Norm Lather Tech. News

Norm,
You'll find this book interesting.
Nels
7/30/76

THE INNOVATION MILLIONAIRES

How They Succeed

Gene Bylinsky

Charles Scribner's Sons · New York

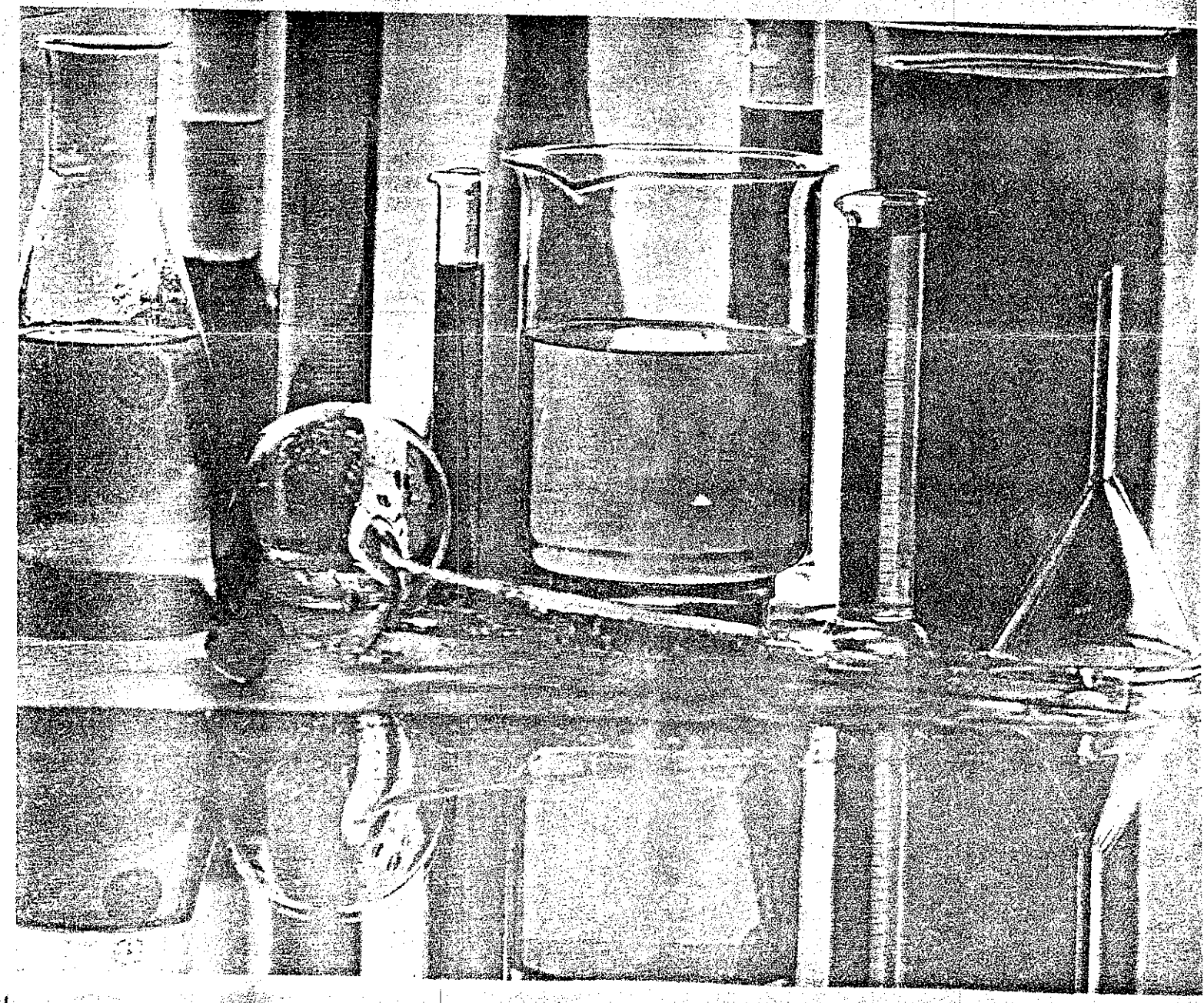
from the foreward

and high drive lose financial control of their enterprises at the troubled crossroads where finance and technology intersect. This is a pity because the really bright ideas appear to spring up in small enterprises. This is an area where the United States has yet to evolve a national pattern of support for technological innovation—to duplicate elsewhere the peculiarly attractive environment that radiates from the Stanford University campus and from Boston's Route 128 complex. The U.S. government agencies have spent fantastic sums for research and development—for example, about $60 billion for space research projects, with only the tiniest drip-out of technological benefits. The National Science Foundation has skirmished with the technological innovation problem, doing case studies of the cardiac pacemaker, steroid contraceptives, electrophotography, hybrid grains, tape recorders, and a few other such developments in an attempt to identify the critical events on the pathway leading from the bright idea to successful technology. I would draw one conclusion: the U.S. government spends the lion's share of its research and development dollars where there is the least likelihood of contributing to the national economy. Defense spending did at one time invigorate certain areas of our technical economy, but this DOD fertilization factor is now very low. The irony here is that countries like Germany and Japan who benefit from our defense hardware are free to divert their R & D dollars to products of consumer value. In effect, we subsidize our competition.

