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March 3, 2016

Dear Senators Wyden and Grassley,

Thank you for this opportunity to provide feedback regarding the report on "The Price of Sovaldi and its impact on the U.S. Health Care System" of December 1, 2015 (Senate Print 114-20), as referenced in your letter of January 21, 2016.

I have previously sent to members of your staff an email expressing my appreciation for their preparation of the Report on Sovaldi. The Report is a most valuable resource for researchers in the field of pharmaceutical regulation and it reflects a high level of objectivity and professionalism.

Your letter raises several specific questions regarding information that would be useful in further addressing policy issues raised by the Report. Like others with interests in this general subject matter area, I have written and published a number of books and papers regarding ways that mechanisms for promoting innovation in the pharmaceutical sector and making improved treatments available to the public at affordable prices might be improved. In this brief response, I confine myself to the attached paper (forthcoming article) that benefited particularly from the information and analysis assembled in the Report.

The attached paper, "Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health" (forthcoming UC Irvine Law Review, Volume 6, Issue 3, Spring 2017), recommends that US antitrust law, and in particular the Sherman Act, should be used to address excessive prices charged by pharmaceutical producers and suppliers. The article notes that US courts have been reluctant to address excessive pricing "as such". Federal courts have generally expressed the view that producers with lawfully secured monopolies should be allowed set prices however they wish as a reward for their skill, acumen or good fortune. The courts have been reluctant to evaluate whether prices are reasonable (or not) on grounds that judges are not specialized regulatory authorities. Federal courts and antitrust authorities consider that excessive prices may evidence underlying anticompetitive conduct that may be addressed by correcting underlying market defects or abuses. Excessive prices are not unlawful in themselves.

The attached article suggests that this judicial view is particularly problematic when addressing monopolists whose positions are effectively established by Congress by virtue of the Patent Act and its implementation. A patent (or regulatory market exclusivity) granted to a pharmaceutical company may confer a lawful monopoly. If the monopoly is lawfully obtained, there may not be a market defect for the courts to correct using existing antitrust doctrine. As a consequence, pharmaceutical companies may charge excessive prices without concern regarding whether their conduct violates antitrust law.

The attached article points out that the Sherman Act was adopted by Congress in 1890, and initially applied by the Supreme Court, to protect the public from abusive monopolists. The Supreme Court expressly affirmed protection of the public interest as the central motive of the antitrust laws. In its early days the Sherman Act was used to defend the public against high prices charged by railroad and oil barons. It was not adopted merely to address potential market defects.

Just so, the antitrust laws should be used today to protect the public from excessive prices charged by pharmaceutical companies under the guise of patents and regulatory market exclusivity. The attached article is not proposing some form of general price control, nor is it quarreling with prices that reasonably take into account risks associated with research and development necessary to develop and market new and improved treatments. The article is aimed at the type of pricing practices identified by the Report on Sovaldi -- prices set by investment bankers and financial engineers to press the absolute limits of public health system tolerance and to extract the maximum amount of financial gain possible without literally bankrupting the payors (including state public health authorities, federal government programs (like the Veterans Administration) and private health insurers.

Pharmaceutical originator companies shield their internal budget data, as Gilead has done with respect to development of Sovaldi. They argue that it is simply not possible to explain the cost of developing a new drug, and that it is sufficient for them simply to say that it costs “a lot”. Congress and the public are warned against seeking to look inside the “black box” of new drug development.

The refusal to provide information is in the interests of the companies. Pharmaceutical originator companies know their R&D costs, both in terms of successfully developed products and related products that do not succeed. Pharmaceutical companies have real budgets. Pharmaceutical executives do not write blank checks for their R&D departments.

The US government has a tremendous stake in understanding the costs of R&D on new drugs, and in understanding how pricing decisions are made. The Report on Sovaldi partially lifts the veil on one new drug that is priced excessively. Congress must do more to secure meaningful data on the costs of new drug development, and on how pricing decisions are made. A tremendous amount of US taxpayer money is spent on new drugs, and Congress should be trying to figure out where taxpayer money is going.

The attached article provides suggestions on methodology for determining how reasonable prices for new drugs may be determined, as a base for deciding whether the prices charged by producers may be excessive.

One reason for suggesting that the Sherman Act and excessive pricing doctrine should be applied in this area is that enforcement of the antitrust laws is not dependent on new legislation, and is not wholly dependent on enforcement actions brought by government authorities. Private litigants may bring

claims under the Sherman Act, and may recover triple damages. Successful private litigation, as well as exemplary cases by public authorities such as the Department of Justice and Federal Trade Commission, may be sufficient to bring some pricing responsibility and discipline to the pharmaceutical sector in the United States.

I once again express my appreciation to your staff for their work in preparing the Report on Sovaldi. The report is an important step in improving the public health system of the United States.

Sincerely,

Frederick M. Abbott

Appended article: Frederick M. Abbott, Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health, UC Irvine Law Review, Vol. 6, Issue 3, forthcoming Spring 2017

Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health

Frederick M. Abbott*

UC Irvine Law Review, Vol. 6, Issue 3, forthcoming Spring 2017

draft of January 19, 2016

I. 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 have entered the stratosphere.[1] In the United States, state pharmaceutical acquisition budgets are at the breaking point -- or have passed it -- and treatment is effectively rationed.[2]

Pharmaceutical products reflecting extraordinary price escalation are principally newly-developed originator small-molecule and biological pharmaceutical ("biologic") products.[3] These products are typically protected by patent and/or regulatory market exclusivity. There are also recent incidents of dramatically increased prices of certain generic products the supplies of which are restricted for one reason or another, providing their suppliers with effective market exclusivity.[4]

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[1] *See, e.g.*, Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2013*, Research Report, AARP Policy Institute, November 2015; Government Accountability Office, *Medicare Part B, Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries*, Report to the Ranking Member, Committee on the Budget, House of Representatives, Oct, 2015, GAO-16-12; Peter Loftus, *Drugmakers Raise Prices Despite Criticisms*, WALL ST. J., Jan. 10, 2016; Matthew Herper, 115 *Doctors Proposed This Solution For Terrifying Cancer Drug Prices*, FORBES, July 23, 2015; Andrew Pollack, *Doctors Denounce Cancer Prices of $100,000 a Year*, NY TIMES, Apr. 25, 2013.

