The Push to Protect Patents on Drugs

The drug industry nearly won last year, but then the political winds changed

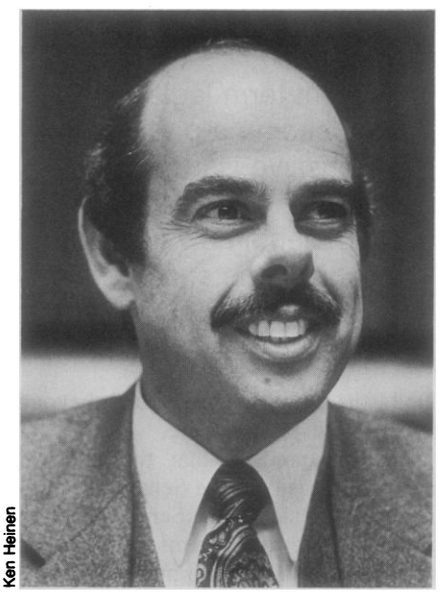
For nearly 3 years, the pharmaceutical industry has been campaigning for a change in patent law that would extend patent protection for drugs and pesticides. The industry contends that the change is needed to redress an injustice: whereas patents convey 17 years of exclusive use on most products, the patent life of drugs is shortened by the time consumed by regulatory review. The industry argues that this reform will encourage innovation and help stave off increasing foreign competition, by making available billions of dollars in new revenues that the industry can spend on research. But the bill's principal effect—the enrichment of one of the country's most profitable industries—is also its main political liability.

Just a year ago, legislation that would have achieved industry's objectives was on the brink of victory. A bill had passed unanimously in the Senate and a similar measure was moving easily through the House. But the political situation has changed dramatically in the past few months and now the legislation's future is at best cloudy.

The chief roadblock is in the House. Two key legislators, Representatives Albert Gore, Jr. (D–Tenn.), and Henry Waxman (D–Calif.) strongly oppose the legislation and have been instrumental in blocking its passage. However, Waxman has introduced a bill designed to aid manufacturers of so-called generic drugs. He badly wants the legislation passed and there is speculation that he may work out a compromise with supporters of patent extension to push his own bill through.

The industry's case is being pushed by the Pharmaceutical Manufacturers Association (PMA). A PMA briefing paper states that "lost patent life reduces incentives to invest in drug research, retards the rate of medical innovation, erodes the U.S. competitive position in an important high technology, and raises the cost of medical care at a time when medical expenditures are a critical national problem."

The PMA paper says that the legislation now before Congress is a "simple and direct antidote." The measure would give companies an incentive to put more money into research and develop new and better drugs. The industry notes that it is taking longer and longer to develop a drug and obtain approval by the Food and Drug Administration (FDA). For example, according to PMA figures, drugs approved in 1981 lost an average of 10.2 years of the statutory 17-year patent lives before their first sale. The number of drugs that come on the market and are new compounds has remained stable. The PMA paper says, "It should be a matter of concern that an industry which has quadrupled in size in two decades has not been able to afford to increase innovation at a comparable rate."



Ken Heinen

Representative Henry Waxman

A possible wedding of his generic drug bill with industry's patent term legislation.

Opponents speculate that the profit windfall created by patent law reform will primarily benefit corporate stockholders, not researchers or the public. Government figures show that the drug industry has consistently spent the same percentage of sales on research and development for several years despite an alleged decline in innovation. Critics also question the reliability of the industry's conclusions. Waxman and Gore, for example, note that the raw data on which the industry's argument is based have not been reviewed by independent analysts. The two legislators have repeatedly asked PMA for data that may resolve a dispute about the real patent lives of drugs. They charge that PMA has looked at only a selected number of drugs and want a complete list. Although the data were requested 2 years ago, PMA did not submit the information until just last week. Waxman and Gore plan to ask the Office of Technology Assessment to analyze the data.

