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Compulsory Licensing as a Remedy Against Excessive Pricing of Life-Saving Medicines

Behrang Kianzad



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COMPULSORY LICENSING AS A REMEDY AGAINST EXCESSIVE PRICING OF LIFE-SAVING MEDICINES

Behrang Kianzad¹

SOUTH CENTRE

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¹ PhD / LLM /Center for Advanced Studies in Biomedical Innovation Law, Faculty of Law, Copenhagen University, Behrang.kianzad@jur.ku.dk. The author wishes to extend thanks to Wolf Sauter (Dutch Competition Authority), Paul Dean (UK Competition and Market Authority) and Elisabetta Lanza (Italian Competition Authority) for assistance with research regarding national cases. This paper partly summarizes some of the findings in Behrang Kianzad, "What makes a Price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law", PhD-Dissertation, Copenhagen University, November 2022.

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South Centre
International Environment House 2
Chemin de Balexert 7–9
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
south@southcentre.int
www.southcentre.int

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ABSTRACT

The COVID-19 crisis intensified decade-long debates on the interaction between intellectual property rights (IPRs), competition law and access to affordable life-saving treatments and vaccines. Compulsory licensing of patented medicines is a tried-and-tested method to expand access, particularly in a situation of “national emergency or other circumstances of extreme urgency” within the meaning of Article 31(b) of the TRIPS Agreement. Some legislations, such as European competition law, offer a toolbox for curbing the exercise of IPRs if they would be found in conflict with certain competition rules, such as rules prohibiting excessive pricing by dominant undertakings. The paper analyses the interface between intellectual property law and competition law in general, moving on to the settled case law of the Court of Justice of the European Union (CJEU) on this matter. It provides a general overview of legal and economics arguments related to excessive pricing prohibition and the main case law of European competition law on the matter and discusses whether compulsory licensing as a remedy against excessive pricing of patented life-saving pharmaceutical products can be a viable and appropriate remedy. Finally, the paper offers policy recommendations relating to compulsory licensing based on excessive pricing.

La crise du COVID-19 a intensifié des débats qui durent depuis une décennie sur l'interaction entre les droits de propriété intellectuelle, le droit de la concurrence et l'accès à des traitements et vaccins vitaux à un prix abordable. L'octroi de licences obligatoires pour des médicaments brevetés est une méthode éprouvée pour élargir leur accès, surtout dans une situation « d'urgence nationale ou d'autres circonstances d'extrême urgence » au sens de l'article 31, point b), de l'accord sur les ADPIC. Certaines législations, telles que le droit européen de la concurrence, offrent un outil permettant de limiter l'exercice des droits de propriété intellectuelle s'ils sont en conflit avec certaines règles de concurrence, telles que les règles interdisant aux entreprises dominantes de pratiquer des prix excessifs. Le document analyse l'interface entre le droit de la propriété intellectuelle et le droit de la concurrence en général, puis la jurisprudence établie par la Cour de justice de l'Union européenne (CJUE) en la matière. Il donne un aperçu général des arguments juridiques et économiques liés à l'interdiction des prix excessifs et de la principale jurisprudence du droit européen de la concurrence en la matière, et examine si l'octroi de licences obligatoires peut constituer une solution viable et appropriée pour lutter contre les prix excessifs pratiqués sur des produits pharmaceutiques brevetés vitaux. Enfin, le document propose des recommandations relatives à la politique d'octroi de licences obligatoires en cas de prix excessifs.

La crisis de COVID-19 intensificó los debates de una década sobre la interacción entre los derechos de propiedad intelectual (DPI), la legislación sobre competencia y el acceso a tratamientos y vacunas asequibles que salvan vidas. La concesión de licencias obligatorias para medicamentos patentados es un método de probada eficacia para ampliar el acceso, especialmente en una situación de «emergencia nacional u otras circunstancias de extrema urgencia» en el sentido del artículo 31(b) del Acuerdo sobre los ADPIC. Algunas legislaciones, como la legislación europea sobre competencia, mantienen una caja de herramientas para frenar el ejercicio de los DPI si se considera que entran en conflicto con determinadas normas de competencia, como las que prohíben la fijación de precios excesivos por parte de las empresas dominantes. El documento analiza la interfaz entre el derecho de propiedad intelectual y el derecho de competencia en general, pasando a la jurisprudencia consolidada del Tribunal de Justicia de la Unión Europea (TJUE) sobre este asunto. Ofrece una visión general de los argumentos jurídicos y económicos relacionados con la prohibición de los precios excesivos y la principal jurisprudencia de la legislación europea sobre competencia

en la materia, y analiza si la concesión de licencias obligatorias como remedio contra los precios excesivos de productos farmacéuticos patentados que salvan vidas puede ser un remedio viable y adecuado. Por último, el documento ofrece recomendaciones políticas relativas a las licencias obligatorias basadas en precios excesivos.

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1. INTRODUCTION – IPRs AND ACCESS TO LIFE-SAVING TREATMENTS

The role of intellectual property rights (IPRs) in relation to pricing of patented, life-saving medicines and treatments, starting with the enactment of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS agreement) and coinciding with the HIV/AIDS crisis in the 1990s, has been once again the centre of the global debate following the COVID-19 pandemic.

