INDUSTRY SHOULD COLLABORATE ON SCALE UP PROBLEMS

Although the laboratory end of biotechnology's stream of development enjoys the lion's share of attention, the scale-up stage of process development determines the feasibility of actually manufacturing a product. The sheer cost in time, equipment, and labor of scaling up presents a roadblock to the small specialist companies that yearn to become large manufacturing and marketing concerns. The ability to scale up, and its cost, will determine whether and how some of the finest new companies will survive through the manufacturing stage, let alone compete with the multinational giants in the world marketplace. The U.K.'s Department of Industry and the Science and Engineering Research Council should be applauded for their attempts to upgrade their country's capacity for industrial scale up through programs that support, respectively, the business and technological development of new companies (see BIO/TECHNOLOGY **1**:834).

In the U.S., where specialty firm start-ups continue to blossom, there is only one integrated program to assist burgeoning contenders in scaling up individual projects: the Small Business Innovation Program (SBIR, see BIO/TECHNOLOGY **2**:22). It may be unrealistic for small and medium-sized businesses to expect the U.S. government to provide assistance for scale up beyond the SBIR program, given the government's reluctance to form partnerships with private enterprise or form multilateral agreements between competing companies and itself. The National Science Foundation, which devotes about $4–5 million to bioengineering through its Division of Chemical and Process Engineering, will commit its resources only to generic scale-up problems.

Specialist firms should explore consortium relationships that enable them to engage in joint R&D and benefit from the resulting technology and licenses while sharing the burden of research costs. The most likely place for joint development centers to form is near universities with strong bioengineering departments. But there should be no reason why companies cannot pool some of their own bioengineering talents with firms that might even compete directly in certain areas, as long as they settle confidentiality and proprietary matters in advance.

Those who scoff at the idea of collaborative scale up studies should look to the computer industry as a model. Fear of losing the international race for new computer technologies has motivated the formation of two important new collaborations between corporations. One collaboration, initiated by William C. Norris, chairman of Control Data Corp., with the cooperation of 18 top industry executives, is an organization that expects to conduct its own research with a $75 million budget supporting 225 researchers by 1985. Known initially as the Microelectronics & Computer Cooperative (MCC), it is now under the presidency of retired Admiral Bobby R. Inman in Austin, Texas. Companies join MCC with a $200,000 entry fee, then provide partial financial support for projects they choose to participate in for three or more years. In return, participants in each project receive licenses to the resulting technology for three years after the project's conclusion. At the end of those three years, the technology can be licensed by any company. Projects are administered by MCC and staffed by researchers lent by the companies, in addition to MCC staff scientists. The Justice Department may allow MCC to function without charges of anti-trust activity, because MCC is developing technology, not products for commerce. In addition, the government may not view MCC as restraining trade, because it does not contain three of the biggest manufacturers in the industry.

The computer industry has spawned a second cooperative effort, called the Semiconductor Research Corp. (SRC). It consists of 19 companies who support 40 research initiatives at 30 universities. Some members of SRC would like to expand into in-house R&D and develop a manufacturing facility.

Ambitious small and medium-sized firms should consider studying these and other models of cooperation to boost their production technologies. As some computer industrialists have painfully learned, it is much easier to stay ahead in high technology through long-range R&D, than to strain to catch up with competitive Goliaths at home and abroad. **—Christopher G. Edwards**

MORE RESEARCH PAPERS FOR OUR READERS

When Macmillan Journals of London decided to launch a new publication called BIO/TECHNOLOGY, it considered several formats before deciding to combine original research data with news, features, and technology assessments. Instead of selecting an undistinguished journal format such as that seen most commonly in the learned society publications, it choose a format that combines tasteful design, four-color illustrations and photographs, and durable paper stock with a production method allowing extremely rapid publication of original research. The result is a journal that looks and functions more like Macmillan's proud progeny, Nature, and AAAS's Science than other academic journals.

In line with our perception of the expanding need for publishing distinguished biological research data with industrial implications, we are preparing to publish a larger number of shorter papers in future issues of BIO/TECHNOLOGY. Harvey Bialy, a molecular biologist who combines a highly imaginative research mind with a rare combination of editorial talents, has recently joined our staff as a research editor, to assist us in this task. We are also pleased to give credit to an editorial board which already has been instrumental in identifying areas of original research that the journal should cover. The scientific section of the editorial board includes:

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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. ◪

CORRESPONDENCE

BIO/TECHNOLOGY invites its readers to respond to all editorials, articles, research papers, or any current events in biotechnology which affect the lives of our readers. Short summaries of original research developments are also welcome. Letters should be addressed to the editor and sent to: BIO/TECHNOLOGY, 15 East 26th St., New York, New York 10010.

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