Humor columnist Dave Barry once opined, “Without question, the greatest invention in the history of mankind is beer. Oh, I grant you that the wheel was also a fine invention, but the wheel does not go nearly as well with pizza.” Certainly, few biological concoctions have achieved that level of popularity — but with a little luck, your company will produce at least one invention with the potential for measurable success in its target market. But with success comes competition, and that’s where protecting your invention becomes important.

We’re living in a time when donating intellectual property to the public is trendy: Linux, Wikipedia, and Creative Commons are just a few examples. For many readers of BioProcess International who have dedicated their careers to improving the human condition, altruistic concepts such as these may be inherently appealing. However, in the absence of sufficient public funding or philanthropy, the high cost of developing effective biopharmaceuticals must be funded by selling ideas or by selling products embodying those ideas. In this context, patents are essential. Other forms of intellectual property protection are listed in the “Other Forms” box.

US law provides the owners of utility patents with the right to exclude others from making, using, or selling their new and useful process, machine, manufacture, or composition of matter — or any new and useful improvement thereof (1). These are monopoly rights given in exchange for adequately disclosing how to make and use an invention. It is a quid pro quo by which an inventor gives the public enough information so that another expert could carry out the invention, and the public allows a limited monopoly to the inventor, lasting 20 years or so (adjusted for delays). Under this exchange, it’s unacceptable to hold back the best way of carrying out an invention. In fact, a patent can be invalidated for doing so.

Patentable Subject Matter
Volumes have been written regarding what exactly is a “machine, manufacture, or composition of matter,” but for now I’ll focus on a definition for the biopharmaceutical industry, particularly relevant to the production of large-molecule biologics and the products of cell or tissue culture. Composition of matter would include products such as genes and polypeptides such as antibodies and other proteins. Alternatively, a process of manufacture would include methods of purification, expression in a host, or antibody selection (2). Methods of medical treatment (e.g., treating a disease with certain gene products) may also be patented, although enforcement is limited against medical practitioners for using a specific procedure, but not the composition or instrument (3).

Patent protection has long been applied to biologically generated products, but what about large molecules and the engineered microorganisms that produce them? To answer that question, it’s helpful to look at a key US Supreme Court decision in this area from 1980, Diamond v. Chakrabarty (4). In that case, it was ultimately determined that a Pseudomonas genus of bacteria, modified using plasmids to be capable of breaking down oil, was a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity — and thus entitled to patent protection.

Of particular note is the presence of three types of claims in Diamond v. Chakrabarty. As stated in the decision, they are “first, process claims for the method of producing the bacteria; [447 US 303, 306] 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 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 microorganisms are “products of nature,” and (2) that as living things they are not patentable subject matter under 35 USC 101” (4).

Patentability of a process for producing a life form or a product that incorporates a life form was thus not in question. Rather, at issue was whether the life form itself was patentable. In deciding that it was, the court noted that, by using “manufacture” and “composition of matter,” modified by the comprehensive any, Congress plainly contemplated that the patent laws would be given wide scope” (4). It’s interesting to note that the dissent in that case believed Congress had specifically provided protection for plants in the form of plant patents and thus did not intend any other life form to be patentable.

Based in part on the Diamond v. Chakrabarty decision, today the criteria in the US Patent and Trademark Office (PTO) are as follows (5):

• “The laws of nature, physical phenomena, and abstract ideas” are not patentable subject matter.

• A “nonnaturally occurring manufacture or composition of matter — a product of human ingenuity having a distinctive name, character, [and] use” is patentable subject matter.

• “[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 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.’”

• “[T]he production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery” is a “manufacture” under 35 USC 101.

The scope of what’s patentable has come back into question recently, however, particularly in light of a 2008 Supreme Court decision, In re Bilski (6). In that case, broadly worded business method claims were deemed nonstatutory subject matter by the PTO. Business methods, including website-related claims, have given rise to significant backlogs in the PTO. Although Bilski is not strictly related to biotechnology, its decision could affect the biotech industry.

In Bilski, to prevent patent claims from seeking to impermissibly “preempt the use of a fundamental principle,” it was determined that a claim must either be tied to a particular machine or apparatus or transform a particular article into a different state or thing. But in an interesting article from November 2008, Professor Christopher Holman notes that a claim for photosynthesis, which transforms carbon dioxide and water into sugar, would satisfy the transformation test in Bilski but violate an earlier Supreme Court precedent that bars the patenting of natural phenomena (7–9).

Holman describes three cases pending in Federal Court that might further define patent applicability to biotechnology: Ariad v. Lilly, Classen v. Biogen, and Prometheus v. Mayo.
In *Ariad v. Lilly* (involving altered activity of a regulatory protein in a cell), it’s argued that the claims wholly preempt use of a natural biological phenomenon.

In *Classen v. Biogen* (involving methods for determining an optimal immunization schedule based on observing disorders in treatment groups), it was argued that merely observing a correlation between homocysteine and vitamin B levels is not transformative. The federal court affirmed the district court on 19 December 2008, noting that the claims did not meet the *Bilski* test.

And *Prometheus v. Mayo* involves observing the level of a drug metabolite in a patient and making a corresponding dosage adjustment, also argued to be nontransformative.

