

MANAGING THE PROVISION OF KNOWLEDGE: THE DESIGN OF INTELLECTUAL PROPERTY LAWS

CARLOS M. CORREA

Intellectual property rights are intended to stimulate innovation and creation by offering the prospect of a monetary reward that allows a titleholder to recover investments in research and development and possibly make a profit. Intellectual property rights generally confer exclusive rights to exploit the protected subject matter. Exclusive rights empower a titleholder to prevent third parties from making commercial use of the protected knowledge without authorization. But exclusive rights also impede the diffusion and use of knowledge.

By its nature, knowledge is nonrival (Stiglitz 1999, p. 309). Nonrival goods can be available for public use, usually at low cost and sometimes at no cost. But knowledge can be made excludable through actions by its possessor or through legal means. A company may prevent its competitors from knowing how a particular manufacturing process operates by, for instance, tightly controlling access to its physical premises and preventing the disclosure of relevant data by its employees. In biotechnology, genetic use restriction technologies (GURTs) render sterile the subsequent generation of seeds (FAO 2001). Such actions may be encouraged or supported by legal means.

In some cases purely legal means are used to exclude third parties from using information that otherwise would be accessible, as with patents and published copyright works. In these cases policy creates a deliberate mode of exclusion for the use of knowledge, based on the recognition of an intellectual property right.

Intellectual property rights evolved in the Middle Ages and obtained universal recognition during the 20th century. (For their history, see David 1993 and Granstrand 1999, pp. 27–30.) Over the past 20 years in particular, large industrial and knowledge-based companies and governments of industrial countries joined forces to broaden and strengthen the rights of knowledge owners (Ryan 1998). A notable result of this concerted effort was the adoption, as part of the Uruguay Round, of the Trade-Related Intellectual Property Rights (TRIPS) agreement.

The TRIPS agreement was a major objective of industrial countries during

the Uruguay Round. One of the agreement's main goals is to establish high international standards for intellectual property rights. During the Uruguay Round it was argued that broader, stronger intellectual property rights would foster creativity and innovation on a global scale. Industrial countries also claimed that stronger protection of these rights would increase flows of technology and investment to developing countries. Both facts would justify having the international community—particularly developing countries—assume the costs associated with granting such rights.

This chapter considers the efficiency effects of intellectual property rights, with a focus on patent rights.¹ Specifically, it examines the dilemma facing policymakers in fostering innovation: how to reconcile the restrictions that intellectual property rights impose on the use of innovations—to encourage their creation by knowledge providers—with society's interest in maximum use of innovative products.

The chapter first discusses the two types of efficiency—static and dynamic—and the different considerations for achieving them. It then examines how intellectual property rights can influence the balance between static and dynamic efficiency. Next it considers the options available under the TRIPS agreement to increase static efficiency, dynamic efficiency, or both. Finally, the chapter discusses the possibility of compulsory licensing as way of increasing static efficiency.

The main finding is that measures to enhance static and dynamic efficiency can go hand in hand. Because enhanced static efficiency often increases equity, the analysis also suggests that efficiency and equity can be combined—and should be so that in the long run inequity does not jeopardize efficiency.

STATIC AND DYNAMIC EFFICIENCY, INTELLECTUAL PROPERTY RIGHTS, AND INDUSTRIAL AND DEVELOPING COUNTRIES

Welfare economics examines the impact of intellectual property rights on economic efficiency. There are two main types of efficiency:

- Static efficiency is achieved when there is an optimal use of existing resources at the lowest possible cost.
- Dynamic efficiency is the optimal introduction of new or better products, more efficient production processes and organization, and (eventually) lower prices.

In general, static efficiency is best achieved through competitive markets. In terms of consumer welfare, competition may lead to allocative efficiency when the price of a product is equal to the marginal cost of producing a unit of it. In this scenario there is maximum diffusion of existing products. When the products are essential for life—as with food and pharmaceuticals—allocative efficiency becomes an important objective on both economic and equity grounds.

But a competitive environment may deter investment in the production of

knowledge. Intellectual property rights provide the opportunity for profits over and above marginal costs both to finance ongoing research and development and as an incentive for further research and development. Thus a basic policy question is how to reconcile providing short-term benefits to consumers (static efficiency) with the need to ensure that long-term benefits are obtained as a result of innovation (dynamic efficiency).

The loss of static efficiency should be set against the growth and welfare benefits accruing from the future introduction of new products and processes. Exclusive rights can be imposed at the cost of sacrificing static efficiency, but they should be subject to strict limits because intellectual property rights lead to underutilization of information—including for the generation of subsequent innovation.

Intellectual property rights are just one appropriation method for the results of research and development. Depending on the technologies and sectors involved, other methods may be far more relevant to innovators. Many studies indicate that patent protection is usually not the driving force behind research and development.² Alternative protection from imitation may result, for instance, from lead time, from the innovator's ability to move ahead on the learning curve quicker than competitors, from the customer loyalty derived from superior sales and services, and from the structure of the market, as with oligopolistic market structures (see Scherer and Ross 1990, pp. 627–28 and Scherer 1999, p. 59).

