



Pharmaceutical antitrust enforcement in the United States and Chile

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Consumers suffer from high drug prices. They split pills in half, decide between paying for medications and rent, and forego needed medicines. High prices stem in large part from pharmaceutical companies' anticompetitive games. This essay discusses the crucial role antitrust enforcement agencies can play in addressing 'pay for delay' settlements and 'product hopping' and draws lessons from this enforcement. As an initial observation, the pharmaceutical industry is unique. In many industries, there are multiple incentives for innovation, with patents low on the list. But in the pharmaceutical industry, patents are important. The reason is simple: it takes a long time to reach the market and is expensive to do so.

At the same time, complicated regulatory regimes are designed not only to increase innovation but also to foster generic competition. When a generic drug enters the market, the price falls dramatically, as much as 85%.¹ As a result, as discussed throughout this essay, brand-name drug companies often engage in conduct to delay generics' entry into the market so they can maintain monopoly profits.

A complex regulatory regime is accompanied by complicated markets. In other industries, a single party—the consumer—makes the price/quality tradeoff. If a new

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1 FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 8 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

product is better than the old, the consumer decides if it is worth paying extra for that improvement. In the pharmaceutical industry, in contrast, no one makes this price/quality tradeoff. One party (the consumer or insurance company) pays for the drug, while a second party (the doctor) prescribes the drug.² In short, a complicated set of regulations and markets creates room for anticompetitive behavior.

Antitrust agencies play an important role in this setting. In the USA, the Federal Trade Commission ('FTC') has developed critical expertise and experience in the pharmaceutical industry.³ For example, at a time 20 years ago when no one was focused on the issue, the FTC started challenging pay-for-delay settlements, which occur when a brand company pays a generic to stay off the market.⁴ In 2002, the FTC issued a report entitled *Generic Drug Entry Prior to Patent Expiration* that examined anticompetitive conduct in the industry and shed light on the settlements.⁵ The FTC also has brought cases challenging these agreements.⁶

Another example involves the FTC's 2009 and 2011 reports on authorized generics, which are 'approved as brand-name drugs but marketed as generic drugs.'⁷ The competitive effects of authorized generics are complex. On the one hand, they introduce more competition because another generic is added to the market. But on the other, they could discourage other generics from entering. The FTC wrestled with these issues in two lengthy and important reports.⁸

Similarly, the Chilean National Economic Prosecutor's Office ('FNE') has also focused on ways to increase competition in the market.⁹ It addressed minimal generic competition resulting from bioequivalence limitations, brand loyalty, and regulations by facilitating drug interchangeability.¹⁰ As discussed below, it brought an important

2 BUREAU OF CONSUMER PROT., DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 2-3 (1979).

3 See, e.g., *Overview of FTC Actions in Pharmaceutical Products and Distribution*, https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf.

4 FTC, PAY-FOR-DELAY, *supra* note 1.

5 Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration*, July 2002, https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf.

6 See e.g., *FTC Concludes that Impax Entered into Illegal Pay-for-Delay Agreement* (Mar. 2019), <https://www.ftc.gov/news-events/press-releases/2019/03/ftc-concludes-impax-entered-illegal-pay-delay-agreement>.

7 Federal Trade Commission, *Report on Authorized Generic Drugs i* (Sept. 2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>; Federal Trade Commission, *Authorized Generics: An Interim Report* (June 2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf>.

8 Federal Trade Commission, *FTC Staff Issues FY 2016 Report on Branded Drug Firms' Patent Settlements with Generic Competitors* (May 23, 2019), <https://www.ftc.gov/news-events/press-releases/2019/05/ftc-staff-issues-fy-2016-report-branded-drug-firms-patent>.

9 Fiscalía Nacional Económica, *FNE publica informe final de estudio de mercado sobre medicamentos* (Jan. 2020), <https://www.fne.gob.cl/fne-publica-informe-final-de-estudio-de-mercado-sobre-medicamentos/>; Fiscalía Nacional Económica, *Recopilación de las Investigaciones de la Fiscalía Nacional Económica: Una Mirada de Libre Competencia a ciertos aspectos de la Industria de la Salud* (Feb. 2016), <https://www.fne.gob.cl/wp-content/uploads/2016/02/Informe-de-Salud.pdf>; and Fiscalía Nacional Económica, *Minuta de lanzamiento del estudio sobre el mercado de medicamentos* (Apr. 2018), https://www.fne.gob.cl/wp-content/uploads/2018/04/Minuta_EM03_2018.pdf.

10 Fiscalía Nacional Económica, *FNE publica informe final de estudio de mercado sobre medicamentos* (Jan. 2020), <https://www.fne.gob.cl/fne-publica-informe-final-de-estudio-de-mercado-sobre-medicamentos/>

product-hopping claim. And it is proposing the enactment of an exclusivity period for the first generic to enter the market. This essay discusses two types of anticompetitive conduct challenged by the FTC and FNE.

