

## Chapter 9: The Pharmaceutical Industry

It is often argued that the best case for patents is in the pharmaceutical industry. The indivisibility is large, with estimates of the average cost of bringing a single new drug to market as high as \$800 million. Patent protection is more limited than in other industries: because of the lengthy gap between discovery and approval of a new drug, the effective monopoly protection is estimated, since the 1990s, to last only 12 years, apart for extensions. Indeed, according to industry surveys, the only industry in which patents are thought to play an important role in bringing new products to market is the pharmaceutical industry.

The pharmaceutical industry is worthy of special consideration also for another, opposite, reason. The technology operated by the pharmaceutical industry – the chemical and industrial processes, through which medicines are produced, packaged, and shipped, seems to fit the constant returns to scale hypothesis almost perfectly. That is, the cost of shipping the ten millionth container of medicine is about the same as that of shipping the first. This is why, after all, everyone complains about the pharmaceutical companies not shipping medicines to poor countries – the actual few additional cents needed to produce the medicine even poor African consumers would be willing to pay make the withdrawal of supply by big pharma as close to economic crime as anything can be. Under these circumstances we would expect that there are many potential producers of a medicine, and that the industry would be relatively competitive. Yet, since the 1970s, pharmaceutical manufacturing has become quite concentrated with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country. Why is this? The industry claims it is because only very large firms can afford the high cost of pharmaceutical R&D.

Therefore, it is reasonable to ask – how strong is the case for patents in pharmaceuticals? If the case is strong, perhaps we need to examine other industries to see if the case for patents might also be strong in those industries. In fact, we shall see that the case for patents in pharmaceuticals is weak – and so, apparently, even under the most favorable circumstances patents are not good for society, for consumers, or in this case, for sick people. Patents are good for monopolists, but that much we knew already.

**History of Pharmaceutical Patents**

Pharmaceuticals are a significant industry, and of growing significance. In the United States, the share of prescription drugs in total national health care expenditure increased from 4.9% in 1980 to 9.4% in year 2000. New drugs are also extremely costly to develop. Hansen, Grabowski and Lasagna, in 1991, provide the following estimates of the cost in millions of dollars of bringing a “new chemical entity” to market, assuming a success rate of 23% for patented drugs.

	<i>0% interest</i>	<i>8% interest</i>
<i>pre-clinical</i>	66	142
<i>clinical</i>	48	72
<i>total</i>	114	214

Notice that the pre-clinical component of cost is large, and especially so when the interest rate is taken into account, since the pre-clinical costs must be paid before going to clinical trials.

Historically, intellectual monopoly in pharmaceuticals has varied enormously over time and space. The summary story: the patent lobbyists have lobbied long and successfully to increase patent protection for pharmaceutical products. Here are the details of their accomplishments.

In the U.S. drugs have been patentable since the beginning, for the very simple reason that chemical products have always been patentable. The U.S. recognizes two distinct forms of patent: the process by which a drug is produced may be patented independently of the chemical formula for the drug. Until 1984 U.S. patent law treated medical discoveries in the same way as other innovations, and no special treatment was reserved for drugs. In more recent years, the USPO and the Federal Court of Appeal have begun to allow longer and more frequent extensions for drug patents than they do for the rest of patented innovations. For example, the Drug Price Competition and Patent Term Restoration Act of September 24, 1984 (the Hatch-Waxman Act) was designed to compensate for regulatory requirements that delay the introduction of new drugs. It is estimated that it increased effective length of patent protection for pharmaceuticals by about 5 years.

In most of continental Europe, until recent years, only the process of producing a drug could be patented, so once a drug was discovered, a second producer could also produce it provided they found a different way of doing so. The rationale behind process

versus product patents is given by the German Association of Chemical Industry in a memoire to the Reichstag. They point out that the same chemical product can be obtained by different processes and methods and even starting from initially different materials and components. Hence, there is social value in patenting a new process, as it rewards the innovator without preventing further innovation. There is negative social value in patenting a specific product, as this would exclude all other from producing it, even through different processes. It should be noted, though, that this did not prevent German chemical companies from patenting their products where possible, the United Kingdom and the United States especially.