Thus policymakers face difficult choices, and achieving both static and dynamic efficiency requires them to fine-tune the tools they use. A fair balance between private and social benefits requires policies that ensure the creation of new technologies as well as their dissemination so that competitors can improve on them. As taught by evolutionary theory on technical change, innovation and diffusion are two sides of the same coin: innovation leads to diffusion, which influences the level of innovative activity (OECD 1992, p. 51). Moreover, from an equity perspective it is essential for policies to ensure that innovations reach those who need them. Obvious examples include pharmaceuticals, diagnostic kits, and other products crucial for human health.³

Considerable emphasis has been placed on the limits of intellectual property rights in generating dynamic effects. Since knowledge is both an output and an input of its production process, a conflict arises between first- and second-generation producers—because the greater are the rights (and hence incentives) of the first generation, the greater are the costs (and hence the lower the incentives) of the second generation (Benkler 2001).

The extent to which static efficiency is sacrificed and dynamic efficiency is attained depends on factors such as market structure and the availability of substitutes for the material protected by intellectual property rights. It also depends on features of intellectual property laws, such as the scope of exclusive rights and the duration of protection. In other words, the reduction in static efficiency and

the deleterious effects of intellectual property rights on future innovations can be attenuated by designing intellectual property laws in a way that reconciles the conflicting social interests underlying the recognition of such rights.

The validity of arguments about the need to sacrifice static efficiency in order to increase dynamic efficiency depends on the context in which they apply. Thus patent protection may be justified when the consumer surplus from new products, albeit limited by the presence of monopoly, outweighs the consumer surplus from current products in the absence of patent protection.

However, intellectual property rights may force some consumers to pay higher prices today without benefiting from the future innovations that their sacrifice is supposed to secure. With pharmaceuticals, for instance, full implementation of the TRIPS agreement will mean that consumers in developing countries are contributing to the research and development budgets of pharmaceutical companies in industrial countries. Such companies focus on producing profitable drugs and neglect those needed in developing countries (Lanjouw and Cockburn 2001; Médecins Sans Frontières 2001). Consumers in developing countries are unlikely to benefit from future innovations to the same extent as consumers in industrial countries—if at all.

Deardorff (1992) offers a model for extending patent protection from one country to another. He shows that when patent protection is extended to a “non-inventing” country, that country’s welfare decreases while the welfare of the “inventing” country increases. Deardorff also shows that while patents involve a tradeoff between technological progress (inducing research and development) and consumer surplus, this tradeoff can be balanced by establishing patent protection only in part of the world. Thus, he concludes, worldwide patent protection may not be desirable—and at the least, the very poorest countries should be exempted from any new agreement to extend patent protection under the General Agreement on Tariffs and Trade (GATT).⁴

In addition, extending intellectual property rights to developing countries may not have the claimed positive effects on innovation, particularly if broad patent rights are recognized. Innovation in those countries is mainly based on incremental developments based on existing technologies rather than on original contributions to the state of the art. Innovation systems are weak in most developing countries, and would not be suddenly transformed by the introduction of stronger intellectual property rights. The development of technological capabilities is a cumulative process that takes time and—contrary to the prediction of “leapfrogging” theory—requires step-by-step upgrading in scientific infrastructure and education, as well as effective learning at the firm level.

As argued by Anderson (1998), in countries where follow-on innovation is most important, narrower (though not necessarily shorter) protection is better than broader. Hence, to accumulate technological capabilities, firms in those

countries will benefit from a strict definition of patent requirements that allow them to develop from existing technology.

Similarly, Panagariya (1999) argues that the geographic extension of patents will increase monopoly power with adverse allocative and transfer effects, and will not increase research and development in developing countries. In his view, “the extension of North’s patent law to South will lead to both efficiency loss and transfer of benefits from Southern consumers to innovators. Since innovators are mainly located in the North, the South will lose on both counts: monopoly distortion and the transfer from its consumers to innovators in the North. Global welfare will also decline” (quoted in Dumont and Holmes 1999, p. 23).

To summarize, intellectual property rights affect different countries in different ways. The static-dynamic efficiency rationale applicable to an industrial country does not necessarily hold where inequality is high. Strong protection for intellectual property rights may have significant negative allocative consequences in developing countries without contributing to—and even impeding—their technological development (Stiglitz 1999).

HOW FAR SHOULD INTELLECTUAL PROPERTY RIGHTS GO? THE BALANCE BETWEEN STATIC AND DYNAMIC EFFICIENCY

Broad, long-lasting intellectual property rights provide strong incentives to innovate. But there are significant tradeoffs—the broader and longer-lasting are such rights, the higher is the cost of knowledge for society. Broad protection (in terms of the subject matter covered or rights of exclusion conferred) and long-lasting rights reduce competition and static efficiency as well as the diffusion of knowledge and dynamic efficiency (see Welfens and others 1999, p. 143). This section discusses how decisions on the coverage of protection, the extent of exclusive rights, and the duration of rights influence the static allocation and dynamic creation of knowledge.

Coverage of protection

Expanding protectable subject matter—as required by the TRIPS agreement in many areas—takes information out of the public domain. Hence one key issue affecting societal welfare is the coverage of the monopoly rights conferred to owners of intellectual property rights. Today’s inventions provide not only the capability to produce new and better products and to produce them more effectively today, but also concepts and starting points for inventive efforts tomorrow. Thus the broader is the coverage of patents, the greater will be the reductions in static as well as dynamic efficiency.