Bylinsky's prose pictures of our technological innovators invite us to speculate about many aspects of the tumultuous interface that exists between science and society, but they do more—they illuminate the human nature of the innovators. They emerge as flesh-and-blood creatures with vanities and peccadilloes—with humor and with pathos. But withal there is a sense of excitement—a thrill of the chase—that Bylinsky skillfully weaves into his narratives. Today's Magellans set out upon uncharted seas on subtle voyages of discovery where monetary rewards are more than matched by the immense payoff in human benefits.

Ralph E. Lapp

Patents and Collaboration between the Private and Public Sectors



Four by Five, Inc.

Four by Five, Inc.

Recent negotiations between nonprofit, "public sector" institutions and commercial, "private sector" firms concerning patent arrangements exemplify how the patent system can serve the public interest. Experiences of the Population Council and the Ford Foundation in negotiating patent rights for contraceptive developments under grants they made are interesting precedents for further collaboration.

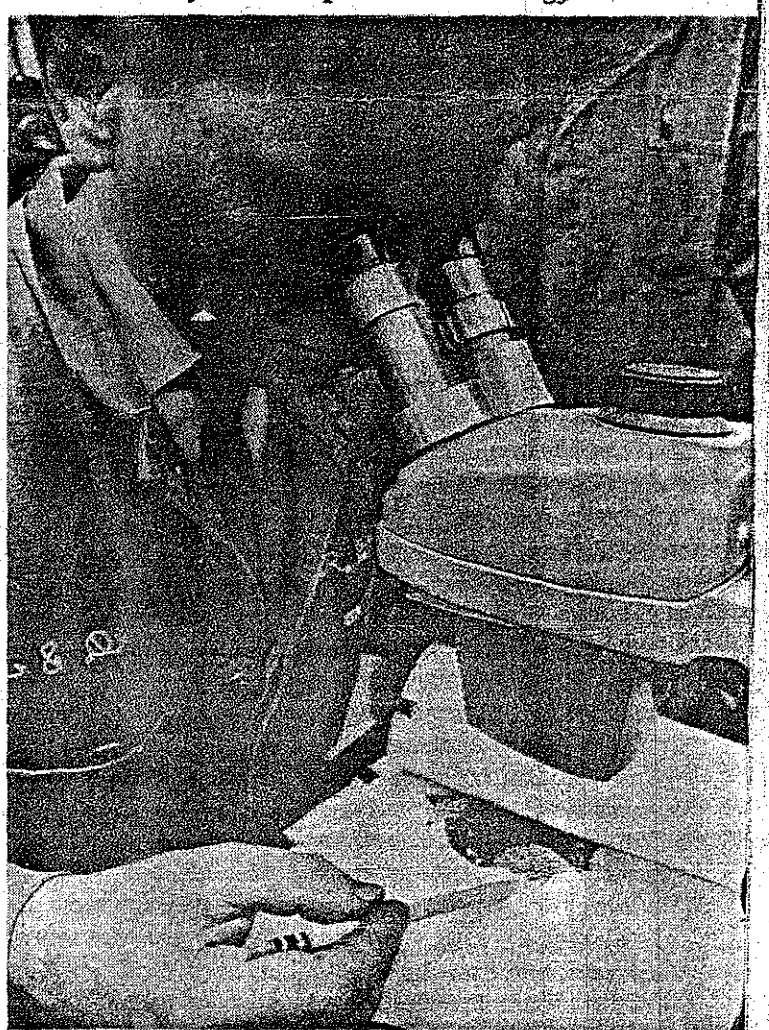
By Sheila Avrin McLean

IN RECENT years the patent system in the United States has been the subject of frequent, critical examination. T.L. Bowes's December, 1975, *American Bar Association Journal* article, "Patents and the Public Interest" (61 A.B.A.J. 1521), usefully summarizes this controversy surrounding our patent system and concludes that the system has served the public interest by helping "this nation become a pre-eminent developer of technology." Some recent negotiations between nonprofit, "public sector" institutions and commercial, "private sector" firms concerning patent arrangements provide an instructive new model of how the patent system can serve the public interest by catalyzing the further development of nonprofit-based research and technology.