In France, under the law of July 5, 1844 pharmaceutical inventions could not be patented. Legislation then evolved, keeping the prohibition for patenting products but allowing patents for processes. The executive Order of February 4, 1959, and, then, the law of January 2, 1966 finally introduced limited patents for pharmaceutical products in France; the ban on patenting drugs was completely lifted only in 1978. In Germany, the law of May 25, 1877 introduced patents for both chemical and pharmaceutical processes, while products were explicitly excluded. The Law of April 4, 1891 extended patent protection to products obtained via a patented process. Finally, the law of September 4, 1967 introduced general patentability of chemical and pharmaceutical products in Germany.

In Switzerland, patents for chemical and pharmaceutical products were explicitly prohibited by the constitution. The Swiss pharmaceutical industry, whose strength does not need to be recalled, has, however, been a historically important competitor for the German. Constant German pressure eventually lead to the adoption of patents for processes with the Swiss Law of June 21, 1907, which was nevertheless quite restrictive. The Law of June 25, 1954 continued to apply only to processes but extended the length of patents from 10 to 18 years. Patents for products were introduced in Switzerland only in 1977.

In Italy, pharmaceutical patents were prohibited until 1978, when the Supreme Court ruled in favor of eighteen pharmaceutical companies, all foreign, requesting the enforcement of foreign patents on medical products in Italy. Despite this complete lack of any patent protection, Italy had developed a strong pharmaceutical industry: by the end of the 1970s it was the fifth world producer of pharmaceuticals and the seventh exporter.

In Spain, the *Ley de Patentes* introduced patents for products in 1986, as a consequence of the country's entrance in the EEC. The law began to be applied only in 1992. Before that date, regulations dating back to 1931 explicitly prohibited the patenting of any substance and, particularly, of any pharmaceutical substance. Patenting of processes was instead allowed.

Pharmaceuticals are also covered by a variety of international agreements. The contemporary era of patenting began with the Convention of the Union of Paris in 1883 following the Vienna Conference of 1873. More recently, the Patent Cooperation Treaty was signed in Washington on June 19, 1970, which started a process of international extension of stronger patent protection for medical products. The Munich Convention of October 3, 1973, implemented since October 7, 1978 defines the notion of an "European Patent." Further revisions and modifications of the original basic agreement led, eventually, to the definition of a European Community Patent, based on a convention signed in Luxembourg on December 15, 1975. While the latter was not ratified by Denmark, Ireland, Greece, Portugal and Spain it has been fully implemented and accepted by E.U. member states since 1992.

It is worth pointing out that under E.U. patent law, programs for computers together with scientific discoveries and theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, and presentations of information are expressly not regarded as inventions and therefore cannot be patented. Since there is a large degree of ambiguity as to what a scientific theory or discovery is, it is unclear of the extent to which a new medicine, or a new biologically engineered product is or is not independent of the underlying chemical and biological model that explains it. Through this ambiguity medical products and treatments have been increasingly patented in the E.U. in ways altogether similar to the U.S.

Now, you may be wondering, why are we boring you with all these details about specific countries, patenting of chemical processes, and pharmaceutical products, and so forth? For a very simple reason: if patents were the source of medical innovation as claimed by intellectual monopoly apologists, the large historical and cross country variations in the patent protection of medical products should have had a dramatic impact on the pharmaceutical industries of the different countries. In particular, at least between 1850 and 1980, most drugs and medical products should have been invented and produced in the United States and the United Kingdom, and

very little if anything in continental Europe. Further, countries such as Italy, Switzerland and, to a lesser extent, Germany, should have been the poor sick laggards of the pharmaceutical industry until the other day. Instead, as everyone knows since high school, the big time opposite is and has been true. This is as macroscopic a contradiction of the intellectual monopoly apologists' argument for patents in general, and for medical patents in particular, as one can possibly imagine.