The impact of the patent system on dynamic efficiency crucially depends on the range to which patent claims can be applied. The original intent of the patent

system to reward inventiveness assumes that inventions marked by considerable originality are produced and protected, rather than technical developments that just build on and add little to existing knowledge—such as when the “invention” results from path-down experimentation that was obvious to many (Barton 2000). As a general rule, if a patent has a broad scope, competitors are deterred from innovating in the field covered by the patent. This outcome is particularly likely when, as is often the case, large companies aggressively use their patent portfolios to discourage competition from other companies. But if the scope of protection is narrowly defined, competitors may safely compete in the next round of inventing.

The breadth of patent protection depends on national legislation, particularly the criteria for judging the patentability of inventions, and on the terms that determine the “equivalence” of inventions. There are few guidelines in international treaties binding states to follow a more or less strict approach to patentability. Some jurisdictions grant patents using very lax patentability standards.⁵ The United States, for instance, grants about 160,000 patents a year—twice the number 10 years ago. Many are for minor, sometimes trivial developments, or for substances (including genes) that already exist in nature and that have merely been discovered, not invented.

This proliferation of patents is the result of loose criteria for patentability,⁶ of the excessive flexibility of patent offices in assessing the innovation, novelty, and usefulness of the applications submitted to them,⁷ and of shortcomings in examination procedures.⁸ In addition, new areas have come under the reach of the patent system, such as “methods of doing business,” for which the number of patents has surged in the past 10 years (Gleick 2000, p. 44).

If patent policies lead, through loose criteria for protection, to monopolistic market structures, owners of intellectual property rights can maintain high price-cost margins, retard innovation, and deny access to innovative products. In contrast, some degree of competitive threat induces firms to innovate and keep prices low. Monopolistic elements should diminish, in particular, where diffusion creates important technological opportunities and where it is needed to satisfy essential societal needs.

An efficiency-enhancing patent system—one that fosters both static and dynamic efficiency—can rely on several policy options for the coverage of protection:

- Patentability requirements should be defined and applied such that exclusive rights are limited to truly “inventive” and novel contributions to the state of the art. Ineffective enforcement of patentability requirements enables inventors to protect inventions that cost considerably less than the value of the monopoly provided by patent law.
- Easily accessible, inexpensive mechanisms should be available to challenge the validity of wrongly granted patents. In some countries such challenges

may be brought before patent offices at any time⁹ or within a certain period after a patent has been granted,¹⁰ avoiding costly judicial procedures.

- Procedures can involve third parties to reduce the granting of improper monopolies. Such procedures may provide for the right of a third party to file an opposition to the grant of a patent or to submit observations on the patentability of an invention after publication of its application¹¹ and before granting.¹² In Japan allowing pre-grant opposition encouraged patent applicants to license their innovations, to discourage competing firms from opposing patent applications. The opposition phase also created incentives for early bargaining between innovators and potential rivals who would be disadvantaged if the patents were granted. Japan's patent system was designed to expedite the diffusion of knowledge contained in patents while maintaining incentives to invest in research and development (Ordoover 1991, p. 48).
- Setting boundaries for protected inventions determines the scope of the rights conferred by a patent. National legislation should define when products or processes not literally described in a claim may be deemed equivalent and so infringing on patent rights. Both static and dynamic efficiency are enhanced if a narrow doctrine of equivalents is used, because it allows more room for competition and follow-on innovation.

Extent of exclusive rights

The power conferred to owners of intellectual property rights vary depending on the type of intellectual property involved. Patents confer the exclusive right to make, use, or sell an invention, generally for 20 years. Patents may be granted for processes and products. Patent protection of a product grants significant market power because the patent owner can prevent third parties from producing or selling the product even if it is obtained through different processes. In contrast, protection of a manufacturing process, unless it is the only possible or feasible approach, does not impede others from obtaining the same product through alternative processes. This distinction explains why large pharmaceutical companies, which only had process patents in many developing countries before the TRIPS agreement, actively sought and ultimately obtained an obligation for all members of the World Trade Organization to protect both pharmaceutical processes and products (see article 27.1 of the TRIPS agreement).

The breadth of patent claims is a key element in determining the degree of competition and the flow of future innovations. Broad patents can be used to stifle competition (reducing static efficiency) and can have adverse long-run effects on innovation (and dynamic efficiency).

Patent claims determine the control that patent holders can exercise over subsequent inventions. The broader is the original patent, the more likely that new inventions in closely related areas will be deemed infringing. Broad patent claims generate greater rewards to primary innovators, but they may discourage subse-

quent innovations.¹³ For example, there is no pervasive evidence that even in the United States the greater breadth of patent claims has led to greater innovation (Dumont and Holmes 1999, p. 27).

Patent offices in some countries have recently tended to admit increasingly broad claims. The drafting of patent claims has become “more an art than a science under current law.” Today’s patent agents “make every effort to phrase claims such that they cover every conceivable improvement of an invention while, at the same time, steering the claims clear of the prior art” (Hart 1994, p. 230). In some cases protection is granted to inventions that embrace all ways of solving a problem. For instance, the first utility patent granted to a plant in the United States described the increase in the plant’s tryptophan content rather than particular genes (Plowman 1993, p. 35). In other cases patents include claims that can extend to many plant varieties or even to entire plant species, such as an *Agracetus* patent related to any manipulation of cotton regardless of the germplasm used (Correa 1999, p. 5).

