

COMPETITION LAW, INTELLECTUAL PROPERTY, AND THE PHARMACEUTICAL SECTOR

MARGARET K. KYLE*

The pharmaceutical sector is often the subject of antitrust scrutiny. In recent years, competition authorities on both sides of the Atlantic have launched investigations into a number of industry practices. It is easy to see why the industry attracts suspicion: markups over marginal cost are very high for patented products, as are standard measures of market concentration, depending on market definition. However, the application of competition law to pharmaceuticals is often problematic. This is particularly true in the European Union where country-level pharmaceutical regulations and intellectual property (IP) law may interfere with the goal of a common market. This article argues that the application of competition law to two particular practices observed in the pharmaceutical industry may harm total welfare, and sometimes consumer welfare as well.

The pharmaceutical industry differs from most others in three respects. First, the marginal costs of production are generally small relative to the fixed cost of development, and the cost of imitation is also usually low. These fixed costs include the clinical trials necessary to comply with regulatory requirements for safety and efficacy and the pursuit of drug candidates that fail in development. Ex post, an imitator incurs little risk of failure, and reverse-engineering of small molecule drugs is fairly straightforward. Other innovative and creative industries (such as software and movie production) share these features.

Second, although not all economists agree on the optimality of patents, and many have proposed alternative innovation policies, the cost structure of pharmaceutical development explains why patents are cited as more important in

* Professor of Economics, MINES ParisTech (CERNA), PSL Research University, and CEPR. This article was prepared for the *Antitrust Law Journal* Symposium on European Competition Law, January 24, 2014. I thank the editors and participants in the Symposium and the Centre for Competition Policy seminar at the University of East Anglia for their comments and advice. I also benefited from exchanges with Jorge Padilla and Farasat Bokhari. The views expressed here are my own.

drugs and chemicals than in all other sectors. Patent protection shields an innovator from imitation for a limited time. During this period, the innovator usually charges a substantial markup over marginal cost to recoup the fixed costs of development.

Again, other industries also rely heavily on IP for similar reasons; copyright protection has historically been critical in the software and entertainment sectors, for example. Patents are especially valuable in the pharmaceutical sector for another reason: at least one type of pharmaceutical patent, the product patent on the molecule itself, is particularly hard to invent around. That is, patents can be a very effective barrier to entry against prospective rivals. In some other technological fields, patent protection is often weaker due to the ease of inventing around or questions of a patent's validity and enforceability.

Finally, government intervention in pharmaceutical markets is extensive. Regulation takes many forms, from inspections of manufacturing facilities to restrictions on advertising. This article focuses on two broad categories of pharmaceutical sector regulation in the European Union: the regulation of entry and the regulation of price. IP policy touches on both. The regulatory requirements for obtaining market authorization are significantly lower for generic drugs than for originator products. However, IP policies protect the position of an originator for some time. Although regulatory standards have been harmonized across EU Member States, some variation in IP persists. IP typically also provides originators¹ some market power in pricing. For pharmaceuticals, price regulations determined at the national level constrain this market power. No coordinated effort to harmonize regulated prices exists. Instead, the European Union has a policy of "exhaustion" of IP rights. An innovator cannot rely on IP to prevent the resale of a product first sold elsewhere in the European Union. Exhaustion of IP enables the free movement of pharmaceutical products across borders, creating arbitrage opportunities if price regulation results in different prices in different Member States.

The primary concerns of EU competition authorities in the pharmaceutical sector arise from two types of activities. The first is the use of patent strategies that may deter or delay generic entry. In particular, authorities have singled out settlements of patent disputes between originator and generic firms for increased scrutiny and restrictions. The second area of concern is attempts

¹ This article uses the terms "originator," "innovator," and "brand-name firm" interchangeably to refer to the owner of a marketing authorization for a novel chemical or biological entity. Strictly speaking, this owner may have licensed the rights to a drug from another firm and may not be the original patentee. Generic or imitator firms have a different business strategy that entails lower investment in R&D, and the aim of this investment is not generally the discovery of a novel substance.

by originator firms to limit the free movement of patented pharmaceuticals, also known as parallel trade.

This article summarizes the economics of both activities, and assesses the adequacy of current competition law for addressing inefficiencies. In effect, authorities are using different rules for the pharmaceutical industry in the case of abuse of the patent system and anticompetitive settlements. While both are important concerns for competition policy, they are concerns that should apply equally to other patent-intensive sectors. In contrast, unlike most other sectors, the pharmaceutical sector in the European Union is constrained by national-level price regulations. Such regulations are inconsistent with the existence of a truly common market. In addition, a common EU market in pharmaceuticals may not maximize social welfare. For this reason, attempts by the pharmaceutical industry to interfere with the free movement of goods merit different treatment by antitrust authorities.

I. ENTRY REGULATION AND PATENT STRATEGIES

Pharmaceutical products require marketing authorizations from regulatory authorities. In the United States, the Food and Drug Administration (FDA) grants approval based on an assessment of safety and efficacy. The regulatory situation in Europe is more complex. The European Medicines Authority (EMA), established in 1995, provides an applicant with authorization to sell an identical product in all EU Member States via the “centralized” procedure. While this procedure is mandatory for some drugs, producers often have the option of selling their products through the national procedure, which is promulgated by the regulatory authority in an individual Member State. Under the mutual recognition procedure, an applicant applies first in one Member State. Subsequent applications in other EU countries do not require those national agencies to conduct their own reviews. Rather, they recognize the decision of the first agency to approve the product. The mutual recognition procedure can result in slightly different presentations (dosage forms, strengths, pack sizes, and brand names) available in different countries.

Generic drugs face a lower regulatory burden. In the United States, the 1984 Hatch-Waxman Act created a new regulatory pathway for the approval of generics.² The Abbreviated New Drug Application (ANDA) requires applicants to demonstrate only bioequivalence with an existing approved drug, rather than proof of safety and efficacy through clinical trials necessary in a New Drug Application (NDA) for an originator. In other words, generic applicants may rely on the clinical trial data provided by the originator. In the

² Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271, 282).

European Union, Directive 2001/83/EC established similar rules.³ In practice, national regulators handle most generic drug applications in the European Union.

The U.S. and EU pathways for generic drug approval are not identical in all respects, however. One key difference is the term of “data exclusivity,” a specified time period during which generic applicants may not rely on the originator’s clinical data demonstrating safety and efficacy in their applications for marketing authorization. The economic logic of data exclusivity is the following. With no protection, the knowledge generated by conducting clinical trials is a public good. While the streamlined regulatory pathways for generic approval reduce potentially wasteful and duplicative spending to establish what is already known, innovators incur large costs to provide the initial evidence of a drug’s quality. Data exclusivity provides them a period during which to recoup those costs. Even in the absence of a patent, therefore, regulatory barriers to generic entry are an explicit policy choice.

Prior to 2005, the data exclusivity term was six years in Austria, Denmark, Finland, Greece, Ireland, Portugal, and Spain (and in the European Economic Community countries Norway and Iceland) and ten years elsewhere. For products first approved after 2005 in the European Union, originators enjoy eight years of data exclusivity, during which no generic application is accepted; two years of additional market exclusivity, during which generic applications are not approved, but may be reviewed in preparation for launch; and, if the originator has provided evidence of clinical benefits from a new use of the product, one additional year, for a maximum of 11 years. Thus, the eligibility of generic entry varied across Member States until 2015, when the tenth year of data exclusivity expires simultaneously across all Member States for all products launched ten years prior. In contrast, the United States grants only five years of data exclusivity.

A. PATENT STRATEGIES

Patents provide an additional barrier to generic entry. Typically, the innovator of a new drug candidate applies for a product patent prior to the start of clinical development, and years before the drug might reach the market. The product patent (sometimes called the primary patent) covers the molecule itself. Often, ten or more years have elapsed between the filing of a product patent application and the launch of the product, leaving only half of the pat-

³ Directive 2001/83/EC of the European Parliament and of the Council of 6 Nov. 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311) 67 (consolidated version, Nov. 16, 2012) [hereinafter Directive 2001/83/EC].

ent term during which to recover research and development (R&D) costs.⁴ This development cycle affects both the level and type of R&D investment,⁵ and pharmaceutical firms may apply for an extension to this term under policies designed to protect innovation incentives. Under the Hatch-Waxman Act in the United States, a patent holder may request an extension of up to five years if the time between regulatory approval and patent expiration does not exceed 14 years.⁶ Similarly, a patent holder qualifies for a “supplementary protection certificate” (SPC) equal to the number of years elapsed between the initial patent application and first marketing authorization in the European Union, up to a maximum of five years beyond the initial expiration date. However, although the validity dates from the first EU marketing approval, it is the national Member State authority that grants the SPC to a national patent. In addition, pricing and reimbursement negotiations in many Member States may delay product launch for several months after marketing authorization.

The United States and European Union differ on “patent linkage,” or tying regulatory approval of a generic drug to the patent status of the originator product. In the United States, the originator must specify the relevant patents requiring a generic firm’s certification, which are published in the FDA’s “Orange Book.”⁷ In accepting an Orange Book certification, the FDA plays no role in determining their validity or relevance, but does consider patent status when reviewing generic applications.

There are four pathways to generic approval under the Hatch-Waxman Act. Under Paragraphs I–III, the applicant states that the patent information has not been filed with the FDA, has expired, or will expire before the generic launches. Under Paragraph IV, the generic applicant asserts that the Orange Book patent is invalid or not infringed. In response to a Paragraph IV challenge, a patent holder usually immediately sues for infringement and receives a 30-month stay during which the FDA will not approve the generic.⁸

As in the United States, the EMA and national regulators do not assess the validity of patents when evaluating applications from generic firms. A key

⁴ The patent term is 20 years from the date of application in the United States and all Member States of the European Union.

⁵ Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2050 (2015).

⁶ The extension is calculated as one-half the time elapsed between the start of human clinical trials, when the Investigational New Drug (IND) application is filed, and approval by the FDA, plus the time required to review the NDA, up to a maximum of five years.

