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ARTICLE

PROSECUTING EXCESSIVE PRICING OF
PHARMACEUTICALS UNDER COMPETITION LAW:
EVOLUTIONARY DEVELOPMENT

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Prosecution of pharmaceutical companies for excessive pricing of products under competition law is now a reality. As recently as a decade ago, such prosecutions were virtually nonexistent. That situation has changed dramatically as competition authorities in Europe and South Africa have pursued a significant number of such prosecutions and have levied substantial fines against the investigated parties. While the United States has traditionally led in policing the pharmaceutical market against anticompetitive misconduct, in this specific arena it has fallen behind, principally because federal courts so far have refused to acknowledge excessive pricing as a cause of action under Section 2 of the Sherman Act.

In a succession of cases European competition authorities have demonstrated concretely the way in which excessive pricing prosecutions may be pursued. This article examines those cases in some detail showing the challenges that competition authorities have faced, and how they have gone about addressing them. The successes in Europe should help put to rest arguments regarding the difficulties in ascertaining how pharmaceutical products are priced, particularly for products no

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longer covered by patents or regulatory market exclusivity. The South African competition authority is undertaking its second major prosecution of excessive pricing of originator products. The ongoing case involves an essential anticancer medicine the pricing of which has deprived individuals in South Africa of life-saving treatment.

Methodologies for investigating and analyzing abusive pricing are being regularized. This is important because competition authorities around the world should be able to rely on generally accepted standards for pursuing misconduct. This article suggests doctrinal improvements in the form of per se baseline rules for establishing excess with respect to generics, and rule of reason balancing tests for assessing the fairness of pricing practices for originator products and generics not encompassed by per se rules. The continued evolution of excessive pricing doctrine does not depend on these improvements. More important is continuing legal, financial, and political support for the efforts of competition authorities in this area.

Patents, regulatory market exclusivity and other structural features insulate the pharmaceutical market from economic pressures that ordinarily create and re-create an equilibrium that protects consumers. For the pharmaceutical market, there must be a means to redress excessive prices in themselves. Competition law enforcement is an important tool for achieving that redress.

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I. INTRODUCTION

A. Background

Access to healthcare is a concern for individuals around the world.¹ Pharmaceutical products, including therapeutics, vaccines and diagnostics, play a major role in the global healthcare system.² Concerns regarding affordability and access to pharmaceutical products are long-standing.³ They are relevant across the range of disease conditions and the manner of addressing them.⁴ They affect high-

¹ See World Health Org. & The World Bank, *Tracking Universal Health Coverage: 2017 Global Monitoring Report* (2017), <https://documents1.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf> (“The report reveals that at least half the world’s population still lacks access to essential health services. Furthermore, some 800 million people spend more than 10 per cent of their household budget on health care, and almost 100 million people are pushed into extreme poverty each year because of out-of-pocket health expenses.”)

² FREDERICK M. ABBOTT & GRAHAM DUKES, *GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW’S WORLD* (Edward Elgar Publ’g 2009).

³ Jay Hancock, *Talk About Déjà Vu: Senators Set to Re-Enact Drug Price Hearing of 60 Years Ago*, Kaiser Health News (Feb. 22, 2019), <https://khn.org/news/talk-about-deja-vu-senators-set-to-re-enact-drug-price-hearing-of-60-years-ago/#:~:text=Hearings%20led%20by%20Sen.,it%20to%20the%20final%20bill.>

⁴ See, e.g., Andrew W. Mulcahy et al., *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies* (RAND Corporation 2021),

income, middle-income and low-income countries.⁵ The COVID-19 pandemic starkly illustrated the intensity of global and local discourse that may take place when pharmaceutical products are not made available in a timely and accessible manner.⁶

There are various legislative and regulatory tools that can be used to address affordability and access to pharmaceutical products. Such tools, including price control systems, are widely employed. For example, in Europe, where most of the cases discussed in this article arose, price control systems are common.⁷ Yet despite the availability and use of these tools, the price of pharmaceutical products in Europe may be high and, as illustrated in this article, may also be “excessive.” Excessive pricing often signals that the national or regional regulatory system for medicines is in some way broken in the sense that pharmaceutical industry actors are able to exploit defects to enable excessive pricing. There are, as will be described, business models consciously built around exploiting “niches” where single suppliers of pharmaceutical products can dominate the market and charge excessive prices. These niches are advertised to investors as attractive opportunities.

Competition or antitrust law is used to address pharmaceutical products and markets, just as it is used to address other subject matter, whether that be automobiles, banks, energy supplies or smartphones. For example, to address abuses involving agreements to fix prices and allocate markets, or to address problematic mergers and acquisitions.⁸

https://www.rand.org/pubs/research_reports/RR2956.html; Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA Network Open e194791 (2019).

⁵ Steven G Morgan, Hannah S Bathula & Suerie Moon, *Pricing of pharmaceuticals is becoming a major challenge for health systems*, 368 BMJ l4627 (2020), <http://dx.doi.org/10.1136/bmj.l4627>. See also *Medicines*, World Health Org., https://www.who.int/health-topics/medicines#tab=tab_2 (last visited March 19, 2023) (“The price of medicine remains the largest impediment to access and the economic impact of pharmaceuticals is substantial. They are the largest public expenditure on health after personal costs in many low-income countries, and the expense is a major cause of household impoverishment and debt. Public expenditure ranges widely between nations, from under 20% of total healthcare costs in high-income countries to up to 66% in low-income countries.”)

⁶ Frederick M. Abbott, *Child-Proofing Global Public Health in Anticipation of Emergency*, 20 WASHINGTON UNIV. GLOBAL STUDIES L. REV. 583, 583-92 (2021).

⁷ PHARMACEUTICAL PRICES IN THE 21ST CENTURY (Zaheer-Ud-Din Babar ed., 2015); OECD, *Pharmaceutical Pricing Policies in a Global Market* (OECD Publications 2008), https://read.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-pricing-policies-in-a-global-market_9789264044159-en#page1.

⁸ See generally Frederick Abbott et al., United Nations Development Programme, *USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES* (UNDP 2014), <https://www.undp.org/publications/using->

In Europe and some other jurisdictions (for example, South Africa) competition laws expressly make it unlawful to abuse a dominant market position to charge an unfair price.⁹ Yet, until a decade ago, competition authorities were reluctant to pursue excessive pricing cases, including with respect to pharmaceuticals.¹⁰ A substantial part of this article is devoted to describing a significant shift in attitude. In Europe prosecutions involving charges of excessive pricing of pharmaceuticals are now fairly common. The South African Competition Authority currently is pursuing a case addressing excessive pricing of a patented treatment for breast cancer.¹¹

In the United States, controversy over the terms of programs such as Medicare and Medicaid, and the pricing of widely used therapeutic treatments such as insulin, are a routine part of the daily news cycle.¹² Yet competition authorities in the United States do not pursue excessive pricing causes of action, primarily because the federal courts have not been receptive.¹³ The courts have questioned whether such prosecutions are technically feasible and whether judges are the right arbiters. This article shows the feasibility of prosecuting cases of excessive pricing. It has been “proven” in Europe. The United States is lagging, and it should be catching up.

This article begins by describing how the landscape of excessive pricing has shifted over the past decade, particularly within Europe, from hesitancy to endorsement, mainly through the pursuit of a series of cases involving excessive pricing of off-patent pharmaceutical products. Before providing the details of these cases, this article briefly explains rules deriving from the seminal judgment of the Court of Justice of the European Union in the *United Brands* case on which these prosecutions rely. The article then provides details of seven prosecuted cases, and

competition-law-promote-access-medicine-0; Frederick Abbott, United Nations Development Programme, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A SUPPLEMENT TO THE GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES (UNDP 2022), <https://www.undp.org/publications/using-competition-law-promote-access-health-technologies-supplement-guidebook-low-and-middle-income-countries>.

⁹ See *infra* notes 31, 299.

¹⁰ See *infra* Part I.B.

¹¹ See *infra* Part III.B.

¹² See, e.g., Remarks by President Biden on Lowering Prescription Drugs Costs, Daily Comp. Pres. Docs., 2023 DCPD N0. 00199 (Mar. 15, 2023), <https://www.whitehouse.gov/briefing-room/speeches-remarks/2023/03/15/remarks-by-president-biden-on-lowering-prescription-drugs-costs/>; Rebecca Robbins, *Sanofi Plans to Cut the Price of Insulin*, N.Y. TIMES, Mar. 16, 2023, <https://www.nytimes.com/2023/03/16/business/sanofi-insulin-price.html>.

¹³ See *infra* Part VII.A–C.

one settlement, in Europe.¹⁴ “How” it was done is an important part of the proof of feasibility.¹⁵

The article then describes and analyzes an ongoing prosecution in South Africa involving pricing of the breast cancer treatment Herceptin.¹⁶ This case is distinguished from those in Europe as it concerns a patent-protected drug. Analysis of excessive pricing in cases involving originator drugs that include research and development (“R&D”) expenses, risk and patents is inherently more complex than addressing generic drugs marketed without substantial investment in R&D.

Based on the cases so far prosecuted, the article synthesizes common elements or approaches that might be used by competition authorities in the future.¹⁷ There are “learning curves” as competition authorities sort through the various technical issues involved in pharmaceutical production and distribution, and associated pricing decisions. Prosecutors should reference and rely on approaches that have previously been developed so that the “wheel” need not be reinvented for each case. Competition authorities are government offices and must deal with budgetary and staffing limitations. Attention should be focused on improving the efficiency of prosecutions to reduce costs and accelerate timelines.

The article suggests that the jurisprudence surrounding competition law prosecutions for excessive pricing could be improved in at least two ways.¹⁸ First, courts or legislative authorities could adopt “per se” rules such that when pricing for generic products exceeds a certain level (above cost-plus) it is automatically deemed to be excessive so that courts and prosecuting authorities do not need to engage in further in-depth investigation and analysis.

Cases that are not captured by the *per se* rules will remain. This article suggests preferred methodologies for establishing excessive pricing in such cases, including cases involving originator products where there is R&D risk adjustment involved.¹⁹

The article then proposes reexamining the jurisprudence arising out of *United Brands*. It recommends moving from the “two step” test to a rule of reason type balancing test to assess whether a price is excessive under the circumstances.²⁰

¹⁴ See *infra* Part II.

¹⁵ Most of the decisions summarized in a page or two run several hundreds of pages, if not more than a thousand.

¹⁶ See *infra* Part III.B.

¹⁷ See *infra* Part IV.

¹⁸ See *infra* Part V.

¹⁹ See *infra* Part V.B.

²⁰ See *infra* Part VI.

The article finally turns to the United States and the judicial reluctance to accept excessive pricing causes of action noting that there is some change in the wind as evidenced, *inter alia*, by the Federal Trade Commission (“FTC”)/States Attorney General prosecution in the case involving Martin Shkreli. The article finally suggests that the FTC pursue a Sector Study looking to determine whether abuses involving niche pharmaceutical products and excessive pricing are taking place in the United States.²¹

B. *The Changing Landscape*

As of 2011, an Organisation for Economic Co-operation and Development (“OECD”) compilation of views of competition authorities regarding excessive pricing reported that there had been no prosecutions in the pharmaceutical sector outside one in South Africa in the early 2000’s.²² At that time competition authorities on the whole expressed a cautious attitude about the prospects for moving forward in this area.²³

European competition authorities have moved forcefully ahead in prosecuting excessive pricing, having initiated eight such prosecutions since 2011.²⁴ They have collectively imposed more than \$600 million in fines.²⁵ So far, the prosecutions in

²¹ See *infra* Part VII.A–E.

²² OECD Directorate for Fin. & Enter. Aff. Competition Comm., Excessive Prices 2 (2012) [hereinafter “OECD Roundtable”] (“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”). In this article, the terms “antitrust law” and “competition law” are used interchangeably. The term “antitrust” is predominantly used in the United States based on the historical context of the Sherman Antitrust Act (1890), while the term “competition” is more widely used globally. Though there are differences in the way that anticompetitive abuses are addressed in different countries, this does not reflect a terminological distinction between “antitrust law” and “competition law.”

²³ *Id.*

²⁴ See case discussion *infra* Parts II, III.

²⁵ Some of those fines have yet to be collected as cases remain under appeal.

Europe have involved generic (off-patent/off-regulatory exclusivity) products,²⁶ though two involve an orphan drug designation.²⁷

South Africa has prosecuted two cases based on excessive pricing of originator/patent protected drugs. The first, more than a decade ago, and the second now under submission to the Competition Tribunal with respect to excessive pricing of Herceptin.²⁸ As we consider potential reforms of competition law globally it is important to examine the 2018 amendments to South Africa's Competition Act that work improvements on the approach originally derived from

²⁶ Pharmaceutical products that are patented and that obtain regulatory approval/market authorization as new drugs are referred to as "originator" products and enjoy periods of market exclusivity of different durations based on these protections. When a drug loses its patent and market exclusivity protection it is subject to competition from third parties producing so-called "generic" drugs, which are also subject to regulatory approval, but typically under an accelerated procedure requiring demonstration of bioequivalence. An originator pharmaceutical company will often continue selling its approved pharmaceutical product even after losing patent and market exclusivity and may do so either with or without the "brand-name" or trademark originally associated with the product. With the brand name, the product would typically be referred to in the US as a "branded generic." But originators may decide to introduce a generic version without using their brand-name, in which case the drug may be referred to as "generic" or as an "authorized generic." *See, e.g.*, U.S. Food & Drug Admin., Generic Drugs: Questions & Answers, <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q2> (Mar. 16, 2021); U.S. Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>. European authorities typically do not refer to off-patent/off-regulatory exclusivity originator drugs as "generics" or "branded generics," but as off-patent originator products. *See, e.g.*, Commission Decision 435/04 of Feb. 10, 2021 relating to a proceeding under Article 102 of the Treaty on the Functioning of the European Union and Article 54 of the EEA Agreement (Case AT.40394 - Aspen), 2021 (summary at 2021 O.J. (C 435) 4), https://ec.europa.eu/competition/antitrust/cases/dec_docs/40394/40394_5350_5.pdf. In this article, the term "generic" is generally used to refer to a pharmaceutical product that is not protected by patent or regulatory market exclusivity (including orphan drug designation that might establish exclusivity), though in some contexts the European convention is followed. "Orphan drugs" are drugs that address rare diseases and/or small patient populations. Some legislatures have considered it useful to establish a system for awarding a period of market exclusivity to orphan drugs to encourage R&D and manufacturing. Such systems vary among jurisdictions. *See, e.g.*, U.S. Food & Drug Admin., Designating an Orphan Product: Drugs and Biological Products, <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products> (July 8, 2022); European Medicines Agency, Orphan Designation: Overview, <https://www.ema.europa.eu/en/human-regulatory/overview/orphan-designation-overview> (last visited Apr. 3, 2022).

²⁷ In the *Leadiant* cases (Italy and the Netherlands) discussed *infra* Parts II.D, II.F, the subject orphan designation was obtained without any additional R&D or other value added to the old pharmaceutical product. For all intents and purposes, the subject pharmaceutical product was "generic."

²⁸ *See infra* Part III.

the Court of Justice of the European Union (“CJEU”) (formerly European Court of Justice) jurisprudence in *United Brands*.²⁹

The United States traditionally has been the leader in policing the pharmaceutical sector against anticompetitive abuse, particularly through the work of the FTC.³⁰ Yet in the arena of excessive pricing, Europe and South Africa have moved substantially ahead.

An important take-away from the European prosecutions involving the generics sector is that there is no practical reason why excessive pricing prosecutions cannot be successfully pursued in the United States, and elsewhere. The Europeans have shown that it can be done. It is time to lay out a roadmap for the United States and other countries drawing lessons from the European and South African experience.

II. EUROPE

A. *The CJEU and the Two-Step Test*

European competition authorities and courts have a certain advantage in that the text of Article 102 of the Treaty on the Functioning of the European Union (TFEU) expressly establishes the charging of unfair selling prices as a form of abuse of dominant position.³¹ A successful prosecution for excessive pricing under Article 102 of the TFEU requires that the party under investigation holds a dominant position on the relevant market for the product(s), as the cause of action is grounded in abuse of dominant position.

Determinations by administrative authorities and courts in the EU, as well as in the UK, regarding excessive pricing of pharmaceuticals by dominant enterprises so

²⁹ Case 27/76, *United Brands Co. & United Brands Cont’l B.V. v. Comm’n of the European Cmtys.*, 1978 E.C.R. I-207 [hereinafter *United Brands*]. See also *infra* Part VI. Competition Act No. 89 of 1998 (S. Afr.), as amended 2018, *infra* note 299.

³⁰ For general background on excessive pricing in competition law relevant to the pharmaceutical sector, see Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 UC IRVINE L. REV. 281, 281–320 (2016), available at SSRN: <https://ssrn.com/abstract=2719095> [hereinafter Abbott 2016].

³¹ Treaty on the Functioning of the European Union, art. 102, May 9, 2008, 2008 O.J. (C 115) 47 [hereinafter TFEU]:

(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.

far apply a jurisprudential formula derived from *United Brands v. Commission*, a 1978 decision of the CJEU.³² This is referred to as the “two-step test.”³³

In the first step, a determination is made as to whether the price of the relevant product (or service) is “excessive.” This is accomplished preferably by ascertaining the cost of supplying that product or service, adding a reasonable margin for profit or return on investment, and comparing that cost-plus figure with the price at which the product is sold. This should yield a spread between selling price and cost-plus that can be stated as a percentage. At this initial stage, the question whether the difference between price and cost-plus is excessive can be ascertained, for example, by comparing the profit secured by the party under investigation with profit levels of other suppliers in the relevant sector.³⁴ In cases where it is impractical to ascertain actual cost, the baseline reasonable (i.e. not excessive) price may be ascertained in other ways, including by looking at prices of the same or comparable products in other markets. The difference between the price under investigation and the price in comparable markets should likewise yield a spread that can be stated as a percentage.

Assuming that a preliminary determination is made that the price is excessive, in the second step the question is whether the price is “unfair.” There are two “prongs” or “limbs” in the second step, and it is necessary for the prosecuting authority to prove only one. That is, the tests of the second step are in the alternative. For the first prong, the prosecuting authority may demonstrate that the price is “unfair in itself.” That means that offsetting factors or circumstances do not justify the excessive price as identified in the first step. Alternatively, the prosecuting authority may demonstrate that the price charged in the investigated market is unfair in comparison to prices charged for the same or a sufficiently comparable/competing product in other markets, which for the EU has typically meant in other member states.

This succinct summary of the two-step test belies the complexity of its application, not only in the sense of the mechanics of ascertaining and comparing costs and prices, but also in the sense of differences among administrative authorities and courts regarding the way the test should be applied from a jurisprudential standpoint, including notably whether and to what extent the two

³² *United Brands*, *supra* note 29.

³³ See detailed explanation in, e.g., Commission Decision, *CASE AT.40394 – Aspen*, 2021 (EC).

³⁴ In its *United Brands* decision, the CJEU did not provide explicit guidance regarding what differential between supplier profits would be considered excessive but said that the price is excessive if it has “no reasonable relation to the economic value of the product supplied,” ¶ 250.

prongs (or limbs) of the second step are true alternatives.³⁵ In Part VI of this article, there is a suggestion regarding replacement of the two-step test with a single contextual test.³⁶

B. The UK Competition and Markets Authority

1. CMA v. Pfizer/Flynn

The UK Competition and Markets Authority (“CMA”) started the wave of European prosecutions when it opened an investigation of Pfizer and Flynn in early 2013. On December 7, 2016, the CMA fined Pfizer £84,196,998 and Flynn £5,164,425 (totaling £89,361,425), for abuse of dominant position by excessive pricing of a pharmaceutical product used to treat epilepsy (the “First Decision”).³⁷

Pfizer/Flynn appealed the First Decision to the UK Competition Appeal Tribunal (“CAT”). The CMA was partially reversed on grounds that it had failed to properly apply the CJEU’s two-step test.³⁸ Relying on an opinion by CJEU then-Advocate General (now Judge) Wahl in the *Latvian Copyright* Case, the CAT said that the CMA should have addressed both prongs of the second step of the two-step test as a type of “sanity check,”³⁹ notwithstanding that this was inconsistent with the jurisprudence of the CJEU, including as it had been confirmed in the *Latvian Copyright* Case.⁴⁰ The CMA appealed, and the UK Court of Appeal reversed the CAT on this question, remitting the case back to the CMA based on a somewhat revised jurisprudence.⁴¹ The Court of Appeal said that while the two prongs of the second-step were indeed alternatives, and that only one needed to be proven, if the

³⁵ See, e.g., Frederick M. Abbott, *The UK Competition Appeal Tribunal’s Misguided Reprieve for Pfizer’s Excessive Pricing Abuse*, IIC – INT’L REV INTELL PROP & COMP L (2018), <https://doi.org/10.1007/s40319-018-0734-y>.

³⁶ See *infra* Part VI.

³⁷ Competition and Markets Authority, Decision on Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK, Case CE/9742-13, 2016 (hereinafter “First Decision”). See Table 7.1 for Pfizer final penalty; Table 7.2 for Flynn final penalty. <https://assets.publishing.service.gov.uk/media/594240cfe5274a5e4e00024e/phenytoin-full-non-confidential-decision.pdf>. See detailed analysis in Abbott, IIC, *supra* note 35. This article retains the citation references to the First Decision, while adding references to the Remittal Decision, to reinforce the consistency of the findings, pointing out meaningful differences as warranted.

³⁸ Flynn Pharma Ltd. v. Competition & Mkts. Auth. [2018] CAT 11.

³⁹ See *id.* ¶¶ 14, 368 (citing Augstākā tiesa [Supreme Court] Apr. 6, 2017, C-177/16 (Lat.) [hereinafter *Latvian Copyright* Case]). See also note 371, *infra*.

⁴⁰ See, e.g., *id.* ¶ 366.

⁴¹ Competition & Mkts. Auth. v. Flynn Pharma Ltd., [2020] EWCA Civ 339, ¶¶ 97, 257, 259, 273, 279 (appeal taken from CAT).

defendant offered evidence that might justify its conduct on the “unused” prong, the CMA should consider it.⁴²

Following remittal, the CMA re-opened its investigation in June 2020 and on July 21, 2022 issued a “Remittal Decision” imposing fines of £63,300,000 on Pfizer and £6,704,422 on Flynn (totaling £70, 004,422).⁴³ Brexit had intervened, and the Remittal Decision would not be based on EU law, but instead only on the British Competition Act 1998, while nevertheless attempting to preserve consistency with the First Decision.⁴⁴ The CMA’s First Decision and Remittal Decision are largely consistent in factual findings and analysis, with a few material differences identified in the discussion following.

