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Patents

Federal Circuit's *Tafas* Decision Could Affect Life Sciences Patents Adversely, Experts Say

In a closely watched case testing the rulemaking authority of the U.S. Patent and Trademark Office, the U.S. Court of Appeals for the Federal Circuit March 20 held that the agency had authority to promulgate rules that, according to plaintiffs, may radically change patent prosecution practice (*Tafas v. Doll*, Fed. Cir., No. 2008-1352, 3/20/09).

Reaction among life sciences attorneys to the decision, which grants PTO rulemaking authority to restrict patent applications, was swift and negative.

The Federal Circuit decision in *Tafas* vacates the district court's barring of new PTO rules that limit the number of an applicant's requests for continued examinations and the number of independent claims. According to attorneys contacted by BNA, the rules illegally expand the PTO's rulemaking authority, as the court held that only the PTO rule limiting continuation applications is invalid.

Christine Vito, a senior biotech patent attorney at K&L Gates, Boston, told BNA March 24 that the appeals court decision has the potential to adversely affect the life sciences industry, especially smaller firms that do not have big bankrolls to finance their discoveries but where innovation is most likely to occur.

''For life sciences companies, there is no unencumbered path to success. It is an iterative path, where you try things and try other things and bring your patent portfolio along with you. It's the type of technology that needs time to cook through R&D and then the Food and Drug Administration. If you are told you only have so many bites of the apple, so many requests for continued examination, so many independent claims to secure patent protection, I am not sure where the fortune-telling skills that would then be necessary are going to come from,'' Vito said.

Cost and certainty are important factors in the life sciences, which relies on the patent system for exclusivity and to create barriers in the marketplace, Vito said. ''This decision allows most of the new rules, and the rules change the balance,'' she said.

''The rules alter the pursuit of patent protection through the actions of an administrative agency so that it is more expensive, less certain, and more cumbersome, and they do not take into account industry standards and the public policy concerns that are part of the legislative process. If there is to be a shift in the patent system in order to produce better patents, a unilateral approach by the PTO is not the way to go,'' Vito said.

George C. Best of Foley & Lardner LLP, Palo Alto, Calif., told BNA March 24 that, ''Because the Obama administration has not identified its choices for PTO leadership, we do not know if the new administration will continue to pursue the changes that were at issue. But if they choose to do so and if the PTO prevails in the litigation that will follow on remand, patent prosecution will become more expensive and complicated.''

Some commentators claimed the court's rejection of the PTO's attempt to limit continuation applications amounted to a victory for inventors like plaintiff Triantafyllos Tafas and health care companies like plaintiff GlaxoSmithKline, but others feared that a concurring opinion by Judge William C. Bryson gave the PTO the means to create a conforming rule that would be equally restrictive and negatively affect the life sciences industry most of all.

The Biotechnology Industry Organization, which filed an amicus brief on behalf of GSK, told BNA it had no comment on the decision.

Procedural, Not Substantive. The four relevant PTO rule changes were issued in August 2007. New Rule 78 sets a threshold limit of two continuation applications, and Rule 114 sets a limit of one request for continued examination, or RCE. Applicants attempting to exceed those limits must show that the ''amendment, argument, or evidence sought to be entered could not have been previously submitted.'' Rule 75 permits applicants to present a total of five independent claims and 25 total claims. Applicants wishing to exceed those limitations must provide an examination support document (ESD) to assist the examiner in determining patentability. Rule 265 establishes the requirements for an ESD.

The U.S. District Court for the District of Columbia on April 1, 2008, permanently enjoined implementation of the rules, stating that the PTO did not have substantive rulemaking authority and that the new rules were substantive and not procedural (2 LSLR 270, 4/11/08). The PTO appealed (2 LSLR 353, 5/9/08)

In the 2-1 March 20 decision, the Federal Circuit held that the new PTO rules are procedural and so within the scope of the agency's authority under the Administrative Procedure Act and Section 2(b)(2) of the Patent Act. The court vacated the district court's summary judgment enjoining the rules but concluded that Rule

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78 restricting continuations is invalid due to conflict with Section 120. In a twist, though, a concurring opinion questioned whether a modification of the rule to cover serial continuations would still present the same conflict, potentially opening a new round of debate on that key issue.

In her remand, Judge Sharon Prost made it clear that the decision was less than definitive for the PTO since the appellate opinion did not decide whether any of the rules, either on their face or as applied, were arbitrary or capricious; whether any of the rules conflicted with the Patent Act in ways not specifically addressed by the Federal Circuit; whether all PTO rulemaking is subject to the notice and comment provisions of the Administrative Procedure Act (APA), 5 U.S.C. § 553; whether any of the rules were impermissibly vague; and whether any of the rules were impermissibly retroactive. Prost said the circuit court believes these ''remain . . . for the district court on remand.''