Merges and Nelson (1990) note that in many industries the efficiency gains that might be achieved through the granting of exclusive rights to the pioneer firm are likely to be outweighed by the loss of competition in developing improvements to the basic invention. Thus they advocate creating a competitive environment for improvements, rather than an environment dominated by the pioneer firm, taking into account the nature of technical advance in the specific industry. The patenting of research tools (such as reagents, DNA sequences, instruments, and other biomedical techniques) is another area where exclusive rights may diminish static and dynamic efficiency because of the time and energy required to avoid infringing on patents and to obtain licenses (see Heller and Eisenberg 1998 and Barton 2002).

In sum, the breadth of patent protection determines the extent to which patent owners can deter other firms from pursuing follow-on innovations and impose unwarranted costs on society.¹⁴ Broad patent claims may defeat the intent of the patent system by stifling competition and delaying follow-on innovation.

Duration of rights

Given its implications for allocative efficiency, economists have extensively discussed the optimal length of a patent grant (Scherer 1972). The duration of exclusive rights is a key element in determining the balance between appropriability and use. A long patent life permits the titleholder to obtain extraordinary profits at the expense of optimal use, because of pricing above marginal cost. On the other hand, a short patent life may not provide incentives to invest in innovation.

The current patent term is largely a function of historical factors that no longer have any relevance.¹⁵ The TRIPS agreement sets forth as a minimum standard a 20-year patent term counted from the date of application, obliging many

countries to extend the protection previously granted under national laws. There is no economic justification for this standard. The pattern and rate of imitation vary substantially between industries, as do the initial expectations of investors.

Though it would be very complex to differentiate patent terms by sector, it may be possible to differentiate between fundamental advances in knowledge and logical, somehow predictable extensions of existing knowledge (Thurow 1997, p. 98). In addition, when a major invention achieves rapid acceptance in the marketplace and quickly permits its titleholder to recover research and development costs and make a profit, the period of patent protection could be shortened. The rationale is that the inventor would have received an adequate reward, and any extension of exclusive rights could exacerbate the potential allocative problems of the original patent (Gutterman 1997, p. 67).

Latitude in the application of patentability requirements has sometimes allowed, as in the pharmaceutical industry, artificial extensions of patent term protection well beyond the expiration of the original patent, based on the patenting of secondary developments (box 1).¹⁶ The extension of a patent term reduces allocative efficiency and can also undermine dynamic efficiency, since new entrants are discouraged. There is considerable evidence that prices fall significantly after a patent elapses (Viscusi, Vernon, and Harrington 1997, p. 853).

Exceptions to exclusive rights

The exclusive rights conferred by patents may be subject to general, unpaid, automatic exceptions. Such exceptions may permit, among other things:

- Activities engaged in privately, on a noncommercial scale or for a noncommercial purpose.
- Use of the invention for scientific research or for teaching purposes.
- Commercial experimentation on the invention (for example, to test or improve it).
- Preparation of medicines under individual prescriptions.
- Experiments performed for the purpose of seeking regulatory approval to market a product after the expiration of a patent (known as the Bolar exception).
- Use of the invention by a third party that had bona fide use of it before the patent application.
- Import of a patented product that has been legitimately marketed in another country (known as parallel imports).

Depending on their formulation under national patent laws, these exceptions are permissible under article 30 of the TRIPS agreement (Correa 2000). Some are particularly important for increasing static (allocative) efficiency, while others are mainly relevant to dynamic efficiency.

Box 1

EXTENSIONS OF PATENT TERMS FOR PHARMACEUTICALS

Pharmaceutical companies use many means to artificially delay the marketing of competing products, include the patenting of:

- *Pharmaceutical forms*—particular ways of administering an active ingredient that may be unpatented,¹⁷ in combination with certain additives.
- “*Selection*” *inventions*—when an element or group of elements of a known large group are patented based on, for example, a feature that was not specifically described in an earlier patent for the larger group.
- “*Analogy*” *processes*—processes that are not in themselves innovative but that allow a product with innovative features to be obtained.
- *Combinations* of known products.
- *Optical isomers*—this takes advantage of the property of many chemical compounds to present two mirror forms. Often, after the mixture of both forms has been patented (racemic mixture), a patent application is made for the most active isomer.
- *Active metabolites*—patenting the active metabolite of a compound that produces the desired effect in the body.¹⁸
- *Parent substances*—compounds that, although themselves inactive, produce a therapeutically active “parent substance” when metabolized in the body.
- *New salts* of known substances.
- *Variants of known manufacturing processes*.
- *New uses* for known products.¹⁹

Experimental use

The experimental use (research) exception permits any third party to experiment on a patented invention without the authorization of the titleholder. In some countries (such as the United States) this exception is allowed only for scientific research. It permits investigators to use previously patented inventions in their research without having to request permission and pay for them, lowering the costs of research and fostering scientific progress.

In many jurisdictions experimental use by third parties is also legitimate for commercial purposes—for instance, to request a license or to test whether the patent has been rightly granted (Correa 2000, p. 76). The adoption of this exception expedites follow-on innovation and technological progress. The exception may allow innovation based on “inventing around” or improving on the protected invention. It clearly enhances dynamic efficiency without reducing static efficiency.

Early working

The early working (Bolar) exception allows manufacturers of generic products to start, where necessary, seeking marketing approval before the expiration of another company's patent, and permits the introduction of competitive products as soon as the patent expires. Thus it increases static efficiency. In the absence of such an exception, the introduction of generic copies may be delayed for months or years, during which the patent owner might charge high prices despite the expiration of the patent.