Pfizer and Flynn had together worked out a complex scheme designed to take phenytoin sodium capsules out of the UK’s system of price controls. This involved a British process referred to as “debranding.”⁴⁵ Pfizer transferred its UK marketing authorization for “Epanutin,” its branded phenytoin sodium capsules, to an intermediary, Flynn, without the associated trademark.⁴⁶ Flynn with its newly genericized product was not subject to price controls,⁴⁷ and this allowed it to dramatically increase the price. The annual cost to the National Health Service (“NHS”) of the identical drug increased from £2 million to £50 million and forced the NHS to spend an additional £169 million during the relevant period.⁴⁸ Pfizer (via Flynn) was the sole supplier of the anti-epilepsy drug (“AED”) with the NHS a captive market.⁴⁹

Pfizer entered into its intermediary arrangement with Flynn because it wanted to avoid the negative publicity that would be associated with its pricing action.⁵⁰

⁴² *Id.* ¶¶ 259–260, 270–273.

⁴³ Competition and Markets Authority, Decision on Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK, Case 50908, 21 July 2022, https://assets.publishing.service.gov.uk/media/63ef6ed5e90e077bb77ed980/Phenytoin_Decision_-_Redacted_1_.pdf (hereinafter “Remittal Decision”), ¶¶ 9.916 & 9.918, 9.214–9.215.

⁴⁴ Remittal Decision, ¶¶ 1.3, 1.95.

⁴⁵ First Decision, *e.g.*, Table 1.1, ¶¶ 3.153 2.181, 3.158 2.223, 3.248, 5.356 9.42.5, 7.21 9.42.6; Remittal Decision, *e.g.*, 1.16, 1.24.3, 2.102, 2.152, 2.157, 2.164, 2.189, 2.290, 6.81, 6.113, 6.143, 8.14.

⁴⁶ First Decision, *e.g.*, ¶¶ 3.237; Remittal Decision, *e.g.*, ¶¶ 1.23.

⁴⁷ First Decision, *e.g.*, ¶¶ 3.155–3.156; Remittal Decision, *e.g.*, 2.152–2.159

⁴⁸ Remittal Decision, *e.g.*, ¶¶ 1.18, 1.34, 2.326, 6.127.

⁴⁹ First Decision, ¶ 5.398. Remittal Decision, ¶ 6.41.

⁵⁰ First Decision ¶ 5.416. Remittal Decision, *e.g.*, 6.113–6.117. The evidence gathered by CMA from Pfizer and Flynn showed that Pfizer executives knew exactly what they were doing in terms of “fleecing” the NHS. Some expressed misgivings at the outset of the process, particularly as the NHS was in the midst of substantial budget tightening. First Decision at ¶ 5.415; Remittal Decision

Pfizer had long provided the drug to the NHS system through its own distribution network. Following its agreement with Flynn, it would supply exactly the same drug from exactly the same factory,⁵¹ but using Flynn as an intermediary that was entitled to its own cut (or distribution margin).⁵² Flynn would be responsible for defending the new elevated pricing in the media and before regulatory authorities.⁵³ Pfizer and its executives would, in theory, be insulated. The UK Department of Health and Social Care (“DHSC”) forcefully objected to the Pfizer/Flynn price increases when they were announced.⁵⁴

Pfizer and Flynn were found to enjoy a dominant position on the UK market for phenytoin sodium capsules.⁵⁵ Because this finding of the CMA was upheld on appeal, first to the CAT, the Remittal Decision “does not include a detailed assessment”.⁵⁶ Important to the market definition aspect of the case—and the finding of abuse of dominance—is that there is risk associated with switching patients to any new formulation of phenytoin sodium capsules once they are stabilized on it, including switching between manufacturers of bioequivalent versions.⁵⁷ In consequence, the Medicines and Healthcare Products Regulatory Agency in the UK advised strongly against switching formulations or manufacturers,⁵⁸ and UK dispensing pharmacists largely followed that advice.⁵⁹ This made it very difficult for third parties to enter the market with competing generics because using same product but from a different source was strongly discouraged.⁶⁰

In its First Decision, the CMA established a “cost-plus” benchmark price for the AED, including direct and indirect costs, and a profit margin of 6% (for both

at ¶¶ 2.201–2.202, 2.214–2.215 As stakeholders in the NHS observed, the dramatic increase in expenditure on phenytoin sodium capsules forced cutbacks for other areas of British healthcare.

⁵¹ First Decision, ¶ 3.75. Remittal Decision, ¶ 2.258

⁵² First Decision, ¶ 3.248. Remittal Decision, ¶¶ 1.26–1.28, 6.80 *et seq.*

⁵³ First Decision, ¶ 5.427. Remittal Decision, ¶¶ 2.237, 2.245, 6.109 *et seq.*

⁵⁴ Remittal Decision, e.g., ¶¶ 6.61, 6.78.

⁵⁵ *Id.*, e.g., § 4, and ¶¶ 1.3, 1.21, 2.1, 2.4, 5.442.

⁵⁶ It rather sets out the relevant markets and conclusions. Remittal Decision, ¶¶ 3.1 *et seq.*

⁵⁷ First Decision, ¶¶ 1.6–1.7. Remittal Decision, ¶¶ 1.22, 2.21. Phenytoin sodium capsules are an old-line treatment for epilepsy and are no longer prescribed for new patients. However, the drug remains effective for patients who are taking it, which the First Decision indicated totaled about 48,000 individuals in Britain. As the UK population ages and new patients are prescribed different treatments, demand for the AED is slowly declining. Initial Decision, e.g., ¶ 3.45. According to the Remittal Decision, the number went from about 57,500 in 2012 to 37,500 in 2019. Remittal Decision, at ¶ 2.47.

⁵⁸ First Decision, e.g., ¶ 3.36. Remittal Decision, e.g., ¶ 2.38.

⁵⁹ First Decision, e.g., ¶ 3.95. Remittal Decision, e.g., ¶ 2.43.

⁶⁰ First Decision, e.g., ¶ 4.46. Remittal Decision, e.g., ¶ 2.133.

Pfizer and Flynn).⁶¹ The principal difference between the First Decision and the Remittal Decision is that the CMA, in the Remittal Decision, adjusted the “plus” element of cost-plus, or the “reasonable rate of return”, to 10% for Pfizer based on a “return on sales” (“ROS”) approach that looked to suitable product or industry comparators.⁶² For Flynn, in the Remittal Decision, the CMA followed a “return on capital employed” (“ROCE”) approach and reduced the reasonable rate of return to about 2%.⁶³

Pfizer argued that continuing to sell phenytoin sodium capsules at the formerly controlled price was not profitable, or at least not sufficiently profitable within its portfolio.⁶⁴ Although it might have obtained approval for a price increase from the British regulatory authorities, it considered that a regulatorily permissible price increase would not be adequate. The CMA accepted that some increase in the price of the product might be justified,⁶⁵ but based on an extensive review of evidence found that Pfizer and Flynn together had grossly or far exceeded the boundaries of justifiable pricing.⁶⁶ The CMA-adopted profit margin reflected that phenytoin sodium capsules are a long-established generic. Price increases by Pfizer and Flynn to the NHS were between 23–2600% of pre-hike prices.⁶⁷

Having found that the prices charged by Pfizer and Flynn were excessive in relation to its cost-plus determination of the benchmark, the CMA found that the prices were unfair in themselves because there was no reasonable relationship between the economic value of the products and the prices charged.⁶⁸ The CMA said that it was not appropriate to determine economic value on the basis that patients would suffer and health system costs would rise if the drug was unavailable. Patients had no real choice as to whether to purchase the products, and Pfizer was not providing any additional value beyond that which had been provided before the price increase.⁶⁹ The CMA noted that, having made a determination that

⁶¹ First Decision ¶ 5.27, including ¶ 5.86 for 6% reasonable rate of return.

⁶² Remittal Decision, *e.g.*, ¶¶ 5.31, 5.143.

⁶³ Remittal Decision, *e.g.*, ¶¶ 5.284, 5.331, 5.333 & Tables 12–13.

⁶⁴ First Decision, *e.g.*, ¶ 3.193; *e.g.*, 2.406.

⁶⁵ First Decision, *e.g.*, ¶ 5.316; Remittal Decision, *e.g.*, ¶ 1.63

⁶⁶ First Decision, *e.g.*, ¶¶ 1.50, 4.57, 5.447; Remittal Decision, *e.g.*, ¶¶ 1.43, 6.15.

⁶⁷ *See* First Decision, *e.g.*, ¶ 3.168; Remittal Decision, *e.g.*, ¶ 1.18. CMA Press Release, CMA fines Pfizer and Flynn £90 million for drug price hike to NHS, “The fines follow prices increasing by up to 2,600% overnight after the drug was deliberately de-branded in September 2012,” Dec. 7, 2016, <https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs>.

⁶⁸ *See* First Decision, *e.g.*, ¶¶ 1.32, 1.40, 1.42, 5.8; Remittal Decision, *e.g.*, ¶¶ 1.46, 4.30, 6.4–6.5, 6.86, 6.99

⁶⁹ First Decision, *e.g.*, ¶¶ 5.279–5.283; Remittal Decision, *e.g.*, ¶¶ 6.87–6.99, 7.8, 9.425

the prices were “unfair in themselves,” it did not need to make a determination as to whether the prices were also unfair when compared to competing products.⁷⁰

In line with the decision of the Court of Appeal that resulted in remittal, the CMA in the Remittal Decision “fairly evaluated relevant evidence put forward by the Parties in their defence, including any *prima facie* valid comparators”, and it found that such evidence did not undermine its conclusion that the prices charged by Pfizer and Flynn were unfair in themselves.⁷¹ The CMA undertook a more extensive review of a proposed tablet comparator in the Remittal Decision than it had in the First Decision.⁷² Pfizer and Flynn had attempted to use high prices charged by Teva for phenytoin sodium “tablets” (as compared with capsules) to justify their price increases. But the NHS and DHSC had strongly objected to Teva’s prices when implemented and considered them unjustifiable. The CMA determined that Teva’s prices were not set in conditions of effective competition and were not a valid comparator.⁷³ Also in the First Decision, for sake of completeness the CMA had taken note,⁷⁴ for example, that Pfizer continued to provide the same drug profitably at much lower prices in other member states of the EU (pre-Brexit), and this observation was reaffirmed in the Remittal Decision.⁷⁵ It recognized that these member states had different regulatory regimes but noted that Pfizer and Flynn had not put forward any “objective dissimilarities,” and said that the disparities in pricing were so large “it is unlikely there would be any ‘*objective dissimilarities*’ that could justify such differences.”⁷⁶

Decisions by the CMA subsequent to the CAT and Court of Appeal decisions addressing the First Decision in Pfizer/Flynn, considered in the following pages of this article (in addition to the Remittal Decision), illustrate the effects of the uncertainty generated by ambiguities inherent in the various appeals processes and decisions. The CMA undertakes multiple lines of duplicative and/or unnecessary analysis as it attempts to properly guess at the legal standards that will be applied on appeal. Preparing these decisions occupies the resources of the competition

⁷⁰ First Decision ¶ 5.476; Remittal Decision, ¶ 1.48

⁷¹ Remittal Decision, ¶¶ 6.137, 6.141.

⁷² In the First Decision, the CMA also declined to use the price of a non-competitive product, phenytoin tablets, as a comparator in regard to excessive pricing or unfairness. *Id.* ¶ 5.518. Tablets were prescribed to a significantly smaller patient population than capsules, and the main provider, Teva, had been criticized by the NHS for its prices, even though the NHS had not formally taken action to lower the price (having achieved a substantial price reduction through informal objection). See *id.* ¶¶ 3.444–3.492.

⁷³ Remittal Decision, ¶¶ 6.192, 6.214, 9.65–9.66.

⁷⁴ First Decision ¶ 5.478.

⁷⁵ Remittal Decision, ¶ 1.47.2, 6.6.2.

⁷⁶ First Decision ¶¶ 5.525–5.526.

authority and slows the processes down. From the side of the parties under investigation, this is a desirable outcome. From the standpoint of protecting the consumer and the British healthcare system, it is not.

2. CMA prosecution of Auden/Actavis (Hydrocortisone)

The *Hydrocortisone* Case prosecuted by the CMA is notable for its focus on a “standard” business model used by investors in the pharmaceutical sector.⁷⁷ This entails identifying and exploiting a “niche” product or market where various factors may accord a protected position that can be exploited to generate high levels of profit.⁷⁸ The “niche products” model appears commonly directed toward generic products since originator products enjoy patent and/or regulatory exclusivity protection and may not require aid from additional regulatory barriers. Nonetheless, originator products may occupy positions protected by factors beyond patents or regulatory exclusivity, just as generics, when regulatory elements such as “use” treatment approvals create distinctions between on-label and off-label markets, with associated pricing and reimbursement differences.

In the *Hydrocortisone* Case, the primary offense of the principal defendant is excessive pricing as a form of abuse of dominant position.⁷⁹ Also, in order to protect its position, the principal defendant negotiated undertakings with potential competitors who refrained from introducing products, a form of market allocation.⁸⁰ The *Hydrocortisone* Case involves exploitation of “quirks” in the UK’s pharmaceutical market regulatory structure.⁸¹

⁷⁷ Hydrocortisone Tablets, Excessive and Unfair Pricing and Anti-Competitive Agreements [2021], Case 50277 (CMA) [hereinafter *Hydrocortisone Case*], <https://www.gov.uk/cma-cases/hydrocortisone-tablets-alleged-excessive-and-unfair-pricing-anti-competitive-agreements-and-abusive-conduct-50277#infringement-decision>.

⁷⁸ “Niche” is a term extensively employed in the CMA decision. *See, e.g., id.* ¶ 3.86 (“The suppliers of such drugs could find themselves in a position of holding significant market power in relation to very old medicines which, although essential to patients, have not been subject to any recent innovation or investment and are shielded from competition. For these drugs, commonly referred to as ‘niche’ generics. . . .”); *see also, e.g., id.* ¶¶ 3.3, 3.30, 3.34, 3.90. *See also* Pfizer/Flynn Remittal Decision, *supra* note 43, at ¶¶ 2.99–2.118.

⁷⁹ *See* Hydrocortisone Case ¶¶ 4.2–4.12. There is an array of corporate restructurings involving the principal defendant over the course of the period under investigation, with the CMA noting that the group of individuals motivating the parties was relatively constant and known to each other. *See, e.g., id.* ¶¶ 3.37–3.40.

⁸⁰ *See, e.g., id.* ¶¶ 1.11, 1.27, 1.32 (referring to negotiated undertakings with potential competitors as “market exclusion agreements”).

⁸¹ *See id.* ¶¶ 1.13, 1.36, 3.244(b) (discussing the results of “quirks” in the UK’s pharmaceutical regulatory structure).

Hydrocortisone is an essential medicine addressing adrenal insufficiency.⁸² It has long been off-patent.⁸³ It was within the British/NHS price control system and was sold for a long time at a low price (circa £1 per pack).⁸⁴ The holder of the market authorization (“MA”), Merck, decided to sell its interest in the product to a buyer, Auden/Actavis.⁸⁵ The buyer followed a preconceived business plan to “debrand” the product. Debranding had the effect of removing it from NHS price controls, though it remained subject to reimbursement through the NHS.⁸⁶ After debranding, Auden/Actavis initiated a series of substantial price increases. It secured a regulatory windfall opportunity when a third-party product obtained an orphan drug designation for an effectively non-competitive product.⁸⁷

Because of an odd timing matter, Auden/Actavis was left as the only company with a marketing authorization that allowed it to supply the principal market for hydrocortisone (i.e., adrenal insufficiency in adults) with a full set of prescription indications of use, in other words, a “full label” product.⁸⁸ What started as a series of significant price increases based on a historically restricted market became a series of additional substantial price increases ostensibly protected by a regulatory timing quirk. But the timing quirk was not absolute. Generic competitor products—exactly the same active ingredient—could also be sold within the NHS prescribing system, but these prescriptions would be “off-label” (referred to as “skinny label” products). The full/skinny label distinction was in practical effect meaningless since the only reason for the labeling restriction had to do with the timing of market authorizations.⁸⁹ But some of the UK largest pharmacy chains refrained from dispensing skinny label hydrocortisone because of concerns with potential liability.⁹⁰ This concern was exacerbated by a marketing campaign Auden/Actavis undertook, directed at persuading physicians not to prescribe skinny label hydrocortisone and pharmacies not to dispense it.⁹¹

This strange set of circumstances resulted in hesitancy among potential generic competitors to enter the market. However, eventually two (Waymade and AMCo) decided to pursue market authorizations and enter as competitors.⁹² Neither

⁸² *Id.* ¶ 1.8.

⁸³ *Id.* ¶ 1.16.

⁸⁴ *Id.*

⁸⁵ *Id.* ¶¶ 3.102–3.103.

⁸⁶ *Id.* ¶¶ 1.18, 3.82–3.85, 6.93(b).

⁸⁷ *Id.* ¶¶ 1.37–1.47.

⁸⁸ *Id.* ¶¶ 1.55–1.72.

⁸⁹ *Id.* ¶ 3.168.

⁹⁰ *Id.* ¶¶ 3.171, 3.277.

⁹¹ *Id.* ¶¶ 3.700, 6.664.

⁹² *Id.* ¶¶ 4.105(b), 4.107, 4.234, 4.239–4.242.

Auden/Actavis nor the two new MA holders would actually manufacture hydrocortisone. This was all done by a third-party contractor.

Foreseeing a substantial risk to its protected market, Auden/Actavis decided to pursue and secure agreements with Waymade and AMCo to refrain from introducing their own products. Under the terms of these agreements, Auden/Actavis sold a defined quantity of products to the potential competitors at prices dramatically discounted from prices to other third parties (£1 versus up to about £87), allowing the potential competitors to resell to pharmacies and earn substantial amounts with little effort (effectively, lump-sum payments), provided they did not introduce their own products to compete with Auden/Actavis.⁹³

Auden/Actavis' principal anticompetitive conduct consisted of abusing its dominant position to dramatically raise the price of hydrocortisone.⁹⁴ The CMA employed the *United Brands* two-step test.⁹⁵ In the first step, it undertook a cost-plus analysis to ascertain whether the prices charged by Auden/Actavis were excessive.⁹⁶ In this case, establishing Auden/Actavis's cost of producing hydrocortisone was fairly straightforward since Auden/Actavis had engaged a contract manufacturer to produce and supply the product to it, and the cost under the supply contract could be ascertained.⁹⁷ Establishing indirect costs of doing business was somewhat more complex, particularly choosing among potential allocation methods, but nothing out of the ordinary.⁹⁸ As the CMA noted on several occasions, the prices charged by Auden/Actavis were so far in excess of its cost plus a reasonable profit—where the reasonable rate of return in this case was determined to be 5%–15%⁹⁹—that the CMA could make assumptions in favor of Auden/Actavis on costs without materially changing the outcome of the decision.¹⁰⁰

Auden/Actavis was determined to have charged prices that exceeded its cost-plus by over 10,000%.¹⁰¹ When Auden/Actavis acquired the product from Merck

⁹³ *Id.* ¶¶ 4.234., 4.241.

⁹⁴ At the time of the CMA's infringement decision, the UK had exited the EU. However, since the period of infringement took place while the UK was a member of the EU, the CMA considered the jurisprudence of the CJEU relevant during the infringement period. *Id.* ¶ 1.6, 421 n.1520.

⁹⁵ *Id.* ¶¶ 5.24–5.28.

⁹⁶ *Id.* ¶¶ 5.29–5.38.

⁹⁷ *See id.* ¶¶ 5.98, 5.304.

⁹⁸ *See id.* ¶¶ 5.101–5.146.

⁹⁹ *Id.* ¶ 5.201.

¹⁰⁰ *See, e.g., id.* ¶¶ 5.160, .200, .308, .6.

¹⁰¹ *Id.* ¶¶ 10.28; *See also* Press Release, UK Competition and Markets Authority, CMA finds drug companies overcharged NHS: The CMA has imposed fines totalling over £260 million for competition law breaches in relation to the supply of hydrocortisone tablets (July 15, 2021), <https://www.gov.uk/government/news/cma-finds-drug-companies-overcharged-nhs>.

in 2007, NHS spent around £500,000 per year on hydrocortisone. At the peak of Auden/Actavis' infringements, the NHS spent £80 million per year on the same drug, which had undergone no change. The CMA determined that the cost-plus for the highest volume product, 10 mg tablets, was less than £5, and for 20 mg tablets, less than £6, based on various generous assumptions.¹⁰² Yet, when it undertook to calculate excessive pricing margins for purposes of determining the extent of infringement, it excluded sales below £20,¹⁰³ in essence deciding that it did not need to pursue 200–300% price increases,¹⁰⁴ presumably leaving this large margin to avoid close questions on appeal.

The CMA then turned to the second step of the two-step test, pointing out that the prongs of “unfair in itself” and “unfair in comparison to competing products” are alternatives.¹⁰⁵ However, in keeping with the Court of Appeal decision in *Pfizer/Flynn*, it noted that if the accused put forward credible evidence on either prong it should nevertheless be considered. The CMA determined that Auden/Actavis' excessive pricing was unfair in itself because there was no added economic value of the products, that the products were necessary for the health of the patients, and that the prices had placed a burden on the NHS.¹⁰⁶ Moreover, Auden/Actavis had engaged in a campaign to persuade doctors not to prescribe skinny label hydrocortisone, and for pharmacies not to dispense it, even though it knew that there was no difference with the full label product.

Although it need not have done so, for the sake of completeness the CMA determined that there were no products effectively competing with Auden/Actavis hydrocortisone in the relevant market until the point at which skinny label products were in direct competition with full label products in 2021. Using those “current” 2021 prices as a comparator, the CMA determined that Auden/Actavis prices during the period under investigation (2008–2018)¹⁰⁷ were unfair, on average by around 2,700% for 10 mg and 2000% for 20 mg tablets¹⁰⁸

The CMA assembled a large body of evidence to support its claims against Auden/Actavis, Waymade and AMCo regarding an agreement to refrain from competition. This included evidence from emails and other texts, including notes of conversations, investor presentations, as well as the results of interviews with

¹⁰² See, e.g., *id.* ¶ 5.443, .474. As of early 2022, pharmacy prices in the UK are much lower, about £2 per pack.

¹⁰³ *Id.* ¶¶ 5.479, .482.

¹⁰⁴ *Id.* ¶¶ 5.18–.20, .223, .271, .309.

¹⁰⁵ *Id.* ¶¶ 5.42–.54.

¹⁰⁶ *Id.* ¶¶ 5.296–.365.