⁷ Hatch-Waxman Act, 21 U.S.C. § 355.

⁸ Changes to U.S. law in 2003 limit patent holders to a single 30-month stay, even if they subsequently notify the FDA of additional patents requiring certification, and introduced limits to the types of patents the NDA holder (the brand-name drug manufacturer) may list with the FDA.

difference, though, is that European regulations preclude patent linkage.⁹ In other words, regulators may review generic applications even if the originator product has some remaining patents, although they must respect the data exclusivity rules described earlier. Because there is no patent linkage, patent information in Europe is less transparent: there is no Orange Book that lists important patents.

Transparency yields some benefits, because the primary patent on the molecule is rarely the only one associated with a drug. Typically, the innovator (or others) files additional patent applications after the initial product patent filing. These applications may cover methods of manufacturing the chemical or biological substance, purified forms, new salts or esters, new uses of the substance, new combinations, new delivery routes, etc. Particularly in the early stages of a drug's development, firms attempt to patent all variations of a promising candidate because it is uncertain which one may be most clinically effective. Later, firms may invest in process innovations as they learn from synthesizing and manufacturing a compound. They may patent new uses identified only after substantial clinical data exists.

The extent of additional protection available from secondary patents depends on country-specific patent laws and strategies. The European Patent Office (EPO) and U.S. Patent and Trademark Office (USPTO), as well as other patent offices around the world, may disagree on the appropriate standard of novelty and what innovations can be patented. In addition, the EPO does not grant a unitary EU patent. Rather, it provides a bundle of country patents, which are enforced at the national level. For example, invalidation in one country does not automatically result in invalidation in other Member States. Courts in different countries may reach different conclusions about infringement. If the threat of generic entry varies (for example, because larger markets are more attractive to generic firms), or if expected enforcement varies, originators may not seek identical protection in all markets. Even within the European Union, therefore, the the number and type of patents associated with a drug may vary across countries.

Patent extensions and SPCs exist precisely because policymakers determined that R&D incentives for new drug development would be too weak without them. These extensions apply, at least in theory, to the primary patent that protects the key innovation, a new molecule. Extending market exclusivity through the use of follow-on patents is not quite the same as doing so through an extension to the primary patent. These secondary patents may also

⁹ Directive 2001/83/EC, *supra* note 3, art. 10(1); Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 Mar. 2004 Laying Down Community Procedures for the Authorisation and Supervision of Medicinal Products for Human and Veterinary Use and Establishing a European Medicines Agency, 2004 O.J. (L 136) 1, 6 (art. 3(3)(b)).

extend the market exclusivity period which the originator enjoys before generic entry occurs. If this is beyond what is the socially optimal balance between incentives for innovation and consumer welfare, then competition authorities are right to worry.¹⁰

As discussed earlier, the product patent is the most difficult to invent around; a generic competitor that enters prior to the expiration of this patent is almost surely infringing. Secondary patents are usually “weaker” than a product patent, either in a legal or a technical sense. For example, a competitor may find ways to invent around a patent on a manufacturing process for a specific molecule. Establishing the existence of prior art may invalidate a secondary patent, particularly if it represents an attempt to patent the same idea twice. In general, follow-on patents form an imperfect barrier to generic entry, and most patent litigation involves disputes regarding secondary or follow-on patents rather than the primary patent.¹¹

Incentives for patent lawsuits are especially high in the United States due to a specific provision of the Hatch-Waxman Act. The first generic firm to challenge a patent successfully on the grounds that it is invalid or not infringed (a Paragraph IV challenge) receives 180 days of exclusivity, during which time the FDA approves no other generic. The Hatch-Waxman Act created the 180-day exclusivity “prize” explicitly for the purpose of rewarding challenges to weak pharmaceutical patents. Without such a prize, a patent challenge is costly for the generic firm that attempts it, and successfully invalidating a patent creates a public good for all other generic firms.

The European Union has no equivalent to the Hatch-Waxman Act incentive for generic firms to challenge brand-name patents. The fragmented EU patent system also complicates patent challenges.¹² Since patent enforcement takes place at the national level, a challenger may find itself fighting multiple infringement suits, should it launch in multiple countries. Although Directive 2004/48/EC attempts to harmonize protection and enforcement of IP across Member States,¹³ courts in different countries may reach different conclusions about the validity of a patent and whether it has been infringed.

¹⁰ These additional patents may have some associated social benefits. For example, extended-release formulations may improve patient compliance and reduce the symptoms and duration of disease. Whether patents directly incentivize and thereby induce pharmaceutical companies to invest in such incremental innovation is an open question, as are the clinical benefits of many other secondary patents.

¹¹ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327–29 (2012).

¹² The December 2012 passage by the European Parliament of a “unitary patent package” still requires ratification by all Member States.

¹³ Directive 2004/48/EC of the European Parliament and of the Council of 29 Apr. 2004 on the Enforcement of Intellectual Property Rights, 2004 O.J. (L 195) 16.

B. PATENT SETTLEMENTS

In recent years, antitrust authorities in both the United States and the European Union have scrutinized pharmaceutical patent settlements involving generic challengers because of particular concern over “reverse payments” or “pay-for-delay” terms. In most other sectors, patent settlements include a cross-licensing agreement or a transfer payment from the accused infringer to the patentee. This is typical of arrangements in semiconductors or telecom, particularly when the firms involved both own many patents. In contrast, cross-licensing between innovator and generic drug firms is unlikely, since generic firms hold much smaller patent portfolios and have little to license out to others. What is also unusual in the pharmaceutical sector is the occasional payment or transfer from the patent owner to the alleged infringer, i.e., from the innovator to the generic firm, rather than in the other direction; hence the term “reverse payment.”¹⁴ The transfer need not be cash. For example, competition authorities generally consider a commitment by the originator not to release an authorized generic (see discussion below) or the purchase of a generic firm’s inventory to be a value transfer. The settlements between an originator and generic often include an agreement on a date when the generic firm will (or at least can) enter. The entry date agreed to in the settlement is later than would be the case if the patent at issue were invalidated immediately, but earlier than would be the case if the patent were found valid.

Economic analysis of these settlements generally reveals that an outright ban on such arrangements is inappropriate, while emphasizing the potential for anticompetitive effects.¹⁵ In contrast to the “scope of the patent” approach of legal scholars, which presumes validity of a granted patent, economic models often assume that patents are “probabilistic” or represent a partial property right: a patent gives its owner the right to sue to exclude others from the market, but there is inherent uncertainty in that lawsuit. By avoiding litigation costs and resolving uncertainty, patent settlements may entail some social benefits. However, they also risk harming consumers. In his analysis of reverse payments specifically, Carl Shapiro notes that a reverse payment exceeding expected litigation costs is particularly suspicious, but acknowledges that reverse payments may be necessary to resolve litigation in the presence of risk aversion, asymmetric information, and other market conditions. He proposes that any settlement that does not reduce consumer welfare should be permitted. A difficulty in the application of this proposal, which the author

¹⁴ Patent settlements are generally confidential, and thus it is unclear whether reverse payments are used in other industries or contexts. Both the FTC and the European Commission compelled disclosure of originator-generic pharmaceutical patent settlements as part of their inquiries into the pharmaceutical sector and provide some statistics on their characteristics.

¹⁵ Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).

acknowledges,¹⁶ is the need to assess a patent's validity when assessing potential harm to consumers.

Recent scholarship proposes a rule based on the size of the reverse payment relative to expected litigation costs, and that does not require an estimate of the legal strength of the patent.¹⁷ In a model in which both the patent holder and a single challenger have complete information about each other's assessment of the patent's validity, Einer Elhauge and Alex Kruger determine that the innovator is willing to pay the challenger more than its expected litigation costs *only* when the settlement delays entry beyond the date at which the innovator expects to face competition. Therefore, the authors assert that any settlement in which the reverse payment exceeds an estimate of litigation costs is anticompetitive and should be treated as illegal per se. Relaxing the assumptions of complete information and a single generic entrant, Jorge Padilla and Valerie Meunier argue that the effects of a reverse payment settlement on consumer welfare are ambiguous even when the payment exceeds expected litigation costs, and can only be determined using an assessment of patent validity.¹⁸ If so, reverse payments must be evaluated on a case-by-case basis.

Licensing arrangements involving "authorized generics" have also raised some tricky questions for competition authorities. An authorized generic is one for which the original patent holder has granted a license to the IP. Entry by authorized generics occurs before all patents have expired (otherwise, no license is necessary), and therefore can have some procompetitive effects: entry occurs earlier than would be the case if all patents were valid. Even if a Paragraph IV challenger has successfully invalidated a patent, an authorized generic may still enter during the 180-day exclusivity period, increasing the number of competitors and potentially lowering prices.

The primary competition law concern is that the exclusivity period is less valuable to a potential generic entrant if an authorized generic is in the market as well. Rather than gaining 100 percent of the share shifted from the branded drug to generics (which has substantial value, due to mandatory generic substitution laws and efforts by payers to promote substitution to lower-cost drugs), the first Paragraph IV challenger would be forced to compete with a rival authorized generic. The 180-day exclusivity "prize" may have contributed to the large increase in generic entry in the United States, and reducing

¹⁶ *Id.* at 397 ("I would like to highlight one key practical problem with the approach advocated and analyzed here: typically, to compare consumer surplus under a settlement with consumer surplus from ongoing litigation requires an informed judgment as to the strength of the patent(s) at issue.").

¹⁷ Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012).