[2] *See, e.g.*, The Price of Sovaldi and Its Impact on the U.S. Health Care System, Staffs of Ranking Member Ron Wyden and Committee Member Charles E. Grassley, Committee on Finance United States Senate, 114th Congress 1st Sess., S. Prt. 114–20, Dec. 2015 (hereinafter "Sovaldi Staff Report"), at pgs. 106-110; Schondelmeyer & Purvis, supra note 1, at 4; David Siders, *Hepatitis C drug's high cost hits California budget*, Sacramento Bee, Jan. 16, 2015 ("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.")

[3] *See, e.g.*, FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY 16-85 (2009), for discussion of pharmaceutical categories.

[4] *See, e.g.*, Anjali Cordeiro and Makiko Kitamura, *Valeant Slumps as U.S. Prosecutors Issue Subpoenas on Prices, Bloomberg Business*, October 14, 2015 < http://www.bloomberg.com/news/articles/2015-10-15/valeant-receives-subpoenas-from-u-s-prosecutors-on-drug-pricing>; Andrew Pollack, *Martin Shkreli's Latest Plan to Sharply Raise Drug Price Prompts Outcry*, NY TIMES, Dec. 11, 2015.

There are a variety of tools that governments may use to regulate the prices of pharmaceutical products, including those covered by patent and/or regulatory market exclusivity.[5] These include the imposition of price controls, the granting of compulsory patent licenses, and the use of monopsony purchasing power to force price concessions. Though they are used in one form or another by many countries there can be political-economy obstacles to making use of these tools.

Competition/antitrust law has rarely been used to address "excessive pricing" of pharmaceutical products.[6] This is a worldwide phenomenon. In the United States, the federal courts have refused to apply excessive pricing as an antitrust doctrine, either with respect to pharmaceutical products or more generally. 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.

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.[7] 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. That is, "fixing the market" so that the underlying defect by which excessive prices are enabled is remedied.

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. This author and other expert commentators have laid out the multilateral framework in which competition law operates in some detail elsewhere,[8] and this article does not revisit that exercise other than to observe the

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[5] *See* recently PHARMACEUTICAL PRICES IN THE 21ST CENTURY (ed, Z.-U.-D. Babar), Springer (2015), including country contributions. *See also* OECD Health Policy Studies, Pharmaceutical Pricing Policies in a Global Market, 24 Sept. 2008, <http://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm>; U.S. Department of Commerce International Trade Administration, Pharmaceutical Price Controls in OECD Countries, Dec. 2004, http://ita.doc.gov/td/health/DrugPricingStudy.pdf.

[6] OECD Directorate for Financial and Enterprise Affairs Competition Committee, Excessive Prices, DAF/COMP(2011)18, Feb 7, 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").

[7] *Id.* at 9.

[8] *See, e.g.*, Frederick M Abbott, *Public Policy and Global Technological Integration: An Introduction*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION (eds. F. Abbott & D. Gerber (Kluwer L. Int'l 1996); Frederick M. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?*, 7 JIEL 687 (2004). Available at SSRN: http://ssrn.com/abstract=917108; Frederick M Abbott, Competition Law in Emerging Markets: the virtue of regulatory diversity, in THE SHAPE OF FUTURE INTERNATIONAL ECONOMIC GOVERNANCE, Essays in Honour of Professor Mitsuo Matsushita (eds. J. Chaisse & T.-Y. Lin, Oxford University Press (forthcoming 2016); Carlos Correa,

flexibility of the framework. Consistent with that earlier work, it recommends that emerging market and developing countries more generally should be cautious in responding to suggestions that new competition rules at the multilateral level would be a good idea. The United States 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.[9] Up until now, the business community has preferred to 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.[10] 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.

II. Excessive Pricing Doctrine

A. Philosophical resistance

US 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.[11] By the late 1980s,

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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. United Nations Development Program (ed. F. M. Abbott)(2014). Available at SSRN: http://ssrn.com/abstract=2439416.

[9] *See, e.g.*, Douglas Melamed (US Dept. of Justice Antitrust Div.), *Antitrust Enforcement in a Global Economy*, Fordham Corp. L. Inst., 25th Ann. Conf. Int'l Antitrust L. & Pol., New York, Oct. 22, 1998 ("We do not believe, however, that it would make sense at this time to commence multinational negotiation of common antitrust principles or rules."); Joel Klein (US Dept. of Justice Antitrust Div.), *No monopoly on antitrust, It would be premature for the WTO to seek to enforce global competition rules*, FIN. TIMES, Feb 13, 1998 ("I continue to believe strongly that WTO negotiations on competition rules would be premature and could even be counterproductive.")

[10] *See* F. Abbott, *Competition Law in Emerging Market*, *supra* note 8, including reference to US Chamber of Commerce report on China.

[11] *See Standard Oil Company of New Jersey v. United States*, 221 U.S. 1 (1911) and cases cited in Frederick M. Abbott, The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of TRIPS. HUMAN RIGHTS AND INTERNATIONAL TRADE, p. 279, T. Cottier, J. Pauwelyn & E. Bürgi, eds., Oxford University Press, 2003. Available at SSRN: http://ssrn.com/abstract=1922847.

