

# Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health

Frederick M. Abbott\*

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\* Edward Ball Eminent Scholar Professor of International Law, Florida State University College of Law. A preliminary draft of this paper was presented at the UC Irvine School of Law “Conference on Patent Sovereignty and International Law” in October 2015. The author notes with appreciation research assistance by Christine Sanders and Lane Turkle.

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#### INTRODUCTION

Public health budgets and individual patients around the world struggle with high prices for pharmaceutical products. Difficulties are not limited to low-income countries. Prices for newly introduced therapies to treat hepatitis C, cancer, joint disease, and other medical conditions are placing great strains on health budgets even within the wealthiest countries.<sup>1</sup> In the United States, state pharmaceutical acquisition budgets are at the breaking point—or have passed it—and treatment is effectively rationed.<sup>2</sup>

Pharmaceutical products reflecting extraordinary price escalation are principally newly developed originator small-molecule and biological pharmaceutical (biologic) products.<sup>3</sup> These products are typically protected by patent, regulatory market exclusivity, or both. There are also recent incidents of

1. See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-12, MEDICARE PART B: EXPENDITURES FOR NEW DRUGS CONCENTRATED AMONG A FEW DRUGS, AND MOST WERE COSTLY FOR BENEFICIARIES (2015); STEPHEN W. SCHONDELMAYER & LEIGH PURVIS, AARP PUB. POLICY INST., TRENDS IN RETAIL PRICES OF SPECIALTY PRESCRIPTION DRUGS WIDELY USED BY OLDER AMERICANS, 2006 TO 2013 (2015); Peter Loftus, *Drug Firms Ring in Higher Prices*, WALL ST. J., Jan. 11, 2016, at B1; Andrew Pollack, *Cancer Specialists Attack High Drug Costs*, N.Y. TIMES, Apr. 26, 2013, at B1; Matthew Herper, *115 Doctors Propose This Solution for Terrifying Cancer Drug Prices*, FORBES (July 23, 2015), <http://www.forbes.com/sites/matthewherper/2015/07/23/155-anxious-doctors-propose-7-solutions-for-terrifying-cancer-drug-prices/#11eefa5b4f82> [<https://perma.cc/9HDE-D9FY>].

2. See, e.g., STAFF OF S. COMM. ON FIN., 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM, 106–10 (Comm. Print 2015) [hereinafter SOVALDI STAFF REPORT]; David Siders, *Hepatitis C Drug's High Cost Hits California Budget*, SACRAMENTO BEE (Jan. 16, 2015), <http://www.sacbee.com/news/politics-government/article7058828.html> [<https://perma.cc/T7GB-W69V>] (“Tucked inside Brown’s annual spending plan was \$300 million for the cost of new hepatitis C drugs, including Sovaldi, the drug approved in December 2013. The single budget item—\$100 million this fiscal year and \$200 million in 2015-16—eclipses proposed general fund spending on state parks or on emergency drought response next year.”); SCHONDELMAYER & PURVIS, *supra* note 1, at 4.

3. See, for example, FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY 2 (2009), for a discussion of pharmaceutical categories. Pharmaceutical products created through synthetic organic chemistry involve the combination of basic elements (i.e., carbon, hydrogen, nitrogen, oxygen, etc.) into more complex molecular structures or compounds, and ultimately into forms suitable for delivery to patients. Although such molecular structures may be complex from a chemical engineering standpoint, the drug compounds are smaller physical structures than the active elements of biological drugs, which are formed from biological materials that are substantially more complex than individual compounds and are of larger physical scale. See, e.g., Thomas Morrow, *Defining the Difference: What Makes Biologics Unique*, BIOTECHNOLOGY HEALTHCARE, Sept. 2004, at 24. For visual image of structures, see, for example, <http://www.nyas.org/image.axd?id=77f1c4ce-4897-416d-af15-fa717c188b1b&t=635316181685700000>.

dramatically increased prices of certain generic products whose supplies are restricted for one reason or another, providing their suppliers with effective market exclusivity.<sup>4</sup>

There are a variety of tools that governments may use to regulate the prices of pharmaceutical products, including those covered by patent or regulatory market exclusivity.<sup>5</sup> Specifically, a government may impose price controls, grant compulsory patent licenses, or use monopsony purchasing power to force price concessions.<sup>6</sup> Though they are currently used in one form or another by many countries, there can be political-economy obstacles to making use of these tools.

Competition, or antitrust, law has rarely been used to address “excessive pricing” of pharmaceutical products.<sup>7</sup> This is a worldwide phenomenon. In the United States, federal courts have refused to apply excessive pricing as an antitrust doctrine, either with respect to pharmaceutical products or more generally.<sup>8</sup> Courts in some other countries have been more receptive to considering the doctrine, but application in specific cases has been sporadic, including with respect to pharmaceuticals.<sup>9</sup>

This remains a paradox of sorts. Competition law experts acknowledge that one of the principal objectives of competition policy is to protect consumers against the charging of excessive prices.<sup>10</sup> Yet, there is a firm reluctance to recommend addressing excessive prices “as such.” A number of reasons are put forward for this reluctance. Not all of these reasons are terribly persuasive. The currently preferred alternative is to address the “structural problems” that allow the charging of excessive prices.<sup>11</sup> That is, “fixing the market” so that the underlying defect by which excessive prices are enabled is remedied.

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4. See, e.g., Andrew Pollack, *Turing Moves to Next Drug*, N.Y. TIMES, Dec. 12, 2015, at B1; Anjali Cordeiro & Makiko Kitamura, *Valeant Slumps as U.S. Prosecutors Issue Subpoenas on Prices*, BLOOMBERG BUS. (Oct. 15, 2015, 1:28 PM), <http://www.bloomberg.com/news/articles/2015-10-15/valiant-receives-subpoenas-from-u-s-prosecutors-on-drug-pricing>.

5. See, e.g., PHARMACEUTICAL PRICES IN THE 21ST CENTURY (Zaheer-Ud-Din Babar ed., Springer Int'l Publ'g Switz. 2015) (including country contributions); OECD HEALTH POLICY STUDIES, PHARMACEUTICAL PRICING POLICIES IN A GLOBAL MARKET (2008); U.S. DEP'T OF COMMERCE INT'L TRADE ADMIN., PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES (2004).

6. See sources cited *supra* note 5.

7. OECD DIRECTORATE FOR FIN. & ENTER. AFFAIRS COMPETITION COMM., EXCESSIVE PRICES (2012) (“This document comprises proceedings in the original languages of a Roundtable on Excessive Prices held by the Competition Committee (Working Party No.2 on Competition and Regulation) in October 2011”) [hereinafter OECD ROUNDTABLE]. The terms “competition” and “antitrust” are interchangeable in referring to a field of law. The term “antitrust” has traditionally been used in the United States because early cases involving anti-competitive business practices addressed a form of business combination known as a “trust.” That type of business combination is no longer associated with anticompetitive business practices, but the term “antitrust” continues to be used, primarily (though not exclusively) in the United States.

8. See *id.* at 299.

9. See *id.* at 10–11.

10. *Id.* at 9.

11. *Id.* at 227.

There is a fundamental problem with the “fixing the market” approach when addressing products protected by legislatively authorized market exclusivity mechanisms, such as patents, and regulatory marketing exclusivity. That is, mechanical aspects of the market are not broken in the conventional antitrust sense. Rather, the market has been designed without adequate control mechanisms or “limiters” that act to constrain exploitive behavior. Political institutions, such as legislatures, that might step in are constrained by political economy (e.g., lobbying), and do not respond as they should.

The field of competition law is subject to limited substantive regulation at the multilateral level.

Developing and developed countries have substantial flexibility within the existing international legal framework to adopt competition law approaches that are suitable to their circumstances and that are consistent with the fundamental objectives that competition law is intended to achieve. Expert commentators, myself included, have laid out the multilateral framework in which competition law operates in some detail elsewhere,<sup>12</sup> and this Article does not revisit that exercise other than to observe the flexibility of the framework. Consistent with that earlier work, this Article recommends that emerging markets, and developing countries more generally, should be cautious in responding to suggestions that new competition rules at the multilateral level are needed.

The U.S. competition authorities, and its multinational business community, have long resisted the negotiation of multilateral competition rules. Understandably, the Department of Justice and Federal Trade Commission wished to preserve their ability to adapt domestic antitrust policy and rules as perspectives and interests changed, particularly when these authorities anticipated that multilateral competition negotiations would reach a least common denominator result.<sup>13</sup> Up until now, the business community has preferred to

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12. See, e.g., Frederick M. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?*, 7 J. INT'L ECON. L. 687 (2004); Frederick M. Abbott, *Competition Law in Emerging Markets: The Virtue of Regulatory Diversity*, in INTERNATIONAL ECONOMIC GOVERNANCE: ESSAYS IN HONOUR OF PROFESSOR MITSUO MATSUSHITA 216 (J. Chaisse & Tsai-Yu Lin eds., Oxford Univ. Press) (2016) [hereinafter Abbott, *Competition Law in Emerging Markets*]; Frederick M. Abbott, *Public Policy and Global Technological Integration: An Introduction*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION 3 (Frederick M. Abbott & David J. Gerber eds., 1997) [hereinafter Abbott, *Public Policy and Global Technological Integration*]; Carlos M. Correa, *Intellectual Property and Competition—Room to Legislate Under International Law*, in UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES 35 (F. M. Abbott ed., 2014).

13. See, e.g., Joel Klein, *No Monopoly on Antitrust: It Would be Premature for the WTO to Seek to Enforce Global Competition Rules*, FIN. TIMES, Feb. 13, 1998, at 1, [https://www.justice.gov/archive/atr/public/press\\_releases/1998/229364.pdf](https://www.justice.gov/archive/atr/public/press_releases/1998/229364.pdf) [<https://perma.cc/T4ML-7QEW>] (“I continue to believe strongly that WTO negotiations on competition rules would be premature and could even be counterproductive.”); A. Douglas Melamed, Principal Deputy Assistant Attorney Gen., U.S. Dep’t of Justice Antitrust Div., *Antitrust Enforcement in a Global Economy*, Address Before the Fordham Corporate Law Institute 25th Annual Conference on International Antitrust Law and Policy 12 (Oct. 22, 1998), <http://www.justice.gov/atr/speech/antitrust-enforcement-global-economy>

operate in a less regulated environment. But, there are signs that the multinational business community calculation is shifting as a consequence of the more aggressive and effective application of competition law by authorities in developing countries.<sup>14</sup> The calculation may now suggest that the risks from being subjected to prosecution under competition law exceed the gains from operating in an unregulated environment. This is a self-interested calculation and does not represent a more benign perspective toward the protection of the consumer and public interest. Proposals to restrain the development of international competition norms should be understood in that context.

Competition law and policy should develop robust doctrine to address excessive pricing in markets lacking adequate control mechanisms. This Article will focus specifically on the pharmaceutical sector because of its unique structure and social importance. This focus is not intended to exclude the possibility that development of excessive pricing doctrine would be useful in other contexts.

This Article is divided into two parts. The first addresses competition policy and why it is appropriate to develop the doctrine of excessive pricing to address distortions in the pharmaceutical sector. The second addresses the technical aspect of how courts or administrative authorities may determine when prices are excessive, and potential remedies.

## I. EXCESSIVE PRICING DOCTRINE

### A. *Philosophical Resistance*

U.S. Supreme Court jurisprudence in the years shortly following enactment of the Sherman Antitrust Act placed protection of consumers at the center of the objectives of antitrust policy.<sup>15</sup> By the late 1980s, the focus of competition policy in the United States had shifted to protection of competitive markets with a focus on assuring a competitive market environment among suppliers.<sup>16</sup> This shift in focus from consumer to market protection reflected, at least in part, the influence of Chicago School economics emphasizing the self-correcting nature of markets,<sup>17</sup> and it was embedded in antitrust guidelines adopted by the Department of Justice

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[<https://perma.cc/K4L7-WBWB>] (“We do not believe, however, that it would make sense at this time to commence multinational negotiation of common antitrust principles or rules.”).

14. See Abbott, *Competition Law in Emerging Markets*, *supra* note 12, at 217 (including reference to U.S. Chamber of Commerce report on China).

15. See *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1 (1911); Frederick M. Abbott, *The ‘Rule of Reason’ and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS*, in *HUMAN RIGHTS AND INTERNATIONAL TRADE* 279 (Thomas Cottier et al. eds., 2005).

16. See Joshua D. Wright & Douglas H. Ginsburg, *The Goals of Antitrust: Welfare Trumps Choice*, 81 *FORDHAM L. REV.* 2405, 2405–06 (2013).

17. See Richard A. Posner, *The Chicago School of Antitrust Analysis*, 127 *U. PA. L. REV.* 925 (1979); see also Joshua D. Wright, *Abandoning Antitrust’s Chicago Obsession: The Case for Evidence-Based Antitrust*, 78 *ANTITRUST L.J.* 241, 243 (2012) (“The Chicago School of antitrust economics is not merely a set of normative prescriptions about antitrust law, such as to ‘let the market solve it.’”).

and Federal Trade Commission in the mid-1990s.<sup>18</sup> The competitive market protection approach was and is thought to address the interests of consumers because, in theory, prices will be driven down to marginal cost in a competitive market.