¹⁸ Jorge Padilla & Valerie Meunier, *Should Reverse Payment Patent Settlements Be Prohibited Per Se?* (May 8, 2015) (unpublished manuscript), ssrn.com/abstract=2604071.

the value of this prize risks lowering entry incentives. Indeed, an authorized generic may enter before any challenger to gain a first-mover advantage, which may deter entry; the FTC finds some evidence of such deterrence in small (low revenue) markets.¹⁹ In the European Union, which provides no exclusivity period as an incentive for generic firms to challenge patents, generic penetration has historically lagged behind that of the United States. The prevalence of generic competition varies substantially across Member States, and may be related more to approval and reimbursement policies than to patent settlements or authorized generics.²⁰ Authorized generics are nevertheless a concern because of the hypothesized first-mover advantage that accrues to an early generic entrant, to the detriment of competition from other generics that might have otherwise entered.²¹ More recently, the FTC has turned its attention to the originator's promise *not* to license an authorized generic. The FTC holds that a commitment by an originator to a generic not to license an authorized generic constitutes a reverse payment in a patent settlement.²²

C. SUMMARY OF EMPIRICAL EVIDENCE

In recent decades, competition from generic producers of off-patent pharmaceuticals has increased substantially. Much of this increase is a direct result of legal changes, such as the establishment of regulatory pathways for generic approval. Factors such as market size, regulations on pharmacies, and reimbursement policies explain much of the difference in the penetration of generics across countries. However, in the United States as well as in Europe, generic competitors have entered more off-patent drug markets, and the market share of prescriptions filled by generics has risen over time. As incentives for generic entry have increased, so have the incentives for originators to protect their inventions with follow-on patents and aggressive enforcement. DG Competition noted the possibility that patent thickets (multiple patents on a single drug) were delaying generic entry and harming consumers,²³ and an explicit goal of the Hatch-Waxman Act is to create incentives for challenges

¹⁹ Joseph Farrell, David Balan, Keith Brand & Brett Wendling, *Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets*, 39 REV. INDUS. ORG. 271 (2011).

²⁰ Patricia M. Danzon & Michael F. Furukawa, *Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs. Physician-driven Markets* (Nat'l Bureau of Econ. Research, Working Paper No. 17226, 2011).

²¹ *Final Report of the DG Competition of the European Commission on the Pharmaceutical Sector Inquiry* 297 (July 8, 2009) [hereinafter *DG Comp Pharma Report*].

²² FED. TRADE COMM'N, *AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT* iv (2011) [hereinafter *FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS*].

²³ *DG Comp Pharma Report*, *supra* note 21, at 201.

to secondary patents in order to speed generic entry.²⁴ With more patents to challenge and more generic firms willing to challenge them, we have observed a corresponding rise in settlement agreements between originator and generic firms. This section summarizes the empirical evidence on the magnitude of these trends, their causes, and their effects on competition.

1. *Patent Thickets and Generic Competition*

A key question for competition authorities is whether patent thickets delay generic entry beyond the socially efficient level. The welfare effects of follow-on patents are both theoretically and empirically unclear. By design, patents create barriers to entry. If follow-on patents lengthen the effective market exclusivity period for innovators, generic entry and the benefits of the price competition it brings are delayed, leading to a social cost in the short run. At the same time, the increased profits earned by the innovator may lead to increased R&D investment and innovation (a dynamic benefit that also increases consumer welfare). When establishing a 20-year patent term, policymakers determined that on average, the costs associated with reduced competition from that barrier were offset by the dynamic effects created by innovation incentives. Adjustments to patent terms and data exclusivity periods attempt a similar balance.

Scott Hemphill and Bhaven Sampat provide evidence from the U.S. market on the relationship between secondary patents and generic entry.²⁵ They show that there are two countervailing forces at play. Generic firms target drugs with large revenues, and often attempt entry using Paragraph IV challenges rather than waiting for the expiration of all Orange Book patents. At the same time, originators have greater incentive to protect drugs with high sales with secondary patents than those with lower sales. Both Paragraph IV challenges and the number of follow-on patents have increased over time. These Paragraph IV challenges offset the increased market exclusivity gained by additional patents, with a net change in market exclusivity of close to zero. Assuming that the socially optimal period of market exclusivity is constant over time, secondary patents do not appear to cause harmful delays in generic entry. The interaction between Paragraph IV challenges and secondary patenting is critical. Without such challenges, secondary patents might indeed cause delays. Without secondary patents, Paragraph IV challenges might reduce market exclusivity and innovation incentives. Of course, both the patenting activity and subsequent litigation incur costs that may be socially wasteful, and little empirical work exists to quantify such costs.

²⁴ FDA CTR. FOR DRUG EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 2 (1998).

²⁵ Hemphill & Sampat, *supra* note 11.

Since Paragraph IV challenges are unique to the United States, what is the relationship between secondary patents and generic entry elsewhere? Table 1 presents summary statistics on generic entry and patenting across several large pharmaceutical markets for different cohorts of drug launches and demonstrates that patenting has increased over time in all countries.²⁶ The United States also appears to have a higher rate of generic entry overall. Conditional on any generic launch, the median number of years between a drug's first global launch and its generic introduction has generally fallen over time. However, with the exception of the United Kingdom, the median duration of the originator's exclusivity within each market increased for the second cohort of drugs. Because originators are launching earlier (the median time between first global launch and entry into each country decreased over time in all countries), they have more time remaining for the initial (usually product) patent clock. Regulatory efforts to accelerate approval of important drugs may also contribute; for example, the FDA offers several pathways for speedier review.²⁷

What constitutes a harmful delay? The average market exclusivity period calculated in earlier studies is 12–13 years,²⁸ which is slightly longer than the 11 years of data exclusivity chosen by EU policymakers. The optimal period of market exclusivity—that which maximizes social welfare and which allows innovators to earn a fair return on their R&D investments—is difficult to determine. Increased R&D investment alone is not enough to justify delaying generic competition; rather, that increased investment must produce innovations yielding sufficient benefits.²⁹ Thus, there are at least two empirical challenges. The first is to estimate the change in R&D investment associated with a change in market exclusivity. The second is to estimate the benefits of the marginal innovation that results from that investment and to compare this with the static losses.

Many economic studies have examined the link between profits and investment in R&D and innovation in the pharmaceutical sector. The preponderance

²⁶ Truncation is an issue for the last cohort of drugs launched between 2000 and 2002: fewer than one-fifth of drugs launched over that time period had seen any generic entry as of 2013, and launch lags and exclusivity are calculated only for this selected sample, which is unlikely to be representative.

²⁷ These include Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. Details are available at *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, FDA (Sept. 14, 2015), www.fda.gov/forpatients/approvals/fast/ucm20041766.htm.

²⁸ Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 *MANAGERIAL & DECISION ECON.* 491 (2007); Henry G. Grabowski, Margaret Kyle, Richard Mortimer, Genia Long & Noam Kirson, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 *HEALTH AFF.* 2157 (2011).

²⁹ Richard Gilbert & Carl Shapiro, *Optimal Patent Length and Breadth*, 21 *RAND J. ECON.* 106 (1990).

of evidence shows that an increase in profits (which can result from many factors, including longer market exclusivity or stronger patents) leads to an increase in R&D investment and the number of new drugs developed. This finding holds for data on a very specific market (childhood vaccines in the United States),³⁰ a national market (the United States),³¹ and the global market.³² Most papers rely primarily on measures of market size or revenues as a proxy for profits, but these papers do not study market exclusivity specifically. Recent work, however, finds that private R&D investment in cancer treatments has shifted away from projects with long commercialization lags (and therefore shorter periods of patent protection post-launch) towards those with longer expected market exclusivity.³³

There are a number of approaches to estimating the benefits of pharmaceutical innovation resulting from R&D investment. Regulatory agencies involved in pricing and reimbursement decisions generally prefer to review clinical studies that assess the medical benefits directly, and some also request an estimate of cost-effectiveness from the originator firm. Economists allow for consumer preferences to depend on additional factors, such as ease of use or taste for a brand.

Most attempts to assess the benefits of pharmaceutical innovation using standard tools of empirical economics face an important challenge, however, which is that patients may not face the “true” price of a treatment due to insurance coverage. In subsidizing the cost of a given pharmaceutical to patients, insurance tends to distort consumption in a way that makes inferring an individual’s willingness-to-pay based on his or her consumption very difficult. In many settings, there is little price variation across substitute treatments because, for example, a patient pays a fixed price regardless of which treatment is prescribed. In addition, it is physicians who choose a drug treatment, and they may be unaware of, or insensitive to, the relative prices of treatment options. There are potential conflicts of interest between the insurer and patient (the insurer may prefer a less costly but less effective treatment, whereas the patient may prefer the most effective treatment regardless of cost) and between the physician and patient. These are rarely accounted for in studies that estimate the benefits of new treatments.

³⁰ Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527 (2004).

³¹ Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049 (2004).

³² Margaret K. Kyle & Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS*, 94 REV. ECON & STAT. 1157 (2012).

³³ Budish et al., *supra* note 5.

In contrast, the static consumer losses associated with delayed generic entry are relatively easy to establish. In pharmaceutical markets that see significant generic penetration and corresponding price reductions, postponing these cost savings leads to a substantial welfare loss.³⁴ If static consumer welfare is the only consideration, then any market exclusivity is problematic. However, not all markets see intense generic competition³⁵ and therefore would experience smaller losses from delayed entry.

2. *Pay-for-delay and Other Licensing Arrangements*

Both U.S. and EU competition authorities have conducted extensive inquiries into patent settlements, with a particular focus on reverse payments or pay-for-delay, and continue to monitor these agreements. The FTC reports that more than 100 patent settlements were filed with the agency each year from 2010 through 2012.³⁶ About one-third of those settlements involved potential pay-for-delay, meaning that the generic firm received some compensation and agreed to a limit on its marketing of the disputed product.

Slightly fewer settlements were reported in the European Union in 2010–2012.³⁷ About 30 percent of these settlements involved no delay. Only 11 percent involved a value transfer from the originator to the generic firm, which is a decline from 22 percent during the 2000–2008 period. The Commission interprets the steady increase in the total number of patent settlements as evidence that its scrutiny “has not hindered companies from concluding settlements in general.”³⁸ However, this conclusion should be based on a comparison of the number of settlements realized to the total number of *potential* settlements, as opposed to the number of actual patent settlements, in order to determine how many settlements have *not* occurred during the period of increased antitrust scrutiny. Unfortunately, the number of patent lawsuits in each jurisdiction (and therefore how many potential settlements litigants have forgone) is not provided in the monitoring reports. Such information would aid in assessing the impact, if any, of increased antitrust scrutiny on patent settlements and reverse payments.