¹⁰⁷ *Id.* ¶ 10.187

¹⁰⁸ *Id.* ¶ 5.396.

officers and employees of the parties.¹⁰⁹ It was clear that the three parties had arranged such that Waymade and AMCo would be generously compensated through sharply discounted supply of hydrocortisone from Auden/Actavis and in return would forgo introducing competitive hydrocortisone onto the UK market. This enabled Actavis to maintain its excessive prices on hydrocortisone until ultimately a few additional third parties elected to enter the market and brought prices down sharply.¹¹⁰ Fines were increased based on the seriousness of the offenses.¹¹¹

This case included a dizzying array of changes in corporate ownership and identity over the course of a decade or so. In the final analysis, the Auden/Actavis-related entities were fined a total of £221.1 million (£155.1 for excessive pricing and £66 million for the unlawful agreements), Waymade £2.5 million and AMCo £42.8 million. Thus an overall total of £266.4 million (or about US\$325 million).¹¹²

The parties under investigation filed appeals of the CMA decision in the Competition Appeal Tribunal, which is being defended by the CMA.¹¹³

3. CMA v. Advanz

The methodology of the CMA in approaching excessive pricing in the generic sector is also illustrated in *CMA v. Advanz*.¹¹⁴ As in *CMA v. Pfizer/Flynn*, the prosecution of Advanz¹¹⁵ involved “debranding” of a generic product,¹¹⁶ in this case liothyronine tablets that are prescribed to treat a thyroid condition (hypothyroidism).¹¹⁷ Liothyronine is prescribed when patients with hypothyroidism do not experience satisfactory results with the far more commonly

¹⁰⁹ *Id.* ¶¶ 6.1–.59.

¹¹⁰ *Id.* ¶¶ 6.91–934.

¹¹¹ See, e.g., *id.* ¶¶ 10.11, .129–.133, .163, .171 *et seq.*

¹¹² *Id.* ¶ 10.417. British pound at 1.22 to US dollar as of March 14, 2023.

¹¹³ *Hydrocortisone Tablets: Alleged Excessive and Unfair Pricing, Anti-Competitive Agreements and Abusive Conduct (50277): CMA Case Timetable*, Gov.uk: Competition and Markets Authority Cases (March 31, 2022), <https://www.gov.uk/cma-cases/hydrocortisone-tablets-alleged-excessive-and-unfair-pricing-anti-competitive-agreements-and-abusive-conduct-50277> (“Advanz Pharma, Allergan plc, Auden Mckenzie (Pharma) Limited, Cinven and Intas Pharmaceuticals Limited filed appeals in the Competition Appeal Tribunal against the CMA’s findings in the Infringement Decision. The CMA will defend the appeals.”).

¹¹⁴ Decision of the Competition and Markets Authority, *Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK [2021]* (“Advanz”) Case 50395, <https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-conduct#non-confidential-infringement-decision>.

¹¹⁵ Advanz is the current parent of several investigated entities, referred to collectively as Advanz by the CMA. *Id.* ¶ 1.2.

¹¹⁶ *Id.* ¶ 1.8.

¹¹⁷ *Id.* ¶ 1.5.

prescribed levothyroxine tablets.¹¹⁸ Although liothyronine tablets are prescribed to a significant number of patients in the United Kingdom, the narrower market contributes to the possibility for a single provider to achieve dominance, in this case Advanz.¹¹⁹

Advanz was found to pursue a business model that sought to identify pharmaceutical products with sufficiently narrow and protectable markets to allow it to secure and maintain a dominant position, and to substantially raise prices while simultaneously avoiding the scrutiny of procurement authorities (in this case, the NHS) and attracting competitive market entry.¹²⁰ This business model was expressly conveyed internally and to Advanz investors.¹²¹ During the period under investigation (10 years) Advanz repeatedly raised prices constituting an increase from £4.052 to £247.87, or a 6021% increase over that period.¹²²

The CMA approached the case as a matter of British competition law under Article 102 of the TFEU given that the UK remained a member of the EU during the period under investigation, noting that Section 18(2)(a) of the UK Competition Act of 1998 includes the same prohibition against directly or indirectly imposing unfair selling prices as an abuse of dominant position.¹²³

The CMA followed the *United Brands* two-step methodology. The CMA used a straightforward cost-plus methodology to establish that the prices charged by Advanz far exceeded its costs by any reasonable measure,¹²⁴ and that under the first step of the two-step test the prices were excessive.¹²⁵

One interesting aspect of that calculation process related to cost of capital, which the CMA decided included either or both the costs of borrowing and the rate of return expected by equity investors.¹²⁶ The inclusion of imputed or alternative costs of capital, rather than direct expenditure, has been controversial at least insofar as these costs have been used to justify originator R&D cost calculations.¹²⁷

¹¹⁸ *Id.* ¶¶ 1.6, 3.38, *et seq.*, 3.48 *et seq.*

¹¹⁹ *Id.* ¶¶ 3.64 *et seq.*

¹²⁰ *Id.* ¶¶ 5.10, .257.

¹²¹ *Id.* at 150 fig. 5.1; *see also id.* at 157 fig. 5.4, *see also id.* ¶¶ 5.15–.29.

¹²² *Id.* ¶ 5.34.

¹²³ *Id.* ¶¶ 2.1–.2, 5.46 *et seq.*

¹²⁴ *See id.* ¶¶ 5.115 *et seq.*, for discussion of indirect costs.

¹²⁵ *Id.* ¶¶ 5.54 *et seq.*, 5.102 *et seq.*

¹²⁶ *Id.* ¶¶ 5.126 *et seq.*, 5.173 *et seq.* The CMA used a 10% reasonable rate of return as the “plus” element. *See, e.g., id.* ¶ 5.189. It tested its results against a “sensitized” 15% benchmark as well (*id.* at 205 n.890), observing that Advanz’ returns were significantly higher than either of those.

¹²⁷ Distinguish “imputed” or “opportunity” or “alternative” cost of capital used by researchers at Tufts and the Pharma industry in offering what they have portrayed as the costs of R&D in the originator sector – what we could have earned if we took our money and invested it elsewhere (Tufts

In this Advanz case, the CMA seems to use cost of capital mainly as a way of describing anticipated profits or return on investment. In that regard, its ultimate conclusion as to cost-plus is the same whether the cost above actual expenditure is referred to as cost of capital or reasonable profit.

This can be compared with the analysis by the European Commission in the Aspen case (discussed in Section II.D. *infra*) where the cost of capital was referred to as the level of profitability needed by the company to justify its investment, i.e., the plus element in “cost-plus.”¹²⁸

At the second step of the two-step test, first prong (which the CMA refers to as a “limb”), the CMA decided that the prices charged by Advanz are “unfair in itself” because there is no objective justification for the prices.¹²⁹ The prices do not reflect additional R&D, manufacturing costs or similar factors, and there is no additional benefit to the patient.¹³⁰ Next there are complications arising from the UK Court of Appeal decision in *CMA v. Pfizer*.

Recall that the Court of Appeal overruled the misguided decision of the Competition Appeal Tribunal and affirmed that the two prongs of the second step are in the alternative. The CMA needs prove only one. But it went on to say that if the accused infringer presents some evidence on the alternative prong (in this case the “unfair in comparison to competing/comparable products” prong), the CMA should nonetheless consider that evidence, perhaps as part of its analysis under the first prong. Consequently, the CMA spent a substantial part of its analysis and opinion in Advanz addressing alternative methodologies proposed by the accused infringer that it ultimately rejects.¹³¹

The CMA imposed total fines of £101,442,899 against the prosecuted entities involved in the infringements. The penalties reflect, *inter alia*, the serious nature of the infringements.¹³²

now publishes both “out-of-pocket” and “opportunity cost of capital” R&D costs—the latter about double). See discussion, *infra* notes 321–25.

¹²⁸ See *infra* note 157, EU Aspen ¶¶ 139–43, 155 (referring to cost of capital as an alternative means of referencing anticipated profits).

¹²⁹ Advanz, *supra* note 114, ¶¶ 5.260 *et seq.*

¹³⁰ *Id.*, e.g., ¶¶ 5.273, 5.360 *et seq.*

¹³¹ *Id.* ¶¶ 5.79 *et seq.*, 5.279–5.359.

¹³² *Id.* ¶¶ 7.32–7.34, 7.197.

The parties under investigation filed appeals of the CMA decision in the Competition Appeal Tribunal, which is being defended by the CMA.¹³³

C. Italian Competition Authority v. Aspen

The Italian Competition Authority (“ICA”) prosecuted the Aspen Group for abuse of dominant position by the charging of excessive prices.¹³⁴

Aspen purchased a suite of products from GSK, including for the Italian market.¹³⁵ These products were older out of patent anti-cancer drugs that were primarily used for the treatment of juveniles and the elderly because of potential sensitivities to alternative treatments.¹³⁶ There were no close substitutes for these products.¹³⁷

The prices of the so-called Cosmos drugs were classified in Class A, where products reimbursed by the National Health Service (“NHS”) are included, subject to Italian price control and potentially subject to a renegotiation with the Italian procurement authority (or to a “delisting” into Class C, that includes non-reimbursed products).¹³⁸ In order to secure maximum price increases, Aspen threatened to delist the products from Class A and have them included among those drugs that are paid for out-of-pocket by the consumer (Class C).¹³⁹ In addition, Aspen threatened that if its price demands were not met it would cease supplying the products directly to the Italian market, necessitating importation from other European markets where prices already were increased.¹⁴⁰ There was evidence that during the period of negotiation supply shortages developed within the Italian

¹³³ See CMA Case Timetable, Sept. 2021 to Oct. 2021, Advanz Pharma, Cinven and HgCapital filed appeals in the Competition Appeal Tribunal against the CMA’s findings in the Infringement Decision. The CMA will defend the appeal. Liothyronine tablets: Suspected excessive and unfair pricing GOV.UK, <https://www.gov.uk/cma-cases/pharmaceutical-sector-anti-competitive-conduct>.

¹³⁴ Italian Competition Authority (Autorità Garante della Concorrenza e del Mercato), A480 – Price Increase of Aspen’s Drugs, Measure No. 26185, https://en.agcm.it/dotcmsDOC/pressrelease/A480_eng.pdf. For a more detailed summary of this case, including methodological approach, see Elisabetta Maria Lanza and Paola Roberta Sfasciotti, *Excessive Price Abuses: The Italian Aspen Case*, J. OF EUR. COMP. L. & PRACTICE, 2018, Vol. 9, No. 6.

¹³⁵ *Id.* ¶¶ 23.

¹³⁶ *Id.*, e.g., ¶ 285.

¹³⁷ *Id.*, e.g., ¶¶ 69–70, 276–277.

¹³⁸ *Id.*, e.g., ¶¶ 36–40, 51–52.

¹³⁹ *Id.* ¶¶ 96, 103–105, 204, 363.

¹⁴⁰ *Id.* ¶¶ 361–363.

market.¹⁴¹ Under pressure from Aspen, the Italian procurement authority accepted price increases from 300 to 1500% on the relevant drugs.¹⁴²

The ICA employed a *United Brands* analysis, while specifying that EU jurisprudence provided substantial flexibility in the way that the analysis was carried out.¹⁴³

It was first determined that the Cosmos products held a dominant position on the market because they were life-saving drugs for which there were no reasonable therapeutic substitutes.¹⁴⁴ Among other things, these anti-cancer drugs could be administered at home in a tablet form that was well tolerated by patients, while alternative therapies would necessitate hospital infusion and risked greater side effects.¹⁴⁵

The ICA on the first step of the *United Brands* analysis undertook a cost-plus analysis to determine the benchmark prices. Aspen was not a producer of any of the drugs, but purchased them from third-party manufacturers. It did not invest in plants and equipment, and it conducted no new research on the drugs. The competition authority was able to use cost data maintained by Aspen, approaching the cost from several different accounting perspectives. It analyzed both direct and indirect costs. Indirect costs were determined by using overall corporate overhead data and allocating a relevant share to the products under consideration. Notably in this case the ICA included in Aspen's direct costs of goods an amount attributable to amortization of its trademark rights acquired from GSK for the subject products. In doing so, the ICA sought to emphasize that the prices charged by Aspen were excessive even taking account of costs that did not add value from a health perspective. It added a 13% profit margin as comparable to that of competitors companies in the generics sector.¹⁴⁶

The prices charged by Aspen to the procurement authority ranged from 300 to 1500% above the pre-increase prices. These prices were shown to be 100 to 350% above cost-plus (that is, cost plus a reasonable profit).¹⁴⁷

Under the second step of the *United Brands* test the competition authority found that there was no justification for the increased prices based on a variety of

¹⁴¹ *Id.* ¶¶ 60–61.

¹⁴² *Id.* ¶¶ 109–110.

¹⁴³ *Id.*, e.g., ¶ 128, and n.113, ¶ 310, and n. 201.

¹⁴⁴ *Id.* ¶¶ 292, 296–306.

¹⁴⁵ *Id.*, e.g., ¶¶ 71–79, 265, 281–287, 297, 300.

¹⁴⁶ *See* tbl. 8.

¹⁴⁷ *Id.*, e.g., ¶¶ 138, 184, tbl. 9, 379.

factors.¹⁴⁸ These included that Aspen had done nothing to improve the products or conduct additional R&D,¹⁴⁹ that the products were necessary for the life and health of patients who had no alternative,¹⁵⁰ that Aspen could not justify its conduct simply on the grounds that it pursued a different business model than GSK,¹⁵¹ and that Aspen could not justify raising prices in Italy simply because it had been able to raise prices in other EU markets (noting that the EU subsequently found Aspen's prices to be excessive) (see Section II.D *infra*).¹⁵² In this regard, the prices were unfair in themselves.¹⁵³ Finally, Aspen had used aggressive threats to secure the price increases.¹⁵⁴ A fine of approximately €5 million was imposed based on Aspen's turnover and the serious nature of the violation.¹⁵⁵

These rulings were ultimately upheld by the Italian Council of State.¹⁵⁶

D. European Commission – Aspen Commitment

In October 2021, the European Commission secured a commitment agreement from Aspen Pharmacare Holdings Ltd. And ASPEN PHARMA IRELAND LIMITED (hereinafter “Aspen”) following a Preliminary Assessment with respect to excessive pricing of certain pharmaceutical products in the EU/European Economic Area (EEA) market.¹⁵⁷ The pharmaceutical subject matter was a group of anti-cancer drugs.¹⁵⁸ Patents on the subject drugs had expired approximately 50 years prior and they were not subject to any other form of exclusivity.¹⁵⁹ In 2009, Aspen purchased the group of products from GSK which continued to manage the

¹⁴⁸ *Id.* ¶ 312, *et seq.*

¹⁴⁹ *Id.* ¶ 171, 311–314, 339, 348.

¹⁵⁰ *Id.* ¶ 346–47.

¹⁵¹ *Id.* ¶¶ 195–198, 334–335.

¹⁵² *Id.* ¶. 97, 110, 337, 376.

¹⁵³ *Id.*, *e.g.*, ¶¶ 307, 311–12, 387.

¹⁵⁴ *Id.* ¶¶ 303, 308, 349, 358–361, 372, 386.

¹⁵⁵ *Id.* “Resolves as Follows” ¶ (d), at 58.

¹⁵⁶ Cons. Stato, 13 marzo 2017, N. 01832/2020REG.PROV.COLL., N. 08447/2017 REG.RIC., Foro amm. III. 2017, (It.), affirming *Aspen Italia et al. v. Italian Competition and Market Authority*.

¹⁵⁷ European Commission Competition DG, CASE AT.40394 – Aspen, Antitrust Procedure, Council Regulation (EC) 1/2003 Article 9 Regulation (EC) 1/2003 Date: 10/02/2021 [hereinafter “EU-Aspen”]. Italy was not included in so far as its national competition authority had already successfully prosecuted Aspen for excess pricing of substantially the same basket of products. For a more detailed summary of the approach of the Commission in this case, and reasoning behind the approaches, see Harald Mische, *The EU Aspen decision: the European Commission's first excessive pricing decision in the pharmaceutical market*, in EU COMPETITION LAW AND PHARMACEUTICALS, W. Sauter, M. Canoy and J. Mulder (eds), Edward Elgar, 2022.

¹⁵⁸ From the standpoint of US terminology, the group of anti-cancer drugs would be referred to as “branded generics” as they are no longer protected by patent or market exclusivity but marketed under the brand name of the originator market authorization holder. In this case, the “originator in fact” sold the portfolio to Aspen which acquired the right to use the brand names.

¹⁵⁹ EU-Aspen, *supra* note 157, ¶ 13.

portfolio until 2011 when the relevant authorizations were transferred to Aspen.¹⁶⁰ Following that transfer Aspen engaged in a concerted strategy to substantially raise prices that involved threats to de-list the products from EU member state reimbursement programs and/or to withdraw market authorizations for the products.¹⁶¹ The period of investigation was from 2012 to 2019.¹⁶²

The investigation involved application of Article 102 of the TFEU.¹⁶³ In its preliminary assessment the Commission determined that Aspen held a dominant position on the markets (120 different product-country pairs) for the subject anti-cancer drugs.¹⁶⁴ While identifying the relevant Anatomical Therapeutic Chemical (“ATC”) level,¹⁶⁵ the Commission also applied a more contextual analysis as these older anti-cancer drugs were necessary for the treatment of a comparatively narrow group, often the elderly, for whom there were no available substitute products.¹⁶⁶

The Commission applied the two-step *United Brands* test methodology. It used a cost-plus analysis for establishing the benchmark or baseline “reasonable” price.¹⁶⁷ The Commitment Decision provides details regarding the Commission’s cost accounting methodology. In order to determine the applicable level of profitability, the Commission mainly used earnings before interest, taxes, depreciation and amortization (“EBITDA”),¹⁶⁸ and referred also to gross margins.¹⁶⁹ Having first determined Aspen’s cost plus a reasonable margin (with a reasonable comparator EBITDA margin of 23%),¹⁷⁰ the Commission determined that Aspen’s profits over cost-plus were generally in the range of 280 to 300%, and sometimes in the level of 400%.¹⁷¹ Those pricing levels far exceeded those of other comparable industry actors, and the Commission determined those levels to be excessive within the meaning of the first step of the *United Brands* decision.¹⁷²

The Commission turned to the second step and noted that a finding of abuse could be based either on the price being “unfair in itself” or “unfair in comparison

¹⁶⁰ *Id.* ¶ 14.

¹⁶¹ *Id.*, e.g., ¶¶ 74, 87–101, 189–193.

¹⁶² *Id.* ¶ 2.

¹⁶³ *Id.*, e.g., ¶¶ 2, 73, 75, 77, 82, 85, 138, 202, 208.

¹⁶⁴ *Id.* ¶¶ 66, 71–80, 186, 207–208.

¹⁶⁵ *Id.*, e.g., ¶ 35 n.21, 43 n.26, 129 ns.88–89.

¹⁶⁶ *Id.* ¶¶ 41, 170.

¹⁶⁷ *Id.* ¶¶ 139–141, tbl. 4.

¹⁶⁸ *Id.*, e.g., ¶¶ 106, 118–140, tbls. 1, 2, 3, 4, 180 & 184, Annex tbls. 1, 2, 3, 4, 5 & 6.

¹⁶⁹ *Id.*, e.g., ¶¶ 106, 118, 123, tbl. 12–4.

¹⁷⁰ *Id.*, e.g., tbl. 3, 139 & 180.

¹⁷¹ *Id.*, tbl. 4, ¶ 141.

¹⁷² *Id.* ¶¶ 142, 144, 160.

to competing products.”¹⁷³ The Commission found that Aspen had provided little or no added value to the products following acquisition from GSK. In essence its only contribution was to substantially raise prices.¹⁷⁴ There had been no material change in manufacturing costs or other cost that would have justified the price increases.¹⁷⁵ Aspen in part attempted to justify the high prices by reference to the high cost of acquisition from GSK,¹⁷⁶ but the Commission found that the acquisition cost had already been reflected in the product prices prior to the series of price increases.¹⁷⁷ The Commission acknowledged that pharmaceutical companies are entitled to make a reasonable rate of return in order to cover their cost of capital. It said “th[e]‘plus’ element allows recovering the costs of capital. In principle, no further recognition of the remuneration of the capital employed in the Products is therefore required.”¹⁷⁸

Recognizing such an analysis was not required under *United Brands*,¹⁷⁹ the Commission nevertheless considered the potential availability of generic comparator products (the second prong of the second step) and found very few products for comparison. Although there were a few recent entrants into the market with still-high prices, the Commission said that these new entrants were still essentially taking advantage of Aspen’s pricing strategy and were not suitable for comparison.¹⁸⁰ Finally, the Commission said that the prices of patent-protected originator anti-cancer drugs were not reasonably comparable because originator pricing reflects recovery of R&D costs and risk.¹⁸¹

As an additional observation, the Commission stressed the aggressive and threatening posture of Aspen towards procurement authorities in the member states,¹⁸² and what appeared to be a disregard of the interest of patients and health

¹⁷³ *Id.* ¶ 162, *et seq.* See European Commission’s amicus curiae observations pursuant to Article 15(3) of Regulation 1/2003 of 14 June 2019 to the UK Court of Appeal in Pfizer/Flynn, accessible at: https://ec.europa.eu/competition-policy/system/files/2021-01/2019_flynn_pharma_limited_pfizer_amicus_curiae_observations_en.pdf

¹⁷⁴ *See, e.g.,* Mische, *supra* note 157, referring to Aspen’s developed and systematically applied pan-European strategy to raise prices with “a big push,” referring to recital 87 of the Commitment.

¹⁷⁵ *Id.* ¶¶ 171–176. The European Commission specifically noted that Aspen outsourced manufacturing to third party manufacturers. *Id.* ¶¶ 14, 174.

¹⁷⁶ *Id.* ¶¶ 153, 203.

¹⁷⁷ *Id.* ¶¶ 156–159.

¹⁷⁸ *Id.* ¶ 154.

¹⁷⁹ *Id.* ¶ 196.

¹⁸⁰ *Id.* ¶ 199.

¹⁸¹ *Id.* ¶ 200.

¹⁸² *Id.* ¶ 193.

systems, notwithstanding some internal resistance within Aspen that brought attention to the adverse consequences of its behavior.¹⁸³

Aspen accepted an undertaking across the range of anti-cancer drugs that would lower the prices on average by 73% across the EEA for a period of 10 years with a potential for review after five years (for, e.g., significant increase in direct costs).¹⁸⁴ In addition, should Aspen decide to exit the market it would be required to provide advance notice and offer the product line for sale under the terms of the commitment.¹⁸⁵

E. The Netherlands – ACM v. Ladiant

A decision by the Netherlands Authority for Consumers and Markets (“ACM”)¹⁸⁶ provides a useful illustration of how a contextual approach to decision-making concerning excessive pricing could be applied, bearing in mind that the Dutch Authority acted in accordance with the two-step test and consistently with prevailing EU jurisprudence.

