

# Appendix B: Pharmaceutical Markets and Innovation

*While North America, Europe and Japan currently account for the bulk of pharmaceutical expenditures, rapidly ageing populations in the emerging markets of Asia could provide important new targets for pharmaceutical companies. However, these populations will lack the buying power of OECD members for the foreseeable future. The Health Impact Fund will enable manufacturers to take advantage of the enormous opportunities for profit this demographic shift brings, while benefiting patients. This Appendix also explores the importance of insurance in pharmaceutical markets, as well as the international rules governing the administration of patents.*

## INTRODUCTION

This appendix provides background material on pharmaceutical markets. Section 2 discusses the distribution of pharmaceutical expenditures globally, as well as their absolute size, and considers how income growth and changes in demography may change this distribution. Section 3 examines the importance of insurance in pharmaceutical markets. Section 4 examines the intersection of pharmaceutical innovation and patents.

## GLOBAL PHARMACEUTICAL MARKETS

Pharmaceuticals are becoming an increasingly important part of health care around the world. Drugs, when properly used, not only improve health but reduce other health care costs, and it seems likely that the trend to increased use of pharmaceutical treatments will continue.

While drugs have become more important for health, expenditures have also risen very substantially, with global expenditures on pharmaceuticals in 2007 estimated at over \$700bn, or approximately one percent of global income. Table 1 shows regional expenditures on drugs in 2005. The data shows ex-manufacturer prices; the final price to payers is considerably greater owing to the costs of pharmacy. The table also shows the global share of population

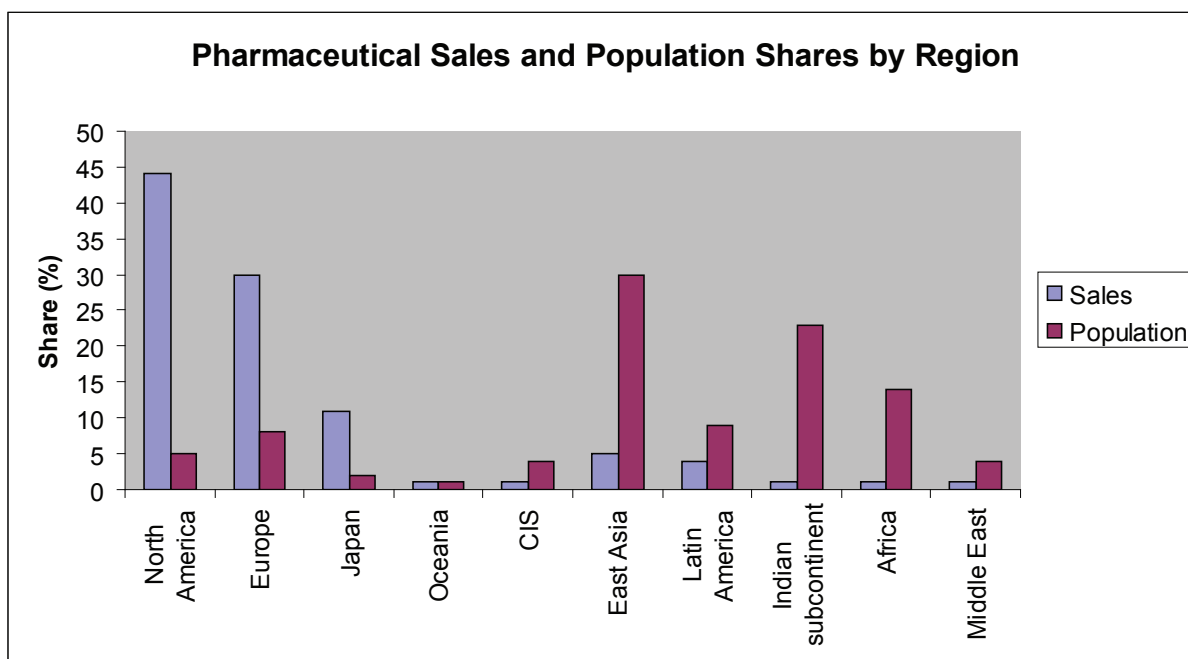
in each region in 2005. These data are represented graphically in Figure 1.

