, devised a less orthodox approach for his second crop of each season. Because he thought such late-season planting "risky," he did not want to pay the premium price that Monsanto charges for Roundup Ready seed. Id., at 78a; see Brief for Petitioner 6. He therefore went to a grain elevator; purchased "commodity soybeans" intended for human or animal consumption; and planted them in his fields[41]. Those soybeans came from prior harvests of other local farmers. And because most of those farmers also used Roundup Ready seed, Bowman could anticipate that many of the purchased soybeans would contain Monsanto's patented technology. When he applied a glyphosate-based herbicide to

[41] Grain elevators, as indicated above, purchase grain from farmers and sell it for consumption; under federal and state law, they generally cannot package or market their grain for use as agricultural seed. See 7 U. S. C. §1571; Ind. Code §15–15–1–32 (2012). But because soybeans are themselves seeds, nothing (except, as we shall see, the law) pre- vented Bowman from planting, rather than consuming, the product he bought from the grain elevator.

his fields, he confirmed that this was so; a significant proportion of the new plants survived the treatment, and produced in their turn a new crop of soybeans with the Roundup Ready trait. Bowman saved seed from that crop to use in his late-season planting the next year—and then the next, and the next, until he had harvested eight crops in that way. Each year, that is, he planted saved seed from the year before (sometimes adding more soybeans bought from the grain elevator), sprayed his fields with glyphosate to kill weeds (and any non-resistant plants), and produced a new crop of glyphosate- resistant—i.e., Roundup Ready—soybeans.

After discovering this practice, Monsanto sued Bowman for infringing its patents on Roundup Ready seed. Bow- man raised patent exhaustion as a defense, arguing that Monsanto could not control his use of the soybeans be- cause they were the subject of a prior authorized sale (from local farmers to the grain elevator). The District Court rejected that argument, and awarded damages to Monsanto of $84,456. The Federal Circuit affirmed. It reasoned that patent exhaustion did not protect Bowman because he had "created a newly infringing article." 657 F. 3d, at 1348. The "right to use" a patented article following an authorized sale, the court explained, "does not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." Ibid. (brackets and internal quotation marks omitted). Accordingly, Bowman could not "'replicate' Monsanto's patented technology by planting it in the ground to create newly infringing genetic material, seeds, and plants." Ibid.

We granted certiorari to consider the important question of patent law raised in this case, 568 U. S. (2012), and now affirm.

II

The doctrine of patent exhaustion limits a patentee's right to control what others can do with an article embodying or containing an invention[42]. Under the doctrine, "the initial authorized sale of a patented item terminates all patent rights to that item." Quanta Computer, Inc. v. LG Electronics, Inc., 553 U. S. 617, 625 (2008). And by "exhaust[ing] the [patentee's] monopoly" in that item, the sale confers on the purchaser, or any subsequent owner, "the right

[42] The Patent Act grants a patentee the "right to exclude others from making, using, offering for sale, or selling the invention." 35 U. S. C. §154(a)(1); see §271(a) ("[W]hoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent").
Cite as: 569 U. S. (2013) 5.

to use [or] sell" the thing as he sees fit. United States v. Univis Lens Co., 316 U. S. 241, 249–250 (1942). We have explained the basis for the doctrine as follows: "[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward . . . by the sale of the article"; once that "purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." Id., at 251.

