

# Patent nonsense: Evidence tells of an industry out of social control

Henry Mintzberg

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What enables the patent-dependent pharmaceutical companies to set the prices they do? Two factors. The first is economic: the companies that make (or at least secure the right to) the discoveries in this marketplace of ideas reap the rewards. The second is legal: governments grant those companies monopolies, in the form of patent protection, for what is called their “intellectual property.”

Usually, governments that have granted such important monopoly powers in the marketplace, for example in electricity and telephone services, have regulated prices carefully — and those that did not have often suffered the consequences. Most countries do, in fact, attempt to control pharmaceutical prices. But the United States, which generally does not, has recently used its bilateral and regional free trade negotiations with countries such as Australia, Peru, Guatemala and other Central American countries to weaken their ability to control drug prices.<sup>1-6</sup>

In this article, I describe the “patent nonsense” of granting public monopolies to private companies, on products that can determine the life or death of the user, with insufficient control of prices. I will discuss the issues surrounding the high price of pharmaceuticals using a framework that represents the stages of the companies’ operations (Fig. 1).

## Research

Pharmaceutical companies’ prime justification for their pricing, namely performance in costly and risky research,<sup>7</sup> may in fact prove to be the weakest link in their chain of argument as well as their chain of operations.

How well do the pharmaceutical companies perform this research? There have certainly been impressive accomplishments. But disturbing evidence is now accumulating of an industry increasingly troubled by its research record.

A 2002 article in *The Economist* wrote of an industry “losing its knack for producing wonder drugs,”<sup>8</sup> and a 2003 editorial in the *British Medical Journal* referred to “concerns ... about the productivity of research being funded by the major pharmaceutical companies.”<sup>9</sup> In 2004, *The Wall Street Journal* reported that “Last year, the Food and Drug Administration [FDA] only approved 21 new drugs, marking a steady decline since a peak of 53 in 1996. Many of the world’s largest drug companies failed to win U.S. approval for a single new drug in 2003. The dearth of new products has forced companies to seek growth by heavily promoting their pills and extending product lines through minor modifications.”<sup>10</sup> Concerning the latter, known as “me-too” drugs, Light and

Lexchin cited evidence that “only 10–15% of ‘new’ drugs provide a significant therapeutic breakthrough over existing drugs” and only “about 18% of the drug industry’s research budget goes to basic research for breakthrough drugs.”<sup>11,12</sup>

These problems may be explained by recent structural changes in the pharmaceutical industry, including consolidation through mergers, expansion of leading companies to unprecedented size, and the advent of “shareholder value,” which drives executives to push up company share prices, thereby breeding a short-term, results-driven mentality antithetical to thoughtful research.

Large scale may be an impediment to effective research. So said Raymond Gilmartin, chief executive of Merck, long renowned for its research: “Scale has been no indicator of the ability to discover breakthrough drugs. In fact, it has been the other way — you get bogged down.”<sup>13</sup> Yet scale is on the rise, as is industry concentration, in consequence especially of company mergers.<sup>14</sup>

A 2003 article in *The New York Times* reported that “9 top scientists” had recently left GlaxoSmithKline because they believed “its laboratory productivity was getting worse, not better. ‘It’s a disaster,’ said one of them, Dr. Peter G. Traber, who was the company’s chief of clinical development until February.” He added: “The effect of mergers on research productivity is an issue that this industry has yet to deal with.”<sup>15</sup>

Research in organization theory has long indicated the effects of company size on the bureaucratization of procedures.<sup>16</sup> Systems become more formal, relationships more impersonal, categories more reified. This can have an especially stifling influence on research, which tends to thrive in open, flexible structures.

A 2004 *Wall Street Journal* article entitled “Drug maker, heal thyself” noted that “When the going gets tough, the tough raise prices. With few new products to launch, major drug makers have been raising the sticker prices of medicines already on the U.S. market, where they’re freest to do so.”<sup>17</sup>

It is time to take a careful look at who does pharmaceutical research, in what ways, for what purposes and with what con-



Fig. 1: Framework representing chain of operations of pharmaceutical companies.

sequences. Certainly there is an important role to be played by the large patent-dependent pharmaceutical companies, although if current trends continue, it may be more in development than in research. And smaller companies clearly have much to contribute in certain critical spheres of research. But we may have lost sight of the important role of other institutions as well as other incentives for discovery.

Consider 3 of the most significant pharmaceutical-related discoveries of the 20th century: penicillin, insulin and the polio vaccine. All came from the laboratories of not-for-profit institutions. Their incentives were clearly not primarily financial. Working in such institutions may in fact contribute to the effectiveness of the researchers. Imagine Alexander Fleming in a corporate laboratory today, expected to maximize “shareholder value” for shareholders he’s never met while having to look at all those compounds on computer screens. What incentive would he have to see the potential of those bacteria in that mould?

“Intellectual property” appears to be a simple enough concept: to the maker of the discovery goes the benefits. But a pharmaceutical discovery is not a piece of land around which lines can be drawn. Discoveries flow into one another, and depend on each other. In particular, “downstream” discoveries, namely marketable products, often depend on “upstream” discoveries in basic research. Yet the former can be more easily patented than the latter because they are more tangible, and so companies that operate downstream may be able to benefit financially from discoveries made by not-for-profit institutions upstream.

