

**B**iotech patent applicants will have to put in more legwork to prove non-obviousness following an April 3 ruling from the U.S. Court of Appeals for the Federal Circuit. The decision almost certainly will be viewed by the U.S. Patent and Trademark Office as further justification to reject patent applications claiming biotech inventions.

In affirming the decision of the Board of Patent Appeals and Interferences in *In re Kubin*, the Federal Circuit rejected a DNA patent application on the basis that “the claimed invention was reasonably expected in light of the prior art and ‘obvious to try.’” Biotech company Amgen’s patent

## Federal Circuit applies ‘obvious to try’ standard to DNA patents

application claimed “a classic biotechnology invention — the isolation and sequencing of a human gene that encodes a particular domain of a protein.” More specifically, the application claimed DNA molecules encoding a protein known as the Natural Killer Cell Activation Inducing Ligand (“NAIL”). Natural Killer (NK) cells play a major role in fighting tumors and viruses. NAIL is a specific receptor protein on the cell surface that plays a role in activating the NK cells.

The Board rejected Amgen’s claim in 2007 on two grounds: inadequate written description for failing to describe any sequence variants despite claims that encompassed variants, and obviousness. On appeal, the Federal Circuit only addressed the issue of obviousness.

The Board found that, because of NAIL’s important role in the human immune response, “one of ordinary skill in the art would have recognized the value of isolating NAIL cDNA, and would have been motivated to apply conventional methodologies...to do so.” Invoking the U.S. Supreme Court’s decision in *KSR International Co. v. Teleflex Inc.*, the Board concluded that Amgen’s claim was rooted in “ordinary skill and common sense,” as opposed to innovation. The Board determined that NAIL cDNA “is not patentable, as it would have been obvious to isolate it.”

“In *KSR*, the Supreme Court pointed out that the Federal Circuit’s standard teaching-suggestion-

motivation test was essentially putting a heavier burden of proof on the Patent Office beyond what was required under *Graham*, such that some claims that should have been rejected as obvious were being allowed by the Patent Office,” says John Kilyk, a member in Leydig’s Chicago office. “The Supreme Court said that you can factor in common sense when considering obviousness and opened the door to rejections on the basis of ‘obvious to try.’”

In *Kubin*, the Federal Circuit determined that the Board had sufficient evidence to demonstrate that ordinary artisans in the field had every motivation to seek and every reasonable expectation of success in achieving the sequence of the claimed invention. In that sense, according to the Federal Circuit, the claimed invention was “obvious to try.”

“The standard for considering obviousness is determining who counts as a person of ordinary skill, and then deciding whether the claimed invention would have been obvious to that person,” says Dan Hefner, a member in Leydig’s Chicago office. “The court focused on a standard biotech laboratory manual, which set out how to identify and isolate a gene using standard techniques. And since *Kubin* referenced this manual in the patent application, it was even easier for the court to use it as a basis for holding the invention obvious.”

The Federal Circuit explicitly indicated that the situation in *Kubin* was not analogous to situations in which the prior art provided “no direction as to which of many possible choices is likely to be successful” or “only general guidance as to the particular form of the claimed invention or how to achieve it.”

“If there’s a story to tell about why a claim isn’t so obvious, we really have to tell the story. Something in the prior art that teaches away from the invention or the existence of surprising results can be extremely helpful,” says Kilyk. “The days of merely telling the Patent Office that no one has done this before, without explaining why this was not an obvious thing to do, are over.”

“This decision will be taken very seriously in the biotech field,” says Hefner. “It’s a clear explanation from the Federal Circuit of how it views *KSR* in relation to biotech claims, and it’s an important case to consider not only in prosecution, but also in litigation, as well as due diligence investigations and licensing.”

# Federal Circuit weighs in on new rules in *Tafas v. Doll*

The U.S. Court of Appeals for the Federal Circuit has issued its decision in *Tafas v. Doll*, vacating the grant of summary judgment for three Patent Office rules and declaring one of the rules invalid.

In the District Court, the plaintiffs moved for summary judgment and sought a permanent injunction against the United States Patent and Trademark Office's (USPTO) new limits on claims and continuations. The plaintiffs argued that some of the Final Rules were "impermissibly substantive, inconsistent with law, arbitrary

and capricious, incomprehensibly vague, impermissibly retroactive, and procedurally defective." The District Court agreed, granting the motion for summary judgment.

On appeal, the Federal Circuit concluded that four of the Final Rules in question are procedural and therefore within the USPTO's authority. However, the Federal Circuit found Final Rule 78, which limits continuations, to be invalid due to a conflict with Section 120 of the U.S. Patent Code.

The Federal Circuit affirmed the District Court's finding that Final Rule 78 is invalid,

vacated the grant of summary judgment for the other three rules, and remanded the case.