In 2008, the pharmaceutical firm Ladiant acquired a drug, Chenodeoxycholic acid (“CDCA”), registered to treat gallstones but since the 1980s commonly used off label by doctors to treat an ultra-rare metabolic disorder called cerebrotendinous xanthomatosis (“CTX”),¹⁸⁷ which at the time was selling for €46 per pack of 100 capsules on the Dutch market.¹⁸⁸ Patients need the treatment to survive. In 2009, Ladiant changed the drug’s name to Xenbilox and raised the price twenty-fold to €885. In 2014, it raised the price to €3,103 and sought an orphan drug designation.¹⁸⁹ In 2017, having secured an orphan drug designation and market authorization, Ladiant raised the price to €14,000, yielding a per-patient annual cost of treatment of €153,300.¹⁹⁰ Orphan drug designation – granted in this case because of the small number of patients – established an exclusive position on the market in the Netherlands for a period of ten years.¹⁹¹ Ladiant asserted that it

¹⁸³ *Id.* ¶¶ 87–94, 170, 176, 188–189.

¹⁸⁴ *Id.* ¶¶ 210–211, 215.

¹⁸⁵ *Id.* ¶ 212.

¹⁸⁶ See Autoriteit Consument & Markt, Summary of decision on abuse of dominant position by Ladiant, ref. ACM/UIT/557, case no ACM/20/041239, 1 July 2021 [hereinafter ACM-Ladiant Summary]. The Summary is Chapter 1 of the decision. The full text is not public at the time of this writing.

¹⁸⁷ *Id.* ¶ 2.

¹⁸⁸ *Id.* ¶ 3.

¹⁸⁹ *Id.* ¶ 3.

¹⁹⁰ *Id.* ¶ 4.

¹⁹¹ *Id.* ¶ 4.

intended to negotiate a much lower price with Dutch health insurers and the government, but took little action to do so.¹⁹²

The ACM established that Leadiant occupied a dominant position on the market (i.e., 100%) for the relevant period (2017–19).¹⁹³ It used a cost-plus (15% reasonable profit) methodology to establish a baseline,¹⁹⁴ giving credit to Leadiant for investments it had made when it decided to pursue orphan drug designation,¹⁹⁵ while noting that no therapeutic value had been added to the treatment.¹⁹⁶ It looked at the price increases starting just before when Leadiant decided to seek orphan drug designation (from €885 to €14,000), observing that this amounted to an increase of more than 15 times,¹⁹⁷ or greater than 1500%.

The ACM indicated that the increased price charged by Leadiant was “exorbitantly high”¹⁹⁸ and went on to also decide that Leadiant’s pricing was “unfair,” referring to a number of factors, including: (1) orphan drug designation was secured without added innovation or change in therapeutic value of the relevant drug; (2) Leadiant had failed to pursue effective or serious negotiations on price reductions with health insurers or the relevant ministry; (3) the drug in question is indispensable to the patients needing it, and; (4) other producers (e.g. a compounder) of the same drug are able to produce and sell it at much lower prices.¹⁹⁹

It fined Leadiant €19,569,500, noting that Leadiant’s conduct had affected Dutch society as a whole because of the added cost to the government, private health insurers and individuals.²⁰⁰

F. Italian Competition Authority v. Leadiant

The Italian Competition Authority prosecuted the pharmaceutical company Leadiant for similar conduct to that in the Netherlands (Section II.E) also related to the pricing policy applied for sale to the NHS of the orphan-designated CDCA used to treat the same “ultra-rare” disease CTX.²⁰¹

¹⁹² *Id.* ¶¶ 6, 14.

¹⁹³ *Id.* ¶ 7.

¹⁹⁴ *Id.* ¶ 12.

¹⁹⁵ *Id.* ¶ 11.

¹⁹⁶ *Id.* ¶ 13.

¹⁹⁷ *Id.* ¶¶ 4–5.

¹⁹⁸ *Id.* ¶ 13.

¹⁹⁹ *Id.* ¶¶ 13–14.

²⁰⁰ *Id.* ¶ 15.

²⁰¹ *Italian Competition Authority v. Leadiant*, Case A524, Decision of May 17, 2022, decision (original Italian) available at <https://www.agcm.it/dotcmsdoc/allegati-news/A524%20chiusura.pdf>.

In this case, Sigma Tau Group (now Essetifin SpA), the controlling corporate authority of Lediand,²⁰² developed and articulated a strategy to establish a dominant position on European markets for what became an “orphan drug,” protected by a 10-year regulatory market exclusivity.²⁰³ This strategy entailed entering into an exclusive supply agreement with the only company capable of supplying regulatory compliant API,²⁰⁴ and through that exclusive supply agreement eliminating the possibility for compounding laboratories at hospitals to make their own CDCA.²⁰⁵ As soon as the compounded products were eliminated from the Italian market, Lediand/Sigma Tau started selling Xenbilox in Italy.²⁰⁶

Prior to the series of price increases, the price of the compounded drug was about €67 per pack of 100 pills.²⁰⁷ Following the price increases, Lediand sold CDCA to the Italian healthcare system for around €15,500 per pack,²⁰⁸ which resulted in an *ex factory* price of around €169,000 per year per patient for treatment.²⁰⁹ The Italian Competition Authority considered the period of investigation in which the violation occurred as 2017-2022,²¹⁰ taking into account acts that occurred prior to 2017 which were in preparation of the abuse.²¹¹ The time period during which the Italian healthcare system was charged the €15,500 per pack price started June 15, 2017.²¹² Lediand, following the initiation of the investigation, lowered the price to about €5000-7000 from December 2019.²¹³

The ICA found that the market for CDCA was limited to its specific active ingredient under ATC 5 because there were no alternative comparable treatments, as recognized by leading medical authorities.²¹⁴ The geographic market was for the nation of Italy, taking account of the differences in regulation of the pharmaceutical sector in different EU member states.²¹⁵ The ICA determined that Lediand enjoyed a dominant position on the Italian market as of the beginning of 2016,²¹⁶ as it was

Author has relied on Google Translate for translation into English. See also ICA Press Release, A524 - ICA fines Lediand 3,5 million euros for abusing its dominant position, May 31, 2022.

²⁰² *Id.* ¶ 1.

²⁰³ *Id.* ¶¶ 29, 41, 79, 92, 103, 107, 117–119, 158, 270–76, 321, *et seq.*, 433, *et seq.*

²⁰⁴ *Id.*, *e.g.*, ¶¶ 53–60, 378.

²⁰⁵ *Id.* ¶¶ 130, 134–35, 398–400, 415–416.

²⁰⁶ *Id.* ¶¶ 415–426.

²⁰⁷ *Id.* ¶¶ 76, 426.

²⁰⁸ *Id.*, *e.g.*, ¶¶ 191, 236, 465, 584, 606.

²⁰⁹ *Id.* ¶ 9.

²¹⁰ *Id.* ¶¶ 9, 80, 218, 264–68, 334, 607.

²¹¹ *Id.*, *e.g.*, ¶ 448.

²¹² *Id.*, *e.g.*, ¶ 606.

²¹³ *Id.* ¶ 607.

²¹⁴ *Id.* ¶¶ 342, 345, 364.

²¹⁵ *Id.*, *e.g.*, ¶¶ 427, 433, 455–463.

²¹⁶ *Id.*, *e.g.*, ¶¶ 79, 321, 531.

able to substantially raise prices without fear of competitors entering based on several barriers: the exclusivity contract mentioned above, the market exclusivity connected to the orphan designation and the prohibition for pharmacies to produce compounded preparations.²¹⁷

In applying the jurisprudence of *United Brands*,²¹⁸ the ICA undertook two different analyses in order to ascertain whether the difference between the costs actually incurred and the price charged was excessive for the product. First, it used a financial methodology that looked at the cash flows deriving from the project and the internal rate of return, and it compared that with the cost of capital, finding that the IRR was at least equal to 250-350% of the cost of capital.²¹⁹ Second, it undertook an accounting cost methodology (i.e., cost-plus) which attempted to use data provided by Leadiant. That data proved in several elements to be incorrect—e.g., Leadiant included within its costs the litigation costs associated with planning for and defending the competition proceedings investigating its abuse!²²⁰ The ICA nevertheless approached this in a way favorable to the company and based its analysis on that data, for instance including those litigation costs in its calculations. It then added a margin of profitability of 21% recognized as very generous in comparison with similar profitability percentages used in comparable cases, and noting that it could have used a number closer to 10%.²²¹ Using the accounting cost methodology, the “lower” €5000-7000 price per pack (that is, after the price was lowered from the peak) exceeded cost by 60 to 70% until the end of 2020.²²² Leadiant already had committed to refunding to the Italian healthcare system the difference between the re-negotiated price and the peak price.²²³ The ICA determined that the price of CADC was excessive under either methodology.²²⁴

Under the second step of *United Brands* methodology, the ICA determined that the price was unfair in itself because the drug protected by the orphan designation from the pharmacological and chemical point of view was exactly the same drug as prior to the designation, that little or no R&D had been conducted in the context of securing the designation beyond a retrospective analysis of prior clinical studies,

²¹⁷ That is, in cases where there exist in the Italian market a drug specifically registered for a given therapeutic purpose.

²¹⁸ *Id.* ¶ 500, *et seq.*

²¹⁹ *Id.* ¶ 514.

²²⁰ *Id.* ¶ 531.

²²¹ *Id.* ¶¶ 526–532.

²²² *Id.* ¶ 526.

²²³ *Id.* ¶ 265.

²²⁴ *Id.* ¶ 530.

and the price was not justified by any value added to the patient with respect to previously-existing therapies.²²⁵

Recognizing that it did not need to engage in an analysis under the alternative prong (comparative) in the second step, the ICA noted that there were no comparable products for the purposes of price comparison.²²⁶

The ICA found that the abuse took place through a specific negotiating strategy: the party under investigation had failed to comply in good faith with requests for information and had deliberately delayed renegotiations with the Italian healthcare system.²²⁷

The Italian Leadiant case illustrates again that anticompetitive schemes to enable the charging of excessive prices are a “business model” used by investors and pharmaceutical companies seeking high returns through the exploitation of regulatory systems. In particular, it highlights the potential abuse of the orphan drug designation in cases such as this where the designation is justified only by a small patient population.²²⁸

The ICA imposed sanctions on Leadiant based on the value of its sales. In this case, the ICA took the sanctioning base amount at 20-30% of sales of CDCA during 2021, amounting to 500,000 and 600,000 euros, with the period of infringement being four years, 11 months and two days, resulting in a fine of amount of €2-3 million, and inserting an additional amount of 20–25% as deterrence.²²⁹ The total fine assessed was €3,501,020.²³⁰

G. Danish Competition and Consumer Authority v. CD Pharma

Consumer Authority v. CD Pharma involved a prosecution by the Danish Competition and Consumer Authority (Konkurrence- OG Forbrugerstyrelsen) of a small pharmaceutical importer and distributor, CD Pharma, for excessive pricing of Syntocinon, a branded form of oxytocin that is typically used by hospitals to induce or aid labor of women in childbirth. On January 31, 2018, the Danish Competition Council found CD Pharma to have infringed Article 102 of the TFEU and the corresponding provision of Danish competition law (Article 11 of the

²²⁵ *Id.* ¶¶ 559–617.

²²⁶ *Id.* ¶¶ 533–558.

²²⁷ *Id.* ¶ 586.

²²⁸ *See, e.g., id.* ¶ 124.

²²⁹ References to euro ranges (rather than specific amounts) reflect the way in which the public (non-confidential) decision was made available.

²³⁰ *Id.* ¶¶ 608–616.

Competition Act), and CD Pharma was ordered to cease its infringing conduct.²³¹ The decision of the Danish Competition Council was largely affirmed by the Competition Appeals Board, and by the Maritime and Commercial Court by decision of March 2, 2020.²³² At the time the judgment was affirmed CD Pharma was in liquidation.

In Denmark, almost all procurement of pharmaceutical products is undertaken through a central procurement authority, Amgros.²³³ Through its ordinary processes, Amgros had entered into a one-year contract (April 1, 2014 to March 31, 2015) with a large European parallel trading firm, Orifarm, to supply its requirements of Syntocinon for that period.²³⁴ The per pack price for Syntocinon (10 IU/ml) under the contract was 43 Danish Kroner (DKK) (about US \$6.20).²³⁵ Orifarm was unable to procure the quantities of product required and contracted for by Amgros (which it almost exclusively provided to hospitals), and Amgros was required to seek alternative sources of supply.²³⁶

CD Pharma had recently entered into an exclusive distribution agreement with an Italian producer of Syntocinon, Sigma-Tau.²³⁷ When Amgros sought to fill the gap left by Orifarm's default, which gap needed to be filled because of hospital requirements, CD Pharma offered Syntocinon at 945 DKK, or about 2000% above the price at which Orifarm had committed to supply.²³⁸ CD Pharma maintained that price until October 26, 2014, when it lowered it to 225 DKK.²³⁹

The Competition Council found that CD Pharma held a dominant position on the Danish market because during the relevant period it had an exclusive supply agreement with the only supplier with a marketing authorization to supply

²³¹ Press Release, Danish Competition and Consumer Authority, CD Pharma has abused its dominant position by increasing their price by 2,000 percent (January 31, 2018). The text of the decision by the Danish Competition Council [hereinafter "Competition Authority Decision"] is included as an annex to the decision of the Maritime and Commercial Court, *infra* note 239.

²³² CD Pharma AB (under liquidation) v. The Competition Council, Case BS-3038/2019-SHR (Maritime and Commercial Court (Den.) March 2, 2020) (author relies for translation on Google Translate). In the appeals process, the time period during which CD Pharma was found to have been dominant in the Danish market was limited to April 28–October 26, 2014. References herein are to the decision of the Maritime and Commercial Court.

²³³ *CD Pharma*, Case BS-3038/2019-SHR, ¶ 45.

²³⁴ *Id.* ¶¶ 43, 105, 201, 207–208, 221.

²³⁵ *Id.* ¶ 213.

²³⁶ *Id.* ¶¶ 125, 666, 809, 841.

²³⁷ *Id.* ¶ 12. A previous supplier to Denmark had been under an exclusive supply agreement with that same Italian producer.

²³⁸ *Id.* ¶¶ 12, 23, 212.

²³⁹ *Id.* ¶¶ 266, 350, 661, 802, 843.

Syntocinon to the Danish market, and there was no evidence that parallel importers other than Orifarm could supply the product in the relevant period.²⁴⁰

A key factor enabling CD Pharma's market dominance during the relevant period was Danish/EU medicines regulatory requirements for allowing products to be supplied to the market, including both for products from different manufacturers and to qualify to supply parallel imports. CD Pharma was in a position to be the sole supplier (other than Orifarm—a qualified parallel importer) to the Danish market because it held the only marketing authorization, thereby allowing it to enforce an excessive price vis-à-vis Amgros.²⁴¹

CD Pharma attempted to justify its excessive price on grounds that it incurred substantial additional costs in supplying the product on short notice. However, CD Pharma was unwilling or unable to provide documentation of such additional costs.²⁴² The Danish Competition Authority, on the other hand, was able to secure information regarding CD Pharma's cost of purchasing the product from its supplier that contradicted CD Pharma's justification effort.²⁴³

The Danish Competition Authority undertook seven lines of analysis for determining CD Pharma's cost, and settled on using information regarding the actual cost of purchase from the manufacturer/supplier, plus a profit increment within the range of other suppliers of the same product to Denmark.²⁴⁴ CD Pharma had a profit margin of 80-90%, compared with that of other suppliers at between 5 and 30%.²⁴⁵ Moreover, its price increase of 2000% was significantly above the

²⁴⁰ *Id.* ¶¶ 367 *et seq.* One issue confronted by the Competition Council was whether a 6-month period in which a company holds market power is sufficient to establish market dominance within the meaning of Article 102 of the TFEU, given that EU Commission guidelines suggest a 2-year period of market power is generally considered satisfactory to meet the market dominance requirement. The Council, citing to various European precedent, found that the Commission reference to 2 years is presumptive and not fixed, and that a contextual approach should be taken regarding the necessary time period for establishing dominance.

²⁴¹ *Id.* ¶¶ 163, 174-181, 321, 393, 691-693, 697, 703-704. Moreover, the fact that Amgros was a monopsony purchaser did not confer offsetting bargaining power in a circumstance where only one supplier was present, and in this case the supplier did not need to be concerned about a basket of products for which future supply contracts might be an issue. *Id.* ¶ 536. In fact, Amgros has a cause of action against Orifarm for failing to deliver under their contractual arrangement, and for damages based on the additional costs that Amgros incurred by purchasing from CD Pharma, but that is not relevant to the competition cause of action. *Id.* ¶ 8.

²⁴² *Id.* ¶¶ 293-96.

²⁴³ *Id.* ¶¶ 296-310, 655, 913-920. CD Pharma purchased its product (Syntocinon) from Sigma-Tau thus allowing the Danish Competition Council to determine CD Pharma's costs by examining the contract prices provided by Sigma-Tau.

²⁴⁴ *Id.* ¶ 928.

²⁴⁵ *Id.* ¶ 1024.

prices charged by previous and alternative suppliers (e.g., Orifarm)²⁴⁶ and was greatly in excess of prices charged in other relevant European countries (approximately 8350% higher than Iceland, Sweden, Finland and Ireland).²⁴⁷ It concluded there were no non-cost related factors that would justify the high price.²⁴⁸ The Competition Authority said it had no doubt the CD Pharma price was unreasonable within the meaning of the first step of the *United Brands* test.²⁴⁹

In the course of its decision, the Danish Competition Authority rejected the suggestion by CD Pharma to include an “alternative cost” in the sense of a profit the company could have made by using its assets for the best alternative (i.e., its lost margin on alternative sales elsewhere).²⁵⁰ *Inter alia*, the Danish Competition Authority found that supplying Syntocinon to Amgros did not prevent CD Pharma from supplying product to other purchasers.²⁵¹

Regarding fairness, CD Pharma was selling the same product from the same manufacturer as had previously been supplied to the Danish market, Syntocinon (or oxytocin) was an essential requirement for Danish hospitals and their patients, and CD Pharma could not justify its conduct by pointing to exceptional costs arising from stepping into the supply arrangement.²⁵² CD Pharma could not support its position by arguing that it would have reduced its price if it had been given an exclusive supply arrangement by Amgros.²⁵³

It is of some interest from a jurisprudential standpoint that the Danish Maritime and Commercial Court refers to the opinion of then-Advocate General Wahl in the CJEU *Latvian Copyright Case* to support a requirement of undertaking multiple lines of analysis to avoid mistakes (in Wahl’s terms, a “sanity check”) which is the same opinion by now-CJEU Judge Wahl relied on by the British Competition Appeal Tribunal in misinterpreting the two-step test of *United Brands*.²⁵⁴

It is worth noting that there was no fine or other recovery imposed in this case, although the matter has been referred to Danish criminal authorities for the potential imposition of monetary penalties.²⁵⁵ As part of conforming its competition law to

²⁴⁶ *Id.* ¶ 1028, 1035.

²⁴⁷ *Id.* ¶ 1073 (named in Competition Authority Decision, supra note 238, § 3.1).

²⁴⁸ *Id.* ¶ 1109.

²⁴⁹ *Id.* ¶ 1121; Competition Authority Decision, supra note 238, § 3.1.

²⁵⁰ *Id.* ¶¶ 966, 1083–1086.

²⁵¹ *Id.* ¶ 1086.

²⁵² *Id.* ¶ 881.

²⁵³ *Id.* ¶¶ 269–274.

²⁵⁴ *Id.* ¶ 922–923

²⁵⁵ Jens Munk Plum, Sonny Gaarslev, Andreas Riis Madsen (Kromann Reumert), *The Danish ECN+ Implementation: Overturning Legal Traditions*, March 9, 2021,

EU ECN+ standards,²⁵⁶ the Danish Competition Authority now has the power to impose civil fines.²⁵⁷

CD Pharma was closing down its unsuccessful business when it acquired the exclusive supply arrangement with Sigma-Tau and suddenly found demand from Amgros. The company sought to resurrect itself by extracting excessive prices from the Danish procurement system. It has gone bankrupt.²⁵⁸ What is not clear from the record is where the excess profits found a home.

III. SOUTH AFRICA²⁵⁹

The prosecution of excessive pricing in the case of patented pharmaceuticals is inherently more complicated than prosecutions involving generic products if for no other reason than patents confer rights to exclude on their owners, thus providing *ab initio* a legal basis for prices above purely competitive market prices. Previous work by this author has explored the various elements that go into an analysis of claimed excessive pricing of originator pharmaceutical products,²⁶⁰ and Section V.B of this article revisits some of those elements. As detailed in Section II *supra*, European competition authorities chose to enter the field of excessive pricing prosecution through the less complex route of challenging suppliers of generic (off-patent) products. The South African Competition Authority, in contrast, chose the more difficult route of challenging originator patent owners recognizing that in each case the Competition Authority was seeking to protect large and vulnerable (politically and economically) populations. In the first case, essential medicines to treat HIV-AIDS during the height of the AIDS epidemic were at stake. In the ongoing case, economically disadvantaged women who need, but are denied, treatment for breast cancer are at the heart of the excessive pricing prosecution. The

<http://cmpetitionlawblog.kluwercompetitionlaw.com/2021/03/09/the-danish-ecn-implementation-overturning-legal-traditions/>.

²⁵⁶ European Union, *Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market*, Brussels, 11 December 2018 (“ECN+ Directive”), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019L0001&from=EN>.

²⁵⁷ Danish Competition Authority, *Competition Authority*, <https://www.en.kfst.dk/competition/regarding-competition-matters/penalties-for-infringing-the-danish-competition-act/>

²⁵⁸ Per the case caption, CD Pharma in “under liquidation.” CD Pharma – Maritime and Commercial Ct.

²⁵⁹ See generally South Africa, *Excessive Pricing in Pharmaceutical Markets – Note by South Africa* (November 28, 2018), [https://one.oecd.org/document/DAF/COMP/WD\(2018\)117/en/pdf](https://one.oecd.org/document/DAF/COMP/WD(2018)117/en/pdf). See also M Keleme and N Moeketsi, *Excessive pricing in the time of COVID-19: insights from a regulator’s perspective*, 2020, <http://www.compcom.co.za/wp-content/uploads/2020/11/Excessive-pricing-in-the-time-of-COVID-19-insights-from-a-regulators-perspective-29.10.20-Final.pdf>.

²⁶⁰ See Abbott 2016, *supra* note 30.

reasons for pursuing these prosecutions, notwithstanding jurisprudential challenges, should be evident.