This philosophical market approach is reflected in recent judicial antitrust doctrine in the United States.<sup>19</sup> There is a presumption that producers charging high prices (e.g., above marginal cost) will attract new market entrants that will eventually bring prices down. A producer that is able to charge a high price through astute business practices or innovation has earned that right, which free market economics encourages. Recent federal court decisions also express skepticism concerning the capacity of judges to determine what fair prices are, given that judges are not technical regulatory experts.<sup>20</sup>

This basic philosophical approach may work to protect consumers in the general case, but its utility is limited in cases where the market is not designed to fluidly adjust. This is the case of the originator pharmaceutical market where products benefit from legislatively granted exclusive marketing rights. An originator pharmaceutical product (small-molecule or biologic) typically will benefit from patent protection that will last twenty-five years from the date of application (the ordinary twenty-year term, plus a five-year extension).<sup>21</sup> Taking into account the lead time for regulatory marketing approval by the Food and Drug Administration (FDA), the effective term of protection will be between ten and fifteen years.<sup>22</sup> In addition to patent protection, the originator pharmaceutical product will benefit from a period of regulatory marketing exclusivity as a consequence of approval by the FDA. In the case of small-molecule chemicals, that regulatory exclusivity probably will not extend beyond the patent term.<sup>23</sup> But, in the case of biologics, the twelve-year period of exclusivity may well extend beyond the duration of patent protection.<sup>24</sup>

As a consequence of exclusive marketing rights (whether through patent or regulatory exclusivity), the originator pharmaceutical product is not subject to

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18. See generally U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES (1997); U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY (1995); U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT GUIDELINES FOR INTERNATIONAL OPERATIONS (1995).

19. See discussion of case law *infra* pp. 289–95.

20. See *infra* notes 41–62 and accompanying text.

21. See generally U.S. FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (2009), <https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report>.

22. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 164, 166 (2003).

23. The U.S. market exclusivity provision applicable to small molecule chemicals was initially adopted in the context of the Hatch-Waxman Act, extended for five years from the FDA's approval of marketing, and was expected to expire prior to the end of the patent term. It is now possible to obtain certain extensions of market exclusivity as a reward for conducting clinical trials with respect to new indications. This may allow extension beyond the term of the patent. 21 C.F.R. § 314.108 (2016).

24. U.S. FED. TRADE COMM'N, *supra* note 21, at vi.

competition from the “same product” during the term of protection from a juridical standpoint.<sup>25</sup> In principle, this enables the originator to charge whatever price it decides upon without fear of competition. In practice, there are potential constraints on pricing. First, there may be pharmaceutical products that are reasonable substitutes even if they are not “the same,” and this introduces the element of potential price competition. Second, the price that the originator can charge will depend on demand for the product, which is influenced by the degree to which it is required by patients (or purchasers), and ultimately by the amount the patients (or purchasers) can afford to pay.<sup>26</sup>

The maximum pricing power for the originator is manifest when it owns exclusive marketing rights for a unique or breakthrough therapy for a life-saving pharmaceutical product. If there is no reasonable substitute product, pricing power is effectively constrained only by the capacity of the patient or health provider to pay. An illustration is found in the pricing power enjoyed by Gilead, the originator-owner of sofosbuvir (Sovaldi) used for the treatment of hepatitis C.<sup>27</sup> When Sovaldi was introduced in late 2013, it was a unique therapy successful in the treatment of hepatitis C. There was tremendous pent-up patient demand for the product. Gilead, with the advice of a team of investment bankers and pharmaceutical market specialists, took advantage of the situation to set a price of \$84,000 for a twelve-week course of treatment and earned over \$14 billion in the first year of sales.<sup>28</sup> Gilead did not develop Sovaldi. The drug was initially developed by a smaller biotechnology company, Pharmasett, which Gilead purchased for \$11 billion in 2011.<sup>29</sup> Prior to its acquisition by Gilead, Pharmasett had been planning to introduce sofosbuvir at less than half the price eventually set by Gilead (approximately \$35,000 for a course of treatment).<sup>30</sup> Gilead purchased Pharmasett because its own research and development (R&D) efforts had failed. While the cost of production of Sovaldi is not the benchmark by which the originator price should be set, it is of interest that the cost of production for the course of treatment is \$350 or less.<sup>31</sup>

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25. *Id.*

26. Pharmaceutical products are ultimately used or consumed by individual patients, but the individual patient may not be the direct purchaser of the product. The purchaser may be a federal or state health provider, a private insurance provider that pays for all or a portion of the product, or some other entity. In many countries, government health department procurement authorities are among the largest buyers of pharmaceuticals.

27. See SOVALDI STAFF REPORT, *supra* note 2, at 29.

28. *Id.* at 17.

29. *Id.* at 123.

30. *Id.* at 19.

31. See Jeffrey Sachs, *The Drug That is Bankrupting America*, HUFFINGTON POST BLOG (Feb. 16, 2015, 11:01 AM), [http://www.huffingtonpost.com/jeffrey-sachs/the-drug-that-is-bankrupt\\_b\\_6692340.html](http://www.huffingtonpost.com/jeffrey-sachs/the-drug-that-is-bankrupt_b_6692340.html) [<https://perma.cc/5Z4Q-SJ9K>].

The process by which Gilead set the price of Sovaldi makes for chilling reading from a public health standpoint.<sup>32</sup> The executives at Gilead essentially set out to determine the maximum price that would stress the limits of political and public opinion, but not quite break it. This was with a clear understanding that the pricing of the drug would severely undermine state public health procurement budgets. Gilead has refused to furnish Congress with direct information regarding its cost of bringing the product to market, despite being requested to do so.<sup>33</sup>

When Gilead introduced Sovaldi, it had strong reason to believe that reasonably comparable alternative treatments would be approved by the FDA and introduced by other originators within a year or two. In other words, there would be a temporal limit to its unconstrained pricing power. In fact, such products were introduced and, approximately one-and-a-half years following the introduction of Sovaldi, Gilead was forced to reduce the price significantly.<sup>34</sup> It may be (and has been) suggested that this demonstrates that market forces will act to constrain pricing power. Yet it remains that Gilead charged an excessive price when it introduced the product, and for more than one year, and that even with the introduction of competition, the price for hepatitis C treatments offered by originators is very high and continues to threaten public health budgets.

This is but one illustration of the general problem of pharmaceutical pricing. The price of a substantial number of anti-cancer drugs has drawn the attention of medical professionals that have called for legislative action to reduce prices.<sup>35</sup> Members of Congress have introduced a number of legislative proposals that would provide some form of control mechanism.<sup>36</sup> State governments have been substantially more active than the federal government in adopting mechanisms intended to limit excessive pricing.<sup>37</sup> However, each of these mechanisms is dependent on political processes that are subject to intervention by corporate lobbyists with interests in maintaining pricing power. The application of antitrust/competition law by private or public parties is not dependent on legislative action.

This Article is not specifically directed toward fixing a problem in the United States, though indeed there is a problem to be fixed. It is intended to more generally address the problem from a global competition law and policy

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32. For an explanation of how Gilead decided to set a price for Sovaldi, see SOVALDI STAFF REPORT, *supra* note 2, at 29–58.

33. *Id.* at 3 (footnote omitted) (“Several months after Gilead agreed to buy Pharmasset, a Gilead executive described the acquisition as a ‘bargain.’ The company failed to provide sufficient information to determine how much additional cost it incurred to complete the development, finish the FDA approval process, and bring the drug to market.”).

34. *Id.* at 112–16.

35. See Pollack, *supra* note 1.

36. See Bronwyn Mixter, *Sanders to Introduce Wide-Ranging Drug Cost Bill*, BLOOMBERG BNA PAT., TRADEMARK & COPYRIGHT J.—DAILY ED. (Sept. 1, 2015), <http://www.bna.com/sanders-introduce-wideranging-n17179935532/> [<https://perma.cc/X9UY-WXEC>].

37. See generally Nancy E. Morden & Sean D. Sullivan, *States’ Control of Prescription Drug Spending: A Heterogeneous Approach*, 24 HEALTH AFF. 1032, 1032–38 (2005) (discussing a number of methods states use to limit excessive pricing).



perspective. Developing and middle-income countries are in a more precarious position than the United States in terms of their capacity to fund pharmaceutical procurement.

Competition law and policy experts recognize that there is a paradox in the reluctance of courts and administrative authorities to tackle the problem of excessive pricing directly. Part of that hesitation derives from a belief that it is overly difficult to determine what constitutes an excessive price, for which the logical predicate is determining what a reasonable price is.

### *B. Jurisprudential Approaches*

In 2011, the Organisation for Economic Co-operation and Development (OECD) Competition Committee convened a Policy Roundtable on excessive prices and published the contributed papers and dialogue.<sup>38</sup> The Roundtable included contributions from major antitrust authorities, including from outside the OECD, and represents an authoritative compilation of the administrative and judicial “state-of-the-art” as of 2011. The contributions to the Roundtable show that states and their respective judiciaries were hesitant to apply “excessive pricing” as a standalone basis for finding violations of competition law. The few cases where the doctrine was applied generally involved industries subject to pre-existing price regulation where the alleged violator acted contrary to the applicable regulatory regime.<sup>39</sup> There are a limited number of exceptions, but those exceptions serve to illustrate the reluctance of judicial authorities to become involved in excessive pricing assessments.

#### *1. The United States*

In their contribution to the OECD Roundtable, U.S. antitrust authorities are categorical:

The U.S. Federal Trade Commission (“FTC”) and Antitrust Division of the U.S. Department of Justice (“DOJ”) (collectively, “the Agencies”) are pleased to provide our perspective on this issue, and explain why U.S. antitrust law does not proscribe excessive pricing as an independent antitrust violation, although high prices may be indicative of other anticompetitive activities.<sup>40</sup>

The author of this Article does not quarrel with this characterization by the FTC and DOJ representatives, which is supported in their contribution and confirmed by independent study of U.S. case law.<sup>41</sup> More recent federal court decisions are

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38. OECD ROUNDTABLE, *supra* note 7 (“This document comprises proceedings in the original languages of a Roundtable on Excessive Prices held by the Competition Committee (Working Party No.2 on Competition and Regulation) in October 2011.”).

39. *Id.* at 10–11.

40. *Id.* at 299.

41. *See id.* at 299–300 (citing *Pacific Bell Tel. Co. v. linkLine Commc’ns, Inc.*, 555 U.S. 438 (2009)); *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004);

consistent with this general line.<sup>42</sup>

Perhaps the most quoted judicial pronouncement regarding the notion of excessive pricing of recent years is from the late Justice Antonin Scalia's 2004 opinion for the Supreme Court in *Verizon v. Trinko*, stating:

The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts “business acumen” in the first place; it induces risk taking that produces innovation and economic growth. To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.<sup>43</sup>

An earlier decision by the Second Circuit in *Berkey v. Eastman Kodak* is to the same effect: “[a] pristine monopolist . . . may charge as high a rate as the market will bear.”<sup>44</sup> Likewise, the Seventh Circuit in *Blue Cross v. Marshfield*: “[a] natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of ‘monopolizing’ in violation of the Sherman Act . . . and can therefore charge any price that it wants . . . for the antitrust laws are not a price-control statute or a public-utility or common-carrier rate-regulation statute.”<sup>45</sup>

To be clear, the federal courts are not providing a blanket approval of pricing practices under U.S. antitrust laws. Price fixing among horizontal competitors remains a *per se* violation of the Sherman Act.<sup>46</sup> Resale price maintenance is assessed under the rule of reason.<sup>47</sup> As the FTC and DOJ point out, high prices may well be reflective of an underlying anticompetitive practice, such as abuse of monopoly power under Section 2 of the Sherman Act<sup>48</sup> or price fixing under Section 1.<sup>49</sup> Enterprises engaged in abusive behaviors that manifest themselves in

*Blue Cross & Blue Shield v. Marshfield Clinic*, 65 F.3d 1406, 1412–13 (7th Cir. 1995) (citing *Nat'l Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020 (8th Cir. 1985)); *Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325 (7th Cir. 1986); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979); *United States v. Aluminum Co. of Am.*, 148 F.2d 416 (2d Cir. 1945); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898).

42. *Cf. Batson v. Live Nation Entm't*, 746 F.3d 827, 833 (7th Cir. 2014) (decided under Illinois Consumer Fraud and Deceptive Business Practices Act).

43. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

44. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979).

45. *Blue Cross & Blue Shield v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995) (citing *Nat'l Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020, 1023–24 (8th Cir. 1985)).

46. *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 223 (1940).

47. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 878 (2007).

48. 15 U.S.C. § 2 (2012) (“Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other persons or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . .”).