Opponents call attention to other information to undercut the PMA's arguments. They point out that industry as a whole received a 25 percent tax credit on R & D in 1981. In contrast to industry's contention, top selling drugs in 1980 had a marketing life nearly equal to a 17-year patent term. Opponents also find it difficult to believe PMA's statement that an extension of patent terms would "do no economic harm to generic firms." Generic firms have been fighting an uphill battle in the marketplace because the large, established drug companies even dominate generic drug sales. The established companies market branded drugs under the trade name or generic name accompanied by the imprimatur of the firm's name, making it difficult for generic firms to compete.

Much of the information that opponents cite is based on findings in a 1981 report by the congressional Office of Technology Assessment (OTA). While OTA officials testified before Congress that the report "neither supports nor refutes the position that innovation will increase significantly because of [patent term] extensions," the report played an important role in the downfall of the House bill last year. Perhaps most significantly, it argued that innovation could be measured several ways and concluded that it is not clear whether innovation in the drug industry had indeed declined. The report also pointed out various ways in which a company can protect its product. For example, according to Donna Valtri, assistant project director of the report, drug companies, in some instances, can secure additional patents on a product. She testified at a House hearing that in some instances, process patents "can be an effective means for ensuring exclusive market positions." The report also said it was unclear whether patent extension would give companies an incentive to increase research in the United States. Valtri points out that domestic companies are increasingly licensing drugs invented by foreign

firms and also testing the drugs abroad where the cost of labor and research is cheaper.

In August 1982 the PMA was almost sure that patent extension legislation would pass Congress. The House Judiciary Committee had already approved a bill. The measure went before the Rules Committee where, according to a count by PMA, a majority of committee members favored the proposal. Furthermore, the bill had the backing of the Reagan Administration and a battalion of other groups, including the American Bar Association, the Chemical Manufacturers Association, the U.S. Chamber of Commerce, the American Heart Association, numerous professional medical societies, and several universities such as Massachusetts Institute of Technology.

But Richard Bolling, former Democrat from Missouri, who was then chairman of the Rules Committee, opposed the bill and refused to bring it up for a vote. The PMA, confident that it had overwhelming support, circumvented the Rules Committee by having the bill brought to the floor under the suspension rule. The rule is designed to assure the passage of noncontroversial bills and requires the approval of a two-thirds majority. But shortly before the floor vote, the political environment changed.

The *New York Times* reversed its position on the bill and, in an editorial that relied heavily on the OTA report, denounced the measure as "unjustified, unsuited to the stated purpose of increasing research, and offensive to the basic principle of a free economy." Gore and Waxman circulated the editorial to all House members. Shortly thereafter, Congress Watch, a Ralph Nader group, released a report, "Sugar Coating a Monopoly, A Study of the Drug Patent Restoration Act." The manufacturers of generic drugs lobbied legislators that a vote for the bill was a vote against the consumer. The legislation lost by four votes.

Frank Fowlkes, PMA vice president of communications, said in a recent interview, "The *Times* editorial hurt a whole lot." The combination of the editorial and the Nader report "scared enough fence-sitters who were up for reelection that the bill was anti-consumer."

Now the drug industry, so close to victory last year, finds itself on the defensive and trying to win back supporters. The issue has become particularly sensitive in an election year because opponents of current legislation now include the American Association of Retired Persons and the AFL-CIO.

For the time being, there is a lull in the action. Congressional aides from the Senate and the House say there is not likely to be much movement on the issue until the new year and even then, it is hard to say what will happen. The OTA analysis of the industry data, which were recently submitted to Waxman and Gore, could also delay legislative action. But PMA is still hopeful and has continued to push the issue hard. Association staff members have blitzed 140 newspapers around the country with packets of information about the bills and have criss-crossed the nation to meet with editors of 75 of the newspapers.

Identical bills, similar to last year's legislation, have been reintroduced in both chambers. They would extend patent protection to drugs and pesticides for a period equivalent to the time the products are filed or registered with the federal government and undergo agency review before approval. The legislation limits the extension to 7 years beyond the patent expiration date.