³⁴ Lee G. Branstetter, Chirantan Chatterjee & Matthew Higgins, *Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry* (Nat'l Bureau of Econ. Research, Working Paper No. 17188, 2011), www.nber.org/papers/w17188; Farasat A.S. Bokhari, *What Is the Price of Pay-to-Delay Deals?*, 9 J. COMPETITION L. & ECON. 739 (2013).

³⁵ Danzon & Furukawa, *supra* note 20.

³⁶ FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FISCAL YEAR 2012 (2013).

³⁷ EUR. COMM'N, DG COMPETITION, THIRD REPORT ON THE MONITORING OF PATENT SETTLEMENTS (July 25, 2012).

³⁸ *Id.* at 15.

Existing studies generally attempt a straightforward calculation of costs and benefits associated with reverse payments by using information on the pre-entry originator price, the price reduction observed post-generic entry and generic share. There are two key shortcomings of this approach. First, the assumed counterfactual is critical. If one assumes that the patent at issue is valid, any settlement that results in generic entry prior to patent expiration will result in a calculation of significant savings.³⁹ A study on pay-for-delay conducted by the FTC determined that settlements involving reverse payments resulted in an average 17-month delay of generic entry, and calculated the forgone savings during that period.⁴⁰ The study design implicitly assumes that there is no difference in the validity of patents involved in settlements with and without reverse payments, an assumption that is unlikely to hold. Of course, assessing the validity—or probability of the originator prevailing in court—of the individual patents at issue is extraordinarily difficult. These studies also focus only on static or short-run effects, and do not consider any longer run change in the behavior of either originator or generic firms in response to a shift in the treatment of reverse payment settlements. For example, would banning reverse payments make settlements less likely overall, raising the expected costs of litigation and in turn reducing the incentive for generic firms to challenge patents? Would allowing them in all circumstances change the incentives of originators or generics to apply for secondary patents? And in the longer run, would the change in originator revenue from either policy decision significantly affect R&D investment and output?

Limited empirical evidence exists on the competitive effects of other licensing arrangements, such as authorized generics. The FTC concluded in its 2011 report on authorized generics that the use of authorized generics did not appear to reduce the number of patent challenges by generic firms in the U.S. market.⁴¹ As noted above, though, the FTC's main concern is the role of authorized generics in reverse payment settlements, which is not addressed in this report. A study of the German market also finds no significant reduction in the probability of generic entry in the presence of an authorized generic.⁴² While the German market is relatively large, potential generic entrants do not enjoy the 180-day exclusivity period granted under U.S. law.

³⁹ IMS Inst. for Healthcare Informatics, *Impact of Patent Settlements on Drug Costs: Estimation of Savings*, IMSHEALTH (June 2013), www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/Impact_of_Patent_Settlements_on%20Drug_Costs.pdf.

⁴⁰ FED TRADE COMM'N, *PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS* (2010).

⁴¹ FED TRADE COMM'N, *AUTHORIZED GENERIC DRUGS*, *supra* note 22.

⁴² Silvia Appelt, *Authorized Generic Entry Prior to Patent Expiry: Reassessing Incentives for Independent Generic Entry*, 97 *REV. ECON. & STAT.* 654 (2015).

One interpretation of these findings is that incentives for patent challenges, and generic entry more generally, are particularly high in large markets. Even if competition from an authorized generic reduces the payoff from a patent challenge or first generic launch, the challenging firm's expected profits remain well above the level required to justify the attempt. Overall, in markets where substantial generic entry usually occurs, a reduction in the number of generic entrants would be unlikely to change prices very much, since the ratio of generic to brand prices is generally stable after more than four or five entrants have launched.⁴³ The effects in smaller (lower revenue) markets may be more important.

D. DISCUSSION

Do patenting strategies and settlements in the pharmaceutical sector merit exceptional treatment by competition authorities and courts? It is not obvious that patent thickets and settlements are markedly more anticompetitive in the pharmaceutical sector than in other sectors. Uncertain patent rights and frequent litigation are problems that continue to plague the semiconductor, information technology, and telecommunications industries. Improving patent law is a more obvious solution than using the tools of competition policy to target a specific industry.

If patent thickets in pharmaceuticals pose unique problems that require a sector-specific fix, efficient policy instruments are available. Patent extensions (and SPCs) to product patents and data exclusivity have several advantages over follow-on patents. Because they enable fine-tuning through varying the length of additional protection and the types of incremental innovation rewarded, such extensions to market exclusivity permit a finer balance between dynamic and static effects than secondary patents that carry a minimum 20-year term. These extensions also reduce uncertainty, a clear problem in using probabalistic secondary patents. If generic firms no longer need to invent around follow-on patents, they may be able to produce an even closer substitute to the original product, yielding clinical benefits.⁴⁴ However, the challenge of determining the optimal length of market exclusivity remains.

The use of clear exclusivity terms would potentially reduce many of the problems associated with patent thickets, patent litigation, and reverse payments. However, the utility of this policy instrument also depends on the

⁴³ David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 *REV. ECON. & STAT.* 37 (2005).

⁴⁴ For example, the FDA revoked the bioequivalence designation provided to two generic copies of Concerta, a drug for attention deficit hyperactivity disorder in November 2014. Concerta is an extended-release drug that is harder for generic firms to copy. Only its authorized generic is still labeled bioequivalent by the FDA.

evolution of patent law. Innovators will almost certainly continue to apply for follow-on patents so long as that option is available, and subsequent patent litigation is therefore also likely. Adjustments to patent law to make the requirements to obtain follow-on patents more rigorous, such as a change to the definition of an inventive step, could also have potentially unwanted effects in other sectors.

As a matter of innovation policy, in particular in establishing the standards of patentability, it is therefore critical to assess whether the dynamic benefits of incremental innovation linked to follow-on patents are significant. In addition, regulatory extensions to exclusivity may be exploited in ways that have unexpected effects. For example, the combination of additional R&D subsidies and extensions to market exclusivity was associated with an increase in the number of drugs developed for orphan diseases, but about 10 percent of this response was a result of how firms defined the diseases for which they sought approval.⁴⁵ Specifically, firms developed drugs for subdivisions of more prevalent diseases, allowing them to qualify for the tax benefits and additional exclusivity provided by the Act.⁴⁶ Exclusivity extensions may not be an optimal solution, but nevertheless are probably better than a thicket of “weak” patents.

Under current patent law, litigation over uncertain secondary patents will continue, as will patent settlements to avoid it. These settlements are potentially anticompetitive, and deserve some scrutiny. Indeed, the industry brought increased scrutiny on itself through a number of settlements in which there was little question of anticompetitive effects. For example, in one of the first settlements concerning reverse payments challenged by the FTC, the two firms agreed on a monthly payment in exchange for delaying launch until a district court judgment concerning their patent litigation.⁴⁷ The settlement clearly did not save litigation costs. Examples like this, as well as the difficulty of assessing the anticompetitive effects of a specific settlement, explain the appeal of treating such arrangements as per se unlawful. Assessing a patent’s validity and estimating the value of noncash value transfers pose considerable challenges to antitrust authorities. However, the theoretical basis for tests based only on the size of the settlement depends on several important assumptions for which there is little empirical evidence, either for or against.

⁴⁵ Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060 (2008).

⁴⁶ Wesley Yin, *R&D Policy, Agency Costs and Innovation in Personalized Medicine*, 28 J. HEALTH ECON. 950 (2009).

⁴⁷ *FTC v. Abbott Labs.*, 853 F. Supp. 526 (D.D.C. 1994).

In its 2013 decision in *FTC v. Actavis, Inc.*,⁴⁸ the U.S. Supreme Court held that reverse payments are not presumptively (or per se) illegal, but that enforcers and private parties may challenge them under the rule of reason. Prior to *Actavis*, a number of lower courts in the United States held that, in evaluating reverse payments in the context of pharmaceutical patent settlements, the relevant patent is presumed to be valid, and any agreement that falls within the “scope of the patent” would raise no antitrust concerns.⁴⁹ The presumption of validity has been hard to sustain in recent years, and once relaxed, such settlements are much harder to assess. The Court in *Actavis* reversed the Eleventh Circuit’s ruling that any settlement with an entry date during the term of the patent was immune from antitrust scrutiny. The Court noted that a large reverse payment might signal a weak patent. However, it rejected the argument that this signal would draw additional challenges from other firms, and that the originator would not find it profitable to buy all of them off. The Court’s skepticism is based on the peculiarities of the Hatch-Waxman exclusivity rules, which create much lower payoffs for subsequent generic challengers that do not benefit from the 180-day exclusivity period.

However, the Court disagreed with the FTC’s argument that reverse payments are per se illegal. They might be, under some circumstances, but the Court determined that other factors affect the risk of anticompetitive harm. As Justice Breyer wrote, “These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.”⁵⁰ In other words, pharmaceutical settlements should be evaluated like those in other industries, without exceptional treatment.

Since *Actavis*, the FTC has had some success in fighting pay-for-delay deals. A federal court agreed that AstraZeneca’s commitment to withhold an authorized generic version of Nexium from the market constituted a large and unjustified value transfer to Ranbaxy.⁵¹ The FTC also settled a pay-for-delay case with Teva in May 2015.⁵²

⁴⁸ *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013).

⁴⁹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 (11th Cir. 2003).

⁵⁰ *Actavis*, 133 S. Ct. at 2237.

⁵¹ *In re Nexium Antitrust Litig.*, 777 F.3d 9 (1st Cir. 2015). Despite finding that the agreement was anticompetitive, the court awarded no damages. Ranbaxy was unable to launch a generic before the date agreed to in the settlement due to manufacturing problems, which led to the FDA banning all Ranbaxy products from the United States for some time.