"There are several different scenarios for this case," says John Augustyn, a member in Leydig's Chicago office. "If the Federal Circuit denies the pending requests for a rehearing or a rehearing *en banc*, a petition for certiorari to the Supreme Court could be filed, or the case could go back to the District Court. Or the USPTO may decide to withdraw the new rules and start again."

We will keep everyone advised.

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## Supreme Court to decide on business method patents

On June 1, 2009, the U.S. Supreme Court agreed to decide *Bilski v. Doll*, a case that will have far-reaching implications for patents and pending patent applications directed to software, financial strategies and other business methods. The case specifically involves whether a process of managing risk costs of a commodity is patentable.

The Court of Appeals for the Federal Circuit determined that Bilski's business method did not qualify for patent protection because it was not tied to a particular machine and did not transform a particular article into a different state or thing.

This decision marks a sharp turn from the Federal Circuit's 1998 decision in *State Street Bank*. In that case, the Federal

Circuit held that any "process" that yielded a "useful, concrete and tangible result" could be patented. The PTO read *State Street Bank* expansively and, over the past ten years, issued many business method patents that arguably do not satisfy the test announced in *Bilski*.

The Supreme Court's decision, expected later this year, will affect a substantial

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## Products-by-process claims cover only products prepared by process steps recited in those claims

The Federal Circuit finally resolved the conflict over the interpretation of product-by-process claims caused by the divergent decisions of *Scripps Clinic* and *Atlantic Thermoplastics*. The Federal Circuit held in *Abbott Laboratories v. Sandoz, Inc.* (May 18, 2009) that process steps limit the scope of product-by-process claims — at least in considering infringement. The Federal Circuit took up the matter *en banc*, without notice to potential amicus parties, in the course of a more typical panel consideration of consolidated appeals of summary judgment and the denial of a preliminary injunction. Both decisions were premised on the construction of product-by-process claims.

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The patent in issue included claims for crystalline cefdinir, "which is obtainable

by" process steps recited in the claims. In affirming the District Courts' rulings, the Federal Circuit held that only product produced by these same process steps could infringe these claims. As a result, the Federal Circuit adopted the view espoused in *Atlantic Thermoplastics* and overruled its earlier *Scripps Clinic* decision, which indicated that such claims could encompass the same product made by a different process.

The decision in *Abbott*, however, revealed sharply differing views within the Federal Circuit.

In an opinion by Judge Rader, the Federal Circuit held that the process steps in product-by-process claims always limit the scope of such claims. The majority opinion explained that this view finds extensive support in a

variety of Supreme Court opinions, which "consistently noted that process terms that define the product in a product-by-process claim serve as enforceable limitations."

A dissenting opinion was provided by Judge Newman. Her opinion raised concerns that the *sua sponte en banc* decision provided no opportunity for amicus briefs and asserted that the majority opinion ignored situations where a new product can only be described in terms of process steps.

Judge Lourie also authored a shorter, dissenting opinion in which he asserted that the case law cited by the majority addressed product-by-process claims in which the recited process was used to produce old products, as opposed to new products.

## Second Circuit holds that sale of trademark as a keyword is 'use in commerce'

The U.S. Court of Appeals for the Second Circuit recently clarified the definition of "use in commerce," which must be shown by the trademark owner to support a finding of trademark infringement under the Lanham Act. In *Rescuecom Corp. v. Google, Inc.*, the Second Circuit vacated a District Court's dismissal of Rescuecom Corp.'s lawsuit for trademark infringement against Google, and it held that Google's sale of Rescuecom's trademark as a keyword amounted to "use" of the trademark "in commerce" and was actionable in federal court.

The case arose from Google's AdWords and Keyword Suggestion Tool programs. Through the AdWords program, Google sold "Rescuecom" as a keyword to competitors of computer repair company Rescuecom. As a result, when people searched for "Rescuecom," advertisements of Rescuecom's competitors appeared in the "Sponsored Links" section of Google's search results. Through its Keyword Suggestion Tool, Google also recommended the "Rescuecom" keyword to competitors. Concerned by these practices, Rescuecom brought claims for trademark infringement and dilution against Google.

"To succeed, Rescuecom has to show that Google used the 'Rescuecom'

trademark in commerce under the Lanham Act," says Caroline Stevens, a member in Leydig's Chicago office. "The Second Circuit found that Google used the mark in commerce to sell its own advertising services," adds Stevens.

The lower court had based its decision on the Second Circuit's earlier decision in *1-800 Contacts, Inc. v. WhenU.com*.

"In the *1-800 Contacts* case, the Second Circuit held that WhenU did not use 1-800 Contacts' trademark within the meaning of the Lanham Act," says Boris Umansky, an associate in Leydig's Chicago office. In that case, WhenU.com, an Internet marketing company, caused pop-up ads for 1-800's competitors to appear after an Internet user accessed 1-800's Web site.