A. HIV Antiretrovirals

As of March 2023, South Africa is the only country where parties have been investigated and/or prosecuted for excessive pricing of pharmaceutical products protected by patents. The first such case was initiated by a coalition of nongovernmental organizations, individuals and physicians, with the lead complainant an individual, *Hazel Tau*, in September 2002.²⁶¹ The respondents were GlaxoSmithKline (Group) (now GSK), and Boehringer Ingelheim (Group). The Complainants alleged that the originator pharmaceutical companies were dominant in the South African market with respect to several HIV-AIDS antiretroviral drugs,²⁶² and had used their market dominance to deny access to essential medicines,²⁶³ to charge excessive prices and to engage in exclusionary acts.²⁶⁴ The complainants provided the Competition Commission with a methodology for establishing the cost of supplying the subject medicines (including taking account of R&D costs and risks), and a reasonable profit (that would allow investments in future R&D).²⁶⁵ The South African Competition Commission determined that the respondents had engaged in excessive pricing, denied a competitor access to an essential facility, and engaged in an exclusionary act. The Commission proposed to refer the matter to the South African Competition Tribunal for an order directing compulsory licenses (with royalty) and imposition of financial penalty.²⁶⁶ However, before such referral took place, the respondent pharmaceutical companies agreed to provide licenses for the production and/or importation of the subject HIV-AIDS antiretrovirals.²⁶⁷

The complaining parties achieved an important remedy and success in this case. There is a limit to the precedential value in terms of jurisprudence because the initial determination by the South African Competition Commission was in the

²⁶¹ See Competition Commission Press Release (South Africa), Competition Commission finds pharmaceutical firms in contravention of the Competition Act, 16 October 2003; UNCTAD Intellectual Property Unit, *Hazel Tau & others v. GlaxoSmithKline, Boehringer Ingelheim & others*, 2002 (South African Competition Commission, Competition Commission Case No. 2002Sep226); STATEMENT OF COMPLAINT IN TERMS OF SECTION 49B(2)(b) OF THE COMPETITION ACT 89 OF 1998, *Hazel Tau & others v. GlaxoSmithKline & others*, <https://vdocument.in/hazel-tau-and-others-v-glaxosmithkline-sa-pty-ltd-and-others-.html?page=1> [hereinafter “*Hazel Tau Complaint*”].

²⁶² *Hazel Tau Complaint* ¶¶ 18, 52 *et seq.*

²⁶³ *Id.* ¶ 30.

²⁶⁴ *Id.* ¶¶ 18, 23, 33, 58, *et seq.*

²⁶⁵ *Id.* ¶¶ 64–98.

²⁶⁶ See *supra* note 261.

²⁶⁷ See UNCTAD Intellectual Property Unit, *supra* note 261.

form of a relatively terse press release that did not include the supporting detail for the determination. That would have been spelled out had the referral to the Competition Tribunal taken place. Nonetheless, the complaint filed in this early case is similar to the complaint filed by the South African Competition Commission against the Roche Group in the Herceptin case following. So, this case provided a model for the subsequent prosecution and referral.

B. Herceptin

On June 13, 2017, the South African Competition Commission initiated a complaint against the Swiss company Roche, including its subsidiary in South Africa, investigating the pricing of its breast cancer treatment trastuzumab (INN), known principally by the brand name Herceptin. On February 8, 2022, the South African Competition Commission applied to the South African Competition Tribunal for an order finding that Roche violated the South African Competition Act (89 of 1998, as amended 2018) through the charging of excessive prices in the private and public sectors from 2011 until 2020.²⁶⁸ In addition to the excessive pricing charge under Section 8 of the South African Competition Act, the Commission also requested finding of violations of the South African Constitution, including the inscribed human right to health.

There are a number of notable features in this case:

First, during most of the period under investigation, Roche held patent rights on Herceptin in South Africa.²⁶⁹ This is the second instance in which the South African Competition Commission made a finding against a company holding patent rights for excessive pricing.²⁷⁰

Second, this prosecution involves Section 8 of the South African Competition Act which was amended with respect to the manner in which excessive pricing is determined in 2018 (with effect in 2019). Because the conduct of the defendant in this case took place primarily prior to the amendment, the terms of the unamended

²⁶⁸ South Africa Competition Commission Press Release, Competition Commission Prosecutes a Multinational Healthcare Company, Roche, for Excessive Pricing of a Breast Cancer Treatment Drug (February 8, 2022), <https://www.compcom.co.za/wp-content/uploads/2022/02/COMPETITION-COMMISSION-PROSECUTES-A-MULTINATIONAL-HEALTHCARE-COMPANY-ROCHE-FOR-EXCESSIVE-PRICING-OF-A-BREAST-CANCER-TREATMENT-DRUG.pdf>. Text of public version of complaint available by request to Competition Commission (on file with author). The Competition Commission of South Africa v. Roche Holdings AG, F Hoffman La Roche AG & Roche Products (Pty) Ltd, CC Case No: 2017Jun0025 [hereinafter Herceptin Complaint].

²⁶⁹ Herceptin Complaint, *supra* note 268, ¶¶ 20, 31.21, Initiation Statement ¶¶ 1–16, 20.

²⁷⁰ See Hazel Tau, *supra* note 261.

Act apply to much of the conduct, but the amended provisions inform the investigation.

Third, the defendant Roche refused to provide information regarding its costs in producing the subject pharmaceutical (Herceptin) both in terms of R&D and production.²⁷¹ This despite persistent efforts by the South African Competition Commission to secure that evidence, including through diplomatic channels and a request for assistance to the Swiss Competition Authority.²⁷² The latter refused to provide assistance ostensibly on grounds of a lack of mutual assistance agreement between South Africa and Switzerland.²⁷³ Because of the refusal of the party under investigation to provide information, the South African Competition Commission was forced to use “proxy” data to establish its baseline cost-plus for the pharmaceutical (in this case, Herceptin is a biologic drug typically infused, but also available in oral formulation).²⁷⁴

Fourth, the South African Competition Commission determined that Roche held a dominant position on the market during the period under investigation because: (1) Herceptin was established as the preferred standard treatment for breast cancer without comparable substitutes;²⁷⁵ (2) Herceptin was necessary to sustain the life and health of patients (i.e., it was essential);²⁷⁶ (3) the market, while subdivided between public and private health service providers (for which different prices were charged), was national,²⁷⁷ and; (4) Roche demonstrated the ability to maintain a very high price without attracting competition, which only emerged at the end of the period under investigation when a biosimilar was introduced by Mylan.²⁷⁸

Fifth, in terms of establishing the cost of production, the South African Competition Commission relied on a general analysis of the cost of producing

²⁷¹ Likewise, the parties under investigation in the Hazel Tau case refused to furnish R&D cost data.

²⁷² Herceptin Complaint, *supra* note 268, ¶ 28.4.

²⁷³ *Id.* and a subsequent request from the South African Department of Justice to the Swiss Federal Department of Justice and Police was likewise refused based on lack of an International Convention on competition law between South Africa and Switzerland. *Id.* ¶¶ 28.5–28.6.

²⁷⁴ *Id.* ¶¶ 81 *et seq.* The “proxy data” was taken from peer reviewed research regarding the cost of manufacturing biological pharmaceutical products that was combined with public data regarding Roche’s percentage of revenues spent on R&D.

²⁷⁵ *Id.* ¶ 37

²⁷⁶ *Id.* ¶¶ 15–16.

²⁷⁷ *Id.* ¶¶ 58–59.

²⁷⁸ *Id.* ¶¶ 62–64, 101

biologic pharmaceutical products, and used the upper end of “hypothetical” calculated costs as the defendant’s cost of producing the product.²⁷⁹

Sixth, in the absence of data from Roche regarding its R&D costs for developing Herceptin, the South African Competition Commission took the reported percentage of Roche Group’s annual expenditures devoted to R&D (about 24–26%).²⁸⁰ Of the various calculations presented by the South African Competition Commission, this is the one that is likely to draw the most attention by the South African Competition Tribunal. Pharmaceutical originator companies typically attempt to justify prices far in excess of manufacturing cost (see, e.g., Gilead and Sovaldi (Hepatitis C), \$300 versus \$84,000)²⁸¹ on the basis of the risk associated with developing a new drug. Another way to look at this problem would be to take the industry’s statements about the cost of developing a new product, perhaps \$2 billion (for direct cost, leaving out imputed cost of capital),²⁸² spreading that out over the lifetime of the patent-protected product (e.g., 10 years)²⁸³ or \$200 million per year, dividing by the number of units sold, and coming up with an amount needed to cover the R&D per unit. Assume that 3 million women worldwide have been treated with Herceptin over a 10-year period (i.e., 300,000 per year).²⁸⁴ A price of \$667 per patient would cover the annual R&D cost of \$200

²⁷⁹ *Id.* ¶¶ 87–97.

²⁸⁰ *Id.* ¶ 91. The percentage is redacted from the public version of the Herceptin Complaint. However, the relevant data is available from published sources. See *Roche’s expenditure on research and development from 2011 to 2022*, Statista (Feb. 3, 2003), <https://www.statista.com/statistics/266518/roches-expenditure-on-research-and-development-since-2007/>.

²⁸¹ See Abbott 2016, *supra* note 30.

²⁸² Based on recent research the \$2 billion figure appears substantially above actual costs, including when capitalized. See Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 JAMA 844 (2020), which estimated the investment at \$985.3 million, with a mean investment at \$1,335.9 million, with differences in therapeutic class ranging from \$765.9 million to \$2771.6 million. The U.S. Congressional Budget Office reported estimates between \$1 billion and \$2 billion, noting that studies differ substantially in terms of methodologies and the types of pharmaceutical products identified, and particularly highlighting that incorporating capitalized costs “skews the average estimate upward.” In one illustration, the actual R&D outlays were reported as \$2.2 billion, with \$3.6 billion added for capital costs. Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021, Pub. No. 57025, <https://www.cbo.gov/publication/57126>. The hypothetical in the text above gives generous allowance to the pharmaceutical originator for actual costs, with the understanding that recent studies suggest that estimates using capitalized costs, with the exception of certain outliers, are significantly lower than the \$2 billion figure used.

²⁸³ See, e.g., Jan Berger and Jeffrey D. Dunn, *How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management*, 22 AJMC 1 (2017), <https://www.ajmc.com/view/a636-article>.

²⁸⁴ See, e.g., *Herceptin with chemotherapy boosts survival significantly in early breast cancer*, UCLA Health, Oct. 6, 2011, (referencing NEJM peer review publication, suggesting “Herceptin is effective in women with HER-2-positive breast cancer, who account for about 20 to 25 percent of

million per year. In reality, Roche has sales of about \$5 billion a year for Herceptin, and 300,000 patients would pay \$16,667 per treatment to reach that total. That figure appears to be in the range of prices charged in South Africa (about \$11,500 in the public sector and \$25,000 in the private sector).

Starting with the \$667 per patient per year cost to cover the actual R&D expense for Herceptin assuming a \$2 billion figure (and leaving out present value discounting), which R&D figure is at the upper end of R&D estimates, in order to reflect risk associated with developing a new drug, some increment could be added reflecting, for example, development efforts abandoned for alternative therapies.²⁸⁵ The greatest expense in developing a new drug is the conduct of Phase 3 clinical trials.²⁸⁶ Even assuming 5–7 such alternative efforts at \$500 million per abandoned effort,²⁸⁷ and a maximum related cost of \$3.5 billion, this would give a total of \$5.5 billion for a generously calculated risk-adjusted R&D cost, which would amount to \$550 million per year to be recovered, divided by 300,000 patients, or a price of \$1833 for the treatment, which remains far below the \$16,667 that approximates what Roche has charged.²⁸⁸ Of course, R&D is not the only cost in producing and distributing a drug, but it is the factor that the originator industry has used to justify very high prices for patented pharmaceuticals, as in the case of Herceptin. Even assuming that adding the manufacturing and distribution costs would double the amount expended on R&D, a price for Herceptin of about \$3500 per patient would be a much different matter than what has been charged by Roche,²⁸⁹ and bearing in mind that this hypothetical has adopted very generous assumptions regarding R&D costs. It should further be noted that recent studies of new pharmaceutical product R&D costs estimate those at between \$1 billion and \$2 billion, with some outliers.²⁹⁰

those diagnosed with the disease every year, or 200,000 to 250,000 women annually worldwide.”) <https://www.uclahealth.org/news/herceptin-with-chemotherapy-boosts-survival>.

²⁸⁵ If net present value discounting of the 10-year cash flow is introduced, the price to cover the \$2 billion figure might as much as double, but even assuming a price of \$1334 is justifiable, it is a long way from \$11,500 to \$25,000.

²⁸⁶ See CBO, *supra* note 282, at 15, noting average total cost of clinical trials for drugs completing phase III at \$375 million. Again, estimates vary, but \$500 million for an abandoned effort which would often precede phase III appears to be “generous.”

²⁸⁷ See Wouters et al., *supra* note 282, at 848 (using median clinical trial outlays of \$319 million and mean outlays of \$374.1 million).

²⁸⁸ Even if that \$1833 price is doubled to \$3666 for net present value discounting the spread is wide.

²⁸⁹ As would a price of \$5500 if the R&D costs, but not manufacturing costs) are doubled. Manufacturing costs do not need adjustment for future revenue flows as would be contemplated for R&D which is recovered over the lifetime of the product.

²⁹⁰ See *supra* note 282.

Seventh, as an alternative to cost-plus the South African Competition Authority used the price of the recently introduced biosimilar trastuzumab, Mylan's Ogivri, as a competitive benchmark or baseline price. The biosimilar had been introduced in the South African market in November 2019.²⁹¹ The public version of the referral to the South African Competition Tribunal does not include the respective prices.

Eighth, as a further alternative, the South African Competition Authority calculated a value-based price which it referred to as incremental cost-effectiveness ratio ("ICER") based on the cost of trastuzumab divided by the additional quality adjusted life years ("QALYs") and asking whether the ICER is greater than the GDP per capita of the South African population during the years comprising the relevant period. If so, the treatment is not considered cost-effective because the maximum an individual can spend on the drug in a year would exceed the GDP per capita. The South African Commission considered the value-based benchmark price to be the price of trastuzumab that equates with one-times the GDP per capita.²⁹² The public version of the decision does not indicate what this price is.

The South African Commission determined in the first step of its analysis regarding cost-plus or other reasonable baseline price that Roche's Herceptin price was excessive.

It then turned to ask whether the price might nonetheless be reasonable based on a series of factors:

1. The cost-effectiveness of trastuzumab;
2. Whether access to essential medicines is restricted;
3. The reasonableness of the price considering and reasonable rewards for innovation; and
4. Whether the pricing promotes access to trastuzumab as a life-saving medicine.²⁹³

A first concern of the South African Competition Commission was that the high prices of Herceptin (public and private sector) cumulatively resulted in approximately 10,698 women in South Africa (nearly 50% of the total number of

²⁹¹ Herceptin Complaint, *supra* note 268, ¶¶ 99–107.

²⁹² *Id.* ¶¶ 110–120.

²⁹³ *Id.* ¶¶ 121, *et seq.*

newly infected patients) being unable to receive treatment between 2011 and 2019. In that regard, it considered the prices charged by Roche unreasonable.²⁹⁴

Second, the South African Commission determined that even accounting for R&D the prices charged by Roche were far in excess of its costs, including manufacturing and distribution. Particularly in light of Roche's total global revenues from sales of Herceptin, the prices were not reasonably justified.²⁹⁵ Also Roche had received substantial public funding from the UK National Institute of Health from 2000 to 2010 for the development of Herceptin.²⁹⁶

Third, the excessive prices caused individual patients and public and private health providers to spend substantially more than necessary to obtain treatment, thereby causing consumer injury.²⁹⁷

Fourth, the South African Constitution accords to citizens the right to the equal protection and benefit of the law, and women were disproportionately affected by absence of access to Herceptin. Individuals also have the right to have their dignity respected and protected, which was not the case because of the indignity suffered by lack of breast cancer treatment. The South African Constitution protects the right to life, which was denied because of inability to afford treatment. Individuals have a right of access to healthcare services which was denied. Roche had a constitutional obligation not to price its Herceptin treatment in a way that caused each of these harms.²⁹⁸

C. *The Competition Act as Amended in 2018*²⁹⁹

The South African competition authority noted in its submission to the 2011 OECD excessive pricing report that the related provisions of its Competition Act (89 of 1998), Secs. 1(ix) & 8(a) were based on the two-step test of the CJEU in *United Brands*.³⁰⁰ In 2018, with effect in 2019, South Africa amended Section 8 to incorporate and modify the definitional element previously in Section 1, and to elaborate a more sophisticated approach to analyzing claims of excessive pricing. It is worthwhile to set out relevant terms of the revised Section 8:

²⁹⁴ *Id.* ¶ 130.

²⁹⁵ *Id.* ¶ 160.

²⁹⁶ *Id.* ¶ 142.

²⁹⁷ *Id.* ¶¶ 151, *et seq.*

²⁹⁸ *Id.* ¶¶ 122–125, 154–160.

²⁹⁹ See South Africa Competition Commission, *Implementation of the Competition Amendment Act No.18 of 2018 to the Portfolio Committee on Trade and Industry 20 OCTOBER 2020* (Oct. 20, 2020), <http://www.thedtic.gov.za/wp-content/uploads/CC-Competition-Act.pdf>.

³⁰⁰ See Abbott 2016, *supra* note 30, at 299.

- (1) It is prohibited for a dominant firm to—
 - (a) *charge an excessive price* to the detriment of consumers or customers;
 - (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
 - (c) . . .
 - (d) . . .
- (2) *If there is a prima facie case of abuse of dominance because the dominant firm charged an excessive price, the dominant firm must show that the price was reasonable.*
- (3) Any person determining whether a price is an excessive price *must determine if that price is higher than a competitive price and whether such difference is unreasonable, determined by taking into account all relevant factors, which may include—*
 - (a) *the respondent's price-cost margin, internal rate of return, return on capital invested or profit history;*
 - (b) the respondent's prices for the goods or services—
 - (i) in markets in which there are competing products;
 - (ii) to customers in other geographic markets;
 - (iii) for similar products in other markets; and
 - (iv) historically;
 - (c) relevant comparator firm's prices and level of profits for the goods or services in a competitive market for those goods or services;
 - (d) the *length of time* the prices have been charged at that level;
 - (e) the structural characteristics of the relevant market, including the extent of the respondent's market share, *the*

degree of contestability of the market, barriers to entry and past or current advantage that is not due to the respondent's own commercial efficiency or investment, such as direct or indirect state support for a firm or firms in the market; and

(f) any regulations made by the Minister, in terms of section 78 regarding the calculation and determination of an excessive price.³⁰¹

(emphasis added).

There are a number of notable features to the 2018 amendments which align with this author's perspective regarding movement away from the CJEU's two-step test toward a more contextual approach along the lines of a rule of reason analysis.

In practical terms, one of the most significant innovations of the 2018 Amendments may prove to be the procedural shifting of the burden of proof in section 8(2). That is, once the competition authority has made out a *prima facie* case that the respondent party holds a dominant position and has charged an excessive price, the burden shifts to that respondent to "show that the price was reasonable." One of the major hurdles to overcome in prosecuting originator companies for excessive pricing is the consistent refusal of these companies to provide data regarding their R&D costs and how they go about establishing their prices. In the Herceptin case, the respondent Roche has steadfastly refused to provide data regarding its R&D costs, and the Swiss government has refused to cooperate in securing that information from the parent company in Switzerland. As the case unfolds and the South African Competition Tribunal assesses the *prima facie* case—where the South African Competition Commission clearly seems to have made out the *prima facie* elements of market dominance and excessive pricing—there does not seem to be an alternative under the statute to demanding that Roche justify its pricing with data or face the jurisprudential consequences. That does not necessarily mean that the South African Competition Tribunal must take the assessment of the South African Competition Commission as a factual conclusion, but failure by Roche to respond to a demand from the Tribunal would appear to make it vulnerable to a significant adverse judgment.

The substantive amendments move South Africa away from the analytic rigidity of the two-step test. While section 3(a) appears largely to follow the approaches so far used by European competition authorities in approaching the two-step test,

³⁰¹ In subsection (4), the amended act goes on to include additional rules with respect to historically disadvantaged persons, and small and medium businesses.

section 3(e) directs the analysis towards structural features of the relevant market. This bears importantly on the originator pharmaceutical sector which is heavily affected by regulatory features, including patents, regulatory market exclusivity and other industry specific barriers to entry. Moreover, section 3(e) expressly directs the analysis toward the degree of government support that may have been received by the dominant firm. This again is a prominent feature of the originator pharmaceutical market where particularly within the United States originator companies receive significant R&D funding from federal government institutions such as the U.S. National Institutes of Health. And, notably, in its Herceptin complaint, the South African Competition Commission refers to the benefits conferred by British NHS support for the development of that drug. The revised Section 8 specifically directs the Competition Commission to consider “all relevant factors.”³⁰²

IV. SYNTHESIS OF THE ELEMENTS

Now that a body of investigations and determinations by competition authorities regarding excessive pricing has evolved, it may be useful to attempt to synthesize some common themes or conclusions from this work.

A. Cost Accounting

One of the principal elements in excessive pricing investigations is determining the baseline cost of the product. So far, in respect to the generic (off-patent/off-regulatory exclusivity) products, determining those baseline costs has been reasonably straightforward. In the preponderance of cases the party under investigation has purchased a formulated product from a third-party manufacturer and there is a contract specifying the price paid by the party under investigation for the product.³⁰³ In this regard, there has not been a need to begin a pricing analysis by identifying the basic chemical components and their acquisition costs, synthesis into APIs, purchase of excipients³⁰⁴ and other production materials, the cost of

³⁰² Amended South African Competition Act (2018), *supra* note 299, § (8)(3).

³⁰³ See, e.g., Hydrocortisone Case, *supra* note 79, at ¶¶ 3.341, 5.98, 5.304; Italian Competition Authority v. Aspen, *supra* note 134, at ¶ 314; European Commission – Aspen Commitment, *supra* note 157, at ¶¶ 4.1, 174; Danish Competition Council v. CD Pharma, *supra* note 232, e.g., ¶ 12.

³⁰⁴ An excipient, per the American Pharmaceutical Review: “Generally, an excipient has no medicinal properties. Its standard purpose is to streamline the manufacture of the drug product and ultimately facilitate physiological absorption of the drug. Excipients might aid in lubricity, flowability, disintegration, taste and may confer some form of antimicrobial function,” <https://www.americanpharmaceuticalreview.com/25335-Pharmaceutical-Raw-Materials-and-APIs/25283-Pharmaceutical-Excipients/>. See also Alison Haywood & Beverley D Glass, *Pharmaceutical excipients – where do we begin?*, 34 AUSTRALIAN PRESCRIBER 112-4 (2011); “Pharmaceutical excipients are substances that are included in a pharmaceutical dosage form not for their direct therapeutic action, but to aid the manufacturing process, to protect, support or enhance

building and/or maintaining a production facility, etc. This is not to suggest that constructing costs “from scratch” would be especially problematic. This is a process routinely undertaken by trade administrative authorities in antidumping and countervailing duty investigations,³⁰⁵ even to the extent of establishing simulated constructed costs when dealing with non-market economies.³⁰⁶ Nonetheless, if the party under investigation is simply purchasing a formulated product from a third-party manufacturer, the process is simplified.

