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Pharmaceutical Regulation and Intellectual Property: the Third Side of the Triangle

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Introduction

The intersection between antitrust law and intellectual property rights, and antitrust law and industry-specific regulation is now well trodden terrain. It has been copiously studied and dissected by lawyers¹ and economists² in both the United States and Europe. Meanwhile, however, the connections between industry-specific regulation and intellectual property has been neglected. Understanding those connections is nonetheless crucial to applying antitrust law wisely to regulated R&D-intensive industries, such as pharmaceuticals.

The Pharmaceutical Sector Inquiry published by the European Commission³ (hereafter, the Inquiry) disappointed observers and stakeholders on several counts⁴. In particular, the Inquiry did not offer firms any guidance on two key questions: Under what circumstances can European antitrust law limit pharmaceutical firms' intellectual property rights? When does influencing a regulatory agency amount to an illegal practice⁵? The Commission probably did not intend to provide such guidance in its Inquiry. But even if it had, it would not have been able to, because it did not take pains to understand the relationship between pharmaceutical regulation and intellectual property law. The Commission consistently compares these two areas to antitrust law, but never to each other. It does not attempt to distinguish between them conceptually, instead equating patent law with regulation⁶.

This chapter seeks to determine the interactions between industry-specific regulation law and patent law in the case of the pharmaceutical industry. It thus attempts to close the third side of the triangle formed by the vertices of antitrust, regulation and intellectual property. For a lack of academic references on the subject⁷, this paper is obviously highly exploratory, raising more questions than it

¹ On the relationship between antitrust law and intellectual property rights in Europe, see, for example, Valentine Korah, *Intellectual Property Rights and the EC Competition Rules*, Hart Publishing, 2006; in the United States, see, for example, the US FTC's report *To Promote Innovation: The Proper Balance of Competition and Patent Law Policy*, October 2003. On the relationship between regulation policy and competition policy in the United States, see, for example, Herbert Hovenkamp, 'Antitrust and the Regulatory Enterprise' *Columbia Business Law Review*, 335, 2004 or Phil Weiser, 'The Relationship of Antitrust and Regulation in a Deregulatory Era,' *Antitrust Bulletin*, Vol. 50, September 2005; for a US/Europe comparison, see Nicolas Petit, 'Circumscribing the Scope of EC Competition Law in Network Industries? A Comparative Approach to the US Supreme Court Ruling in the Trinko Case' *Utilities Law Review*, 6, 2004.

² On the relationship between regulation policy and competition policy, see, for example, Perrot, 'Les frontières entre régulation et politique de concurrence', *Revue Française d'Economie*, Vol. XVI, n° 4, avril 2002; David Newbery, 'The Relationship between regulation and competition policy for network utilities', *Cambridge Working Papers in Economics* n° 0631, Mars 2006. On the relationship between intellectual property rights and competition policy in Europe, see, for example, Claude Crampes, David Encaoua and Abraham Hollander, 'Competition and Intellectual Property in the European Union,' in *New Developments in UK and EU Competition Policy*, Roger Clarke and Eleanor J. Morgan (eds.), Edward Elgar, 2006. For a comparison of the United States and Europe, see François Lévêque and Howard Shelanski, (ed.), *Antitrust, Patents and Copyright - EU and US Perspectives*, Edward Elgar, 2005. For an instructive overview, 'Intellectual Property and Competition Law', in François Lévêque and Yann Ménière, *The Economics of Patents and Copyright*, Chapter 5, 2004: <http://www.bepress.com/leveque>

³ European Commission, Directorate General for Competition, Pharmaceutical Sector Inquiry, Final Report, July 8, 2009: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>

⁴ The preliminary report of the Inquiry attracted numerous comments, particularly from trade organizations: http://ec.europa.eu/competition/consultations/2009_pharma/index.html

⁵ See Catriona Hatton, Robert F. Leibenluft, Suzanne Rab, Jean-Michel Coumes and David Cardwel, 'European Commission Pharmaceutical Sector Inquiry Report - Drug Problems Remain But Commission Softens Its Stance', Antitrust Update, Hogan & Hartson L.L.C. 15.07.2009: <http://www.hhlaw.com/pressroom/newspubs/pubdetail.aspx?publication=4665>

⁶ Patent law, along with market authorizations, pricing and reimbursement status of drugs, is included in the "regulatory framework" section of the preliminary and final reports of the Inquiry.

⁷ Except for some articles focused on pharmaceuticals, which touch on the issue. See, for example, C. Scott. Hemphill, 'Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem', *New York University Law Review*,

answers. The first section of the chapter contains an overview of the intersection between the three areas of law and a discussion of the differences and similarities between regulation and intellectual property law. The second section studies the previously neglected side of the triangle in the case of the pharmaceutical industry. The third section concludes with considerations on the application of antitrust law in the regulated, R&D-intensive pharmaceuticals industry.

Antitrust law, sector-specific regulation law and intellectual property law

Very broadly, modern antitrust, sector-specific regulation and intellectual property protection policies seek the same goal, namely to promote competition and innovation, which are essential conditions for increasing the general welfare, and in particular consumer welfare. The laws that enact those policies and the specialized agencies that apply them are, however, quite different. The common goal is achieved by different routes, since each of the three areas of law meets a specific purpose, and employs different instruments and different procedures. Let's look at some illustrations. Antitrust law protects market competition by punishing collusive practices between firms and practices that exclude rivals. However, this also affects innovation, because competition is a powerful driver of innovation. Industry-specific regulation law facilitates competition by lowering entry barriers and by facilitating access to scarce resources. It affects innovation through its action on competition but also through investment by imposing prices, quotas, or quality standards on firms. Intellectual property law⁸ protects inventions and creations by granting temporary exclusive rights to innovators. It also fosters competition – in its dynamic dimension this time –, by stimulating the race to innovate and the multiplication of artistic paths and technological solutions.