Consistent with that rationale, the doctrine restricts a patentee's rights only as to the "particular article" sold, ibid.; it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item. "[T]he purchaser of the [patented] machine . . . does not acquire any right to construct another machine either for his own use or to be vended to another." Mitchell v. Hawley, 16 Wall. 544, 548 (1873); see Wilbur-Ellis Co. v. Kuther, 377 U. S. 422, 424 (1964) (holding that a purchaser's "reconstruction" of a patented machine "would impinge on the patentee's right 'to exclude others from making' . . . the article" (quoting 35 U. S. C. §154 (1964 ed.))). Rather, "a second creation" of the patented item "call[s] the monopoly, conferred by the patent grant, into play for a second time." Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U. S. 336, 346 (1961). That is because the patent holder has "received his reward" only for the actual article sold, and not for subsequent recreations of it. Univis, 316 U. S., at 251. If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale. Bowman himself disputes none of this analysis as a general matter: He forthrightly acknowledges the "well settled" principle "that the exhaustion doctrine does not extend to the right to 'make' a new product." Brief for Petitioner 37 (citing Aro, 365 U. S., at 346).

Unfortunately for Bowman, that principle decides this case against him. Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator; so too he could consume the beans himself or feed them to his animals. Monsanto, although the patent holder, would have no business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make additional patented soybeans without Monsanto's permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best; applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how "to 'make' a new product," to use Bowman's words, when the original product is a seed. Brief for Petitioner 37; see Webster's Third New International

Dictionary 1363 (1961) ("make" means "cause to exist, occur, or appear," or more specifically, "plant and raise (a crop)"). Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him[43].

Were the matter otherwise, Monsanto's patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, "receiv[e] [its] reward" for the first seeds it sells. Univis, 316 U. S., at 251. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator.

The grower could multiply his initial purchase, and then multiply that new creation, ad infinitum—each time profiting from the patented seed without compensating its inventor. Bowman's late-season plantings offer a prime illustration. After buying beans for a single harvest, Bowman saved enough seed each year to reduce or eliminate the need for additional purchases.

Monsanto still held its patent, but received no gain from Bowman's annual production and sale of Roundup Ready soybeans. The exhaustion doctrine is limited to the "particular item" sold to avoid just such a mismatch between invention and reward.

Our holding today also follows from J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U. S. 124 (2001). We considered there whether an inventor could get a patent on a seed or plant, or only a certificate issued under the Plant Variety Protection Act (PVPA), 7 U. S. C. §2321 et seq. We decided a patent was available, rejecting the claim that the PVPA implicitly repealed the Patent Act's coverage of seeds and plants. On our view, the two statutes established different, but not conflicting schemes: The requirements for getting a patent "are more stringent than those for obtaining a PVP certificate, and the protections

[43] This conclusion applies however Bowman acquired Roundup Ready seed: The doctrine of patent exhaustion no more protected Bowman's reproduction of the seed he purchased for his first crop (from a Monsanto-affiliated seed company) than the beans he bought for his second (from a grain elevator). The difference between the two purchases was that the first—but not the second—came with a license from Monsanto to plant the seed and then harvest and market one crop of beans. We do not here confront a case in which Monsanto (or an affiliated seed company) sold Roundup Ready to a farmer without an express license agreement. For reasons we explain below, we think that case unlikely to arise. See infra, at 9. And in the event it did, the farmer might reasonably claim that the sale came with an implied license to plant and harvest one soybean crop.

afforded" by a patent are correspondingly greater. J. E. M., 534 U. S., at 142. Most notable here, we explained that only a patent holder (not a certificate holder) could prohibit "[a] farmer who legally purchases and plants" a protected seed from saving harvested seed "for replanting." Id., at 140; see id., at 143 (noting that the Patent Act, unlike the PVPA, contains "no exemptio[n]" for "saving seed"). That statement is inconsistent with applying exhaustion to protect conduct like Bowman's. If a sale cut off the right to control a patented seed's progeny, then (contrary to J. E. M.) the patentee could not prevent the buyer from saving harvested seed. Indeed, the patentee could not stop the buyer from selling such seed, which even a PVP certificate owner (who, recall, is supposed to have fewer rights) can usually accomplish. See 7 U. S. C. §§2541, 2543. Those limitations would turn upside-down the statutory scheme J. E. M. described.

