PATENT TERM EXTENSION: AN EXPENSIVE AND UNNECESSARY GIVEAWAY

by Albert Gore, Jr.

In recent years, it has become commonplace to blame the national government for virtually all of the problems that afflict our society. In view of the increasing role of government in the past fifty years, this perception is understandable and some of the criticism is justified.

The Reagan administration, however, has taken a more malign view of government as the root-of-all-evil to new extremes, creating an environment in which many industries are emboldened to seek compensation from the government for any impositions, real or imagined. The proposal to extend patent terms for new drugs is a good example of this phenomenon.

Large drug companies, often identified as research-intensive firms, claim that government safety and efficacy regulation is becoming increasingly onerous and is inhibiting the development of new drugs. As compensation, they are asking for an extension of their patent terms. Careful scrutiny of their elaborately constructed arguments, however, indicates that the factual base upon which the arguments are founded is fatally flawed and that the "problem," as they described it, does not really exist.

The inherent tension between free market competition and innovation has long been recognized. Article I, Section 8 of the U.S. Constitution grants the Congress "Power To . . . promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors exclusive Right to their respective writings and discoveries. . . ." The phrase "limited Times" indicates that the authors of the Constitution were concerned about promoting innovation, but not at the expense of precluding competition indefinitely.

Historians of the Congress agree that the seventeen-year term was enacted as a compromise. The Patent Act of 1861 evolved from legislation introduced in the House of Representatives, which specified a fourteen-year term with a conditional extension of seven years, and a

Senate bill, which provided a fixed fourteen-year term. In the years after 1861, a variety of patent extension and modification bills have been introduced, but only in the 97th Congress has the issue been given serious consideration.

The legislation which has been introduced in the 97th Congress would extend the patent term for pharmaceuticals (and a few other products subject to premarket regulatory review, such as agricultural chemicals) by the amount of time consumed in the premarket regulatory review period, up to a maximum of seven years. Enactment of this legislation is of overriding importance to the research-intensive drug firms who claim that they want to increase innovation, but who leave unsaid the fact that they stand to profit enormously from such a change in the patent law.

The relationship between research-intensive and smaller production-intensive or generic firms is strongly adversarial. Large companies view smaller generic competitors as parasitic. Generic manufacturers, on the other hand, believe that large companies seek to inhibit competition by erecting barriers to market entry by other firms.

Industry Profits Are Increasing

Implicit in the large drug companies' argument for patent term extension is the notion that the industry is in distress and thus in need of infusions of capital that would result from higher drug prices. Additional capital, according to the argument, would lead to greater innovation. This cry of distress, however, rings hollow. The Office of Technology Assessment published a thorough report in August, 1981 entitled *Patent-Term Extension and the Pharmaceutical Industry* that is recognized by both sides of the debate as the definitive work on this subject. Although it avoids taking sides, the OTA report is devastating to the large drug companies' arguments. It concludes that:

> Since the 1950's, the U.S. pharmaceutical industry has been considered one of the most profitable of all major manufacturing industries. . . . (T)he industry's after-tax rate of return on stockholder's equity has remained stable at a relatively high level and has exceeded the average after-tax rate of return for all manufacturing.

Actually, the rate of return has increased steadily since 1975.

Clearly then, the "problem" is not that the industry is unable to make enough money. It is doing fabulously well, even as other parts of the economy are withering.

The central argument for patent term extension is that innovation is declining under existing law. There are various measures of innovation, but the two that are most widely used and that are usually cited by the industry are: (1) the amount of spending on research and development,

and (2) the number of new drugs being approved for marketing by the Food and Drug Administration (FDA).

Let us take them one by one, beginning with R&D spending. Is it declining? No, it is increasing in constant dollars year by year. The large drug companies argue that spending for research and development as a percentage of sales is declining. While that contention may be true, the relevant indicator is the trend in R&D spending measured alone when adjusted for inflation. And in truth, real spending for pharmaceutical research and development has increased substantially over time, according to the OTA report. When pinned down under questioning, the Pharmaceutical Manufacturers Association (PMA), represented by Mr. Peter Hutt, did not dispute this point in hearings before the Investigations and Oversight Subcommittee of the Science and Technology Committee.