It could be that a party under investigation has paid an unusually high price to a third-party manufacturer, but so far this does not seem to have been an issue. In the cases undertaken to date, the mark-ups charged by the party under investigation have been so high that “precisely” identifying the price that might have been paid to a third-party manufacturer has not been an issue.³⁰⁷ The competition authorities have tended to use the higher of the available benchmarks to avoid subsequent challenge.³⁰⁸

The party under investigation is typically marking up and distributing the product to procurement authorities or pharmacies. In the process of distribution and marketing, the party under investigation will entail direct and indirect costs. If that party is distributing a portfolio of products, and/or is distributing across multiple jurisdictions, the direct and indirect costs of those activities must be allocated so that the share attributable to the product(s) subject to investigation can be determined. Competition authorities have laid out various potential methodologies

stability, or for bioavailability or patient acceptability. They may also assist in product identification and enhance the overall safety or function of the product during storage or use.”

³⁰⁵ Antidumping and countervailing duty investigations address certain forms of unfair trade practices. “Dumping” refers to export of products at below fair value, and antidumping duties may be applied to bring the import price up to that fair value so as to avoid damaging producers in the importing country. Countervailing duties are applied to offset government subsidies that unfairly benefit exporters of one country at the expense of producers in the importing country. These trade remedies are governed by international rules and are investigated through international and national proceedings. At the international level, see WTO, *Technical Information on anti-dumping*, https://www.wto.org/english/tratop_e/adp_e/adp_info_e.htm; WTO, *Subsidies and countervailing measures*, https://www.wto.org/english/tratop_e/scm_e/scm_e.htm.

³⁰⁶ See, e.g., *Nation Ford Chemical Co. v. U.S.*, 166 F.3d 1373 (1999).

³⁰⁷ See, e.g., *Hydrocortisone Case*, *supra* notes 106–07; *ICA v. Leadiant*, *supra* notes 227–28, where in addition to using a substantially higher reasonable profit margin than it might have to establish the cost plus benchmark, the ICA included the respondents cost defending itself in the case as part of its product costs, and *ACM v. Leadiant*, *supra* note 193, 204, in which the Dutch Competition Authority calculated price increases starting only from the point at which the respondent applied for orphan drug designation, when it could have used an earlier much lower price that would have yielded a significantly higher level of excessive pricing.

³⁰⁸ See, e.g., *Hydrocortisone Case*, *supra* note 83, 110–11, in which the CMA ignores sales below £20 that would show 200-300% increase.

for allocation of direct and indirect costs of distribution.³⁰⁹ This can be done, for example, by taking either the volume of product or the revenue from product and using that as the numerator against the denominator of the total of direct and indirect costs.³¹⁰ This type of allocation of costs is a common matter for cost accountants. And, as with production costs, the competition authorities have been amenable to using approaches that yield the highest reasonable figure for costs in order to avoid “quibbling” in subsequent challenges,³¹¹ again bearing in mind that the level of excessive pricing in these investigations has been so high that small marginal increments do not materially affect the ultimate calculation.

That said, it would seem useful for national competition authorities to further share information regarding the approaches so far used in cost accounting, potentially coming to some type of consensus regarding the best mechanisms. If a common approach could be identified, this might help alleviate the burden placed on investigating authorities to develop and justify the cost accounting approach used in each individual case. There may be limits to such an endeavor in the sense that the structure of parties under investigation—the way they organize their business—may be sufficiently different that a common approach will not yield the expected benefit. Nonetheless, it is an idea that may be worth pursuing.

B. The Plus Element

A recurring element in the excessive pricing determination is the “plus” part of the cost-plus equation. This is generally understood to refer to the reasonable or acceptable profit margin that should be accorded to the benchmark against which the price charged by the party under investigation is compared.

A straightforward approach can be followed by attempting to determine what is considered an ordinary profit margin by companies in a particular market segment. At a broad level, for example, the profit margins earned by generic companies in a competitive market are ordinarily fairly low.³¹² The profit margins

³⁰⁹ See, e.g., Hydrocortisone Case, *supra* note 84, ¶¶ 5.97–5.146 for a detailed description of direct and indirect cost calculation alternatives, noting that cost allocation was ultimately based on relative sales volume of product (e.g., ¶ 5.146; and CMA. v. Advanz, *supra* note 121, 131, where again a sales volume to allocate common costs methodology is used). The CMA said: “Undertaking the cost allocation exercise across a company’s whole portfolio (*i.e.*, calculating the proportion of Liothyronine Tablet sales volumes relative to all of Advanz’s sales) ensures that total common costs are recovered and no more,” ¶ 5.120.

³¹⁰ This CMA in Hydrocortisone and in Advanz, uses a volume of sales allocation approach, *id.*

³¹¹ See, e.g., discussion in ICA v. Ladiant, *supra* Part II.F.

³¹² According to Statista: “Generic manufacturers worldwide had an almost 20 percent profit margin on generics in fiscal year 2016, which has been gradually decreasing to 12.8 percent profit margin in FY 2019.” KPMG, *Profit margin for generics manufacturers worldwide from FY 2016 to FY 2019 Statista*, TIME, Sep. 17, 2021, <https://www.statista.com/statistics/1248196/profit-margin->

for the originator industry as an overall market segment are substantially higher reflecting the higher level of risk for investors in that sector.³¹³

In some proceedings, competition authorities, including the CMA, have referred to the “plus” element as “cost of capital” that has generally been defined as the expectation of investors regarding the return on investment that the business is expected to generate.³¹⁴ Put another way, what percentage return is required to induce the investment.

There should not be a difference between the level of profitability of the business determined by examining industry benchmarks and the expectation of investors regarding the amount needed to induce investment. It would appear that the different discussions are directed towards ascertaining the same thing. But, further investigation on this should be considered, toward coming to a common understanding as to what is meant by the “plus” element of the cost-plus equation.

However, these two concepts should be distinguished from the approach that has been used by researchers at Tufts and the Pharma industry in offering what they have portrayed as the costs of R&D in the originator sector.³¹⁵ They have referred

for-generics-manufacturers-worldwide/; In the Pfizer/Flynn First Decision, the CMA used a profit margin of 6% as an ordinary rate of return in the industry. In the Remittal Decision it raised the reasonable rate of return for Pfizer to 10%, and for the intermediary Flynn it lowered the rate to 2%. See notes 62–63 *supra*. In other cases, the rates have been somewhat higher, *e.g.*, about 13% in Hydrocortisone, *supra* note 106.

³¹³ Aggregated data on profit margins for originator pharmaceutical products is less well reported. Statista shows gross profit margins on selected US biotech and drugs companies as of the third quarter 2022 from 95% to 25%, with a single outlier losing money. See CSIMarket, *Gross profit margin of selected U.S. biotech and drugs companies as of Q3 2022 Statista*, TIME, Feb. 16, 2023, <https://www.statista.com/statistics/274572/gross-profit-margin-of-united-states-biotech-companies/>; see also Ned Pagliarulo, *High prices fuel pharma profits. New research provides more context*, BIOPHARMADIVE, March 3, 2020, <https://www.biopharmadive.com/news/pharma-prices-profits-too-high-jama-study/573376/> (“The median gross profit margin among the 35 drugmakers studied was 77%, easily more than double the 29% median calculated across 357 other companies in the S&P 500.”)

³¹⁴ As noted in discussion of the European Commission Commitment from Aspen, the “plus” element in a cost plus calculation is intended to provide remuneration of the cost of capital. EU-Aspen, *supra* note 185. See also, CMA v. Advanz, *supra* note 121.

³¹⁵ See Abbott 2016, *supra* note 30, at 306–08, 314–15. The question of “cost of capital” has been the subject of a heated pharmaceutical-economics debate that has gone on for quite a few years now. In Abbott 2016 this author referred to works by Joseph DiMasi dating back to 1991. Joseph A. DiMasi et al., *Cost of Innovation in the Pharmaceutical Industry*, 10 J. HEALTH ECON. 107, 107–08 (1991). This issue gained increased prominence when the leading originator pharmaceutical industry association (PhRMA) relied on DiMasi’s work to identify the cost of developing a new medicine. PhRMA, *2015 Profile: Biopharmaceutical Research Industry*, http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf. In a 2016 publication addressing this issue, DiMasi, et al., referenced 13 publications addressing the cost of capital issue. Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20-33 (2016).

to an imputed or alternative cost of capital during the period of R&D. They have described or defined this as a hypothetical amount that could have been earned by the company undertaking the R&D investment if it had invested the same capital somewhere else.³¹⁶ So for example, if the company could have invested its money in high-yield bonds and gotten an 8% return on investment, then an 8% per annum imputed cost of capital is added across the duration of the R&D. As the authors of the Tufts study have acknowledged by more recently posting an “out-of-pocket” R&D cost in addition to the R&D cost including imputed (or alternative) cost of capital, the R&D figure is approximately cut in half by removing the imputed cost of capital.³¹⁷

This author has previously criticized the use of imputed cost of capital in determining R&D costs because the company investing in R&D is provided with its capital by investors for the purpose of engaging in R&D.³¹⁸ The company is not paying for that capital on an ongoing basis. Instead, the results of the R&D efforts are eventually booked as profits or losses, or they result in an increase or decrease in the share price and/or in the payment of dividends to the investor. The Pharma company compensates its investors through the success (or failure) of its business. The Pharma company could have said “we will not conduct R&D, instead we will invest the money in high-yield bonds” and so could have returned 8% per annum to our investors, but that would have been a different company or business. Likewise, the company instead of using shareholder equity contributions to fund its operations could go into the financial market and issue its own bonds, which would represent an actual cost of capital. That would reduce the profitability of its R&D effort. But the decision by the company to use debt financing as opposed to equity financing should not be used to boost its nominal R&D cost since ultimately the success or failure of the R&D effort is reflected in the value of the company to the

³¹⁶ The various sides of the debate over inclusion of costs of capital and how it is calculated is summarized in the work by Avman Chit et al., stating:

“The cost of financing pharmaceutical R&D is the return needed to entice funders to commit resources to pharmaceutical R&D instead of other investments. The underlying idea is that investors will only commit resources if they expect to receive an amount that they can earn on other equally risky investments. The amount that can be obtained elsewhere constitutes the investor’s “opportunity cost” of capital. . . . Investors in pharmaceutical firms, that is, shareholders, only wish to be in the pharmaceutical R&D business if they receive as much in compensation as they do in other equally risky ventures.”

Ayman Chit et al., *The Opportunity Cost of Capital*, 52 INQUIRY: J. HEALTH CARE ORG., PROVISION, & FIN 1 (2015).

³¹⁷ See DiMasi et al. (2016), *supra* note 30, at *e.g.*, Abstract.

³¹⁸ *Id.*

investor base, and it is reflected in the share price.³¹⁹ It is, simply put, a decision regarding the way to maximize returns.

In this author's view, the "plus" element of cost-plus is the rate of return or profitability ordinarily earned by a business in the relevant sector assuming the absence of anticompetitive restraints. This can be framed as "cost of capital" if it is understood in the same sense. But there should not be an additional "imputed" cost of capital reflecting how the business might have invested its money had it not chosen to conduct R&D.

C. *The Fairness Element*

A consistent theme of the excessive pricing cases prosecuted to date (with the exception of the originator cases) is that the party under investigation has not undertaken any actions that improve the pharmaceutical product regarding which prices have been raised, even to create some type of new formulation. The essence of the activity is to exploit a circumstance that for one reason or another allowed prices to be raised without quickly attracting competitors.

The argument has been made (e.g., in *Pfizer/Flynn*, *CD Pharma*) that keeping a drug on the market that might otherwise become unavailable is a valuable contribution, and that margins prior to the price increases were insufficient to justify continued manufacture and distribution.³²⁰ But, it appears that this type of argument has not been adequately substantiated.

Moreover, competition authorities have been prepared to acknowledge that price increases are justifiable when undertaken responsibly.³²¹ In the cases under investigation, the parties under investigation have abused their position of market dominance to charge prices far in excess of those that would be deemed to reflect responsible behavior.³²²

Given that the generics/orphan cases so far have involved no arguable "value-added" contribution by the parties under investigation, it is difficult to draw from the prosecutions meaningful conclusions about common features that might argue for "fairness." As in a traditional "rule of reason" type of balancing analysis, there

³¹⁹ To be sure, the author of this article is not the first or only person who has objected to the cost of capital figures used by DiMasi et al., and on the same or similar grounds. See, e.g., Donald W. Light & Rebecca Warburton, *Demythologizing the high costs of pharmaceutical research*, *BIOsocieties*, 6, 34–50 (2011).

³²⁰ *Pfizer/Flynn*, *supra* note 37, 43, 68–69.

³²¹ See, e.g., *id.*; EU-Aspen Commitment, *supra* note 157.

³²² This point is made by the competition authority in each of the cases prosecuted. See, e.g., Hydrocortisone Case, *supra* note 84; ACM-Leadiant, *supra* note 193; CD Pharma, *supra* note 239.

has been no “positive value-added” element to offset the abusive behavior. Bear in mind that a producer’s investment in manufacturing equipment or research and improved formulations should already be taken into account in the “cost” element of the cost-plus benchmarking.

Arguably the case that does not involve “merely raising prices” is the *Herceptin* case currently being prosecuted against Roche in South Africa and its predecessor, the *Hazel Tau* case.³²³ Here we are dealing with the originator of a life-saving drug and the alleged excessive price does not reflect a recent increase, but rather an excessive price essentially charged from the outset, ostensibly to recoup R&D and provide funds for future R&D.³²⁴ The argument concerning fairness from the competition authority standpoint is that the high price forecloses access to a large group of patients who would otherwise have been treated, and burdens healthcare more generally.³²⁵ Part of the fairness analysis involves a demonstration that the level of GDP per capita in South Africa in comparison to the price of the pharmaceutical product effectively forecloses access. Furthermore, the originator company seems certainly in a position that it could substantially lower the price of the subject pharmaceutical and continue to sell it profitably.³²⁶ In other words, this is not a choice between the health of the patient and the bankruptcy of the healthcare provider. It is a question of the balance of the interests of the parties.

An originator pharmaceutical company that has invested in R&D and introduced an important “new” therapy deserves credit for its accomplishment. This credit should be reflected in the “risk increment” incorporated in a cost-plus assessment. In a balancing regarding whether the price charged is justified, some additional margin might be attributed to the fact of success.³²⁷ But this does not justify “excess.”

³²³ *Supra* notes 268, *et seq.*

³²⁴ While the Respondent Roche had not at the time of writing filed a response before the South African Competition Tribunal, its only foreseeable justification for its pricing of Herceptin is the need to recover its R&D costs and to invest in future R&D.

³²⁵ *See Herceptin case, supra* notes 275, *et seq.*

³²⁶ Each of the methodologies employed by the South African Competition Commission to establish a benchmark price for Herceptin, including cost (including risk adjusted R&D) plus a reasonable profit is asserted to be far in excess of the prices charged by Roche. It seems highly doubtful that there is not a price between those charged by Roche and a risk adjusted cost plus price that would permit Roche to sell Herceptin profitably. Of course, only the completed litigation or a settlement will definitively answer that question.

³²⁷ Abbott 2016, *supra* note 30, at 315 (“[A] modest efficacy premium may be in the nature of a prize given to a successful venture.”)

D. The Business Model

One of the striking conclusions that can be derived from reviewing the case law so far is the extent to which the investing business community views the opportunity to charge excessive prices for pharmaceutical products as an attractive motivator for acquiring a generic product line. Evidence in the *Hydrocortisone* case, for example, included slide presentations by private capital firms to investors spelling out the plan to take the products out of the British price control system and leverage a protected market position to secure extraordinarily high return on investment.³²⁸ If there was thought given to the impact this would have on the affected patients and the NIH system, it is difficult to see that in the case record.

An element that runs through several cases, e.g., *Pfizer/Flynn*, *Hydrocortisone* (*Auden/Actavis*) and *Aspen*, as well as cases involving orphan drug designations, e.g., *Leadiant*, is the deliberate effort by the parties under investigation to exploit regulatory systems by taking advantage of unintended constraints or consequences that create limited niche markets.³²⁹ The parties under investigation defend their conduct on the grounds that there is nothing illegal about exploiting legal loopholes.³³⁰ While the ethics of such attitude is certainly open to question, the existence of a loophole in a regulatory structure does not entitle the party exploiting it to engage in an independent abusive practice, that is abuse of dominant position to charge an excessive price. This is one reason why excessive pricing as a cause of action is so important in competition law. The abusive exploitation of a loophole is similar to abusive exploitation of a patent. Taking advantage of a loophole in the law and enforcing a patent are not in themselves contrary to law. It is the abuse that is contrary to law.

³²⁸ *Hydrocortisone*, *supra* note 83, at ¶ 3.84. See also *Advanz*, *supra* note 126.

³²⁹ See, e.g., *Hydrocortisone*, *id.*, and CMA discussion of niche products model.

³³⁰ This reasoning underlies the defense throughout the various cases. The parties have knowingly engaged in behavior that takes advantage of the possibility to dramatically increase pricing without objective justification. The schemes are directed at specific features of the drug regulatory systems that allow this to happen, e.g., in *Advanz* using an advertising campaign against bioequivalent drugs known to be just as effective, but with a different label. In defense the parties do not concede illegality. Inherent in the defense is the argument that the exploitative conduct was not illegal.

In cases such as those involving an orphan drug designation (e.g., the *Leadiant* cases), the legislator created a system that was designed to confer pricing power on the awardees of the designation. What the legislator presumably did not foresee was the extent to which the awardee of the orphan drug designation would leverage its position by putting drug procurement authorities, doctors and patients in an untenable position by threatening the continued supply of medicines essential to life. This might be classified more as an "unintended consequence" than exploitation of a loophole (i.e., a legal avenue that is in fact open, but not used for a purpose intended by the legislator). Whether a loophole or an unintended consequence, the matter remains to be redressed by legislative action or competition law enforcement.

Two outside parties in this affair are the lawyers and the legislators/regulators. Business executives typically are not experts in regulatory affairs (though they may be) and rely on lawyers to identify the loopholes that might be exploited. Similar to the criminal defendant who has the right to an attorney and a defense no matter how terrible the conduct, does the pharmaceutical industry lawyer argue that he/she has an obligation to identify legal loopholes on behalf of his/her clients? Does that justify the hourly rate? And, of course, the legislator/regulator can either draft legislation so as to avoid creating loopholes in the first place or can close them as soon as they are detected. One lesson is that legislators should avoid creating legislation portending unintended consequences. But, the secondary effects of legislation may be difficult to predict, particularly as the regulated community will be implementing it over time and may come to identify potential behaviors or loopholes that the legislator would have difficulty foreseeing. Part of the issue perhaps is convincing legislators that there is always a group of businesses and/or individuals who will “act badly” and seek to take advantage of avenues for profit opened up by a regulatory structure.

*E. Transparency and Cooperation*³³¹

Prosecutions for excessive pricing should address originator pricing of patent and/or marketing exclusivity protected pharmaceuticals. Establishing the reasonable baseline cost, and the reasonable “plus” element for originator products will generally, but not always, require the building in of a risk factor which takes into account the unique characteristics of the pharmaceutical industry and the manner in which R&D is financed.³³² Even assuming that a risk factor stated, for example, in percentage terms can be arrived at, there will still remain the question of the actual expenditures by the originator in conducting R&D (including its associated activities, e.g., clinical trials).

The ongoing *Herceptin* case in South Africa drives home the extent to which the originator companies will attempt to preclude an opening of their books to investigators. Not only did the party under investigation, Roche, refuse to provide data to the investigators in South Africa on grounds that the data was located in Switzerland, but diplomatic approaches to Switzerland’s Department of Justice and a request for assistance to the Swiss Competition Authority were refused. The Swiss Competition Authority refused on grounds of the lack of an information-sharing

³³¹ The importance of transparency and access to information regarding research and production costs is the subject of a substantial literature. See discussion in Abbott 2016 and, e.g., UNDP 2022, *supra* note 8.

³³² Abbott 2016, *supra* note 30.

agreement with South Africa.³³³ This latter refusal implies that competition prosecutors cannot cooperate with overseas colleagues in the absence of a pre-existing international agreement. It could be the case that under Swiss law the government does not have authority to demand information from a Swiss national that is not being used to enforce local/domestic legislation.³³⁴

One lesson, which is not new, is that it is in the interest of competition authorities to enter into mutual assistance agreements with authorities in foreign states. As such agreements have the force of law in the respective countries this should facilitate cross-border evidence gathering, though this does not necessarily mean that the road will be smooth.

What this case highlights *again* is that the pharmaceutical industry will not willingly open its books to investigation for purposes of providing data regarding R&D costs. It may provide such data to certain parts of the investment community.

V. IMPROVEMENTS TO PROSECUTION

A. *Per Se* Rules and/or Weight of Presumptions

The preceding review of prosecutions in Europe and South Africa illustrate the complex nature of antitrust law as it applies to excessive pricing. Competition authorities invest significant resources not only in securing the data necessary to successfully prosecute, but also in analyzing that data in ways that will withstand scrutiny by appeals bodies. The authorities are challenged at every step, with delays at each of those steps. Because of this, competition authorities almost certainly pursue fewer investigations than they might, given the resource costs entailed. The question that arises from the prosecutions undertaken to date is whether it is feasible to establish a more efficient mechanism for prosecuting excessive pricing, particularly as the phenomenon affects the generics product market.³³⁵

The traditional tool for accelerating competition enforcement is the promulgation or adoption of *per se* rules that identify certain types of conduct as anticompetitive as a matter of law, without the possibility for any defense involving

³³³ Herceptin case, *supra* ns. 269, 280–81.

³³⁴ If the Swiss authorities wanted to assist South Africa they could open their own investigation of Roche for potential competition violations within Switzerland. There are also mechanisms for judicial request for evidence from foreign parties that potentially could be used by South Africa with respect to the Swiss authorities (e.g., letters rogatory), but these rely on the cooperation of the receiving country.

³³⁵ As suggested by this author, see Frederick M. Abbott, *Excessive Pricing Doctrine in the Pharmaceutical Sector: The Space for Reform*, EU COMPETITION L. AND PHARMACEUTICALS 16-32 (W. Sauter, M. Canoy & J. Mulder eds., Edward Elgar 2022).

the demonstration of counterbalancing pro-competitive elements.³³⁶ *Per se* rules have generally been applied to certain types of agreement among enterprises, such as agreements to fix prices or allocate geographic territories between horizontal competitors. Such agreements are identified through routine evidentiary processes. The more complex balancing alternative is generally referred to as “rule of reason” analysis.³³⁷

To date, *per se* rules have not formed part of excessive pricing jurisprudence. Excessive pricing is not typically characterized by an agreement between enterprises or undertakings (although it can involve such an agreement). Excessive pricing is a subtype of “abuse of market power,” whereby a dominant enterprise extracts a price(s) that is unreasonable (or abusive) by virtue of its control over the relevant market (e.g., the market for a specific pharmaceutical product). The excessive price refers to the “spread” between the “normal” non-abusive price and the unreasonable/abusive price. Calculating that spread, or differential, entails establishing a cost (or other) baseline and comparing that with the price actually charged. Establishing a *per se* rule appears to require some agreement on what constitutes an acceptable level of spread, which in turn requires some agreement on the appropriate methodology (or methodologies) for determining the baseline.