49. 15 U.S.C. § 1 (2012) (“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is

prices higher than competitive market prices violate the antitrust laws. But, neither the antitrust authorities nor the courts view high prices as potential antitrust violations “as such.”

There is not much to add in terms of philosophical approach to the few quotations laid out above. If a “pristine monopolist,” that is, a monopolist that has acquired its dominant position by lawful means, is able to charge a high price, this reflects some business acumen or innovation for which the monopolist is entitled to be rewarded. The courts are not self-appointed price regulatory authorities. They may lack the skill set or technical tools by which to undertake the task of price assessment.

The case of the originator pharmaceutical company with patent and/or regulatory marketing exclusivity protection at first glance may appear exceptionally insulated from assessment under excessive pricing doctrine because the monopoly position is based on congressional authorization (administered by the U.S. Patent and Trademark Office or the FDA). That is, unless the patent was procured by fraud or other misadventure, or the FDA was somehow taken advantage of, the monopoly is “pristine.” But, does this mean that the price charged by an originator company for a pharmaceutical product can never “as such” violate the antitrust laws (i.e. without an additional element such as price-fixing with a horizontal competitor)?

It is important to take notice of the Supreme Court’s more recent decision in *FTC v. Actavis*<sup>50</sup> in which it rejected the idea that a patent insulates an originator pharmaceutical company from scrutiny under the antitrust laws stating, *inter alia*: “this Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”<sup>51</sup> In this decision, the Court noted, for example, that a price-fixing agreement among patent owners is not insulated from antitrust scrutiny because of the monopolies conferred by patents.<sup>52</sup> It said:

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declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony . . .”).

50. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2231 (2013).

51. *Id.*

52. The *Actavis* Court stated the following:

[I]n *Line Material*, supra, at 308, 310-311, 68 S.Ct. 550, the Court held that the antitrust laws forbid a group of patentees, each owning one or more patents, to cross-license each other, and, in doing so, to insist that each licensee maintain retail prices set collectively by the patent holders. The Court was willing to presume that the single-patentee practice approved in *General Electric* was a “reasonable restraint” that “accords with the patent monopoly granted by the patent law,” 333 U.S., at 312, 68 S. Ct. 550, but declined to extend that conclusion to multiple-patentee agreements: “As the Sherman Act prohibits agreements to fix prices, any arrangement between patentees runs afoul of that prohibition and is outside the patent monopoly.” *Ibid.* In *New Wrinkle*, 342 U.S., at 378, 72 S. Ct. 350, the Court held roughly the same, this time in respect to a similar arrangement in settlement of a litigation between two patentees, each of which contended that its own patent gave it the exclusive right to control production. That one or the other company (we may presume) was right

[I]n *Standard Oil Co. (Indiana)*, the Court upheld cross-licensing agreements among patentees that settled actual and impending patent litigation, [*Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163, 168], which agreements set royalty rates to be charged third parties for a license to practice all the patents at issue (and which divided resulting revenues). But, in doing so, Justice Brandeis, writing for the Court, warned that such an arrangement would have violated the Sherman Act had the patent holders thereby “dominate[d]” the industry and “curtail[ed] the manufacture and supply of an unpatented product.” . . . These cases do not simply ask whether a hypothetically valid patent’s holder would be able to charge, *e.g.*, the high prices that the challenged patent-related term allowed. Rather, they seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.<sup>53</sup>

The implication of this quoted passage is recognition by the Court that a patent ordinarily allows a patent owner to charge “high prices,” but at the same time requires that the patent owner not engage in anticompetitive practices to achieve that end.

The Supreme Court has not generally endorsed excessive pricing doctrine, and the *Actavis* decision does not provide that endorsement. At the same time, the Court appears to have made clear that should it be approached with a case involving application of excessive pricing doctrine and should that case involve a patent, the patent will not insulate its owner from analysis under the antitrust laws.<sup>54</sup> In doing so, given the Court’s generally sympathetic view toward the innovation-promoting role of patents, the Court would probably give substantial leeway to the patent owner regarding pricing practices, but this does not mean the patent owner would be accorded a “blank check.” In other words, the *Actavis* decision indicates that the Court has an open mind on the relationship between patents and antitrust law in general. That does not suggest any new approach by the Court specifically regarding excessive pricing doctrine.<sup>55</sup>

A notable recent decision by the California Supreme Court in *In re CIPRO Cases I & II*,<sup>56</sup> is to the same effect regarding patents as *Actavis*, but under

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about its patent did not lead the Court to confer antitrust immunity. Far from it, the agreement was found to violate the Sherman Act. *Id.*, at 380, 72 S. Ct. 350.

*Id.* at 2232.

53. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. at 2232–33.

54. *Id.*

55. The resistance of subordinate courts to placing limitations on drug prices is not to be underestimated. For example, the U.S. Court of Appeals for the Federal Circuit rejected the efforts of the District of Columbia to implement a statute precluding excessive pricing of patented drugs, citing with favor its prior decision which noted that, with respect to patent exclusivity, “the only limitation on the size of the carrot [i.e. the reward of higher prices] should be the dictates of the marketplace.” *See Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1372–73 (Fed. Cir. 2007) (citing *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)).

56. *In re Cipro Cases I & II*, 61 Cal. 4th 116 (2015).

California's antitrust legislation. The California Supreme Court goes a bit further than the U.S. Supreme Court in terms of placing a burden on the patentee-defendant in a reverse payments case to justify its conduct, and perhaps such burden-shifting might be useful in an attack on excessive pricing (i.e. requiring the originator to justify its pricing practices).<sup>57</sup> In other words, if a plaintiff (public or private) establishes a prima facie case that a price is excessive, the burden may shift to the originator patent owner to justify the price as reasonable.<sup>58</sup>

There is no reason in principle why the Sherman Act should not address excessive pricing "as such." In *Standard Oil of New Jersey v. United States*, the Supreme Court identified the underlying motivation for the Sherman Act:

[T]he main cause which led to the legislation was the thought that it was required by the economic condition of the times; that is, the vast accumulation of wealth in the hands of corporations and individuals, the enormous development of corporate organization, the facility for combination which such organizations afforded, the fact that the facility was being used, and that combinations known as trusts were being multiplied, and the widespread impression that their power had been and would be exerted *to oppress individuals and injure the public generally*.<sup>59</sup>

The object of the Sherman Act was to protect the public from the harm that can result from the "oppressive" exercise of monopoly power.<sup>60</sup> The motivation was not a desire to assure competitive supply chains or to allow businesses to compete more fiercely with each other.

The holder of a patent on a unique and important medicine enjoys a monopoly authorized by Congress. But, even though that monopoly may have been acquired by lawful means, this does not mean that it may not be used "to oppress individuals and injure the public generally."<sup>61</sup> Thus, for example, the paradigm case of Gilead's conduct in pricing Sovaldi. The company consciously set out to extract the maximum price at the limits of U.S. budgetary tolerance knowing that to do so would restrict access to the drug and knowing that it would place severe burdens on state public health budgets. It did not invent the drug. It

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57. *See id.*

58. While federal antitrust law does not embrace excessive pricing doctrine, there are state statutes that provide remedies against abusive pricing. This Article does not address those statutes, recognizing that they may play some role in respect to pharmaceutical prices. Moreover, a number of U.S. states have taken action to control drug prices through their authority regarding Medicaid reimbursement and similar programs. These may be alternatives to antitrust approaches. *See, e.g.*, D.C. CODE § 28-4553 (2005) (barred excessive pricing of patented drugs, but was held unconstitutional in *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2005)); FLA. STAT. § 409.91195 (2015) (reduces or offsets state expenditures for Medicaid by giving savings to citizens and providing benefits to manufacturers placed on the "preferred drug list"); 22 ME. STAT. tit. 22, § 2681 (2015) (prohibiting profiteering and excessive pricing by drug manufacturers, enforced by civil penalties).

59. *Standard Oil Co. v. United States*, 221 U.S. 1, 50 (1911) (emphasis added).

60. JÉRÔME MATHIS & WILFRIED SAND-ZANTMAN, INSTITUT D'ECONOMIE INDUSTRIELLE, WELFARE STANDARDS IN COMPETITION POLICY 17 (2015).

61. *Standard Oil Co.*, 221 U.S. at 50.

was engaged in virtually pure financial engineering. Should it not under a rule of reason be required to justify its pricing to the satisfaction of judge and jury?

Under conventional Sherman Act doctrine the acquisition of monopoly power is not in itself unlawful, nor should it be. Monopolization is only unlawful if it is achieved through anticompetitive conduct. But, a monopolist may abuse its monopoly power notwithstanding that the monopoly was lawfully acquired. It may use its monopoly to suppress competition. In *United States v. Microsoft*,<sup>62</sup> Microsoft used its monopoly control over a computer operating system to prevent the emergence of competing technologies.<sup>63</sup> The archetypal bad behavior of the monopolist is to flex its power to block competition, thereby enabling it to charge a price above a competitive market price and to sustain that price over a period of time.

The originator pharmaceutical company has the power to charge a price above a competitive market price (i.e. a generic price) because it is insulated by the market exclusivity granted by a patent. It is a lawfully acquired monopoly. This does not mean, however, that it should be able to flex its market power without attention to the impact on the public. The originator pharmaceutical company has the power to cause real injury by the charging of an excessive price. Why should that conduct be insulated from antitrust scrutiny?

This, of course, takes us back to the reluctance of the federal courts, and competition authorities more generally, to pursue excessive pricing cases on the following grounds: (1) that it is difficult to establish what is a reasonable price and therefore to establish what price might be excessive; (2) that the courts are not constituted as price control administrators; and (3) that Congress has legislated the patent system and has the responsibility for controlling its impact.

In the second part of this Article, the case will be made that it is indeed possible to determine the reasonable price of a pharmaceutical and to establish what price may be excessive. This is not an assessment that will be unique to the United States. As to the perspective that courts are not price control administrators, this view discounts the many ways that court decisions intervene in economic affairs in the United States, including by the assessment of royalty levels in intellectual property disputes. Given that pharmaceutical originators appear to rely on investment bankers for determining the price of their products, as witnessed by the Senate staff report on Gilead, there is no good reason why federal judges and juries cannot weigh in on pricing as well. Indeed, Congress can act to control pharmaceutical prices, but chooses not to do that. However, it has not so far attempted to intervene in the implementation of the Sherman Act, and the federal courts are routinely developing new doctrines and approaches to antitrust matters. The fact that Congress could limit application of the Sherman Act does not preclude the courts from taking a new approach with respect to

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62. *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30 (D.D.C. 2000).

63. *Id.* at 36–37.

excessive pricing. Perhaps Congress would welcome action by another branch, despite its unwillingness to take action on its own.

## 2. *The European Union*

The European Union (EU), through the Commission Competition Directorate and the Court of Justice of the European Union (CJEU), has been somewhat more receptive than the United States to the use of excessive pricing as a competition law doctrine. Yet, the doctrine has been used in a limited number of cases and in a conservative manner. One of the reasons why the EU has been more receptive is that the Treaty on the Functioning of the European Union (TFEU) in its Article 102 regarding abuse of dominant position appears to directly identify excessive pricing as a competition law violation, providing:

### Article 102

(ex Article 82 TEC) Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in:

(a) directly or indirectly *imposing unfair purchase or selling prices* or other unfair trading conditions;<sup>64</sup>

Of course, the terminology “unfair” prices is not identical to “excessive” prices, but, if anything, the former would appear to establish a lower bar for a violation than the latter, since “fairness” can be equated with what reasonable people might expect from a transaction, while “excess” is more suggestive of something extreme or pushing boundaries.

The lead case that establishes the current basis of CJEU doctrine regarding excessive pricing is *United Brands v. Commission* decided in 1978.<sup>65</sup> In this case, the CJEU set out a two-part test for determining whether a price is excessive within the meaning of Article 102 (then Article 86 of the European Community Treaty).<sup>66</sup> The test is elaborated by the Court as follows:

The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under Article 86 [now 102] of the Treaty.

It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.

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64. Treaty on the Functioning of the European Union, art. 102, May 9, 2008, 2008 O.J. (C 115) 47 [hereinafter TFEU] (emphasis added).

65. Case 27/76, *United Brands Co. & United Brands Cont'l B.V. v. Comm'n of the European Cmty.*, 1978 E.C.R. I-207 [hereinafter *United Brands Co.*].

66. TFEU, art. 102.

In this case charging a price which is excessive because *it has no reasonable relation to the economic value of the product supplied* would be such an abuse.

This excess could, *inter alia*, be determined objectively if it were possible for it to be calculated by making a *comparison between the selling price of the product in question and its cost of production*, which would disclose the amount of the profit margin . . . .