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. 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,[12] and it was embedded in antitrust guidelines adopted by the Department of Justice and Federal Trade Commission in the mid-1990s.[13] The competitive market protection approach was and is thought to address the interests of consumers because, in theory, in a competitive market prices will be driven down to marginal cost.

This philosophical market approach is reflected in recent judicial antitrust doctrine in the United States.[14] 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.

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 25 years from the date of application (the ordinary 20 year term, plus a five year extension).[15] Taking into account the lead time for regulatory marketing approval by the FDA, the effective term of protection will be between 10 and 15 years. 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.[16] But, in the case of biologics, the 12-year period of exclusivity may well extend beyond the duration of patent protection.

As a consequence of exclusive marketing rights (whether through patent or regulatory exclusivity), the originator pharmaceutical product is not subject to competition from the "same product" (from a juridical standpoint) during the term of protection. In principle, this enables the originator to charge whatever price it decides upon without fear of competition. In practice, there are potential constraints

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[12] *See* Richard A. Posner, *The Chicago School of Antitrust Analysis*, 127 U. PENN. L. REV. 925 (1979); Joshua D. Wright, *Abandoning Antitrust's Chicago Obsession: The Case for Evidence-Based Antitrust*, 78 Antitrust Law Journal 301 (2011), although critiquing it as a overly simplified view of Chicago School antitrust, noting "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.'" (at p. 303).

[13] US Department of Justice (DOJ) and Federal Trade Commission (FTC), Horizontal Merger Guidelines, April 2, 1992; DOJ and FTC, Antitrust Guidelines for the Licensing of Intellectual Property, April 6, 1995; DOJ and FTC, Antitrust Enforcement Guidelines for International Operations, April 1995.

[14] *See* discussion of case law, *infra*.

[15] *See* generally for explanation, Federal Trade Commission Report, Emerging Health Care Issues: Follow-on Biologic Drug Competition, June 2009.

[16] The US 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 CFR 314.108.

on pricing. First, there may be pharmaceutical products that are reasonable substitutes (even if 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 patient/consumers, and ultimately by the amount the patient/consumers can afford to pay.

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/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.[17] 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 12 week course of treatment, and earned over US$14 billion in the first year of sales. Gilead did not develop Sovaldi. The drug was initially developed by a smaller biotechnology company, Pharmasett, which was purchased by Gilead for $11 billion in 2011.[18] 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). Gilead purchased Pharmasett because its own 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.[19]

The process by which the price of Sovaldi was set by Gilead makes for chilling reading from a public health standpoint.[20] The executives at Gilead essentially set out to determine what would be 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.

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 1.5 years following the introduction of Sovaldi, Gilead was forced to reduce the price significantly. While it may be suggested that this demonstrates that market forces will act to constrain pricing power, 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

[17] *See* Sovaldi Staff Report, *supra* note 2.
[18] Sovaldi Staff Report, *id.,* at 123.
[19] *See, e.g.*, Jeffrey Sachs, *The Drug That Is Bankrupting America*, HUFF. POST, Feb. 16, 2015.
[20] Sovaldi Staff Report, *supra* note 2.

legislative action to reduce prices.[21] Members of Congress have introduced a number of legislative proposals that would provide some form of control mechanism.[22] State governments have been substantially more active than the federal government in adopting mechanisms intended to limit excessive pricing.[23] But, 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 perspective. Developing and middle income countries are in a more precarious position than the United States in terms of 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 OECD Competition Committee convened a Policy Roundtable on excessive prices and published the contributed papers and dialogue.[24] The Roundtable included contributions from the 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 explain and confirm that as of its preparation competition authorities and respective judiciaries were very 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. 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 USA

In their contribution to the OECD Roundtable, US 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

[21] *See* note 1, *supra*.
[22] *See, e.g.*, Bronwyn Mixter, *Sanders to Introduce Wide Ranging Drug Cost Bill*, Bloomberg BNA Pharm. Ind. & L. Rept., Sept. 1, 2015.
[23] Nancy E. Morden and Sean D. Sullivan, *States' Control Of Prescription Drug Spending: A Heterogeneous Approach*, HEALTH AFF, July 2005, vol. 24, no. 4, 1032-1038.
[24] OECD Directorate for Financial and Enterprise Affairs Competition Committee, Excessive Prices, DAF/COMP(2011)18, Feb 7, 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").

> independent antitrust violation, although high prices may be indicative of other anticompetitive activities.[25]

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 the US case law.[26] More recent federal court decisions are consistent with this general line.[27]

Perhaps the most quoted judicial pronouncement regarding the notion of excessive pricing of recent years is from Justice 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."[28]

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".[29] 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."[30]

To be clear, the federal courts are not providing a blanket approval of pricing practices under the US antitrust laws. Price fixing among horizontal competitors remains a *per se* violation of the Sherman Act.[31] Resale price maintenance is assessed under the rule of reason.[32] As the FTC and DOJ point out, high prices may well be reflective of an underlying anticompetitive practice, such as abuse of monopoly

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[25] *Id.* at 299.
[26] *See* citations by FTC/DOJ to *Pacific Bell Telephone Co. v. linkLine Communications, Inc*., 555 U.S. 438 (2009); *Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004); *Berkey Photo, Inc. v Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979); *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406 (7th Cir. 1995), citing *National Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020 (8th Cir. 1985); *U.S. v. Aluminum Co. of America*, 148 F.2d 416 (2d Cir. 1945); *Ball Memorial Hospital, Inc. v. Mutual Hospital Ins., Inc.*, 784 F.2d at 1325 (7th Cir. 1986); *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898).
[27] *Cf.*, Batson v. Live Nation Entertainment, 746 F.3d 827, 833 (7th Cir. 2014) (decided under Illinois Consumer Fraud and Deceptive Business Practices Act).
[28] *Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).
[29] *Berkey Photo, Inc. v Eastman Kodak Co*., 603 F.2d 263, 297 (2d Cir. 1979).
[30] *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995), citing *National Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020, 1023-24 (8th Cir. 1985)
[31] *U.S. v. Socony-Vacuum Oil*, 60 S. Ct. 81 (1940).
[32] *Leegin Creative Leather Products v. PSKS*, 127 S.Ct. 2705 (2007).