From a very general economic viewpoint, the concept of monopoly runs through the three laws. It unites them but also differentiates them. We could say that antitrust law fights monopolies, whereas regulation law administrates them, and intellectual property confers them. That definition is a little simplistic, because antitrust law only fights some monopolies (e.g., cartels, where a group of firms acts as a single entity) and some monopoly behavior (e.g., predatory strategies), regulation law opens and controls access to so-called natural monopolies (e.g., the local telephone loop, or high-voltage power lines), and intellectual property law allocates exclusive rights that only the lack of a substitute technology or a similar work turns into a monopoly.

Although rough-and-ready, the expression above nonetheless highlights how the three areas of law can conflict, despite their common general aim. The way antitrust law on the one hand, and industry-specific regulation law or intellectual property law on the other, intersect and sometimes clash, is abundantly covered in legal literature. *Trinko*, *Deutsche Telekom*, *Magill*, *Xerox*, *Astra Zeneca* and *Glaxo-SmithKline* are some of the major cases that moved case law and academic discussion of the issue forward. Some of the many issues addressed by scholars include: the organization and operation of agencies, how they work together; their vulnerability to influence by pressure groups; complementarity, friction points, similarities and differences between antitrust law and the others; instruments used, procedures followed, sources and imperfections of information that characterize the application of each body of law. Amid the huge variety of issues covered, two key questions come up

1553 (2006) and Stacey L. Dogan and Mark Lemley, 'Antitrust and Regulatory Gaming', *Texas Law Review*, Vol. 87, n°4, March 2009.

⁸ In this article, intellectual property law is considered to be patent law and copyright law. Trademark law is considered separately by economists because it responds to a different problem: signaling to consumers the quality of goods and services, not encouraging manufacturers to innovate.

repeatedly in the literature: the academic question of the pre-eminence of antitrust law over the other two areas of law, or, from another perspective, the immunity of intellectual property law and industry-specific regulation law vis-à-vis antitrust law; and the pragmatic question of the application of antitrust law when a dispute involves intellectual property rights or concerns regulated firms. In both cases, research focuses on the relationship with antitrust law. That polarization is attributable to a fundamental difference between antitrust law and the other two areas of law: antitrust law intervenes *ex post*⁹ whereas industry regulation law and intellectual property law intervene *ex ante*. The latter two guide the market towards socially desirable outcomes (e.g., by offering incentives, by correcting imperfections), whereas antitrust law remedies socially undesirable past behavior. Because of this temporal difference, antitrust agencies can be tempted to compensate for failings in the regulatory framework or the patent system. They are able to return after the fact to something that was previously authorized, for example by watering down the advantages of a regulation for a firm or by eroding a firm's intellectual property.

As mentioned above, the relationship between industry regulation law and intellectual property law is not a question studied in academic journals. It is barely considered by practitioners either. This can probably be attributed to the fact that few cases prompt such an investigation. Indeed, there are few economic sectors that are subject to specific regulations and whose economic model is highly dependent on intellectual property. The pharmaceutical industry without doubt belongs to that almost empty set¹⁰. Before studying the intersection of the two areas of law in this industry, let us examine some of their differences and similarities, while keeping an eye on antitrust law.

We will first argue that intellectual property law does not belong under regulation. It clearly does not belong under industry-specific regulation, since intellectual property law is designed for and applies to all industries. That is a feature it shares with antitrust law. More fundamentally, from my viewpoint as economist, the key difference between intellectual property law and regulation is that the application of the former is entirely non-economic. That point warrants explanation. Naturally, I do not challenge the economic purpose of patent law and copyright. Like regulation and antitrust law, intellectual property law was designed and is now perceived as contributing to wealth creation. Redistribution and equity have been relegated to secondary concerns.

My point is that the application of intellectual property law is in no way determined by economic analysis and that the agencies (i.e., patent offices) do not take the economic effects of their decisions (i.e., to approve a patent application) into account. In this respect, the contrast with regulation – and with antitrust law – is striking. Which markets and firms should be regulated? Which imperfections should be corrected? Which prices and obligations should be imposed on a monopoly? Which anti-competitive practices should be prosecuted? On what basis can a distinction be made between the elimination of a competitor through normal competition, and predatory practices? How can the pro-competitive and anti-competitive effects of an agreement be identified and put in the balance? All these questions confronting industry-specific regulators and antitrust agencies call for economic analysis.

Apart from its normative and instrumental role, economics plays a major part in the decisions of antitrust and regulation agencies. These agencies *are* concerned about the economic consequences of their actions. For example, one proposal for an access tariff to a monopoly infrastructure will be chosen over another because it minimizes the risk of future under-investment. Or, a practice that

⁹ We leave out merger control law, which intervenes *ex ante* and which in many respects is similar to regulation.