*Table 1: World Pharmaceutical Market by Region in 2005 (Ex-manufacturer prices)*

Region	Sales (\$bn)	Global share of sales (%)	Global share of population (%)
North America	268.8	44	5
Europe	180.4	30	8
Japan	69.3	11	2
Oceania	7.7	1	1
Commonwealth of Independent States	5.0	1	4
East Asia	28.8	5	30
Latin America	26.6	4	9
Indian subcontinent	7.2	1	23
Africa	6.7	1	14
Middle East	4.9	1	4
World	605.5	100	100

*Source: Sales data: CIPIH 2006, p. 15. Population data extracted from Source: Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat, World Population Prospects: The 2006 Revision, <http://esa.un.org/unpp>, last accessed July 25 2008. (There may be imperfect matching of regions between sales and population, as the sales data does not disclose region boundaries.)*

Figure 1: World Pharmaceutical Market by Region in 2005



What is most striking about these data is the extent to which expenditures are dominated by North America, Europe and Japan, which collectively have 15% of the global population and 85% of pharmaceutical expenditures. This helps explain the interest pharmaceutical innovators have shown in addressing principally diseases prevalent in those areas.

What also appears clearly is that the emerging markets of Asia – and especially India and China – represent enormous commercial opportunities for pharmaceutical companies as populations age. A key feature for pharmaceutical markets in developing countries is the extraordinary growth in the proportion of the population over 50. In developed countries, pharmaceutical expenditures per person tend to rise with age. For example, Morgan (2006) shows that pharmaceutical expenditures in Canada rise by approximately 3.5% per year of age between the ages of 35 and 65. Pharmaceutical demand in developing countries is likely to be similar, and this implies that the rapid increase in the average age, and especially in the proportion of the population over 50, is likely to yield enormous increases in pharmaceutical demand.

China offers a good example of a population which is rapidly aging. Figure 2a shows the population distribution in 2008; Figure 2b shows the ex-

pected distribution in 2020. It is clear that there will be substantial growth in the population in older age ranges. The US Census Bureau figures shown here predict an increase of 45% to 455m in the number of people aged over 50 in just twelve years. A similar transition is occurring in India, where the population aged 50 and over is expected to rise 52% to 274m by 2020. The predicted increase in the population aged over 50 in the US and France, in contrast, is predicted to be approximately 25% and 17%, respectively.

Given this demographic shift in population age, demand for – and the potential impacts on health of – pharmaceuticals in the emerging markets such as India and China will unquestionably grow at a rapid annual rate for many years. For the HIF, the growth in the target population of older people who have a modest ability to pay for pharmaceuticals implies that there will be very substantial opportunities for new drugs which treat global diseases. Since incomes in developing countries will not rise to European levels for many years, drug companies will miss out on huge opportunities if drugs are priced to maximize profits from OECD sales only. The HIF will offer a way for drug companies to profit from the large populations in need of pharmaceuticals.