power under Section 2 of the Sherman Act[33] or price-fixing under Section 1.[34] Enterprises engaged in abusive behaviors that manifest themselves in 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" 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 lack the skill set and/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 US Patent and Trademark Office and/or Food and Drug Administration). That is, unless the patent was procured by fraud or other misadventure, or the FDA was somehow taken advantage of, the monopoly is "pristine". That is, it was acquired by lawful means. 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 relatively recent decision in *FTC v. Actavis*[35] 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."[36] 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.[37] It said:

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[33] 15 U.S. Code § 2 - Monopolizing trade a felony; penalty: "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person 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…"

[34] 15 U.S. Code § 1 - Trusts, etc., in restraint of trade illegal; penalty: "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 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, …"

[35] 133 S.Ct. 2223 (US Sup. Ct. 2013).

[36] *Id.,* at 2231.

[37] Stating: "[I]n Line Material, [United States v. Line Material Co., 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948)], 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 [United States v. General Elec. Co., 272 U.S. 476, 489, 47 S.Ct. 192, 71 L.Ed. 362 (1926)], 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, [United States v. New Wrinkle, Inc., 342 U.S. 371, 378, 72 S.Ct. 350, 96 L.Ed. 417 (1952) (applying antitrust scrutiny to patent settlement)] the

> [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." Id., at 174,…. 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.

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. 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 (*see*, e.g., *Trinko supra*), 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. [38]

A notable recent decision by the California Supreme Court in *In re CIPRO Cases I & II,*[39] is to the same effect regarding patents as *Actavis,* but under California's antitrust legislation. The California Supreme Court goes a bit further than the US 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). In

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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 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."

[38] The resistance of the subordinate courts to placing limitations on drug prices is not to be underestimated. For example, the US 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 noting 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" (*Biotechnology Industry Organization v. District of Columbia*, 496 F3d 1362, 1372-73 Fed. Cir. 2007, citing *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed.Cir.1995).

[39] 61 Cal.4th 116 (Cal. Sup. Ct. 2015).

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.[40]

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*, 31 S. Ct. 502 (1911), 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*." (31 S. Ct. at 512, italics added)

The object of the Sherman Act was to protect the public from the harm that can result from the "oppressive" exercise of monopoly power. 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." 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 US 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 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*,[41] the company used its monopoly control over a computer operating system to prevent the emergence of competing technologies. The archetypal bad behavior of the monopolist is to flex its power to block competition,

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[40] 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 US 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., 22 ME. STAT. 22, § 2681 (2015) (prohibits profiteering and excessive pricing by drug manufacturers, enforced by civil penalties); 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"); D.C. CODE § 28-4533 (2005) (barred excessive pricing of patented drugs, but was held unconstitutional in *Biotechnology Industry Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2005)).

[41] 87 F. Supp. 2d 30 (DDC 2000).

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 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 equally well weigh in on pricing. Indeed, Congress can act to control pharmaceutical prices, but chooses not to do that. But, it has not 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 excessive pricing. Perhaps the 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 European Court of Justice, 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; [italics added][42]

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 which establishes the current basis of ECJ doctrine regarding excessive pricing is *United Brand v. Commission* decided in 1978.[43] In this case, the ECJ set out a two-part test for determining whether a price is excessive within the meaning of Article 102 (then Article 86 of the EC Treaty). 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.
>
> 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*.

The test as stated by the Court in the final paragraph quoted above is somewhat curious. It first asks whether there is a too large spread between cost and price, and 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

[42] Consolidated version of the Treaty on the Functioning of the European Union - Part Three: Union Policies and Internal Actions - Title VII: Common Rules on Competition, Taxation and Approximation of Laws - Chapter 1: Rules on Competition - Section 1: Rules Applying to Undertakings - Article 102 (ex Article 82 TEC), Official Journal 115 , 09/05/2008 P. 0089 – 0089 http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E102&from=EN.
[43] European Court of Justice, Case C-27/76 [1978].

test is difficult to meet. (In *United Brands*, the ECJ 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.) Not only must the price be "excessive", but it must be "unfairly excessive".

In *Bodson v. Pompes funèbres*,[44] a preliminary ruling decided in 1988, the ECJ 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. In a preliminary ruling in *SACEM*,[45] an action brought by discotheque owners against a French copyright Society, the ECJ 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. 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 UK excessive surcharges without justification.[46] 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.[47] In *Rambus*, based on its preliminary conclusions the Commission secured a commitment on the limitation of royalties charged in respect to a technical standard.[48] The Commission has not often prosecuted cases based on excessive pricing doctrine.

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.[49]

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.[50]

That the EU has approached excessive pricing doctrine cautiously is confirmed by other commentators.[51] That said, the EU is more receptive to application of excessive pricing doctrine

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[44] *Corinne Bodson v SA Pompes funèbres des régions libérées*, Case 30/87 [1988].
[45] *F. Lucazeau v. Societé des Auteurs, Compositeurs et Editeurs de Musique Cases* 110/88, 241/88 & 242/88 [1989].
[46] *Deutsche Post AG – Interception of cross border mail*, Commission decision COMP/36.915.
[47] *Scandlines Sverige AB v Port of Helsingborg*, Commission decision COMP/36.568.
[48] Commitment Decision of 09/12/2009, see the non-confidential version of the decision on the Commission's website: http://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf.
[49] OECD Rountable, at 317.
[50] *Id*. at 321.
[51] *See* Damien Geradin, *The necessary limits to the control of "excessive" prices by competition authorities – A view from Europe*, TILEC Discussion Paper, DP 2007-032, October 2007, and citations therein.

than the United States. The two-part test elaborated by the ECJ 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.[52] There may well be an opening for competition actions directed specifically towards excessive pricing.