⁵² Press Release, Fed. Trade Comm’n, *FTC Settlement of Cephalon Pay for Delay Case Ensures \$1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go to Purchasers Affected by Anticompetitive Tactics* (May 28, 2015), www.ftc.gov/news-events/press-releases/2015/05/ftc-settlement-cephalon-pay-delay-case-ensures-12-billion-ill.

In the European Union, competition authorities have taken positions similar to the FTC's. While press releases note that most patent settlements usefully avoid expensive litigation, the language in the Commission's annual monitoring reports suggests a "restriction by object" approach to settlements that include reverse payments. The 2013 *Lundbeck* decision clarified that the Commission considers reverse payments anticompetitive by object.⁵³ The *Lundbeck* decision is the subject of ongoing appeals, and the European Court of Justice (ECJ) has yet to validate the Commission's position on reverse payments. Interestingly, EU policy does not provide the asymmetric benefits to the first generic challenger that Hatch-Waxman does, so the claim that large reverse payments induce additional challenges may have greater validity. The *Lundbeck* case included payments by an originator to four generic firms.

Little empirical work examining the consequences of these recent decisions yet exists, and the confidentiality of patent settlements (at least outside the agencies, which have compelled firms to provide them) limits analysis. It is too early to say whether the divergence in legal treatment between the United States and Europe has changed the nature of the settlements in the two jurisdictions, for example, with a resulting difference in time-to-generic-entry.

II. PARALLEL TRADE

Articles 34–36 of the Treaty on the Functioning of the European Union (TFEU) (formerly Articles 28–30 of the European Community (EC) Treaty) prohibit most actions preventing the free movement of goods between Member States. Over the last several decades, the ECJ has established a policy of "community exhaustion" of patent rights and other forms of IP, such as trademarks and copyrights. Despite the fact that no unitary EU patent (yet) exists, the ECJ stated in 1996 that IP rights "are not intended to allow their owners to partition national markets and thus promote the retention of price differences which may exist between Member States." Effectively, once a firm places a product on the market in any EU Member State, the firm cannot prevent the resale of that product by a third party within the European Union by appealing to IP. Exhaustion allows parallel trade, or resale of goods between countries without the authorization of the IP owner; such trade is considered essential to the free movement of goods within the European Union.

Parallel trade arises when prices differ between countries, i.e., when there is an arbitrage opportunity. It therefore undermines the ability of firms to use differential pricing, or to price discriminate, across countries. In general, a firm earns profits at least as high by using differential pricing compared to setting a uniform price across countries. For this reason, firms with IP—in

⁵³ Case AT.39226—*Lundbeck*, Comm'n Decision, 2013 O.J. (C 80) 13.

sectors such as software, book publishing, and many others—usually oppose parallel trade. The issue is especially contentious in pharmaceuticals, primarily because price differences across countries are at least partially determined by national price controls rather than the outcome of a firm's profit maximization strategy. IP owners in some cases have strong incentives to minimize parallel trade. Competition policy is relevant in this context because some of the potential responses to parallel trade by owners of IP are considered anticompetitive.

A. BACKGROUND

Differences in income, preferences, and other market characteristics often produce wide disparities in price across the European Union. However, the pricing of pharmaceuticals is regulated at the national level throughout the European Union. The regulated prices may also reflect differences in income or preferences, as well as the size or bargaining power of national payers and budget constraints. The existence of price differences that are locked-in by price regulations creates arbitrage opportunities for parallel traders, who purchase pharmaceutical supply in countries with low prices for resale in countries with high prices.

Parallel trade in pharmaceutical products is subject to considerable regulation, and is therefore not truly free trade. However, the regulatory burden on firms engaged in parallel trade is much lower than that for producers of originator products (which must establish safety and efficacy) or producers of generic products (which must establish bioequivalence to the originator product). Usually, a firm wishing to engage in parallel trade needs to demonstrate only that the product in the country of origin has the same chemical composition, dosage form, and strength as the original product in the country of import. The brand name and packaging may differ, and in this case the parallel trader must relabel or repackage the product to reduce consumer confusion; similarly, translation of package inserts containing important patient information may also be necessary.

The regulatory pathway for approval of a parallel import depends on that used for the approval of the originator product. Original products approved by the EMA are, by definition, equivalent in all the EU countries in which they are sold. For such products, a parallel trader may apply for a single marketing authorization from the EMA, designating both the countries of export (source countries) and the countries of import (destination countries). Original products approved under the decentralized or mutual recognition procedures may vary slightly in chemical composition or dosing across countries. Parallel traders must apply for a license for import in each destination country and provide information about the equivalent product in the source country.

After obtaining a license, a parallel trader must locate distributors or wholesalers in the source country and buyers in the destination country. The ease of the former depends on several factors, such as the extent to which the originator firm is vertically integrated into distribution and the availability of supply. Finding willing buyers can be difficult as well. Patients in the European Union are usually price-insensitive because they pay relatively low co-payments for prescription drugs and the bulk of the cost of drugs is typically reimbursed by health insurance. Therefore, EU patients may be reluctant to purchase parallel import of a product from another EU Member State, especially if their co-payment is the same as for the original version. Since the profit margins of pharmacists are regulated in many EU countries, they too may have little incentive to stock parallel imports absent other policy changes.

Historical differences in the IP protection granted by EU Member States has led to situations in which some products had patent protection in only a subset of the countries in which they were marketed. In countries where no patent protection (or weaker protection) was available, marketing the product would not exhaust its IP. Accordingly, parallel exports from some countries were limited for some time, known as the derogation period. For Spain and Portugal, which entered the European Union in 1995, the derogation period ended in 1998. Since product patents for pharmaceuticals were introduced relatively recently in some Central and Eastern European Member States,⁵⁴ the Accession Treaty of 2003 banned parallel exports of pharmaceuticals if the originator owned a patent or Supplementary Protection Certificate (SPC) in the destination country and if the product could not have been patented in the source country at the same time. For example, a drug patented in the United Kingdom in 1992 could not have received a product patent at the same time in Hungary, which did not introduce product patents until 1994. Therefore, the originator could prevent parallel trade in this product from Hungary to the United Kingdom for the duration of its patent or SPC. However, the Czech Republic introduced product patents in 1991, so if the originator had received a patent on this drug in the Czech Republic in 1992, or if the originator had not bothered to patent the drug in the Czech Republic, then parallel trade from the Czech Republic to the United Kingdom would be legal. No such derogation period existed for Cyprus and Malta, which became EU members in 2004, or for Bulgaria and Romania, which joined in 2007.

⁵⁴ Czech Republic (1991), Estonia (1994), Hungary (1994), Latvia (1993), Lithuania (1994), Poland (1993), Slovenia (1993), and Slovakia (1991).

B. ECONOMIC MODELS OF PARALLEL TRADE

Most theoretical papers on parallel trade study the welfare impact of a move from differential pricing across countries to uniform pricing.⁵⁵ This move can have either positive or negative effects on total welfare in the simplest case of two markets, without consideration of any dynamic effects on incentives for innovation. The uniform price, assuming that firms may freely choose it or that it results from parallel traders' arbitrage, will be between the two prices that prevail under differential pricing. While firm profits stay the same or decrease, the effect on consumers may vary. Those consumers in the market with higher demand elasticity (and the lower price under differential pricing) will be worse off, while consumers in the other market benefit from the uniform price. Depending on the size of the two markets and their demand curves, total supply may increase or decrease; total welfare is higher only if supply rises.

Under some circumstances, firms are better off serving only the higher price market. Such an outcome clearly reduces total welfare by restricting the availability of pharmaceuticals, and large differences in demand across countries may yield this result.⁵⁶ The disparities in population size and income levels among EU Member States suggest that indeed firms would use differential pricing across markets in the absence of price controls and without parallel trade. Most economists agree that international price discrimination in pharmaceuticals yields higher total welfare than uniform pricing. While firm profits are higher, the number of consumers—particularly the most price-sensitive, who are often the poorest—with access to the product is also higher. For example, as one prominent health economist writes:

[A] single price set so as to cover at least all of the firm's fixed costs would price out of the market many highly price-sensitive customers who would be willing and able to cover at least the purely incremental production costs (and perhaps more) of additional output, but who are unwilling or unable to pay the higher single price with full-cost recovery. Clearly, serving such price-sensitive customers would yield added social benefits.⁵⁷

Static models usually ignore how a loss of profits caused by uniform pricing might change investment in R&D.⁵⁸ Several recent papers address this ques-

⁵⁵ These papers build on Hal R. Varian, *Price Discrimination and Social Welfare*, 75 AM. ECON. REV. 870 (1985).

⁵⁶ David Malueg & Marius Schwartz, *Parallel Imports, Demand Dispersion, and International Price Discrimination*, 37 J. INT'L ECON. 167 (1994).

⁵⁷ Uwe E. Reinhardt, *Perspectives on the Pharmaceutical Industry*, 20 HEALTH AFF. 136 (2001).

⁵⁸ Malueg & Schwartz, *supra* note 56.

tion.⁵⁹ The impact of parallel trade on long run welfare may be negative if R&D investment or the quality and quantity of innovation fall when profits decrease. That is a big “if.” Views on the relationship between higher profits and R&D explain some of the differences in positions taken by advocates general in the European Union. AG Jacobs emphasized the importance of maintaining a firm’s R&D competitiveness (i.e., its ability to generate innovation in the future) as a valid defense for limiting parallel trade.⁶⁰ Ruiz-Jarabo Colomer rejected this justification,⁶¹ and expressed skepticism about a causal link between parallel trade and reduced R&D investment.⁶²

Also critical to economic models of parallel trade is the treatment of price regulation. Regulators are usually assumed to be fully rational, so that they account for the effect of their price decisions on R&D investment in the future. Because R&D investment is a public good, regulators may be tempted to free ride on the incentives created by high prices in other markets. Parallel trade may reduce this free riding if the regulator realizes that setting a low price in his country will result in the same price in the other country, due to arbitrage by parallel traders. In addition, the firm’s threat of withholding the product from one country is more credible. Consequently, it is possible for parallel trade to cause regulators to increase price in relatively low-price countries, which increases profits and may cause R&D investment and total welfare to rise.⁶³ However, it is worth noting that originator pharmaceutical firms strenuously oppose parallel trade, suggesting that they do not see an increase in profits stemming from parallel imports. Rather, they argue that price controls reduce their ability to adjust price in response to parallel trade, reducing profits and R&D investment.