This exception was introduced by the United States in 1984 and has since been established in Argentina, Australia, Canada, and Israel, among other countries.²⁰ The U.S. Drug Price Competition and Patent Term Restoration Act permits testing to establish the bioequivalency of generic products before the expiration of the relevant patent. This exception was intended to help generic drug producers place their products on the market as soon as a patent expired, allowing consumers to obtain medicines at much lower prices. In exchange for this exception, the patent term of the original drug could be extended up to five years. An analysis of the welfare implications of this act indicated that "from the perspective of economic welfare, the Act is the source of large potential positive gains of two types. First, it eliminated costly scientific testing which served no valid purpose. Second, the Act lowered prices to consumers with some elimination of deadweight losses and large transfers from producers to consumers" (Viscusi, Vernon, and Harrington 1997, p. 857).

After the act was adopted, the average generic product was introduced at a price equal to 61 percent of the brand name product's price—and after two years fell to 37 percent (table 1). Despite these lower prices, after two years generics had just 49 percent of market share (in terms of units sold), and former patent owners were able to maintain and even raise their prices (Viscusi, Vernon, and Harrington 1997, p. 853).

In sum, the early working exception has positive effects on allocative efficiency. And because the patent holder is able to keep its monopoly until the patent expires, the exception is unlikely to reduce dynamic efficiency.

Parallel imports

The admission under national law of parallel imports (as allowed under article 6 of the TRIPS agreement) implies a partial derogation of the exclusive right to import generally granted to owners of intellectual property rights. This derogation is justified under the doctrine of exhaustion of rights, according to which titleholders have no right to control the use or resale of goods that they have put on a foreign market directly or through a licensee.²¹

Parallel imports can be a powerful tool for increasing allocative efficiency. If consumers can get legitimate products from foreign countries at prices lower than those charged locally by the owners of the products' intellectual property rights,

Table 1

Average prices of brand name and generic drugs after the expiration of patent protection in the United States, 1984–88

Indicator	At date of entry	One year after entry	Two years after entry
Brand name price index	1.00	1.07	1.11
Generic price index	1.00	0.78	0.65
Ratio of generic price to brand name price	0.61	0.46	0.37
Generic market share in units (percent)	9	35	49

Note: Prices are based on unweighted averages for 18 categories of drugs.

Source: Grabowski and Vernon 1992.

it increases static efficiency and does not necessarily reduce dynamic efficiency—because the owners of the rights have been remunerated (in the foreign market) for their intellectual contributions. The profits may be lower than those obtainable if the owners were able to fragment markets and charge higher prices in the importing countries, but that does not mean that the owners will not be able to recover their spending on research and development.

The pharmaceutical industry has claimed that parallel imports may endanger research and development. The industry has argued that exports of drugs sold at low cost in developing countries to higher-priced markets will affect its ability to fund future research and development.²² That may be true if parallel trade becomes significant, but there is no indication that this is likely to happen. Trade in medicines is subject to stringent national regulations that erect effective barriers to market access. Moreover, parallel imports occur only where price differences are significant. To make parallel imports difficult or unattractive, pharmaceutical firms could reduce such differences or sell patented products under different trademarks or packaging in major markets (Watal 2000). Further, any country can adopt legislation to prevent parallel imports.

It has been suggested that, to maintain tiered pricing and prevent low-priced medicines in developing countries from flowing to industrial countries, developing countries should adopt measures to prevent their exportation.²³ But such export restraints may not be consistent with World Trade Organization rules, particularly in light of article XI of the General Agreement on Tariffs and Trade (GATT).

COMPULSORY LICENSES

A compulsory license is an authorization that a national authority gives a person to exploit—without the consent of the titleholder—information protected by a

patent or other intellectual property rights.²⁴ During the 20th century compulsory licenses became a common feature of patent laws worldwide. In the early 1990s about a hundred countries recognized such licenses based on, for example, the lack or insufficient working of a patented invention, public interest, government use, and anticompetitive behavior. In addition, some countries (Canada, France, the United Kingdom) allowed compulsory licenses specifically for certain products such as food, medicines, and surgical or curative devices.

Compulsory licenses can enhance static efficiency, as when they are granted to remedy anticompetitive practices or to address public health emergencies by ensuring access to cheaper drugs. The granting of such licenses will force prices down, benefiting consumers.²⁵ And when the licensee undertakes production, such licenses can also increase dynamic efficiency.²⁶ The use of the patented process or the manufacturing of the patented product can lead to follow-on innovations or new innovative concepts. As evolutionary theory on innovation has shown, routine productive activities and cumulative learning at the plant level are important sources of innovation (Cooper 1994, p. 8). Hence, while improving allocative efficiency, compulsory licenses can also increase future flows of innovations and dynamic efficiency. As noted by Gutterman (1997, p. 69):

Compulsory licensing might be considered as a means for reducing some of the adverse costs of the patent system. For example, requiring compulsory licensing at reasonable rates may reduce the underutilization costs of the patent system; however, uses of lesser value than the royalty rate would still not be covered. Compulsory licensing might also reduce to some extent the contribution of the patent system to monopoly power, the wasteful duplication of research efforts, the problem of blocking patent strategies, and the concerns about research in areas that may well already be covered by patents.