Bowman principally argues that exhaustion should apply here because seeds are meant to be planted. The exhaustion doctrine, he reminds us, typically prevents a patentee from controlling the use of a patented product following an authorized sale. And in planting Roundup Ready seeds, Bowman continues, he is merely using them in the normal way farmers do. Bowman thus concludes that allowing Monsanto to interfere with that use would "creat[e] an impermissible exception to the exhaustion doctrine" for patented seeds and other "self-replicating technologies." Brief for Petitioner 16.

But it is really Bowman who is asking for an unprecedented exception—to what he concedes is the "well settled" rule that "the exhaustion doctrine does not extend to the right to 'make' a new product." See supra, at 5. Reproducing a patented article no doubt "uses" it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit others from making the thing his patent protects. See, e.g., Cotton-Tie Co. v. Simmons, 106 U. S. 89, 93–94 (1882) (holding that a purchaser could not "use" the buckle from a patented cotton-bale tie to "make" a new tie). That is because, once again, if simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention. The undiluted patent monopoly, it might be said, would extend not for 20 years (as the Patent Act promises), but for only one transaction. And that would result in less incentive for innovation than Congress wanted. Hence our repeated insistence that exhaustion applies only to the particular item sold, and not to reproductions.

Nor do we think that rule will prevent farmers from making appropriate use of the Roundup Ready seed they buy. Bowman himself stands in a peculiarly poor position to assert such a claim. As noted earlier, the commodity soybeans he purchased were intended not for planting, but for consumption. See supra, at 2–3. Indeed, Bowman conceded in deposition testimony that he knew of no other farmer who employed beans bought from a grain elevator to grow a new crop. See App. 84a. So a non-replicating use of the commodity beans at issue here was not just available, but standard fare. And in the more ordinary case, when a farmer purchases Roundup Ready seed qua seed—that is, seed intended to grow a crop—he will be able to plant it. Monsanto, to be sure, conditions the farmer's ability to reproduce Roundup Ready; but it does not—could not realistically—preclude all planting. No sane farmer, after all, would buy the product without some ability to grow soybeans from it. And so Monsanto, predictably enough, sells Roundup Ready seed to farmers with a license to use it to make a crop. See supra, at 2, 6, n. 3. Applying our usual rule in this context therefore will allow farmers to benefit from Roundup Ready, even as it rewards Monsanto for its innovation.

Still, Bowman has another seeds-are-special argument: that soybeans naturally "self-replicate or 'sprout' unless stored in a controlled manner," and thus "it was the planted soybean, not Bowman" himself, that made replicas of Monsanto's patented invention. Brief for Petitioner 42; see Tr. of Oral Arg. 14 ("[F]armers, when they plant seeds, they don't exercise any control . . . over their crop" or "over the creative process"). But we think that blame-the-bean defense tough to credit. Bowman was not a passive observer of his soybeans' multiplication; or put another way, the seeds he purchased (miraculous though they might be in other respects) did not spontaneously create eight successive soybean crops. As we have explained, supra at 2–3, Bowman devised and executed a novel way to harvest crops from Roundup Ready seeds without paying the usual premium. He purchased beans from a grain elevator anticipating that many would be Roundup Ready; applied a glyphosate-based herbicide in a way that culled any plants without the patented trait; and saved beans from the rest for the next season. He then planted those Roundup Ready beans at a chosen time; tended and treated them, including by exploiting their patented glyphosate- resistance; and harvested many more seeds, which he either marketed or saved to begin the next cycle. In all this, the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto's patented invention.

Our holding today is limited—addressing the situation before us, rather than every one

involving a self- replicating product. We recognize that such inventions are becoming ever more prevalent, complex, and diverse. In another case, the article's self-replication might occur outside the purchaser's control. Or it might be a necessary but incidental step in using the item for another purpose. Cf. 17 U. S. C. §117(a)(1).