¹⁰ The media and telecoms sectors could probably be included in this category. The issues of fees for Internet service providers to compensate for losses from content piracy, and hold-up of technology standards by patents would probably also be better understood if the intersection between regulation and intellectual property law was studied.

results in the elimination of a competitor will not be condemned if it is not harmful to consumers. By contrast, patent offices base their examinations on a purely technical approach. A patent is only granted if the innovation is new and inventive¹¹. These criteria are roughly the same in all jurisdictions. They underpin the decisions of the US, Japanese, Chinese and European patent offices. It is chiefly on the basis of these criteria that patent examiners approve a patent application and define its scope¹². Yet these criteria have only a tenuous link to R&D costs, the value of the patent or the value of the patented technology¹³. Moreover, patent offices do not request or search for any economic information. A patent is thus granted and its scope defined independently of what it might have cost and what it is likely to generate in revenue. The nature of patent offices' work and even more so the number of applications they process – the US Patent and Trademark Office grants nearly half a million patents a year! – go a long way to explaining why economic considerations are not taken into account in every micro decision.

Now for the common features between industry-specific law and intellectual property law. The fact that both bodies of law intervene *ex ante* has already been mentioned. The second key feature they share is in their impact on investment. From the viewpoint of economic analysis, industry-specific regulation and patents respond to the market's failure to achieve the optimal level of investment when production of a good involves increasing returns (as in the case of a natural monopoly) or when free consumption is hard to prevent (as in the case of information). In particular, the two areas of law avoid duplication of some investment. Building two tunnels side by side under the English Channel or two high-speed railway lines linking Paris and Lyon would be wasteful for the community: the fixed costs are such that the average unit cost decreases with volume; therefore, a single infrastructure should meet all demand. This is also the case for scientific and technical knowledge. Once produced, information can be disseminated at very low cost and its use by others does not destroy it. By providing a means of protection other than secrecy, a patent avoids having to reinvent the wheel. Just as regulation limits duplication of investment in infrastructure to which it authorizes access, patent law, by facilitating a user's licenses, limits duplication of investment in R&D. Less theoretically, the two areas of law impact on firms' investment decisions, because they set certain parameters in advance that ensure firms' profitability (e.g., length of protection and patent renewal fees, rules for calculating access tariffs and cost recovery). In economic jargon, industry-specific regulation law and intellectual property law are said to impact on *dynamic* economic efficiency.

Note again that this second feature in common is not shared by antitrust law. In its application, antitrust law tends to emphasize static or short-term economic inefficiency, i.e., poor resource allocation due to collusion between rivals or due to the elimination of competitors. Moreover, the only signal that antitrust law sends firms in terms of investment is not to invest in the illegal acquisition of a dominant position, for example by selling at a loss initially then recouping that expenditure by practicing monopoly pricing once competitors have been removed.

The third feature in common between regulation law and intellectual property law is that their rules are subject to industry capture.

¹¹ A third criterion – usefulness or industrial application – must also be met. However, it is rarely a ground for examiners to reject a patent application or for courts to invalidate a patent. It was left out here to simplify the analysis.

¹² Patent applications include claims proposed by the filer that define the scope of the patent. The examiner can approve the patent with all the claims or only some of the claims.

¹³ Hence the statistical dispersion by industry and firm of the number of patents per euro or dollar invested in R&D, the incremental gain generated by the patent over other ways of recouping R&D costs, and revenues from the sale of patented technologies. For a summary of patent evaluation methods, see François Lévêque and Yann Ménière, 'Patents and Innovation: Friends or Foes' Berkeley Center for Law and Technology, Paper 28, March 22, 2007: <http://repositories.cdlib.org/bclt/lts/28/>.

Regulatory capture is an old concept in economic theory¹⁴ used to explain how law and regulation are influenced or “captured” by special interests, in particular industrial lobbies, which are more powerful than groups that defend the interests of consumers or taxpayers. According to the theory, elected representatives, the government and bureaucrats pursue private interests (e.g., re-election, career). They design laws and regulations to fulfill those interests (e.g., campaign financing, comfortable jobs in industry) rather than in the general interest. By extension, regulatory capture refers specifically to the risk of a regulatory agency acting in the interest of the regulated firms. Industry capture is facilitated by information asymmetry: the firm knows its costs and performance better than the regulator; even though he needs to know this information in order to act, and the regulator knows the intensity and the purpose of his efforts better than the agency in charge of supervising him, even though it needs to know this information to ensure that the regulator is acting in the general interest, or is at least not corrupt.

Economic theory has paid less attention to regulatory gaming. This newer concept describes how firms exploit loopholes in the regulations to obtain an economic advantage that was not desired by the legislator. Let's take an example from the pharmaceutical industry. In the United States, pharmaceutical firms must disclose the patents covering each of their products in a public register, the Orange Book. Under the Hatch-Waxman Act of 1984, generic manufacturers wishing to enter the market before the patents covering the molecule they are imitating expire must claim either that their product does not infringe the patents, or that the patents are invalid. The patent-holding drug company is entitled to challenge that claim in litigation against the generic manufacturer. In that event, the market authorization of the generic drug is automatically suspended for 30 months. Since the act did not initially stipulate whether this preliminary injunction could be granted once or several times, some firms sought to delay the entry of competitors indefinitely by adding new patents to the Orange Book and by taking new legal action against the generic manufacturer to obtain an additional suspension. In 2003 Congress passed a new law that provides for a single 30-month period, regardless of the number of patents protecting the molecule.

From a legal viewpoint, regulatory gaming is similar to abuse of rights, because the regulations are exploited to achieve the opposite outcome to the one that was intended. From an economic viewpoint, regulatory gaming is simply the *ex post* version of regulatory capture. An interest group can seek to obtain an economic advantage by lobbying for the passage of a particular law, or by influencing its content. Regulatory gaming thus occurs *ex ante*, i.e., before the law is passed. It can also occur *ex post* by exploiting gaps in the legislation. For an economist, who analyzes the gains and losses for agents caused by public policies, regulatory gaming is a way of altering *ex post* the redistributive effects engineered *ex ante* by the new law. A legal scholar would say that the law strikes a balance between different interests and that abuse tips that balance. The idea is the same, however. In the previous example, the 1984 Hatch-Waxman Act represented a balance struck by Congress between the interests of generic manufacturers and R&D intensive firms, and, in the background, between society's short-term interest in having cheaper drugs and society's long-term interest in enabling pharmaceutical research to continue. The repeated extension of 30-month suspensions tipped the balance to the detriment of generic manufacturers.