Whether one aligns with the position that IPRs carry the potential of impeding access to essential medicines, as claimed by some,¹ or one endorses the opposing position, advancing the necessity of IPRs for pharmaceutical innovation,² the manifest economic impact on health budgets by way of increased pharmaceutical spending, resultant from the ability of charging supra-competitive prices during the patent term, ought to be a contentious theme.

Global health budgets, already strained in the recent decade due to rapid increase of health spending relative to overall GDP-growth,³ partially caused by an aging population, innovative but more expensive medicines, also had to deal with a prolonged pandemic that increased health spending across OECD members and other countries dramatically.⁴

Seen against law and policy efforts in recent years to combat excessive pharmaceutical pricing⁵ and keeping health spending in check, this area of law and economics is prone to become all the more intensified in the coming years. The nature of the goods in question, the competitive and regulatory structure of pharmaceutical sector, as well as the delicate interaction between intellectual property law, competition law, regulatory approaches and right to health complicate the analysis further, as also evidenced by a submission of the European Union to OECD roundtable on excessive pharmaceutical pricing.⁶

As many of the vaccines were developed with substantial public funding,⁷ and as originator companies noted an equally substantial rise in mark-ups and profits from initial predictions,⁸

¹ Carlos M Correa, "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries," *South Centre Research Paper No. 5*, October 1999.; Subhashini Chandrasekharan et al., "Intellectual Property Rights and Challenges for Development of Affordable Human Papillomavirus, Rotavirus and Pneumococcal Vaccines: Patent Landscaping and Perspectives of Developing Country Vaccine Manufacturers", *Vaccine* 33, no. 46 (November 2015): 6366–70.

² The International Association for the Protection of Intellectual Property (AIPPI), "AIPPI's Position Paper on the Waiver for Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 Proposed by Some Countries within the WTO.", May 12, 2021.

³ World Health Organization, "Global Spending on Health: A World in Transition," 2019, accessed 2021-06-23.

⁴ As noted by OECD Health at a Glance 2021 "The COVID-19 pandemic has led to a sharp increase in health spending across the OECD. Coupled with reductions in economic activity, the average health spending to GDP ratio jumped from 8.8% in 2019 to 9.7% in 2020, across OECD countries with available data. Countries severely affected by the pandemic reported unprecedented increases. The United Kingdom estimated an increase from 10.2% in 2019 to 12.8% in 2020, while Slovenia anticipated its share of spending on health rising from 8.5% to more than 10%.". Available from <https://www.oecd.org/health/covid-19-pandemic-underlines-need-to-strengthen-resilience-of-health-systems-says-oecd.htm>, accessed 2021-01-03.

⁵ OECD, Excessive Prices in Pharmaceutical Markets Background Note by the Secretariat - DAF/COMP(2018)12.

⁶ European Union, "Excessive Pricing in Pharmaceutical Markets - Note by the European Union - OECD Roundtable on Excessive Pharmaceutical Pricing - DAF/COMP/WD(2018)112", November 23, 2018.

⁷ Niall McCarthy, "Which Companies Received The Most Covid-19 Vaccine R&D Funding?", *Forbes*, May 6, 2021; Kavya Sekar, "Domestic Funding for COVID-19 Vaccines: An Overview", (Congressional Research Service, March 29, 2021); Richard G Frank, Leslie Dach, and Nicole Lurie, "It Was The Government That Produced COVID-19 Vaccine Success", *Health Affairs*, May 14, 2021.

⁸ Michael Erman, "Pfizer, Moderna Seen Reaping Billions from COVID-19 Vaccine Booster Market", *Reuters*, 13 2021.

and seen in the context of the manifest unequal global access vaccines despite initial pledges of global solidarity,⁹ this dynamic generated public outcry.

The issue of “vaccine nationalism”, where the United States (US) and European Union (EU)¹⁰ opted to impose export bans on both vaccines as well as raw materials needed to produce the COVID-19 vaccines,¹¹ as well as shortages of deliveries to COVAX,¹² plus the manifest hoarding by pre-ordering vast amounts of vaccines in excess of their population, have all made matters worse.

Seen against this background, a joint proposal¹³ seeking to waive intellectual property rights for COVID-19 vaccines and treatments supported by India, Brazil and South Africa and some 100 other countries—mostly developing countries—, was debated intensely at the WTO TRIPS Council. The main conflict lines¹⁴ were drawn largely between what impact on access and innovation are attributable to the role of IPRs surrounding COVID-19 vaccines and treatments; and whether a waiver would be an efficient tool to solve the problem of access.

The outcome of the 20-month-long negotiations saw the Ministerial Conference in June 2022 waive one existing provision in the TRIPS agreement on compulsory licensing, instead of opting for a broad waiver as originally proposed.¹⁵ The final text allows “eligible members”- (developing countries-, other than those with existing capacity to manufacture COVID-19 vaccines that decide to opt out)-to export under a compulsory license without complying with the requirement of predominantly supplying the domestic market and makes some clarifications. Nonetheless, the waiver has been criticised as unable to bring about the affordable and rapid access needed to curb the pandemic in parts of the developing world.¹⁶

⁹ Behrang Kianzad and Jakob Wested, “‘No-One Is Safe Until Everyone Is Safe’ – Patent Waiver, Compulsory Licensing and COVID-19”, *European Pharmaceutical Law Review* 5, no. 2 (2021): 71–91.