We need not address here whether or how the doctrine of patent exhaustion would apply in such circumstances. In the case at hand, Bowman planted Monsanto's patented soybeans solely to make and market replicas of them, thus depriving the company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct. We accordingly affirm the judgment of the Court of Appeals for the Federal Circuit.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

ASSOCIATION FOR MOLECULAR PATHOLOGY ET AL. v. MYRIAD GENETICS. INC. ET AL.

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

[June 13, 2013]

Justice Thomas delivered the opinion of the Court.

Respondent Myriad Genetics, Inc. (Myriad), discovered the precise location and sequence of two human genes, mutations of which can substantially increase the risks of breast and ovarian cancer. Myriad obtained a number of patents based upon its discovery. This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U. S. C. §101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. We, therefore, affirm in part and reverse in part the decision of the United States Court of Appeals for the Federal Circuit.

I

(A)

Genes form the basis for hereditary traits in living organisms. See generally Association for Molecular Pathology v. United States Patent and Trademark Office, 702 F. Supp. 2d 181, 192–211 (SDNY 2010). The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA, which takes the shape of the familiar "double helix" that Doctors James Watson and Francis Crick first described in 1953. Each "cross-bar" in the DNA helix consists of two chemically joined nucleotides. The possible nucleotides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide: A pairs with T; C pairs with G. The nucleotide cross-bars are chemically connected to a sugar-phosphate backbone that forms the outside framework of the DNA helix. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as "exons." Nucleotides that do not code for amino acids, in contrast, are known as "introns."

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used as a template to create a complementary ribonucleic acid (RNA) strand. The nucleotides on the DNA strand pair naturally with their counterparts, with the exception that RNA uses the nucleotide base uracil (U) instead of thymine (T). Transcription results in a single strand RNA molecule, known as pre-RNA, whose nucleotides form an inverse image of the DNA strand from which it was created. Pre-RNA still contains nucleotides corresponding to both the exons and introns in the DNA molecule. The pre-RNA is then naturally "spliced" by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production.

DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well known laboratory methods. These methods allow scientists to isolate specific

segments of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used. It is also possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The result is the inverse of the mRNA's inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as complementary DNA (cDNA).

Changes in the genetic sequence are called mutations. Mutations can be as small as the alteration of a single nucleotide—a change affecting only one letter in the genetic code. Such small-scale changes can produce an entirely different amino acid or can end protein production altogether. Large changes, involving the deletion, rearrangement, or duplication of hundreds or even millions of nucleotides, can result in the elimination, misplacement, or duplication of entire genes. Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical breakthroughs.

(B)

This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can dramatically increase an individual's risk of developing breast and ovarian cancer. The average American woman has a 12- to 13-percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 percent for breast cancer and between 20 and 50 percent for ovarian cancer. Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.

Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million. Association for Molecular Pathology v. United States Patent and Trademark Office, 689 F. 3d 1303, 1328 (CA Fed. 2012). Within

those chromosomes, the BRCA1 and BRCA2 genes are each about 80,000 nucleotides long. If just exons are counted, the BRCA1 gene is only about 5,500 nucleotides long; for the BRCA2 gene, that number is about 10,200. Ibid. Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence.[44] That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient's BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. Nine composition claims from three of those patents are at issue in this case. [45]See id., at 1309, and n. 1 (noting composition claims). Claims 1, 2, 5, and 6 from the '282 patent are representative. The first claim asserts a patent on "[a]n isolated DNA coding for a BRCA1 polypeptide," which has "the amino acid sequence set forth in SEQ ID NO:2." App. 822. SEQ ID NO: 2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes. See id., at 785–790. Put differently, claim 1 asserts a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO: 2.

