Appendix D.—Patent Policy Regarding Medical Devices

Introduction

The U.S. patent system started with British-based colonial patent systems which continued after the American Revolution. It is derived from a specific provision in the Constitution (357):

> The Congress shall have the Power . . . to promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors, the exclusive . . . Right to their . . . Discoveries.

The Supreme Court has interpreted this clause in our Constitution to mean that (132):

> The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must promote the progress of . . . useful Arts. This is the standard expressed in the Constitution and it may not be ignored. And it is in this light that patent validity requires references to a standard written into the Constitution . . .

There are four types of property rights in information, or intellectual property—patents, trade secrets, trademarks, and copyrights. Patents give the right to exclude others from using inventive concepts during the life of the patent. Trade secrets, traditionally under State not Federal law, give the owner of a technical or commercial secret the right to prevent someone with access to the secret from disclosing it or using it for personal gain. But if the secret can be discovered independently or is discovered by legitimate means (e.g., from analysis of the product), there is no protection. Trademarks give merchants the right to restrict their use by others who might benefit from the exploitation of established products (e.g., Coca Cola®, Darvon®, SweetnLow®). Copyrights provide the right to exclude others from copying the form of a work of art or a writing, but do not prevent others from using the ideas expressed in the copyrighted work (347).

Lately, a property right called a "tangible research property" has emerged separate and distinct from patents, copyrights, trademarks, and trade secrets. For example, in March 1982, Stanford University developed a separate policy on tangible research property to protect Stanford's ownership of "tangible (or corporeal) items produced in the course of research projects." This policy covers such items as "biological materials, computer software, computer data bases, circuit diagrams, engineering drawings, integrated circuit chips, prototype devices and equipment, etc. " (289).

There are four types of patents, one of which, the "utility" patent, applies to useful processes, machines, manufactured articles, or compositions of matter. "Design" patents protect ornamental designs. "Plant" patents apply to asexually reproduced plants other than tubers or a plant found in an uncultivated state. "Plant variety protection certificates" provide patent-like protection to sexually reproduced plants. Certificates are administered through the U.S. Department of Agriculture. Utility, design, and plant patents are administered through the Patent and Trademark Office in the U.S. Department of Commerce (347).

The law on utility patents is as follows (347):

- An invention, to-be patentable, must be useful and must be a process, machine, manufactured good, or composition of matter.
- A patent can be granted only for an invention that, at the time of the claim: 1) was not known to others, and 2) was not so obvious that a person of ordinary skill in the art could have made the same invention.
- A patent can be granted only to the inventor(s).
- A patent gives the owner the right to exclude others from making, using, or selling the invention in the United States. (There are some important conflicts between the patent laws of the United States and those of other countries.)
- A patent is granted for 17 years.

About 100,000 patent applications are filed per year, of which about two-thirds are eventually granted. The average time from application to action is about 2 years. During this time, a patent examiner determines whether the invention is novel and not obvious (see above), primarily by searching files within the Patent and Trademark Office that contain information on U.S. and foreign patents and on literature such as professional journals (347).

Tables D-1 and D-2 summarize the number of patents granted by the U.S. Patent Office between 1970 and mid-1983. In table D-1, patents are enumerated by the date of the patent grant, while in table D-2, successful patent applications are listed by the dates when patent applications were first filed. The date when an application is filed is a more accurate reflection of when the technology was developed. Fluctuations in data based on application dates are more likely to reflect changes in technological activity, since such fluctuations would be unaffected by changes in the Patent and Trademark Office's processing of patent applications. For example, the 1979 patent grant data

Table D-l.–Patent Activity by Date of Patent Grant, U.S. and Foreign Origin, 1970-83

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983
Total.	64,429	78,317	74,810	74,143	76,278	72,002	70,226	65,269	66,102	48,854a	61,819	65,771	57,889	24,383[b]
U.S. origin	47,077	55,984	51,524	51,504	50,650	46,713	44,277	41,484	41,254	30,081	37,356	39,223	33,896	14,144
(Percent)	(73)	(71)	(69)	(69)	(66)	(65)	(63)	(64)	(62)	(62)	(60)	(60)	(59)	(58)
Foreign origin..	17,352	22,333	23,286	22,639	25,628	25,289	25,949	23,785	24,848	18,773	24,463	26,548	23,993	10,239
(Percent)	(27)	(29)	(31)	(31)	(34)	(35)	(37)	(36)	(38)	(38)	(40)	(40)	(41)	(42)

[a]This number is artificially low because the patent and Trademark Office issued fewer patents than normal because of alackof fundsto print patents.
[b]Includes data only to June 1983.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, ''OTAF Custom Report, All Technologies Report, 1/1963-6/1983" (mimeo), 1983.