To sum up, the law can be hijacked *ex ante* when it goes from bill to law or when it is applied by the regulator; or abused *ex post* by one of the parties it affects. In all these cases, capture is enabled by information problems (e.g., asymmetry between the interest group and the legislator to the former's benefit; and uncertainty, which makes it impossible to accurately predict *ex ante* all the effects of a law)

¹⁴ See the seminal paper by G. J. Stigler, 'The Theory of Economic Regulation', *Bell Journal of Economics and Management Science*, n° 2(1), 1971, pp 3-21. For an instructive overview of regulatory capture (in French), see François Lévêque, *Economie de la Réglementation*, Coll. Repères, Edition La Découverte, 2d édition, 2004.

and governance problems (e.g., How can the private interests of regulators and governments be aligned with the public interest?).

As their names suggest, regulatory capture and regulatory gaming are associated in the literature with regulation, particularly industry-specific regulation. But they also feature strongly in the reform and application of intellectual property law. Three illustrations of this are¹⁵: the extension of copyright protection, the operation of the US patent office, and patent trolls:

In 1999 the US senate passed the Sonny Bono Act, which extended copyright terms by 20 years. The bill was ardently supported by the Walt Disney Company, whose first Mickey Mouse drawing would have entered the public domain in 2003, followed closely by Donald Duck and Pluto. At first glance, the reform appears to be driven by a political will to promote creation, because it offers more incentive to authors. But in fact, the retroactive application of the act to existing works cannot be justified on those grounds, since the authors had already created them! Moreover, for future creators, the additional years of protection increase expected earnings only marginally, owing to present value (i.e., a dollar tomorrow is worth less than a dollar today). Sonny Bono was only the tenth regulation benefiting the entertainment industry: in 40 years, copyright terms have been extended 11 times¹⁶.

The US Patent and Trademark Office processes almost half a million new patent applications every year. The number of applications has doubled since 2000. Patent examiners are overloaded, delays are growing, and the quality of patents is suffering. To pick out but one example, a patent¹⁷ was granted to K. T. Amiss and M. H. Abbott for inventing a method of exercising a cat with the beam of light from a laser device directed onto the floor or the wall! The explosion in the number of patents is partly due to firms increasing filings, less to protect their innovations than for defensive reasons to protect themselves against the risk of future litigation. Having a buffer of patents enables them to dissuade their competitors from suing them for infringement because they probably hold patents that their competitors infringe too. The explosion in the number of patents is also facilitated by a perverse system of incentives. The US patent office, like most of its counterparts around the world, is remunerated by the fees paid by applicants, including renewal fees to maintain patents. Consequently, if the office became more selective, it would have less revenue. Furthermore, examiners' bonuses depend on the number of cases processed. It takes more time to reject a patent application (because of having to write a report, or respond to an appeal) than to approve one. One sign of the capture of the US office is that, in its 1996 Strategic Plan, the office referred to applicants as its customers. The plan explained that the two main goals of the US PTO were to be a leader in developing intellectual property rights policy and to give its customers the highest possible level of quality and services¹⁸.

Patent trolls, also referred to as non-practicing entities, are firms not involved in R&D or goods production that buy patents in order to file suits against potential infringers. They choose their prey carefully. For example, they start by suing a vulnerable company that has a lot to lose or a company that has limited means of defending itself. They hope that a settlement or ruling will set a precedent convincing other firms in the sector to pay for licenses. The case of NTP suing RIM is the most emblematic illustration of this type of strategy. NTP holds patents on email accessible via mobile telecommunications, and RIM is the manufacturer of the BlackBerry. NTP sued RIM for patent infringement in 2000. The judge ruled in NTP's favor, and ordered RIM to pay \$53 million in damages,

¹⁵ For an overview (in French), see Jean Tirole, Claude Henry, Michel Trommetter and Laurence Tubiana, '*Propriété intellectuelle*', Rapport du Conseil d'Analyse Economique, juillet 2003.

¹⁶ Lawrence Lessig, *The Future of Ideas*, Vintage Books, 2002.

¹⁷ US patent 5443036, see <http://www.freepatentsonline.com/5443036.html>

¹⁸ See: <http://beta.uspto.gov/about/stratplan/ar/1996/exec.html>

and put a rapid stop to its infringement. The injunction would have forced RIM to suspend all the email communication of its customers in the United States. After many legal twists and turns¹⁹, the parties reached a settlement in March 2006 just before the injunction went into effect. In the end, RIM agreed to pay NTP \$612.5 million. NTP has since sued a large number of telecoms firms, including AT&T, Verizon and T-Mobile, for infringing the same patents.