¹⁰ Politico, “Brussels blocks vaccine exports in all but name”. Available from <https://www.politico.eu/article/vaccine-export-block-europe-coronavirus-astrazeneca/>, accessed February 9, 2022.

¹¹ Ralf Peters and Divya Prabhakar, “Export restrictions do not help fight COVID-19”, UNCTAD, <https://unctad.org/news/export-restrictions-do-not-help-fight-covid-19>. Accessed February 9, 2022.

¹² COVAX, co-led by the World Health Organization (WHO), Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations (CEPI), serves as the vaccines pillar of ACT-A (Access to COVID-19 Tools), which is the main global system put in place to fight COVID-19 set up by WHO.

¹³ WTO communication from India and South Africa, IP/C/W/669, 2. October 2020, sec. 13

¹⁴ For a summary of arguments pro waiver, see MSF Position paper the Scope and Duration of the TRIPS Waiver for COVID-19. Available from https://msfaccess.org/sites/default/files/2021-11/COVID-19_Statement_MSF-AC_TRIPS-Waiver_Scope_ENG_Nov2021.pdf, accessed February 9th 2022; Contrary, for a summary of arguments against the waiver, see IFPMA, “Challenges and solutions to scaling-up COVID-19 vaccine manufacturing capacity”, available from <https://www.ifpma.org/global-health-matters/challenges-and-solutions-to-scaling-up-covid-19-vaccine-manufacturing-capacity/>, accessed February 9, 2022. For some scholarly comments on the subject of waiver, see: Hilty et al., “COVID-19 and the Role of Intellectual Property - Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021”, available from https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_25_Position_statement_Covid_IP_waiver.pdf, accessed February 9th 2022; Michael Sinha, Sven Bostyn, and Timo Minssen, “Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond”, *SSRN Electronic Journal; Forthcoming*, I. Glenn Cohen, Abbe Gluck, Katherine Kraschel, & Carmel Shachar, *COVID-19 and the Law: Disruption, Impact and Legacy*. Cambridge University Press, 2022, 2021; Editorial, “A Patent Waiver on COVID Vaccines Is Right and Fair”, *Nature (London)* 593, no. 7860 (2021): 478–478; Talat Chaudhary and Arshi Chaudhary, “TRIPS Waiver of COVID-19 Vaccines: Impact on Pharmaceutical Industry and What It Means to Developing Countries”, *The Journal of World Intellectual Property* 24, no. 5–6 (2021): 447–54; Behrang Kianzad and Jakob Wested, “‘No-One Is Safe Until Everyone Is Safe’ – Patent Waiver, Compulsory Licensing and COVID-19”, *European Pharmaceutical Law Review* 5, no. 2 (2021): 71–91, <https://doi.org/10.21552/eplr/2021/2/4>; Henning Grosse Ruse-Khan and Federica Paddeu, “A TRIPS-COVID Waiver and Overlapping Commitments to Protect Intellectual Property Rights Under International IP and Investment Agreements”, January 2022, <https://www.southcentre.int/research-paper-144-27-january-2022/>.

¹⁵ MINISTERIAL DECISION ON THE TRIPS AGREEMENT, WT/MIN(22)/30 WT/L/1141, ADOPTED ON 17 JUNE 2022, (World Trade Organization, June 22, 2022).

¹⁶ Carlos M Correa and Nirmalya Syam, The WTO TRIPS Decision on COVID-19 Vaccines: What Is Needed To Implement It?”, Research Paper 169 (Geneva, South Centre November 2022), 36; Anna S Y Wong, Clarke B Cole, and Jillian C Kohler, *TRIPS Flexibilities and Access to Medicines: An Evaluation of Barriers to Employing Compulsory Licenses for Patented Pharmaceuticals at the WTO*, Research Paper 168, (Geneva, South Centre,

As the final text was a compromise, naturally neither the advocates for waiving the IPRs nor the advocates for preserving the same rights were content. Organisations such as MSF condemned the inability to reach global consensus in the midst of a global pandemic, noting that:

This agreement fails overall to offer an effective and meaningful solution to help increase people's access to needed medical tools during the pandemic, as it does not adequately waive intellectual property on all essential COVID-19 medical tools, and it does not apply to all countries.¹⁷

Looking across the aisle, the response from the pharmaceutical industry was in the negative for completely opposite reasons, with the International Federation of Pharma Manufacturers and Associations noting:

Today's decision sends a dangerous signal not only to the pharmaceutical industry but to all innovative sectors. Dismantling the very framework that has brought solutions to tackle COVID-19 and facilitated the unprecedented number of partnerships, voluntary licensing, and knowledge-sharing taking place during this pandemic can have ripple effects for the future.¹⁸

What motivated the waiver proposal was the unequal access to COVID-19 vaccines and treatments, as low- and middle-income countries trail the high-income countries regarding the rate of vaccination. As of January 2022, some low-income countries in Africa had only been able to vaccinate 6 per cent of their population, in comparison with a vaccination rate of above 70 per cent in developed and high-income countries.¹⁹

Naturally, there are a host of other factors affecting the access dimension, such as additional legal barriers by IPRs such as data exclusivity, access to raw materials, technical know-how and manufacturing capacities, the respective health infrastructures and even geography and religion,²⁰ but such matters are beyond the scope of the present paper, nevertheless their importance.

