Appendix

Appendix

Patent-Term Extension for Other Industries

The Medical Devices Industry

The medical devices industry manufactures products that are used in the diagnosis, treatment, or prevention of diseases or conditions. The benefits of these products reside in their ability to affect the structure or function of the human body through means other than chemical action. [1]The definition includes simple products, such as surgical instruments and orthopedic shoes, and vastly complex products, like cardiac pacemakers and diagnostic equipment. The Food and Drug Administration (FDA) regulates this industry, and only in certain instances is premarket approval required.

The medical devices industry emerged after World War II as a result of technological developments. In the last two decades, the industry has experienced substantial growth in sales: between 1974 and 1980 sales increased by more than 100 percent, with **1980** sales estimated at about $11.5 billion. [2]The industry is comprised of several thousand firms, many of whom are quite small.[3]Several relatively large firms in the industry appear to play a dominant role in the market. [4] According to one source, the larger firms constitute the stable portion of the industry; but the turnover rate for smaller firms is high. This difference does not derive from differences in the types of devices produced. Since a company need not have a large minimum plant size to produce medical devices, it appears that medical devices in general are not characterized by great economies of scale. [5]Thus, entry is not dependent on large amounts of capital.

Sales in the industry are made through a large independent distributor network. Recently, there has been a shift in the character of this network from small local/regional dealers to major national suppliers. [6] Under these circumstances, larger manufacturers have a distinct advantage because they are capable of delivering the quantity a national distributor would require. Insofar as the larger medical-device manufacturer may tend to be a multiproduct concern, its reputation in one line will influence a distributor's decision to carry another of its product lines. Thus, the development of a national distribution network may act as an entry barrier for the smaller medical device company.

For several reasons, the patent system is not as important in this industry as it is in the pharmaceutical industry. First, there are generally many more substitutes available for any one medical device than there are substitutes for drugs. Second, there is a very high turnover in technological achievements in the industry and products are often outmoded before their patents expire. Third, devices are generally simpler to invent around than drugs and the patent, therefore, may provide little protection from imitators. Fourth, premium prices commanded by patented medical devices may not be as great as premium prices in the pharmaceutical industry because some downward price pressure is exerted through an informed and price-conscious market (hospitals, laboratories, and independent distributors, etc.). Thus, while the patent may be viewed by the industry as one of several avenues for the minimization of risk, it is typically not the overriding incentive for innovative activity.

The growth in sales and in the number of firms in the industry seems to indicate a reasonable degree of competition and therefore an environment conducive to innovation. However, insufficient information exists for a reliable evaluation of the industry's competitiveness. First, we have not studied how concentrated any particular device area may be within the industry (e. g., we do not know if one firm or a thousand produces X-ray equipment). Second, regulation of the industry began recently (1976) and its effects may not yet be evident.

FDA began its present scope of regulation of medical devices in 1976 with the passage of the medical device amendments to the Food, Drug, and Cosmetic Act. Prior to 1976, some devices such as soft contact lenses, IUDS, hemostats and others, fell under the purview of FDA because the agency had these devices classified as "drugs. " As well, prior to

1 Health Industry Manufacturers Association, Summary Report, ' (Washington, D C HIMA, October 1978), p. 8.

2Predicasts Inc Value of Shipment, (SIC code 2831 3841-43, 3693) 1980

3Health Industry Manufacturers Association Summary Report,' reported over 1,000 members in 1978 with 72 percent having sales less than $10 million Thus 280 companies had $73 billion of the 1978 $8 billion sales figure.