I. PAY-FOR-DELAY SETTLEMENTS

The first behavior involves pay-for-delay settlements. The setting is as follows. A brand company files a patent lawsuit claiming that a generic company infringes the brand's patent. The parties then settle their case. Most of those agreements do not present competitive concern because the parties settle based on the strength of the patent. The problem arises when the brand company adds a payment; in that case, the parties settle based not on the strength of the patent but on the payment. The brand company, in other words, is paying the generic to delay entering the market.¹¹

Between 2005 and 2012, US courts upheld these settlements. They held that the brand company owned a patent and so it could not be liable within the 'scope of the patent'.¹² The problem with this formalistic test is that it assumes that the patent is valid and infringed. Many of the patents, however, cover not the active ingredient but a more minor aspect, like the drug's formulation. For these cases, it is much more likely that the generic can show that the patent is invalid.¹³ But if the brand company pays the generic to drop its patent challenge, we never find out.

In 2013, in *FTC v. Actavis*,¹⁴ the US Supreme Court held that these agreements could have anticompetitive effects and violate the antitrust laws. The court held that the settlements prevented the 'risk of competition'—in other words, the chance that the patent is invalid or not infringed.¹⁵ *Actavis* was an extremely important ruling. As a result of the decision (and as seen in reports the FTC issues every year), while the total number of settlements since 2013 has increased, the number involving payment and delayed entry has significantly fallen.¹⁶

In Chile, the FNE is proposing enacting an exclusivity period for the first generic to enter the market. In its January 2020 Market Study Findings and Recommendations, the FNE sought to 'increase entry incentives and increase competition' by recommending the creation of 'an additional incentive for the entry of generic bioequivalents' through an exclusivity period lasting between 180 and 365 days.¹⁷

This is not a new proposal in the Chilean context. In 2016, the agency that enforces intellectual property ('INAPI') made the same recommendation before the Diputados' Chamber of Congress during hearings in an 'Inquiry Commission on the Role of

(providing comment of FNE head at time FNE's Market Study was launched that 'a structural reform is required in this market . . . [to address] the major problem in this industry which is brand competition').

11 FED. TRADE COMM'N, PAY-FOR-DELAY, *supra* note 1.

12 Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 SANTA CLARA L. REV. 615, 630 (2020).

13 See C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1386–87 (2013) (finding that patent holders win only 32% of cases involving secondary patents covering 'ancillary aspects of drug innovation').

14 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

15 *Id.* at 157.

16 *FTC Staff Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors*, Dec. 3, 2020, <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent>.

17 Fiscalía Nacional Económica, *Estudio de Mercado sobre Medicamentos* ¶¶647–48 (Jan. 2020), <https://www.fne.gob.cl/wp-content/uploads/2020/01/Informe-Final.pdf>.

Governmental Bodies regarding Medicines' acquisition and access by Citizens'.¹⁸ INAPI proposed additional exclusivity mechanisms as well. We introduce cautions for this proposal below.

II. PRODUCT HOPPING

A second form of potentially anticompetitive conduct is 'product hopping.' This behavior involves a brand company switching from one version of a drug to a second, often just to keep the generic off the market. Empirical analysis has shown that roughly 80% of reformulations take place at a time that generics are not expected to be on the market.¹⁹ Those reformulations do not present concern; brand companies are allowed to change their product to improve it and the fact that a generic is not expected to enter the market indicates that the reformulation was not intended to delay generic entry.

Sometimes, however, the change is made just to harm the generic. Brand companies sometimes know about an improvement but delay it for years until the generic is about to enter the market. Each time the brand company makes one of these changes, the generic must go back to the drawing board, reformulating its drug, obtaining approval from the FDA, confronting a new round of patent litigation, and not being able to be substituted at the pharmacy counter.²⁰

Courts in the USA have distinguished between 'hard switches,' viewed as anti-competitive because the brand removes the original drug from the market, and 'soft switches,' viewed as not concerning because the original remains on the market.²¹ But this distinction should not be accorded dispositive significance, as both types of behavior could violate antitrust law.

In particular, even when a brand firm leaves the original drug on the market, it can harm competition by combining a reformulation that destroys generic substitutability with an encouragement to write prescriptions for the reformulated (rather than original) product when the only reason is to impair generic entry.²² Because these soft switches could present competitive concern, the FTC should consider challenging this conduct.