Having illustrated regulatory capture, regulator capture and gaming in intellectual property law, let's look at antitrust law. Unlike intellectual property and industry regulation, antitrust has a very low risk of capture. That feature is stressed in most comparative studies of antitrust and industry regulation policies²⁰. There are several reasons for this. Firstly, antitrust law covers all industrial sectors. Gains and losses for firms that result from antitrust legislation, reform and enforcement are more diffuse and, on average, low. Let's look at the example of fines for anticompetitive practices in Europe. Although such fines are now substantial for the firms concerned, compared with the total number of firms in the European Union, they are negligible. Firms therefore have little incentive to organize into lobbies²¹ to combat this development. Secondly, antitrust agencies are only in contact with firms in a discontinuous way over time. The risk of regulator capture related to the expertise acquired by civil servants and their desire for a career in industry is therefore lower. Thirdly, since antitrust law acts *ex post* and is highly flexible, it does not offer much opportunity for firms to hijack it or exploit its loopholes. Clemency programs to combat cartels seem to be an exception here. Much theoretical research has shown that these have the potential to be manipulated²². There is also a rumor among practitioners that some firms disguise harmless agreements and industry deals as false cartels in order to penalize their competitors. But this exception would confirm the rule because clemency programs are like regulation in that they act *ex ante*, not *ex post*.

To conclude, the key similarities and differences between industry regulation law, intellectual property law and antitrust law are recapitulated in the table below.

	Antitrust law	Sector-specific regulation	Intellectual property law
Aims	Protecting competition in markets	Promoting competition and regulating access to some markets	Promoting innovation and creation
Action	Ex post	Ex ante	Ex ante
Application focused on a particular industry	No	Yes	No

¹⁹ Including an appeal to the Supreme Court of the United States, which the court refused to hear.

²⁰ See, for example, Perrot, note 2 above. For the few examples of antitrust capture, see R. Preston McAfee and Nicholas V. Vakkur, 'The Strategic Abuse of Antitrust Laws', *Journal of Strategic Management Education* 1(3), 2004.

²¹ In fact, probably only firms that belonged or belong to a cartel would have an incentive in lobbying against the increase in fines, thus identifying themselves...

²² See, for example, Joseph E. Harrington, 'Optimal Leniency Programs', *The Journal of Industrial Economics*, Vol. 56, n°2, June 2008.

	Antitrust law	Sector-specific regulation	Intellectual property law
Impact on investment	Marginal	Significant	Significant
Economic considerations taken into account in decisions and rules	Yes	Yes	No
Risk of ex ante and ex post capture	Low	High	High

The interaction between pharmacy regulation and patent law

The pharmaceutical industry is one of the few sectors that is subject to specific regulation – pharmaceutical law – and whose economic model is highly dependent on an intellectual property right – patents. The effects of the two bodies of law obviously interact. An obvious example is the tightening of the requirements for market authorization of a drug. It lengthens the period of clinical trials, and therefore shortens patent protection, and thus lowers the incentives it offers. Conversely, tightening the requirements for patent approval leads to a decrease in the number of patents granted, which means a shorter wait for entry of generic drugs, and therefore enhances regulatory measures that seek to promote competition between originator and generic drugs. The two laws can thus restrict or enhance each other's effects. Let's look at how in detail, by examining the specific regulation of protection for pharmaceutical innovations, the regulation of market authorization for generics and the regulation of drug prices.

Specific regulation of protection

Patent law is all-industry. The same rules apply to innovation in industries as varied as automobiles, food, and telecoms. The length of protection and the approval criteria are therefore the same for everyone. This intrinsic uniformity of the patent can however be circumvented by industry regulation through specific protection measures.

Specific measures can add to patent law by setting an additional requirement or eliminating an uncertainty:

In the United States, as we have seen, the Hatch-Waxman Act requires pharmaceutical firms to disclose the patents protecting every one of their drugs. This obligation is completely alien to patent law, under which the onus is on the competing innovators to search patent office databases to find existing patents that can potentially block them. This act, which reverses the onus of searching, makes things easier for generic manufacturers. It also eliminates the risk of their being unaware of an existing

patent. And this risk is usually significant, given the very large number of patents. The American economist M. Scherer²³ has compared innovation to a minefield. Even if an innovator has carefully studied the maps to locate other firms' inventions, he risks having a leg blown off at any time by inadvertently stepping on someone else's patent. That someone else can claim damages from him that will sink his business idea.

In Europe, as in the United States, generic manufacturers can now take advantage of the information disclosed in patents to prepare their applications for market authorization before patent protection has even expired. Before the Hatch-Waxman Act of 1984 and European Directive 27/2004, the legal framework was ambiguous. On the one hand, patent law immunized experimental research against infringement. The purpose of that rule was to avoid the patent blocking academic research. On the other hand, it was not clear whether tests by generic manufacturers were eligible for that exemption. Bolar clauses²⁴ in American and European pharmaceutical legislation eliminated that uncertainty. Some national patent laws, for example in Hungary, Slovenia and Poland, state explicitly that the research exemption applies to generic manufacturers' tests. In those countries, patent law itself clears up the ambiguity. However, it is worth noting that this correction erodes the all-industry principle of patent law, by specifying a rule for a specific industry.

Specific measures can also add to patent law by granting exclusivity or by extending the exclusivity granted by patent offices.

In Europe, the innovator of a drug is entitled to eight years of protection for his test data, starting from the first market authorization. More specifically, the drug agency cannot start examining an imitator's application for market authorization until that time is up. Furthermore, the drug innovator is also granted ten years of marketing exclusivity, starting from the first market authorization. In the United States, data protection lasts for five years and marketing exclusivity is only granted under some circumstances, such as when a pediatric formula of the drug has been developed. Lastly, in both Europe and the United States, the effective length of patent protection has been extended by five years. The European supplementary protection certificate offers about five years of additional protection that, together with patent protection, grants up to 15 years of exclusivity from the date of the first market authorization to the expiration of the patent. Thus, if a patent was granted in 1995, and the patented drug is released in 2004, it will be protected for three years after the patent expires, i.e., until 2018. This additional protection, introduced into Regulation 1728/1992, is the counterpart of a US decision incorporated into the Hatch-Waxman Act in 1984. These measures do not change the formal legal term of drug patents. That term remains the same, regardless of the fields of application of the invention. Instead, the regulation corrects a shortcoming in patent law that appeared in a given industry and alters the *de facto* term of patent protection.