Claim 2 of the '282 patent operates similarly. It claims "[t]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1." Id., at 822. Like SEQ ID NO:2, SEQ ID NO:1 sets forth a long list of data, in this instance the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1. Importantly, SEQ ID NO:1 lists only the cDNA exons in the BRCA1 gene, rather than a full DNA sequence containing both exons and introns. See id., at 779 (stating that SEQ ID NO:1's "MOLECULE TYPE:" is "cDNA"). As a result, the Federal Circuit recognized that claim 2 asserts a patent on the cDNA nucleotide sequence listed in SEQ ID NO:1, which codes for the typical BRCA1 gene. 689 F. 3d, at 1326, n. 9; id., at 1337 (Moore, J., concurring in part); id., at 1356 (Bryson, J., concurring in part and dissenting in part).

Claim 5 of the '282 patent claims a subset of the data in claim 1. In particular, it claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1." App. 822.

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[44] Technically, there is no "typical" gene because nucleotide sequences vary between individuals, sometimes dramatically. Geneticists refer to the most common variations of genes as "wild types."

[45] At issue are claims 1, 2, 5, 6, and 7 of U. S. Patent 5,747,282 (the '282 patent), claim 1 of U. S. Patent 5,693,473 (the '473 patent), and claims 1, 6, and 7 of U. S. Patent 5,837,492 (the '492 patent).

The practical effect of claim 5 is to assert a patent on any series of 15 nucleotides that exist in the typical BRCA1 gene. Because the BRCA1 gene is thousands of nucleotides long, even BRCA1 genes with substantial mutations are likely to contain at least one segment of 15 nucleotides that correspond to the typical BRCA1 gene. Similarly, claim 6 of the '282 patent claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2." Ibid. This claim operates similarly to claim 5, except that it references the cDNA-based claim 2. The remaining claims at issue are similar, though several list common mutations rather than typical BRCA1 and BRCA2 sequences. See ibid. (claim 7 of the '282 patent); id., at 930 (claim 1 of the '473 patent); id., at 1028 (claims 1, 6, and 7 of the '492 patent).

(C)

Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome. The patents would also give Myriad the exclusive right to synthetically create BRCA cDNA. In Myriad's view, manipulating BRCA DNA in either of these fashions triggers its "right to exclude others from making" its patented composition of matter under the Patent Act. 35 U. S. C. §154(a)(1); see also §271(a) ("[Whoever without authority makes . . . any patented invention . . . infringes the patent").

But isolation is necessary to conduct genetic testing, and Myriad was not the only entity to offer BRCA testing after it discovered the genes. The University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) and others provided genetic testing services to women. Petitioner Dr. Harry Ostrer, then a researcher at New York University School of Medicine, routinely sent his patients' DNA samples to GDL for testing. After learning of GDL's testing and Ostrer's activities, Myriad sent letters to them asserting that the genetic testing infringed Myriad's patents. App. 94–95 (Ostrer letter). In response, GDL agreed to stop testing and informed Ostrer that it would no longer accept patient samples. Myriad also filed patent infringement suits against other entities that performed BRCA testing, resulting in settlements in which the defendants agreed to cease all allegedly infringing activity. 689 F. 3d, at 1315. Myriad, thus, solidified its position as the only entity providing BRCA testing.

Some years later, petitioner Ostrer, along with medical patients, advocacy groups, and other doctors, filed this lawsuit seeking a declaration that Myriad's patents are invalid under

35 U. S. C. §101. 702 F. Supp. 2d, at 186. Citing this Court's decision in MedImmune, Inc. v. Genentech, Inc., 549 U. S. 118 (2007) , the District Court denied Myriad's motion to dismiss for lack of standing. Association for Molecular Pathology v. United States Patent and Trademark Office, 669 F. Supp. 2d 365, 385–392 (SDNY 2009). The District Court then granted summary judgment to petitioners on the composition claims at issue in this case based on its conclusion that Myriad's claims, including claims related to cDNA, were invalid because they covered products of nature. 702 F. Supp. 2d, at 220–237. The Federal Circuit reversed, Association for Molecular Pathology v. United States Patent and Trademark Office, 653 F. 3d 1329 (2011), and this Court granted the petition for certiorari, vacated the judgment, and remanded the case in light of Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U. S. (2012). See Association for Molecular Pathology v. Myriad Genetics, Inc., 566 U. S. (2012).