During the past several years competition authorities in various jurisdictions in Europe have shown their ability to make sound determinations regarding the cost-plus baseline and the spread. Typically, the subject product has been on the market, and while there may have been R&D investment in improving the production process, for example, the costs can be calculated with some certainty. The price charged for the product by the producer can be determined (e.g., by examining invoices). Establishing the spread between the baseline “normal” price and the price charged by the producer is straightforward. The differential may be stated as a percentage.

Is there some standard level at which the selling price of a generic pharmaceutical product exceeds the cost-plus baseline by so much that it should be considered abusive *per se*?

In the cases decided so far, the differential between cost-plus price and the actual selling price is high. In several cases well over 1000%.³³⁸ It is here posited

³³⁶ For an explanation of *per se* rules in competition law, 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, 59–75 (2014).

³³⁷ *Id.*

³³⁸ See, e.g., Pfizer/Flynn and ACM Leadiant cases, *supra* note 37.

that for a generic producer to charge more than 10 times the cost of production plus a reasonable profit is excessive on its face—that is, *per se* excessive. That would seem relatively uncontroversial. However, there is some level(s) between the cost-plus (the baseline) and selling price that is less blatantly unreasonable but could still qualify as excessive on its face. That level might be 150%, 300%, 500% or 750%. A relevant factor may be the period of time over which price increases were implemented depending on correlation to broader economic circumstances.

There is no obvious social or economic norm to rely on for establishing what should be considered a lower bound on *per se* excessive pricing. Doubtless the pushback from the industry on a level like 25% would be substantial,³³⁹ even though that percentage (and lower) is applied in some price gouging statutes.³⁴⁰ This paper leaves the question open: what minimum threshold percentage level of price over cost might be considered *per se* excessive for a generic pharmaceutical product?

Should a producer be allowed to rebut an initial finding of *per se* excessive pricing by demonstrating that some special circumstance justified the extreme price differential (recognizing that this might not then be considered a *per se* rule as such)? It is difficult to know what such a special circumstance might be. For example, a producer might assert that the shortage of a particular chemical input on the market required it to pay far more for that input than it previously had, contending that the very high price was justified. However, the input price already would be included as part of the cost determination and should already have been taken into account.

Nonetheless, a new rule might not be a *per se* rule, as such, but a strong presumption against the producer, still allowing some scope for demonstrating a legitimate justification. However, such an alternative would go against the objective of increasing prosecutorial and judicial efficiency.

Establishing an excessive pricing baseline in the case of originator products that involve research and development (R&D) and a degree of risk (variable depending

³³⁹ Though in a substantially different context, the European Commission determined that the price charged by the German postal service for the forwarding and delivery of incoming cross-border mail exceeded the average economic value by at least 25% and constituted an unfair selling price within the meaning of Article 102 (then 82). See European Commission of 25 July 2001, COMP / C-1 / 36.915 - Deutsche Post AG - Interception of cross-border mail, ¶¶ 166–67.

³⁴⁰ In fact, a number of US state price gouging statutes establish 10% above the pre-event price as excessive, subject, for example, to proof provided by the accused party of the additional costs it incurred. See, e.g., Cal. Penal Code § 396. See also FindLaw, *Price Gouging Laws by State*, <https://www.findlaw.com/consumer/consumer-transactions/price-gouging-laws-by-state.html>, for a list of other statutes.

on the circumstance) is more complex than the relatively straightforward cost-plus determination with respect to generic products. The originator pharmaceutical industry argues that the cost of developing new pharmaceutical products is highly indeterminate thereby justifying what may often appear to be excessive prices.³⁴¹

While some new originator products do indeed represent breakthrough therapies based on previously unknown science, there are also many originator products that are merely product line extensions based on minor modifications of existing formulations.³⁴² For that latter category of product, looking at the differential between the price for the “new and improved” product and its predecessor on the market, and comparing that to the cost of the improvement may not be so difficult.

For “breakthrough therapies” that involve high-risk R&D, determining a baseline or normal price may be more difficult. The level of acceptable differential between development costs and selling price may be greater in order to account for the degree of risk and the extent of the benefit of the new therapy. This does not mean that the price of a new breakthrough originator drug may not be excessive, but probably less susceptible to *per se* analysis. With that said, there are means by which establishing the R&D costs of a new drug could be facilitated for competition law purposes and others, which are considered also in the following section.

This article proposes the utility of *per se* rules in addressing excessive pricing, particularly when such practice involves pharmaceutical products that are off-patent and no longer protected by regulatory market exclusivity. In other words, when the cost of the products does not reflect added investment in R&D entailing risk factors that are presumed recouped during the period of patent protection and/or innovation-based market exclusivity. The author recognizes, however, that at least for the European Union the recent tendency of the CJEU is to limit the use of *per se* rules, albeit not in cases addressing excessive pricing of pharmaceuticals.

³⁴¹ See, e.g., Deloitte, In the Face of Uncertainty: The Deloitte Center for Health Solutions 2014 Survey of US Health Care Consumers (2014), https://www2.deloitte.com/content/dam/Deloitte/lu/Documents/life-sciences-health-care/us_consulting_Inthefaceofuncertainty_040614.pdf (relied upon by PhRMA in its 2015 annual report explaining drug development costs).

³⁴² See for explanation of product line extensions, Matthew Fowler, *Pharmaceutical Pricing in the United States: An Overview* 3 (National Bureau of Economic Research, 2017), <https://www.nber.org/sites/default/files/2022-09/WhitePaper-Fowler10.2017.pdf>. (“Because of the lower costs of R&D and the market protections offered to line extensions, a profit maximizing pharmaceutical firm can strategically introduce line extensions to increase revenue.”)

1. The European Union

Decisions of the CJEU over the preceding five years suggest a certain reticence to employ *per se* rules, including with respect to application of Article 102 and abuse of dominant position. This reticence was manifest by the CJEU in overruling the decision of the General Court in the *Intel* case in 2017 (*Intel v. Commission*, CJEU Case C-413/14 P, 6 Sept. 2017), resulting in the annulment of a €1.06 billion fine imposed by the Commission (*Intel v. Commission*, Gen. Court, Case T-286/09 RENV, 26 Jan. 2022).³⁴³ In relevant part, the Commission had determined that an arrangement that tied purchasers to exclusively obtain all or most of their requirements from the dominant supplier (whether through agreement, loyalty rebate, etc.) were by their nature anticompetitive, and that further analysis such as applying an efficient competitor test (“AEC”) was not required. In other words, the Commission determined that the exclusive dealing arrangement was *per se* illegal. The CJEU disagreed with the Commission and the General Court, holding that if the party under investigation brought forward evidence that its conduct was not capable of restricting competition, or that there is a benefit to consumers outweighing the exclusionary effects of its conduct, this evidence must be assessed.³⁴⁴

³⁴³ The judgment of the General Court has been appealed by the Commission to the CJEU and remains pending.

³⁴⁴ The CJEU said:

137. In that regard, the Court has already held that an undertaking which is in a dominant position on a market and ties purchasers—even if it does so at their request—by an obligation or promise on their part to obtain all or most of their requirements exclusively from that undertaking abuses its dominant position within the meaning of Article 102 TFEU, whether the obligation is stipulated without further qualification or whether it is undertaken in consideration of the grant of a rebate . . .

138. However, that case-law must be further clarified in the case where the undertaking concerned submits, during the administrative procedure, on the basis of supporting evidence, that its conduct was not capable of restricting competition and, in particular, of producing the alleged foreclosure effects.

139. In that case, the Commission is not only required to analyse, first, the extent of the undertaking’s dominant position on the relevant market and, secondly, the share of the market covered by the challenged practice, as well as the conditions and arrangements for granting the rebates in question, their duration and their amount; it is also required to assess the possible existence of a strategy aiming to exclude competitors that are at least as efficient as the dominant undertaking from the market . . .

140. The analysis of the capacity to foreclose is also relevant in assessing whether a system of rebates which, in principle, falls within the scope of the prohibition laid down in Article 102 TFEU, may be objectively justified. In addition, the exclusionary effect arising from such a system, which is disadvantageous for competition, may be counterbalanced, or outweighed, by

Subsequently, in the ENEL case (*SEN/ENEL v. Italian Competition Authority*, CJEU Case C-377/20, 12 May 2022), pursuant to a reference from the Italian Council of State, the CJEU affirmed the approach in a case involving an exclusionary practice undertaken by a dominant supplier on the Italian electricity market that preferentially provided commercial marketing information to affiliated entities, while effectively withholding such information from potential competitors. The CJEU said:

46. [A]s the Advocate General pointed out...the well-being of consumers, both intermediate and final, must be considered the ultimate objective justifying the intervention of competition law to suppress abusive exploitation of a dominant position on the internal market or on a substantial part of it. For this reason, as already stated by the Court, an undertaking holding such a position can prove that an exclusionary practice does not incur the prohibition set out in Article 102 TFEU, in particular by demonstrating that the effects that such practice can produce are counter balanced, if not overcome, by advantages in terms of efficiency that also benefit consumers, in particular in terms of prices, choice, quality or innovation [see, to this effect, judgments of 6 September 2017, *Intel / Commission*, C-413/14 P, EU: C: 2017: 632, paragraphs 134 and 140³⁴⁵

advantages in terms of efficiency which also benefit the consumer ... That balancing of the favourable and unfavourable effects of the practice in question on competition can be carried out in the Commission's decision only after an analysis of the intrinsic capacity of that practice to foreclose competitors which are at least as efficient as the dominant undertaking.

141. If, in a decision finding a rebate scheme abusive, the Commission carries out such an analysis, the General Court must examine all of the applicant's arguments seeking to call into question the validity of the Commission's findings concerning the foreclosure capability of the rebate concerned. CJEU Case C-413/14 P, 6 Sept. 2017.

³⁴⁵ The CJEU continued:

47. Therefore, a competition authority discharges the burden of proof against it if it proves that a practice of an undertaking in a dominant position is capable of affecting, by using resources or means other than those on which normal competition hinges, a structure of effective competition, without it being necessary for the same to demonstrate that said practice has, in addition, the capacity to cause direct damage to consumers. The dominant undertaking in question can nevertheless escape the prohibition laid down in Article 102 TFEU by demonstrating that the foreclosure effect that may arise from the practice in question is offset, if not overcome, by positive effects for consumers. CJEU Case C-377/20, 12 May 2022.

This article is not a general review of the state of jurisprudence in the EU regarding *per se* rules under Article 102. However, it would be imprudent to ignore the potential significance of the trend in CJEU decisions, particularly as the *Intel* prosecution was portrayed as an important part of the Commission's efforts to restrain anticompetitive behavior in the high technology sectors, and the reversal by the CJEU was perceived as a setback to those efforts.

In this regard, the author acknowledges that persuading the European Commission, the national competition authorities and the courts to pursue a *per se* approach to excessive pricing is a challenge, and that establishing a strong presumption based on levels of excessive pricing may be more realistic under current circumstances. Pendulums in jurisprudence swing both ways, and European jurisprudence may shift back toward recognizing that certain practices are abusive as such.

2. The United States

The US Supreme Court has long endorsed the use of *per se* rules in certain contexts, including in the application of Section 2 of the Sherman Act prohibiting monopolization and attempted monopolization.³⁴⁶ For example, in cases involving below cost pricing or refusal to deal, US courts have generally taken a *per se* approach.³⁴⁷ This observation is not intended to mask the complexity of addressing the circumstances in which *per se* and rule of reason approaches will be followed by US courts. There are areas where the Supreme Court has moved from a *per se* approach to a rule of reason approach, such as resale price maintenance (see *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2725 (2007)). For present purposes, it is sufficient to observe that there is room under Section 2 for *per se* rules based on pricing criteria, including excessive pricing. As US courts currently do not acknowledge a Section 2 cause of action based on excessive pricing standing alone,³⁴⁸ the question whether such a cause of action might incorporate either *per se* or presumptive standards is secondary. There is no obvious reason why a *per se* rule could not be adopted.

B. Agreement on Analytic Tools

Whether or not there is agreement on *per se* rules, there will be circumstances in which in-depth analysis of factual elements is required. For example, in cases

³⁴⁶ See discussion, e.g., in US Department of Justice, Competition and Monopoly: Single-Firm Conduct under Section 2 of the Sherman Act; Chapter 5, updated March 18, 2022.

³⁴⁷ See, e.g., *Brooke Group v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993); *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-4168, 2014 WL 1343254 (D.N.J. Mar. 28, 2014).

³⁴⁸ See *infra* note 388, *et seq.*

involving generic products when the level established as the *per se* anticompetitive level of the differential is not met, or in specific cases involving products protected by exclusivity rights where a balancing analysis may be more appropriate. We therefore move on to the second major area for reform, which is the possibility of agreement on the analytical tools by which excessive pricing can be identified.

1. Cost Adjusted for Risk

The preferred benchmark pricing methodology should be an analysis of cost elements, adjusted for risk. This approach is grounded in verifiable facts, and avoids the subjectivity involved in relating the “worth” of a pharmaceutical product to human life. Prior work on this subject focused on overcoming the industry argument that determining a normal or reasonable benchmark price for a new pharmaceutical product is not possible because the data resides within a black box.³⁴⁹

The originator industry and its financial advisors and investors routinely place values on new product portfolios, whether in the R&D phase or the market approval phase.³⁵⁰ This entails a substantial degree of objective assessment of underlying economic data, including an assessment of the probabilities of success. This type of analysis is also used when making decisions about potential mergers and acquisitions. And, of course, pharmaceutical originator companies do not simply guess at their budgeting requirements. Within companies, there is an understanding of R&D costs. This is not to say that there is not an element of uncertainty associated with a cost/risk adjusted analysis.

One reason for the difficulty of pursuing cost-based assessment is gaps in access to company data. This gap has received substantial attention over the past several

³⁴⁹ Cost-plus becomes more complex as new products are assessed and should be adjusted for risk. See Abbott 2016, *supra* note 30, for greater detail on risk and other factors, such as:

- a) New therapy or product line extension;
- b) Incorporation of costs of related R&D efforts;
- c) Multi-product enterprise or single purpose;
- d) Issue of alternative cost of capital; and
- e) Subsidy and other federal assistance.

³⁵⁰ See, e.g., Daniel Tobias Michaeli et al., *Valuation and Returns of Drug Development Companies: Lessons for Bioentrepreneurs and Investors*, THERAPEUTIC INNOVATION & REGULATORY SCIENCE (2022) 56:313–322, <https://doi.org/10.1007/s43441-021-00364-y>; Girotra, K., Terwiesch, C., & Ulrich, K. (2007), *Valuing R&D Projects in a Portfolio: Evidence From the Pharmaceutical Industry*, MANAGEMENT SCIENCE, 53 (9), 1452–1466, <http://dx.doi.org/10.1287/mnsc.1070.0703>. See also, discussion in Staff of S. Comm. on Fin., 114th Cong., *The Price of Sovaldi and Its Impact on the U.S. Health Care System* (Comm. Print 2015), regarding the factors that went into pricing decisions regarding Sovaldi, including the costs associated with acquiring Pharmasset, the original developer of the drug.

years but despite this, it is not clear that the business sector has lost the broad scope of protection against access to data, including by government authorities.³⁵¹ The trend toward heightening the protection of trade secrets generally seems to be putting additional obstacles in the way.³⁵²

One way to address this gap would be to require the originators to provide their R&D and other cost data as part of the regulatory process, such as a condition for receiving regulatory marketing approval.³⁵³ In the context of regulatory approval, there would be a form of *quid pro quo* that might serve as an inducement for the industry to overcome its reluctance to share. Another route would be to require pharmaceutical suppliers to provide evidence of R&D and other costs in connection with procurement by national or international procurement programmes.³⁵⁴ A third option would be for governments to develop common formulas for determining originator costs based on the recommendations of expert groups.³⁵⁵ Each of these routes has been the subject of legislative proposals or rules in some jurisdictions.³⁵⁶

³⁵¹ Competition authorities have the power to compel the production of evidence in the conduct of investigations, but to this point that authority has not been used successfully to secure information with respect to the R&D costs of originator pharmaceutical companies. Perhaps more remarkably, legislative authorities such as the US Congress with manifest interest in ascertaining the R&D costs of originator drugs have not compelled the production of cost data. And, as the South Africa Herceptin case illustrates, jurisdictional hurdles can be used to inhibit efforts to secure evidence. Lawyers representing originator companies would certainly resist production of evidence involving R&D costs and assert business confidentiality concerns. But there is no reason in principle why competition authorities should be unable to secure evidence regarding R&D costs.

³⁵² In the competition law enforcement context data may be kept confidential within proceedings and in the body of public decisions.

³⁵³ See, e.g., legislation proposed in the US Congress in 2022 to require submission of clinical trial cost data to the National Institutes of Health (for a publicly accessible database), and reporting of disaggregated R&D expenditures to the Securities and Exchange Commission for drug products for which approval has been sought from the FDA. Pharmaceutical Research Transparency Act of 2022, S. 4037 and H.R. 7474, 117th Cong., 2d Sess., Apr. 7, 2022; <https://www.congress.gov/117/bills/hr7474/BILLS-117hr7474ih.pdf>, <https://www.congress.gov/117/bills/s4037/BILLS-117s4037is.pdf>, <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Pharmaceutical%20Research%20and%20Transparency%20Act%20of%202022%20One%20Pager.pdf>.

³⁵⁴ See, e.g., Italian decree requiring the submission of data regarding subsidization of R&D in connection with pricing and reimbursement negotiations, Svět Lustig Vijay, *Italy Publishes National Regulation Requiring Pharma Disclosure of Public Support for R&D on New Drugs*, Health Policy Watch, July 28, 2020, <https://healthpolicy-watch.news/76047-2/>.

³⁵⁵ See, e.g., Li Zhou, *The New Bipartisan Senate Bill Aimed at Making Big Pharma Lower Drug Prices*, Vox.com, July 31, 2019, <https://www.vox.com/policy-and-politics/2019/7/31/20746601/senate-prescription-drug-prices-chris-van-hollen-rick-scott-we-paid-act> (explaining “it would commission a study conducted by the National Academies of Science, Engineering, and Medicine. The National Academies would review key information about the drug, including its prices in other countries, distribution costs and the amount of investment that went into research and development. They would use this data to determine how best to figure out a reasonable price.”).

³⁵⁶ See *supra* notes 353–55.

Establishing “normal” or reasonable baseline prices for originator products will be more complicated than for generics that have a settled cost history. However, in an era in which processing of enormous amounts of complex data is commonplace, this approach is not out of reach.³⁵⁷

It is notable that vaccine technology development agreements entered into by the US federal government (e.g., through HHS and BARDA) during the COVID-19 pandemic included extensive reporting requirements imposed on originator pharmaceutical/vaccine companies regarding costs,³⁵⁸ and that major development agreements entered into by private sector companies likewise included detailed requirements regarding substantiation of costs,³⁵⁹ in each of these cases with audit rights attached. These requirements illustrate that the pharmaceutical industry knows what its costs are, including the costs of R&D, notwithstanding suggestions to the contrary.

2. Health Technology Assessment

There are alternatives for establishing reasonable or normal baseline originator prices, some of which have been suggested by economists associated with the Dutch Competition Authority. These include using some form of health technology assessment (“HTA”) to establish a benchmark for a normal or reasonable price.³⁶⁰ Drug regulatory authorities (“DRAs”) in various jurisdictions use an HTA approach to decide whether to list new drugs for reimbursement by national health plans, and so on. It is thus not “novel” to suggest using an HTA to establish reasonableness from a pricing standpoint. Perhaps blending risk-adjusted cost and HTA could be workable.

The principal reason for questioning the use of HTA in establishing baselines for excessive pricing determinations is that the HTA essentially attempts to calculate the benefit to society from the introduction of a drug product. But pharmaceutical products are, by their nature, expected to provide a benefit to

³⁵⁷ A different field of regulation in which determining costs is important concerns antidumping and countervailing duty cases in the field of international trade. Economists within trade ministries, such as the US Department of Commerce International Trade Administration (ITA), use highly detailed methodologies to assess the cost of goods in order to establish benchmarks against which allegedly dumped or subsidized products may be evaluated.

³⁵⁸ See, e.g., BARDA/HHS – Moderna, <https://ghiaa.org/wp-content/uploads/2021/01/Moderna---BARDA-Agreement-Contract-No.75A50122C00034-for-Development-of-an-mRNA-Vaccine-for-Sars-Cov-2.pdf>.

³⁵⁹ See, e.g., Amended and Restated Collaboration Agreement by and between Pfizer Inc. and BioNTech SE, March 17, 2020, https://www.sec.gov/Archives/edgar/data/1776985/000156459021016723/bntx-ex444_416.htm.

³⁶⁰ See Marcel Canoy and Jan Tichem, *Lower drug prices can improve innovation*, EUROPEAN COMPETITION JOURNAL, Vol 14, No 2-3 (2018) (tandfonline.com).

society. What is the purpose of conferring an additional reward to a pharmaceutical company for doing what it is expected to do, and which is already addressed by granting a patent and regulatory exclusivity that allow companies to charge “higher-than-competitive-market” prices? Recall that the excessive pricing doctrine is directed only towards the abuse of market power, not toward precluding a fair reward to the innovator.

Recognizing that there is often a value in heterogeneous approaches to regulatory matters, which may over time reveal the “best” alternative(s), the development of a preferred common approach to addressing excessive pricing of originator pharmaceutical products, and generic products that are subject to rule of reason analysis, may help competition authorities face the inevitable judicial challenges.

C. *Industry Response*

The response of the pharmaceutical industry to any proposal to make it easier to prosecute competition enforcement actions will be that it is unfair to deprive them of their right to self-defense. The importance of process will be invoked, and this is indeed the approach being taken in the negotiation of trade and investment agreement chapters addressing competition.³⁶¹ The industry knows what it is doing. It wants to slow things down, and it wants to bring in the government finance and trade people to help to achieve this.³⁶²

D. *Deterrence*

A counter-argument to the proposition that excessive pricing prosecutions should be made more efficient is that a limited number of prosecutions adequately serves the purposes of public policy because the imposition of substantial penalties, even in a limited number of cases, has a deterrent effect that will police the market effectively. Although the number of successful prosecutions is growing, it is doubtful that a large enough dataset exists to draw any meaningful conclusions

³⁶¹ See Frederick M Abbott, *Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity*, 49 IIC – INT’L REV. OF INTELL. PROP. & COMP. L. 259 (2018), .