Patent term legislation has become a particularly sensitive issue in an election year because opponents now include organizations such as the AFL-CIO.

Fowlkes predicts that the bill will again pass easily in the Senate. According to a staff aide to the Senate judiciary subcommittee on patents, copyrights, and trademarks, the bill may be marked up by the subcommittee some time in November. Again, the biggest hurdle will be in the House where the situation has become very complex.

Although the House bill was introduced in June, a judiciary subcommittee has not yet held hearings on it. Subcommittee chairman Robert Kastenmeier (D–Wis.), who sponsored patent extension legislation last year, is opposed to this year's version of the bill which would allow a greater number of drugs to qualify for the extension. Gore is still fighting the legislation.

At present, attention is focused mainly on Waxman. He has been a formidable foe of patent extension. Fowlkes said, "We didn't anticipate that Waxman would make the legislation a do-or-die issue like he did." But it may be Waxman, a master of compromise and political tactic, who will provide a legislative vehicle that will achieve his goal and that of the drug industry.

For several years, Waxman has championed the need for generic drugs and, in July, introduced legislation that is designed to encourage their production and reduce the cost of drugs for the consumer. In essence the bill would make it much easier for generic companies to copy drugs whose patents have expired. The bill, however, has not gone far in the House. To ease the bill's passage, Waxman is now talking with PMA to see if there is a way to combine his wish list with theirs.

Waxman's bill addresses a gap in FDA policy that has constrained the production of a wider variety of generic drugs. The agency imposes few restrictions on generic drugs that were approved before 1962. (In 1962, FDA reformed its drug regulations and required drugs to be not only safe but effective.) In effect, generic companies do not need to conduct lengthy clinical trials to again prove the safety and effectiveness of an old drug.

But FDA treats off-patent drugs approved after 1962 much differently. The agency says that to duplicate post-1962 drugs, a generic company must either conduct clinical trials or submit data from scientific journals that show the duplicate drug is safe and effective. Generic companies have problems meeting either requirement because the firms, which frequently are small, cannot afford the research and because studies on patented drugs are usually considered proprietary information and are not reported in the scientific literature.

Waxman's bill would eliminate the distinction between the pre- and post-1962 drugs. Fowlkes says that PMA has no problem with the concept provided that the drugs have adequate patent protection before they are duplicated by the generic companies. PMA in fact submitted a draft bill to Waxman in September which sandwiched together proposals for generic drug production and patent restoration. But Waxman rejected the entire proposal because it was so lopsided in favor of PMA members. That Waxman even entertained a draft proposal from PMA has led some observers of the fray to venture that some sort of compromise might eventually be struck.

Waxman's bill may be complicated by an FDA proposal that is now before Margaret Heckler, Secretary of Health and Human Services. Like PMA's bill, the FDA proposal contains provisions on generic drug production and patent extension.

The plan would provide more encouragement than PMA's draft bill for the

production of generic drugs, but not as much as Waxman's legislation. The main potential problem with the proposal is that it attempts to extend the patent life of drugs by an administrative ruling rather than through legislative change in patent law. The plan would guarantee that drugs could not be duplicated generically for up to 15 years after FDA approval. At a hearing in August, Waxman challenged FDA's authority to carry out the proposal and the measure would almost certainly be challenged in court if approved by Heckler.

Although it appears that all the parties involved are at loggerheads, there may be room for compromise. Some opponents of patent extension, such as Public Citizen Litigation Group, have suggested a modest form of patent extension that even PMA says would be better than nothing. PMA's best hope is that the period of patent extension would be measured from the date when a company applies to FDA to begin clinical trials to the date when the drug is approved. Public Citizen has proposed that the clock start running when a company applies to FDA for permission to begin marketing the drug. The consumer group argues that this is actually the period when a drug undergoes federal review. This period would add perhaps 2 years, far fewer than the time allotted by the draft legislation. A House aide involved in the issue said that the shorter way of measuring the patent extension "is a major improvement" over the current legislation. Nevertheless, according to this aide and others, Gore and Waxman still believe that the drug industry has yet to prove its case.—**MARJORIE SUN**

World Model for the Joint Chiefs

The Joint Chiefs of Staff (JCS) are getting a new toy that should make other government agencies green with envy: a computerized global model of political, resource, and social data that represents a step toward catching up with private sector capacities.