Figure 2a: Population Distribution of China in 2008

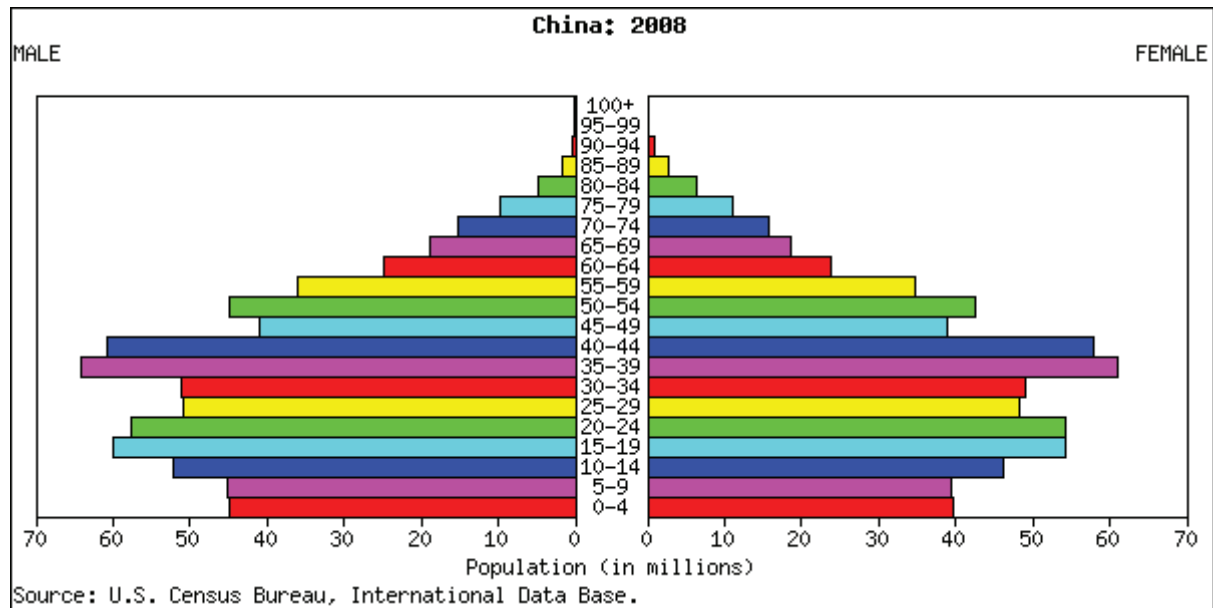
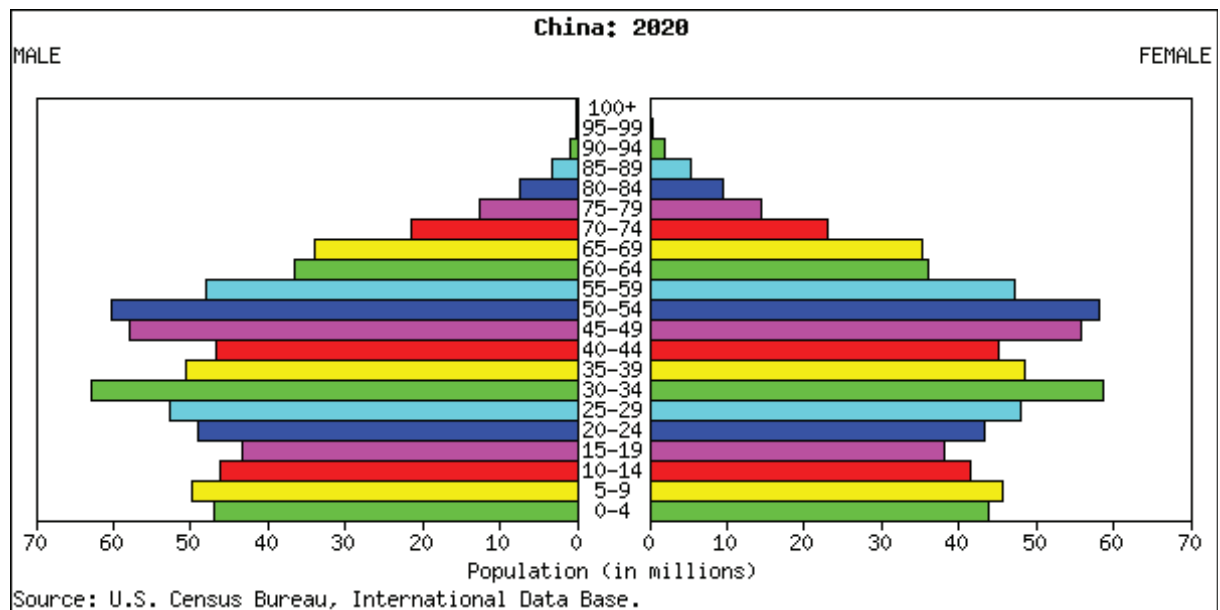


Figure 2b: Projected Population Distribution of China in 2020



**INSURANCE AND PRICING**

Pharmaceutical markets are highly complex, and have many peculiar characteristics. In most developed countries – and for over 90% of total sales dollars as shown in Table 1 – patients rely on physicians to prescribe the pharmaceuticals they consume. Most patients in developed countries do not pay the full cost of the drug consumed, but rely (at least partly)

on insurance. Thus, one party chooses, another pays, and a third consumes, which makes pharmaceutical markets extremely unusual. This is not a market like that for automobiles, in which the consumer assesses the characteristics and prices of different cars, purchases a car, and then drives it. Thus, the simple assumption that what works in other markets should work in pharmaceuticals is likely to lead to mistaken policy conclusions.

