

# Patent Claim Buildup Haunts Biotechnology

*The backlog of unprocessed patent applications grows by the day as the patent office struggles with limited resources*

FOR the hundreds of American biotechnology companies developing new drugs, plants, and industrial organisms, success is often measured by the issuance of a patent. But the wait for a patent decision can be long and frustrating when an application involves recombinant DNA or other techniques that fall under the category called "biotechnology." The problem—a backlog of patent applications at the Office of Patents and Trademarks—has been a growing concern to the industry.

With biotechnology products from U.S. industry now starting to pour out of laboratories, companies are clamoring for faster action by the agency in telling them the extent to which their inventions will be protected by patent law. Industry patent attorneys say this can be especially important in cases where several companies are vying to market the same drug such as tissue plasminogen activator (TPA), a clot buster for heart attack victims.

"You don't know what the shape of the market is going to be when you don't have a ruling," says Brian C. Cunningham, general counsel for Genentech. The company is presently selling the drug in the United States and has licensed rights to Boehringer Ingelheim for marketing TPA in West Germany. But the patent office is still considering Genentech's application. Meanwhile, companies such as Searle, SmithKline Beckman, and Burroughs Wellcome are readying their own TPA drugs for the U.S. market.

Biotechnology companies and their trade associations are not faulting the management at the patent office. Rather, the industry wants Congress to provide the patent office with additional resources for reviewing biotechnology patent claims. Companies worry that the biotechnology section of the patent office could be buried under a mountain of patent applications in the coming years. "We need a strong biotechnology group in the patent office," says Steven M. Odre, patent counsel for Amgen.

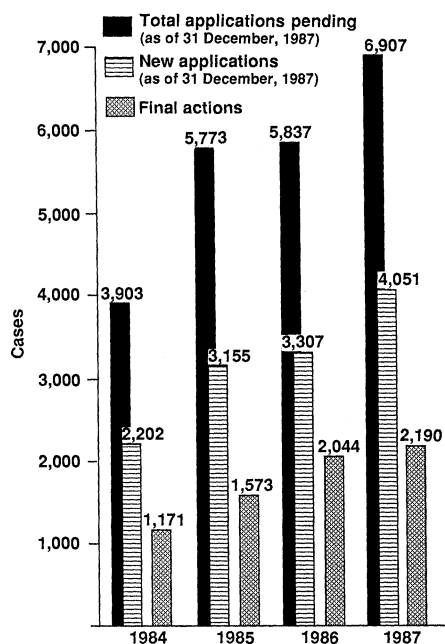
Although the number of final actions on pending applications increased by 21% to 2472 in 1987, companies now must wait about 2.5 years before an examiner looks at an application. Then it takes 25.3 months

on average to render a final decision. In contrast, patent applications for pharmaceuticals based on organic compounds can typically receive a final ruling within 2 years of the filing date.

Charles E. Van Horn, director of the organic chemistry and biotechnology examining group, says that 10 positions have been added to his biotechnology branch in the past year, bringing the total to 42. The patent office also plans to add other resources in the coming year, but even so, Van Horn says the backlog of applications may not recede anytime soon.

Indeed, there are strong indications that the number of applications related to biotechnology will increase rapidly in the coming years. The total backlog of pending applications, including appeals and amendments, climbed to 6907 as of 31 December compared to 5837 a year earlier. More significant, though, is the rise in new applications that were awaiting action at the end of 1986. They totaled 4051, a 22% jump in 12 months.

The work load problem is made worse,



**Rising demand.** The number of new biotechnology patent applications awaiting processing has increased 22% in 12 months.

says Van Horn, because of turnover in personnel. Seventeen examiners in the biotechnology branch have left in the last 2 years. These examiners and managers, who usually have a doctorate or master's degree in molecular biology or biochemistry, are often lured away by law firms that offer them higher salaries and better working conditions, officials note.

"In patents you need continuity in personnel, especially when it comes to biotechnology," says Odre. The turnover in staff is distressing to companies whose applications are abandoned by a departing examiner in the midst of a review. "It can mean you have to start all over again with a new examiner and that can mean delay," observes David Glass, director of patents and regulatory affairs at Biotechnica International.

To help tackle the rising flow of biotechnology patent applications, the patent office in April is expected to consolidate branches reviewing proteins, diagnostics, and asexually produced plants with Van Horn's section to create a biotechnology "supergroup." Barry Richman, who oversees reviews of patent applications covering analytical chemistry diagnostic devices, believes the move will dramatically improve the patent office's ability to handle an increased volume of applications.

But the nation's two biotechnology trade organizations, the Industrial Biotechnology Association (IBA) and Association of Biotechnology Companies (ABC), are not sure that this will suffice. "If they are going to keep people, they are going to have to do something about salaries and working conditions. There is no getting around it," says Iver Cooper of ABC.

Genentech's Cunningham says his company and others are not expecting the federal government to bear the full cost of expanding the patent office's biotechnology capabilities. "We continue to talk about whether there are ways that we could pay more fees to allow the agency to hire bright, capable people," says Cunningham. "We have made this offer publicly and privately." But levying a dedicated fee, for which there is no precedent, requires congressional approval.

IBA members are slated to meet this month to assess the situation. The organization may send recommendations to Congress on how to address the problems. The staffs of the House subcommittee on regulation and business opportunities and the Senate Judiciary Committee also are examining the matter. Industry officials say the solutions seem obvious. And, unless Congress provides additional support, the backlog will grow larger and future applications will take longer to process. ■

MARK CRAWFORD