The opponents of the waiver, beyond raising the relevance of IPRs, have also pointed to some of the above issues acting as greater barriers to access than patents on vaccines. They point as a case example that of mRNA vaccines, although Moderna has pledged not to enforce its patents during the pandemic, the patents alone do not solve the puzzle of how to actually manufacture a safe and stable product. Moderna refused to share its know-how with the WHO-

October 2022). Available from https://www.southcentre.int/wp-content/uploads/2022/10/RP168_TRIPS-Flexibilities-and-Access-to-Medicines_EN.pdf.

¹⁷ Médecins Sans Frontières Access Campaign, "Press Release: Inability to Agree a Real Pandemic Intellectual Property Waiver at WTO Is a Devastating Global Failure for People the World Over", June 17, 2022.

¹⁸ International Federation of Pharma Manufacturers and Associations, "Press Release: Pharmaceutical Industry Expresses Deep Disappointment with Decision on Waiving Intellectual Property Rights Adopted at the World Trade Organization Ministerial Conference", June 17, 2022.

¹⁹ IMF Global COVID-19 Access Tracker, <https://www.covid19globaltracker.org/#vaccination>, accessed February 9, 2022; see also Mark McClellan et al., "Reducing Global COVID Vaccine Shortages: New Research and Recommendations for US Leadership" (Duke Global Health Institute, April 15, 2021) <https://healthpolicy.duke.edu/publications/reducing-global-covid-vaccine-shortages-new-research-and-recommendations-us-leadership>, accessed 2020-06-20. Also John Hopkins University provided updated global data on vaccination rates, see <https://coronavirus.jhu.edu/vaccines/international>, accessed February 9, 2022.

²⁰ Jason Beaubien, "Vaccinators in Peru's Amazon are challenged by religion, rivers and a special tea", NPR, available from <https://www.npr.org/sections/goatsandsoda/2021/12/12/1062397183/vaccinators-in-peru-amazon-are-challenged-by-religion-rivers-and-a-special-tea?>, accessed February 9, 2022.

backed vaccine plant that was set up in South Africa, and instead announced plans to set up its own manufacturing plant.²¹

Others, such as the European Union, advanced the use of existing TRIPS flexibilities,²² such as compulsory licensing,²³ as a more efficient and legally certain way of dealing with the perceived negative impact of exercise of IPRs on access and affordability. Some scholars also advanced this option,²⁴ while others criticised the system of compulsory licensing as not being as expeditious and effective as envisaged.²⁵

Compulsory licenses for COVID-19 treatments (Remdesivir, Lopinavir) were issued during the pandemic, namely in Israel, Russia and Hungary, to name some examples from the developed world.²⁶ The compulsory license by Russia for Remdesivir resulted in the usual criticism²⁷ and a lawsuit²⁸ amid calls for intensifying compulsory licensing efforts.²⁹ The US was the first country to issue a government use / compulsory license to provide Moderna with the authorization to use Arbutus's invention related to the now bespoke mRNA-technology already in August 2020.³⁰

Russia issued a compulsory license related to Remdesivir in February 2021³¹ and other processes regarding compulsory licenses were started in Indonesia, Dominican Republic,

²¹ NPR, "Moderna won't share its vaccine recipe. WHO has hired an African startup to crack it", October 19, 2021. Available from <https://www.npr.org/sections/goatsandsoda/2021/10/19/1047411856/the-great-vaccine-bake-off-has-begun>, accessed February 9, 2022.

²² European Union, "Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property – Communication from the European Union to the Council for TRIPS – IP/C/W/680", June 4, 2021.

²³ Frederick M. Abbott and Rudolf V. Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Papers (The World Bank, 2005), <https://doi.org/10.1596/978-0-8213-6292-1>.

²⁴ Michael Liu et al., "March-In Rights And Compulsory Licensing—Safety Nets For Access To A COVID-19 Vaccine", *Health Affairs*, May 6, 2020; Vãn Anh Lê, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?*, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?* (Cham: Palgrave Macmillan, 2022); Sparsh Sharma, "The Debate around the Access to Vaccine and Licensing amidst Second Wave of COVID-19 in India", *The Journal of World Intellectual Property* 24, no. 5–6 (2021): 436–46; Behrang Kianzad and Timo Minssen, "Legal Remedies In Times of Global Pandemic Crisis-Price Gouging, Compulsory Licensing and the Role of Antitrust", Conference presentation, available from Faculty of Law; University of Copenhagen, 2020 https://curis.ku.dk/ws/files/261156192/Nordic_Network_presentation_final.pdf, accessed February 9, 2022.