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. [Italics added]

In addition, Canada's Patented Medicines Price Review Board specifically addresses excessive pricing, and has the power to order price reductions.[53]

b. South Africa

South Africa's Competition Act[54] expressly identifies the charging of an excessive price as a competition law violation, providing:

> 1. Definitions and interpretation
> (1) In this Act -
> (i) …
> (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);

[52] *See* European Commission, Competition DG, Pharmaceutical Sector Inquiry, Final Report, adopted July 8, 2009.
[53] *See* generally, Joel Lexchin, *Drug Pricing in Canada*, PHARMACEUTICAL PRICES IN THE 21ST CENTURY 25-41, *id*.
[54] Competition Act, No. 89 of 1998, as amended through 2001 < http://www.compcom.co.za/wp-content/uploads/2014/09/pocket-act-august-20141.pdf>.

8. Abuse of dominance prohibited
It is prohibited for a dominant firm to –
(a) *charge an excessive price* to the detriment of consumers;… [Italics 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 ECJ in the *United Brands* case.[55]

It is noted that there have been six cases brought before the Competition Tribunal alleging abuse of dominance by excessive pricing.[56] 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.[57] 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. 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.[58] The complaint-against companies settled the matter by granting voluntary licenses enabling generic production.

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. 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.

c. 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.[59] 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. The OECD Roundtable report makes clear that so 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. 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.

[55] South Africa, OECD Roundtable, *supra* note 24, at 363.
[56] OECD Roundtable, South Africa, pgs. 363-73.
[57] *See* discussion in Jonathan Berger, *Market Definition* 96, at 199-22 in UNDP, Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries (May 19, 2014). United Nations Development Program (ed. F. M. Abbott)(2014) . Available at SSRN: http://ssrn.com/abstract=2439416
[58] *See* Sean Flynn, *Comparative perspectives through country case studies* 24, at 31, in UNDP, id.
[59] *See, e.g.*, OECD Roundtable Report.

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.[60]

C. The Need for Change

Because of their long history in developing and applying antitrust/competition law, the United States and European Union have traditionally been looked to for leadership in the development and application of competition/antitrust law. There is, however, a significant movement among emerging market and other developing countries toward developing and applying competition law,[61] and among OECD countries others specifically address excessive pricing in their legislation and judicial doctrine. 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 addressing the pharmaceutical sector. It fails to take into account the special characteristics of the sector. Originator pharmaceutical products are typically protected by patent that affords a statute-based monopoly. US 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.

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 of 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. Thus, a virtuous cycle 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, are going to 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.

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[60] *See recently* PHARMACEUTICAL PRICES IN THE 21ST CENTURY, *supra* note 5.

[61] *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, Oct. 23, 2015; A. Singh, Competition and competition policy in emerging markets: international and developmental dimensions, in GROWTH & ECONOMIC DEVELOPMENT (P. Arestis et al. eds., 2006); OECD, Implementing Competition Policy in Developing Countries (2007), http://www.oecd-ilibrary.org/docserver/download/4307081ec009.pdf?expires=1453144260&id=id&accname=guest&checksum=394320E459AD87F12C9D88C0C4997CA3; Bernard Hoekman & Peter Holmes, Competition Policy, Developing Countries and the WTO, 22 The World Economy 6, 875 (2002), and; cases cited in UNDP, Using Competition Law, supra note 8.

As the courts have pointed out, and without quarrel here, the higher than competitive market prices enabled by pharmaceutical patents provide the basis for continuing investment in necessary R&D. Certainly there are 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 does not argue 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 till the end of the effect of patent term for treatment: 10 or 15 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. And, 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.

And, what about the cases of generic producers enjoying "effective monopolies" because they are the last of the remaining suppliers?[62] There are a good number of recent incidents of very large price increases involving these circumstances. Is 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. 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. 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.

[62] *See, e.g.*, Andrew Pollack, *Martin Shkreli's Latest Plan to Sharply Raise Drug Price Prompts Outcry*, NY TIMES, Dec. 11, 2015; and Anjali Cordeiro and Makiko Kitamura, *Valeant Slumps as U.S. Prosecutors Issue Subpoenas on Prices*, Bloomberg Business, October 14, 2015 < http://www.bloomberg.com/news/articles/2015-10-15/valeant-receives-subpoenas-from-u-s-prosecutors-on-drug-pricing>.

This is not an argument against patents. It is an argument against using patents as a basis for charging of excessive prices. It is an argument that even in the context of patent protected pharmaceuticals there is such 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 a reasonable price is? 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, and that takes us to Part II of this Article.

III. The Excessive Pricing Determination

As the European Court of Justice 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. Once the cost is determined, the differential between cost and price can be identified, and a determination made whether that differential is "excessive".

In the case of originator pharmaceutical products the cost must include the research and development (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.[63] This is called "reference pricing". This type of methodology has been used by the European Court of Justice and Commission in assessing prices in various cases, including the *Port of Helsingborg* case. 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/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.[64]

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[63] *See, e.g.*, OECD Health Policy Studies, Pharmaceutical Pricing Policies in a Global Market, 24 Sept. 2008, <http://www.oecd.org/els/pharmaceutical-pricing-policies-in-a-global-market.htm>; U.S. Department of Commerce International Trade Administration, Pharmaceutical Price Controls in OECD Countries, Dec. 2004, http://ita.doc.gov/td/health/DrugPricingStudy.pdf; Pharmaceutical Prices in the 21st Century (ed, Z.-U.-D. Babar), Springer (2015), *supra* note 5, including country contributions.