On remand, the Federal Circuit affirmed the District Court in part and reversed in part, with each member of the panel writing separately. All three judges agreed that only petitioner Ostrer had standing. They reasoned that Myriad's actions against him and his stated ability and willingness to begin BRCA1 and BRCA2 testing if Myriad's patents were invalidated were sufficient for Article III standing. 689 F. 3d, at 1323; id., at 1337 (opinion of Moore, J.); id., at 1348 (opinion of Bryson, J.).

With respect to the merits, the court held that both isolated DNA and cDNA were patent eligible under §101. The central dispute among the panel members was whether the act of isolating DNA—separating a specific gene or sequence of nucleotides from the rest of the chromosome—is an inventive act that entitles the individual who first isolates it to a patent. Each of the judges on the panel had a different view on that question. Judges Lourie and Moore agreed that Myriad's claims were patent eligible under §101 but disagreed on the rationale. Judge Lourie relied on the fact that the entire DNA molecule is held together by chemical bonds and that the covalent bonds at both ends of the segment must be severed in order to isolate segments of DNA. This process technically creates new molecules with unique chemical compositions. See id., at 1328 ("Isolated DNA . . . is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule"). Judge Lourie found this chemical alteration to be dispositive, because isolating a particular strand of DNA creates a non-naturally occurring molecule, even

though the chemical alteration does not change the information-transmitting quality of the DNA. See id., at 1330 (*"The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact. We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature").* Accordingly, he rejected petitioners' argument that isolated DNA was ineligible for patent protection as a product of nature.

Judge Moore concurred in part but did not rely exclusively on Judge Lourie's conclusion that chemically breaking covalent bonds was sufficient to render isolated DNA patent eligible. Id., at 1341 *("To the extent the majority rests its conclusion on the chemical differences between [naturally occurring] and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims to human genes are directed to patentable subject matter").* Instead, Judge Moore also relied on the United States Patent and Trademark Office's (PTO) practice of granting such patents and on the reliance interests of patent holders. Id., at 1343. However, she acknowledged that her vote might have come out differently if she "were deciding this case on a blank canvas." Ibid.

Finally, Judge Bryson concurred in part and dissented in part, concluding that isolated DNA is not patent eligible. As an initial matter, he emphasized that the breaking of chemical bonds was not dispositive: "[*T]here is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken." Id., at 1351. Instead, he relied on the fact that "[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes."* Id., at 1355. Judge Bryson then concluded that genetic "*structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive."* Ibid. More- over, Judge Bryson gave no weight to the PTO's position on patentability because of the Federal Circuit's position that "*the PTO lacks substantive rulemaking authority as to issues such as patentability."* Id., at 1357.

Although the judges expressed different views concerning the patentability of isolated DNA, all three agreed that patent claims relating to cDNA met the patent eligibility requirements of §101. Id., at 1326, and n. 9 (recognizing that some patent claims are limited to cDNA and that such claims are patent eligible under §101); id., at 1337 (Moore, J.,

concurring in part); id., at 1356 (Bryson, J., concurring in part and dissenting in part) *("cDNA cannot be isolated from nature, but instead must be created in the laboratory . . . because the introns that are found in the native gene are removed from the cDNA segment").*[46]

We granted certiorari. 568 U. S. (2012).

II

(A)

Section 101 of the Patent Act provides:

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

We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." Mayo, 566 U. S., at (slip op., at 1) (internal quotation marks and brackets omitted). Rather, " 'they are the basic tools of scientific and technological work' " that lie beyond the domain of patent protection. Id., at (slip op., at 2). As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." Id., at (slip op., at 17). This would be at odds with the very point of patents, which exist to promote creation. Diamond v. Chakrabarty, 447 U. S. 303, 309 (1980) (Products of nature are not created, and " 'manifestations . . . of nature [are] free to all men and reserved exclusively to none' ").