²⁵ Eduardo Urias and Shyama V. Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence", *Journal of International Business Policy* 3, no. 4 (December 2020): 367–84; Kyung-Bok Son, Chang-yup Kim, and Tae-Jin Lee, "Understanding of for Whom, under What Conditions and How the Compulsory Licensing of Pharmaceuticals Works in Brazil and Thailand: A Realist Synthesis", *Global Public Health* 14, no. 1 (January 2, 2019): 122–34; Reed Beall and Randall Kuhn, "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis", Nathan Ford, ed., *PLoS Medicine* 9, no. 1 (January 10, 2012); Dipika Jain and Jonathan J Darrow, "An Exploration of Compulsory Licensing as an Effective Policy Tool for Antiretroviral Drugs in India", *Health Matrix* 23, no. 2:34; Magdalena Krawczyk, "Compulsory Licensing of Pharmaceuticals since the Doha Declaration: A Public Health Triumph or Failure?," *Zeszyty Naukowe Towarzystwa Doktorantów UJ Nauki Społeczne*, 15, no. 4 (2016).

²⁶ South Centre, "Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic", Available from <https://www.southcentre.int/wp-content/uploads/2021/02/Compulsory-licenses-table-Covid-19-rev2021.pdf>, accessed 2022-02-10.

²⁷ Ephraim Heiliczer, "The Worldwide Stakes of Israeli Compulsory Licenses for Anti-Coronavirus Drugs", March 24, 2020, Pearl Cohen, <https://www.pearlcohen.com/the-worldwide-stakes-of-israeli-compulsory-licenses-for-anti-coronavirus-drugs/>, accessed 2021-06-23.

²⁸ Ed Silverman, "Gilead sues Russia over a compulsory license issued to a company making remdesivir", STAT News, May 4, 2021, <https://www.statnews.com/pharmalot/2021/05/04/gilead-sues-russia-over-a-compulsory-license-issued-to-a-company-making-remdesivir/>, accessed 2021-06-23.

²⁹ Hillary Wong, "The case for compulsory licensing during COVID-19", *Journal of Global Health*, 2020.

³⁰ Knowledge Ecology International, Moderna Claims Compulsory License from U.S. Government to Use Third Party Patents in its COVID-19 Vaccine", <https://www.keionline.org/37751>, accessed 2022-11-15.

³¹ Reuters, " Russian firm seeks to produce COVID-19 drug without patent, Vedomosti reports", <https://www.reuters.com/article/health-coronavirus-russia-remdesivir/russian-firm-seeks-to-produce-covid-19-drug-without-patent-vedomosti-reports-idINL8N2HO0XS>, accessed 2022-11-15.

Chile and Colombia in 2021 and 2022.³² A recent review of literature nevertheless demonstrates that compulsory licensing as a tool to access to life-saving medicines has been fraught with many legal and political challenges, where the main elements of a successful compulsory licensing are conditioned by local manufacturing capacity, import possibilities, and political pressure and retaliation.³³ To this we might add the feasibility of parallel imports.³⁴

The above background connects with the “moral” element of whether and at what levels profitability should be considered “efficient” and “incentive inducing” for vaccine innovation propelled by immense public funding during a pandemic affecting all branches of society. The *ratio legis* of IPRs, including patents on lifesaving, essential drugs, is to secure necessary public goods through sustainable innovation.

Previous experience with health crises such as HIV/ AIDS made for a grim future prospect, as noted by one commentator:

In 1996, a treatment for HIV/AIDS was developed and priced at £6500 per person. Despite the determination of HIV/AIDS campaigners, it took eight years—and many millions of unnecessary deaths—before the treatment was made available at prices that were affordable for people in countries such as South Africa and India.³⁵

It is yet controversial what strategies could have been more successful during the COVID-19 pandemic, whether a broad IPRs waiver or a harmonised compulsory licensing³⁶ or voluntary licensing scheme. Instead of entertaining such hindsight questions, the present document rather focuses on excessive pricing as ground for issuance of a compulsory license within the TRIPS Agreement framework.

It is when a medicine or vaccine has actually been offered for sale, or the technology offered to be licensed, albeit at an excessive price, that the analysis in the present paper becomes relevant. A blanket refusal to license is more a matter of refusal to license, than excessive pricing.

It is argued that the consideration of excessive pricing has advantages vis-à-vis the “normal” route of basing compulsory licensing claims on instances of public health emergencies. This approach would reconnect with the normative goal of granting IPRs, i.e. increased societal welfare, an aim which also underpins competition law.

The suggested approach would also be more feasible procedurally, and provide greater *ex ante* legal certainty, provided there are national rules on both compulsory licensing and

³² For an overview, see Medicines Law & Policy, The TRIPS Flexibilities Database. Available from <http://tripsflexibilities.medicineslawandpolicy.org/>, accessed 2022-11-15.

³³ Shyama V Ramani and Eduardo Urias, “Access to Critical Medicines: When Are Compulsory Licenses Effective in Price Negotiations?,” *Social Science & Medicine* 135 (April 23, 2015): 75–83; see also Eduardo Urias and Shyama V. Ramani, “Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence,” *Journal of International Business Policy* 3, no. 4 (December 2020): 367–84.