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The fact that prescribing is done by an expert is very important in pharmaceutical markets. First, it means that pharmaceutical firms tend to market their products primarily to physicians, since physicians are in effect the gateway to sales. Second, it means that the individual choosing the drug is in most cases completely insensitive to its price.

Patients, in many cases, are also insensitive to price, since they are fully or at least partially insured. This insensitivity is compounded by an inability to prescribe for oneself, either because of laws or because of uncertainty as to which product (if any) is the most suitable.

Insurers, therefore, cannot rely on patients or doctors to act as a controlling factor on drug prices. Instead, the insurer must try to control drug prices through bargaining over inclusion of the drug in the formulary. When a drug is too expensive, relative to its effect on health, the insurer may exclude the drug from reimbursement, which tends to lead to very low sales volumes, and may harm the patients who are therefore unable to benefit from the product.

Many countries in which the dominant insurer is government impose some form of price controls to achieve low prices without exclusion. The price controls have been based on a variety of factors, including drug company profits, and prices charged for the same product in other countries, or similar products in the same country. In many countries, cost-effectiveness analysis is applied explicitly in the coverage decision.

Using cost-effectiveness analysis as a tool to control the pricing of new drugs is problematic, since it encourages firms to price their product up to the limit of what the insurer deems to be cost-effective.

It is helpful to compare standard cost-effectiveness analysis to the HIF. First, the HIF only undertakes effectiveness analysis, and does not need to set any artificial thresholds to determine whether a given price meets that threshold. Second, rather than firms raising their price to the level at which the insurer is only just willing to include the product in its formulary, firms compete to obtain payments. Third, drugs registered with the HIF do not need to be rationed, or restricted on the basis of price, since the price to the patient is low and the cost to the HIF of having

another unit sold is zero, given a fixed reward fund. Fourth, the HIF has an approach to paying for innovation which focuses on incremental health impact, not total health impact, compared to no treatment at all. This means that “me too” or “follow-on” drugs which offer little therapeutic benefit obtain small payments from the HIF.

## INNOVATION AND PATENTS

### The Cost of Developing a New Drug

The costs of developing new drugs are enormous, not least because drugs require very expensive clinical testing before marketing approval can be granted. This section briefly reviews the process of drug development and the costs associated with it.

Identifying possible candidate new drugs for the diagnosis, prevention and treatment of disease often requires that hundreds or possibly thousands of compounds are made and tested before one is found that shows clear promise of producing desired results. The process might involve a series of test-tube experiments (assays) in which compounds are added one at a time to enzymes, cell cultures or cellular substances grown in a laboratory, with the goal of identifying which additions show important effects. Naturally occurring compounds such as fungi, viruses and molds can also be tested to determine whether they have a desirable effect on the target molecule. Computers can be used to simulate a chemical compound and design chemical structures that might work against it. And vast libraries of compounds have been built up that can be ‘mined’ through high-throughput screening for leads on potentially useful molecules.

Once a promising compound is identified, a period of rigorous chemical and pharmacological testing follows to identify possible toxicity to bodily organs and how the product is absorbed and metabolized by the body. Data from these tests are required by government regulatory agencies such as the US Food and Drug Administration (FDA), which must be satisfied that the drug (termed at this stage an ‘investigational new drug’ by the FDA) is reasonably safe before approving it for human use in initial, small-scale clinical studies. In the discussion below, the process

of regulatory approval in the United States is referred to. However, this process is similar to that in other developed countries.

It should be noted that not all pharmaceutical patent applications are for new drugs in the strict sense of the word (New Molecular Entities or NMEs). Applications for the approval of non-NMEs are common (around two-thirds of drugs approved by the FDA are non-NMEs) and typically involve alterations to the original drug to produce new desirable features relating to dosage or means of administration (CBO 2006, 2; GAO 2006, 8). FDA approvals for NMEs increased significantly over the 1980s and peaked in the mid 1990s, reaching a high of 53 in 1996. In the following years the number fell back, with only 20 NMEs approved in 2005. Approvals for so-called priority NMEs (the subset of NMEs that the FDA considers to offer a “significant therapeutic or public health advance”) have not shown a clear upward or downward trend over the last 20 years, moving largely in a range between five and eighteen annually (CBO 2006, 11-12).