Much of upstream research is government subsidized, which means that tax dollars may be converted into profits for pharmaceutical companies. A US Congress report of 2000 noted that “Of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques from federally funded research.”<sup>18</sup> In one case, a company “benefited from substantial investments in research conducted or funded by the NIH [National Institutes of Health],” with sales of the products amounting to \$9 billion between 1993 and 2002. The company gave the NIH \$35 million in royalty payments, a small fraction of what the NIH estimated to be of its own spending on the related research.<sup>19</sup>

## Development

The major pharmaceutical companies are increasingly letting biotechnology companies and start-up companies “take the big risks of research.” They then buy their innovations and develop them. “The evidence clearly suggests that smaller, younger organizations are more likely to deliver true innovations,” claimed a pharmaceutical executive.<sup>20</sup>

That approach may be reasonable. But the profits resulting from it may not be. It is telling that Pfizer, the company known especially for mergers and for buying or licensing its way into new products,<sup>21</sup> has become by far the largest pharmaceutical company and the most profitable.

Some of these profits, of course, end up with the small firms that make the discoveries. But much ends up with the

buyers of these innovations, and that has to do with market power, not research. The small firms may be adept at doing some of the research but are less so at doing much of the development, that is to say, carrying the discovered compounds to registration through testing. Here is where scale can be helpful, and indeed the formal procedures of the large companies. In fact, given their size and position in certain market segments, as a consequence of their established channels of distribution and massive expenditures on promotion, these companies can become the de facto gatekeepers of the registration and distribution processes. As such, they can reap huge economic benefits. Of course, no company can justify these profits on the basis of development, and certainly not on the basis of manufacturing (by one estimate, 3% of the ex-factory price on average<sup>22</sup>) or promotion. So the large pharmaceutical companies justify their profits on the basis of research — even when it is not their own.

## Promotion

At the end of the pharmaceutical chain of operations is promotion, much of which may benefit the companies at the expense of their customers.

The expenditures to pull the products through the channels, via physicians to users, are enormous. *Fortune* magazine has described Pfizer as a “marketing machine” that “spends roughly 39% of its revenues ... on sales and marketing,”<sup>13</sup> — more, in fact, than it spends on research and development. To this must be added the time required of physicians. (The industry alone reportedly spends \$6000 to \$11 000 per physician per year.<sup>23</sup>)

“Promotion” is not meant to inform in any balanced way, but rather to convey the advantages of a product while obscuring its disadvantages. A reliance on promotion to inform about pharmaceutical products can thus lead to distortions in their use and to excessive prescribing, especially given the growing, and questionable, practice of advertising directly to consumers. “Timely, independent, comprehensive, and accurate information on new drugs is hard to find,”<sup>24</sup> noted 2 health policy academics. Might not health care be better served by having independent clearinghouses screen and make available all the relevant information on pharmaceutical treatments?

A great deal has been revealed in recent years about biases in pharmaceutical companies’ reports on their medicines. These include “the preponderance of positive company-sponsored studies,” threats of “legal action to stop nominally independent researchers from publishing negative material” and research contracts that allow “the sponsoring company to delete information from the report and to delay publication.”<sup>25</sup> Embarrassed by this, some pharmaceutical companies have announced changes in their intentions to report.

## Conclusion

In a 2001 *Business Week* article, Carey and colleagues<sup>20</sup> reported that “since 1988, the return on equity of the five biggest U.S. based drugmakers ... has averaged 30% a year,”

far in excess of Standard & Poor's 500 index, and that "drug-makers show a consistently higher return on equity compared with companies in other sectors." They concluded that "the price set for a drug has little to do with its development cost. ... The producers charge what the market will bear." Profits do vary, and crises (as in the case of Merck recently), do arise. But companies continue to charge what the market will bear. Unfortunately, what the market will bear is not necessarily what the ill can afford.

The problem of high pharmaceutical prices is not without solutions. Many are obvious enough, and some have been implied in this article, including firmer regulation of pricing, the use of independent clearinghouses for balanced information on products, research efforts more widely spread across different types of institutions and a stop to direct-to-consumer advertising. However, there is a lack of sufficient will to confront the problem directly, in part because of the power of the industry and its influence on political processes. The current situation in the patent-dependent pharmaceutical industry is not just unacceptable, it is shameful. It will remain so until concerned citizens gather the energy to change it.

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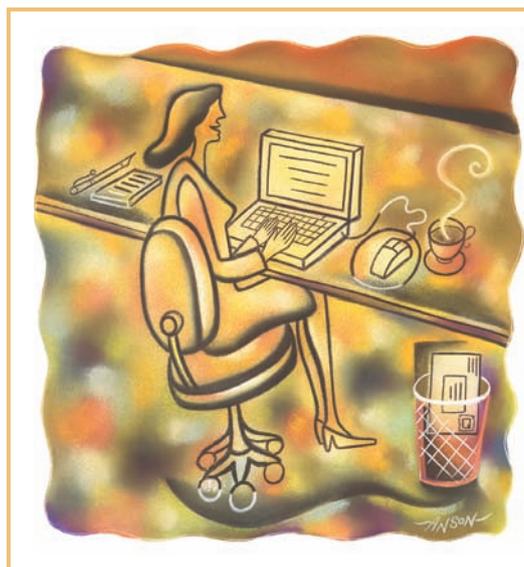
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