lem here will be to choose genes that we know how to isolate and whose insertion into crop plants will produce desirable changes. Herbicide resistance genes are an attractive possibility. Genes for nitrogen fixation, while a potentially more lucrative objective, present many complications and may not work in plant cells. Any good ideas that may exist in industrial research laboratories are likely to be top secret; one would infer from the activity in this area that there are many. It is clear, in any case, that a few more technical developments will enormously increase the scope of plant genetic engineering.

Mary-Dell Chilton, Ph.D., is an associate professor of biology at Washington University. Her research centers on the use of T-DNA as a vector for plant genetic engineering. In June she will become the executive director of the agricultural biotechnology research unit at CIBA-Geigy.

INTELLECTUAL PROPERTY

IBA SEMINAR: BIOTECHNOLOGY PATENT ISSUES

Representatives from universities, corporations, government, and legal firms recently attended a seminar entitled "Patent Issues," sponsored by the Industrial Biotechnology Association on March 1–2.

Patent attorneys representing both universities and industry, emphasized that biotechnology, particularly molecular biology, presents a new set of problems for patent practitioners. They reminded the audience that, concerning the issue of intellectual property, recognizing a need does not mandate a means of filling it. Entirely new standards of patentability must be advocated in an area where there are no guarantees until experiments are performed.

Bertram Rowland of Townsend and Townsend (Palo Alto, CA) discussed the Cohen-Boyer recombinant DNA patent proceedings. Stanford University had opened the pending application to public inspection, but Rowland has reinvoked the cloak of secrecy provision to allow a conventional and orderly resolution of the issues. Rowland noted that the case involves complex issues: the consequences of limited disclosure by a third party more than one year prior to filing a patent application, the legal implications of a technical error in an illustrative example, and reinterpretation of data used in support of the invention.

Rowland also emphasized the difficulties in applying patent law to living organisms. The enablement requirement, which states that a patent must be sufficiently clear to be reproducible by those ordinarily skilled in the art to which the invention relates, is problematic because isolation of a particular recombinant DNA or organism may require numerous repetitions for reproducibility.

Another problem in this area is that organisms may change over time in unpredictable ways; these changes may necessitate reinterpretation of the original data after a patent application has been filed. Rowland noted that placing a sample of a modified organism in a depository, such as the American Type Culture Collection, does not ensure that the organism will not change over time.

J. Reimers (Stanford University Office of Technology Licensing), offered a plan for a patent pooling program for universities. An organization called University Licensing Association for Biotechnology (ULAB) would serve as a licensing agent for patents covering tools that are held by different universities. Tools are techniques as opposed to materials. ULAB would offer blanket licensing in consideration for a royalty fee that would be used to cover operating expenses and to contribute to a fellowship fund. The potential legal problems of such an arrangement are currently being studied.

Lorance L. Greenlee, chief patent counsel of Agrigenetics (Denver, CO), explained the two different administrative routes for protection of new agricultural strains: the Plant Variety Protection Act and the conventional patent laws. Although Greenlee did not mention it, the existence of two independent systems can be problematic. Filing in one system may require simultaneous filing in the other because there are no crossover provisions between them.

The perspective of the U.S. Patent and Trademark Office was given by Donald J. Quigg, Deputy Commissioner of Patents and Trademarks. Quigg noted that the office was expanding its staff to include more examiners with expertise in biotechnology. He also described his efforts to simplify and expedite interference proceedings, the Patent Office's mechanism for resolving inventorship disputes.

Quigg explained that many biotechnology products require approval by other government agencies, such as the FDA. Waiting for this approval, which often takes years, can use up much of the lifetime of a patent. He suggested that the large number of biotechnology industries affected by the lag period will help spur congressional action on a patent term extension bill.

The U.S. still lacks a provision in its laws that would protect against importation of patented products manufactured in a foreign country where product protection was not obtained in the U.S. Quigg emphasized that this protection exists in most other developed countries and that the U.S. laws should be changed.

The International Trade Commission (ITC) has some authority in this area because enforcement of patents is within its jurisdiction. For example, they can prevent importation of products of a patented process. Paula Stern, ITC commissioner, called on the biotechnology industries to provide help in guiding the activities of the commission. Only in this way, she said, will they be able to balance the needs of the industry with the need to ensure a proper flow of goods into the country without fear of retaliatory closure of foreign markets.

James F. Haley, Jr. of the law firm of Fish & Neave, (New York, New York) noted that the need for patent protection often conflicts with the need to publish, a hallmark of academic research. The U.S. laws allow one to file for a patent within one year of a barring publication, e.g. an article in a technical magazine that describes the invention, but this is not the case in many foreign countries. In absolute novelty countries, such as France and Germany, any publication or use, even an oral disclosure between parties, can be a bar to obtaining a valid patent. In most countries, if an application is filed within one year of filing in the U.S., it is recorded as having been filed at the same time as the U.S. application and interim publications have no consequence. However, some countries, such as Taiwan, do not honor this convention.

In summary, the meeting provided a broad overview of the current status of biotechnology patent issues and helped define the special problems that exist in this new and dynamic field. If full protection of intellectual property is to be ensured, there must be informed cooperation between all parties—inventors, attorneys, the U.S. government, and foreign patent offices.

John P. Grinnell is a member of Christie, Parker & Hale, Pasadena, specialists in intellectual property.