Obviously, if research and development spending is increasing in real terms, then the public is being asked to remedy a problem that does not exist. By couching their contention in terms of spending as a percentage of sales, however, the large drug companies obscure this straightforward relationship. (Moreover, they often disingenuously contract their argument into the misleading statement, "Real R&D spending has declined.")

All that is demonstrated by the relative trend cited by the PMA is that sales are increasing faster than R&D. It is fallacious to leap from that statement to the conclusion that real spending for R&D is declining. It emphatically is not. *Fortune* magazine, in its 19 October 1981 issue, documents the most recent R&D trend:

> Merck is pouring a colossal $280 million into R&D this year, nearly four times more than ten years ago, while Eli Lilly's $210 million for 1980 was three times more than in 1971. Pfizer's research expenditure, which quintupled from 1970 to 1980, will grow by nearly 16% this year, to around $180 million, while Squibb has boosted spending 84% in the last five years to $91 million.

Furthermore, there are strong indications that the trend toward increased spending for R&D will accelerate in the future. *U.S.News and World Report,* 5 October 1981, noted: "Dramatic advances in biology promise to turn the 1980s into a golden era for new drugs that can treat a wide range of diseases from depression and cancer to arthritis and heart failure." Advances in genetic engineering and better understanding of substances that occur naturally in the body, such as interferon, are creating an unprecedented surge in R&D spending. Add to that the generous new 25 percent tax credit for R&D that is just taking effect and

one must conclude that these companies really have eyes bigger than their stomachs.

There Has Been No Decline In Innovation

Examining the second measure of "innovation," approval for marketing of new chemical entities (NCEs), one is similarly hard-pressed to find any evidence of a decline in innovation. Since the landmark change of 1962, there has been no decline at all.

The PMA, however, in an argument that is even more slippery than their definition of "real R&D spending," argues that the number of NCEs approved for marketing has dropped dramatically "since 1960," and indeed, it has. But again, the drug companies make a forensic leap that is insufficient to clear the factual chasm. This "decline since 1960" is attributed to increasing government regulation. The comparison of 1960 and 1980, however, totally ignores the changes in the Food, Drug, and Cosmetic Law adopted in 1962. These changes instituted the efficacy requirement into new drug testing.

The addition of the efficacy requirement, the result of international incidents such as the Thalidomide tragedy, substantially increased the testing required prior to marketing. The result of the change, one that is supported by the PMA and most health professionals (including the current Commissioner of the Food and Drug Administration, Arthur Hull Hayes, Jr.), was to alter sharply the character of new drugs reaching the market.

The number of NCEs having "little or no therapeutic gain," that is, those drugs that were most susceptible to challenge on the grounds that they were not effective, dropped radically. This reduction has accounted entirely for the reduction of NCEs approved since 1960. For drugs having modest or important therapeutic gain, there has been no downward trend in market approvals since well before the 1962 amendments took effect. In fact, since the 1962 amendments took effect, there has been no downward trend in approvals of NCEs overall. Last year twenty-seven NCEs were approved by the FDA for marketing, the largest number since the 1962 amendments. Surely, the drug companies should not attempt to blame "onerous" government regulation for a reduction in new drug approvals that occurred fully twenty years ago when ineffective new drugs were no longer approved for marketing, particularly when the reduction resulted from a change in the law which they fully support.

It is misleading, therefore, to choose 1960 as the benchmark year from which to make comparisons. If one measures from the beginning of the modern era of drug regulation, the fall of 1962, there has been no decline

whatever. Clearly innovation, as measured by the number of NCEs annually approved for marketing, is not decreasing.

"Effective Patent Life"

To recap briefly, the state of affairs we are asked to "remedy": innovation is not declining, drug company profits are climbing steadily, and the amount spent on R&D is growing in real terms year by year. But wait, there is more. In suggesting that increasing government regulation is reducing innovation, proponents of patent term extension have focused attention on "effective patent life." Effective patent life is defined as the period of patent protection for a drug remaining once the drug is approved by the FDA for marketing. According to patent term extension proponents, the "effective patent life" has been declining, again largely as a result of increased government regulation. They cite an article by Dr. William Wardell and Martin Eisman that concludes that effective patent life declined from 13.6 years to 9.5 years between 1966 and 1979. PMA has concluded that the effective patent life for drugs approved for marketing in 1980 was 7.4 years. The suggested decline is precipitous. Once again, however, one must look much more closely to get the real story.