4Manufacturers of Medical Devices Join the Choruses of Regulatory Critics *The National Journal* (Sept 20, 1980) p 1566, reported more than **5,000 manufacturers** in 1980

5Office of Planning and Evaluation, Economics Staff Study 53, Food and **Drug** Administration (Washington, D C FDA, 1980)

6Ibid

7SRI International **Structure** of the **U S** Medical Supply Equipment and Dev 1Icc\Indu\t ry (Stanford, Calif. SRI In ternationa 1 Print ing, 1979)

1976, FDA had postmarked surveillance regulatory powers for devices. That is, FDA could remove a device from the market if it was not safe and had power to ensure that the product's label was not misleading. Thus, while regulation of the industry is not as recent a phenomenon as it might appear, the scope of the regulation has widened considerably since **1976.** Currently, the thousands of medical device products are divided among three groups. Class I devices are noncritical items such as bedpans and are subject to generally the same standards of regulation as all devices were prior to **1976,** that is postmarked surveillance techniques. Class II devices include items thought to require something more than Class I regulation to ensure safety but not as much control as a premarket approval. Regulation of Class II devices takes the form of setting performance standards. Class III devices (those previously classified as "drugs" as well as others whose use can be similarly dangerous) require premarket approval. The process for obtaining Class III premarket approval is quite similar to that required for drug approval.

Devices can short-cut the regulatory procedures by being judged "substantially equivalent" to pre-1976 devices. In the 4 years since the medical devices amendment was enacted, about 98 percent of premarket notifications were declared "substantially equivalent."[7] Notifications are required 90 days prior to the marketing of a device to ensure that it will not be a member of Class III and require extensive testing.

The full effect of these regulations on the competition and innovation in the industry has not yet been felt. The uncertain}' about future regulations may change the weight of the patent as a factor in the innovative process. However, some general tendencies can be noted. The performance standards for Class II devices may dampen innovative activity, as the standards need only be met, not exceeded, to obtain approval.

In addition, FDA has been exploring the concept of voluntary standards for Class II devices. Larger device companies, by virtue of their larger voices, would appear to be able to have their products' standards emerge quickly and effectively as the accepted measure of voluntary standards, To the extent that smaller companies' voluntary standards are different from those of large companies, competition and innovation may become more difficult for smaller device manufacturers.

FDA regulations concerning "substantially equivalent" devices may hold the potential for dampening competition simply by encouraging manufacturers to produce devices that are based on minor changes in old products. However, such products may not be able to obtain patents. If manufacturers claim substantial equivalency at FDA, they may injure their chances to get a patent approved, i.e., an old device may be considered prior art for patent purposes. On the other hand, the issuance of a patent may be considered proof that a device is not substantially equivalent because patents are supposed to be granted for new and unobvious inventions. Thus, the patent may become much less important than it currently is for devices similar to existing products. By the same token, patents may become more important to first entrants with wholly new products.

Two other trends that may affect the industry's competitiveness should be noted. First, while medical devices are more price sensitive than pharmaceuticals, this industry is becoming more subject to price insulation from third-party reimbursement. [a]Compared to most industries, the medical device industry is considered price insensitive, however, hospital cost containment programs often look toward medical devices for areas of savings. Future competition may increasingly be based on other considerations in addition to price and, to the extent that this leads to higher profits, entry may be encouraged. It has been reported that the larger device manufacturers have generally been generating far more cash than they are able to reinvest profitably and thus can be expected gradually to lose their current market shares unless reinvestment alternatives emerge.[9]

In summary, the medical devices industry is likely to continue to be reasonably competitive and innovative in many product lines and patent-term extensions may, therefore, be unnecessary. However, for Class I and II devices, the level of innovation may depend on the balance struck between the attractiveness of obtaining a patent and the desirability of receiving rapid approval for "substantially equivalent devices." In this regard, patent-term extensions could have a limited, but perhaps important, positive effect by shifting the balance toward innovation.

Finally, regulation of this industry is in the early stages. As more devices become available for uses with potentially hazardous side effects, more aggressive regulatory measures may be seen in the future; that is, technological sophistication may lead to a larger portion of devices being classified as Class III (those requiring premarket approval).

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[7]"New Device Introductions on the Rise," in *Devices and Diagnostics Letter vol. 1,* Aug. 12, 1980.

[a]Arthur Young & Co., "A Profile of the Medical Technology Industry and Governmental Policies," draft final report (Washington, D. C.: Arthur Young & Co. Printing, Mar. 31, 1981), pp. IX-7.