The rule against patents on naturally occurring things is not without limits, however, for "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law." 566 U. S., at (slip op., at 2). As we have recognized before, patent protection strikes a delicate balance between creating "incentives that lead to

[46] Myriad continues to challenge Dr. Ostrer's Declaratory Judgment Act standing in this Court. Brief for Respondents 17–22. But we find that, under the Court's decision in MedImmune, Inc. v. Genentech, Inc., Dr. Ostrer has alleged sufficient facts "under all the circumstances, [to] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." (internal quotation marks omitted).

creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention." Id., at (slip op., at 23). We must apply this well-established standard to determine whether Myriad's patents claim any "new and useful . . . composition of matter," §101, or instead claim naturally occurring phenomena.

(B)

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. In- stead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in Chakrabarty is central to this inquiry. Brief for Respondents 14, 23–27. In Chakrabarty, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U. S., at 305, and n. 1. The Court held that the modified bacterium was patentable. It explained that the patent claim was "not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.' " Id., at 309–310 (quoting Hartranft v. Wiegmann, 121 U. S. 609, 615 (1887) ; alteration in original). The Chakrabarty bacterium was new "with markedly different characteristics from any found in nature," 447 U. S., at 310, due to the additional plasmids and resultant "capacity for degrading oil." Id., at 305, n. 1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry. In Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U. S. 127 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. Id., at 128–129. The ability of the bacteria to fix nitrogen was well known, and farmers commonly "inoculated" their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. Id., at 129–130. Upon learning that several nitrogen-fixing bacteria

did not inhibit each other, however, the patent applicant combined them into a single inoculant and obtained a patent. Id., at 130. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. Id., at 132 *("There is no way in which we could call [the bacteria mixture a product of invention] unless we borrowed invention from the discovery of the natural principle itself").* His patent claim thus fell squarely within the law of nature exception. So do Myriad's. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes "new . . . composition[s] of matter," §101, that are patent eligible.

Indeed, Myriad's patent descriptions highlight the problem with its claims. For example, a section of the '282 patent's Detailed Description of the Invention indicates that Myriad found the location of a gene associated with increased risk of breast cancer and identified mutations of that gene that increase the risk. See App. 748–749.[47] In subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome 17. See Ibid.[48] The '473 and '492 patents contain similar language as well. See id., at 854, 947.

Many of Myriad's patent descriptions simply detail the "iterative process" of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought.[49] See, e.g., id., at 750. Myriad seeks to import these extensive research efforts into the

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[47] The full relevant text of the Detailed Description of the Patent is as follows: "It is a discovery of the present invention that the BRCA1 locus which predisposes individuals to breast cancer and ovarian cancer, is a gene encoding a BRCA1 protein, which has been found to have no significant homology with known protein or DNA sequences. . . . It is a discovery of the present invention that mutations in the BRCA1 locus in the germline are indicative of a predisposition to breast cancer and ovarian cancer. Finally, it is a discovery of the present invention that somatic mutations in the BRCA1 locus are also associated with breast cancer, ovarian cancer and other cancers, which represents an indicator of these cancers or of the prognosis of these cancers. The mutational events of the BRCA1 locus can involve deletions, insertions and point mutations." App. 749. Notwithstanding Myriad's repeated use of the phrase "present invention," it is clear from the text of the patent that the various discoveries are the "invention."

[48] "Starting from a region on the long arm of human chromosome 17 of the human genome, 17q, which has a size estimated at about 8 million base pairs, a region which contains a genetic locus, BRCA1, which causes susceptibility to cancer, including breast and ovarian cancer, has been identified." Ibid.