Consider whether your invention as claimed could be tied to a machine or transform something — or is it merely an attempt to patent natural phenomena? If you have difficulty in deciding, maybe you have something in common with Woody Allen, who once declared, “I am at two with nature.”

**OTHER RECENT SUPREME COURT DECISIONS**

Three recent Supreme Court cases generally affect the patent environment and are thus important to biotechnology. In 2006, *eBay v. MercExchange* altered the playing field for obtaining a permanent injunction against infringement (11). Previously, a permanent injunction was essentially automatic if infringement was found. After this case, however, issuance was determined to be within the trial court’s discretion. The court reasoned that, at least in this case, an injunction would have been hard to enforce, a license route was available, and irreparable harm would have been done by issuing a permanent injunction.

In 2007, *KSR v. Teleflex* somewhat raised the bar for determining what is obvious and thus ineligible for patent protection (12). This is a double-edged sword: As a manufacturer, you may be spared having to defend against patents that should never have been issued. For inventors, the road to obtaining patents could be more difficult. Before this case, we looked at whether what was already known (the “prior art”) would have either taught, suggested, or motivated those “skilled in the art” to produce a claimed invention. Now, although the same factors are relevant, we must also consider that people skilled in the art would use a certain measure of common sense and creativity, particularly when motivation is implicit in the prior teachings.

Also in 2007, in *MedImmune v. Genentech* (13), it was determined that a licensee could sue for a declaratory judgment of invalidity while continuing to honor a license agreement. Previously, you had to first repudiate a license agreement under the theory that a justiciable controversy required a reasonable apprehension of being sued. The court reasoned that fear of an injunction or treble damages for infringement acted as a form of coercion, thus giving rise to the justiciable controversy.

An additional case of interest is *Biomedical Patent Management Corp. (BPMC) v. California Department of Health Services* (14, 15), wherein it was argued that the state could not at once rely on the 11th amendment to claim immunity from paying for infringement and extensively use the Federal patent system for its own benefit. The court (16) affirmed in favor of the state, placing limitations upon the circumstances in which a state can be deemed to have waived immunity, the court relying on an intervening Supreme Court decision, *Florida Prepaid* (17), which determined that the Patent Act could not abrogate a state’s sovereign immunity. The Supreme Court refused to hear the case (18), leaving the federal circuit decision to stand.

**POLITICS AND PATENT REFORM**

The PTO is falling behind, and as part of efforts to address the problem it has proposed rules that could have a profound effect on the patenting process in the United States. At one point late in 2008, it had planned to implement new rules that would, among other things, reduce the number of attempts allowed to convince the PTO of patentability, and reduce the number of continuing (related) applications having the same priority date (19). The office attempted to implement those rules without Congressional action, and a lawsuit succeeded in stopping their implementation (20, 21). But the PTO continues to pursue these reforms (21).

A peer review program is also being evaluated that would enable the public to search for related prior art and provide a PTO examiner with art deemed most closely related (22). The goal was to ensure that the most relevant art is considered, so the quality of issued patents would rise because of the greater likelihood that all relevant art is considered.

The Patent Reform Act of 2007 (passed by the House in 2008) proposed to bring US patent law more into line with international laws, particularly with respect to who has priority when there are two inventors of the same invention (23, 24). Uniquely in the United States, the first to invent is considered entitled to patent protection. In the rest of the world, however, it’s the first to file a patent application. The act would have additionally reduced infringement damages, limited the choice of venue for litigation, increased opportunity for postgrant opposition, and given more power to the PTO for enacting regulations (23, 24). Now that we have a Democratic president, some parties promoting this Act will change, and it’s likely that alternative measures will be considered, such as the Patent Reform Act of 2009 (S.515), which was approved by the Senate Judiciary Committee on 2 April 2009 (25). Among other things, this act moves the United States toward a first-to-file system, codifies and defines certain aspects of damages, and excludes the “best mode” requirement as a basis for holding patents invalid or unenforceable under certain circumstances.

Barack Obama paid attention to patent law issues in his campaign, and he supports patent law reform (26–28). Part of his plan included providing more resources to the PTO as well as a more open process including citizen review. In addition, he suggested an
opportunity for the office to conduct an additional administrative procedure for postgrant administrative review of patent validity when a patent is asserted against a claimed infringer (26–28).

Certain online blogs provide good, up-to-the-minute patent information, including Patenty-O (http://patentlaw.typepad.com), the Patent Barista (http://patentbaristas.com), and Patent Docs (http://patentdocs.typepad.com), the latter focusing exclusively on biotechnology. In a recent post there, it was pointed out that President Obama modified his website to remove references to patents forged to be “gold plated” by extensive public peer review, but that he maintains an emphasis on citizen review for the purposes of reducing uncertainty and wasteful litigation. It’s not clear what further process might be introduced, but this is clearly an area in which significant change may be realized. A peer review process currently being evaluated could be expanded (22).

Many issues remain unresolved, and campaign promises are not always kept. Thus, the future of patent law and its effect on the biopharmaceutical industry cannot be gauged with certainty. Perhaps that’s all for the best, for in the words of Mary Wolcottscraft Shelley, “Invention, it must be humbly admitted, does not consist of creating out of void, but out of chaos.”

REFERENCES


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