[64] 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 in order to take into account

The pharmaceutical industry prefers that discussions about price be based on the "value" to healthcare systems in terms of alternatives.[65] For example, without treatment by a new drug a patient would develop symptoms, visit doctors, be subject to tests, be admitted to a hospital(s), 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. 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. 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.[66] That does not make that value reasonable.

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income levels, 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 cost 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 50% lower than prices in the United States, and antitrust inquiry might well ask what justifies the price differential. The industry doubtless answers the lower price in Europe or Canada reflects price controls, as indeed it does. But, it also suggests that the originator industry makes a decent profit at the lower price, raising the question why it is necessary to double the price in the United States market. In other words, is the price discrimination justifiable?

[65] This may be technically 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 health-care 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 as to whether to buy a drug. If 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 15% of annual expenditures, so some pricing increment should reasonably be added into the pricing equation for future R&D, but there remains another 85% 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.

[66] 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. The 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

Another method for determining whether a price is excessive, an alternative type of reference pricing, is to compare with prices established between monopsony purchasers (e.g., government health programs) and monopoly suppliers (i.e., originator suppliers).[67] 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.[68] The originator pharmaceutical industry has aggressively resisted providing data regarding its R&D costs. This resistance traces back as early as 1950s U.S. Senate

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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 10 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 the 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 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?

[67] 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 to author dated 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 US Medicare Part D legislation. Jim Hahn, RL33782 -- Federal Drug Price Negotiation: Implications for Medicare Part D, Jan. 5, 2007. Nonetheless, neither a bargaining among monopolists or 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 Hahn, id.

[68] *See* Arthur Daemmrich, *U.S. Healthcare Reform and the Pharmaceutical Industry*, Working Paper, 12-015, September 14, 2011, Harvard Business School; Donald W. Light and Rebecca Warburton, *Demythologizing the high costs of pharmaceutical research*, BioSocieties 1–17, www.palgrave-journals.com/biosoc/; F.M. Scherer, *R&D Costs and Productivity in Biopharmaceuticals*, Faculty Research Working Paper Series, December 2011, RWP11-046; F.M. Scherer, The Pharmaceutical Industry (1298-1336), in HANDBOOK OF HEALTH ECONOMICS, Volume 1 (eds. A.J. Culyer and J.P. Newhouse)(Elsevier Science 2000); Martijn Broekhof, *Transparency in the pharmaceutical industry: A cost accounting approach to the prices of drugs*, Groningen: Community Research Centre Economics (Publications of the Community research Centre Economics EC 121) (2002); Christopher Paul Adams and Van Vu Brantner, *Spending on New Drug Development*, Health Econ. 19: 130–141 (2010); Donald Light and Joel Lexchin, *Pharmaceutical research and development: what do we get for all that money*?, BMJ 2012;344:e4348 doi: 10.1136/bmj.e4348 (Published 7 August 2012).

investigations into pharmaceutical pricing in the United States,[69] has manifested itself in litigation in countries as diverse as South Africa and India,[70] and continues to this day as reflected in Gilead's refusal to provide R&D data to the U.S. Senate in response to request from the Finance Committee.[71] 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.

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.[72] 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).[73] In addition, the results are criticized because of a lack of

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[69] CQ Quarterly Online Edition, Subcommittee Investigates Drug Prices, An article from CQ Almanac 1960, Document Outline, Background, 1959 Hearings, 1960 Hearings, FDA Report, Rules (Senate Judiciary Antitrust and Monopoly Subcommittee, headed by Sen. Estes Kefauver (D Tenn.).

[70] The author of this article served as legal consultant to the Government of South Africa during the litigation brought by 39 originator pharmaceutical companies to challenge provisions of the Medicines and Related Substances Control Amendments 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, Pretoria, 2001, in author's files.

The decision by the 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 (In the Matter of Natco and Bayer, Application for Compulsory Licence Under Section 84(1) of the Patents Act, 1970 In Respect Of Patent No.215758, Compulsory License Application No.1 of,2011, decision of March 9, 2012). 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.

[71] *See* Sovaldi Staff Report, *supra* note 2.

[72] *See, e.g.* PhRMA, 2015 Profile, Biopharmaceutical Research Industry, at p. 13, note 8 (Citing to the 2014 Tufts data for the proposition "It takes at least 10 years and an average of $2.6 billion to develop and bring a new FDA-approved medicine to market."). See Tufts Center for the Study of Drug Development, Briefing, Cost of Developing a New Drug, November 18, 2014; Joseph A. DiMasi, Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, November 18, 2014 <http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf >; Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski & Louis Lasagna, *Cost of innovation in the pharmaceutical industry*, Journal of Health Economics IO (1991) 107-142; Joseph A. DiMasi & Henry G. Grabowski, R&D Costs and Returns to New Drug Development: A Review of the Evidence, 21-46, in THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (eds. P. Danzon & S. Nicholson)(Oxford 20[12])

[73] 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, seeking better access to the data underlying the reported results (Letter from UACT to DiMasi of Feb. 3, 2015); the lead author responded (Response of DiMasi to UACT of March 2, 2015, http://csdd.tufts.edu/news/complete_story/cost_study_press_event_webcast). *See also* James Love, *Evidence Regarding Research and Development Investments in Innovative and Non-Innovative Medicines, Consumer Project on Technology*, September 22, 2003; Public Citizen, *Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card"*, Congress Watch, July 2001; Steve Morgan, Paul Grootendorst, Joel Lexchin, Colleen Cunningham, Devon Greyson, *The cost of drug development: A systematic review*, HEALTH POLICY 100 (2011) 4–17.