The system, called FORECASTS, is in its second year of development, at a cost of $1.2 million. It will be tested for 6 months by the Army Corps of Engineers before the Joint Chiefs get it next year. The primary reason for the acquisition is to help the JCS make their 4-year Joint Long Range Strategic Appraisal, a new exercise, started in 1980, to evaluate global and national trends up to 30 years hence. The services, which do their own appraisals, will also be using the model.

For several years the JCS has had the use of the World Integrated Model (WIM), FORECASTS' predecessor. But the new one goes far beyond WIM, according to Patricia G. Strauch, president of Prospective Decision Models, Inc., the contractor. WIM, which is in use in several other government agencies, has a much smaller data base, it divides the world by multination regions, and contains little information on such critical areas as the environment.

Unlike WIM, which is designed for long-range projections, FORECASTS has three modes of operation: a data base covering the years 1960 to 1980, short-range statistical procedures for extrapolations up to 5 years, and a long-range program which contains complex feedback and interactive capacities for projections up to 30 years in the future.

While most global models divide the world into regions or sectors (such as agriculture), FORECASTS can present data on a national as well as a regional basis. The vastly expanded data base contains information on vital characteristics ranging from land use to international political agreements. There is a new "political stability" module capable of being decoupled if security demands it. The model contains extensive detail on population, including sex, fertility, employment, urban-rural distribution, and migration, as well as social, religious, and linguistic subdivisions.

In recognition of the discontinuities that mark the present and probable future, says Strauch, a fundamental premise of the model is that "the past won't repeat itself." In facilitating economic analysis, for example, designers of the model place reliance on detailed data about human-resource interactions rather than building in traditional and now-dubious assumptions about the causes and effects of inflation or unemployment.

Knowing the capacities of the new system does not answer questions about how it will be used. What sort of questions, for example, is it uniquely equipped to address? Colonel James Edgar of the JCS submits that it would be interesting to know if 20 years ago FORECASTS could have cued analysts in to the emergence of the Middle East as the world's energy fulcrum. It might also be asked whether the model will be used by the military to reinforce prior assumptions, or whether it will result in the introduction of a greater variety of nonmilitary, nonpolitical factors and a keener awareness of global interdependencies into defense analyses. Says Mihajlo Mesarovic of Case Western Reserve University, who developed WIM: "Using strategic planning models is absolutely essential in analysis of long-term policies, but in the hands of people without insight into future options it would be grossly misleading and dangerous to use—like a gun."

It would be interesting to speculate how this capability might alter the relation of the defense establishment to the Central Intelligence Agency and the State Department when it comes to assessing long-range political trends. State, in particular, is deeply attached to traditional ways and, says an official, tends to think of long-range planning as "anything over 6 months." Gerald O. Barney, who headed President Carter's Global 2000 effort, says the department has "very little expertise in the use of models" and little interest in them. Yet, he asserts, they are "ultimately going to have a big impact on the way foreign policy is formulated."

Comprehensive attempts at global modeling, starting with *Limits to Growth* in 1972, are often associated with "gloom and doom" visions of the world's future (*Science*, 22 July, p. 341). The White House, for example, has criticized calls for a centralized "foresight" capability as being motivated by an anti–free market, progovernment intervention ideology. Perhaps, then, the most significant contribution of FORECASTS will be to decouple global modeling from ideology and present it as a valuable tool in a world where some mistakes have become too costly to make.—**CONSTANCE HOLDEN**