Table D-2.–Patent Activity by Date of Patent Application, U.S. and Foreign Origin, 1970-83

	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983
Total.	'65,942	66,353	63,356	66,278	66,381	65,807	65,695	65,697	64,931	64,081	58,228a	23,816a	1,647a	1a, b
U.S. origin	45,851	45,580	42,429	42,733	41,830	42,198	41,566	40,652	39,222	37,978	34,403	14,765	1,150	0
(Percent)	(70)	(69)	(67)	(64)	(63)	(64)	(63)	(62)	(60)	(59)	(59)	(62)	(70)	(o)
Foreign origin. . . .	20,091	20,773	20,927	23,545	24,551	23,609	24,129	25,045	25,709	26,103	23,825	9,051	496	
(Percent)	(30)	(31)	(33)	(36)	(37)	(36)	(37)	(38)	(40)	(41)	(41)	(38)	(30)	(100)

[a]Data incomplete because of lag time between application and approval.
[b]Includes data only to June 1983.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, 1/1963-6/1983" (mimeo), 1983.

(see table D-1) are low, not because of a decrease in technological activity, but because the Patent Office issued fewer patents than normal because of a lack of funds to print patents.

Table D-2, summarizing successful patent applications by the date of patent application, shows that U.S. patents have remained at approximately 65,000 per year through the 1970s (data for 1980 and subsequent years are incomplete because of the delay between application and final ruling by the Patent and Trademark Office). During this period, patents of foreign origin increased from 30 to 40 percent of successful applications. About one-fourth of these patents of foreign origin were Japanese, closely followed by patents from West Germany (217).

Table D-3 summarizes 1981-83 data for selected indexes. In addition to the fact that about 40 percent of patents were of foreign origin, more than 75 percent were of corporate origin, about 2 percent were U.S. or foreign-government owned, and about 7 percent were owned by a foreign-resident inventor but assigned to a U.S. organization.

A patent can be sold (assigned), or it can be licensed on an exclusive or nonexclusive basis. An exclusive licensee has the right to enforce the patent. Nonexclusive licenses, granted to more than one party, are simply promises that licensees will not be sued for patent infringement. Payment for a license is usually by fee (e.g., $10,000 per year) or by royalty, based on some measure of income such as frequency of use of the invention or percent of sales of the invention (or products incorporating it).

Patent owners police their own patents. If they believe that their patents are being infringed, they may let unauthorized uses continue and try to collect licensing fees from the unauthorized users. But if the users refuse to cooperate, patent owners must go to court to obtain an injunction against the unauthorized use and to collect damages.

Table D-3.–Data on Patent Approvals, Selected Indexes, 1981-83[a]

Percent corporate-owned	76.87%
Percent government-owned	2.37%
Percent foreign-origin	41.06%
Percent U.S.-owned of foreign	7.170/0

[a]Definitions: **Percent** corporate-owned: 1981-83 U.S. patents **assigned to corporations/1981-83** patents x 100. Percent **government-owned:** 1981%3 U.S. patents assigned to the U.S. or foreign governments/1981-83 patents x 100. Percent **foreign-origin:** 1981-83 U.S. patents with foreign resident inventor/1981-83 patents x 100. **Percent U.S.-owned of** foreign: 1981-83 U.S. patents with a foreign resident inventor that are assigned to a U.S **organization/1981**-83 patents with a foreign resident inventor x 100.

SOURCE: U.S. Department of Commerce, Patent and Trademark Office, Office of Technology Assessment and Forecast, "OTAF Custom Report, All Technologies Report, January 1983 to June 1983 (mimeo), 1983.

The U.S. patent system is currently undergoing major changes. In July 1981, reexamination proceedings were initiated under which anyone can request that a patent be reexamined (accompanied by a $1,500 fee). The Patent and Trademark Office can refuse to reexamine on the basis that no substantially new question was raised. In the same law (Public Law 96-517) that authorized reexamination (in which other parties can challenge a patent), Congress also required the Patent and Trademark Office to submit a plan to Congress by December 1982 on modernizing its files.