The use of external (international) reference pricing, whereby the price in one country is set at the minimum or average level of prices in a basket of foreign markets, produces many of the same theoretical outcomes as free movement of pharmaceuticals through parallel trade. Parallel trade, as price arbitrage, tends to equalize prices across markets. Similarly, external reference pricing has the effect of creating more uniformity of cross-country

⁵⁹ E.g., Anna Rita Bennato & Tommaso Valletti, *Pharmaceutical Innovation and Parallel Trade*, 33 INT’L J. INDUS. ORG. 83 (2014); Stefan Szymanski & Tommaso Valletti, *Parallel Trade, Price Discrimination, Investment and Price Caps*, 20 ECON. POL’Y 705 (2005); Tommaso M. Valletti & Stefan Szymanski, *Parallel Trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis*, 54 J. INDUS. ECON. 499 (2006).

⁶⁰ Case C-53/03, *Syfait v. GlaxoSmithKline plc*, 2005 E.C.R. I-4609 (Opinion of Advocate General Jacobs, 2004, ¶ 89).

⁶¹ Joined Cases C-468/06 to C-478/06, *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEEV*, 2008 E.C.R. I-7139 (Opinion of Advocate General Ruiz-Jarabo Colomer, 2008, ¶ 121).

⁶² *Id.* ¶ 109.

⁶³ Gene M. Grossman & Edwin L.-C. Lai, *Parallel Imports and Price Controls*, 39 RAND J. ECON. 378 (2008).

prices. Firms have an incentive to avoid markets where price controls are more binding (i.e., lower) if that market serves as a source of parallel exports or if that country's price is referenced by others.

As noted above, whether uniform pricing is a desirable outcome is theoretically unclear. The author's view is that differential pricing in pharmaceuticals is likely to increase access and social welfare for the reasons described above: there are large income differences across Member States, and the poorest are more likely to have access under differential pricing than under uniform pricing. However, should uniform pricing be a policy aim,⁶⁴ external reference pricing or price negotiation at the EU level are probably more efficient means of achieving that goal than relying on arbitrage by parallel traders, particularly if arbitrageurs do not pass through all cost savings to consumers or health systems.

There are a number of limitations to the theoretical models described above. All generally assume that when parallel trade is allowed, complete arbitrage occurs, so that a uniform price results. This is certainly not the case for EU parallel trade in pharmaceuticals (as will be discussed in the following section). Most models consider only two countries, one of which may have price controls. The European Union obviously encompasses multiple countries, each of which regulates price to some extent. Few theoretical papers explicitly consider attempts by firms to limit parallel trade, which are the activities that worry competition authorities because they may limit the free movement of goods across borders. For example, competition cases have concerned the rationing of supply to source countries, "dual pricing" (the use of a lower price for a product consumed domestically than that which is re-exported), and restrictive contracting terms. These are potentially costly means of restoring differential pricing. Their welfare effects hinge on whether welfare is higher under differential pricing, accounting for the costs associated with segmenting markets.

C. SUMMARY OF EMPIRICAL EVIDENCE

A complete empirical study of parallel trade should include data on both importing and exporting countries. Difficulties in obtaining reliable data on parallel trade patterns make this a challenge. Price information is generally not public, nor is data on the quantity of a specific product traded between two countries. Consequently, it is a challenge to present a complete and accurate overview of the importance of parallel trade in Europe. One crude measure of the extent of parallel trade, and its importance between pairs of countries, is the number of parallel import licenses granted.

⁶⁴ Perhaps in keeping with the goal of a common EU market.

The EMA grants licenses for parallel distribution of original products that received approval under the centralized procedure. Each license specifies the destination (importing) markets as well as the source (exporting) countries, and refers to a specific package presentation for a drug. In practice, licenses typically list one or two destinations but many potential sources. Table 2 below shows the number of EMA licenses granted each year from 2007–2013, as well as the frequency with which each of the five largest EU markets was listed as a destination.

Germany is by far the most common importing country, followed by the United Kingdom. France, Italy, and Spain are rarely destinations. The second panel of Table 2 provides the frequency with which five more recent Member States were listed as source countries. There is a substantial increase during this period for all five. Parallel trade in products approved at the national level, rather than through the centralized procedure, requires a license granted by each importing country. However, only some countries disclose the name of the exporting country for each license, and the information available from each country also changes over time. A complete database of import licenses with the countries of export is difficult to construct, because not all national agencies make the information public. Table 3 presents the frequency with which specific exporting countries were listed on licenses for parallel imports into five countries that provide reasonably complete information. Italy, Spain, Greece, Portugal, and France are often the main sources of parallel exports. In recent years, newer EU members, such as Poland, Romania, and the Czech Republic, have played a more important role in exporting. However, even countries that are important importers, such as the United Kingdom and Germany, sometimes serve as sources of exports. Taken together, these patterns show substantial variation in the importance of parallel trade across countries and over time, as well as in the role particular countries play.

Clearly, the consequences of parallel trade differ across countries. Most empirical work at the individual country level has examined countries that import, and which should see benefits. In a study of the 50 bestselling drugs in Sweden, the prices of original products fell in response to competition from parallel imports.⁶⁵ Similarly, research in Germany finds a reduction in the prices of original products with parallel trade leads to a small gain in consumer surplus.⁶⁶ The effect of parallel imports is tempered by the presence of

⁶⁵ Mattias Ganslandt & Keith E. Maskus, *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union*, 23 J. HEALTH ECON. 1035 (2004).

⁶⁶ Tomaso Duso, Annika Herr & Moritz Suppliet, *The Welfare Impact of Parallel Imports: A Structural Approach Applied to the German Market for Oral Anti-Diabetics*, 23 HEALTH ECON. 1036 (2014).

price and other regulations at that country level.⁶⁷ While the possibility of parallel trade improves the bargaining position of Norwegian pharmacies in determining the wholesale price, strict regulation of retail prices weakens competition from parallel imports: if the prices of original products are constrained to be low, parallel imports are less attractive. Empirical evidence suggests that lower price caps on products facing parallel imports are associated with higher sales for originators and lower sales for parallel importers.

As noted above, a study that examines only the importing side misses half the story. Exporting countries are more likely to see negative effects of parallel trade, in the form of reduced launch, product shortages, or higher prices. There is ample evidence that pharmaceutical firms adjust their marketing strategies in response to price regulation, particularly when different national markets are linked through external reference pricing or parallel trade. First, firms delay launch (or decline to launch) new products in countries where price controls are most stringent.⁶⁸ The cost structure of pharmaceuticals is characterized by high fixed costs of drug development and regulatory compliance, but relatively low marginal costs of production. Launch delays or limited product launches make economic sense only if either the country-specific launch costs are higher than expected revenues or if launch reduces revenues in other countries. Policies that encourage uniform pricing throughout the European Union, which include external reference pricing and parallel trade, are associated with reduced access to new products in a subset of countries. In recent years there have been many reports of product shortages in countries such as Greece, which is typically a source of parallel exports. The president of the Greek drug regulator was quoted as saying that “[c]ompanies are ceasing these supplies because Greece is not profitable for them and they are worried that their products will be exported by traders to other richer countries through parallel trade as Greece has the lowest medicine prices in Europe.”⁶⁹ Parallel trade thus harms the welfare of at least some consumers.

Some research concludes that prices in the European Union have changed very little as a result of parallel trade.⁷⁰ The prices of parallel imports and original products are usually very close, although this outcome could result

⁶⁷ Kurt R. Brekke, Tor Helge Holmås & Odd Rune Straume, *Price Regulation and Parallel Imports of Pharmaceuticals*, 129 J. PUBLIC ECON. 92 (2015).

⁶⁸ Margaret K. Kyle, *Pharmaceutical Price Controls and Entry Strategies*, 89 REV. ECON. & STAT. 88 (2007).

⁶⁹ Elizabeth Sukkar & Helena Smith, *Panic in Greek Pharmacies as Hundreds of Medicines Run Short*, THE GUARDIAN (Feb. 27, 2013), www.theguardian.com/world/2013/feb/27/greece-blames-drug-companies-shortages.

⁷⁰ Panos Kanavos, Joan Costa-i-Font, Sherry Merkur & Marin Gemmill, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* (London School of Econ. and Pol. Sci., Special Research Paper, 2004), www.fda.gov/ohrms/dockets/dockets/04n0115/04n-0115-ts00015-04-Kanavos5-01.pdf.

from intense competition between nearly identical products or from minimal competition from a supply-constrained seller of parallel imports. Importantly, this work suggests that arbitrageurs have appropriated most of the benefits of parallel imports, with government payers and consumers realizing little savings. Subsequent work examines the price dispersion of a subset of drugs in the European Union, and compares patterns to those observed in countries that are not linked through parallel trade.⁷¹ The EU trend towards uniform pricing (i.e., a reduction in price dispersion) was not especially marked. These patterns are consistent with more recent evidence of price divergence since 2007 for 10 on-patent drugs across 15 EU countries.⁷² Originators did not appear to change the prices of products already on the market. Since price controls limit their flexibility in doing so, this is not surprising. However, parallel imports were not associated with a significant reduction in prices either, for two reasons. First, despite large price differentials, parallel trade did not occur very often. Second, when parallel trade did occur, the average share of parallel imports was less than 10 percent. While there is considerable heterogeneity across products in the importance of parallel trade, and parallel trade may increase with the entry of new countries into the European Union, these findings nevertheless suggest that competition from parallel imports is unlikely to be the most effective means of reducing drug prices.