Once approval is given for a new drug to be used on human subjects, three phases of clinical trials must be undertaken.<sup>1</sup> Phase 1 trials involve the initial introduction of the new drug into humans. These trials are closely monitored and usually involve healthy volunteer subjects. Phase 1 studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, any side effects associated with increasing doses, and if possible early evidence on effectiveness. During this phase sufficient information should be gathered about the drug’s pharmacokinetics (what the body does to the drug) and pharmacodynamics (what the drug does to the body) to facilitate the design of well-controlled, scientifically-valid Phase 2 studies. Phase 1 studies normally involve from 20 to 80 subjects.

Phase 2 studies are designed to obtain preliminary data on the effectiveness of the drug for a particular disease in patients with the disease. This phase of testing also helps to determine any common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled (they involve comparisons with control groups involving, for example, treatment with a placebo, no treatment,

or treatment with a known effective therapy), closely monitored and conducted in a relatively small number of patients, usually several hundred.

Phase 3 involves expanded controlled and uncontrolled trials. This phase is undertaken after preliminary evidence suggesting that the drug is effective has been obtained in Phase 2. Phase 3 trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies are also designed to provide an adequate basis for extrapolating the results of the studies to the general population and transmitting that information in so-called physician labeling, a primary means of providing critical information about drugs to practitioners (regulatory agencies such as the FDA review and approve the physician labeling initially proposed by manufacturers). Phase 3 studies usually include several hundred to several thousand people.

The FDA has provisions allowing promising new drugs (termed treatment investigational new drugs) to be used to treat desperately ill patients as early as possible in the drug development process. It has a specialized accelerated development and review program to speed up the development of drugs that promise significant benefit over existing therapies for life-threatening illnesses. It has a parallel track which allows patients prevented by their AIDS conditions from participating in controlled clinical trials to receive investigational drugs shown in preliminary studies to be promising.

Once the Phase 3 trials are complete, an application for approval to market the drug is filed with the relevant regulatory authority. The review process typically involves the reviewer attempting to confirm the applicant’s conclusions that the drug is safe and effective for its proposed use. It may involve a reanalysis or an extension of the analyses performed by the applicant. The review usually involves pharmacologists and toxicologists, physicians (to synthesize the results of toxicological, pharmacological and clinical reviews), chemists (to ensure that compounds are reproducible and stable; if a compound either can’t be reproduced or is unstable the validity of the clinical testing is brought into serious question); and statisticians (to evaluate the statistical relevance of the data

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submitted in the application). Other areas of expertise are called in as required. The approval process may also involve inspection of the applicant's manufacturing facilities and clinical trial sites. It is only when this process is complete and approval is given that the applicant is able to market the new drug. Regulatory agencies typically undertake post-market surveillance, in which they reassess risks based on the analysis of new data gathered after the drug has come to market.

At each stage of the discovery and development process significant attrition occurs, with only a tiny proportion of compounds that begin the journey finding their way onto the market. According to the industry organization Pharmaceutical Research and Manufacturers of America (PhRMA), 10,000 compounds initially investigated might lead to 250 compounds receiving sustained preclinical testing. Only five of these will make it to the clinical testing stage, and only one of these will receive marketing approval (quoted in US Government Accountability Office: New Drug Development, November 2006). PhRMA suggests that the discovery of a new drug and the preclinical phase typically takes around 6.5 years, the clinical trials a further 7 years and the regulatory body's review process 1.5 years (GAO 2006, 8).