Patent protection is intended to stimulate invention by giving potential inventors the exclusive right to any benefits for a substantial time. A patent is also granted as a reward for the early disclosure of the invention to the public and not as a reward for either its discovery or for investment in its commercial development and exploitation. If the public would benefit eventually from the invention through its public disclosure or commercial use, no reward would be necessary and no patent would be given (101). This is the reason for the patenting requirements of novelty and not being obvious to someone working in the same field, and for the requirement that the patent application must contain enough information so that someone else can copy it.

Some International Aspects of Patents

Only some of the international aspects of patents are discussed here. One example of differences between the United States and other countries in the area of patent law is the concept of "prior art." In the United States, there is a l-year grace period between publishing of the invention (e.g., of a new technique in a professional journal) and filing for a patent. Most universities routinely require researchers to report promptly inventions with potential commercialization so that the university can assess their potential and file for a patent. Most other countries do not have such a grace period.

Another example is that under current U.S. patent law, it is legal to import a product made in another country by a process covered by a U.S. patent without permission of the patent holder. A proposal to make this an infringement of the U.S. patent was reportedly part of the Patent and Trademark Office's 1983 legislative proposals (220).

Under the Paris Convention of 1883, patent holders are given a commercial monopoly (subject to certain conditions) for their inventions in 92 signatory countries. Patent holders must publish details of their discoveries in the signatory countries for other scientists to study, but the invention may not be copied for

profit. Member countries may allow rival manufacturers to produce the invention if patent holders abuse their monopoly, for example, by neglecting to produce the invention in the affected countries.

The Paris Convention is administered by the United Nations' World Intellectual Property Organization. In the third conference on revisions of the Paris Convention for the Protection of Industrial Property, held in Geneva in October 1982, the main issue was a proposal that would make it easier for developing countries to confiscate and manufacture patented inventions.

Third-world governments had wanted a provision giving them the right to take over and manufacture on an exclusive basis any potential invention if the original patent holder did not produce it in their country within 30 months of receiving a patent. The intent was to force foreign manufacturers to produce their inventions in the developing country instead of producing them elsewhere and importing them. Third-world countries claimed that large companies that hold most patents can use imports to undercut a local manufacturer allowed to use their technology, so an exclusive license barring even the original patent holder was necessary for local production. The proposal would also have allowed a registered patent to be confiscated altogether after 5 years.

The developed countries opposed the proposal as an expropriation of private property and because large companies would become more secretive about their inventions and reluctant to invest in developing countries. Chemical and pharmaceutical companies were thought to be most vulnerable, because their patented products are relatively easy to make once their formulas are known.

Prior to the October 1982 conference, Japan and the West European countries had agreed to the proposal, arguing that developing countries would find a way to do it anyway, and that defining the conditions under which exclusive licenses were granted would give more, not less, protection. At the conference, the United States offered a compromise proposal that would grant nonexclusive licenses, but no agreement was reached (194).

Patents and New Product Development

The value of patents in the decision to undertake innovative activities depends on the type of invention and on the type of decisionmaker. For example, the pharmaceutical industry rarely pursues the development and regulatory approval processes for a new drug unless it can be patented. Also, recall that drugs and other chemicals, once identified, are relatively easy to copy. In the 97th Congress, extension of the patent term to recover time lost to the regulatory approval process was the Pharmaceutical Manufacturers Association's number one legislative priority, but it lost narrowly in the supplemental session of Congress. In contrast, much of the innovation in the electronics industry has occurred without patents.

The importance of patents to small businesses is also variable. Many small firms depend on trade secrets rather than on patents. Reasons include the expense of obtaining or having to defend patents, and the uncertain outcome if the patent is challenged (234).

But the smaller of the small firms usually consider patents to be more critical than do large businesses. There are anecdotes of the importance of patents in securing financial support. In interviews conducted for another OTA study (347), eight venture capitalists distinguished between two types of investments: 1) those that rely on a firm's management team and rapid advances in technology to provide protection from competition, with the emphasis on short-term payouts on the investments; and 2) technologies that require a long research and development period, for which patents become almost a prerequisite for investment.

In essence, the confidence that is placed in patents is a key to determining the incentives for innovation provided by patents. Little is statistically known about these factors, but it appears that the degree of confidence varies over a wide range.

