Chemical & Engineering News
Serving the chemical, life sciences and laboratory worlds

Business

December 17, 2007
Volume 85, Number 51
pp. 19-20

Patent Anxiety

GlaxoSmithKline's move against changes at the Patent Office highlights a perceived threat to drug research

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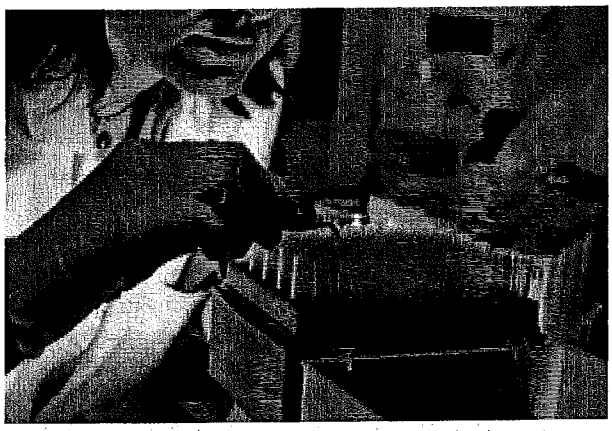
DRUG AND BIOPHARMACEUTICAL companies are up in arms over the Patent Reform Act of 2007, a bill aimed at streamlining U.S. patenting procedures. But lately, they have shifted their focus to a more urgent concern: an independent move by the Patent & Trademark Office (PTO) to overhaul its rules for vetting patents.



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unnerved GSK and other drug companies say proposed limits on patent claims and continuations will impede drug discovery and development.

The proposed rules, which would set limits on the number of claims and continuations that can be filed on a patent application, were to have gone into effect on Nov. 1, but they were stayed in a last-minute injunction by the U.S. District Court for the Eastern District of Virginia in a lawsuit brought by GlaxoSmithKline.

The broader patent reform bill, introduced in 2005, has pitted the pharmaceutical industry against others on a range of issues having to do with applying for and prosecuting patents. Drug companies claim that the bill would cut into incentives and protections necessary in the expensive and risky enterprise of bringing drugs to market. It was passed in the House earlier this year but is currently stalled in the Senate.

PTO's proposed rule changes would have a comparable impact, according to GSK's lawsuit. The proposal also poses a more immediate threat than the overall patent law reform, according to Jeffrey D. Hsi, a pharmaceutical patent attorney with the law firm Edwards & Angell. "The rule changes were more pressing," Hsi says. "They would significantly impact applicants, and the final proposal wasn't even released until late August. So everyone made a beeline to focus in on that."

Under the proposed changes, patent applicants wishing to submit more than five independent claims or more than 25 total claims in initial patent applications would be required to provide for each claim an examination support document (ESD), which entails an extensive search for prior art relevant to the claim. Applicants would also be allowed to file two continuation applications to extend existing patents and one request for a third continuation application. Any further filing for a continuation would require a special

petition.

Trade groups for both the drug and biotech industries supported GSK's lawsuit. According to Hsi, some in the drug industry view the proposal as going beyond PTO's administrative authority by shifting the burden of examining an application from PTO to the applicant. Hsi says it is not surprising that the drug industry, which relies on the ability to negotiate claims and continuations over a long product development period, would move quickly to stall the PTO rule change.

John J. Doll, commissioner for patents at PTO, discredits the notion that the new rules would create a special barrier to pharmaceutical companies. Rather, he emphasizes the need to increase efficiency in patent processing.

"It's part of our overall strategic plan to improve the quality of the patents we issue and improve the efficiency of the system," he says. Doll says the office currently has 760,000 applications awaiting examination and that about 30% of them are continuations.

He adds that the changes would create mechanisms such as ESDs in addition to petitions that would accommodate claims and continuations beyond the proposed limits. "You get five independent claims and 25 total. Need more? File an examination support document," he says. "If you need more continuation applications, we have given you an opportunity to tell us why."

It's not that simple, counters Sherry M. Knowles, global head of intellectual property (IP) at GSK. She says the requirement that applications for continuations prove that amendments and new claims could not have been filed previously sets a standard that is virtually impossible to meet. In the rule proposal, Knowles points out, PTO provides examples of how it would respond to a variety of petitions. "Their guidance is that they would reject virtually all petitions," she says.

Similarly, she says an ESD requires applicants to search for prior art without specific definition. "There is no guidance on whether the search is manual or electronic, what countries you have to search in, what libraries," she says. "On its face, the requirement is an open-ended demand that applicants look at all documents in the world with relevance to the invention and without regard to cost. As the worldwide head of IP at GSK, I would not be in a position to be able to instruct other attorneys in our IP group on exactly what steps need to be taken to comply."

Knowles says the pharmaceutical industry would be particularly hard hit by the changes. "We have one of the, if not the, longest lead times to get a product to market—10 years from identification of compound to final Food & Drug Administration approval." The cost over 10 years can reach $1 billion, she says, all of which is at risk given the high attrition rate in drug development.

"We need special protection," Knowles contends, "in order to be able to go from early stages in fundamental research and protect a genus of chemical compounds around the lead compound as we go through preclinical and clinical trials." In the case of failures along the way, researchers need to go back to initial patent applications and file claims on second and third lead compounds, she says.

Doll insists that the drug industry is not unique in its need to file claims and continuations. "I don't think they are different from any other industry—computers, telecommunications, mechanical devices," he says. "They are required by law to fully and completely disclose their invention when they file their application." He adds that patent laws have built-in protection to cover regulatory delays for regulated industries.

Teresa A. Lavoie, an attorney with the law firm Fish & Richardson, notes, however, that pharmaceutical companies have several unique patent challenges, including competition from an aggressive generic drug sector.

DRUG INDUSTRY patent offices have had to contend with changes to the patent law, including the Hatch-Waxman Act of 1984, which Congress passed to promote generic drugs while protecting the R&D investments of drug companies. The 1995 shift in patent coverage from 17 years from issuance date to 20 years from initial filing also put pressure on drug firms because of the length of time a drug is in development.

Lavoie adds that it is especially important that pharmaceutical companies be able to amend filings with claims or continuations late in drug development. "It is most significant during the FDA approval process," she says. "If you are forestalled from going back during development to tweak claims or get claims that cover your product—or maybe prevent a competitor from entering the marketplace—it has a huge impact. The PTO rules will significantly and drastically affect pharmaceutical companies."

Although drugmakers are fighting the proposed rule change, Lavoie says they are also preparing themselves for the eventuality that the rules will be approved early next year. "A lot of review and analysis is going on," she says. "It will take a couple of years for the dust to settle."

Chemical & Engineering News
ISSN 0009-2347