The Commission's first activity in this area was a \$50 million settlement with Reckitt Benckiser for shifting prescriptions for opioid-addiction-treating Suboxone from a tablet to a film version while falsely claiming that the film version was safer.²³ The

18 Commission's 18th session minutes of July 18, 2016, https://www.camara.cl/verDoc.aspx?prmID=81567&prmTipo=DOCUMENTO_COMISION [Sesión 18 de la Comisión Investigadora del Rol de los Organismos Públicos respecto de la Adquisición de Medicamentos y del Acceso a ellos por parte de la población. Período Legislativo 2014–2018. Celebrada el día lunes 18 de julio de 2016.] The Commission's final report is available at: <https://www.camara.cl/legislacion/comisiones/informes.aspx?prmID=1063>.

19 Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 *RUTGERS L.J.* 1, 27 (2009).

20 Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 *FLA. L. REV.* 1009, 1018 (2010). Product hopping can harm not only generics that have entered the market but also those that are considering entry.

21 *Compare Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (denying motion to dismiss in context of hard switch) with *Walgreen Co. v. AstraZeneca Pharmaceuticals*, 534 F. Supp. 2d 146 (D.D.C. 2008) (granting motion to dismiss in context of soft switch).

22 Michael A. Carrier and Steve Shadowen, *Product Hopping: A New Framework*, 92 *NOTRE DAME L. REV.* 167 (2016).

23 *FTC, Indivior Inc.*, July 24, 2020, <https://www.ftc.gov/enforcement/cases-proceedings/1310036/indivior-inc>.

FTC should continue its efforts by engaging in activities like bringing a case, filing amicus briefs,²⁴ issuing guidelines, or holding hearings. Given the nuanced harms of soft switches, the attention of the leading agency focused on drug competition would be valuable.

In 2016, the FNE brought a product hopping case against G.D. Searle, a Pfizer subsidiary.²⁵ The FNE claimed that Searle used its patent rights to prevent entry by anti-inflammatory-treating generics. Searle had obtained a secondary patent with questionable tactics and effectively enforced it against challengers. In addition, Searle deployed aggressive marketing and other exclusionary strategies preventing entry. Searle grounded its defense on the legitimate use and enforcement of its patent rights and business reasons regarding its marketing campaign and its distribution agreements.

It is noteworthy that Searle made no change to the product at all. The first patent protected the chemical compound Celecoxib. The second patent was on the exact same product but covered a specific dosage plus the procedure for obtaining it, apparently being acquired only so the company could obtain an extra 15 years of patent protection. The FNE settled with the company. Searle committed to grant licenses for free, non-exclusive, and non-revocable generic manufacturing and to cease-and-desist enforcement actions and restricted marketing and distribution arrangements relating to its secondary patent. The settlement, approved by the Competition Tribunal, sought to increase competition and lower prices for consumers.²⁶

The activities of settlement and product hopping offer lessons for the path forward.

III. LESSON 1: CHALLENGING PATENTS

The first lesson arises in the settlement context. The USA is unique in providing a period of exclusivity to the first generic to challenge a brand firm's patents. This period can be useful in promoting challenges to invalid patents. If one generic firm is successful in showing that a patent is invalid, any other generic could enter the market. For that reason, the Hatch-Waxman Act provided 180 days of exclusivity to the first generic to claim that the patent 'is invalid or will not be infringed by the generic drug.'²⁷ When there is only one generic on the market, the price is nearly the same as the brand price; when multiple generics enter, the price falls dramatically.²⁸ As a result, this period has been extremely valuable to generics, worth—according to the Supreme Court—'several hundred million dollars.'²⁹

24 See, e.g., Brief for Amicus Curiae Federal Trade Comm'n in Support of Plaintiff-Appellant Mylan Pharms. Inc.'s Petition for Rehearing and Rehearing En Banc (3d Cir. Oct. 19, 2016).

25 Professor Carrier served as an expert in this case.

26 Fiscalía Nacional Económica, *FNE presenta requerimiento por abuso de posición dominante en contra de compañía farmacéutica G.D. Searle LLC, ligada a Pfizer* (June 2016), <https://www.fne.gob.cl/fne-presenta-requerimiento-por-abuso-de-posicion-dominante-en-contra-de-compania-farmacéutica-g-d-searle-llc-ligada-a-pfizer>; Fiscalía Nacional Económica, *TDLC aprueba acuerdo conciliatorio entre FNE y G.D. Searle LLC que fomenta la participación de competidores en el mercado de medicamentos que contienen Celecoxib* (Nov. 2016), <https://www.fne.gob.cl/tldc-aprueba-acuerdo-conciliatorio-entre-fne-y-g-d-searle-llc-que-fomenta-la-participacion-de-competidores-en-el-mercado-de-medicamentos-que-contienen-celecoxib/>.

27 21 U.S.C. §355(j)(2)(A)(vii).

28 FDA, *Generic Competition and Drug Prices*, <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> (last visited Jan. 20, 2021).