For products that require large capital costs, such as automobile manufacturing, patents may have little bearing on investment decisions because of the limited ability of a competitor to enter the market. But patents have another use for both large and small firms—defensive use to prevent others from stopping the patent holder in proceeding with his or her invention. One example is in the development of the computed tomography (CT) scanner (258):

> Before CT, few X-ray companies bothered with patents, since all the X-ray companies recognized that no one company had a monopoly on the patents, each would have had to license from the other to stay in business—the result being "why bother with patents?" EMI, who was new to the X-ray business, heavily patented their CT designs, and by the end of the decade was requiring substantial royalties from all the CT suppliers. As a defensive measure, the X-ray companies substantially had to change their patent practices; for example, we [General Electric] went from having the part-time use of one patent attorney to having three full-time patent attorneys. This, I believe, was totally the result of EMI's changing the practice of an industry.

Patenting of Medical Devices

The U.S. Patent and Trademark Office classifies patents into 400 to 500 functional categories, and no specific category encompasses all medical devices. The Food and Drug Administration's (FDA) Office of Economic Analysis decided which categories should be considered medical devices, and further categorized these devices as either "low" or "high" technology, depending on how "sophisticated" the device was (390).

Table D-4 identifies which types of medical devices have been categorized by FDA's Office of Economic Analysis as low or high technology and their patent categories and subcategories as classified according to the Patent and Trademark Office. Figures 2 and 3 in chapter 5 summarize U.S. and foreign medical device patents for these low- and high-technology medical devices by application date for 1968 to 1979. Low technology patents increased in the early *1970s* from about 800 per year to a peak during 1973 to 1974 of between 1,200 to 1,300 per year and remained at that general level for the rest of the 1970s. Patents for high-technology medical devices, on the other hand, continued to increase throughout the 1970s, doubling from more than 500 per year in 1970 to more than 1,000 per year by 1979.

In sum, in the 1970s: 1) there was a modest increase in the annual number of successful patents for medical devices, while there was essentially no increase in annual total patents granted; 2) patents for low-technology medical devices increased in the early 1970s but remained essentially constant for the rest of the decade, while patents for high-technology medical devices continued to increase throughout the decade; and 3) while the percent of foreign-origin patents increased for both medical devices and all inventions by approximately 10 percent, the percent of foreign-origin medical device patents (30 percent) was still lower than the percent for all patents (40 percent) by the end of the 1970s.

Table D-4.–High- and Low-Technoiogy Medical Devices as Classified by FDA's Office of Economic Analysis

High-technobgy devices:
A. Diagnostic equipment
   1. Cardiac devices (128) 695-715a
   2. Vascular devices (128) 669-694
   3. Respiratory devices (128) 716-730
   4. Stimulators, neurological, etc. (128) 731-746, 639-644
   5. Radiation (128) 653-667
   6. Other (128) 630-782, minus above codes plus 3-23
B. Respiratory methods
   1. Mixing (128) 203.12-204.14
   2. Supply (128) 204.18-205.26 plus 207.14-207.18
   3. Substance removal (128) 205.27-207.13
   4. Other (128) 200.11-200.23 and 204.15-204.17
C. Electrical systems and energy applicators (128) 419 R-804
D. Implantable artificial body members
   1. Cardiovascular (3) 1.4-1.7
   2. Legs, arms, bones, etc. (3) 1.913-2
   3. Other (3) 1-1.2 and 13-36
E. Dialysis and blood filters (210) 321A-3216 and (422) 44-48
F. Miscellaneous (includes incubators, hearing aids, magnetic devices) (128) 1R-1.5 and (181) 126-137

Low-technology devices:
A. Kinesitherapy (128) 24R-67
B. Orthopedic (128) 68-80J, 81 A-81R, 581-623
C. Bandages and trusses (128) 82-171
D. Mediators (604) 1-7, 11-19, 23-42, 46-72, 77-93, 104-170, 173-238, 239-263, 272-279, 285-302, 303-311, 403-416, 890-897
E. Instruments (604) 8-10, 43-45, 94-103, 171-172, 264-271, 280-284
F. Dental
   1. Orthodontics (433) 2-24
   2. Apparatus (433) 25-166
   3. Prosthodontics (433) 167-214
G Ophthalmic
   1. Examining equipment (351) 1-40
   2. Frames (351) 41-158
   3. Lenses (351) 159-177
H Miscellaneous (includes receptors, baths, canes) (604) 20-22, 73-76, 312-377, 378-402, (128) 362-403

[a]Numbers refer to categories (in parentheses) and subcategories according to the Manual of Classification, U.S. Department of Commerce, Patent and Trademark Office

SOURCE US. Department of Health and Human Services! Food and Drug Administration, Office of Economic Analysis, Rockville, MD, personal communication, December 1983.