Some observers—such as the research-based pharmaceutical industry—argue that to the extent that compulsory licenses lower the prices of patented products and the expected profits of patent owners, such licenses undermine incentives to undertake future research and development (Rozek and Rainey 2001). But Scherer (1998, pp. 107–08) analyzed the extent to which compulsory licenses affected spending on research and development, and particularly whether such licenses diminished or destroyed incentives for patent holders to undertake research and development. His findings, based on 70 companies, showed no negative effect on research and development in companies subject to compulsory licenses. On the contrary, such companies showed a significant increase in research and development relative to companies of comparable size not subject to such licenses.²⁷

Moreover, according to Tandon (1982, p. 485): “Firms spend large sums of money on efforts to ‘invent around’ the patents of their competitors. Under gen-

Table 2

Elements of patent law that enhance static and dynamic efficiency

Element	Static efficiency	Dynamic efficiency
Strict standards of patentability	X	X
Limited breadth of claims	X	X
Narrowly defined doctrine of equivalents	X	X
Experimental exception		X
Early working exception	X	X ^a
Parallel imports	X	
Compulsory licenses		
With manufacturing	X	X
Without manufacturing	X	

a. Mainly in relation to manufacturing processes and new applications.

eralized compulsory licensing, these expenditures would be unnecessary, which might increase the welfare benefits.” Hence compulsory licenses may increase both static and dynamic efficiency.

CONCLUSION

This chapter has showed that patent law may be designed to increase static efficiency, dynamic efficiency, or both (table 2). The intensity of a law’s effects depend on the context in which protection is applied and, particularly, on the market structure and the characteristics of the national innovation system.

Static and dynamic efficiency may be promoted by strict standards of patentability, a limited breadth of patent claims, a narrowly defined doctrine of equivalents, an early working exception, and in some cases by compulsory licenses. Parallel imports and compulsory licenses may increase static efficiency in developing countries without affecting global dynamic efficiency since the development of new products and processes is likely to be only marginally affected by such measures.

NOTES

1. The economic effects of patents have been considered more extensively than any other intellectual property right (Benkler 2001).

2. For example, a classic study by Levin, Klevorich, and Nelson (1987) found that firms in 130 lines of business reported that patents were the least important means of securing competitive advantage for new products. Still, a firm may obtain a patent

even if an innovation would have occurred without it. In such cases a patent represents a windfall gain for the firm at the expense of social efficiency (Hart 1994, p. 232)

3. A resolution approved (with 52 votes and 1 abstention) on 23 April 2001 at the 57th session of the United Nations Commission on Human Rights calls on governments to ensure the accessibility of pharmaceuticals and medical treatments used to treat pandemics such as HIV/AIDS, as well as “their affordability for all,” in accordance with international laws and agreements. The resolution also calls on governments “to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties.”

4. See Deardoff (1992, p. 37). The TRIPS agreement does not accord such an exemption to the least developed countries. Such countries can delay the application of the agreement until 2006 and subsequently request extensions of that term (article 66.1). The Doha Ministerial Declaration on TRIPS and Public Health, adopted on 14 November 2001 by the members of the World Trade Organization (WTO), authorized least developed countries to further delay the patenting of pharmaceutical products until 2016 (see WT/MIN(01)/DEC/W/2, para. 7).

5. Ongoing negotiations (under the auspices of the World Intellectual Property Organization) on an international treaty to harmonize certain substantive aspects of patent law, if successful, may eventually limit states’ freedom to decide on this matter.

6. The notion of “local” innovation disseminated by media other than publication outside the United States has led, for example, to the patenting of plants and knowledge widely used and developed in developing countries (Correa 1999).

7. Examples of patents granted in the United States include one for an “invention” consisting of elastic bands worn across the mouth, allowing wearers to breathe but preventing the intake of food (US 4,883,072); a patent for a hunting device consisting of a cape and a hat serving as a decoy for prey (US 5,197,216); and a patent for a hat for four-legged animals (US 4,967,317). From Feinberg (1994).

8. For example, less than half of the examinations conducted by the U.S. Patent Office refer to relevant background bibliographies; examinations are largely limited to analyzing previous patents (Aharonian 2000).

9. In the United States patent holders can ask the Patent Office to reexamine earlier patents before or during an infringement lawsuit, to determine whether prior art invalidates one or more new patent claims (33 USC 302).

10. The European Patent Office provides for an opposition procedure after a patent has been granted.

11. Most countries publish applications before granting patents. The United States recently adopted this rule (Public Law 106-113, of 29 November 1999), but only for inventors who filed abroad before applying in the United States.

12. This procedure is provided for in some laws, such as in Argentina and in Decision 486 of the Andean Group countries.

13. One reason broad patents discourage follow-on innovation is that the nego-

tiation of patent rights for such innovation could be difficult. In addition, cross-licensing is likely to occur, discouraging follow-on innovation.

14. The optimal solution from society's perspective would be to determine the breadth of each patent based on the nature of the innovation and the relevant markets—an approach that is not easy to build into intellectual property law (see Scotchmer 1998 and Thurow 1997).

15. See Gutterman (1997, p. 67) and Hart (1994, p. 231), who argues that “to be efficient, a patent term should also reflect the costs of research and development involved. Current patent law awards the same patent term no matter what the inventive process costs; this cannot be efficient. The higher the cost of research and development, the longer the patent duration that is need to induce efficient investment, and therefore, the longer the patent term should be.”