[49] Myriad first identified groups of relatives with a history of breast cancer (some of whom also had developed ovarian cancer); because these individuals were related, scientists knew that it was more likely that their diseases were the result of genetic predisposition rather than other factors. Myriad compared sections of their chromosomes, looking for shared genetic abnormalities not found in the general population. It was that process which eventually enabled Myriad to determine where in the genetic sequence the BRCA1 and BRCA2 genes reside. See, e.g., id., at 749, 763–775.

§101 patent-eligibility inquiry. Brief for Respondents 8–10, 34. But extensive effort alone is insufficient to satisfy the demands of §101.

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a non-naturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

Finally, Myriad argues that the PTO's past practice of awarding gene patents is entitled to deference, citing J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U. S. 124 (2001). See Brief for Respondents 35–39, 49–50. We disagree. J. E. M. held that new plant breeds were eligible for utility patents under §101 notwithstanding separate statutes providing special protections for plants, see 7 U. S. C. §2321 et seq. (Plant Variety Protection Act); 35 U. S. C. §§161–164 (Plant Patent Act of 1930). After analyzing the text and structure of the relevant statutes, the Court mentioned that the Board of Patent Appeals and Interferences had determined that new plant breeds were patent eligible under §101 and that Congress had recognized and endorsed that position in a subsequent Patent Act amendment. 534 U. S., at 144–145 (citing In re Hibberd, 227 USPQ 443 (1985) and 35 U. S. C. §119(f)). In this case, however, Congress has not endorsed the views of the PTO in subsequent legislation. While Myriad relies on Judge Moore's view that Congress endorsed the PTO's position in a single sentence in the Consolidated Appropriations Act of 2004, see Brief for Respondents 31, n. 8; 689 F. 3d, at 1346, that Act does not even mention genes, much less isolated DNA. §634, 118Stat. 101 ("None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism").

Further undercutting the PTO's practice, the United States argued in the Federal Circuit and in this Court that isolated DNA was not patent eligible under §101, Brief for United States as Amicus Curiae 20–33, and that the PTO's practice was not "a sufficient reason to hold that isolated DNA is patent-eligible." Id., at 26. See also id., at 28–29. These concessions weigh against deferring to the PTO's determination.[50]

(C)

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.[51] Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." Brief for Petitioners 49. They nevertheless argue that cDNA is not patent eligible *because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." Id., at 51. That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature"* and is patent eligible under §101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.[52]

III

[50] Myriad also argues that we should uphold its patents so as not to disturb the reliance interests of patent holders like itself. Brief for Respondents 38–39. Concerns about reliance interests arising from PTO determinations, insofar as they are relevant, are better directed to Congress. See Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U. S. (2012) (slip op., at 22–24).

[51] Some viruses rely on an enzyme called reverse transcriptase to reproduce by copying RNA into cDNA. In rare instances, a side effect of a viral infection of a cell can be the random incorporation of fragments of the resulting cDNA, known as a pseudogene, into the genome. Such pseudogenes serve no purpose; they are not expressed in protein creation because they lack genetic sequences to direct protein expression. See J. Watson et al., Molecular Biology of the Gene 142, 144, fig. 7–5 (6th ed. 2008). Perhaps not surprisingly, given pseudogenes' apparently random origins, petitioners "have failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA." Association for Molecular Pathology v. United States Patent and Trademark Office, 689 F. 3d 1303, 1356, n. 5 (CA Fed. 2012). The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.

[52] We express no opinion whether cDNA satisfies the other statutory requirements of patentability. See, e.g., 35 U. S. C. §§102, 103, and 112; Brief for United States as Amicus Curiae 19, n. 5.

It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents *"were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach,"* 702 F. Supp. 2d, at 202–203, and are not at issue in this case.

Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, *"[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications."* 689 F. 3d, at 1349.

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of §101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material.

* * *

For the foregoing reasons, the judgment of the Federal Circuit is affirmed in part and reversed in part.

It is so ordered.

Texts of the decisions have been downloaded from the webpage: http://lp.findlaw.