### ***Chemicals Without Patents***

Prior to the rise of the pharmaceutical industry, the most important form of chemical production was the paint and coloring industry. Indeed, it is the strong patent protection for this industry in France and its absence in Switzerland that was largely responsible for the development of the important Swiss chemical, and then pharmaceutical, industry. In 1868 in France, the chemical company "La Fousine" was pushed to bankruptcy by the new enforcement of laws allowing patents on coloring products. This put the many French companies constituting the paint and coloring industry on notice, resulting in a large movement of firms to Switzerland, where patents were illegal. In case this reminds you of how the Hollywood movie industry was created by migrating entrepreneurs running away from Edison's patents, you are beginning to see a pattern. The migrating French firms located in and around Basel and were rapidly followed by other chemical companies. The movement was so dramatic that just before the First World War, Haber observes that in France there was no production of chemical products, either organic or inorganic.

Haber explicitly attributes the absence of a French chemical industry to the presence of patents stifling competition and making innovation impossible. He points out that, in a similar way, the slow growth of the coloring industry in the U.S. before the First World War was largely due to patent protection: most patents were held by the large German companies, such as Bayer, BASF, Hoechst and IG Farben. The chemical industry in the US was so underdeveloped, that during the First World War the U.S. was forced to import dyes from Germany via submarines to bypass the British blockade.

This would be humorous, if it were not sad: German chemical companies competed heavily at home and across most European markets, where chemical products could not be patented. This situation forced them to innovate frequently and to develop production processes able to guarantee a very high productivity. Such intense competition already gave them a "competitive edge"

relative to the Anglo-Saxon companies living in a world of generalized patenting. To this initial advantage was added the opportunity to patent products in the U.K. and the U.S., allowing the German chemical companies to erect insurmountable barriers to entry in the chemical market.

It is only the end of the two World Wars and the de-facto expropriation of German chemical know-how, first by the French and British and then by the victorious Allies, that restored competition in the chemical industry for a few decades. Indeed, in the end, the WWI blockade did work – allowing Du Pont to enter the dyestuff market by ... pirating German products. The British government provided Du Pont with access to the industrial secrets found in a Hoechst plant in the U.K. that had been confiscated at the start of the WWI; the U.S government allowed Du Pont free access in 1919 to all German chemical patents, as these were confiscated at the end of the war.

Here is how Murmann summarizes the main findings from his historical study of the European synthetic-dye industries during the 1857-1914 period

*German and Swiss firms in the early years of the synthetic dye industry created superior technological competencies than their British and French counterparts precisely because they were initially not able to obtain patent monopolies in their home markets. When Germany later was about to pass a patent law and dye firms feared negative consequences of patent monopolies for their industry, they collectively organized themselves to influence patent legislation so that it would create a sufficient amount of competition within Germany and force firms to maintain better organizational capabilities than their foreign rivals.*

In England, before the First World War the Baadische Chemical Company held a patent covering all textile coloring products. Levinstein and Co. developed a new and superior process to deliver the same product. Baadische Chemical sued and obtained a court restraint, preventing Levinstein from using the new process to obtain the old product. Interesting enough, Baadische could not use the new process, as they did not know how it worked. The outcome was a move of Levinstein to the Netherlands, where the patent was not enforced, and the consequent demise of the British coloring industry.

Even more interestingly, the industry most favored by the British and American strict enforcement of patent protection was the German chemical industry. As we learned before, pharmaceutical products could not be patented in Germany at the time, but they could be patented in the United Kingdom. This created an incentive for the then dominant German chemical companies, which were competing at home and thereby intensely innovating, to patent their products in England and the USA: why give away some monopoly profits, if a dumb foreign government allows you to grab them? So, before the First World War, medicines and other chemical products were scarce and expensive in England as German companies held most patents. This led, in 1919, to the modification of the English Patents Act of 1907 with the addition of section 38A which introduced mandatory licenses for medicines. Again, the report of the Sargent Committee of 1937 pointed out the shortage of medicines and its relation with strong patents in England. In the Patents Act of 1949, section 41, No. 2, a new special procedure was introduced to favor mandatory licensing of food and drug products.

What is especially striking, again, is that during this period Germany itself did not enforce product patents, only process patents. The British government spent about forty years fiddling around with its patent laws, without ever abolishing them, in the vain hope of lowering the prices of medicines and creating incentives for its pharmaceutical industry to catch up with the German. It did not succeed, as we all know: the German companies kept innovating, even if their new products were not protected by any patent at home, and the British pharmaceutical industry never came close to being competitive. Aspirin, that wonder drug, was a German invention, not a British one!