In contrast, data from EUROSTAT demonstrates that despite persistent price differences, there is a clear trend towards price convergence in other product categories across the EU-27 countries since 1995.⁷³ Though this study does not examine parallel trade or pharmaceuticals, the reported price variation is lowest in such categories as consumer electronics, personal transport equipment, and clothing. These categories, with relatively low transportation costs, are those with the greatest potential for parallel trade. A natural question is therefore why pharmaceuticals, which also have low transportation costs, display a distinctly different pattern.

Strategic behavior by pharmaceutical firms may limit the extent of parallel trade in pharmaceuticals.⁷⁴ One response by originators exploits the fragmented EU market. Many existing products were approved prior to the estab-

⁷¹ Margaret K. Kyle, Jennifer S. Allsbrook & Kevin A. Schulman, *Does Reimportation Reduce Price Differences for Prescription Drugs? Lessons from the European Union*, 43 HEALTH SERV. RES. 1308 (2008).

⁷² Christine Leopolda et al., *Is Europe Still Heading to a Common Price Level for On-Patent Medicines? An Exploratory Study Among 15 Western European Countries*, 112 HEALTH POL'Y 209 (2013).

⁷³ Barbara Kurkowiak, *Significant Differences in Consumer Prices Across Europe*, EUROS-TAT STATISTICS IN FOCUS 28/2011 (June 20, 2011), ec.europa.eu/eurostat/documents/3433488/5578988/KS-SF-11-028-EN.PDF/8f6cd227-4d91-4fff-bea7-0cb1c6f6a7ab.

⁷⁴ Margaret Kyle, *Strategic Responses to Parallel Trade*, 11 B.E. J. ECON. ANALYSIS & POL'Y, no. 2, Dec. 2011.

ishment of the EMA and the centralized procedure or elected to use the decentralized or mutual recognition regulatory pathways. This can lead to slight variations in product characteristics across countries. For example, a drug may be offered as a 10mg capsule in one country and a 5mg tablet in another. These variations limit the number of potential parallel import licenses, since the parallel trader has more difficulty showing that they are truly identical. Pharmaceutical firms also use different brand names and packaging across the European Union, which raises the cost to a parallel trader as well. Finally, patterns of supply interruption to countries that are typically sources of parallel exports, and specifically in products that are most likely to be exported, were consistent with attempts by pharmaceutical firms to limit the potential supply available to parallel traders.

Identifying the effect of parallel trade on R&D investment is particularly difficult. In the 20 years during which the parallel trade market has grown in the European Union, emerging markets, such as India, China, and Brazil, have introduced stronger IP rights and expanded health coverage. Net R&D investment during this time period reflects at least these two countervailing forces, and likely many others. The author is unaware of any published research that isolates the R&D response to parallel trade. Instead, studies that provide estimates of the effect of parallel trade on R&D rely on estimates of the elasticity of R&D produced in other papers.⁷⁵

D. DISCUSSION

Some efforts to limit parallel trade have been prosecuted as violations of Articles 101 and 102 TFEU (previously, Articles 81 and 82 of the EC Treaty). Practices that raise legal suspicion include the use of clauses banning re-export in contracts with wholesalers or distributors; restricting supply to markets that have relatively low prices; and dual-pricing.

While the legal arguments vary from case to case, there are three general claims from large pharmaceutical firms to justify restrictions on parallel trade. First, price differentials between EU countries result (at least in part) from price regulation. Since the pharmaceutical industry is atypical in this respect, EU competition law should exempt efforts to curb parallel trade by the pharmaceutical industry. Second, pharmaceutical firms assert that parallel trade yields few consumer benefits. Finally, they warn that because parallel trade reduces their profits, it harms innovation.

The author's view is that if EU competition policy seeks to maximize overall EU welfare (or total welfare), this does not necessarily imply imposing a truly common market in the case of the highly regulated pharmaceutical in-

⁷⁵ See, e.g., Finkelstein, *supra* note 30; Acemoglu & Linn, *supra* note 31.

dustry. Price discrimination is likely to be socially beneficial, even when only static welfare is considered. This has been recognized in the global public health community, in which many now advocate increased use of differential pricing of drugs in order to increase access to needed drugs in poorer countries.⁷⁶ The European Commission's Tiered Pricing Regulation⁷⁷ explicitly recognizes the benefits of differential pricing for access outside the European Union. Under Article 168(7), EU Member States retain the right to impose pharmaceutical price controls as part of managing their health systems, presumably because a "one-size-fits-Europe" price is not optimal. So long as large gaps in income and demand exist between EU Member States, differential pricing is likely to increase total access there as well.

Pharmaceutical firms have clear incentives to segment the European market, as their profits will generally be higher under differential pricing than under uniform pricing, and firms employ several ways to implement this segmentation. Many of these means do not violate competition law, but may nevertheless be socially costly. For example, the differentiation of products across EU countries is almost certainly inefficient, unless consumers have very heterogeneous preferences that this differentiation appeals to. Some measures that may violate EU competition law, such as selling an identical product throughout the European Union with rationed supply to low-price countries, is likely to be preferable to product differentiation from a welfare standpoint. On the other hand, if total welfare is higher under uniform pricing (under the conditions described above), then setting a single uniform price throughout the European Union would be a more efficient means of obtaining that outcome than relying on parallel traders to do so.

Parallel trade and uniform pricing do not, of course, have identical effects across countries. Countries with relatively high prices should generally benefit from uniform pricing, in contrast to those with lower prices. However, as discussed earlier, there is mixed evidence that parallel trade in pharmaceuticals yields consumer gains in high-price countries in the European Union. Of course, there may be unrealized consumer gains due to imperfect competition from parallel imports. Parallel traders face entry barriers, both regulatory and strategic. Few parallel importers enter most drug markets, which remain concentrated. Other policies that make consumers and pharmacists insensitive to price limit the potential benefits of competition from parallel imports as well. Thus, the market outcomes we currently observe are not inevitable. They sug-

⁷⁶ For example, differential pricing is identified as a strategy to increase the affordability of medicines by the World Health Organization, www.who.int/trade/glossary/story002/en/.

⁷⁷ Council Regulation (EC) No. 953/2003, 2003 O.J. (L 135) 5, eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R0953&from=EN.

gest limits, however, to relying on parallel trade to achieve uniform pricing and substantial consumer benefits in high-price countries.

Some countries in the European Union actively encourage the domestic use of parallel-imported products, mainly through the provision of incentives to pharmacists. Underlying these policies is the belief that parallel imports, by competing with the originator product available in a country, yield lower prices. Of course, lower prices on the originator product could also be obtained more directly through the use of price controls. It is rather curious that some countries seek low prices through competition from parallel imports, indicating a free-market orientation, when the imported products usually face price controls rather than free markets in their country of origin. Effectively, promoting parallel imports relies on price controls in other countries to lower the domestic price. If one assumes that a lower domestic price is optimal and market failures result in a higher free-market price, using direct price controls would be more efficient.

In the long run, parallel trade may also have consequences for R&D investment by pharmaceutical firms. These consequences are theoretically ambiguous and empirically difficult to demonstrate. While it is tempting to conclude that parallel trade has little impact on originator profits because relatively few products face competition from parallel imports, it is important to realize that this is a result of strategic adjustments by pharmaceutical firms to its threat. The relevant counterfactual is a world in which firms make pricing and supply decisions without regard to parallel importer behavior, and it is also necessary to account for the additional costs that originators incur in their efforts to reduce its impact. The R&D-intensive set of pharmaceutical firms strongly objects to parallel trade and argue that it harms profits and innovation.⁷⁸

While the link between profits and innovation has been established empirically, proving (or disproving) a direct link with parallel trade is far from straightforward for a number of reasons. Firms make R&D investment decisions based on expectations of global profits, which are affected by a large number of policies enacted outside the European Union as well as within it. Empirically distinguishing the change in innovative effort due to a reduction in profits caused by parallel trade from that caused by a change in price regulation, enforcement of IP in emerging markets, or health care reform in the United States is a daunting task. Therefore, while it is important that competition policy allow for the potentially negative consequences of parallel trade on

⁷⁸ Testimony Summary of John J. Castellani, President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), Before the House Energy & Commerce Subcommittee on Commerce, Manufacturing and Trade 3 (July 24, 2013), www.phrma.org/sites/default/files/pdf/HHRG-113-IF17-Wstate-CastellaniJ-20130724.pdf.

innovation, it is unlikely that firms can provide conclusive proof of such effects at the level of an individual product or organization.

The arguments presented here against parallel trade are hardly new, and have largely failed to persuade policymakers and antitrust authorities. One justification for their tolerance or support of parallel trade is the theory that regulators are economically rational actors that account for price controls outside their jurisdictions, and internalize the effect of their pricing decisions.⁷⁹ However, these are theoretical concepts and there is no empirical work testing these predictions. The industry's arguments related to R&D investment are difficult to prove, for reasons outlined above, and are also not specific to pharmaceuticals.

From the author's perspective, the strongest case against parallel trade is its possible negative effects on access, either through higher prices or launch delays, in the relatively poor Member States. There is empirical support for this claim within the European Union.⁸⁰ Pharmaceutical firms often receive criticism for insufficient use of differential pricing. For example, for the pricing of a novel Hepatitis C (HCV) drug, "advocates are urging Gilead Sciences, sofosbuvir's manufacturer, to sell the drug at a steep discount to cash-strapped countries, which are home to more than 100 million HCV-infected people."⁸¹ The Access to Medicines Foundation evaluates pharmaceutical firms on their use of "tiered pricing that aims to ensure affordability for the poorest population segment,"⁸² among other factors, in order to promote access to treatments in low-income countries.

