

# Biotech patents: looking backward while moving forward

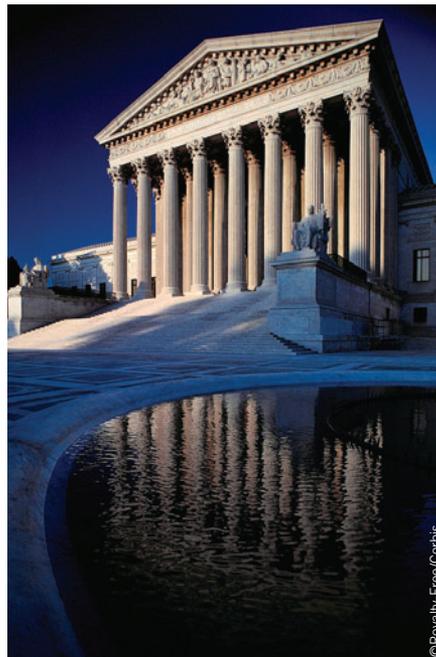
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*Laboratory Corporation v. Metabolite Laboratories* may signal renewed interest on the part of the US Supreme Court in what is, and what is not, patentable in biology.

Although the patent system is designed to promote the progress of science and the useful arts<sup>1</sup>, it is slow to adapt to technological change. The statutory framework for US patent law, which has remained remarkably constant over the past two centuries, sets forth essentially the same rules for inventions in all fields of technology<sup>2</sup>. Some observers have argued that the courts in fact apply these rules differently in different technological fields<sup>3</sup>, but US courts are bound to apply the rules laid down by US Congress and are therefore severely restricted in their ability to fine-tune the law as new technologies arise. Moreover, the common law method makes a discipline of looking backward to resolve new controversies in accordance with precedent, rather than forward in anticipation of change.

On the other hand, patent applicants have every reason to look forward. They stand to profit from drafting patent claims that cover their inventions in a durable way so that those who make incremental adaptations cannot easily get around their patents. Strategic claim drafting is itself an evolving art that advances in tandem with technology, subject to the constraints of patent law.

When patent claims on new technologies present unresolved legal issues, it typically takes years for these issues to reach the point of resolution in the courts. Only in the past year, for example, has the US Court of Appeals for the Federal Circuit had occasion to consider basic questions concerning the patentability of expressed sequence



Murky waters: The US Supreme Court recently granted a review of the case of *Laboratory Corporation v. Metabolite Laboratories*, ostensibly to examine the issue of patent eligibility.

tags (ESTs), a technology that is more than a decade old, and in deciding that case, the court relied on previous decisions involving technologies that are older still<sup>4</sup>. In theory, the focus on precedent in the legal system makes decisions more predictable, promising that future cases will be resolved consistently with past cases. But technological change often leads patent applicants to pursue novel patent claiming strategies that bring new questions into view, creating uncertainty as to the meaning of the applicable rules.

## *Diamond v. Chakrabarty*

Consider, for example, a case that came before the US Supreme Court in the early years of the biotechnology era, *Diamond v. Chakrabarty*<sup>5</sup>. That case involved a patent claim on a genetically modified, oil-eating bacterium. The US Patent and Trademark Office (PTO) rejected the claim on the ground that the subject matter was “living,” setting the stage for lengthy appellate litigation. Previously, living organisms had generally been assumed to be ineligible for patent protection. In keeping with this understanding, pharmaceutical firms that used microbial strains to produce antibiotics had typically sought patent protection on methods of production, but not on the strains themselves<sup>6</sup>. But the basis for exclusion that had been articulated in judicial precedents was not that the organisms were “living,” but rather that they were “products of nature”<sup>7</sup>. The rhetoric of these cases presented nature as having done the heavy lifting, creating products and phenomena with awesome capabilities. The value added by human inventors, consisting primarily of figuring out what nature had done and then making minor adaptations, was relatively trivial.

In the anxious rhetoric surrounding genetic engineering in the 1970s, the relationship between nature and human inventors was pictured quite differently. Rather than merely copying from nature, humans seemed to be altering nature’s plans in unprecedented ways, making the concerns and intuitions that persuaded previous courts to leave natural products and natural phenomena outside the patent system seem inapposite in this context. By the time the issue was presented to the Supreme Court, the anxiety surrounding genetic engineering

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had begun to subside, and medically important genes had been cloned in microorganisms. The commercial potential of biotech had become manifest, and a host of *amicus curiae* briefs from the scientific community urged the court to uphold the patentability of genetically engineered microorganisms<sup>8</sup>.