Regulation of market authorization and entry of generic manufacturers

Regulation of market authorization for pharmaceuticals is determined chiefly by scientific and medical considerations. That technical aspect is reiterated several times in the European Commission's Inquiry, which stresses that market authorizations are based on a product's quality, safety and efficacy, and that the agencies that examine applications should not take any other element into consideration; in particular they do not have to consider whether the product is patented or not²⁵. Regulation of market authorization nevertheless comprises an economic aspect because there are clauses that facilitate the entry of generic drugs.

²³ Michael Scherer, 'Testimony at the FTC Hearings on Global and Innovation-Based Competition', October 21, 2005.

²⁴ Bolar clauses take their name from the generic manufacturer sued by Roche for infringement on these grounds in 1984.

²⁵ See last paragraph of page 131 of the final report of the Inquiry.

The market authorization procedure for generic drugs is simpler. The Hatch-Waxman Act and Regulation 2309/93 exempt the generic manufacturer from repeating trials of the princeps drug he is imitating as long as he can prove that his product is equivalent to the originator drug. By avoiding needless effort, this proof of bio-equivalence fulfils one of the functions of the patent, namely to limit duplication of redundant investment. From a static economic viewpoint, it is socially efficient.

The simplified authorization procedure also benefits generic manufacturers by lowering their costs and enabling them to access the market earlier. It can thus be assimilated to “asymmetrical regulation”, whereby, in order to promote competition in a market where it is low or non-existent, the legislator offers new entrants more favorable conditions than the incumbents. Note that this does not interfere with patent law²⁶. The abridged authorization procedure only reduces the time to generic entry after patents have expired; it does not challenge the length of patent protection. Moreover, authorization is granted independently of intellectual property rights. As the Commission indicates, as for applications for approval of originator drugs, “marketing authorization bodies cannot take the patent status of the originator medicine into account when deciding on marketing authorizations of generic medicines”²⁷.

Conversely, in the United States, the rules on market authorization of generic drugs do intersect with patent law. The Hatch-Waxman Act seeks to promote generic entry after – but also before – patents expire. It contains a clause that grants 180 days of marketing exclusivity to the first generic manufacturer to obtain an authorization. In other words, the first competitor to win the imitation race is assured of half a year of duopoly profit, when his product and the princeps drug share the market between them. That prospect strongly encourages imitators not to wait for the patents on the originator molecule to expire, but to bypass or challenge them. In the abridged authorization application, the generic manufacturer must state that his product does not infringe the patents or that the patents are invalid. Between the early 1980s and the late 1990s, the percentage of generic manufacturers who sought entry in that way rose from 2% to 20%²⁸. Naturally, the applications mostly concerned drugs with high sales and/or weak patents. Hemphill²⁹ has calculated that, in a market worth \$60 million, a 20% probability of winning a patent challenge is enough for a generic manufacturer to recoup his costs. In the early 2000s, the probability of winning was close to 75%³⁰.

In theory, giving the first imitator 180 days of marketing exclusivity is a socially efficient solution. It solves the problem of free-riding associated with patent challenges. Patent invalidation after litigation benefits both the filer of the suit and his competitors, since they will all be able enter the market. The collective nature of the benefit dissuades rival firms from initiating litigation because the one that challenges the patent will gain less than the others. It will obtain the same benefit as the others but alone will pay the costs of litigation. Offering an exclusive reward to the patent challenger would therefore seem to restore balance. However, that the reward should be an exclusive marketing right that freezes the structure of the market, even only temporarily, seems inappropriate. In a given market, the profit of a monopoly firm is always higher than the sum of the profit of each member of a duopoly. The manufacturer of the originator drug and the first generic manufacturer therefore have an interest in coming to an arrangement. It is more profitable for the originator manufacturer to pay the imitator not to enter the market more than what he would make by entering. Hence the authorities suspicion when a princeps drug maker pays a generic manufacturer when the parties settle patent

²⁶ Except Bolar clauses analyzed above.

²⁷ § 336, p. 130 of the Inquiry.

²⁸ See Federal Trade Commission, above, note 1.

²⁹ Above, note 7.

³⁰ See Federal Trade Commission, above, note 1.

litigation and the settlement includes postponed generic entry³¹. The 180-day rule has created the conditions for regulatory gaming, in particular delaying the start of the 180-day exclusivity in order to block subsequent generic manufacturers. Indeed, the FDA cannot authorize their products until the first imitator has exercised his exclusivity.

Aside from its perverse effects, the 180-day rule shows how the regulatory framework governing market authorizations for drugs can erode patent protection. Intellectual property law prevents the entry of pure imitators before the expiration of the temporary exclusivity right, but industry regulation encourages imitators to enter before expiration. It thus undoes some of what patent law bestows³². Let's look at how drug pricing policies have a similar impact.

Regulation of drug prices

In many member states of the European Union, governments set drug prices. In some countries, such as France and Italy, the state also regulates sales, volumes or profit. That economic regulation fundamentally distorts the incentives offered by the patent system.