It is important to recognize that collaboration between the private and public sectors is increasingly essential to the development of products that are ultimately useful to the public. Carl Djerassi, a founder of Syntex and now a Stanford professor, forcefully pointed out seven years ago in *Science* that while many basic discoveries and important steps leading to technological developments are made by researchers based in the nonprofit or public sector, pharmaceutical firms—private sector firms—"play an indispensible role in the development of any drug." His observations have been reinforced by a 1974 report prepared for the Federal Council for Science and Technology, which reflects the obvious point that universities and nonprofit hospitals do not engage in direct manufacture. Thus, industry must bring university inventions to the market place.

Since collaboration is so essential, consideration of new arrangements for bringing the private and public sectors together for their mutual benefit may be helpful to lawyers advising either sector. Some experiences of the Population Council and the Ford Foundation in negotiating patent rights for contraceptive developments under grants they had made serve as interesting precedents for further collaboration in that and other areas.

Inventions in the field of contraceptive research illustrate the way in which patented technology is often



Candida Photo

AUTHOR'S NOTE: This article is based on a report prepared for the Reproductive Biology and Contraceptive Development project under the direction of Roy O. Greep, Laboratory of Human Reproduction and Reproductive Biology, Harvard School of Medicine, which was sponsored by the Ford Foundation. The views expressed in this article are those of the author and do not represent an official policy of the Ford Foundation.

developed. Individual university-based researchers may conceive of new ideas for fertility-regulating drugs or devices or combinations thereof. Through their universities, they receive initial "seed" funding from governmental or philanthropic agencies. But to some extent the invention and to a greater extent the necessary initial research are done at organized laboratories by teams of professionals associated with medical schools, research hospitals, or nonprofit research institutions. The inventor-professor usually is required by employment arrangements to convey patent rights to the employer-university, at least in part. The work in the nonprofit sector typically does not result in a product that can be distributed to the public. Additional research and much of the necessary development is done by specially trained teams at well-equipped laboratories, frequently those maintained by profit-oriented pharmaceutical firms. This is particularly the case when development of the invention requires the Food and Drug Administration's approval, necessitating extensive and costly clinical testing.

In these cases there is a potential for conflict between the public and private sectors in the differing philosophies underlying the funding of research by public sector organizations, the availability of patent protection for new inventions, and the further funding provided by the pharmaceutical firm. The public sector donor proceeds on the premise that its reward for helping to finance an invention will be public access to the results of the supported research at minimum expense. The patent laws, on the other hand, are based on the philosophy of encouraging the development of new ideas by giving the inventor the right under a patent for a limited period to profit from the invention—either by use of the patent or through royalty arrangements with others. Because an inventor may choose to obtain patent protection in more than one country, it is possible to obtain virtually worldwide patent rights for an invention, albeit for limited periods of time.

Marketing Creates Interest in Royalties

Simply stated, if a patented invention is marketed, several parties involved in its development—the university or hospital where the original research was conducted, the investigator (inventor) in whose name the patent was prosecuted, and the pharmaceutical firm where further research and development are carried on—become interested in royalties under the patent and in the exclusive right to control the manufacture and sale of the product.

The public sector donor (for example, the Population Council, the United States Agency for International Development, or the Ford Foundation) usually retains some form of license—usually a royalty-free, nonexclusive license to make, use, and sell the invention—but it is usually impractical for these funding agencies to consider exercising this license. Not being in the business of manufacturing and not typically in the business of distributing drugs or devices, they must develop alternatives to safeguard their original purpose of public sector access, at low cost, to the patented invention they helped to finance.

Experience has shown that in exchange for providing venture capital and other support for further necessary research and development, pharmaceutical firms are likely to require an exclusive license under the patent—the exclusive right to make, use, and sell the new invention. Sometimes working together, and sometimes separately, the Population Council and the Ford Foundation have developed with pharmaceutical firms an interesting and innovative approach to this aspect of patents under research grants. At the stage when a grant for research is made, the grantee institution (usually a university) and the principal investigator enter into a patent agreement with the foundation or council under which the institution or investigator is responsible for obtaining patents on inventions and may grant only nonexclusive licenses of any patentable invention resulting from the sponsored research. The agreement requires the foundation's or council's consent before the institution or investigator may permit an exclusive license of the patent. Drug companies interested in further development and marketing of the invention usually do request the foundation's or council's consent to exclusive licenses before they will make the substantial investment to develop, test, and market the drug or device.

Royalties Can Be Fed Back into Research

The foundation and council have made an initial decision not to demand royalties in return for their consent to an exclusive license, even though it might be simpler to negotiate standard royalty arrangements with pharmaceutical firms. The donor agencies could then feed these royalties back into further research. The Population Council, for one, has considered and rejected this approach on the ground that its objectivity in advising on the use of contraceptives might be impugned if it were viewed as having a financial stake in a particular product.