The questions therefore to be determined are *whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*<sup>67</sup>

The test as stated by the Court in the final paragraph quoted above is somewhat curious. It first asks whether there is too large a spread between cost and price, and it goes on to ask whether that price is unfair. This leaves open the possibility that there may be an excessive price that is yet fair. This two-part test is difficult to meet. In *United Brands*, the CJEU rejected the Commission's determination of excessive pricing based on inadequacy of evidence, although the defendant was found to have engaged in other competition law violations.<sup>68</sup> Not only must the price be "excessive," but it must be "unfairly excessive."

In *Bodson v. Pompes Funèbres*,<sup>69</sup> a preliminary ruling decided in 1988, the CJEU said that differences between prices charged by exclusive funeral home concessionaires and those not operating under concession could be used as the basis for determining whether the prices charged by the concession holder were fair.<sup>70</sup> In a preliminary ruling in *SACEM*,<sup>71</sup> an action brought by discotheque owners against a French copyright society, the CJEU in 1989 said that significant differences in royalty rates charged in France and other EU member states could form the basis for an excessive pricing action.<sup>72</sup> The Commission successfully secured a settlement undertaking in *Deutsche Post* in 2001 because, *inter alia*, the German postal service had charged mailings coming from the United Kingdom excessive surcharges without justification.<sup>73</sup> In *Port of Helsingborg*, a proceeding decided by the Commission in 2004, the finding was that excessive prices were not charged by a port operator in light of its specific geographic and other circumstances.<sup>74</sup> In *Rambus*, based on its preliminary conclusions the Commission

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67. *United Brands Co.*, 1978 E.C.R. at 301 ¶¶ 248–52 (emphasis added).

68. *Id.* at 285–303.

69. Case 30/87, *Bodson v. Pompes Funèbres des Régions Libérées*, 1988 E.C.R. 2481.

70. *Id.*

71. Case 110/88, *Lucazeau v. Société des Auteurs, Compositeurs et Éditeurs de Musique*, 1989 E.C.R. 2811.

72. *Id.*

73. Commission Decision 36.915, *Deutsche Post AG – Interception of Cross Border Mail*, 2001 (EC).

74. Commission Decision 36.568, *Scandlines Sverige AB v. Port of Helsingborg*, 2004 (EC).



secured a commitment on the limitation of royalties charged in respect to a technical standard.<sup>75</sup> This relatively brief summary of CJEU case law and Commission action as of 2011, the date of the OECD Roundtable, evidences that neither the Commission nor private claimants have commonly pursued competition law actions based on excessive pricing doctrine, notwithstanding that such actions are expressly contemplated by the terms of the TFEU. It is not self-evident from the face of the reported decisions or outcomes that there are insurmountable hurdles to successfully pursuing excessive pricing cases, yet reluctance appears a real phenomenon.

The OECD Roundtable report by the EU competition authorities summarizes the foregoing case history in this way, “The case law . . . shows that the Commission and European Courts addressed the question of excessive prices only in markets with an entrenched dominant position where entry and expansion of competitors could not be expected to ensure effective competition in the foreseeable future.”<sup>76</sup>

The EU report for the OECD went on to say:

In view of the limited experience with cases concerning excessive prices, not all questions can be answered at this stage. At the same time, the relatively small number of cases that we have been able to deal with, may already indicate that addressing excessive prices is an area of antitrust where limited and very cautious intervention is warranted.<sup>77</sup>

Other commentators have confirmed that the EU has approached excessive pricing doctrine cautiously.<sup>78</sup> That said, the EU is more receptive to application of excessive pricing doctrine than the United States. The two-part test elaborated by the CJEU may set a relatively high bar, but there is the prospect for successfully pursuing an excessive pricing action. The Commission has taken a fairly aggressive approach toward anticompetitive practices by the originator pharmaceutical companies, including those involving patent abuse.<sup>79</sup> There may well be an opening for competition actions directed specifically towards excessive pricing.

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75. Commission Decision 36.636, *Rambus*, 2009 (EC).

76. OECD ROUNDTABLE, *supra* note 7, at 317.

77. *Id.* at 321.

78. See generally Damien Geradin, *The Necessary Limits to the Control of “Excessive” Prices by Competition Authorities – A View from Europe* (Oct. 23, 2007) (unpublished paper), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1022678](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1022678).

79. See *Pharmaceutical Sector Inquiry Final Report* at 532 (July 8, 2009), [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf) [<https://perma.cc/RQG9-ZPFH>].

### 3. *Canada and South Africa*

#### a. *Canada*

Canada's Competition Act expressly identifies the unreasonable enhancement of price based on a patent, trademark, copyright, or protected integrated circuit design as a violation, providing:

32. (1) In any case where use has been made of the exclusive rights and privileges conferred by one or more patents for invention, by one or more trade-marks, by a copyright or by a registered integrated circuit topography, so as to . . .

(c) prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity *or unreasonably enhance the price thereof*, . . .

the Federal Court may make one or more of the orders referred to in subsection (2) [including voiding an agreement, preventing carrying out of the terms, revoking a patent, the registering other IP forms, or such other remedies as deemed necessary] in the circumstances described in that subsection.<sup>80</sup>

In addition, Canada's Patented Medicines Price Review Board specifically addresses excessive pricing and has the power to order price reductions.<sup>81</sup>

#### b. *South Africa*

South Africa's Competition Act<sup>82</sup> expressly identifies the charging of an excessive price as a competition law violation, providing:

##### 1. Definitions and interpretation

(1) In *this* Act -

. . . .

(ix) 'excessive price' means a price for a good or service which -

(aa) bears no reasonable relation to the economic value of that good or service; and

(bb) is higher than the value referred to in subparagraph (a);

. . . .

##### 8. Abuse of dominance prohibited

It is prohibited for a dominant *firm* to -

(a) charge an *excessive* price to the detriment of consumers;<sup>83</sup>

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80. Canada Competition Act, R.S.C. 1985, c C-34 (Can.).

81. See Joel Lexchin, *Drug Pricing in Canada*, in PHARMACEUTICAL PRICES IN THE 21ST CENTURY, *supra* note 5, at 25, 25-41.

82. Competition Act 89 of 1998 § 1 (S. Afr.).

83. *Id.* at 21 (emphasis added).

The South African report for the Roundtable indicates that the excessive pricing provision of the Competition Act is based on the two-part test developed by the CJEU in the *United Brands* case.<sup>84</sup>

It is noted that there have been six cases brought before the Competition Tribunal alleging abuse of dominance by excessive pricing.<sup>85</sup> From the standpoint of originator pharmaceutical pricing, the most notable is a case initiated before the Competition Commission involving access to HIV-AIDS antiretroviral medicines.<sup>86</sup> The Commission issued a terse determination stating that the patent holders of certain antiretroviral medicines had engaged in excessive pricing under the Competition Act, had refused access to essential facilities, and had engaged in exclusionary conduct.<sup>87</sup> It referred the matter to the Competition Tribunal for an order granting a compulsory license for the production of generic medicines in return for a reasonable royalty.<sup>88</sup> The complaint-against companies settled the matter by granting voluntary licenses enabling generic production.<sup>89</sup>

The South African Competition Commission has successfully secured a number of settlement undertakings based on allegations of excessive pricing. The report for the OECD Roundtable notes that all but the pharmaceutical case have involved former state-owned enterprises.<sup>90</sup> In a major case litigated through the Competition Tribunal to the Competition Appeals Court (CAC), the CAC rejected the methodology used by the Tribunal to establish excessive pricing, holding that it did not properly account for long-run equilibrium pricing factors, and referred the matter back for further proceedings.<sup>91</sup>

#### 4. General Provisions

The competition laws of most countries make abuse of dominant position an offense, and among the types of offense that may be considered are abuses relating to price.<sup>92</sup> In that regard, a specific legislative provision identifying “excessive pricing” or unfair pricing is not a prerequisite to actions involving the charging of excessive prices.<sup>93</sup> The OECD Roundtable report makes clear that, so

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84. See *United Brands Co.*, *supra* note 65; see also OECD ROUNDTABLE, *supra* note 7, at 363 (South Africa).

85. OECD ROUNDTABLE, *supra* note 7, at 363–73.

86. See Jonathan Berger, *Market Definition*, in USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW-AND MIDDLE-INCOME COUNTRIES 96, 99–122.

87. Sean Flynn, *Comparative Perspectives Through Country Case Studies*, in USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES 24.

88. *Id.*

89. OECD ROUNDTABLE, *supra* note 7, at 363.

90. *Id.* at 364.

91. *Id.* at 365.

92. See *id.* at 317.

93. See *id.* at 9.

far, excessive pricing doctrine has been used in a limited way, and that competition authorities have generally resisted use of the doctrine because of uncertainties concerning how it should be applied and how actions will ultimately be reviewed by the courts.<sup>94</sup> Yet, there is no indication of countries that have rejected the doctrine outright, with the possible exception of the United States where, so far, the federal courts have not been willing to entertain antitrust actions based on excessive pricing “as such,” as compared with excessive prices standing as evidence of anticompetitive abuse.<sup>95</sup>

This Article is not directed toward price control mechanisms used by governments to control pharmaceutical prices that do not involve application of competition law. There are many such mechanisms in place around the world and a substantial literature addressing those mechanisms.<sup>96</sup>

### C. *The Need for Change*

Because of their long history in developing and applying antitrust and competition law, the United States and European Union have been traditionally looked to for leadership in the development and application of competition and antitrust law. There is, however, a significant movement among emerging markets and other developing countries toward developing and applying competition law,<sup>97</sup> and among OECD countries others specifically address excessive pricing in their legislation and judicial doctrine.<sup>98</sup> This Article encourages the further development and application of excessive pricing doctrine among all competition authorities and courts.

Current antitrust doctrine is not well suited to address the pharmaceutical sector. It fails to take into account the special characteristics of the sector. Originator pharmaceutical products are typically protected by patents that afford a statute-based monopoly. U.S. antitrust law *ab initio* effectively provides an exemption for monopolists who acquired their position lawfully. It is not illegal to be a monopolist. It is illegal to acquire a monopoly using unlawful means.

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94. *See id.*

95. David S. Evans & A. Jorge Padilla, *Excessive Prices: Using Economics to Define Administrable Legal Rules 2* (CEMFI, Working Paper No. 0416, 2004), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=620402](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=620402).

96. *See* PHARMACEUTICAL PRICES IN THE 21ST CENTURY, *supra* note 5.

97. *See, e.g.*, PROCEEDINGS OF CONFERENCE ON ANTITRUST IN EMERGING AND DEVELOPING ECONOMIES: AFRICA, BRAZIL, CHINA, INDIA, MEXICO, Concurrences Review and NYU Law School, New York (2015); AJIT SINGH, *Competition and Competition Policy in Emerging Markets: International and Developmental Dimensions*, in GROWTH & ECONOMIC DEVELOPMENT (Philip Arestis et al. eds., 2006); OECD, IMPLEMENTING COMPETITION POLICY IN DEVELOPING COUNTRIES (2007); Bernard Hoekman & Peter Holmes, *Competition Policy, Developing Countries and the WTO*, in 22 WORLD ECON. 6, 875 (2002); cases cited in UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW-AND MIDDLE-INCOME COUNTRIES, *supra* note 12.

98. *See* OECD ROUNDTABLE, *supra* note 7.

Monopolists may abuse their power by engaging in practices deemed anticompetitive. Generally speaking, charging a high price is not considered anticompetitive. In fact, the federal courts have tended to view high prices as *pro*-competitive in so far as they encourage market entry by third parties seeking to take advantage of the consumer demand for lower-priced versions of the same products.<sup>99</sup> Thus, a virtuous cycle arises in which attempts to extract producer surplus lead to dissipation of that surplus.

Originator pharmaceutical products protected by patent and regulatory marketing exclusivity may reflect circumstances that are not subject to the virtuous cycle; or at least not within a timeframe suitable for consumer/patients and public health budgets. New drugs that treat previously untreatable diseases, or treat them in a significantly better way, will be demanded by patients regardless of their price. The drugs are not subject to price elasticity in the same way as virtually any other goods. If the maker of a breakthrough television sets a price far above those of existing/ordinary television sets, only consumers with high levels of readily disposable income will buy them. Others will find a way to manage without better TV quality. That is not the case with drugs essential to life and well-being.

As the courts have pointed out, higher than competitive market prices—enabled by pharmaceutical patents—provide a basis for continuing investment in necessary R&D.<sup>100</sup> There are certainly other ways that pharmaceutical R&D could be managed and/or encouraged, and there are other ways that R&D takes place. But, this Article is not arguing for a change in the basic idea of pharmaceutical patents as incentives for R&D.

Yet, with all that said, there remains the patented pharmaceutical for which an excessive price is demanded based on the monopoly granted by the patent. Certainly no one would argue that patients should wait until the end of the effect of a patent term for treatment—ten or fifteen years depending on the period of effective exclusivity. The argument instead is that competing therapies will enter the market and bring prices down. So, even in the paradigm case of Sovaldi, prices have fallen. But, prices have not fallen so far as to make the therapeutic class accessible. Furthermore, the class of hepatitis C antivirals treats a large number of patients, providing opportunity for very significant profit even at somewhat lower prices. For drugs treating more rare forms of cancer, blood disease, and other conditions, prices may fall more slowly even with the introduction of competitive therapies.