This lengthy process is costly, although exactly how costly is a matter for debate. DiMasi, Hansen and Grabowski (2003) suggest an average development cost per drug of at least \$800 million, but this has been questioned. Critics argue that the DiMasi figure is based on 'self-originating new chemical entities' (NMEs created entirely in-house by the drug company), the most expensive class of new drugs. It also includes the expense of using money for drug research rather than other investments (the opportunity cost of capital), while not including the tax deductions that companies ordinarily obtain for R&D. The US Government's Office of Technology Assessment found that, after subtracting tax deductions and the opportunity cost of capital, the cash outlay in 1990 dollars for the development of a NME was \$65.5 million (CPIH 2006, 17; Congress Watch 2001).

One of the important developments now occurring in pharmaceutical innovation is out-sourcing of research and of clinical trials. With increased glo-

balization of R&D, there are likely to be considerable cost savings. However, the extent to which those savings are realizable will in part depend on the development of suitable regulatory controls over clinical trials in developing countries.

### **Patents and the Discovery and Development of New Drugs**

A patent is a form of property right. It is a creation of government whereby a patent owner is given the right to apply to the legal system to stop unauthorized use of the innovation disclosed in the patent, typically for a period of 20 years. The patent system is designed to provide a reward for inventions which are made public, and it does so by temporarily preventing any competition relying on the patented innovation. Patents are particularly important in the pharmaceutical industry, since competition with generic products tends to be fierce and the costs of product research and development relatively high. In a purely free market system firms would be unable to recoup any investment in research and development, and would therefore not invest in it.

In the case of new drugs a patent application is usually entered when a promising compound has been identified and is ready to be subjected to pre-clinical testing. A patent application needs to demonstrate that the product (or process) for which the patent is sought represents a significant innovation. This requires a detailed examination of the field ('prior art') to support the claim to innovation.

Patents have a number of functions. By granting protection from competition for a specified time and therefore increasing the likely returns to a given product/process, they create incentives for investment. By giving agents in the development process property rights in particular aspects of their work they take on a transactional function, whereby the trading of these rights is facilitated, primarily through licensing agreements. Patents have a disclosure function, in that they require the patentee to make publicly available all relevant technical information about the patented product or process. Patents can also serve a signaling function by demonstrating a firm's innovative capabilities and thereby encouraging invest-

ment in the firm. This signaling function is especially important for start-up companies in fields such as biotechnology, which rely on protected intellectual capital to raise funding (CIPIH 2006, 20-1).

While all these functions are important, it is the incentive function that receives most attention. An important aspect the HIF is that it enhances the incentive function, while not harming these other aspects of the patent system.

### **Impact of Patent Law on Drug Discovery/Development Process**

Changes in patent law have had a significant impact on the development of the pharmaceutical and related industries. A US Supreme Court case in 1980, *Diamond v. Chakrabarty*, confirmed the patentability of genetic inventions. This decision was vital to the development of the biotechnology industry by investing property rights, and therefore potential commercial value, in knowledge in 'upstream' genetic technologies. The biotechnology industry has subsequently become a major contributor to research and development in biomedicine. Patents have also been important in facilitating the interchange of knowledge between institutions and disciplines, increasingly important in pharmaceutical research, through systems of licensing and contracts based on intellectual property rights (CIPIH 2006, 39-40).

The US Bayh-Dole Act of 1980 was another development with important ramifications for the pharmaceutical industry. To encourage the development and application of university-based research, this Act permitted universities to take out patents on inventions that arose from publicly-funded research (CIPIH, 40). A rapid growth of patenting in universities has followed, resulting in universities and public institutions becoming significant players in patenting and licensing in, among other fields, biomedical research and development.

According to the 'linear model' of scientific research, innovation is grounded in basic research which is motivated purely by the quest for knowledge, without commercial or industrial objectives (CIPIH, 33). This knowledge, according to the model, is largely paid for through the public purse in universi-

ties and research institutes, and is then readily available to (primarily) commercial interests to be turned into marketable products. However, closer examination suggests that basic science, applied research and product development are far more interdependent than this linear model suggests, with priorities for research often influenced by views about where opportunities for solving specific human problems lie (CIPIH, 34). The work of Louis Pasteur is a compelling historical example, with fundamental discoveries in microbiology and immunology resulting from Pasteur's desire to solve pressing medical problems.