Instead they take steps in their agreements with the drug companies to assure that the public sector will be able to purchase the new contraceptive devices at a price lower than that which the drug company would charge the private sector (for example, commercial suppliers to private physicians). The key issues forming the basis of these agreements are (a) definition of the "public sector," (b) pricing formulas, and (c) guaranty of supply to the public sector. "Public sector" is defined, for example, as national and voluntary family planning programs. A pricing formula for the public sector, for example, may take into account the cost of the product to the pharmaceutical firm but not give any profit to the firm from public sector purchasers. The guaranty-of-supply provisions attempt to assure

that public sector agencies that order the product at the special public sector price will have it supplied to them.

The details vary with circumstances, such as the sums of money the various parties have contributed, or will have to contribute, to research and development. Negotiating these arrangements can be extremely complex and time consuming, and the legal fees can be substantial. There are at least four parties—the donor agency, the hospital or university in which the inventor works, the inventor, and the drug company. The interests of the various parties are not, of course, identical. The hospital and inventor usually work out royalty arrangements at the same time the donor agencies negotiate the special public sector pricing formula. But if the parties approach the negotiations in good faith, and with a sense of humor, their agreement can be a workable model for collaboration between philanthropy and industry.

Justice Department Issues Position

The Justice Department has recently announced its position on a patent licensing arrangement between a nonprofit, public sector organization and several private sector pharmaceutical firms. The public sector concern is the Salk Institute for Biological Studies, a publicly supported, nonprofit organization in California that performs biological research. Salk outlined to the Justice Department a proposed licensing arrangement of patents for a drug (Somastostatin) intended to treat diabetes. Salk would grant world-wide, nonexclusive patent licenses to five pharmaceutical firms and would also agree not to grant additional licenses for a period of three years after the first sale of the drug. At the end of three years Salk would again be free to grant additional nonexclusive licenses. In return, the pharmaceutical firm licensees would pay the institute royalties and would commit themselves to clinical testing necessary to obtaining the Food and Drug Administration's approval to distribute the drug.

In February, 1975, the Antitrust Division of the Justice Department issued an unfavorable business review letter with respect to these proposed arrangements. But in December, 1975, the division reversed its earlier position. In the December letter, it found that temporary limitation of the number of licensees appeared reasonable because Salk had been unable to obtain license agreements with qualified and interested firms without such a limitation. In addition, the division found that the terms in Salk's licensing agreement were designed to minimize the anticompetitive consequences of that limitation.

This discussion of patents has focused on public access to patented inventions initially funded by the public sector. It is important to remember that the life of patents is limited in the United States for seventeen years. Indeed, some of the patents on contraceptives invented in the late 1950s and early 1960s have expired or are about to expire. For example, Syntex's patent on Norethindrone and Searle's patent on Norethynodrel expired in 1972. Once the patent expires, the invention, including all the data related to it contained in the patent application, is dedicated to the public.

Sheila Avrin McLean is associate general counsel of the Ford Foundation. A former member of the Executive Committee of the Association of the Bar of the City of New York, she was graduated from Smith College (A.B. 1963) and Yale Law School (LL.B. 1966).

In certain cases the patent holder and those with licenses to make the invention will have a large head start in developing technical know-how and market acceptance for the product, and their market position may not be affected adversely by the expiration of the patent. This may be true for patented devices such as intrauterine devices carrying releasing compounds. On the other hand, replication of available contraceptive compounds used for the female contraceptive pill is relatively simple and inexpensive. The end of patent protection on these products will almost certainly invite competition and reduce the monopoly profits assured by the patent.

Life of a Patent May Be Extended

Because the Food and Drug Administration and other regulatory requirements demand a lengthy period of testing before a patented product can be approved for general use, Carl Djerassi has suggested that the life of a patent be extended for a specified number of years after a contraceptive product has been approved by the regulatory agency. Congressional consideration might be given to granting these extensions, by amending the patent law, in return for a *quid pro quo* benefiting the public, as, for example, a stipulation that the product be made available at a special low price (at "cost") to nonprofit or governmental programs distributing the product (nonprofit government sponsored family planning programs).

As indicated by these examples, imaginative use of patent arrangements can facilitate the development and marketing of public sector inventions by collaboration between the private and public sectors despite the differing interests of the parties involved. The suggested model may encourage other public funding agencies, universities, nonprofit research institutes, and private, profit-oriented companies—and their legal counsel—to look at their negotiations over patent rights as a helpful tool for mutually beneficial collaboration. ▲