From a theoretical point of view, it is not hard to understand the devastating impact of patents on innovation in the chemical industry. The chemical industry is a classic case of the innovation chains – new compounds and processes are built on the knowledge of existing ones. As we observed, patents are particularly harmful in this case, since the increased incentive to innovate is, as in the chemical industry, more than offset by the increased difficulty of doing so.

It could be, and sometimes is, argued that the modern pharmaceutical industry is substantially different from the chemical industry of the last century. In particular, it is argued that the most significant cost of developing new drugs lies in testing numerous compounds to see which ones work. Insofar as this is true, it would seem that the development of new drugs is not so dependent on the

usage and knowledge of old drugs. However, this is not the case according to the chief scientific officer at Bristol Myers Squibb, Peter Ringrose, who

*told The New York Times that there were 'more than 50 proteins possibly involved in cancer that the company was not working on because the patent holders either would not allow it or were demanding unreasonable royalties.'*

So it seems that the impact of patent law in inhibiting research remains even in the modern pharmaceutical industry.

### **Medicines Without Patents**

Patents for medicines were introduced in Italy, under the pressure from foreign multinationals, in 1978. Maybe, because of the strengthening of IP protection, the Italian pharmaceutical industry witnessed a period of unusual growth after that, and new medicines were invented at a pace much higher than the one observed during the previous decades. Yes, maybe. During the period 1961-1980 a total of 1282 new active chemical compounds was discovered around the world. Of these, a total of 119 came from Italy (9.28%). During the period 1980-1983 a total of 108 compounds were discovered. Of these, 8 came from Italy (7.5%). While we do not have data covering the most recent decades, the impression of the informed observer is that things have become worse, not better. Professors Scherer and Weisburst, in fact, took the pain of carefully studying the evolution of the Italian pharmaceutical industry after the adoption of patents. Here is the summary verdict, in Scherer's own words

*Research by Sandy Weisburst and mentored by me showed, for example, that Italy, with a vibrant generic drug industry, did not achieve any significant increase in the discovery of innovative drugs during the first decade after the Italian Supreme Court mandated the issue of pharmaceutical product patents.*

A number of historical and empirical studies makes evident that, absent patents, the Italian pharmaceutical industry did not suffer particularly until 1978. On the one hand, foreign companies holding patents abroad entered the Italian market, via direct investment and the establishment of local production units, in order to protect the market share of their own products. On the other hand,

the possibility of freely imitating products patented elsewhere favored the creation of a large number of Italian imitative firms, which improved upon existing products and, at the same time, allowed for their diffusion at much lower prices. In spite of this, the forty largest Italian firms did not simply imitate but developed their own products and innovated extensively, either by using existing products as ingredients (25%) or by using products which were not patentable or with expired patents (31%).

Strong evidence that concentration and patent protection go hand in hand comes from the Italian experience before and after the 1978 watershed. Before 1978 the Italian pharmaceutical industry was characterized by the presence of a large number of small and medium sized independent firms. After 1978, industry concentration proceeded rapidly: the total number of independent firms went from 464 in 1976 to 390 in 1980 and 335 in 1985. During the same period, no concentration of the productive activity took place in the pharmaceutical industry of the other large western countries. The Italian pharmaceutical industry, in the meanwhile, has lost market share at a constant pace both nationally and worldwide; as one of us, from time to time, tries to keep up with what is happening back there, we learn from alarmed politicians and newspaper reporting that the Italian pharmaceutical industry is, in fact, practically disappearing, together with the most valuable and patentable drugs it did not invent since 1978.

Since 1978, India has taken over as the primary center of pharmaceutical production without patent protection. The growth and vitality of the Indian industry is similar to the pre-1978 industry in Italy. Sadly, India has now been forced to introduce product patents on pharmaceutical products – from the Italian experience, we can expect this to put an end not only to imitation in India, but innovation as well.

