FINAL WORD

by Iver P. Cooper

DO WE NEED A SPECIAL PATENT LAW FOR BIOLOGICAL INVENTIONS?

In 1980 the U.S. Supreme Court held, 5–4, that a living organism could be patented as a "manufacture" or "composition of matter" if it satisfied the other requirements of the patent laws. While this decision was a milestone for the biotechnology industry, it should not encourage a blind acceptance of the patent laws as they stand today. The development of a patent law, written with biological invention in mind, may serve to avert legal bloodshed in the future. For example, the Plant Variety Protection Act of 1970 can be generalized and refined to cover biological invention in its broadest sense.

For years now the utility patent law has creaked and groaned as lawyers attempted to apply it to biological invention. Its deficiencies first became apparent when plant breeders lobbied Congress for legislation that would protect novel plant varieties. In 1930, while Congress was deliberating the merits of H. R. 11372, "A Bill to Provide for Plant Patents," Commissioner of Patents Thomas Robertson observed that there were some interpretative problems in extending the benefits of the existing patent statute to plant breeders. First, he felt that it might not be possible "by ordinary descriptions of the physical qualities of the plant, or the fruit, or the bloom, or all three, to so accurately define this new variety that it can be differentiated from all known varieties and from all subsequently created new varieties."

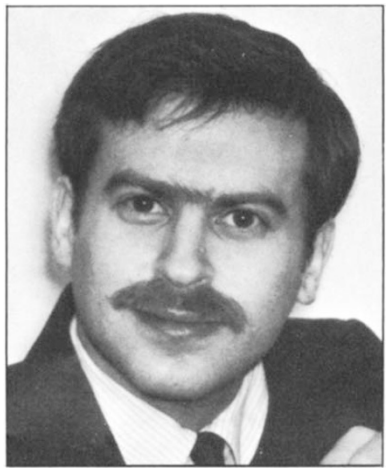
Second, he pointed out that a living thing could not be formulated from a recipe, as could a new chemical: "if after the new varieties were produced...an application for patent was filed with the most explicit description that it is possible to furnish, and all the plants...were destroyed...by fire, then there would be no way of reproducing this new species. The written description...would be useless..."

Finally, Commissioner Robertson noted that the patent grant was of the exclusive right to make, use, and sell the claimed invention. He was concerned that the natural growth of the plant after grafting would not be considered as the "making" of the new variety by human activity.

The plant patent provisions of the patent statute ameliorated the problems recited by Commissioner Robertson by declaring that the description of the new variety is acceptable if it is "as complete as is reasonably possible," and that the patent grant was of the right to use the asexually reproduced plant.

Industrial microbiology, however, did not receive special statutory treatment. Instead, the special problems of applying utility patent law to biological invention have been dealt with on a case-by-case basis by the courts. Thus, in the Argoudelis case decided in 1870, the Court of Customs and Patent Appeals held that the disclosure requirement could be satisfied in the case of a fermentation process utilizing a novel microorganism if, before filing, it was deposited in the U.S. Department of Agriculture culture collection under a contractual arrangement whereby it would be freely available to the public after the patent was issued. A later decision indicated that the depository need not be a governmental or domestic collection; several collections are accepted as International Depository Authorities under the Budapest Treaty. However, many questions remain unclarified: When, if ever, may industrial or academic depositories be utilized for patent purposes? May a depositor ask a collection to restrict access to his deposit for safety or ethical reasons? How long must a deposit be maintained? Is the depositor under duty to inform the collection of an error in the taxonomic classification of the deposited organism? What information or undertakings should be required from those questioning subcultures?

Like patent claims to organisms, patent claims to DNA, RNA, or amino acid sequences present special problems. In the case of a "classical" polymer such as rubber, the ommission or insertion of a few monomeric units has only a minor effect on the properties of the molecule. In those polymers that carry or express genetic information, a deletion or insertion of even a single unit may drastically affect their biological activity. On the other hand, it is possible to drastically alter certain regions of natural DNA molecules without significantly changing their biological activity. What kind of claims therefore should be allowable to the developer of a new plasmid, a more efficient promoter, or a high performance expression vector? If the claims are too broad, then we may discourage future innovation. If the scope of protection is too narrow, then we will discourage innovation right now. The proper balance should be struck by Congress, guided by the experience and knowledge of both molecular biologists and patent lawyers.



Iver P. Cooper

A rather pressing question at this time is whether the determination and isolation of the naturally occuring DNA molecule that codes for a natural product warrents the issuance of a patent on that molecule per se. While, speaking abstractly, a product of nature is not patentable, there are patents on purified products of nature such as epinephrine (adrenalin) and vitamin B-12.