transparency regarding the underlying data used by the researchers.[74] The most recent report of results provides both "out-of-pocket" and "capitalized" cost results, so that for those objecting to the inclusion of imputed capital costs the direct expenditure approach can be viewed.[75] 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. 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.[76] 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 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

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[74] *See, e.g.*, letter from UACT, id.; Bruce Booth, *A Billion Here, A Billion There: The Cost olf Making a Drug Revisited*, FORBES PHARMA & HEALTHCARE, Nov. 21, 2014, < http://www.forbes.com/sites/brucebooth/2014/11/21/a-billion-here-a-billion-there-the-cost-of-making-a-drug-revisited/#2715e4857a0b605a33e032ca>. 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. United States Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks, and Rewards, February 1993, OTA-H-522.

[75] 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. Slide presentation, supra. The large difference explains why critics of the Tufts methodology have pointed to 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.

[76] Rohi Malpani, *R&D Cost Estimates: MSF Response to Tufts CSDD Study on Cost to Develop a New Drug*, Nov. 18, 2014 (http://www.doctorswithoutborders.org/article/rd-cost-estimates-msf-response-tufts-csdd-study-cost-develop-new-drug) stating further:

> 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.

new pharmaceutical products. This would not be a "philosophical question". The United States 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). 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.[77] Other statutory authority may be available to agencies such as the NIH to investigate drug pricing,[78] but agencies have not been inclined to use this investigative authority.[79] There is no question but 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".[80] Part of 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 have been federal subpoenas issued by prosecutors, though apparently not emanating from Congress.[81]

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.[82] And, in recent years there has been considerable controversy regarding apparent conflicts of interest with respect to clinical trial "outside" expert reviewers.[83]

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[77] *See Bowsher v. Merck*, *supra*.

[78] 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, e.g., National Institutes of Health Office of the Director Determination in the Case of Norvir® Manufactured By Abbvie, Francis S. Collins, Dir. of NIH, Nov. 1, 2013, https://www.ott.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf; Michael Mezher, Lawmakers Urge HHS to Exercise 'March-in' Rights to Fight Higher Drug Costs, Regulatory Affairs Professional Society, 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 .

[79] 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, Frequently Asked Questions About Drugs, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082690.htm#5>.

[80] 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.

[81] *See* Anjali Cordeiro and Makiko Kitamura, Valeant Slumps as U.S. Prosecutors Issue Subpoenas on Prices, Bloomberg Business, October 14, 2015 < http://www.bloomberg.com/news/articles/2015-10-15/valeant-receives-subpoenas-from-u-s-prosecutors-on-drug-pricing>.

[82] *See, e.g.*, Tracy R. Lewis, Jerome H. Reichman & Anthony D. So, *The Case for Public Funding and Public Oversight of Clinical Trials*, THE ECONOMISTS' VOICE 4.1 (2007), and Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQUETTE INTELLECT PROP LAW REV. 1 (2009).

[83] *Conflict of Interest in Medical Research, Education, and Practice,* Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice; Lo B, Field MJ, eds.,Washington (DC): National Academies Press (US); 2009 http://www.ncbi.nlm.nih.gov/books/NBK22926/; Ed Silverman, *Did Researcher Conflicts Influence Evidence for Studies of Flu Drugs*?, WALL ST. J. PHAMALOT, Oct. 7, 2014,

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.[84] 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;

In a report prepared by the Rapporteur for the Parliamentary Assembly of the Council of Europe, concerns about data regarding R&D are echoed.[85]

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

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<http://blogs.wsj.com/pharmalot/2014/10/07/flu-drug-study-sees-ties-between-pharm-cos-and-researchers-positive-findings/>.

[84] Resolution 2071 (2015)1, Provisional version, Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?, Parliamentary Assembly, Council of Europe, adopted September 29, 2015.

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> 36. … the 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.
> 37. 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 between 2010 and 2012 originated from small or medium-sized enterprises, academia, public bodies and public-private partnerships.

Explanatory memorandum by Maury Pasquier, rapporteur, Doc. 13869 Report, pgs. 10-11 [footnotes omitted]

provided significant amounts of data to its investment bankers and pharmaceutical pricing consultants.[86] 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 *infra*); (2) using costs reported to tax authorities, and; (3) examining data provided to securities exchange officials (e.g., the US Securities and Exchange Commission) for public securities filings.

1. 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 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".[87]

2. 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. 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 pre-clinical and clinical trial costs, and so forth. Most of the new drugs that are developed fall within this general category of products.[88] This is research

[86] *See* Sovaldi Staff Report, at, e.g., pgs. 13-25.

[87] 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.

[88] *See* United States Government Accountability Office, NEW DRUG DEVELOPMENT, GAO-07-49, Nov. 2006, and; Abbott & Dukes, *supra* note 3, at 62-72.

with a high probability of success, research with a low level of uncertainty, or "low risk" research.[89]

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 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/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 and/or types of compounds or biological substances, i.e. a multi-focus enterprise.[90]

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

[89] *See, e.g.*, Hauke Riesch, Levels of Uncertainty, in S. Roeser et al. (eds.), Essentials of Risk Theory, SpringerBriefs in Philosophy, DOI: 10.1007/978-94-007-5455-3_2, 2013, 29-56.

[90] 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.

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) Determinate 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.

Government-subsidized research	University/graduate research, teaching hospitals, small startups	Multiple projects with 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.