### ***Rent-Seeking and Redundancy***

In addition to the problem of innovation chains, there is much evidence of redundant research on pharmaceuticals. The National Institute of Health Care Management reveals that over the period 1989-2000, 54% of FDA-approved drug applications involved drugs that contained active ingredients already in the market. Hence, the novelty was in dosage form, route of administration, or combination with other ingredients. Of the new drug approvals, 35% were products with new active ingredients, but only a portion of these drugs were judged to have sufficient clinical improvements over existing treatments to be granted priority status.

In fact, only 238 out of 1035 drugs approved by the FDA contained new active ingredients and were given priority ratings on the base of their clinical performances. In other words, about 77% percent of what the FDA approves is “redundant” from the strictly medical point of view. The New Republic, commenting on these facts, pointedly continues

*If the report doesn't convince you, just turn on your television and note which drugs are being marketed most aggressively. Ads for Celebrex may imply that it will enable arthritics to jump rope, but the drug actually relieves pain no better than basic ibuprofen; its principal supposed benefit is causing fewer ulcers, but the FDA recently rejected even that claim. Clarinex is a differently packaged version of Claritin, which is of questionable efficacy in the first place and is sold over the counter abroad for vastly less. Promoted as though it must be some sort of elixir, the ubiquitous "purple pill," Nexium, is essentially AstraZeneca's old heartburn drug Prilosec with a minor chemical twist that allowed the company to extend its patent. (Perhaps not coincidentally researchers have found that purple is a particularly good pill color for inducing placebo effects.)*

This redundancy has two economic consequences. As in the computer software industry, it suggests that the indivisibility is not such a significant factor in the innovation process; in other words, the true fixed cost to be recouped via monopoly profits is small. Second, it suggests a substantial amount of socially inefficient rent-seeking, artificially created by the patent system itself. Insofar as new drugs are replacements for drugs that already exist, they have little or no economic value – yet cost on the order of \$800 million to bring to market because the existence of patents forces the producers to “invent something” the USPO can pretend to be sufficiently different from the original, patented, drug. Where does that money go? What are the social gains from this kind of investments? None: the only social gain from introducing a “me-too” drug is that the supply of the beneficial active ingredient increases, and average prices possibly decreases slightly. But this could be achieved, much more rapidly and at a cost orders of magnitude smaller, by simply copying the old drug, and improving upon it. Money spent in obtaining a “me-too” drug that can be patented is money wasted for

society that will be charged to consumers: Rent-seeking and monopoly profits can be very costly for all of us, indeed.

A different way of looking at the same problem stresses the marketing of drugs over the R&D expenditure to search for new drugs.

*A better explanation for the pharmaceutical slump is a shift in priorities toward marketing, particularly since the FDA first allowed companies to directly target consumers five years ago. According to data collected by Alan Sager, a professor at the Boston University School of Public Health, the number of research and development (R&D) employees at companies making patented drugs declined slightly between 1995 and 2000, while the number of people working in marketing shot up 59 percent. “Drug companies trumpet the value of breakthrough research, but they seem to be devoting far fewer resources than their press releases suggest,” says Sager.*

Libraries have been written on the obvious connection between marketing and the lack of competition. The pharmaceutical industry is no exception to this rule, and the evidence Professor Sager, and many other, point at has a simple and clear explanation: because of generalized and ever extended patenting, pharmaceutical companies have grown accustomed to operate like monopolies. Monopolies innovate as little as possible and only when forced to; in general they rather spend time seeking rents via political protection while trying to sell at a high price their old refurbished products to the powerless consumers, via massive doses of advertising.

*[Pharmaceutical] Companies today have found that the return on investment for legal tactics is a lot higher than the return on investment for R&D,” says Sharon Levine, the associate executive director of the HMO Kaiser Permanente. “Consumers today are paying an inordinate premium under the guise of the creating the stream of innovation in the future. But it's actually funding lawyers.”*

Economists call this “socially inefficient rent-seeking.” It is ugly, but the polite academic jargon of “rent-seeking” means “corruption” and all that comes with it. We have already mentioned the music industry, where corruption has become the standard marketing practice, as exemplified by the sorry story of Payola. In

industries that are highly monopolized and in which the returns from capturing the main distribution and information channels are potentially enormous, the temptation to bend and then break the rules is too strong to resist, as public choice theory and economic common sense suggest. In the pharmaceutical industry the main distribution and information channels are not the radio and TV stations, but our beloved medical doctors. Hence, the unavoidable and continue temptation to capture the doctors, to make them “promote” our drug, and be silent over the other drugs, by whatever means available. This is why we have started to learn, more and more frequently, that “As Doctors Write Prescriptions, Drug Companies Write Checks”, as Gardiner Harris aptly titled his report on how drug companies mail nice fat checks to doctors in exchange for “consulting activities” that amount to ... doing absolutely nothing, just keep prescribing our drugs, thank you.