16. This practice is often called “evergreening” of patents.

17. This type of patent may have significant practical consequences. For example, in Thailand—there was no patent for didanosine (ddl) as such. Nevertheless, Bristol Myers Squibb (which did not discover the product but obtained a license for it from a federal U.S. laboratory) patented a formulation of ddl, blocking the Thai government's attempts to purchase the drug at a much lower price.

18. For example, after terfenadine had been on sale for several years, a patent was obtained for its active metabolite. The courts decided that this was an unacceptable attempt to extend the original patent.

19. An example of a patent for the use of a known drug is AZT (Retrovir), which was synthesized in 1964 by the Karmanos Cancer Institute (formerly known as the Michigan Cancer Foundation) as a possible anticancer drug. Another more recent example is sildenafil (Viagra).

20. In European countries an early working exception has been gradually admitted by case law based on the right of a third party to conduct experiments without the authorization of the patent owner (Cook 1997; NERA 1998).

21. Under some formulations of this doctrine the consent of the titleholder in the exporting country is needed for “exhaustion” to occur (“consent theory”). Legally, however, exhaustion may be considered to have occurred when the titleholder was rewarded in the exporting country (“reward theory”), including through a compulsory license.

22. Another argument against parallel imports is that they increase opportunities for “counterfeit and substandard products to enter the market” (Bale 2000, p. 18), but this is essentially a law enforcement problem that can be addressed under normal procedures.

23. At the WTO TRIPS Council first special session on intellectual property and access to medicines, held on 20 June 2001, the U.S. delegation argued that “In our view, advocates of parallel importation overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for

example, products sold for low prices in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men. The lack of parallel import protection can also have significant health and safety implications. Our law enforcement and regulatory agencies, especially the Food and Drug Administration, have commented on how very difficult it is for them to keep counterfeit and unapproved drugs out of our country even with the strong parallel import protection provided in the United States. Advocating parallel imports, therefore, could work to the disadvantage of the very people on behalf of whom the advocates purport to be speaking. As World Health Organization Director-General Dr. Brundtland in Oslo recently noted, ‘For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower priced drugs from finding their way back into rich country markets.’”

24. Compulsory licenses are often also called “nonvoluntary licenses.” The TRIPS agreement (article 31) refers to “Other use without the authorization of the right holder.”

25. According to the Paris Convention (article 5A) and the TRIPS agreement (article 31), compulsory licenses must be nonexclusive—meaning that licenses to use a patent may be given to more than one company.

26. A compulsory license can apply to manufacturing or importation of the protected product. Both options are admissible under the TRIPS agreement.

27. Scherer’s studies also indicated a decline in patenting activities among firms subjected to compulsory licensing. However, that result does not necessarily mean that the firms’ spending on research declined—but rather that the firms could rely on alternative methods of protection, such as trade secrets.

REFERENCES

- Aharonian, Greg. 2000. “Patent Examination System Is Intellectually Corrupt.” *Patnews*, 1 May. [<http://swpat.ffii.org/vreji/prina/patrupt.pdf>]. March 2002.
- Anderson, Robert D. 1998. “The Interface between Competition Policy and Intellectual Property in the Context of the International Trading System.” *Journal of International Economic Law* 1 (4): 655–78.
- Bale, Harvey. 2000. “TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development.” Paper presented at the World Health Organization workshop on the TRIPS Agreement and Its Impact on Pharmaceuticals, 2 May, Jakarta.
- Barton, John. 2000. “Reforming the Patent System.” *Science* 287 (17 March): 1933–34.
- . 2002. “Research-tool Patents: Issues for Health in the Developing World.” *Bulletin of the World Health Organization* 80 (2): 121–25.
- Benkler, Yochai. 2001. “A Political Economy of the Public Domain: Markets in

- Information Goods versus the Marketplace of Ideas.” In Rochelle Dreyfuss, Diane Zimmerman, and Harry First, eds., *Expanding the Boundaries of Intellectual Property*. Oxford and New York: Oxford University Press.
- Cook, Trevor. 1997. “Pharmaceutical Patents and the Generic Sector in Europe.” *Patent World* (February).
- Cooper, Charles, ed. 1994. *Technology and Innovation in the International Economy*. Hants, U.K. and Brookfield, Vt.: Edward Elgar and Tokyo: United Nations University Press.
- Correa, Carlos. 1999. “Access to Plant Genetic Resources and Intellectual Property Rights.” Background Study Paper 8. Food and Agriculture Organization, Commission on Genetic Resources for Food and Agriculture, Rome.
- . 2000. *Intellectual Property Rights, the WTO and Developing Countries*. Penang, Malaysia: Zed Books/Third World Network.
- David, Paul A. 1993. “Intellectual Property Institutions and the Panda’s Thumb: Patents, Copyrights, and Trade Secrets in Economic Theory and History.” In M. Wallerstein, M. Moguee, and R. Schoen, eds., *Global Dimensions of Intellectual Property Rights in Science and Technology*. Washington, D.C.: National Academy Press.
- Deardorff, Alan. 1992. “Welfare Effects of Global Patent Protection.” *Economica* 59: 35–51. Reprinted in Kym Anderson and Bernard Hoekman, eds., 2000, *The Global Trading System*, New York: I. B. Tauris.
- Dumont, Béatrice, and Peter Holmes. 1999. “The Breadth of Intellectual Property Rights and Their Interface with Competition Law and Policy: Divergent Paths to the Same Goal.” Paper presented at the International Conference on Innovation, Appropriation Strategies and Economic Policy, 19 November, Paris.
- FAO (Food and Agriculture Organization). 2001. “Potential Impacts of Genetic Restriction Technologies (GURTs) on Agricultural Biodiversity and Agricultural Production Systems.” CGRFA/WG-PGR-1/01/7. Commission on Genetic Resources for Food and Agriculture, Rome.
- Feinberg, Rick. 1994. *Peculiar Patents*. New York: Citadel Press.
- Gleick, James. 2000. “Patently Absurd.” *The New York Times Magazine*, March 12: 44–49.
- Grabowski, Henry G., and John M. Vernon. 1992. “Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act.” *Journal of Law and Economics* 35 (2): 331–50.
- Granstrand, Ove. 1999. *The Economics and Management of Intellectual Property*. Clentenham, U.K. and Northampton, Mass.: Edward Elgar.
- Gutterman, Alan. 1997. *Innovation and Competition Policy: A Comparative Study of Regulation of Patent Licensing and Collaborative Research & Development in the United States and the European Community*. London: Kluwer Law International.