Universities and publicly-funded research institutions have always played a role in applied research, often in partnership with the private sector. But changes in patent law have increased this role and encouraged the further involvement of universities in applied research. In many cases university scientists receive a share of licensing revenues which patents make possible, and many have played a role in establishing new companies to exploit the research conducted in their universities. The lines between basic (upstream) and applied (downstream) research have become increasingly blurred, as have the lines between the roles of universities, research institutes and commercial companies in pharmaceutical innovation (CIPIH 2006, 40).

### **Patenting: Scale and Trends**

In 2005 about 1.6 million patent applications were filed in patent offices around the world (WIPO 2007, 10). Five patent offices accounted for 77 percent of the patents filed. The Japanese Patent Office and the United States Patent and Trademark Office were the two largest in terms of filings, followed by the Chinese Patent Office, the Korean Intellectual Property Office and the European Patent Office (WIPO 2007, 12). The World Intellectual Property Organization's (WIPO) patent databases, which stretch back to the 19th century, show acceleration in the use of patents beginning in the 1960s. Since 1995 the average annual increase in total patent filings has been around 4.7 percent (WIPO 2007, 10). Pharmaceutical patenting forms a significant part of patenting activity, with pharmaceuticals and cosmetics the third fastest

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growing field in 2006 in terms of international patent applications published under the Patent Cooperation Treaty (WIPO 2007, 30).

### **The Internationalization of Patents**

Patent laws are issued by national governments. They should therefore be expected to reflect national needs and priorities. For poor countries, cost-benefit considerations would seem to weigh against patents. The high prices of patented products represent a clear cost (in the case of pharmaceuticals, not just a financial cost but a human cost in increased mortality and morbidity), while the lack of research capacity significantly limits the ability of these countries to benefit from the incentives that patents offer. The balance is different in rich countries with substantial research capacities, and it is unsurprising that it is in these countries that patent systems have received most support and been most developed.

The existing pharmaceutical patent system is defined primarily by the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, signed at the end of the Uruguay Round of the World Trade Organization (WTO) negotiations in 1995. This agreement governs nearly all aspects of intellectual property in international trade. TRIPS requires all WTO member states to maintain strict patent protection laws for patented pharmaceuticals, with a guarantee of at least 20 years of market exclusivity. The patent system, while still defined in domestic law and enforced in each national jurisdiction by its government, has now become effectively internationalized through the TRIPS agreement. Prior to TRIPS, different countries had different patent laws, which often reflected their level of development and the social goals that patent laws were thought necessary to achieve. Developed countries typically had the most restrictive patent laws, providing strong protection for monopoly manufacturing and sale of patented products.

Access to cheap generic versions of patented medicines ended in 2005 for most poor countries when the 10-year compliance window for TRIPS came to a close in all but the so-called least developed countries. WTO members were required to bring their domestic patent laws up to the standards of TRIPS,

effectively universalizing the strong patent protection favored in developed countries. TRIPS did contain a number of flexibilities – for example, it enabled countries to exclude from patentability therapeutic methods for the treatment of humans and new indications of known products which amount to a therapeutic method, and allowed patented products to be licensed for cheaper sale on various grounds (CIPHI 2006, 21-2). However, TRIPS provisions have in some cases been supplemented by bilateral “TRIPS-plus” measures as part of bilateral trade agreements that further strengthen the protection of pharmaceutical patents, sometimes extending monopolies beyond 20 years through “data protection.”<sup>2</sup>

Until quite recently, patent laws were much less generous to innovators in most developed countries than is now the case. It is therefore striking that even the poorest developing countries have been pressured to sign on to TRIPS at the same level of patent protection as that given in the most developed countries. It is clear that relatively poor small countries have little to gain directly from TRIPS, since they can gain little from domestic patents. Such countries can, of course, simply free ride on the innovation incentives created in the rest of the world, to which their own domestic patents would add only negligibly. However, their domestic consumers are harmed by the high domestic prices that patents enable. Developing countries have agreed to a standard of protection of ideas that is high even when compared to the level of patent laws which existed in developed countries only thirty years ago.

The TRIPS process has led to a significant degree of harmonization of substantive patent law. At the same time much has been done to harmonize patent administration, through greater cooperation between national patent offices and greater integration of countries into the Patent Cooperation Treaty.