In the specific instance, federal prosecutors in Boston were sending subpoenas to just about every big global drug company in the country, as part of a nationwide effort to put a stop to these marketing practices. And, lest we get carried away by the understandable illusion that this is the usual story of the few rotten apples, we read in the same report that

*Last month, Pfizer agreed to pay \$430 million and pleaded guilty to criminal charges involving the marketing of the pain drug Nuerontin by the company's Warner-Lambert unit. AstraZeneca paid \$355 million last year and TAP Pharmaceuticals paid \$875 million in 2001; each pleaded guilty to criminal charges of fraud for inducing physicians to bill the government for some drugs that the company gave the doctors free.*

*Over the last two years, Schering-Plough, which had sales of \$8.33 billion last year, has set aside a total of \$500 million to cover its legal problems - mainly for expected fines from the Boston investigation and from a separate inquiry by federal prosecutors in Philadelphia who are investigating whether Schering-Plough overcharged Medicaid.*

No, ladies and gentleman, the system is not functioning, and it cannot be otherwise, given the insane degree of monopoly and the complete lack of competitive discipline that pharmaceutical companies have become accustomed to. Yes, chances are that your

medical doctor, the trusted counselor you see twice a year to make sure everything is all right, is getting gifts and promotional Caribbean vacations from a company that wants him to recommend their anti-depressive, not the other company's anti-depressive, even if both of them are useless. Anyone acquainted with the world of medical doctors has long known – often by listening to loud bragging at some cocktail party – that this is THE main marketing practice of large pharmaceuticals: buy out the doctors. Buy them with kickbacks, with paid vacations, with gifts, with phony symposia and conferences in expensive resorts where they are welcome to come “accompanied,” with preposterous consulting jobs. The bill is on the consumer, or on the taxpayer, whichever comes first: it is the same person, in any case.

### ***Are Pharmaceutical Patents Socially Desirable?***

A recent NBER paper, sponsored by Avantis Pharmaceuticals, attacks directly the costs and the benefits of drug patents. They conclude that if the appropriate rate of interest for discounting the social benefits of new drugs is less than about 5%, then the costs of eliminating patents is greater than the benefit. Since the social benefits of pharmaceuticals are risky, and indeed in this study by Hugh, Moore and Snyder, assumed to be perfectly correlated with private risk, an appropriate interest rate is the rate of return in the pharmaceutical industry. Indeed, the interest rates used for cost benefit calculations for government projects, is usually around 15%, which is the same as the rate of return Hugh, Moore and Snyder assume for pharmaceutical R&D. Since this is substantially in excess of 5%, the correct conclusion to draw from this study is that the benefits of eliminating patents in the pharmaceutical industry altogether exceed the cost. This is a significant conclusion, since it suggests that it is a good idea to eliminate all patents for all ideas. Since this is also one of the few studies to attempt to carefully quantify the costs and benefits of intellectual monopoly, it is worth examining the calculations carefully.

Hugh, Moore and Snyder assume that demand for pharmaceuticals is linear. From the perspective of cost-benefit analysis, this assumes that as output expands past the monopoly level, demand falls off at a constant rate. If demand falls abruptly, then the loss of consumer surplus is much smaller than would be estimated by a linear demand function, and we would get a more favorable case for patents. However, there is some reason to think that demand for pharmaceuticals depends upon income, and if this is

the case, the linear demand assumption is a reasonable one. Other parameters of the Hugh, Moore and Snyder model are calibrated to the data. They assume that 75% of pharmaceutical revenue is generated by drugs still under patent; that market exclusivity lasts 9 years; and that the lifetime of a new drug is 25 years. They assume that it will take generic manufacturers one year to enter after innovation. Also based on data about competition between generic and non-generic drugs after patent expiration, they attribute a first mover advantage to the innovator by assuming that they will be able to charge the monopoly price and still serve 20% of the market. In fact, evidence from India suggests that it takes closer to five years for generics to enter; and relatively unbiased sources such as the Congressional Budget Office suggest that market share after the entry of generics is substantially larger than 20%.

