THE PATENT TERM RESTORATION ACT OF 1981—S. 255

HEARING

BEFORE THE

COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

FIRST SESSION

ON

S. 255

A BILL TO AMEND THE PATENT LAW TO RESTORE THE TERM
OF THE PATENT GRANT FOR THE PERIOD OF TIME THAT NON-
PATENT REGULATORY REQUIREMENTS PREVENT THE MAR-
KETING OF A PATENTED PRODUCT

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SUMMARY

Recent economic analyses of the pharmaceutical industry are broadly supportive of the concept of patent restoration as proposed under S255. Patent protection in this industry now averages less than 10 years in length and has been declining over time. This decline has not been the result of conscious policy decisions, but rather has been the indirect result of longer clinical development and longer regulatory approval times. Given the significant costs and risks of R and D activity in pharmaceuticals, and the potential for significant social benefits from the discovery and development of new drug therapies, shorter patent protection terms for pharmaceuticals would not appear to be in the public interest.

There are strong reasons to expect that patent protection will become an increasingly important incentive for R and D investment activity over future periods. The emerging environment for research oriented firms combines higher R and D costs, longer development times, and increased generic competition after patents expire. The latter phenomena is occurring as a result of the growth of the state substitution laws and the government's Maximum Allowable Cost Program. In a sensitivity analysis of the mean profitability of new drugs inntroduced in the period 1970-1976, performed by John Vernon and myself, we found an average product life of 12 to 19 years is now needed by firms to cover R and D costs and provide a real rate of return on investment of 8 to 10 percent. Average effective patent life is therefore currently considerably less than average product life necessary for profitable operation. In the emerging environment of increased competition from generic products after patent expiration, the length of patent protection will necessarily become an increasingly critical factor underlying the willingness and ability of research oriented firms to undertake long term R and D activity of a risky and costly nature.

Thank you Senator Mathias, and other members of the Committee, for inviting me to speak on S. 255.

I would like to direct my comments specifically to the expected effects of patent restoration on the incentives for R and D and innovation in the pharmaceutical industry. Over the past six years my colleague, John Vernon,

and I have been studying various aspects of the drug innovational process under grants from the National Science Foundation. In addition, three years ago, we prepared for the staff of the Federal Trade Commission an analysis of the effects on the returns to drug R and D of increasing generic substitution in an environment of shortened patent lives. This analysis was commissioned as part of the FTC's model drug product selection law project and an expanded version of our study for the FTC subsequently has been published in the journal Law and Contemporary Problems (see A1)*. During the academic year 1979-80, I was also on leave from Duke University to the Health Care Financing Administration where one of my principal tasks involved a study of competition in the pharmaceutical industry.

Based on my own analysis of the pharmaceutical industry and those of other researchers, I believe there is a strong case at the present time for patent restoration as called for in S255.

There is currently considerable excitement about the scientific possibilities for significant new drug therapies based on many important advances in basic science in recent years. At the same time, however, the drug innovational process has been subject to several adverse economic trends over recent years. These adverse trends raise uncertainties and doubts about whether recent advances in basic science will be translated into new therapies as rapidly as good science permits.

From an economic standpoint, the process of discovering and developing new drugs has become a long and costly business investment subject to high levels of uncertainty. Over the past two decades, R and D costs per new drug introduction have accelerated much faster than the rate of inflation. Economic analyses indicate that the present value of R and D costs for producing a new drug introduction is now over 70 million dollars (more than an order of magnitude increase since the early Sixties) (A1). The process usually takes over 10 years from initial synthesis to actual commercial introduction. Furthermore, many promising drug candidates fall by the wayside during the R and D process. More than 90 percent of the drugs tested clinically in man fail to be commercially introduced (A2). Several academic studies have found the more stringent regulatory

*References cited in this paper are from items contained or listed in Appendices A1-A4 which provide reprints and drafts of previously completed papers bearing on this issue.

climate for new pharmaceuticals which has evolved during the past two decades to be a major factor driving up the cost and development times for new drugs and in lowering R and D productivity in this industry. (A1, A2).