Perhaps if the Supreme Court had considered the issue promptly after Chakrabarty's patent application was filed in 1972, it would have been more inclined to see the issuance of a patent on living subject matter as unprecedented. Ruling instead in 1980, it saw the exclusion of living subject matter as unprecedented, holding that Congress intended that patent protection be broadly available for "anything under the sun that is made by man."

In stark contrast to the public controversy surrounding the patentability of Chakrabarty's invention, the patenting of DNA sequences in the late 1970s and 1980s drew hardly any attention from the media. Following precedents upholding the patentability of purified versions of such naturally occurring products as adrenaline<sup>9</sup> and vitamin B<sub>12</sub> (ref. 10), the PTO had no trouble allowing patents on "purified and isolated" DNA sequences and recombinant constructs incorporating such sequences. In the early days of the biotech industry, patenting the genes encoding therapeutic proteins looked like a high-tech variation on the familiar practice of patenting drugs. As a matter of legal doctrine, the courts and the PTO treated these inventions as chemicals<sup>11</sup>. Although the analogy may never have been perfect, the characterization provided an extensive body of precedent to consult in establishing the patent ground rules for this emerging field, and doubtless reduced the considerable uncertainty confronting investors in new biotech firms. The scientific community did not register significant opposition to the patenting of DNA sequences until the early years of the Human Genome Project, when the US National Institutes of Health (NIH) began filing patent applications on ESTs<sup>12</sup>. By this point, categorical objections to the patenting of DNA sequences seemed untimely and out of touch.

### Anything under the sun?

Over the past quarter century, following the Supreme Court's broad directive in *Diamond v. Chakrabarty*, the Federal Circuit has gradually eviscerated what once appeared to be time-honored categorical exclusions from the patent system for such subject matter as "business methods"<sup>13</sup> and "mathematical algorithms"<sup>14</sup> in favor of a 'big tent'

approach to patent eligibility. Most of the cases that have raised issues of patent eligibility during this time period have involved information technology rather than biotech.

Since *Diamond v. Chakrabarty*, the Federal Circuit has gradually abdicated its authority to police these boundaries in favor of an approach that collapses the traditional restrictions on patent eligibility into a simple requirement that the invention be "useful".

More important than categorical exclusions in limiting the reach of the patent system for biotech have been the utility and disclosure standards for patent protection<sup>15</sup>.

Recently, however, the Supreme Court has signaled its interest in taking up the threshold issue of patent eligibility once again in a case called *Laboratory Corporation v. Metabolite Laboratories*<sup>16</sup>. This case involves a patent claim to a method of correlating elevated homocysteine levels in body fluids with cobalamin or folate deficiencies. The PTO issued the patent, and the patent holder successfully enforced it both at trial and before the Federal Circuit. The Supreme Court granted Metabolite Laboratories' request for review solely on the question of whether the patent "can validly claim a monopoly over a basic scientific relationship used in medical treatment."

The Supreme Court has been inundated with *amicus curiae* briefs in the *Laboratory Corporation* case, as it was 25 years ago in the *Chakrabarty* case. But whereas almost all of the *Chakrabarty amici* wrote in support of patent eligibility, the *Laboratory Corporation amici* are more sharply divided. Organizations that join Metabolite in urging the Court to rule against patent eligibility include the American Medical Association (Chicago), the American College of Medical Genetics (Bethesda, Maryland), the American College of Obstetricians and Gynecologists (Washington, DC), the Association for Molecular Pathology (Bethesda, Maryland), the Association of American Medical Colleges (Washington, DC), the College of American Pathologists (Northfield, Illinois), the American Heart Association (Dallas, Texas), the American Clinical Laboratory Association (Washington, DC), the American

Association of Retired People (Washington, DC), Computer and Communications Industry Association (Washington, DC), IBM (Armonk, New York), Bear Stearns (New York), Lehman Brothers (New York), and Affymetrix (Santa Clara, California). Several brief writers are urging the Court to refrain from addressing the issue of patent eligibility and to resolve the case on other grounds, including the Solicitor General and American Express Company (New York). Some are frankly more interested in the implications of the case for patents on other kinds of subject matter, including business method patents, than they are in its implications for biomedical subject matter.