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. There may be a competition among originator companies for a promising drug candidate. The smaller enterprise may be a publicly traded company whose investors expect a premium in exchange for tendering control. 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.[91] 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

[91] 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 recently 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.

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.[92] Production processes that are grossly inefficient may distort establishment of reasonable prices, and might be adjusted on that basis.

3. 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).[93] 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.[94]

(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.[95]

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[92] Author's discussion with Pharmexcil Director General in India regarding history of Indian price controls, and identification of inefficient practices. Hyderabad, 2015. Frederick M. Abbott, *Report on Indian policies intended to promote local manufacturing of pharmaceutical products and the protection of public health*, WHO (forthcoming 2016).

[93] *See, e.g., NIH unveils FY2016–2020 Strategic Plan, Detailed plan sets course for advancing scientific discoveries and human health*, December 16, 2015, http://www.nih.gov/news-events/news-releases/nih-unveils-fy2016-2020-strategic-plan; NIH-Wide Strategic Plan, Fiscal Years 2016-2020, http://www.nih.gov/sites/default/files/about-nih/strategic-plan-fy2016-2020-508.pdf

[94] 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.

[95] 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 INVESTING, Nov. 24, 2015.

(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 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 non-trivial 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 a $188 million "departure package" when he left the company.[96] The public and global public health budget reimburse 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 multi-focus enterprise.

5. 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 relation to its R&D cost is a different one. That is, for example, whether a public health system should reimburse for the "reasonable price" based on the patient outcome. This introduces the further question whether the developer of the new drug, should it be particularly useful, receive a price premium based on its utility to patients. An argument can be made that such a premium should not be paid since the R&D costs are sunk costs, and that there is no advantage to the patient/consumer from

Tax authorities are increasingly turning attention to allocation of patent-based income and related tax avoidance, e.g., Vanessa Houlder, *Plans unveiled to crack down on corporate tax avoidance*, FIN. TIMES, Oct. 5, 2015.

[96] Nathaniel Parish Flannery, *Executive Compensation: The True Cost of the 10 Largest CEO Severance Packages of the Past Decade*, Forbes, Jan.19, 2012 < http://www.forbes.com/sites/nathanielparishflannery/2012/01/19/billion-dollar-blowout-top-10-largest-ceo-severance-packages-of-the-past-decade/#2fac142425655dacf8eb2565>.

increasing the price because the drug is more effective than alternatives. On the other hand, the premium may be in the nature of a prize given to the successful venture. An argument in favor of some premium can be made.

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 be 5-10% of patent-protected originator prices, and the US GAO estimates that generic drugs are on average price 75% lower than originator drugs in the United States.[97] 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.

Originator companies do not typically report the prices of their pharmaceutical products in relation to their costs of R&D. The 10 or 20x 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, 10 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 $1 billion to develop and produce, and would sell 10 million units for each of 10 years, or 100 million units over a ten-year period, the reasonable price of the drug would be $10 per pill. Adding a generous $500 million for future R&D, would establish a price per pill of $15.[98]

If the reasonable price per pill is $15, what would be "excessive"? If the originator charged $30, would that be unfairly excessive? What if the price was $150 per pill?

One of the benchmarks used by the ECJ in the *United Brands* decision is how comparable suppliers price similar products. Should it matter that other originator pharmaceutical producers charge $150 per pill when a reasonable fair price is $15 per pill? In the context of an industry

[97] *See, e.g.*, See Andrew Creese and Jono Quick, Differential Pricing Arrangements and Feasibility: Context Setting Paper, World Health Organization, 21 Jan. 2001. Letter from Government Accountability Office to Sen. Orrin Hatch, January 31, 2012, re: GAO-12-371R Savings from Generic Drug Use ("On average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.")

[98] Pfizer states that 29 million people in the United States have been prescribed prescribed Lipitor, <http://www.lipitor.com/about>. Assuming one pill per day, or 352 pills per year, that would amount to a volume of 10,208,000,000 pills per year. Multiplying that by 10 would yield 102,208,000,000 pills. In 2011, Pfizer earned more than $5 billion revenue from sales of Lipitor in the United States. Assuming a 10 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 accounted for by the fact that while 29 million people were at one point prescribe the drug, not all of them maintained a regimen. Or, it may represent the margin of the supply chain following sale by Pfizer. In any event, the order of magnitude is comparable.

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 10 times a price that would return R&D, production costs and a 50% 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 finally 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. For the United States, an advantage is that private litigants with the proper doctrinal tools can seek to recover triple damages for antitrust violations.[99] 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/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 maximum pricing limits, periodic reviews, benchmarking relative pricing, extensions of third-party licensing, and so forth.

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

[99] 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 UNDP, Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries 58, at 84-93 (ed. F. M. Abbott)(2014). Available at SSRN: http://ssrn.com/abstract=2438875 or http://dx.doi.org/10.2139/ssrn.2438875.

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 patient/consumers.

IV. 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 US competition authorities, have long resisted the negotiation of multilateral competition rules.[100] The business community because of a self-interest in avoiding regulation; the competition authorities wishing 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 calculus is reflected in a report by the US Chamber of Commerce regarding China's competition law and policy that finds difficulty in identifying substantive multilateral rules that might constrain China's authorities.[101]

US 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

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[100] *See* Abbott, Public Policy and Global Technological Integration: An Introduction, *supra* note 8.

[101] US 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/report/competing-interests-chinas-competition-law-enforcement-chinas-anti-monopoly-law-application> accessed 11 September 2015. See discussion in Abbott, Competition Law in Emerging Markets: the Virtue of Regulatory Diversity, *supra* note 8.

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[102] - 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 is today 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 US 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.

[102] With the world community composed of more than 200 countries, it is always difficult to make categorical generalizations about the rules followed "everywhere".