Since the number of drugs approved for marketing in any single year is relatively small, analysis based on mean averages such as that described above is subject to wild distortion by anomalous examples. The problem is accentuated when an effort is made to measure the simultaneous effect of two largely independent variables. In this case, the time between patent application and IND filing (IND filing is the initiation of the complex regulatory process) is time under the companies' control and is one variable that must be assessed in determining effective patent life. The other variable is the regulatory review period (defined as the time between IND filing and approval for marketing).

The declines in "effective patent life" have been measured by simple averages. Although these averages are useful, they obscure the true relationship between the variables described above. In an effort to avoid these problems, the Office of Technology Assessment evaluated patent and regulatory data for the twelve drugs approved for marketing in 1980, based on data supplied by the PMA.

OTA employed a regression analysis, a simple analytical technique that assessed the effect of the two variables on effective patent life. Both the time under the companies' control and the regulatory period were analyzed for their effect on effective patent life. The results were startling.

Contrary to assumptions previously made by individuals on both sides

of the issue, the government regulatory period was found *not* to be a statistically significant determinant of effective patent life for those drugs. And in contrast, there was a very strong relationship between effective patent life and the time the company waited after filing for a patent to begin the regulatory process.

This finding, if it holds for other years, would end the debate over patent term extension. Not surprisingly, efforts to obtain the critical public patent and regulatory data from the PMA, the best source of the information, have not been successful.

Industry has rejected efforts to obtain this information by the various excuses that it would be "too much work," that it might "confuse" the Congress, and that it is "irrelevant." Unspoken is the PMA's fear that the relationships observed in 1980 would indeed hold for the other years and that their arguments for patent term extension would be irreparably damaged.

The final argument advanced by proponents of patent term extension is that extension is warranted as a matter of equity because the patent system did not envision a significant regulatory period. However, few inventions enjoy a full seventeen years of market protection, and the Congress was fully cognizant of that fact when the balance was struck at such a long period of time. Marketing arrangements and other matters significantly shorten patent protection, even for products that are not regulated by the government. If the patent system is stimulating innovation by protecting profits of the innovator for a sufficient period of time, and clearly this is the case with pharmaceuticals, then the system is working as it was intended to work.

Moreover, the peculiar characteristics of the drug industry maintain a de facto monopoly for top-selling drugs long after the patent has technically expired. Librium, for example, had been off patent for three years in 1979, yet it still commanded 90 percent of the dollar volume in its market, compared with 10 percent for all of its competitors put together. In 1979, the brand name version of Librium was priced nearly sixteen times greater than the cheapest generic competitor. Today, the brand name price is twenty times greater than the cheapest generic competitor. Indisputably, the monopoly position of Librium has not been challenged since the drug went off patent. Nevertheless, the manufacturer has the temerity to join the collective complaints about an erosion of "effective patent life," and ask for more government protection against its pitiful "competition."

Nor is the regulatory process voraciously consuming increasing amounts of time without regard for the implications of that action. The FDA has undertaken efforts to speed the drug approval process. An FDA panel is

reviewing proposals for expediting new drug approvals overall. A new "fast track" has been instituted to assign priority in the review process to drugs with particular therapeutic potential.

The time to be saved from these efforts, however, is relatively small. Estimates of savings range from a few months to a year at most. Any additional shortcuts would undermine essential testing for safety and efficacy. The large drug companies acknowledge this point in admitting that most of the testing required by the FDA would be done even without the regulatory requirements, largely as a result of product liability requirements. Protection from potential lawsuits resulting from use of a drug would lead companies to engage in years of testing even if there were no Food, Drug, and Cosmetic Act and no FDA. Should they be compensated for that time, too?