Longer development and regulatory approval times also have meant shorter real terms of patent exclusivity on new pharmaceuticals. Average patent life for the new drug therapies introduced during the past three years have been under 10 years in length. Furthermore, at both the federal and state levels, government officials have been enacting various programs designed to promote the use of generic drugs after patents expire and imitative drugs come on the market. These include the Maximum Allowable Cost program for Medicaid and Medicare reimbursements and the various state drug substitution laws. (A1).

Although all of these policy efforts may be characterized as well inten-tioned and addressed to valid social goals, taken in combination, they have the effect of adversely affecting the incentives and capabilities of many firms to invest in pharmaceutical R and D. The collective signals sent to the innovative firm by various government agencies cannot have been very encouraging in recent years. The uncertainties arising from increased regulation, shorter patent lives, and the various government programs to encourage generic competition add significantly to the technical uncertainties surrounding long term R and D investment projects.

In an economy characterized by double digit inflation and scarce capital funds, these costly R and D investments are becoming increasingly difficult for many firms to sustain. My own research shows there are now substantially fewer domestic independent industrial sources of pharmaceutical innovation than was the case earlier in the past World War II period (A2). Smaller U.S. firms in parti-. cular have dropped out of the business of discovering and developing new drugs. These activities have become increasingly concentrated in the larger U.S. and foreign multinational firms. Even the latter firms have increased their degree of diversification across other industrial fields in recent years. (A2, A3)

The proposed patent restoration legislation under discussion here should operate to increase the expected returns from new drug innovation and also provide firms that are successful in introducing major new products with added cash flows to finance future research activities.

In order to gain some insights into whether patent restoration would have a significant quantitative effect on the expected returns from pharmaceutical R and D, my colleague John Vernon and I have recently performed a sensitivity analysis

bearing on this issue. In particular we examined the relation between drug
profitability and product life for the 37 U.S. discovered new drugs introduced
during the period 1970-76. For each of these 37 new drug introductions, we
calculated a profitability index which is defined as the ratio of the
present value of projected revenues to the present value of R and D costs.
Current and historical data on costs and revenues were used to extropolate
to future periods using a number of assumptions discussed in our draft paper.(A4)
I would like to briefly highlight here some of our main results.

A major finding of our analysis is that if the real interest rate is 10%,
the product life must be 19 years for our sample of 37 drugs before the mean
profitability index reaches one in value. Stated another way, it takes 19
years for firms to cover average R and D costs and earn a 10% real rate of
return on their invested capital. At an 8% real rate of return, product life
must be 12 years in value. These results are displayed graphically in
Figure 1 of the paper attached as Appendix A4.

Economic analysis indicates that historically, investors have received
a rate of return of approximately 9 percent for investment in a general
portfolio of stocks on the New York stock exchange. Given that investments
in pharmaceutical R and D appear more, or at least as risky as, a general
portfolio of common stocks, a real rate of return in the range of 8 to 10
percent would appear warranted here to sustain long term reinvestment of cash
flows in drug R and D activity.

Another major finding of our analysis is that the rate of return distri-
bution for new drug therapies is highly skewed in character. We found that
even if one assumes a 20 year lifetime for all of the 37 new drug introductions
in our sample, only 13, or roughly 35 percent, had a profitability index of
1 or more in value. This indicates that the majority of the new drug intro-
ductions do not cover their full R and D investment costs (i.e. when allowing
for both discovery costs as well as the large attrition rate on new product
candidates or "dry holes"). In effect, firms are dependent on a relatively
few "big winners" to cover their full costs and generate the required return
on their R and D investment portfolio.

This last point is reinforced by a forthcoming analysis performed
by Professor Lacy Thomas of the University of Illinois. His analysis shows
there is a significant concentration of pharmaceutical revenues in a small number
of products for most of the major U.S. firms. In particular he found the

leading three products currently account for a large fraction of sales (frequently over 50 percent) for several of the major firms in the industry.