[9]Mitch and Martinelli, "An Analysis of Business Performance in the Health Care Industries," *Business Economics,* March 1980.

The Pesticide Industry

Because the pesticide industry and the pharmaceutical industry are subject to similar regulations, the effects of patent-term extension will be similar for the two industries.

Companies selling the most pesticides are often very large and diversified; pesticide sales frequently account for 20 percent or less of company sales.[10] The pesticide industry manufactures herbicides, insecticides, and fungicides, all of which are subject to premarket regulatory approval by the Environmental Protection Agency (EPA). The products are regulated under the Federal Insecticide Fungicide and Rodenticide Act which was amended in 1972 and now requires a demonstration of human safety. As in the pharmaceutical industry, the more stringent requirements have increased the costs and times associated with research and development. The regulatory process in 1975 required about 7 years to complete in contrast with a little less than **3** years in 1960.

The measures of innovation available in the pesticide industry indicate that innovation has, thus far, been virtually unaffected by the increased costs and times required for regulatory approval. Table A-1 below illustrates a steady rate of new pesticide chemicals being registered per year in the United States between 1967 and 1979. It should be noted that fluctuations in pesticide registration are primarily a function of legal and administrative measures at the EPA and are not necessarily a sound measure of innovation in the industry.

Figure A-1 illustrates the growth in research and development (R&D) expenditures in both constant (1967) and current dollars. As can be seen, real growth in R&D expenditures has occurred, with particularly evident spurts taking place after 1975, when one would have expected the effects of the 1972 amendments to be felt.

In table A-2 below, we see similar constant growth in sales (at least for 1970-76).

No measure of the qualitative value of pesticides was available to this study. One can reasonably assume that regulatory requirements for efficacy did not produce a decline in the value of pesticides marketed since 1972.

The research companies appear to be continuing to increase R&D expenditures at the present time, regardless of the trends in patent life. Uncertainty exists as to whether R&D expenditures would increase more rapidly with patent-term extension or whether, without the extension, R&D expenditures would continue to increase if effective patent lives decline.

One important characteristic of the pesticide industry that is dissimilar from the pharmaceutical industry is the role of the Federal Government in pesticide research and development. The Conservation Foundation reports that the Department of Agri-

[10]The Conservation Foundation, "Product Regulation and Chemical Innovation," March 1980, p II-8

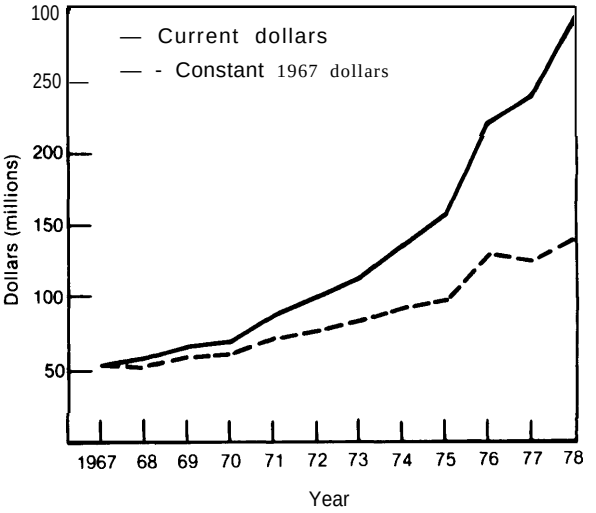
Table A-1.— New Pesticide Chemicals Registered in the United States, 1967-79

Year	Total number[a]
1967	16
1968	18
1969	14
1970	10
1971	4
1972	17
1973	13
1974	21
1975	34
1976	12
1977	4
1978	5
1979	17

[a]Herbicides, insecticides, fungicides, and others

SOURCES Organization for Economic Cooperation and Development, "Regulation and Innovation in the Chemical industry—A Preliminary Assessment of the Impact of Recent Chemicals Legislation," p 28; and The Conservation Foundation, *Production Regulation arrd Chemical Innovation,* March 1980, p III-14

Figure A-1.—Pesticide R&D Expenditures, Domestic Manufacturers Reporting to NACA, 1967-78



SOURCE: National Agricultural Chemicals Association, Industry Profile Surveys.