### Boundaries of eligibility

Inasmuch as the Federal Circuit did not consider the issue of patent eligibility in the facts of this case, it is highly unusual that the Supreme Court granted review on that issue, suggesting that the Court is going out of its way to find an opportunity to address the topic. The chorus of *amici* that have seized upon this opening to voice their competing views about the expanding reach of the patent system can only confirm the Court's suspicion that the issue is important and timely. But the failure of the Federal Circuit to address the issue of patent eligibility in this case leaves the Supreme Court with a poor record on which to consider the issue. This is particularly troubling because, if and when the Court takes up the topic of patent eligibility, it will be hard pressed to find any guidance on how to draw reasonable subject matter boundaries for the patent system in decisions of the past 25 years. Since *Diamond v. Chakrabarty*, the Federal Circuit has gradually abdicated its authority to police these boundaries in favor of an approach that collapses the traditional restrictions on patent eligibility into a simple requirement that the invention be "useful"<sup>17</sup>. The PTO has ultimately acquiesced in this liberal approach to the threshold requirement of patent eligibility<sup>18</sup>, diminishing the likelihood that the issue will come before the courts for review.

To find authority for limitations on patentable subject matter, the Court would have to go back to its own decisions from the 1970s and earlier. These decisions are riddled with contradictions and were hardly up to the task of guiding examination of the patent claims that were arriving at the PTO 30 years ago.

Yet the aspiration in these decisions to preserve an unpatented "storehouse of knowledge of mankind...free to all men and reserved exclusively to none"<sup>19</sup> remains a worthy and inspiring goal, and one that is

fully consistent with the purpose of the patent system. That so many institutions with a stake in promoting innovation are urging the Supreme Court to return to the teachings of these decisions should be a wake-up call for the Federal Circuit and the PTO that the boundaries of the patent system are badly in need of fortification.

1. US Constitution, Art. 1, § 8, cl. 8.
2. US Patent Act, 35 US Code §§ 1 et seq.
3. Burk, D. & Lemley, M. Policy levers in patent law. 89 *Va. L. Rev.* 1575 (2003).
4. *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).
5. 444 US 1028 (1980).
6. See, e.g., *In re Mancy*, 499 F.2d 1289 (CCPA 1974).
7. See *Funk Bros. Seed v. Kalo Inoculant*, 333 US 127 (1948).
8. For a detailed review of the *Chakrabarty* case, see Eisenberg, R.S. The Story of *Diamond v. Chakrabarty*: Technological Change and the Subject Matter Boundaries of the Patent System. in *Intellectual Property Stories* (eds. Ginsburg, J.C. & Dreyfuss, R.C.) 327-357 (Foundation Press, New York, 2006).
9. *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F.95 (SDNY 1911), *aff'd*, 196 F.496 (2d Cir. 1912).
10. *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4th Cir. 1958).
11. See, e.g., *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied sub nom. Genetics Institute v. Amgen*, 502 US 856 (1991) ("A gene is a chemical compound, albeit a complex one....").
12. See Adler, R.G. Genome research: fulfilling the public's expectations for knowledge and commercialization. *Science* **257**, 908 (1992); Eisenberg, R.S. Genes, patents, and product development. *Science* **257**, 903 (1992); Healy, B. Special report on gene patenting. *N. Engl. J. Med.* **327**, 664 (1992); Kiley, T.D. Patents on random complementary DNA fragments? *Science* **257**, 915 (1992).
13. *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 US 1093 (1999).
14. *AT&T v. Excel Communications*, 172 F.3d 1352 (Fed. Cir.), *cert. denied*, 528 US 946 (1999).
15. 35 US Code §§ 101, 112.
16. *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted*, 126 S. Ct. 543 (2005), *vacated, reconsidered, and cert. granted*, 126 S. Ct. 601 (2005); Supreme Court docket posted at <http://www.supremecourtus.gov/docket/04-607.htm>.
17. See, e.g., *State St. Bank & Trust v. Signature Financial Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1999). ("Unpatentable mathematical algorithms are identifiable by showing they are merely abstract ideas constituting disembodied concepts or truths that are not 'useful.'...to be patentable an algorithm must be applied in a 'useful' way.")
18. *Ex parte Lundgren*, 76 USPQ (BNA) 1385 (Bd. Pat. App. & Interferences 2005); USPTO, Request for comments on interim guidelines for examination of patent applications for patent subject matter eligibility. 70 *Federal Register* 75451 (Dec. 20, 2005).
19. *Funk v. Kalo Inoculant*, 333 US 127, 130 (1948).