Concept of 'Procedural' Broadened. In dissent, Judge Randall R. Rader wrote that because he viewed the rules at issue as substantive he would have held that they exceeded PTO authority and affirmed the district court's ruling. Rader also dissented with respect to the majority's conclusion that Rules 75, 114, and 265 were properly adopted.

Vito said that she was personally surprised by the decision. ''I thought the Federal Circuit would have affirmed the findings of the lower court, but instead they showed a high degree of deference to the PTO as an administrative body promulgating rules and regulations.''

According to Michael M. Murray of Milbank, Tweed, Hadley & McCloy, New York, ''the majority seems to be effectively broadening the PTO's rulemaking authority.'' While the opinion was clear that the PTO lacks substantive rulemaking authority, he added, it ''seems to broaden the scope of what rules will qualify as procedural by rejecting the 'affect individual rights and obligations' test used in the past to differentiate procedural from substantive rules.''

Courtenay C. Brinckerhoff of Foley & Lardner, Washington, said the majority's decision seems ''to give the PTO a lot of power where we were hoping that its power would be restrained.'' She found particularly troubling the court's statement that the substantive/procedural distinction should be litigated on a rule-by-rule basis. ''In this economy, how many people are going to have the time and money to get a decision?'' she asked.

Rule 78 Invalidity Mitigates Impact? Some commentators argued that the decision's impact is mitigated by the rejection of Rule 78. In fact, John M. Desmarais of Kirkland & Ellis, New York, who represented plaintiff-appellee Smith-KlineBeecham Corp. d/b/a GlaxoSmith-Kline in the case, said that, for his client, stopping the implementation of Rule 78 was ''the primary goal'' (though he added, ''Of course, we don't like the rest of the rules either'').

Jill Uhl of Arizona Technology Enterprises, Scottsdale, Ariz., told BNA, ''At least the court got it right in the case of Rule 78. The limit on continuations would have been a huge issue for life sciences companies. This was the one change that I thought had to be blocked to avoid making patent protection unavailable to pharmaceutical companies. As long as you can file continuations, the limit on claims is less problematic. For example, I can limit my claims to five independent claims and file a continuation to pursue additional independent claims.''

However, William Gaede, cochair of McDermott Will & Emery's life sciences practice in Menlo Park, Calif., and a life science trial lawyer, told BNA that the invalidation of Rule 78 would not stop the additional cost of prosecution if the ruling stands.

''If upheld, the decision allowing the rules will raise the costs of prosecution and also delay the ability of life science companies to obtain comprehensive patent coverage for their products and processes,'' Gaede said. ''The reason for this is that Final Rule 78 on restricting the number of continuation applications as a matter of right to two was struck down, and thus an applicant may continue to apply for as many continuation applications as otherwise proper. However, Final Rule 75 was upheld and that rule limits the number of independent claims and total claims in an application to 5 and 25, respectively. The limits on the number of claims and the practical effect that subject matter will have to be pursued in continuations to obtain comprehensive coverage will delay the ability of the entity to obtain comprehensive coverage, potentially to its detriment.''

When asked to elaborate, Gaede said, ''There may be an inability or delays to enforce or license/monetize intellectual property because issued patents are delayed and, perhaps more importantly, a cloud could be put on the financing efforts because the entity has not yet obtained sufficient issued patent coverage for its product or process such that investors are confident that the intellectual property assets can be protected.''

Bryson's Unanswered Question. There was considerable concern about a comment in the concurring opinion. Bryson said that, while he agreed with Prost that Rule 78 was not consistent with the statute and, therefore, could not be upheld, an unanswered question remains: ''whether [Rule 78] is invalid as applied to serial continuances; i.e., a series of continuances in which each was co-pending with its immediate predecessor, but in which only the second in the series was co-pending with the first application.''

Kevin T. Kramer of Pillsbury Winthrop Shaw Pittman, Washington, who submitted an amicus brief on behalf of Elan Pharmaceuticals Inc., said that Bryson's question signaled a possible strategy for the PTO to pursue in the future. A colleague of Murray's at Milbank Tweed, Blake Reese, read Bryson's potential modification of Rule 78 as ''a de facto advisory opinion for the PTO.''

Stephen G. Kunin, with Oblon, Spivak, McClelland, Maier & Neustadt, Alexandria, Va., said such a change would affect the pharmaceutical, chemical, and biochemical industries the most since that is ''where you see the greatest number of chains of continuations.'' Because companies in those industries do not know where the value is going to be until after market approval, he said, serial continuances are important to their patent rights.

Another concern of commentators is that the majority opinion found the ESD to be ''a facially reasonable procedural requirement'' that could be challenged later if implementation ''makes compliance essentially impossible and substantively deprives applicants of their rights.''