What about the cases of generic producers enjoying “effective monopolies” because they are the last of the remaining suppliers?<sup>101</sup> There are a good number of recent incidents of very large price increases involving these circumstances. Is

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99. Carole E. Handler & G. Michael Halfenger, *High Court Rulings Have Limited Antitrust Liability*, LAW360 (Aug. 28, 2007, 12:00 AM), <http://www.law360.com/articles/33552/high-court-rulings-have-limited-antitrust-liability> [<https://perma.cc/8T5T-9G49>].

100. *Id.*

101. *See* sources cited *supra* note 4.

the theory that the public must wait for Congress to legislate against large price increases by generic producers? Will that happen? It has not happened yet. Should there not be some form of legal action that can be pursued by state health authorities, health insurers, and/or the public more generally? Why not excessive pricing under the antitrust law?

The arguments against application of excessive pricing doctrine are essentially arguments against government interference in the free market. But, no market is “less free” than the pharmaceutical market. It is regulated every step of the way, except in the United States with respect to prices. And it is somewhat odd to argue that patent owners protected by legislative monopolies are pricing in a freely competitive market. It is obvious that they are not.

In the *Trinko* case, Justice Scalia was writing in the context of telecommunications pricing.<sup>102</sup> The telecommunications carrier may be able to charge a higher than market price for a limited period of time and that may be a suitable reward for telecommunications innovation.<sup>103</sup> Call that the genius of the free market. But, should we transpose a decision involving telecommunications to life-saving pharmaceutical therapies? This is where the problem of the focus on supply market characteristics in antitrust law becomes problematic. There may not be specific constraints imposed on suppliers of patented pharmaceutical products, other than the patents themselves. But the injury to consumers is potentially great, and the patent is an obstacle to the consumer as well as to competing suppliers.

This is not an argument against patents. It is an argument against using patents as a basis for charging excessive prices. It is an argument that even in the context of patent protected pharmaceuticals there is such a thing as a “reasonable price” and, conversely, an “excessive price.” It is an argument in favor of returning to the original objective of the Sherman Act: protection of the public.

That brings us to the second question, is it feasible to determine what constitutes a reasonable price? There is much argument by the pharmaceutical industry that the cost of developing a new drug is incalculable or, at the least, so high that we should not even inquire about how prices are determined. This argument does not survive close scrutiny, taking us to Part II of this Article.

## II. THE EXCESSIVE PRICING DETERMINATION

As the Court of Justice of the European Union concluded in the *United Brands* decision, the logical starting point for determining whether the price of a product is unfair is the manufacturer’s cost of making the product.<sup>104</sup> Once the cost is determined, the differential between cost and price can be identified and a determination made as to whether that differential is “excessive.”<sup>105</sup>

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102. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. at 398.

103. *Id.* at 398–99.

104. See *United Brands Co.*, 1978 E.C.R. at 301 ¶ 251.

105. *Id.* at 301 ¶ 252.

In the case of originator pharmaceutical products, the cost must include the R&D that goes into discovery and refinement of the product, including the cost of clinical assessment. Because securing marketing approval for a pharmaceutical product involves trial and error, account reasonably must be taken of failures along the path to success. In other words, the cost of developing and approving a new product must include a risk factor. The originator pharmaceutical industry suggests that when these factors are taken into account, it is unreasonable to inquire as to the cost of a particular new pharmaceutical product. For reasons discussed below, this is not a compelling argument.

Nonetheless, it is worthwhile to note at the outset that there are alternative methodologies for determining whether a price is excessive, even if those methodologies are not as direct as the cost/price methodology. For example, governments outside the United States routinely determine what they are willing to pay for originator pharmaceutical products based on comparative pricing across baskets of countries.<sup>106</sup> This is called “reference pricing.” This type of methodology has been used by the Court of Justice of the European Union and the Commission in assessing prices in various cases, including the *Port of Helsingborg* case.<sup>107</sup> While this methodology may provide a relatively straightforward and transparent basis for excessive pricing determinations based on discrimination across markets, it is not preferable to the cost versus price approach. It is entirely possible that the lowest baseline price (or the average) among a basket of markets is excessive, not least in the case of originator pharmaceutical products.<sup>108</sup>

The pharmaceutical industry prefers that discussions about price be based on the “value” to healthcare systems in terms of alternatives.<sup>109</sup> For example, without

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106. See sources cited *supra* note 5.

107. *Scandlines Sverige AB v. Port of Helsingborg*, Commission of the European Communities, 48 (July 23, 2004).

108. The most commonly used method of calculating a fair pharmaceutical price is “reference pricing.” This involves using the prices from a basket of countries, typically at a similar level of development to take into account income levels, in order to determine what might be a general market value. This methodology has obvious limitations in terms of ascertaining whether the price in a particular market is “excessive” because it assumes that the average price across markets is reasonable. In the case of originator pharmaceutical products, where markups are often thousands of percent above production costs, the fact that a new drug may be sold for only several thousand percent above production costs does not imply that the drug price is reasonable.

Nonetheless, to the extent that prices of originator pharmaceutical products in Europe or Canada may well be fifty percent lower than prices in the United States, an antitrust inquiry might well ask what justifies the price differential. The industry answers the lower price in Europe or Canada reflects price controls. But, it also suggests that the originator industry makes a decent profit at the lower price, raising the question of why it is necessary to double the price in the United States market. In other words, is the price discrimination justifiable?

109. This may technically be within the discipline of “pharmacoeconomics,” or comparing the value of one drug or therapy to another, or may generally look to health economics and the overall savings as compared to healthcare alternatives. From the standpoint of a public health system, it makes sense to ask whether buying a particular pharmaceutical product will save money as compared with alternative patient outcomes in making a determination whether to buy a drug. If

treatment by a new drug, a patient would develop symptoms, visit doctors, be subject to tests, be admitted to a hospital, become disabled, and potentially die. The cost of hospitalization can be quite high, and the price of hospitalization for an extended period can run into the millions of dollars. Therefore, in “value” terms based on alternatives, even a high-priced medicine may be a “bargain.”

This type of value assessment is essentially a “hostage” bargaining model.<sup>110</sup> The drug is under the control of the monopoly patent owner, and the price of ransoming the drug is whatever the party seeking to obtain it can pay. If the ransom is not paid, the consequences may be terrible, and in that regard the ransom can be characterized as a bargain. But it is only a bargain because of the threat. A similar “value proposition” could be worked out for virtually any essential product.<sup>111</sup> Water is often “largely free,” but if water is withheld from a person for several days, that person will die. In that context, it may seem quite reasonable to demand a large payment for water because of its value. But, there is no reasonable relationship between the cost of water and the ransom price. Indeed, it is possible to spin out any number of scenarios in which the value of a product or service might be quite high under the threat of being withheld, but only because of the threat.<sup>112</sup> That does not make that value reasonable.

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purchasing a drug for \$100,000 will prevent the expenditure of \$2 million in hospitalization costs, it makes sense from the health system perspective to purchase the drug. Yet, this really says little about whether the \$100,000 price for the drug is a reasonable one. If the R&D and production costs combined for the drug are \$10,000, is it reasonable to pay the originator another \$90,000 so that profits are enhanced, advertising is increased, executive salaries are boosted, and dividend payouts increase? Pharmaceutical originator R&D budgets are about fifteen percent of annual expenditures, so some pricing increment should reasonably be added into the pricing equation for future R&D, but there remains another eighty five percent to be accounted for. The problem, again, is that from the standpoint of the consumer-patient, paying the high price is not optional to the limits of available financial resources. The pharmaceutical company prices the drug at a very high level “because it can,” not because of financial need.

110. Michelle Chen, *Patents Against People: How Drug Companies Price Patients Out of Survival*, DISSENT MAG. (Fall 2013), [www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival](http://www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival) [https://perma.cc/864N-46E5].

111. See generally Per Skälén et al., *Exploring Value Propositions and Service Innovation: A Service-Dominant Logic Study*, 43 J. ACAD. MARKETING SCI. 137, 137–58 (2015).

112. This type of question could be posed with respect to any situation in which a consumer is confronted with a time-sensitive demand and as to which failure to fulfill the demand may lead to substantial adverse consequences. Imagine a consumer preparing to board an airplane to attend an important business meeting in a faraway city. An airline representative says, “I am sorry but we cannot allow you to board this flight with your current ticket. Our database research shows that you are going to present a proposal that may lead to a very large contract for your employer, and we do not believe that we are being fairly compensated for our side of getting you to your meeting. So, you can only board the aircraft if you agree to pay us ten times the current price of your ticket because the value to you of getting to your meeting is much higher than that.”

If your intuition is that this is an abusive pricing practice, what is your intuition about a drug company that says: “You have a fatal illness. If left untreated, you will be hospitalized for a period of months, if not years, attended to by nursing staff and doctors, and prescribed palliative medications. This will cost a great deal of money, which either you or your health insurer will pay. So, we have decided to charge you for this new medicine an amount somewhat lower than the total cost of the



Another method for determining whether a price is excessive, an alternative type of reference pricing, is to compare the prices demanded by originators with prices established between monopsony purchasers (e.g., government health programs) and monopoly suppliers (i.e., originator suppliers) where such procurement arrangements are in place.<sup>113</sup> Even though this method does not examine the direct costs of creating and producing a drug, it may reveal the “best available” bargained price since the monopsony purchaser is presumed to have the greatest leverage in negotiations with the supplier.

This Article focuses on cost/price methodology because it is the most direct methodology for determining the profit of the supplier and therefore the most reasonable way to determine whether the price is higher than it should be.

### A. The Cost of a Drug

#### 1. The Present Indeterminate State

The cost of researching and developing originator pharmaceutical products is deliberately shrouded in mystery.<sup>114</sup> The originator pharmaceutical industry has aggressively resisted providing data regarding its R&D costs. This resistance traces back as early as the 1950s U.S. Senate investigations into pharmaceutical pricing in

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treatment you would receive if your disease were allowed to progress to its final stage; at which point you will die. Under these circumstances, do you not think our price fair?”

113. Peter Drahos has pointed out that the Australian Pharmaceutical Benefit Scheme considers that a reasonable price may be identified by observing the results of bargaining between a monopoly supplier and a monopsony purchaser. Email from Peter Drahos, Professor, Austl. Nat’l Univ., to author (Sept. 26, 2015). This is an alternative to a cost-plus approach, and it is a methodology for establishing price that has been strongly resisted by the pharmaceutical industry, as in the ban on government price negotiating in the U.S. Medicare Part D legislation. JIM HAHN, CONG. RESEARCH SERV., RL33782, FEDERAL DRUG PRICE NEGOTIATION: IMPLICATIONS FOR MEDICARE PART D, 1 (2007). Nonetheless, neither a bargaining among monopolists nor a reference price approach is likely to yield a price based on the true costs of R&D. This methodology presumes that the bargaining power of the monopsony purchaser counterbalances the exclusivity power of the monopoly supplier, resulting in a “more fair” price. In the United States, for example, the Veterans Administration has typically negotiated substantially lower prices with the originator companies than private health insurers because of its very large purchasing power and control patient market. *See id.* at 4–5.

114. *See* Arthur Daemrich, *U.S. Healthcare Reform and the Pharmaceutical Industry* 11–12 (Harvard Bus. Sch., Working Paper No. 12-015, 2011); Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 *BIOsocieties* 34, 36–38 (2011); F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals* (Harvard Kennedy Sch. Faculty Research, Working Paper Series No. RWP11-046, 2011); F.M. Scherer, *The Pharmaceutical Industry*, in 1 *HANDBOOK OF HEALTH ECONs.* 1298 (A.J. Culyer & J.P. Newhouse eds., 2000); MARTIJN BROEKHOF, CMTY. RESEARCH CENTRE ECONs., UNIV. OF GRONINGEN, *TRANSPARENCY IN THE PHARMACEUTICAL INDUSTRY: A COST ACCOUNTING APPROACH TO THE PRICES OF DRUGS* (2002); Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 *HEALTH ECON.* 130 (2010); Donald W. Light & Joel R. Lexchin, *Pharmaceutical Research and Development: What Do We Get for All that Money?*, *BRITISH MED. J.*, August 2012, at 1, 1–5, <http://www.bmj.com/content/345/bmj.e4348>.

the United States,<sup>115</sup> has manifested itself in litigation in countries as diverse as South Africa and India,<sup>116</sup> and continues to this day as reflected in Gilead's refusal to provide R&D data to the U.S. Senate in response to a request from the Finance Committee.<sup>117</sup> The industry defends its refusal to provide data on various grounds, such as problems that would arise from providing data to competitors and difficulties of disaggregating costs for particular drugs.<sup>118</sup>

Some originator companies in the United States have cooperated with a group of academic researchers based at Tufts University in providing select data, and the main aggregate numbers used by the Pharma industry to portray the costs of new drug R&D are sourced from reports issued by Tufts.<sup>119</sup> The methodology used by the Tufts-based research team has been criticized on various grounds, including for the inclusion of imputed costs of capital (and the rates at which costs of capital are calculated).<sup>120</sup> In addition, the results are criticized because of a lack

115. See *Subcommittee Investigates Drug Prices*, in CQ ALMANAC 1960, at 11-743 to 11-749 (16th ed., 1960), <http://library.cqpress.com/cqalmanac/cqal60-880-28173-1331186> [<https://perma.cc/A6P4-42XQ>].