³⁴ Lorelei Garagancea, “Access to Medicines: The Interplay between Parallel Imports, Compulsory Licensing, and Voluntary Licensing,” *European Pharmaceutical Law Review* 5, no. 1 (2021): 37–56; Ellen FM ‘t Hoen et al., “Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016,” *Bulletin of the World Health Organization* 96, no. 3 (March 1, 2018): 185–93; Reed Beall and Randall Kuhn, “Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis” Nathan Ford, ed., *PLoS Medicine* 9, no. 1 (January 10, 2012).

³⁵ Nabil Ahmed, “A call for a people’s vaccine”, *BMJ Opinion*, July 16, 2020, <https://blogs.bmj.com/bmj/2020/07/16/a-call-for-a-peoples-vaccine/>, accessed 2021-06-27.

³⁶ See COM(2023)224 - Proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006, https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en, accessed 2024-01-23.

competition law in the country. The following sections will investigate the relationship between IPRs and competition law, moving on to the law and economics of excessive pricing prohibition and some relevant case law related to excessive pharmaceutical pricing, and finally detailing how compulsory licensing can be based on the imposition of unfair/excessive pricing.

It should be noted that the legal statute relied upon, Article 102a of the Treaty on the Functioning of the European Union (TFEU), uses the word “unfair pricing”, while the case law and doctrine more often use the wording “excessive” pricing, thus in this document the wordings are interchangeable and represent the same legal-economic concept in the context of Article 102a TFEU.

The case law emanating from *United Brands*³⁷ onwards make a distinction between “excessiveness” and “unfairness” of the price, but this is a function of the *United Brands* test to seek out whether conditions for the prohibition are fulfilled and does not impact the conceptual framing of the prohibition in Article 102a TFEU and its legal history.

³⁷ Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, ECLI:EU:C:1978:22 (n.d.).

2. THE INTERFACE BETWEEN INTELLECTUAL PROPERTY, COMPETITION LAW AND INNOVATION

As one of the key elements of IPRs is the right to exclude, the *ratio legis* of granting such exclusive rights must be balanced against other societal concerns, a matter which is also addressed in the most important agreement on intellectual property rights, the TRIPS Agreement.³⁸

This balanced approach regarding the societal function of IPRs is also mirrored in the European legal tradition and its approach regarding the intersection of IPRs and competition law, with European competition law prohibiting excessive and unfair pricing. Recently a string of excessive pharmaceutical pricing cases has been pursued on both WTO member states and at the European Union level,³⁹ despite a longstanding doctrinal opposition⁴⁰ to the prohibition of unfair pricing, including during crises and pandemics.⁴¹

An opposition which manifestly rests on misguided reading of the legal and economic history and reasoning behind Article 102a TFEU, where claims such as the “scarcity” of cases⁴² or that the prohibition would make “no economic sense” simply do not stand closer scrutiny.⁴³ As indicated above, the impact of IPRs protection on innovation is a highly complex matter dependant on a range of factors beyond the legal incentives,⁴⁴ notably because the *ratio legis* and economic justification for providing innovators with intellectual property protection entails the prospect of supra-competitive prices in order to recoup costly and risky investments.

The resulting trade-off between innovation and access can be approached by way of competition law, acting as a moderating and equalising force and arbiter. The IPRs and competition law interface is thus a highly timely issue in regard to the distribution of scarce resources, as it was the case for COVID-19-vaccines and treatments.⁴⁵

The *ratio legis* of IPRs, including patents on lifesaving, essential drugs, is to secure necessary public goods through sustainable innovation, i.e., those are rights granted to serve a “purpose”.⁴⁶ As IPRs are legally granted monopolies, thereby shielding the rightsholder from

³⁸ Trade-related aspects of Intellectual Property Rights (TRIPS), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

³⁹ B. Kianzad and T. Minssen, “How Much Is Too Much? Defining the Metes and Bounds of Excessive Pricing in the Pharmaceutical Sector”, *European Pharmaceutical Law Review* 2, no. 3 (2018): 133–48.

⁴⁰ For a summary of arguments against enforcement of excessive pricing prohibition, see: Frédéric Jenny, “Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment”, in *Excessive Pricing and Competition Law Enforcement*, Yannis Katsoulacos and Frédéric Jenny, eds. (Cham: Springer International Publishing, 2018), 5–70; Behrang Kianzad, “What makes a Price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law”, PhD-Dissertation, Copenhagen University, November 2022.

⁴¹ Behrang Kianzad, “The Giant Awakens: Law and Economics of Excessive Pricing During the COVID-19 Crisis”, in *Law and Economics of the Coronavirus Crisis*, Klaus Mathis and Avishalom Tor, eds. vol. 13, Economic Analysis of Law in European Legal Scholarship (Cham: Springer International Publishing, 2022), 123–76.

⁴² Behrang Kianzad, Are excessive pricing cases few and far between? A quantitative analysis of fifty years of European jurisprudence 1971–2021, September 2023, Concurrences N° 3-2023, Art. N° 113222 www.concurrences.com.

⁴³ Kianzad, B, Doctoral thesis, 2022, *What Makes A Price (Un)Fair? Excessive Pharmaceutical Pricing in European Competition Law*. bind 2, Det Juridiske Fakultet, København.