Finally, a critical assumption is the connection between producer surplus and the number of new drugs discovered. That is, higher expectations of profit due to monopoly lead to more pharmaceutical research, and consequently more drugs. Notice, however, that his effect can be negative, since the monopolization of existing drugs may also make it harder to discover new drugs, and we saw that this was empirically important in the history of the chemical industry. Hugh, Moore and Snyder assume that the number of new drugs discovered is proportional to producer surplus. That is, since they estimate that without a patent profits are about 25% of what they would be with a patent, they assume that there will 25% as many drugs discovered without patents. Even without the problem of innovation chains and the cost of “inventing around existing patents” discussed earlier, this assumption is very favorable to the patent system. The number of discoveries is scarcely likely to drop 25% if profits are reduced to 25% – based on survey data from industry interviews (which, in turn, probably understate the number of drugs that would be developed without patents) a figure of 40% would appear to be closer to the mark. We should also note that our own estimate is that without patents, firms would earn closer to 80% of what they earn with patents, rather than 25%.

In any case, accepting the Hugh, Moore and Snyder assumptions, they find the following: they estimate that using a 2% interest rate there is a loss of roughly 2500 in consumer surplus (due to fewer inventions) against a gain of roughly 840 (due to the elimination of the monopoly distortions in quantity and prices) – that is, the patent system is quite valuable. Using a more realistic (although still very low) interest rate of 5%, they estimate about a 675 loss against a 725 gain, so that even at this very low interest rate

and in spite of their extreme assumptions, welfare would be improved by eliminating pharmaceutical patents.

Much of the case for drug patents rests on the high cost of bringing drugs to market. Most studies have been sponsored by the pharmaceutical industry and are so quite suspect. The Consumer Project on Technology examined the cost of clinical trials for orphan drugs – good data are available for these drugs because they are eligible for special government benefits. A pharmaceutical industry sponsored study estimated the average cost of clinical trials for a drug at about \$24.5 million 1995 dollars. However, for orphan drugs where better data are available, the average cost of clinical trials was only about \$6.5 million 1995 dollars – yet there is no reason to believe that these clinical trials are in any way atypical.

A 2002 report of the Center for Economic and Policy Research also estimates costs orders of magnitude less than those claimed by the pharmaceutical companies. It also finds that, holding output of pharmaceutical products constant, private companies tend to spend twice as much as public medical research centers to come up with new drugs. As one might suspect, the report documents that the additional costs of the private drug monopolists are mostly legal and advertising costs: the first to get patents and defend them, the second to convince doctors to prescribe “their drug” instead of the alternative, most often a generic and cheaper alternative.

The pharmaceutical industry is also less essential to medical research than their lobbyists might have you believe. In 1995, according to a study by two well reputed University of Chicago economists, the U.S. spent about \$25 billion on biomedical research. About \$11.5 billion came from the Federal government, with another \$3.6 billion of academic not funded by the feds. Industry spent about \$10 billion. However, industry R&D is eligible for a tax credit of about 20%, so the government also picked up about \$2 billion of the cost of “industry” research. So private industry pays for only about 1/3<sup>rd</sup> of biomedical R&D. By way of contrast, outside of the biomedical area, private industry pays for about 2/3<sup>rd</sup>s of R&D.

Many infected with HIV can still recall the 1980s when no effective treatment for AIDS was available, and being HIV positive was a slow death sentence. Not unnaturally many of these individuals are grateful to the pharmaceutical industry for bringing to market drugs that – if they do not eliminate HIV – make life livable.