The incentive function of the patent is based on a decentralized mechanism that ensures that innovations that are worth more than what they cost will be produced³³. Planners do not instruct innovative firms how much to invest in R&D, which field of investigation to choose, or which path of research to follow. Those decisions are up to the innovator, who is the best placed to assess the opportunities and potential profit they offer. However, when the prices, volumes and profits of patented products are set administratively, the invisible hand of the patent is held back, and the innovator's revenues depend entirely on the public body.

Let's show how this works within a highly simplified analytical framework. A patent ensures the investor in a new pharmaceutical molecule that he will enjoy the maximum level of revenues allowed by the constraints of demand and competition from drugs produced by other innovative firms. The resulting price is set by the innovator and reflects his monopoly power. Once the patent expires, new competition appears from generic drugs, and a new equilibrium price is established, which erodes the innovator's market power. Upstream, the innovator estimates his revenues over both periods (monopoly and competition), assesses his R&D costs and the probability of his success, and decides on his investment policy accordingly. When prices are set by the government, the innovator loses control of his revenues and the framework of the patent loses its economic meaning. During the period of patent protection, the administered prices of different princeps drugs determine competition between rival pharmaceutical firms and hence revenues. When patent protection ends, and when the price of generics is also administered, the government determines competition between imitators as well as that between innovators and imitators, by controlling everyone's revenues. The rivalry between all the firms determined by the market and patent law is now based on

³¹ For a description of litigation and agreements between US pharmaceutical firms and generic manufacturers, see Hemphill, above, note 7. For an analysis of these agreements (in French), see Emmanuel Combe and Heiner Haug, 'Les laboratoires pharmaceutiques face à la concurrence des génériques: quels enjeux pour l'antitrust?', *Concurrences*, n° 1-2006.

³² We disregard the alternative interpretation that the 180-day rule corrects patent law. While the rule does solve the problem of free-riding, it should not be local, i.e., restricted to pharmaceutical patents. For an all-industry solution, see Richard Gilbert, 'Patent Pools: Antitrust for Patent Pools: A Century of Policy Evolution', *Stanford Technology Law Review*, April 2004. R. Gilbert proposes creating a public fund that would be used to file suits against patents of dubious validity that lock down some markets.

³³ This is a simplification because the inventor does not reap the full social benefit of his innovation because of the dead-weight loss and the time limit on his exclusivity. For a detailed explanation, see Lévêque and Ménière, note 2 above, Chapter 2.

administered prices. Logically, perfect price regulation removes the need for policies to promote generic drugs. There is no need to authorize generics in order to bring down the price of the princeps drug when the government can influence prices directly. In theory, when the state is omnipotent (i.e., it can set the price of drugs unilaterally) and omniscient (i.e., it can calculate the socially optimal price), economic regulation of market entry and patent law become useless.

According to that analysis of the interactions between pharmaceutical law and patent law, pharmaceutical law appears to correct or significantly distort the incentives that patent law offers innovators and imitators. When specific protection regulation, industry regulation of market entry and price regulation come into play, the signal sent by patents is considerably weakened.

However, the conclusion that patents are weakened by pharmaceutical industry regulation does not take the whole picture into account, because the analysis is incomplete. We have not examined the aspects of patents over which industry-specific regulation has no or little influence. We have seen that non-price sector regulation mainly influenced the length of patents. But patents have other essential economic features, particularly breadth and number. Let's see how these two characteristics are largely unaffected by industry regulation.

Legally speaking, breadth refers to the claims associated with the patent. These are drafted by the applicant and accepted or rejected by the examiner according to how well they match the filer's description of the invention. From an economic viewpoint, the breadth of the invention refers to the scope of monopoly power conferred by the patent in the product market. The broader the patent, the better the protection it provides against infringement. A broader patent excludes a larger number of products that are different from the patented product but that can be substituted for it. Howard Head's patent on over-sized tennis rackets illustrates this idea neatly. In his application, the inventor claimed an exclusive right over racket head sizes ranging from 85 to 130 square inches. If he had settled for a size range of, say, 100 to 120 square inches, his patent would have been narrower and his monopoly power more limited. The breadth of a patent also makes it harder for competitors to develop a close substitute. The broader the patent, the higher the R&D costs required to imitate the patented invention without infringing the patent. Whatever the economic definition used, breadth is a key element in the value of a patent. It is at least as decisive as length, but unlike length, breadth is not affected by industry-specific regulation. It depends solely on examiners' decisions and patent office policies³⁴.

The number of patents protecting the same innovation, whether filed simultaneously or in succession, is also a key parameter. Until now we have assumed that a new pharmaceutical molecule is protected by a single patent once and for all. However, as the Inquiry revealed, the active ingredients of a drug are protected by several patents from the outset as well as by new patents filed years later. The resulting patent thickets extend both the breadth and length of protection. Consequently, all other things being equal, it becomes more costly for competitors to enter the market. As a result, the number of competitors falls and they enter the market later. As for breadth, regulatory measures have no impact on the number of patents³⁵.

In other words, depending on their attitude to applications for broad patents, the multiplication of patents, and secondary patents, patent offices have a decisive indirect influence on competition between princeps and generic drugs, independently of industry regulation, which has no control over those aspects of patents. Note that the influence of patent offices is – and can only remain – passive.

³⁴ Some patent offices, such as the US PTO, are in favor of broad patents when an invention represents a major technical or scientific advance, whereas others, such as the Japan Patent Office, only grant very narrow patents.

³⁵ Unless radical measures are considered, such as limiting drug protection to a single patent application.

As we stressed in the first section of the chapter, patent law is all-industry and non-economic in its application. Examiners cannot apply a specific interpretation of the criteria of novelty and inventive step to drug patent applications; they cannot take economic factors into account in order to reduce the breadth of protection of an active ingredient; and they cannot have tougher requirements for secondary patents.