³⁶² Threats to disrupt trade relations and to limit access to financial facilities has been a well-known tool used by the pharmaceutical industry and host country governments to protect against measures that might adversely affect intellectual property interests. See The United Nations Secretary-General's High-Level Panel On Access To Medicines Report, Sep. 2016, <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>, at, *e.g.*, 9 & 20.

about deterrent effects, particularly as cause and effect in terms of industry pricing may be very difficult to link.³⁶³

A significant objection to excessive pricing actions raised in the 2018 OECD study was that the risk of errors (Type 1) that would deter future investment in R&D may exceed the benefits of strict enforcement.³⁶⁴ As with the general argument about deterrence, it seems doubtful that sufficient data exists to robustly predict the potential adverse impact of enforcement on future R&D.³⁶⁵

Levels of revenue and profit that may be achieved through the successful launch of a new originator product are probably enough to overcome any insecurity caused by the risk of enforcement against excessive pricing.

E. Price controls

A typical response to the problem of enforcement is to point to the main alternative for controlling excessive pricing, namely some form of legislative or regulatory price control mechanism.³⁶⁶ It may be true that competition law enforcement is second-best to price controls, and most countries maintain some form of price control mechanism.³⁶⁷ However, as shown by the EU experience, price control systems are subject to anti-competitive abuse, just as patents and market exclusivity systems. Price controls are not a substitute for robust competition law enforcement.

³⁶³ The current data set is the prosecutions referenced in this article, most of which are recent. This makes it doubtful that a cause-and-effect correlation with pharmaceutical pricing, even in Europe, could be robustly drawn on this basis.

³⁶⁴ See OECD, *Excessive Prices in Pharmaceutical Markets*, Background Note by the Secretariat, DAF/COMP(2018)12 [hereinafter OECD 2018], at 11. As explained in the OECD report, a “type 1 error” refers to mistaken intervention (e.g., prosecuting when unwarranted because the market may self-correct); conversely, a “type 2 error” refers to a mistake failure to intervene.

³⁶⁵ The hypothesis is that as a consequence of over-enforcing competition law pharmaceutical companies that otherwise might choose to invest in new R&D projects would decide against because of risk they would not earn the returns they believe are needed to justify their investments. This author believes that in light of the relatively recent nature of the excessive pricing prosecutions and the limited number it would be difficult to draw a robust mathematical correlation to pharmaceutical industry R&D budgets.

³⁶⁶ See, e.g., OECD 2018.

³⁶⁷ Price controls in the pharmaceutical sector may have their own built-in problems if employed too rigidly. For lower margin products there may be a tendency to cause underinvestment in implementation of new technologies because maximum prices are frozen and a way to improve margins is cutting costs. Frederick M. Abbott, *China Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health*, Geneva: World Health Organization (2017), available at SSRN: <https://ssrn.com/abstract=2963892>; Frederick M. Abbott, *Indian Policies to Promote Local Production of Pharmaceutical Products and Protect Public Health*, Geneva: World Health Organization (2017), available at SSRN: <https://ssrn.com/abstract=2963867>.

F. Sector Inquiries or Studies

Another common response to the temporal challenge of enforcement is the encouragement of “sector inquiries” or “studies” and the potential outcome of proposals for legislative or regulatory reform.³⁶⁸ Sector inquiries or studies are a valuable tool and should be encouraged, and they may well point the way toward subsequent enforcement actions. The author encourages the FTC to undertake a sector study. Such studies are not, however, a substitute for enforcement action as the latter entails injunction/prohibition, monetary penalty and other remedies (e.g., licensing and monitoring).

VI. EUROPE AND REVISITING THE TWO-STEP TEST³⁶⁹

Recognizing that much has transpired since its decision in 1978, the CJEU perhaps was misunderstood to have established a two-step test in *United Brands*,³⁷⁰ notwithstanding that in subsequent jurisprudence the Court itself seems to have accepted this premise.³⁷¹

In *United Brands* the Commission accused a large multinational producer and distributor of bananas (based in the United States) of multiple forms of abuse of dominant position in certain parts of the EU market. The Commission proved that United Brands had abused its dominant position (i) by refusing to supply a distributor, and (ii) charging different prices in different EU member states without

³⁶⁸ *Id.*

³⁶⁹ This section is based on another work by this author, Frederick M Abbott, Excessive pricing doctrine in the pharmaceutical sector: the space for reform, in *EU COMPETITION LAW AND PHARMACEUTICALS* (W. Sauter, M. Canoy and J. Mulder eds., Edward Elgar), 2022.

³⁷⁰ *United Brands*, *supra* note 29. See explanation of two-step test, *supra* Part II.A.

³⁷¹ See, e.g., Latvian Copyright case, C-177/16 *Autortiesību un komunikēšanās konsultāciju aģentūra / Latvijas Autoru apvienība* EU:C:2017:286, and cases cited therein, <https://curia.europa.eu/juris/document/document.jsf?jsessionid=96338805CA1BE511C43395AD1FBE2AA9?text=&docid=194436&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=1376875>.

The CJEU states:

36 In that regard, the questions to be determined are whether the difference between the cost actually incurred and the price actually charged is excessive, and, if the answer to that question is in the affirmative, whether a price has been imposed which is either unfair in itself or unfair when compared with competing products (judgment of 14 February 1978, *United Brands and United Brands Continentaal v Commission*, 27/76, EU:C:1978:22, paragraph 252).

justification, thus effectively partitioning the market. The Commission also sought to make out a claim of excessive pricing, but here it failed.³⁷²

The CJEU emphasized strongly that the best mechanism for proving excessive pricing was to establish the cost of production of the accused party and then compare that cost with the price actually charged.³⁷³ The Court fully acknowledged that establishing the cost of production can be a complicated task when taking account of factors such as administrative and indirect costs, of allocating costs of facilities and other elements.³⁷⁴ But the Commission did not directly determine the cost to United Brands of producing and distributing bananas (e.g., using cost accounting methodology). Instead, the Commission looked at the price in one country market, Ireland, for which United Brands had stated in a letter that it had made little profit. The Commission inferred from that statement (which United Brands had retracted) that the price in the Irish market must represent United Brands' cost price.³⁷⁵

The Commission's explanation did not satisfy the CJEU, which pointed to databases maintained by UNCTAD which it suggested would have been adequate to establish the cost of the bananas.³⁷⁶ Moreover, United Brands asserted that the prices in the various member state markets were justified based on business factors.³⁷⁷ Even though United Brands failed to support that assertion with concrete evidence, the CJEU said that it was for the Commission to prove the costs and to refute United Brands' argument.³⁷⁸ The Court said that it was open to the Commission's alternative methodology of comparing the costs for the same product in different member state markets (in this case, relying on Ireland for its baseline),³⁷⁹ but the Court was *very clear* that this was *not* its preferred alternative. The Court was skeptical of the Commission's approach and ultimately rejected it.³⁸⁰

³⁷² *United Brands*, ¶ 3.

³⁷³ *Id.* ¶¶ 251–52.

³⁷⁴ *Id.* ¶ 254.

³⁷⁵ *Id.* ¶¶ 259 & 264. United Brands indicated it had in fact suffered losses in the Irish market. The Commission attempted to justify its lack of direct proof of cost by referencing the fact that United Brands was headquartered in the United States (even though its European subsidiary was a party in the case) and that for some reason United Brands did not provide the Commission with sufficient data.

³⁷⁶ *Id.* ¶ 255. The CJEU Also refers to data from the Food and Agriculture Organization (“FAO”), *id.* ¶¶ 32, 281, but in parts of the decision distinct from the excessive pricing discussion.

³⁷⁷ *Id.* ¶¶ 245–247.

³⁷⁸ *Id.* ¶ 265.

³⁷⁹ *Id.* ¶ 253.

³⁸⁰ *Id.* ¶¶ 258–267.

The Court's decision in *United Brands* is internally ambiguous. The decision states that a price is excessive if it is not reasonably related to the economic value of the product.³⁸¹ At one point, the Court says that after the Commission demonstrates that a price is excessive, it should also demonstrate that it is unfairly so.³⁸² It does not explicitly say what it means by this. But subsequently, in the same part of the decision, the Court collapses the distinction it has apparently drawn between "excessive" and "unfair," stating: "although it is also true that the price of Chiquita bananas and those of its principal competitors is different, that difference is about 7%, a percentage which has not been challenged and which cannot automatically be regarded as *excessive and consequently unfair*" [italics added].³⁸³

Here, the Court equates "excessive" and "unfair." Has the court really established a two-step test? It seems to say that if the price is excessive, it is also unfair. Moreover, it is also hard to ignore the very strong language the Court uses in support of basing excessive pricing determinations on the difference between cost and price, acknowledging that accounting issues may be tricky.

Subsequent jurisprudence in Europe, as evidenced by the cases discussed in Section II, has turned the initial *United Brands* decision into a mandate for a two-step test, including a second step with two prongs (i.e., unfair in itself or compared to products in other markets). It may have made better sense all around to say that the test for excessive pricing involves determining the differential between cost and price and whether that differential is justified. In an exceptional case in which a cost baseline cannot reasonably be established, some other basis for looking at a normal baseline can be used.

Eliminating the two-step test as it presently stands would not make determining excessive pricing in the European Union easy. Determining the cost of bananas was not so easy. But such a change in perspective would help avoid the jurisprudential discord over meeting the criteria of different steps and prongs, which has been a significant obstacle to prosecution. It would be up to the competition authority, whether the European Competition Directorate or the relevant national authority, to make the case on cost versus price and contextual elements—a type of rule of reason assessment. It would be up to the courts to decide whether the abuse had been proven, but that decision could be based on factors relevant to the specific

³⁸¹ *Id.* ¶ 250.

³⁸² "The question to be determined is therefore whether the difference between the costs actually incurred in 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." *Id.* ¶ 252.

³⁸³ *Id.* ¶ 266.

case. We would no longer be asking whether a price may be excessive and yet fair. The decision to be made is whether the price is excessive under the circumstances.

VII. THE WAY FORWARD FOR THE U.S.

A. *Philosophical Persuasion*

Focusing on the situation of the United States,³⁸⁴ it seems accepted that the Sherman Act itself does not preclude federal courts from adjudicating causes of action involving claims of excessive pricing as an abuse of monopoly under Section 2.³⁸⁵ It seems equally well established at least for the moment the courts have not yet allowed for that possibility. On one hand, the federal courts have resisted based on a philosophical view of the Sherman Act as directed toward removing supply-side constraints so as to return the market to competitive equilibrium. There is here the matter of convincing the federal courts that there are parts of the pharmaceutical sector that do not “self-correct” based on intellectual property and/or regulatory features in one form or another.³⁸⁶ While the US Supreme Court helped to clear the path by holding in *FTC v. Actavis*³⁸⁷ that validly granted patents do not provide a shield against antitrust liability, this view has yet to manifest itself as a willingness to address abusive patents or other regulatory exclusivities by charging excessive prices. Persuading the federal courts to address excessive pricing under the Sherman Act will require persuading them that protecting consumers should be on an equal footing with removing supply-side constraints. European and South

³⁸⁴ The US Federal Trade Commission more recently reviewed judicial precedent in this area and issued a “Report on Standalone Section 5 to Address High Pharmaceutical Drug and Biologic Prices,” June 24, 2019. This was accompanied by a “Statement of Commissioners Rohit Chopra and Rebecca Kelly Slaughter Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes.” The majority and dissenting FDC members did not disagree on the status of the jurisprudence, but rather on the issue whether agency resources should be devoted to pursuing excessive pricing prosecutions [hereinafter FTC Excessive Pricing Statement].

³⁸⁵ The full FTC acknowledged that a restraint did not arise from the Sherman Act or Section 5 of the FTC Act, with the majority declining to recommend initiating cases on grounds of likely jurisprudential resistance based on precedent, and the minority in disagreement on that.

³⁸⁶ As an outgrowth of ascendance of the Chicago-school hypotheses that markets are self-correcting and that removing anticompetitive restraints reestablishes competition, the courts and enforcement agencies have focused on addressing supply-side restraints. However, the hypothesis of the self-correcting nature of markets does prove out in the pharmaceutical sector where patents, regulatory market exclusivity, other regulatory constraints and structurally entrenched positions militate against self-correction. Patents are accorded to originators through a legislated framework. Granted patents are presumed legitimate and underlie market power. Patents, however, can act as tools for anticompetitive abuse, including through excessive pricing. Unless courts are prepared to address lawfully granted patents and protected products. The bases of judicial resistance in the United States were previously identified. *See* Abbott 2016, *supra* note 30. There has been no material change on that front. *See* FTC Excessive Pricing Statement.

³⁸⁷ 570 U.S. 136 (2013). Also, in terms of invalidation, action has been taken against so-called “sham patents,” *see, e.g.,* *FTC v. AbbVie*, 976 F. 3d 327 (3rd Cir. 2020).

African prosecutions might help persuade the federal courts on this account, but the work of US academics, including lawyers and economists, may be needed to help in the persuasion.

B. Legislative Change

An alternative to persuasion regarding judicial philosophy would be an amendment to the Sherman Act to align it with Article 102 of the TFEU and similarly drafted competition statutes. That is, adding language to the effect that the charging of unfair purchase or selling prices constitutes an abuse of monopoly. While this might be the easier route in terms of producing the desired result, it may be the more difficult route from a political standpoint.

C. The US and the Shkreli Case

The United States does not presently recognize a doctrine of excessive pricing “as such.” However, a recent prosecution of involving Martin Shkreli and Vyera Pharmaceuticals for anticompetitive conduct regarding the drug Daraprim used to treat a parasitic disease—price increased from \$13.50 to \$750 per tablet—came rather close to excessive pricing “as such,” and it may signal at least the beginning of a shift in FTC willingness to pursue this road.³⁸⁸ As with the behavior addressed in Europe, here the party under investigation identified a niche market for a drug long off patent or other market exclusivity where it could defend a position as sole supplier.³⁸⁹ Once it had acquired the marketing authorization for the drug, the owner engaged in concerted practices to block potential generic competitors from acquiring the API needed to formulate the product and from purchasing a quantity of product sufficient to allow the development of a bioequivalent product. Among other things, Vyera (the company controlled by Shkreli) entered into exclusive supply agreements with API suppliers, effectively paying them not to supply third parties.³⁹⁰

Martin Shkreli became a media sensation in the United States mainly because of his abrasive personality which he displayed in congressional hearings in Washington, and in various media interviews.³⁹¹ The focus of media attention was

³⁸⁸ Fed. Trade Comm’n v. Shkreli, 581 F. Supp. 3d 579 (S.D.N.Y. 2022) [hereinafter *FTC v. Shkreli*].

³⁸⁹ *Id.*, at 621.

³⁹⁰ *Id.*, at 610–18.

³⁹¹ See, e.g., Haley Sweetland Edwards, *Pharma ‘Bad Boy’ Martin Shkreli Mocks Congress*, TIME, February 4, 2016, <https://Time.Com/4207931/Martin-Shkreli-Congress-Turing-Pharmaceuticals-Hearing/>.

the excessive pricing of Daraprim.³⁹² During early stages of reporting, the details of “how” the excessive pricing was enabled were not much discussed. The FTC in cooperation with several State Attorneys General successfully prosecuted Shkreli and the company he controlled, Vyera, and secured a large monetary judgment³⁹³ and an order barring Shkreli from ever again participating in the pharmaceutical industry in the United States.³⁹⁴ The cause of action of the complaint was abuse of a dominant market position to deny access to samples,³⁹⁵ and entering into an exclusive supply agreement intended to foreclose competition. These activities were found to be unlawful under the Sherman Act. But “the heart of the matter” was excessive pricing.³⁹⁶

D. Presenting a Workable Model

Beyond strict adherence to the philosophy of self-correcting markets, the other two grounds for U.S. judicial resistance are the embedded view that judges are not price regulatory authorities and lack the capacity to adequately assess pharmaceutical pricing issues.³⁹⁷

Europe here may lead the way by example. On one hand, throughout Europe pharmaceutical prices are regulated by governments through one or another mechanism.³⁹⁸ Yet judges are called upon to address excessive pricing notwithstanding those controls because, *inter alia*, the complex systems regulating price are vulnerable to abuse. Judges are not acting as price regulatory authorities; Europe already has them. The judges are protecting consumers (including government procurement entities) from abuse.³⁹⁹ For the US judge, the takeaway

³⁹² Eric Owles, *The Making of Martin Shkreli as ‘Pharma Bro’*, N.Y. TIMES, June 22, 2017, <https://www.nytimes.com/2017/06/22/business/dealbook/martin-shkreli-pharma-bro-drug-prices.html>.

³⁹³ FTC v. Shkreli, at 640-42, “the Plaintiff States’ calculation of \$64.6 million in excess profits from the sale of Daraprim is adopted.”

³⁹⁴ *Id.*, at 638-40.

³⁹⁵ *Id.*, at 614-18.

³⁹⁶ *Id.*, at 629-38. By way of comparison, one could say that the prosecution of Aspen by the Italian Competition Authority was directed toward abuse of dominant position by threatening to cut off supplies to the Italian healthcare market, which would itself seem to have constituted a sufficient basis for a remedy as a refusal to deal. But, the heart of the matter was the end result, the excessive pricing, and that is how it was approached under Article 102 of the TFEU.

³⁹⁷ See Abbott 2016, *supra* note 30.

³⁹⁸ *Pharmaceutical Prices in The 21st Century* (Zaheer-Ud-Din Babar ed.) SPRINGER INT’L PUBL’ SWITZ. (2015).

³⁹⁹ Judicial decisions addressing excessive pricing, in Europe and elsewhere, are inherently directed toward protecting consumers as excessive prices do not create a market entry barrier for competitors. If anything, excessive prices induce competitive market entry seeking to capture part of the excess. It is the dominant market position that prevents that. The European Commission takes note of this in the Aspen Commitment when it refuses to consider comparative prices of recent

may be that deciding an antitrust case involving a cause of action for excessive pricing under the Sherman Act does not reconstitute the judge as a price regulator. There is a difference between the price regulator and the judge.

As to the capacity of judges to assess prices in regard to whether they are excessive, here the cases from Europe provide assurance that competition law tribunals are up to the task of assessing whether prices are reasonable, on one hand, or excessive, on the other. With respect to generics cases, this is not “rocket science.” It is cost plus a reasonable profit versus the price of the product. If the margin between those two appears unusually high, has the defendant adequately justified that unusually high margin? If not, a finding of excessive pricing is made.

This article has suggested that judges (or the legislature) might well establish a *per se* rule regarding the difference between cost-plus and price such that prices beyond that margin are automatically found excessive. We have left open the margin that might be settled upon.

The main point, and the reason for this article, is to demonstrate that it can be done, and has been done. That is, European competition authorities have successfully prosecuted excessive pricing in the pharmaceutical sector and have seen off challenges in the courts.

E. Scoping the Environment

One approach to facilitating prosecutions for excessive pricing in the United States would be for the Federal Trade Commission to undertake a study of the generic pharmaceutical sector seeking to identify pricing abuses, and to understand the regulatory and other environmental factors that allow such abuses to take place. In part, at least, looking for the types of “quirks” that have facilitated excessive pricing by generic companies in Europe. A sector study by the FTC could lay the foundation for subsequent prosecutions. This is not to suggest, by the way, that the FTC is not currently pursuing anticompetitive behaviors in the generics sector. It is. This would be an additional avenue.

The reason for limiting the proposed initial study to generics is one of political economy. In the first place, prosecuting originator companies for excessive pricing would entail more complex evidentiary showings, and the evidence gathering processes would likely be more time-consuming. In that regard, as have the Europeans, starting with the comparatively more straightforward cases involving

market entrants that more recently are competing with Aspen products on grounds that the new competitors are taking advantage of the Aspen-created excess. *See supra* note 187.

generics could lay the groundwork from the standpoint of legal approaches and analysis. In the second place, and perhaps more important, originator pharmaceutical companies sensing the prospect of prosecution for excessive pricing would almost certainly engage their full lobbying muscle in the Congress, no doubt suggesting an analogy similar to the favored “killing the golden goose” of the 1990s (and perhaps resurrecting it).⁴⁰⁰ The FTC and Department of Justice would come under pressure from Congress to cease and desist.

Better to “start small” and for the FTC (or Department of Justice) to show that it can be done, and to establish a beachhead and launching off point for subsequent actions against originator excessive pricing. It is the originator prices that most exceptionally take unfair advantage of consumers. It is also, to paraphrase Warren Buffett, the practice defended by the widest moat.⁴⁰¹

VIII. A GLOBAL CONCERN

Excessive pricing of pharmaceutical products is a worldwide problem that impedes access to necessary medicines for large parts of the global population. Insulin is but one example of a pharmaceutical product for which supply does not come close to meeting global demand, and where the market and pricing is dominated by a few multinational pharmaceutical companies.⁴⁰² Recent detailed studies have highlighted the extent to which insulin prices are based on business and financial calculation, and not on underlying R&D expenses or increased costs.⁴⁰³ Competition authorities and courts have an important role to play in reining in excessive pricing and making medicines more affordable. Cooperation among competition authorities is an important element in improving the prosecution environment. Valuable resources are squandered if each prosecution is treated as a one-off, with the wheel of appropriate methodologies for analysis reinvented for

⁴⁰⁰ See, e.g., for usage of terms, Barton Gellman, *An Unequal Calculus of Life and Death*, Wash. Post, Dec. 27, 2000, <https://www.washingtonpost.com/archive/politics/2000/12/27/an-unequal-calculus-of-life-and-death/4f6d22c0-d918-441c-b6e9-e270554bc73b/>; Lee Branstetter et al., *Killing the Golden Goose or Just Chasing it Around the Farmyard?: Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation*, NBER working paper no. 16254, Jan. 16, 2014, https://funginstitute.berkeley.edu/wp-content/uploads/2013/12/Golden_Goose.pdf.

⁴⁰¹ Liz Moyer, *Warren Buffett Likes ‘Wide Moat’ Stocks. Should You?*, WALL ST. J., June 9, 2019, <https://www.wsj.com/articles/warren-buffett-likes-wide-moat-stocks-should-you-11560132600>.

⁴⁰² See Frederick M. Abbott & Padmashree Gehl Sampath, *A Competition Law Approach to Accessing Insulin: A Working Paper*, United Nations Development Program (2023), <https://www.undp.org/publications/competition-law-approach-accessing-insulin-working-paper>.

⁴⁰³ See, e.g., US Senate Finance Committee, ‘Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug’, Staff Report, Washington, DC, 14 January 2021, pp. 16–18. Available at [www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](http://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

each occasion. A shared understanding of best practices would facilitate policing of markets, whether national, regional, or global.