This point is a telling blow to the large drug companies' argument. For if only a few months to a year of the regulatory period can truly be attributed to government, then it is unfair to other inventors to extend drug patents for a period of testing that would occur independent of any regulatory requirements. Moreover, since the FDA is currently taking measures to wring out some of this excess time, the rationale for patent term extension, misty at best, evaporates.

Existing Avenues For Large Drug Companies

In considering the public policy issue of patent term extension, the implications of the legislation must not be examined in isolation. Major changes in the tax law, particularly the tax credits to encourage increased expenditures for research and development, create an extremely favorable climate for R&D. Yet despite these important developments, the pharmaceutical industry remains adamant in its position that more is needed.

The interest in the industry in maximizing patent protection has long been self-evident. Under existing law, companies already utilize complicated strategies to extend patent life. This end is achieved both prior to the issuance of a patent and through subsequent patents. It is to a drug company's advantage to delay issuance of a patent simply because the seventeen-year clock does not begin to run until a patent issues. If a drug cannot be marketed for several years after discovery due to premarket testing, then the later a patent issues, the longer a drug will be protected from competition.

Patent issuance can be delayed through amendments to a patent application already pending or through dividing a single application into two or more parts. According to drug patent lawyers, these techniques are common practice in pharmaceutical patents.

Patent protection can be prolonged after issuance of an initial product patent by the subsequent issuance of patents governing manufacturing processes and uses. Generic drug companies argue strenuously that these subsequent patents effectively preclude competition long after expiration of the initial patent. The PMA recognizes the value of subsequent patents as well.

Curiously, however, the drug companies do not include mention of these subsequent patents in their calculation of effective patent life. For example, in 1980, if subsequent patents are averaged in, the mean average of effective patent life for drugs approved that year increases 25 percent over PMA's calculation.

Other supporters of the large drug companies maintain that subsequent process and use patents are not effective guards against competition. In this instance, the truth is somewhere between these extremes. In many cases, but not all, subsequent patents do afford extra market protection.

Toward Innovation and Reasonable Pricing

Large drug companies would have the public believe that pharmaceutical innovation and reasonably priced prescription drugs are incompatible social goals. This cynical argument should be rejected as being without merit. When challenged about the anticompetitive implications of patent term extension, these companies hide behind a facade of concern for the public interest.

They say that they are concerned that new lifesaving drugs may not be developed. But real spending for research and development is increasing, the number of new drugs being approved for marketing is not decreasing, and the FDA is expediting its drug approval process. All of this is occurring under existing law. Moreover, profits for drug companies have been increasing from levels already higher than those for most other manufacturing industries in the United States. These facts the companies have chosen to ignore, obscure, or misconstrue. Such actions do not serve the public interest.

Our society can have lifesaving drugs and have them at reasonable prices. Patent term extension would substantially increase prescription drug costs to consumers without any assurances whatever that any of the extra revenue derived would be reinvested in pharmaceutical R&D. Even if historical reinvestment patterns hold, with companies reinvesting either 8.5 or 12 percent of additional revenue (depending on which methodology is used, but both figures remain stable over time), it is evident that the public is getting an unjustifiably low return if it pays one dollar for twelve cents of research.

A far more sensible approach is the already-enacted investment tax credit to stimulate R&D. This change in the tax law provides a far greater degree of certainty that additional revenue will be plowed back into research and development.

After carefully weighing the evidence, one is led to the conclusion that large drug companies are anxious to have patent term extension, not to stimulate new drug development, but to buttress their patent protection during an age of rapid growth in the industry. This growth is occurring without patent term extension. If this legislation is enacted, pharmaceutical profits will be significantly enhanced. The public interest, on the other hand, will suffer. Higher prescription drug costs will limit the availability of these drugs to a growing segment of the population.

If on the other hand the Congress rejects the proposal, then growth in the industry will continue unabated. At the same time, the competitive forces in the economy that work to the advantage of consumers through accountable pricing will ensure greater access to prescription drugs.

Last year, in an atmosphere of complete sympathy and agreement with industry, the Congress passed tax breaks for large corporations, many of which were unwise and potentially devastating to the economy. By maintaining existing patent law, the Congress can avoid a repetition of the error of succumbing to facile and beguiling rhetoric in the face of common sense. The public interest requires us to do better this year.