⁴⁴ Yi Qian, “Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002”, *Review of Economics and Statistics* 89, no. 3 (August 2007): 436–53, <https://doi.org/10.1162/rest.89.3.436>.

⁴⁵ Ben Saunders, “Equality in the Allocation of Scarce Vaccines”, *Les Ateliers de l'éthique* 13, no. 3 (2018): 65.

⁴⁶ Hanns Ulrich, “Intellectual Property: Exclusive Rights for a Purpose – the Case of Technology Protection by Patents and Copyright”, *Contribution to Problemy Polskiego i Europejskiego Prawa Prywatnego, Księga Pamiatkowa Professora Mariana Kepińskiego*, Klafkowska- Wasniowska et al., eds.), (*Contributions in Honour of*

actual or potential competition during the protection period (in the case of patents, 20 years plus secondary protection certificates, etc.), the rightsholder is able to set and enforce supra-competitive, monopolist prices. Some, such as Joseph Schumpeter, posit this possibility and probability of monopolistic profits and dynamic competition as the main drivers of innovation.⁴⁷^[OBJ]

There are nevertheless many objections to enforcement against excessive/fair pricing to be found in the doctrine,⁴⁸ including a supposed negative impact on investments and the concomitant “chilling effect”⁴⁹ and being detrimental to long-term consumer welfare,⁵⁰ thus casting the legal prohibition as being in opposition with “sound economics”.⁵¹

Contrary to the general claims oftentimes forwarded regarding the importance of IPRs relating to innovation, as phrased by Dosi and Stiglitz “...the mantra of the advocates of stronger IPR—that the stronger the system of intellectual property rights, the faster the pace of innovation—has itself no intellectual basis”⁵², since innovation is dependent on a myriad of other factors beyond the prospect of supra-competitive profits due to exclusivity.⁵³

There is to date few conclusive empirical industrial organization research which convincingly demonstrates a causal relationship between increased IPR protection matched by an increase in innovation or even R&D activity and spending.⁵⁴ Nor are there many studies demonstrating a causal link between increased profits and increased R&D investments⁵⁵ and subsequent innovation.⁵⁶ One of the reasons for these manifest gaps in the research is the near

Marian Kepinski), Warsaw (Wolters Kluwer Polska, 2012), 425 – 459, Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2179511, Accessed February 9, 2022.

⁴⁷ Richard Gilbert, “Looking for Mr. Schumpeter: Where Are We in the Competition Innovation Debate?”, in *Innovation Policy and the Economy*, vol. 6 (Cambridge: MIT Press, 2006), 159–215; Jonathan B Baker, “Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation”, *Antitrust Law Journal* 74, no. 3 (2007): 575–602.

⁴⁸ David S. Evans and A. Jorge Padilla, “Excessive Prices: Using Economics to Define Administrable Legal Rules”, *Journal of Competition Law & Economics* 1, no. 1 (January 1, 2005): 97–122, <https://doi.org/10.1093/joclec/nhi002>.

⁴⁹ Amelia Fletcher and Alina Jardine, “Towards an Appropriate Policy for Excessive Pricing”, in *European Competition Law Annual 2007: A Reformed Approach to Article 82 EC*, Claus-Dieter Ehlermann and Mel Marquis, eds. (Hart Publishing, 2008), 533–47.

⁵⁰ Frédéric Jenny, “Abuse of Dominance by Firms Charging Excessive or Unfair Prices: An Assessment”, in *Excessive Pricing and Competition Law Enforcement*, ed. Yannis Katsoulacos and Frédéric Jenny (Cham: Springer International Publishing, 2018), 5–70.

⁵¹ Peter Davis and Vivek Mani, “The Law and Economics of Excessive and Unfair Pricing: A Review and a Proposal”, *The Antitrust Bulletin* 63, no. 4 (December 2018): 399–430; C. Calcagno and M. Walker, “EXCESSIVE PRICING: TOWARDS CLARITY AND ECONOMIC COHERENCE”, *Journal of Competition Law and Economics* 6, no. 4 (December 1, 2010).

⁵² Giovanni Dosi and Joseph Stiglitz, “The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction”, in *Intellectual Property Rights: Legal and Economic Challenges for Development*, ed. Mario Cimoli et al. (Oxford: Oxford University Press, 2014).

⁵³ Olivier J. Wouters et al., “Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment”, *The Lancet* 397, no. 10278 (March 13, 2021): 1023–34.

⁵⁴ For some comprehensive research overviews see: World Intellectual Property Organization, “*The Economics of Intellectual Property: Suggestions for Further Research in Developing Countries and Countries with Economies in Transition*”, (Geneva, Switzerland: World Intellectual Property Organization, 2009). ;Alexi Maxwell and David Riker, “The Economic Implications of Strengthening Intellectual Property Rights in Developing Countries”, *United States International Trade Commission - Journal of International Commerce and Economics*, 2014; Carsten Fink and Keith E. Maskus, eds., *Intellectual Property and Development: Lessons from Recent Economic Research*, Trade and Development Series (Washington, DC : New York: World Bank ; Oxford University Press, 2005); John Hudson and Alexandru Minea, “Innovation, Intellectual Property Rights, and Economic Development: A Unified Empirical Investigation”, *World Development* 46 (June 2013): pp. 66–78; Petra Moser, “How Do Patent Laws Influence Innovation Evidence from Nineteenth-Century World Fairs”, *NBER WORKING PAPER SERIES* Working Paper 9909 (August 2003).