*No one who's been a sentient human being could have missed the campaign that the entire political left ... has been waging against pharmaceutical companies. I've no doubt that some of these companies deserve tough scrutiny. But I also have no doubt that when the history of this period is written, one of the biggest stories will be the revolution in pharmaceutical research that has transformed the lives of millions from sickness to health.*

But it is wise to remember that the modern “cocktail” that is used to treat HIV was not invented by a large pharmaceutical company. It was invented by an academic researcher: Dr. David Ho.

### ***Life, Death and Drugs***

Whatever one feels about patents and the “property rights” of monopolists, it is hard to fathom the defense of existing patents when millions of lives are at stake. The current situation – with respect to AIDS, or with respect to the possible “avian flu” pandemic – reminds us of nothing so much as a scene from the movie *Dr. Strangelove*. The British Captain Mandrake must call the President of the United States with information that will save the world from destruction – the only means of communication is a pay telephone, and neither he nor his escort Colonel Guano have any change. Mandrake spies a Coke machine in the corner and asks Guano to shoot it. To which Colonel Guano astutely replies “That’s private property.” The U.S. Navy during the First World War acted somewhat more creditably. When a dispute over patents between the Wright Brothers and Glenn Curtiss threatened to derail airplane production, they simply ordered them to stop fighting – or lose the patent.

Whatever religious altar one worships at, whether it be a more traditional religion, the religion of capitalism, or that of monopoly, there can be no excuse for allowing either the idea or reality of private property to interfere with the business of saving one’s fellow man. If compensation for the taking of medical and pharmaceutical patents need be paid, so be it. But we can only hope that along with the great mass murderers of the 20<sup>th</sup> Century – the Stalins and the Hitlers – there is a special place in hell reserved for those who stood by and refused to act while those around them died.

### **Notes**

The cost of developing drugs is from Hansen et al [1991]. For information about the interest rates used in capitalizing and discounting costs and benefits in the pharmaceutical industry, see DiMasi et al [2003], which is written by essentially the same group of authors. The estimate length of medical patent protection is from Grabowski [2002], while the impact on it of the Hatch-Waxman Act is from Grabowski and Vernon [1986]. The department of commerce reports an implicit GDP price deflator in the first quarter of 1987 of 72.487 and in 2000 of 99.317, which is used to convert the \$200 million year 1987 dollars of the earlier estimate to year 2000 dollars.

The German chemical industry analysis of processes versus products is from Bercovitz [1974], while White [1979] p. 326 discusses Italian pharmaceuticals and provide additional information about the dates of the patent laws we reported in this chapter. The absence of both organic and inorganic chemical production in France is noted by Haber [1958, 1971], from which many other details about the history of the chemical industry are also drawn. The demise of the British coloring industry is discussed by Penrose [1974] p. 103.

Information and data about the Italian pharmaceutical industry are from Campanella [1979], Ferraguto et al. [1983], and Paci [1990]. The quotation by Professor Scherer is from his remarkable study of the welfare impact that worldwide drug patents have, Scherer [2003], the conclusion of which is, in case you are wondering, that medical patents are bad for our health.

The information about drug companies writing fat checks to doctors, and all that comes with it, are from Harris [2004] and other sources linked in that article. The string of quotations on “me-too” drugs and their distinctive purple color, on the ratio between R&D and marketing employees in pharmas, and on what consumers are financing with the outrageous prices they are forced to pay for drugs are all from [www.thenewrepublic.com/docprint.mhtml?i=20021007&s=thompson100702](http://www.thenewrepublic.com/docprint.mhtml?i=20021007&s=thompson100702). Additional information on the economics, and immorality, of patenting imitative drugs and then marketing them to the medical profession, are in Angell and Relman [2002].

The Hugh, Moore and Snyder study is [2003]. The 40% estimate of the fraction of drugs that would be developed without patent is from the Levin et al [1987] survey. Information about

generics in India is from Lanjouw [1999], information about market share after generic entry is from CBO [1998], and our own calculations are in Boldrin and Levine [2005b,c]. The CEPR study comparing the cost of inventing new drugs for private and public research centers is Baker and Chatani [2002]. The orphan drug study is Love [1997], and overall R&D expenditure are from Murphy and Topel [1999]. The quotation is from Andrew Sullivan on his blog.