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''The ESD is a huge change in patent practice,'' Robert Greene Sterne of Sterne Kessler Goldstein Fox, Washington, said, anticipating that both plaintiff-appellants may be concerned enough to continue litigation on that point specifically. ''Any time there is a fundamental breakthrough, there is also a high likelihood of exceeding the claim limits,'' he added.

Uhl said, ''I doubt that anyone will be willing to file an ESD regardless of whether it actually switches the burden or not. There is too much to lose by characterizing the prior art in the manner required.''

Gaede noted that the ESD does address his concerns about the limit to the number of claims and the practical effect that subject matter will have to be pursued in continuations, but he stressed that it does so at an additional cost and with additional risks.

''The rules limiting the number of claims do permit additional claims to be filed so long as the applicant files an ESD. But this is very unpopular because it requires a pre-examination prior art search and providing to the Patent Office a list of the most relevant references, an explanation of how each independent claim is patentable over the references, and a showing of where in the specification each limitation is disclosed in accordance with 35 U.S.C. § 112, first paragraph. This is a burdensome, costly, and cumbersome procedure that also gives rise to fears of creating a record for inequitable conduct. There is no specific impact on life science companies in general as it applies to all companies, but it is a way to pursue in the initial application greater than 25 claims—but at greater cost—than under the old rules,'' Gaede said.

Questions on Remand. None of the commentators thought the questions Prost posed for the district court to address on remand represented any specific signal to that court. ''The first time I read it, I thought it was a road map'' to overturn the remaining rules, Brinckerhoff said, but on further review, she said she did not think plaintiffs' arguments were strong. Most commentators agreed that the record in the lower court was not fully developed, and the lower court's summary judgment opinion was narrow and focused.

Bradley C. Wright of Banner & Witcoff Ltd., Washington, suggested that the Federal Circuit wanted the issues reflected in the remanded questions ''fleshed out in more detail'' before ruling.

Asked whether patent practitioners should do anything differently in light of the decision, Reese said that, if Rules 75 and 265 ultimately are enacted, those applicants who expect to exceed the claim limits ''should consider accelerated examination via a petition to make special. An applicant that satisfies the requirements of an ESD also will substantially satisfy the requirements for such a petition, and 'special' applications will typically have a shorter time to issuance.''

But Murray suggested a wait-and-see approach and Wright said that there is ''nothing that applicants could or should do at this point to take advantage'' of the decision. Still, Scott A. Felder of Wiley Rein, Washington, said that, given that it is unclear what time frames will apply to ESD requirements for pending cases, it might be wise to look at applications that might need RCE or divisional applications now.

What's Next? The PTO March 20 issued a statement saying it was ''pleased'' with the decision insofar as it ''confirmed that the final rules are within the agency's rulemaking authority and that the rules regarding requests for continued examination, claims, and examination support documents are consistent with the law.'' However, the statement continued that the agency is ''further considering other aspects of the opinion, including the Federal Circuit's conclusion that the rule regarding continuations conflicts with the Patent Act.'' In a separate March 23 statement, the PTO said that in light of the remand, it will not be implementing the rules at this time.

Both Desmarais and Steven J. Moore of Kelley Drye & Warren, Stamford, Conn., who represented plaintiff-appellee Tafas, told BNA they were considering their options, including whether or not to petition for a rehearing en banc at the Federal Circuit or fight over the remaining questions in the district court.

''We surely haven't seen the end of this,'' Vito said. ''The decision was not unanimous, and Judge Rader gave a strong dissent. There's the remand, appeal to the full panel, and possibly to the Supreme Court. And we haven't heard the end of debating whether the rules are procedural or substantive.''

Many commentators noted that the injunction is still in effect, and Kunin said that, so long as litigation continues in some form, it will be many months before any final decision is made that would give the PTO the authority to make any final rules effective. However, James D. Crowne, director of communications at the American Intellectual Property Law Association, Arlington, Va., told BNA the injunction could well be lifted as to claim limitations if the district court finds no alternative grounds to hold them unauthorized.

Vito suggested that there was a possibility that the PTO might take a fresh look at the rules. ''They could go back to the drawing board and reflect on what their customers are saying. Look, the PTO is undergoing what is the worst nightmare of every person in business: they can't keep up with demand. Perhaps the PTO became impatient with the slowness of patent reform in Congress and decided to flex its rulemaking muscles. But the path they've chosen is not the best way to accomplish what they want to accomplish. It needs a concerted effort among all parties involved. If the PTO took the high road and looked at the rules again, they might engender concessions in other ways,'' Vito said.

Best said, ''The PTO's rules are designed to force patentees to do more work for the office and to do that work earlier in the process. Given the long product development timelines that are common in the life sciences, if the rules go into force companies will have to work closely with counsel to minimize the adverse impact of the rules on their businesses.''

BY TONY DUTRA AND JOHN T. AQUINO

Full text of the decision is at http://pub.bna.com/ptcj/081352Mar20.pdf.