With regard to infringement, an important question to be resolved by the patent system is whether "derivation" should be a necessary element of patent infringement. In the chemical patent law, of course, if a chemical compound is patented per se, anyone who produces the compound infringes the

(Continued on page 179)

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EDITORIAL (Continued from page 109)

In addition to expanding the number of noteworthy papers in each issue, we are implementing a process for further streamlining the methods of publishing research. The journal has begun, for example, to accept manuscripts that are transmitted electronically through computer modems. As we "scale up" in our publication of research data, we invite our readers to continue submitting manuscripts that deserve the serious attention of the industrial research community.

—Christopher G. Edwards

COMMENTARY (Continued from page 110)

The alternative is a more sophisticated procedure. Straw could be baled, as at present, and then be inoculated with the mixture of fungus and bacterium before being incubated under controlled conditions. The product would be a rich compost for use in horticulture.

But BTG chiefs no doubt have wider applications in mind, too. It may well be that the Letcombe discovery holds promise for the profitable conversion of straw and similar wastes into fertilizer at many other places and times than in stubble-burning Britain. Either way, this looks like being an elegant success for ecological thinking and the Selman Waksman approach to microbiology. ◪

FINAL WORD (Continued from page 192)

claim, even if the compound is obtained by a radically different synthetic approach. Under the patent law, the courts have held that an infringer is one who derives his own plants from those of the patentee, i.e., only clones infringe. One commentator has suggested that once the patentee has proven the similarity of the two plants and the defendant's access to the plaintiff's plants, that it be up to the defendant to establish his innocence of infringement by showing that his development was independent. Others have suggested that the judicial decisions inferring a "derivation" requirement were wrongly decided and have called for the elimination of that requirement.

A recent Patent Office Board of Apeals decision, *ex parte* Jackson, could have, if accepted by the courts, the practical effect of limiting the scope of claims to novel microorganisms to organisms derived from the deposited cultures, regardless of their taxonomic similarity.

The last major revision of the substantive patent law for chemical, and mechanical inventions occurred in 1952. The following year, James Watson and Francis Crick proposed a model for the physical structure of DNA, and thereby laid the groundwork for the molecular genetics industry. Clearly, the legislators did not have an opportunity to think about the problems of patenting DNA sequences or genetically engineered microorganisms when they drafted the 1952 statute.

The Plant Variety Protection Act (PVPA) of 1970, on the other hand, was written with classical plant genetics in mind. For that reason, despite its limitations, we may point to it as a model for a biological patent statute. The most attractive feature of the PVPA is its approach to the definition of a "new variety." Instead of the traditional patent requirements of novelty, utility, and nonobviousness, these are instead requirements of distinctness, uniformity, and stability. These concepts may be applied, not only to plant varieties, but also to animal varieties, cell lines, and microorganisms.

We may also commend the drafters of the PVPA for expressly allowing plant breeders to engage openly in experimental testing of seeds, without fear that they will lose the right to file a patent application. Under the utility patent law, there is a statutory bar to filing after one year of "public use." While there is also a judge-made exception for the experimental use of an invention, it is difficult for inventors to determine when they are protected within the exception. The Plant Patent Committee of the American Bar Association has expressed its concern that, since it is common to test-grow all new plant varieties, normally in open fields, this conventional testing might be regarded as public use under the general patent statute.

Another issue is the significance to be attached to written descriptions of a new organism. An early plant patent case held that a plant patent claim could not be anticipated by a mere catalogue description, and a microbiological case held that the use of a novel strain in a fermentation process could not be *prima facie* "obvious" if the strain were not available from a depository. The PVPA, however, makes a catalogue description effective as a reference if it clearly indicates a source from which a specimen of the new variety may be obtained.

The PVPA has its weaknesses, too. For example, it is not a model of legislative clarity when defining the protection afforded by a Plant Variety Protection Certificate. In particular, the farmers' exemption to the general infringement provision is both verbose and confusing.

Also the PVPA is concerned purely with the "production of a variety by seed." It is not really prepared to cope with the potentialities of "genetic engineering" at the molecular level as a means of obtaining new varieties, and offers no starting point for appropriate protection for genetic engineering techniques and DNA sequences themselves.

Still, the 1970 act was a significant step toward the broader goal of tailoring the patent system to encourage innovation in the field of biological invention. Scientists, patent lawyers, and businessmen interested in the future of biotechnology, working both individually and under the aegis of organizations like the Industrial Biotechnology Association and the Association of Biotechnology Companies, must lay the groundwork today for the law that will govern biological inventions in the future. ◪

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