Table A-2.--U.S. Pesticide Sales in 1970 Constant Dollars

Year	Total sales (millions of dollars)
1970	$ 70
1971	81
1972	91
1973	91
1974	93
1975	107
1976	118

SOURCE Organization for Economic Cooperation and Development, "Regulation and Innovation in the Chemical Industry—A Preliminary Assessmentoftheimpact of the Present Chemical Legislation," p.29,

culture and the State experiment stations spent $332.6 million on research and implementation of pest control and pest management programs in 1978.[11] Several other Government agencies contribute to pest control research as well. While Government agencies also contribute to pharmaceutical research, the proportion of those funds as a percentage of the total is smaller. In cases where the funds support industry research which, in turn, produces an industry-owned patent, patent-term extension may entail double rewards.

Some of the similarities between the pesticide and pharmaceutical industries are also worth highlighting here in order to provide additional understanding of the possible effects of patent-term extension. First, while some 80 companies actually produce pesticides, another 5,300 are pesticide formulators, or companies involved in the combining and packaging of pesticide products for specific uses. As with the production-intensive pharmaceutical firms, the patented innovations made by formulators will not benefit from extensions of the patent term.

Finally, the pesticide industry has an analogous situation to the "orphan drug" research problem in the pharmaceutical industry. Minor crops do not present enough potential market for a pesticide company to invest in research for that crop. Here patent-term extensions also cannot be expected to induce firms to increase expenditures for minor crop research.

The Chemical Industry

The title of this industry is somewhat misleading; although pharmaceuticals and pesticides are chemicals, they are not meant to be included in this discussion. The chemicals considered here are basic industrial chemicals that are used to make other chemicals or products. Also included are dyes, pigments, paints, plastics, synthetic rubber, and synthetic fibers. The vast majority of the industry's sales are of intermediate goods; that is, they are used to make other products which are then used by consumers.

Chemical products, other than pharmaceuticals, pesticides, food additives, and cosmetics are regulated under the 1976 Toxic Substances Control Act (TSCA), which is administered by EPA. TSCA, in contrast to the laws regulating pharmaceuticals and pesticides, does not require Government approval before a product can be marketed. It requires only that the manufacturer submit a notice to EPA 90 days before he intends to begin manufacture. The notice must contain information about the use of the chemical, the anticipated volume of production, and the expected exposure of workers and others to the chemical, but EPA cannot require manufacturers to submit specific tests with the notice. If the notice does not contain enough information for EPA to evaluate the risks which may be posed by a chemical and if there is reason to believe that the chemical may pose a risk, the agency can delay manufacture of the chemical until adequate information is submitted. If the agency finds that a chemical for which a notice has been submitted will pose an unreasonable risk, it can impose any of a wide variety of restrictions, including a prohibition on manufacturing the chemical.

Because EPA is given only 90 days to review a chemical notice (the 90-day period can be extended up to 180 days), patent-term extension will not be applicable to the great majority of chemical products. Some new chemicals will fall into categories of chemicals which are required to be tested under section 4 of the Act, and for such chemicals a patent extension for the period it takes to conduct the required tests is meaningful. Manufacture of a chemical can also be delayed if the manufacturer submits inadequate information (TSCA sec. 5(e)) or if EPA finds that the chemical will pose an unreasonable risk to health and the environment (TSCA sec. 5(f)). Patent-term extension for chemicals delayed under section 5(e) or 5(f) might reduce the incentives for firms to conduct adequate testing or provide adequate information, since there would be no patent penalty for not doing so. Patent-term extension could be abused by premature filing of a notification without previously conducting adequate testing or withholding pertinent information.

[11] Ibid., p 11-10.

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