116. The author of this Article served as legal consultant to the government of South Africa during the litigation brought by thirty-nine originator pharmaceutical companies to challenge provisions of the Medicines and Related Substances Control Amendment Act of 1997. During the trial before Judge Nwepe of the Pretoria High Court, the government requested that the originator companies justify their claim for high antiretroviral prices with data concerning their R&D costs. Counsel for the companies refused on grounds that assembling such data would be overly time-consuming. The case settled shortly thereafter with dismissal of the complaint by the originator companies and payment of the government's legal fees. See Notes of Frederick M. Abbott on Pretoria litigation, 2001, (on file with author).

The decision by the India Controller of Patents in the matter of the application of the generic company Natco for a compulsory license to produce the Bayer cancer drug Nexavar reaffirmed the continuing refusal of the originator industry to provide meaningful data with respect to the R&D costs on an important treatment. See *Natco Pharma Ltd. v. Bayer Corp., Compulsory License Application No.1/2011* (Controller of Patents, Mumbai, Mar. 9, 2012), [http://www.ipindia.nic.in/ipoNew/compulsory\\_License\\_12032012.pdf](http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf) [<https://perma.cc/Q9PC-7J9N>]. Bayer relied on general data reported with respect to its overall R&D costs and did not attempt to explain the specific methodology by which Nexavar was priced for the Indian market.

117. See SOVALDI STAFF REPORT, *supra* note 2, at 3.

118. See BROEKHOF, *supra* note 114, at 36.

119. See PHARM. RESEARCH & MFRS. OF AM., 2015 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 13 n.8 (2015) ("It takes at least 10 years and an average of \$2.6 billion to develop and bring a new FDA-approved medicine to market.") (citing to the 2014 Tufts data for the proposition); JOSEPH A. DIMASI, TUFTS CTR. FOR THE STUDY OF DRUG DEV., COST OF DEVELOPING A NEW DRUG, slide 8 (Nov. 18, 2014), [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18\\_2014.pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18_2014.pdf) [hereinafter DIMASI, COST OF DEVELOPING A NEW DRUG]; Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107, 107-08 (1991); Joseph A. DiMasi & Henry G. Grabowski, *R&D Costs and Returns to New Drug Development: A Review of the Evidence*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 21, 23 (Patricia M. Danzon & Sean Nicholson eds., 2012).

120. Subsequent to the release of the most recent Tufts study, the Union for Affordable Cancer Treatment transmitted a request to the lead author, Joseph DiMasi, Center for the Study of Drug Development (Feb. 3, 2015), [http://csdd.tufts.edu/files/uploads/UACTLetterDiMasi\\_Feb2015.pdf](http://csdd.tufts.edu/files/uploads/UACTLetterDiMasi_Feb2015.pdf) [hereinafter Union for Affordable Cancer Treatment Letter]. For the lead author's response, see Response of Joseph DiMasi, Center for the Study of Drug Development, to Union

of transparency regarding the underlying data used by the researchers.<sup>121</sup> The most recent report of results provides both “out-of-pocket” and “capitalized” cost results, so that those objecting to the inclusion of imputed capital costs can view the direct expenditure approach.<sup>122</sup> The November 2014 Tufts estimate of R&D costs for a new prescription drug in 2013 was \$2.558 billion using capitalized costs and \$1.395 billion using out-of-pocket costs.<sup>123</sup>

Doctors Without Borders has strongly criticized the results of the Tufts study on grounds that it has been demonstrated that new drugs can be developed for as little as \$50 million, or up to \$186 million if you take failure into account. Doctors Without Borders observes that “these figures are nowhere near what the industry claims is the cost,” including by reference to a leading industry figure who has portrayed the higher numbers as mythological.<sup>124</sup> At the aggregate level, there is a great deal of controversy regarding the cost of developing a new drug. That said, the Tufts researchers do not purport to provide cost data regarding specific drugs or classes of drugs.

A major contribution of antitrust/competition litigation directed toward excessive pricing would be to require the originator industry to provide concrete

for Affordable Cancer Treatment (Mar. 2, 2015), [http://csdd.tufts.edu/files/uploads/DiMasi\\_Response\\_to\\_UACT.pdf](http://csdd.tufts.edu/files/uploads/DiMasi_Response_to_UACT.pdf) [<https://perma.cc/YN2J-WU4K>]. See also JAMES LOVE, CONSUMER PROJECT ON TECH., EVIDENCE REGARDING RESEARCH AND DEVELOPMENT INVESTMENTS IN INNOVATIVE AND NON-INNOVATIVE MEDICINES, 3–6 (2003); BOB YOUNG & MICHAEL SURRESCO, PUB. CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY’S R&D “SCARE CARD” 2–4 (2001); Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POL’Y 4, 11 (2011).

121. See, e.g., Union for Affordable Cancer Treatment Letter, *supra* note 120; Bruce Booth, *A Billion Here, A Billion There: The Cost of Making a Drug Revisited*, FORBES: PHARMA & HEALTHCARE, (Nov. 21, 2014, 9:48 AM), <http://www.forbes.com/sites/brucebooth/2014/11/21/a-billion-here-a-billion-there-the-cost-of-making-a-drug-revisited/#2715e4857a0b605a33e032ca> [<https://perma.cc/EP53-WCAE>]. The methodologies used at Tufts also were the subject of a study of pharmaceutical R&D costs by the federal Office of Technology Assessment in 1993, which generally supported the methodology used by Tufts. A principal author of the Tufts study was included among the experts working on that report. See U.S. CONG. OFFICE OF TECH. ASSESSMENT, OTA-H-522, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993).

122. In the 2014 results, the capitalized costs for a new drug compound are reported at \$2.558 billion, while the out-of-pocket costs are stated at \$1.395 billion. See DIMASI, COST OF DEVELOPING A NEW DRUG, *supra* note 119, at slide 21. The large difference explains why critics of the Tufts methodology have pointed to the use of capitalized costs as raising serious issues. This author does not agree with the inclusion of imputed cost of capital since the originator companies are capitalized by equity investors who are bearing the risk of investment, and are not (or do not need to be) borrowing money from financial institutions in order to conduct R&D. To this author, inclusion of imputed cost of capital effectively double-counts the investment.

123. *Id.*

124. See Rohit Malpani, *R&D Cost Estimates: MSF Response to Tufts CSDD Study on Cost to Develop a New Drug*, DOCTORS WITHOUT BORDERS (Nov. 18, 2014), <http://www.doctorswithoutborders.org/article/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug> [<https://perma.cc/8BLY-AZSX>] (“The pharmaceutical industry-supported Tufts Center for the Study of Drug Development claims it costs US\$2.56 billion to develop a new drug today; but if you believe that, you probably also believe the earth is flat. GlaxoSmithKline’s CEO Andrew Witty himself says the figure of a billion dollars to develop a drug is a myth; this is used by the industry to justify exorbitant prices.”).

data regarding the cost of R&D on individual drugs that are subject to assessment. To be clear, this does not mean that the methodology for determining whether the price of a new drug is excessive should not take into account risk that may be associated with failures bearing a reasonable relationship to an individual success.

## 2. *Access to Data*

Using the United States as an example, it is not clear why greater demand has not been made by government authorities for access to direct data regarding the cost to industry of developing new pharmaceutical products. This would not be a “philosophical question.” The U.S. Government is a major funding source for industry R&D (inter alia, directly and indirectly through the National Institutes of Health (NIH)), and the federal government is a very significant purchaser of drugs from the originator industry (through, inter alia, the Veterans Administration and indirectly through its Medicare and Medicaid programs).<sup>125</sup> In the early 1980s, the Government Accountability Office (GAO) pursued cost data from the originator industry, and the Supreme Court weighed in on the side of the originator companies that refused to provide it based on limiting language in the statute authorizing certain GAO audits.<sup>126</sup> Other statutory authority may be available to agencies such as the NIH to investigate drug pricing,<sup>127</sup> but agencies have not been inclined to use this investigative authority.<sup>128</sup> There is no question that Congress has the power to subpoena pricing data from the pharmaceutical companies. But, Congress has chosen not to use its subpoena power, relying instead on less formal “requests.”<sup>129</sup> Part of the congressional reluctance appears to arise out of conflict between the political parties. However, in connection with recent investigations into large price increases by certain generics companies, there

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125. See HAHN, *supra* note 113, at 4.

126. See *Bowsher v. Merck & Co.*, 460 U.S. 824, 844–45 (1983).

127. For example, NIH could use its authority under the march-in rights provision of the Bayh-Dole Act, but has refused to do so. See FRANCIS S. COLLINS, NAT’L INSTS. OF HEALTH, OFFICE OF THE DIR., DETERMINATION IN THE CASE OF NORVIR® MANUFACTURED BY ABBVIE 4 (2013), <https://www.otn.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf> [<https://perma.cc/5C8K-H36B>]; Michael Mezher, *Lawmakers Urge HHS to Exercise ‘March-in’ Rights to Fight Higher Drug Costs*, REG. AFF. PROFS. SOC’Y (Jan. 11, 2016), <http://www.raps.org/Regulatory-Focus/News/2016/01/11/23878/Lawmakers-Urge-HHS-to-Exercise-March-in-Rights-to-Fight-Higher-Drug-Costs/#sthash.1sHX4XKL.dpuf>.

128. The FDA has taken the position that it does not have the authority to investigate drug prices and sympathetically refers online inquirers to the Federal Trade Commission. See *Frequently Asked Questions About Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082690.htm#5> [<https://perma.cc/835R-WHIV6>] (last updated Nov. 27, 2015).

129. While various Congressional committees have conducted inquiries into pharmaceutical pricing, including inviting senior pharmaceutical company officials to testify under oath, they have not generally subpoenaed documents from pharmaceutical companies. See U.S. CONG. OFFICE OF TECH. ASSESSMENT, OTA-H-522, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993).

have been federal subpoenas issued by prosecutors, though apparently not emanating from Congress.<sup>130</sup>

A lack of transparency regarding originator pharmaceutical research is not limited to cost data. Independent researchers have for a good number of years sought to improve access to clinical trial data for a variety of public-interest purposes, such as to verify risks of potential side effects.<sup>131</sup> And, in recent years there has been considerable controversy regarding apparent conflicts of interest with respect to clinical trial “outside” expert reviewers.<sup>132</sup>

Lack of access to data regarding R&D costs is a well-known problem. The Council of Europe recently adopted a resolution regarding public health and the pharmaceutical sector in which it demands greater transparency with respect to pharmaceutical R&D expenses.<sup>133</sup> The resolution provides, “6.2. with regard to research and development for new therapeutic molecules, to: 6.2.1. oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion.”<sup>134</sup>

In a report prepared by the Rapporteur for the Parliamentary Assembly of the Council of Europe, concerns about data regarding R&D are echoed.<sup>135</sup>

With respect to data, the idea that originator companies do not know their R&D costs, including regarding specific drugs or drug candidates, defies common sense. Enterprises in this industry must keep track of their expenses. Otherwise,

130. See Cordeiro & Kitamura, *supra* note 4.

131. See, e.g., Tracy R. Lewis et al., *The Case for Public Funding and Public Oversight of Clinical Trials*, *ECONOMISTS’ VOICE*, 2007, at 2; Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach. Law: From Private to Public Good?*, 13 *MARQ. INTELL. PROP. L. REV.* 3, 48–52 (2009).

132. See *INST. OF MED. OF THE NAT’L ACADS., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE* 101–02 (Bernard Lo & Marilyn J. Field eds., 2009); Ed Silverman, *Did Researcher Conflicts Influence Evidence for Studies of Flu Drugs?*, *WALL ST. J.: PHARMALOT BLOG*, (Oct. 7, 2014, 1:32 PM), <http://blogs.wsj.com/pharmalot/2014/10/07/flu-drug-study-sees-ties-between-pharm-cos-and-researchers-positive-findings>.

133. EUR. PARL. DOC., *Resolution 2071*, 30th Sitting (2015) ¶ 1.

134. *Id.*

135. EUR. PARL. DOC., *Public Health and the Interests of the Pharmaceutical Industry: How to Guarantee the Primacy of Public Health Interests?*, Doc. No. 13869 (2015) ¶¶ 36–37.