- Hart, Michael. 1994. "Getting Back to Basics: Reinventing Patent Law for Economic Efficiency." *Intellectual Property Journal* 8 (2).
- Heller, Michael A., and Rebecca S. Eisenberg. 1998. "Can Patents Deter Innovation? The Anticommons on Biomedical Research." *Science* 280: 698–701.
- Kaul, Inge, Isabelle Grunberg, and Marc Stern. 1999. "Defining Global Public Goods." In Inge Kaul, Isabelle Grunberg, and Marc A. Stern, eds., *Global Public Goods: International Cooperation in the 21st Century*. New York: Oxford University Press.
- Lanjouw, Jean, and Ian Cockburn. 2001. "New Pills for Poor People? Empirical Evidence after GATT." *World Development* 29 (2): 265–89.
- Levin, Richard, Alvin Klevorick, Richard Nelson, and Sidney Winter. 1987. "Appropriating the Returns from Industrial Research and Development." *Brookings Papers on Economic Activity* 3. Washington, D.C.: Brookings Institution.
- Médecins Sans Frontières. 2001. *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*. Geneva.
- Merges, Robert, and Richard Nelson. 1990. "On the Complex Economics of Patent Scope." *Columbia Law Review* 90 (4): 839–916.
- NERA (National Economic Research Associates). 1998. *Policy Relating to Generic Medicines in the OECD: Final Report for the European Commission*. London.
- OECD (Organisation for Economic Co-operation and Development). 1992. *Technology and the Economy*. Paris.
- Ordovery, Janusz A. 1991. "A Patent System for Both Diffusion and Exclusion." *Journal of Economic Perspectives* 5 (1): 43–60.
- Panagariya, Arvind. 1999. "TRIPS and the WTO: An Uneasy Marriage." Seminar paper prepared for the World Trade Organization, Geneva. Quoted in Dumont and Holmes 1999.
- Plowman, Ronald. 1993. "Intellectual Property Protection of Plants"—The Agricultural Research Service Perspective." In *Intellectual Property Rights: Protection of Plant Materials*. CSSA Special Publication 21. Madison, Wisc.: Crop Science Society of America.
- Rozek, Richard, and Renee Rainey. 2001. "Broad-based Compulsory Licensing of Pharmaceutical Technologies—Unsound Public Policy." *Journal of World Intellectual Property* 4 (4).
- Ryan, Michael. 1998. *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property*. Washington, D.C.: Brookings Institution Press.
- Scherer, Frederic M. 1972. "Nordhaus's Theory of Optimal Patent Life: A Geometric Reinterpretation." *American Economic Review* 62.
- . 1998. "Comments." In Robert Anderson and Nancy Gallini, eds., *Competition Policy and Intellectual Property Rights in the Knowledge-based Economy*. Alberta: University of Calgary Press.

- . 1999. *New Perspectives on Economic Growth and Technological Innovation*. Washington, D.C.: Brookings Institution Press.
- Scherer, Frederic M., and David Ross. 1990. *Industrial Market Structure and Economic Performance*. Dallas, Tex.: Houghton Mifflin.
- Scotchmer, Suzanne. 1998. "Incentives to Innovate." In P. Newman, ed., *New Palgrave Dictionary of Economics and the Law*. London: Macmillan.
- Stiglitz, Joseph E. 1999. "Knowledge as a Global Public Good." In Inge Kaul, Isabelle Grunberg, and Marc A Stern, eds., *Global Public Goods: International Cooperation in the 21st Century*. New York: Oxford University Press.
- Tandon, Pankaj. 1982. "Optimal Patents with Compulsory Licensing." *Journal of Political Economy* 90 (3).
- Thurow, Lester. 1997. "Needed: A New System of Intellectual Property Rights." *Harvard Business Review* (September–October).
- Viscusi, W. Kip, John Vernon, and Joseph Harrington. 1997. *Economics of Regulation and Antitrust*. Cambridge, Mass.: MIT Press.
- Watal, Jayashree. 2000. "Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPS Agreement." *World Economy* 23 (5).
- Welfens, Paul, John Addison, David Audretsch, Thomas Gries, and Hariolf Grupp. 1999. *Globalization, Economic Growth and Innovation Dynamics*. Berlin: Springer.