These results underscore the importance of patent restoration in the competitive environment that is likely to hold over the final two decades of this century. The research intensive firms are increasingly dependent on a relatively small number of major new drugs, those capable of winning relatively large market shares, here and abroad, to finance and provide the returns on their overall portfolio of R and D investment projects. These major products however, also provide the most attractive markets for generic follow-on producers. The degree of competition provided by these latter firms is bound to substantially increase in the new marketing environment characterized by drug substitution laws and the MAC program (A1). If patent terms are insufficient to provide significant premia on these research winners, there will in turn be insufficient investment funds forthcoming to exploit all the scientific opportunities for developing socially beneficial new drugs.

In another recently completed paper, we have analyzed the determinants of pharmaceutical R and D investment expenditures (A3). Our statistical analysis indicates that firms do respond to higher or lower returns from R and D in the expected manner but the adjustment process is a gradual one. Our results also indicate a statistically significant positive relation between firm R and D outlays and the availability of internally generated investment funds. For the firms in our sample, a 1 million dollar increase in cash flow was associated on average with a quarter million dollar increase in R and D expenditures. This relation was quite robust over the 12 year period (1963-1975) analyzed by our study. Our study of the determinants of R and D expenditures in pharmaceuticals therefore indicates firm outlays are sensitive to both expected returns and the availability of internally generated funds.

Since restoration of patent life increases the expected returns from new drug innovation and also provides firms that are successful in new product introduction with increased profits and cash flow, it should lead to a significant increase in R and D investments on both these grounds.

The effect of patent restoration on the character of R and D investment and firm research strategies is more difficult to predict. However, patent restoration can be expected to increase R and D on "breakthrough" type drugs to the extent that these drugs are subject to above average riskiness and also to the extent they have longer product lives before they are made obsolescent

by competitors' new products. If a drug has a relatively short product life before being made obsolete by rival introductions, it will essentially be unaffected by patent restoration. Patent restoration will provide maximal incentives for drugs expected to have a high degree of "durability" over time and many breakthrough drugs appear to fit into this category.

As a final point, it should be observed that patent restoration, while providing a significant positive incentive for new drug investment outlays, will not be a perfect substitute or offset (at least on a one for one basis) for time and resources used up in the regulatory process. Patent restoration influences only the latter years of product life. Many products will be supplanted by rival firm introductions before the period of patent restoration comes into play. Furthermore, the value in economic terms of time added on to the end of the patent period will be worth much less than time restored at the front end of product life (through for example, reduced regulatory approval time). This is because of the time value of money. (A4)

In our sensitivity analysis, for example, we found that a 1 and 1/2 year reduction in the time it takes for a new drug application to be approved would reduce the time it takes for a drug company to recoup its R and D investment by a full 5 years--from 19 years to 14 years (see appendix A4, Figure 6). While it may not be possible to reduce the new drug approval time by this amount of time, this finding points up the continued importance of making the drug regulatory process as efficient as possible, consistent with societal objectives in drug safety. Hence regulatory reform should continue to be a high priority matter even if patent restortation is enacted.

Appendicies

A1   "Substitution Laws and Innovation in the Pharmaceutical Industry" by Henry Grabowski and John Vernon, Law and Contemporary Problems, Winter Spring 1979, p. 43-66.

A2   "Consumer Protection Regulation in Ethical Drugs" by Henry Grabowski and John Vernon, American Economic Review, February 1977, p. 359-364.

A3   "The Determinants of Research and Development in the Pharmaceutical Industry" by Henry Grabowski and John Vernon in Robert Helms, editor, Drugs and Health, American Enterprise Institute, Washington, D. C., 1981.

A4   "A Sensitivity Analysis of Expected Profitability of Pharmaceutical R and D" by Henry Grabowski and John Vernon, Draft, Duke University Department of Economics, April 1981.