[T]he cost of R&D is somewhat controversial, not only because it is never revealed in detail and it is impossible to verify the accuracy of the figures given, but also because often it does not take into account public-sector funding and also includes opportunity costs, that is what the company could have hoped to obtain by investing elsewhere than in R&D, for example on the stock market. As for public-sector research, this was traditionally limited to basic research, namely clarifying the mechanisms underpinning diseases and identifying promising intervention points. Today it also plays an ever growing role in “applied” research, which leads to the discovery of medicines to treat diseases. A study published in the United States in 2011 found that in the last 40 years, a total of 153 new drugs, vaccines or new indications for existing drugs had been discovered through research carried out by public-sector research institutes. More than half of these drugs had been used in the treatment or prevention of cancer or infectious diseases. Similarly, in the European Union, 44% of innovative medicines recommended for marketing authorisation [sic] between 2010 and 2012 originated from small or medium-sized enterprises, academia, public bodies and public-private partnerships.

planning and budgeting would be infeasible. Company financial planners must allocate a certain amount of funding for the various costs involved. It is implausible that financial controllers provide “blank checks” to research departments and do not examine expenditures. In short, while there may be a level of uncertainty regarding R&D costs, for the companies this is not a “black box.”

In addition, firms in the investment banking and merger and acquisition areas have fairly refined analytic tools used to calculate the future expected earnings of their subject clients and targets.<sup>136</sup> Pfizer may not be inclined to provide access to its data to the GAO or to public health NGOs, but it likely provides fairly significant access to J.P. Morgan Chase, Goldman Sachs, and Morgan Stanley. The Senate Staff Report regarding Gilead and Sovaldi suggests that Gilead provided significant amounts of data to its investment bankers and pharmaceutical pricing consultants.<sup>137</sup> The investment bankers are almost certainly under obligations of confidentiality and in any case may not have an interest in challenging the cost structures reported by the client/target companies, such as by questioning executive salaries, administrative expenditures, legal fees, and the like. But, in matters such as mergers and acquisitions, their buying and selling clients must take an interest in the cost structure of the businesses involved. The point is that while the originator industry may not make its R&D costs available to the public or the government at a “granular level,” it may well supply that data to others.

Securing hard data directly from the originator industry is the preferable way for determining R&D costs. Nonetheless, there are alternative routes for securing relevant data, though perhaps less robust. These include: (1) assessing the cost of acquiring R&D and/or business entities engaged in R&D (discussed further below); (2) using costs reported to tax authorities; and (3) examining data provided to securities exchange officials (e.g., the U.S. Securities and Exchange Commission) for public securities filings.

### 3. Basic Principles of Cost Assessment

A determination of the cost of a new drug is only relevant in the excessive pricing context if the R&D project has been successful. It is a retrospective exercise. Risk and failure are relevant. It is appropriate to account for expenditures on reasonably related R&D investments on the path to a successful result. But, because establishing cost starts from a known endpoint, it should not involve significant speculation. The fact that there may be greater overall risk of R&D in the pharmaceutical sector than in some other sectors may justify a higher profit

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136. David Biello, *Can Math Beat Financial Markets?*, SCI. AM., Aug. 16, 2011, <http://www.scientificamerican.com/article/can-math-beat-financial-markets>; Gary Stix, *Trends in Economics: A Calculus of Risk*, SCI. AM., Sept. 15, 2008, <http://www.scientificamerican.com/article/trends-in-economics-a-calculus-of-risk>. *But see* Dion Harmon et al., *Anticipating Economic Market Crises Using Measures of Collective Panic*, PLOS ONE, July 2015, at 1, 1.

137. *See* SOVALDI STAFF REPORT, *supra* note 2, at 13–25.

margin with respect to an ultimately approved product, but that margin should still bear a reasonable relationship to the enterprise cost of developing it. It should not be “excessive.”<sup>138</sup>

#### 4. Degrees of Risk

##### a. Low Risk

Companies that invest in projects toward developing new drug therapies accept risk across a spectrum of uncertainty. There are very low risk projects in which companies develop new delivery mechanisms, new dosages, and improved formulations in which there is sufficient existing technology and knowledge of human biology to fairly safely predict an outcome.<sup>139</sup> Even in such an environment there may be failures, otherwise there would be zero risk, but the failure probability may be low. In such a circumstance, calculating the cost of developing a “new” drug should be fairly straightforward. The allocated budget costs of the scientific research team, the research and testing equipment, the preclinical and clinical trial costs, and so forth. Most of the new drugs that are developed fall within this general category of products.<sup>140</sup> This is research with a high probability of success, research with a low level of uncertainty, or “low risk” research.<sup>141</sup>

In the low-risk environment, determining the cost of developing a new medicine should not be especially problematic. The level of financial risk may depend on the total capitalization of the company undertaking the research. A small company that is capitalized at a low level may face a larger financial risk than a highly capitalized, large company because a single failure may have more severe consequences for the company as a going concern. This is a general risk factor with respect to operating a business.

##### b. High Risk

At the other end of the research spectrum there are investments in disease treatments involving a large number of unknowns, such as the underlying cause of the disease or condition or knowledge concerning the mechanisms for intervening in the causal biologic process. If the cause is unknown and the potential mechanisms for intervention are unknown, there may be a high level of

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138. There are likely to be more and less successful originator companies. Some may go out of business as a consequence of R&D failures. But pricing by a single enterprise should not be making up for third party losses. Those losses are risks borne by investors and are common to seeking returns.

139. See generally U.S. GOV'T ACCOUNTABILITY OFF., GAO-07-49, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS (2006).

140. See *id.*; ABBOTT & DUKES, *supra* note 3, at 62–72.

141. See Hauke Riesch, *Levels of Uncertainty*, in ESSENTIALS OF RISK THEORY 29 (Sabine Roeser et al. eds., 2013).

uncertainty regarding research undertakings and investments and concomitantly a higher level of financial risk. This is “high-risk” research. In terms of cost, high-risk research should generally be expected to be more expensive than low-risk research because there are more likely to be avenues that are explored but which do not yield commercially viable results. In this regard, determining the cost of R&D should include reasonably ancillary efforts of the enterprise that are unsuccessful, as well as the successful effort. It should be possible for an originator pharmaceutical company to identify the projects that are reasonably relevant to the introduction of a successful pharmaceutical product.

The degree of relevance is something that can be subject to judicial and factual assessment, and it may be that there will be some disagreement among experts regarding where lines should be drawn. This would not appear to be a particularly unusual litigation problem, as accounting for expenditures is undertaken in various types of litigation.

R&D companies may be single focus ventures for which the total R&D expenditures may roughly correlate with the R&D expenditures of the company; or, the enterprise is undertaking research across a variety of different disease targets, types of compounds, or biological substances, i.e. a multi-focus enterprise.<sup>142</sup>

Within the multi-focus enterprise, the typical R&D department will be subdivided either with respect to disease targets and/or mechanism of action approaches. It should be possible to segregate from a cost-accounting standpoint the expenditures involved in operating a subdivided unit, since presumably for its own internal budgetary purposes the enterprise will have determined a budget. Again, presuming reasonably efficient use of funds, it may be reasonable to take into account the successes and failures of a subdivided unit of a multi-focus enterprise in terms of allocating costs of R&D for a successful treatment.

### *c. Determining Pricing of Risk*

Pharmaceutical originator companies reduce risk by relying on a broad cross-section of graduate researchers, hospitals, and small “startup” enterprises to make initial progress toward identifying promising drug candidates, then purchasing (through one mechanism or another) the promising candidates. Risk can be spread by simultaneous investments across a range of projects of different risk profiles.

To the extent that the originator has purchased the results of graduate research, or has purchased a small start-up, this may provide fairly clearly defined identifiable cost up to a particular stage of research.

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142. Even with respect to a portfolio of promising candidates, it will be difficult to calculate the probabilities of any single candidate succeeding as a major revenue contributor. But major originator companies have substantial experience managing portfolios. This is in the very nature of the financial market assessment of the “product pipeline” of an originator company. The sophisticated financial analyst must look at the overall portfolio of the originator company and make an assessment of whether there will be successful outcomes, and across what probability spectrum.



Originator purchases of smaller R&D-based enterprises with promising drug candidates may include a significant “pricing premium” that is paid to the smaller enterprise for one or more reasons, including: (1) there may be a competition among originator companies for a promising drug candidate; (2) the smaller enterprise may be a publicly traded company whose investors expect a premium in exchange for tendering control; or (3) the smaller enterprise may be a privately held company whose investors expect to receive a significant profit above their investment cost. The cost of acquiring a drug candidate through the purchase of a smaller enterprise should be evaluated in terms of ordinary cost accounting for the R&D expenditures on the part of the smaller enterprise and a reasonable profit on the sale, not at whatever price the originator elects to pay.<sup>143</sup> Originator companies have attempted to justify large, unexpected pricing increases on grounds that they have paid substantial premiums for acquisition targets. The public and public health budgets should not be reimbursing these premiums to investors through the purchase of medicines.

#### *d. Clinical Trials*

The cost of conducting clinical trials should be capable of determination with a relative degree of precision. The originator pharmaceutical industry typically identifies the cost of clinical trials as the most significant part of its R&D expenditure. Since detailed records are maintained in clinical trials, they should facilitate cost allocation.

#### *e. Production Costs*

The reasonable price of a drug must include production costs. There is no argument from the industry that production costs are indeterminate. That said, originator patent owner pharmaceutical companies have not traditionally paid attention to efficient production because of the high profit margins associated with products in which they hold exclusive rights.<sup>144</sup> Production processes that are grossly inefficient may distort establishment of reasonable prices and might be adjusted on that basis.

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143. The problem associated with paying high prices for “incubator enterprises” is a recurring one. Originator companies justify raising prices on existing drugs, or charging excessive prices for newly developed drugs, based on high payments made for the incubators. A related problem is recurring in the generics sector where companies such as Valeant have made acquisitions of other enterprises and significantly raised prices, justifying the price increases at least in part on the cost of acquiring the other enterprises. The U.S. Congress has been somewhat more willing to address price increases in the generics sector than in the originator sector, presumably because there is less lobbying influence from the generic companies.

144. FREDERICK M. ABBOTT, INDIAN POLICIES TO PROMOTE LOCAL PRODUCTION OF PHARMACEUTICAL PRODUCTS AND PROTECT PUBLIC HEALTH (World Health Org., 2017) (discussing the history of Indian price controls, and identification of inefficient practices).

### 5. *Cost to Be Excluded*

#### *a. Government Subsidization*

Because of the high level of uncertainty, basic research regarding underlying causes of disease conditions is funded by the government in the United States (generally through the National Institutes of Health).<sup>145</sup> At very early stages of research with high levels of uncertainty, the risk associated with financial investment is high because “return on investment” may be sufficiently far in the future that business managers are unwilling to commit available investment funds. Risk can be reduced by government subsidization of early-stage research.

In general, research funded by the government should not be included within the originator/private-sector cost of developing a new drug. The price charged to the public should not be based on recovering government-sponsored research funds.<sup>146</sup>

#### *b. Tax Benefits*

In a similar vein, tax benefits must be accounted for in the cost of R&D on a new drug. If a government provides an R&D tax credit that an enterprise may use to offset taxes otherwise payable, that provides a net benefit to the enterprise and effectively amounts to a reduction in R&D cost.<sup>147</sup>

#### *c. Opportunity Cost of Capital*

As noted in discussion of the Tufts study, the originator pharmaceutical industry incorporates opportunity cost of capital as part of its own explanation of high R&D costs. It will be up to judges and juries to decide whether it is reasonable to include the opportunity cost of capital as part of drug R&D costs. Presumably, there will be experts on both sides of this issue. From this author’s perspective, incorporating opportunity cost of capital double counts investment because capital for R&D is contributed by outside investors and reflected in the

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145. See Press Release, Nat’l Inst. of Health, NIH Unveils FY2016–2020 Strategic Plan: Detailed Plan Sets Course for Advancing Scientific Discoveries and Human Health (Dec. 16, 2015) (on file with author), <http://www.nih.gov/news-events/news-releases/nih-unveils-fy2016-2020-strategic-plan>; NAT’L INST. OF HEALTH, NIH-WIDE STRATEGIC PLAN: FISCAL YEARS 2016–2020 (2015).

146. It may be that the basic research in itself has some indeterminacies in terms of cost to the taxpayer, but that indeterminacy should not be relevant to the final cost of R&D to the private sector patent owner.

147. Issues related to taxation of pharmaceutical enterprises are a large-scale problem because of the way income shifting is used to avoid tax payment. The avoidance of tax payment in countries where pharmaceutical-based income is generated increases the burden regarding public health expenditure for the government. Antoine Gara, *Pfizer’s Tax Inversion Isn’t a Miracle Drug: Just Ask Monsanto and Towers Watson*, FORBES (Nov. 24, 2015), <http://onforb.es/1lgbVbE>. Tax authorities are increasingly turning attention to allocation of patent-based income and related tax avoidance. See, e.g., Vanessa Houlder, *Plans Unveiled to Crack Down on Corporate Tax Avoidance*, FIN. TIMES (Oct. 5, 2015), <http://www.ft.com/cms/s/0/307c921a-6b45-11e5-aca9-d87542bf8673.html>.

equity share price of the pharmaceutical company. If the company is successful, the share price increases, dividends are paid, and the investor may get a return on its capital by selling its shares. While an originator company may elect to borrow money (i.e. debt) to finance R&D, this is an internal business decision presumably reflecting a determination that borrowing money is less costly to the current shareholder base (in terms of dilution) than offering and selling additional equity securities. As noted above, the inclusion of opportunity cost of capital can double the reported R&D costs of the industry. This is clearly a nontrivial issue from the standpoint of fairly determining R&D cost and ultimately for excessive pricing determinations.