29 *FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

Despite the intent behind the 180-day period, it has played a central role in anti-competitive settlements. In the USA, later-filing generics cannot enter the market until 180 days after (even a delayed) first-filing generic enters.³⁰ In the years since the passage of the Hatch-Waxman Act, the drafters of the legislation have unequivocally expressed their disapproval of reverse-payment settlements. Representative Waxman explained that such agreements were an ‘unfortunate, unintended consequence’ of the Act that ‘turned the . . . legislation on [its] head.’³¹ And Senator Hatch similarly found such agreements ‘appalling’ and ‘concede[d], as a drafter of the law, that we came up short in our draftsmanship.’³²

In January 2020, as a result of its Market Study, the FNE issued 15 recommendations, some of which addressed drug entry. One of those recommendations involved the introduction of an exclusivity period of 180–365 days for the first generic to enter the market.³³

It is unclear whether the effort and recommendations by the FNE will become mandatory provisions. Since 2015, the Chilean Congress has been considering a bill (‘Fármacos II’) for which many of the FNE’s recommendations are expected to be adopted. Even if the bill is approved, detailed regulation will be essential in incorporating it.

Chile does not appear to be treating the exclusivity incentive for generic entry as a means to encourage challenges to invalid patents. But it still should consider the potential downsides from exclusivity periods that could make it easier for brand firms to keep generics off the market. The exclusivity periods in the USA were never expected to delay generic entry. But they have. Chile should keep this in mind as it weighs adopting a similar provision, examining incentives not only for increased patent challenges but also for delayed generic entry.

IV. LESSON 2: CHALLENGING ANTICOMPETITIVE SWITCHES

A second lesson arises from actions challenging product hopping in the USA and Chile. Drug companies reformulate their products all the time. And most of these take place at a time when generic competition is not expected. As a result, any attempt to challenge product hopping must be cognizant of the effect on innovation.

The *Suboxone* and *Searle* cases point to one method of distinguishing between legitimate reformulations and anticompetitive product hopping: asking if the conduct makes any economic sense other than harming the generic. Such a conservative framework defers to the drug company as long as it can offer a justification for its conduct other

30 The 2003 Medicare Amendments, designed to encourage expedited entry by specifying events leading to a forfeiture of the exclusivity period, were largely toothless. The reason is that they provide for forfeiture upon the later of: (1) 75 days after FDA approval; and (2) 75 days after an appellate court decision finding invalidity or non-infringement. But appellate court decisions typically are not issued until years after a lawsuit challenging settlement is filed. Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7, 15 (2014).

31 *Motion and Brief for Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner* at *v, FTC v. Schering-Plough Corp., 548 U.S. 919 (2006) (No. 05–273), 2005 WL 2462026.

32 148 CONG. REC. S7566 (daily ed. July 30, 2002) (statement of Sen. Hatch).

33 FNE, *Estudio de Mercado* ¶¶ 647–48 (Jan. 2020), <https://www.fne.gob.cl/wp-content/uploads/2020/01/1nforme-Final.pdf>.

than impairing the generic. But if the only reason for the switch is to harm the generic, it presents anticompetitive concern.³⁴

In the FTC's settlement with Reckitt Benckiser, for example, it made no sense for the company to falsely claim that the film version was safer than the tablet.³⁵ Nor did it make sense to make a switch that would lead to 'as much as 30% fewer' sales of the drug.³⁶ The switch was also costly to Reckitt, with the company raising the price of its original tablets in relation to the reformulated film version even though the film was more expensive to manufacture and package.³⁷

Similarly, Searle obtained a questionable secondary patent in spite of—as the Chilean IP agency later found—the lack of inventive step relative to the first. And it deployed aggressive marketing and other exclusionary strategies preventing entry. Protecting its secondary patent, Searle sent cease-and-desist letters to generic competitors and submitted a complaint based on unfair competition against a rival. Searle's marketing strategies sought to ensure that Searle brands saturated the market and to prevent entry of two of its competitors into a pharmacy retail chain. These actions only make sense in delaying generic entry.

V. CONCLUSION

At the end of the day, drug pricing is an extremely important issue. This is literally a matter of life and death for consumers that cannot afford their medication. The pharmaceutical industry sometimes claims that any limits on patents or application of antitrust will harm innovation. But none of the antitrust enforcement discussed above would affect innovation. We can benefit from lower drug prices while still witnessing robust innovation by stopping these anticompetitive games.

The FTC and FNE can consider how incentives for patent challenges could harm competition and can target conduct that makes no sense other than by harming the generic. And they can play a crucial role in challenging conduct like pay-for-delay settlements and product hopping, in the process lowering prices for consumers.

34 See Carrier and Shadowen, *supra* note 21.

35 FTC, *Indivior Inc.*, July 24, 2020, <https://www.ftc.gov/enforcement/cases-proceedings/1310036/indivior-inc>.

36 End Payor Plaintiffs' Consolidated Amended Class Action Complaint ¶ 37, *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014) (No. 2:13-md-02445).

37 *Id.* ¶¶ 38, 42.