III. CONCLUSION

How adequate is competition policy in addressing problems in pharmaceutical markets? In general, there is a tension between providing dynamic incentives for innovation through barriers to entry, such as patents, and promoting competitive markets. The pharmaceutical sector presents some difficulties in reconciling these goals that are distinct from those in other high-technology industries. In particular, the application of a pan-EU competition policy to drug markets is complicated by national-level regulations, and these regulations ensure that the assumptions of most economic models of competition almost never hold. This article focuses on two areas of the pharmaceutical industry in the European Union that have attracted the most attention by com-

⁷⁹ Grossman & Lai, *supra* note 63.

⁸⁰ Kyle, *supra* note 68.

⁸¹ Jon Cohen, *Advocates Protest the Cost of a Hepatitis C Cure*, 342 *SCIENCE* 1302, 1302–03 (2013).

⁸² ACCESS TO MEDICINE FOUNDATION, ACCESS TO MEDICINE INDEX 2014, at 83–100 (2014), www.accessstomedicineindex.org/sites/2015.atmindex.org/files/2014_accessstomedicineindex_fullreport_clickablepdf.pdf.

petition authorities: patent settlements and parallel trade. At present, EU competition policy treats the pharmaceutical industry as exceptional in the matter of patent settlements, but not in the matter of parallel trade.

We have little proof that patent settlements are significantly more anticompetitive in pharmaceuticals than in other sectors. The problems associated with patent thickets and generic entry, and patent settlements by extension, are not easily fixed by competition policy. These are problems of IP law as well as policies specific to the sector (and sometimes country) regulating the use of generic products. Indeed, patent settlements are considered an efficient means of resolving disputes over IP in other sectors. Addressing these issues by adjusting and harmonizing IP law and other regulations is therefore more appropriate.

Specifically, if the policy aim is to reduce barriers to entry faced by generics, a revision of the legal definition of patentability to exclude the types of secondary patents that form patent thickets is an obvious step. The establishment of a unitary EU patent would also reduce uncertainty over IP rights and lower the cost of challenging weak patents in court (which today needs to be done on a country-by-country basis). Some aspects of EU policy have moved in a positive direction over the past ten years. For example, changes to EU pharmaceutical regulation in 2004 included a research exemption for generic firms and harmonized data exclusivity periods across all Member States. However, country-level policies designed to encourage generic use are likely to be far more important in determining the extent of generic competition than any decision on patent settlements or authorized generics at the EU level.

In contrast to the exceptional treatment of patent settlements, competition policy in the European Union does not acknowledge the unique features of the pharmaceutical sector when evaluating practices to interfere with parallel trade. The use of national-level price controls on drugs is unique among high-technology sectors. Indeed, the justification for this exception is that uniform pricing of pharmaceuticals would make them unaffordable in poorer Member States. The consequences of uniform pricing for consumer welfare applies to other types of products: a uniform price charged by Apple for a song on iTunes in all Eurozone countries is almost certainly “too high” in Slovakia or Estonia, with less than half the gross domestic product per capita of France or Germany. The difference in the case of pharmaceuticals is that Apple is free to adjust prices,⁸³ while pharmaceutical firms are not.

⁸³ Note that Apple and other sellers of digital goods restrict resale of their products in order to segment markets, including within the European Union; non-Eurozone EU members face different prices because arbitrage is difficult.

It makes no sense to advocate a common market while permitting national-level price controls, which is itself an acknowledgement that there is substantial heterogeneity in the demand and ability to pay across EU countries. Requiring pharmaceutical firms to fulfill all orders from wholesalers or removing other barriers to parallel trade would force a uniform price on the EU market, and this uniform price would be the maximum that any individual country could tolerate to assure supply. Small, lower-income countries—i.e., most recent entrants to the European Union—tend to be harmed by policies that lead to uniform pricing. If higher-income countries want lower prices, they have many other (and more effective) policy levers to pull. A competition policy that promotes a common market in this context is hardly the best approach.

TABLE 1: SUMMARY STATISTICS OF PATENTING AND ENTRY

	FRANCE			GERMANY			UNITED KINGDOM			UNITED STATES		
	1990– 1994	1995– 1999	2000– 2002	1990– 1994	1995– 1999	2000– 2002	1990– 1994	1995– 1999	2000– 2002	1990– 1994	1995– 1999	2000– 2002
First global launch	2.00	3.00	3.00	2.50	3.00	3.00	2.00	3.00	3.00	2.00	5.00	5.00
Patents in country (median)	8.00	11.00	12.00	9.00	11.00	12.00	7.00	10.00	12.00	12.00	18.00	18.00
Patents in country (90th percentile)	0.58	0.68	0.67	0.60	0.72	0.71	0.53	0.71	0.67	0.54	0.75	0.70
Fraction launched	2.76	1.50	1.62	2.38	1.00	0.75	1.75	1.00	1.00	1.63	0.25	0.37
Originator launch lag (median), in years	0.45	0.41	0.14	0.46	0.47	0.13	0.52	0.43	0.13	0.59	0.48	0.21
Fraction with generic entry	15.76	14.76	11.01	13.88	14.14	10.76	14.76	14.64	8.25	14.01	13.76	8.76
Generic launch lag (median), in years	11.01	13.01	9.63	10.50	12.51	9.75	13.88	13.63	8.25	11.51	13.01	8.51
Originator exclusivity (median), in years												

Source: Author's calculations using IMS MIDAS and IMS Lifecycle databases.

TABLE 2: EMA LICENSES FOR PARALLEL DISTRIBUTION

Year	Licenses #	Frequency listed as destination						Frequency listed as source					
		DE	FR	UK	IT	ES	BG	RO	CZ	SI	PO		
2007	1937	669	1	786	0	0	10	11	154	109	114		
2008	1588	857	8	279	0	9	28	30	109	85	92		
2009	1821	1045	7	222	1	17	289	388	376	269	333		
2010	2285	1230	7	349	4	22	411	545	551	384	461		
2011	2226	869	8	348	2	13	599	742	761	633	707		
2012	2069	870	43	295	9	9	699	783	810	691	770		
2013	2342	1065	29	279	13	10	855	965	1002	759	956		

Source: Author's calculations using data on EMA licenses, www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000120.jsp

TABLE 3: NATIONAL LICENSES FOR PARALLEL IMPORT, TOP FIVE SOURCES BY COUNTRY

Destination	2005	2006	2007	2008	2009	2010	2011	2012	2013
Denmark	ES (24)	IT (18)	UK (18)	UK (33)	UK (88)	UK (80)	UK (79)	UK (41)	
	UK (22)	ES (17)	IT (16)	FR (17)	GR (39)	PL (76)	GR (64)	NL (39)	
	GR (14)	FR (16)	PT (11)	PT (16)	PL (33)	GR (70)	ES (49)	ES (20)	
	FR (13)	UK (14)	ES (9)	GR (15)	PT (33)	ES (42)	PL (40)	GR (20)	
	PT (13)	GR (13)	FR (9)	ES/PL (13)	FR (32)	CZ (39)	IT (34)	PL/RO (17)	
Ireland	UK (24)	UK (69)	UK (46)	UK (78)	UK (322)	UK (252)	UK (176)	UK (68)	UK (43)
	GR (17)	IT (30)	ES (18)	IT (34)	IT (79)	IT (79)	IT (53)	PL (29)	IT (29)
	ES (11)	ES (27)	GR (18)	GR (17)	ES (34)	ES (27)	FR (24)	IT (24)	GR (9)
	IT (11)	GR (21)	IT (14)	DE (16)	PL (24)	PL (26)	HU (23)	FR (10)	ES (8)
	NL (9)	FR (16)	NL (10)	PL (16)	GR (17)	FR (14)	ES (19)	ES (9)	PL (8)
Netherlands	UK (19)	IT (17)	IT (15)	IT (27)	UK (61)	GR (58)	GR (42)	IT (38)	FR (34)
	IT (15)	FR (8)	GR (11)	UK (24)	GR (18)	UK (43)	PL (39)	PL (34)	CZ (29)
	GR (14)	UK (5)	PT (6)	FR (13)	IT (16)	IT (28)	IT (33)	ES (30)	ES (29)
	FR (6)	DE (4)	FR (5)	DE (12)	PL (10)	FR (22)	UK (28)	RO (27)	GR (28)
	ES/PT (4)	PT (4)	BE/UK (4)	GR (12)	ES/FR (9)	RO (13)	PT (24)	FR/UK (24)	RO (28)
Norway	FR (23)	IT (21)	IT (13)	UK (18)	PL (19)	UK (10)	PL (13)	PL (29)	IT (17)
	ES (22)	CZ (20)	ES (8)	DE (9)	UK (10)	NL (4)	RO (13)	BG (28)	GR (13)
	GR (21)	DE (10)	PL (6)	ES (9)	GR (8)	PL (4)	GR (11)	CZ (21)	ES (12)
	PT (18)	ES (10)	GR (5)	PL (9)	ES (5)	LT (2)	IT (8)	RO (20)	CZ (10)
	UK (13)	UK (10)	DE/FR (4)	PT (9)	AT/BE/NL /RO (3)	SK (2)	UK (8)	IT (17)	RO (8)
UK	IT (275)	IT (341)	IT (541)	IT (325)	IT (229)	PL (196)	PL (159)	IT (204)	IT (187)
	ES (152)	ES (200)	ES (225)	FR (163)	ES (184)	ES (128)	ES (115)	PL (172)	ES (178)
	GR (119)	FR (94)	FR (208)	ES (156)	PL (130)	IT (112)	DE (93)	ES (142)	IE (123)
	FR (100)	GR (68)	PT (164)	PL (121)	FR (127)	RO (105)	IT (93)	RO (124)	PL (122)
	DE (85)	DE (61)	DE (147)	DE (117)	RO (104)	FR (84)	RO (76)	DE/IE (113)	GR (56)

Source: Author's calculations based on data available on ministry of health websites in each of the destination countries.