In conclusion, the analysis of the interactions between pharmaceutical industry regulation and patent law yields contrasting results. On the one hand, by defining specific protection and by regulating entry of imitators onto the market, industry regulation strongly distorts the incentives of patent law to innovate and imitate. On the other hand, patent law remains impervious to the concern of regulation to lift obstacles to competition in the pharmaceutical industry.

Conclusion: consequences for the application of antitrust law

The idea suggested at the beginning of this chapter was that understanding the differences and interactions between industry regulation and intellectual property law is crucial to judicious application of antitrust law in an industry such as pharmaceuticals. After having compared those two areas of law and examined their intersection in the case of the pharmaceutical industry, in conclusion let's recapitulate the main arguments in favor of closing the third side of the antitrust/regulation/intellectual property triangle.

Firstly, by not analyzing the regulatory framework and the patent framework separately, the antitrust authority cannot determine the exact point of equilibrium between competition and innovation. Patent law sets that point at one place and industry-specific regulation law at another. Antitrust law has to determine equilibrium on the basis of both areas of law³⁶. The role of antitrust is not to tip the balance by taking advantage of its *ex post* intervention to refer opportunistically either to regulation or to intellectual property.

Secondly, when patents and regulation are differentiated, the issue of the immunity of intellectual property law from antitrust law is framed in quite different terms. It should be borne in mind that for some lawyers, patent law has an almost sacrosanct quality. It is enshrined in international treaties and sometimes, as in the United States, in national constitutions. The patent owner has an exclusionary right, which would appear to forestall condemnation by antitrust law of practices that exclude rivals. Intellectual property law thus seems to take precedence over antitrust law. Without taking sides for or against this doctrine, let us remark simply that when industry regulation exists alongside patent law, this situation changes. In the case of pharmaceuticals, the legislator has created a specific regulation of protection, which alternately supplements and restricts the patent system of all-industry protection. The legislator's intent should therefore be taken into account in the discussion of the application of antitrust law when exclusive protection rights are involved.

Thirdly, by recognizing the differences in the nature of industry regulation and intellectual property law, the antitrust authority is compelled to treat the anti-competitive effects of *ex post* capture (i.e., regulatory gaming) differently for the two fields. The regulatory framework of pharmaceuticals has a partly pro-competitive purpose, namely to facilitate the entry of generic

³⁶ Here we are considering competition policy that seeks to protect competition, not to reinforce competition when it is weak owing to structural features of the market or because of legislation that weakens or eliminates competition.

products. Practices that subvert the regulations to neutralize or reverse that purpose are therefore contrary to the legislator's intent. They are also contrary to antitrust law if they are not associated with any short-term or long-term benefit for consumers. We can thus admit that this condition is sufficient to establish the illegality of regulatory gaming. It can apply here because regulation, like antitrust law, takes the side of consumers. Such a test cannot, however, be used to condemn regulatory gaming by patents. Patent law does not have a pro-competitive purpose. It even repels the entry of some rivals – pure imitators. Nor is it concerned with consumers.

What would be an appropriate test here? Since the purpose of patent law is pro-innovative, could a test be based on the benefit for innovation? That's what the European Commission suggests when it denounces the strategy of defensive patenting, which aims to exclude competitors without investing in innovation³⁷. In other words, the practice of filing many patents, particularly non-simultaneously, to protect a new molecule, would constitute an infringement of antitrust law if there is no concomitant benefit in terms of innovation.

From our viewpoint, that test is not relevant either. Patent law does not use the same concept of innovation as antitrust law. If an invention right was granted, it is by definition associated with an innovation benefit in the sense of patent law, since the patent application satisfied the criteria of novelty and inventive step. Moreover, the publication of the patent publicizes information that can be used to undertake new research. A patent grant is therefore intrinsically pro-innovative. But a patent grant might also not lead to additional investment in R&D, not be read by anyone, and have no value for society! In that sense, the patent generates no pro-innovative benefit. Innovation in the technical sense of patent law and innovation in the economic sense of antitrust law are too different for the test suggested by the Commission to be applicable.

In general, antitrust agencies should refrain from intervening in cases of regulatory gaming via patents. That would amount to redefining *ex post* and according to economic criteria rights that were granted *ex ante* outside of any economic considerations. The powerlessness of industry regulation to restrict the number and breadth of pharmaceutical patents is no justification for the antitrust authorities to show such opportunism.

Lastly, taking into account the different natures of industry regulation and patent law makes it easier to understand the corrective role of antitrust agencies. Exclusionary practices by firms that take advantage of loopholes in pharmaceutical regulation can be combated by antitrust law. In addition, regulation law can be corrected and amended to limit attempts at regulatory gaming. In the endless chase between the legislator and regulated firms, antitrust agencies also play a useful role as advocates of competition. Their know-how assists the legislator to identify and close regulatory gaps.

Conversely, exclusionary practices by firms that exploit gaps in patent law are harder to combat. It is not clear which necessary or sufficient conditions render them illegal in terms of antitrust law. The influence of antitrust agencies is also limited by the all-industry nature of patent law. Proposing to amend patent law in order to remedy competition problems arising in a particular industry, even a major industry such as pharmaceuticals, is less convincing than the case of loopholes in industry-specific regulation. In its final report, the European Commission puts forward many relevant proposals for reforming patent law. It would be more persuasive if these were supported by a detailed general study of the imperfections of patent law rather than by a superficial examination of the shortcomings of patents in the pharmaceutical industry.

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³⁷ See the Inquiry, in particular § 1571.