#### *d. Executive Salaries*

Pharmaceutical originator company executives often earn salaries far in excess of what might be considered reasonable. A former CEO of Pfizer, Hank McKinnell, who had presided over a precipitous decline in the price of the company's shares with an extensive streak of bad decision-making, was awarded over \$180 million when he left the company.<sup>148</sup> The public and global public health budget reimbursed this expense through Pfizer's pharmaceutical prices. It is self-evident that there must be a limit to the level of executive salary that can be included in establishing the cost of R&D on a new drug. The amount paid to Hank McKinnell is not reasonably related to drug development costs. Of course, only a proportionate share of executive salary should be allocated to the relevant subdivision in a multifocus enterprise.

#### *6. Summary*

The foregoing suggests that there are methodologies that can be used to calculate with some reasonable precision the cost of R&D on a new drug that takes into account the risk of failure. The issue whether the drug provides "value for money" in efficacy terms in relation to its R&D cost is a different one. That is, for example, whether a public health system should adjust its calculation of a reimbursable "reasonable price" with some factor that takes into account the patient outcome. An argument can be made that efficacy-based premiums should not be paid since the R&D costs are sunk costs and that there is no advantage to the patient or consumer from increasing the price because the drug is more effective than alternatives. On the other hand, a modest efficacy premium may be in the nature of a prize given to a successful venture.

#### *B. What Is "Excessive"?*

Prices of originator pharmaceutical products typically exceed those of generic products by substantial margins. It is not uncommon for generic prices to

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148. The Associated Press, *Pfizer's Ex-Chief to Get Full Retirement Package*, N.Y. TIMES, Dec. 22, 2006, at C2.

be five to ten percent of patent-protected originator prices, and the US. GAO estimates that generic drugs are, on average, priced seventy five percent lower than originator drugs in the United States.<sup>149</sup> Originator prices in the order of 1000% above the later generic prices are not unusual. That is, a \$10 price for a generic pill may translate into \$100 for an equivalent originator pill. The theory behind the 1000% multiplier is that the originator must recover its costs of research and development, as well as accumulate capital for further R&D.<sup>150</sup>

Originator companies do not typically report the prices of their pharmaceutical products in relation to their costs of R&D. The ten or twenty times the price compared to the generic price does not bear a relationship to production cost. A reasonable way to determine whether the price of an originator pharmaceutical product is excessive is by comparing it to the cost of research, development, and production, and adding some amount for “future R&D.” Reasonably, the “normal” price of an originator drug would take the remainder of the exclusivity term (by way of example, ten years), calculate the anticipated demand for the product over that term (i.e. the potential level of sales), set a price that would compensate for the “all in cost,” and derive a price that would return the cost plus a reasonable increment to account for future R&D. If a drug was determined to cost one billion dollars to develop and produce, and would sell ten million units for each of ten years, or 100 million units over a ten-year period, the reasonable price of the drug would be ten dollars per pill. Adding a generous \$500 million for future R&D would establish a price per pill of fifteen dollars.<sup>151</sup>

If the reasonable price per pill is fifteen dollars, what would be “excessive”? If the originator charged thirty dollars, would that be unfairly excessive? What if the price was \$150 per pill?

One of the benchmarks used by the CJEU in the *United Brands* decision was how comparable suppliers priced similar products.<sup>152</sup> Should it matter that other

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149. See Letter from John E. Dicken, Director, Health Care, to Orrin G. Hatch, Senator, U.S. Congress (Jan. 31, 2012) (on file with) (“On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.”).

150. Nadia Kounang, *Pharmaceuticals Cheaper Abroad Because of Regulation*, CNN (Sept. 28, 2015), <http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/> (“According to PhRMA, the pharmaceutical trade group, high prices are a reflection of the research and development costs it takes to bring a drug to market.”).

151. Pfizer states that 29 million people in the United States have been prescribed Lipitor. *About Lipitor*, LIPITOR, <http://www.lipitor.com/about>. (last visited Feb. 21, 2016 at 12:00 p.m.). Assuming one pill per day, or 352 pills per year, that would amount to a volume of 10.208 billion pills per year. Multiplying that by ten would yield over 102 trillion pills. In 2011, Pfizer earned more than \$5 billion revenue from sales of Lipitor in the United States. Assuming a ten-year patent term, this yields \$50 billion over the course of protection. Based on that, the price for Lipitor was about two dollars per pill, or about \$700 per year for treatment. In fact, it appears that the annual prescription price was about \$1290 in 2006 up to \$2140 in 2012. The spread between the hypothetical price and the actual revenue may be attributed to the fact that, while 29 million people were at one point prescribed the drug, not all of them maintained a regimen. Alternatively, it may represent the margin of the supply chain following sale by Pfizer. In any event, the order of magnitude is comparable.

152. *United Brands Co.*, 1978 E.C.R.

originator pharmaceutical producers charge \$150 per pill when a reasonable fair price is fifteen dollars per pill? In the context of an industry under scrutiny for charging what appear to be unreasonable prices, looking to other providers in the industry does not seem to be a logical focal point.

A similar, but better, approach would be to look to other innovative industries where higher than “normal” prices are charged to compensate for innovation. It is doubtful that we can find another technology-related industry where the spread would be so wide, mainly because pharmaceuticals are subject to inelastic demand when discussing necessary treatments.

This may be a case where courts and juries have to make somewhat subjective judgments about what is reasonable. We can venture that charging ten times a price that would return R&D, production costs, and a fifty percent future R&D increment is “unfairly excessive.” Five times would probably be excessive. Is three times excessive?

The point is that in the cases where pharmaceutical pricing is “stratospheric,” a judge or jury may not need a finely tuned methodology for determining when a price is unfairly excessive. Taking advantage of the public by charging prices that far exceed what is reasonable is excessive.

### C. Remedies

As the OECD Roundtable notes, another reason why competition law authorities and courts hesitate to pursue excessive pricing actions is difficulty in crafting appropriate remedies.<sup>153</sup> For the United States, an advantage is that private litigants with the proper doctrinal tools can seek to recover triple damages for antitrust violations.<sup>154</sup> A plaintiff representing either a class or a large-volume purchaser of originator pharmaceuticals might secure a civil remedy at an order of magnitude sufficiently large to persuade the industry to begin to ameliorate its pricing. In addition, because violations of the Sherman Act may be criminally prosecuted, the Department of Justice and Federal Trade Commission may be able to exercise substantial power over pricing decisions by bringing a few exemplary cases.

It does not seem so improbable that a court would fashion a remedy that would include future pricing of a pharmaceutical product. Given that the evidence would already be available regarding what would constitute a reasonable price, using that price as a benchmark should allow court supervision of a pricing order.

Antitrust and competition cases initiated by government authorities are often settled with an agreed-upon remedy. There are various ways that settlement agreements could accommodate modification of prices, including establishing

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153. OCEC ROUNDTABLE, *supra* note 7, at 321.

154. For a detailed discussion of available remedies in the United States and elsewhere, see Frederick M. Abbott, *Anti-Competitive Behaviours and the Remedies Available for Redress*, in USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW-AND MIDDLE-INCOME COUNTRIES, *supra* note 12, at 58, 84–93.

maximum pricing limits, periodic reviews, benchmarking relative pricing, extensions of third-party licensing, and so forth.<sup>155</sup>

Fully litigated cases typically include injunction against future misconduct, and court orders may be tailored to the specific circumstances. It will be important for courts to fashion remedies that take into account efforts by parties against whom compliance orders are directed to circumvent pricing restrictions, for example by transferring assets to other entities, developing minor modifications of products subject to order and relabeling, licensing to third parties, and other alternative strategies.

In a more proactive sense, remedial orders could include distribution of excessive pricing profits to purchasers, including healthcare plans and individual patients and consumers.

### III. COMPETITION LAW FROM THE GLOBAL PERSPECTIVE

This Article has mainly focused on doctrinal development in the United States and European Union. With a long history of competition law and policy evolution, competition authorities and courts in these countries/regions have traditionally been looked to by competition authorities around the world for leadership.

As emerging market and other developing countries have taken on greater roles in the international economy, and are catching up with the United States and EU in terms of legal infrastructure development, a more level relationship in terms of competition policy development and implementation is coming about. It is not an overnight process. Nonetheless, there is increasing use of competition law in emerging markets and developing countries and recognition that the policies best suited to these countries/regions may not be precisely the same as those for the United States and EU.

The business community in the United States and U.S. competition authorities have long resisted the negotiation of multilateral competition rules.<sup>156</sup> The business community because of a self-interest in avoiding regulation; the competition authorities because of a desire to retain the capacity to adapt policy and law as circumstances warrant. Today, the calculus by the business community is changing as emerging market and other developing country competition authorities are exercising their enforcement powers. This change in calculus is reflected in a report by the U.S. Chamber of Commerce regarding China's

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155. Edward Cavanagh, *Antitrust Remedies Revisited*, 84 OR. L. REV. 147, 150 (2005) (stating that the Department of Justice Antitrust Division has "leeway in choosing antitrust remedies"). See generally C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 674–76 (2009).

156. See Abbott, *Public Policy and Global Technological Integration*, *supra* note 12.

competition law and policy that finds difficulty in identifying substantive multilateral rules that might constrain China's authorities.<sup>157</sup>

United States antitrust jurisprudence has resisted the incorporation of excessive pricing doctrine for reasons discussed earlier. This Article argues that this resistance is misplaced and that it should be rethought, particularly in the context of subject matter where monopoly power is entrenched and likely to persist, such as when conferred by patent and regulatory market exclusivity. Excessive pricing doctrine is needed for the protection of the consumer and the public health budget. Pharmaceutical pricing by originator companies has gotten out of hand, and legislators have been slow to react. Public and private antitrust plaintiffs can assume the role of protectors of the public interest.

But, even if the United States retains its entrenched position resisting excessive pricing doctrine, this does not stand in the way of its evolution and application in other jurisdictions, including the European Union and the rest of the world. The United States is an outlier in respect to control of pharmaceutical prices, one of the few—and perhaps only<sup>158</sup>—countries where originator pharmaceutical companies are permitted to charge whatever price the market will bear. Other countries and regions start from a step ahead in this arena.

Because competition law today is lightly regulated at the multilateral level, countries have substantial flexibility in developing and implementing policy, including with respect to excessive pricing. For this reason, among others, there is substantial risk involved in the potential pursuit of common multilateral rules that would be sought by U.S. industry with a view toward limiting competition law controls.

The policy prescription of this Article is twofold: first, the United States should incorporate excessive pricing doctrine in its antitrust arsenal; and second, other countries should maintain the status quo with respect to multilateral competition rules that allow them flexibility to develop and refine doctrine, including excessive pricing doctrine, that is best suited to their circumstances and interests.

The economic and institutional mechanisms under which new drugs are developed and distributed in the United States, and globally, are not the result of some “optimal planning exercise” that assessed the most effective ways to encourage meaningful innovation with a view toward maximizing access for patients. The existing “modern” architecture, in the United States and globally, evolved over decades based on pushes and pulls from disparate stakeholders, reaction to military conflict and public health emergency, developments in the

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157. *See id.*; U.S. CHAMBER OF COMMERCE, COMPETING INTERESTS IN CHINA'S COMPETITION LAW ENFORCEMENT: CHINA'S ANTI-MONOPOLY LAW APPLICATION AND THE ROLE OF INDUSTRIAL POLICY (2014), [https://www.uschamber.com/sites/default/files/aml\\_final\\_090814\\_final\\_locked.pdf](https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf).

158. With the world community composed of more than two hundred countries, it is always difficult to make categorical generalizations about the rules followed “everywhere.”

sciences, changes in public perceptions and expectations, negotiation of trade and investment rules, and changes in the way capital markets operate. There is continuous demand for reform of the existing architecture, and there is continuous resistance to reform. While incremental changes are made at the margins, there is reason to be cautious about expectations for profound reform in the United States and globally, at least for the near term. In the meantime, patient groups and public health systems must deal with the reality they face. This reality includes the excessive pricing of critical drug treatments. Competition law is an important tool that can be used to constrain excessive pricing. It can and should be used to deal with the very real problems that are confronting the United States and other countries in terms of pharmaceutical prices. Competition law is not a substitute for reform of the architecture under which new drugs are developed and supplied in the United States and globally. It is a means to help assure that the existing architecture is not abused.