### **Patent Cooperation Treaty**

The Patent Cooperation Treaty, which has 139 Contracting States, is a procedural treaty that allows an applicant to make one international application that designates countries that are members of the treaty as targets of a national application in that country.

(Applicants can exclude particular member countries if they wish.) While the PCT allows a so-called international application, this leads to national patents in the designated countries, not to one international patent.

Under the PCT, an international application has to be the subject of an international search, which lists so-called prior art (all existing similar developments or inventions) relevant to the patentability of the applicant's invention. An international search must be carried out by a patent office that has been appointed an International Searching Authority (ISA) under the Treaty. Along with the search report the ISA also provides a preliminary written opinion on the novelty, inventiveness and industrial applicability of the invention and thus on its patentability. Applicants under the PCT also have the option of requesting an international preliminary examination, which provides a more detailed analysis of the application. This examination is carried out by an International Preliminary Examination Authority (IPEA; all International Searching Authorities are IPEAs). A favorable IPEA report can lead to expedited passage through a national patent examination.

Most applicants with global patenting strategies begin the process by establishing a priority date in a major national office and then move to the PCT. The national filing gives them a period of 12 months under the Paris Convention for the Protection of Industrial Property in which to file a PCT application. From that filing applicants have a further 18 months before the international application turns into a bundle of national applications. Essentially applicants can therefore defer national entry for 30 months or so. Deferral of national entry is a common goal of PCT applicants since it allows them time to gather more information about the commercial desirability of moving to the national phase of the patent application process, and also enables them to defer the costs associated with that process (WIPO 2001). Companies from industries with long product development and marketing lead times, like the pharmaceutical industry, find advantage in delay, while those with relatively short lead times, such as information technology, may prefer to move quickly to grant. Both options are possible under the PCT.

While companies can use a number of different patenting routes to obtain a national patent, the PCT route has become the single most important one for most companies: it is a very important route for pharmaceutical companies.

Most national patent offices are part of the PCT system in that they function as receiving offices for PCT applications. However, only a few offices meet the standards needed to function as International Searching and Preliminary Examining Authorities in the PCT system.

### Cost of Patenting

Obtaining effective patent protection is enormously costly, in part because relevant patents may be filed in a variety of countries. Part of the difficulty is that pharmaceutical innovators are commercially motivated to file patents on as many aspects of a drug as possible, in order to protect their exclusivity for as long as possible. A recent report claims:

Scores of lawyers at both pharmaceutical and medical device companies now submit documents of 50,000 pages or more, in order to prevent the copying of not only the product but also the process. The submissions have to be made in all the companies' major markets and countries where generic manufacture and patent-busting is rife. The total cost of the exercise can reach US\$100m per product. [Deloitte 2005, p. 6]

Costs at this level represent about one tenth of the average cost of R&D for a new product. Therefore any mechanism which could reduce the costs of obtaining patent protection could be of immense value. The internationalization of patent administration may reduce costs over time by streamlining the examination work needed in each national jurisdiction. But the HIF may also have significant cost reduction implications, by allowing the innovator to choose not to patent in every country.

### SUMMARY

Pharmaceutical markets are complex and difficult. International differences in diseases, incomes, and demography make innovation and access problematic under our existing systems. Insurance for pharmaceuticals distorts incentives of buyers and sellers. And patents are complicated and their application to pharmaceuticals problematic because they are a general mechanism applied to a very unusual market.

The Health Impact Fund has the potential to address these problems very successfully, because its mechanism is specifically designed for pharmaceutical markets. And because it treats all human lives as of equal value, it is able to address international inequities in a morally appealing way.

### NOTES

1. The following discussion of the regulatory pathway for new drugs is based largely on CDER.
2. An important part of pharmaceutical innovation is the performance of clinical trials to demonstrate the safety and efficacy of the drug. Generic companies usually rely on the data from these trials as the basis for approval of their bio-equivalent generic drugs. Many countries now grant “data protection” of 5-10 years to the firm which performed the trials, preventing any generic company from obtaining marketing approval for their products on the basis of the trial data during that time. The period of data protection is frequently synchronous with the patent protection, though in some cases it may increase the period of effective protection from generic competition.