"However, in the *Rescuecom* decision, the Second Circuit went to great lengths to distinguish the two cases," says Umansky.

The Second Circuit noted in its decision, "[I]n contrast to *1-800*, where we emphasized that the defendant made no use whatsoever of the plaintiff's trademark, here what Google is recommending and selling to its advertisers is Rescuecom's trademark."

"The Second Circuit did not overrule *1-800 Contacts*, but in looking at the facts specific to this case, in which a keyword

purchase could trigger ads, they saw it as a clear example of 'use in commerce,'" Umansky says. "They also took issue with Google's Keyword Suggestion Tool, stating that the search engine's recommendation and sale of trademarks as keywords is not purely an internal use, as Google had argued."

"Rescuecom alleged that Google makes 97 percent of its revenue through its AdWords program. Presumably, the case is a priority to both Google and Rescuecom, but the case is not won or lost for either party yet," says Stevens. "To succeed with regard to the infringement claims, Rescuecom still must show that there is a likelihood of consumer confusion." The case has been remanded to the District Court for this determination.

"This decision is important because, after a series of mixed rulings, it clarifies the meaning of 'use in commerce' and provides guidance," says Umansky.

Despite the *Rescuecom* ruling, "use in commerce" in the Digital Age is still a nebulous concept. In an Appendix to the decision, the Second Circuit acknowledged that the statutory meaning of "use in commerce" is ambiguous, and stated, "It would be helpful for Congress to study and clear up this ambiguity."

## European patent fees increase; other changes looming

The European Patent Office (EPO) has introduced a series of new rules in an overall effort to speed up the patent prosecution process. Changes to the EPO fee structure became effective April 1, 2009, while changes to search report practices, multiple claims and divisional applications will go into effect April 1, 2010.

Fee changes include a €12 charge for each additional page over 35 pages for European patent applications including original, divisional, and regional phase applications. Additional fee changes include a new €500 fee for each claim after the 50th. The previous charge of €200 per claim for claims 16 through 50 remains in effect.

"Prior to these changes, the EPO was charging a small, flat fee per claim, and applicants were filing numerous claims at once," says Xavier Pillai, a member in

Leydig's Chicago office. "This increased the burden on the examiner because each claim needed to be researched and examined. The hope is that the added expense will keep the numbers lower."

As of April 1, 2010, applicants will be required to respond to objections found in search reports even before a formal examination report is prepared by the European examiner. These rules will affect patent applicants who normally file European patent applications through the Patent Cooperation Treaty route.

If these applicants had asked the EPO to carry out a patentability search, then soon after entering the European regional phase, they must file a response to the objections found in the international search report. Otherwise, the European application will be deemed withdrawn. In addition, the EPO

has restricted applicants' ability to submit voluntary amendments.

The EPO has also introduced new time limits for filing divisional applications. As of April 1, 2010, applicants will have 24 months to file a divisional from the date of the first examination report. Current rules allow filing of multiple divisionals without a time limit.

"To cope with the tightened deadlines and increased costs, clients should rethink their patent filing strategy," says Pillai. "For example, in the international stage, it should be decided whether or not the EPO will be designated as the searching authority. Further, patent applications should be drafted clearly, presenting the most important invention first. And, since divisional applications are expensive to file and prosecute, patent applications should avoid unity of invention issues."

## Leydig Announces

### Events

Leydig, Voit & Mayer is proud to be a sponsor at the Intellectual Property Owners Association Annual Meeting, to be held Sept. 13-15, 2009, at the Hilton Chicago.

The firm sponsors a robust summer program, and the following law students will be introduced to the practice of intellectual property law:

**Elizabeth M. Crompton\*** (chemistry) is a student at George Mason University, class of 2010.

**Michael J. Brandt** (general engineering) is a student at Chicago-Kent College of Law, class of 2011.

**James E. Quigley** (electrical engineering) is a student at the University of Texas School of Law, class of 2011

**Damien J. Howard** (electrical engineering) is a student at Northwestern University School of Law, class of 2010

**John E. Munro** (mechanical engineering) is a student at the University of Illinois College of Law, class of 2010.

\*Elizabeth will participate from Leydig's Washington, D.C. office. All other participants will be located in the firm's Chicago office.

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number of issued patents and pending patent applications pertaining to business methods. Moreover, the "machine-or-transformation" test may have broader implications. Patent applicants may now have to tie inventive software and even industrial processes to a particular machine, or claim a process that otherwise transforms an article into a different state or thing.

Obtaining patent protection for business methods undoubtedly will become more difficult if the Supreme Court affirms the Federal Circuit's decision. However, many valuable business methods may still satisfy the more stringent machine-or-transformation test if drafted carefully.

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