⁵⁵ Carmelo Giaccotto, Rexford E. Santerre, and John A. Vernon, “Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry”, *The Journal of Law and Economics* 48, no. 1 (April 2005): 195–214, <https://doi.org/10.1086/426882>.

⁵⁶ Jennifer L. Troyer and Alexander V. Krasnikov, “The Effect of Price Regulation on Innovation in the Pharmaceutical Industry,” *Journal of Applied Business Research (JABR)* 18, no. 4 (January 31, 2011), <https://doi.org/10.19030/jabr.v18i4.2131>.

unsurmountable methodological and empirical difficulties⁵⁷ in shaping a comprehensive research agenda.

While there are many theoretical claims and assumptions regarding the importance of supra-competitive, even monopolistic prices related to innovation, other empirical research often does not support such a causal relationship, at times even demonstrating counter-intuitive results regarding the impact of higher profits on innovation.⁵⁸ On the matter of assumptions, as noted by FM Sherer:

If one believes that the expectation of patent rights is the principal inducement to innovation, one will be wrong more often than right in balancing antitrust objectives against intellectual property considerations in rule of reason cases. It is like positioning a 300-pound gorilla on the pro-patent side of the balancing scale when the real-world counterpart is a 35-pound chimpanzee. A correction in the intellectual foundations of U.S. antitrust policy toward intellectual property is clearly needed.⁵⁹

This is not to negate the importance of intellectual property protection for easily copied innovations, which often do require substantial and risky investments. Nevertheless, intellectual property law is silent on the level of profits necessary to recoup the said investments. Looking at the case concerning excessive pricing of intellectual property protected goods, the legal-economic presumption is that prices will fall post patent expiry, while high prices for off-patent medicines have formed an integral part of excessiveness and unfairness analysis in many recent cases.^{60,61} The length and breadth of protection and its impact on innovation and welfare was addressed already decades ago in the seminal work by William Nordhaus.

While there are many theoretical claims elevating the importance of supra-competitive, even monopolistic prices related to innovation, other empirical research oftentimes seems not to support such a causal relationship, sometimes even demonstrating counter-intuitive results regarding the impact of higher profits on innovation.

The arguments for limiting the exercise of IPR rights including pricing when it can be approached by competition law can be found in the costs they induce on societies, healthcare systems and consumers, from an economic point of view. One legal rationale behind granting of patent rights lie in the total welfare gains of society as a whole.

A patent proprietor can charge a premium price during the term of patent protection. This induces high costs on the patients and health systems, but it is assumed that without the patent-enabled premium price we would not have the treatment, or that the price is worth the healthcare-gain.⁶²

⁵⁷ Robert P. Merges, "Economics of Intellectual Property Law," in *The Oxford Handbook of Law and Economics: Volume 2*, ed. Francesco Parisi (Oxford: Oxford University Press, 2017).

⁵⁸ Ondřej Krčál, "The Relationship between Profitability, Innovation and Technology Gap: A Basic Model," *Review of Economic Perspectives* 14, no. 3 (September 1, 2014): 215–31; See also Richard G Frank and Paul B Ginsburg, "Pharmaceutical Industry Profits And Research And Development", *Health Affairs*, November 13, 2017, 9.

⁵⁹ F.M. Scherer, "The effect of conservative economic analysis on US Antitrust", p. 39, in Pitofsky, R. (Ed.). (2008). "How the Chicago school overshot the mark : The effect of conservative economic analysis on US Antitrust", Oxford University Press.

⁶⁰ Case no. 1001/1/1/01, in the Competition Commission Appeal Tribunal, NAPP pharmaceutical holdings limited and subsidiaries and Director General of Fair Trading, 15 January 2002, Case N. 01832/2020, Aspen, Consiglio di Stato, 13/03/2020; Sag Bs, Case BS-3038/2019-SHR, CD Pharma v Danish Competition and Consumer Authority, Judgement of Maritime and Commercial Court, March 2 2020.

⁶² Peter Zweifel, Friedrich Breyer, and Mathias Kifmann, *Health Economics*, Second edition (Berlin Heidelberg: Springer, 2009).

However, potential societal and consumer gains are nullified to a great extent if anti-competitive practices such as excessive / unfair pricing over marginal costs occur on a long term, especially in un-disputed markets, since patent-protected vaccines do bar competitors from entry. Accordingly, such markets with little to no competition due to the existence of a legal monopoly (patents, market authorization, etc.) are surely to be considered as a market apt for such an analysis. Hence, seen from a law and economics perspective, detrimental effects to consumers are created due to high or excessive prices, leading to creation of deadweight losses.⁶³

Some commentators caution, however, that

"...antitrust enforcement is only warranted in “exceptional circumstances”. And such exceptions are to be interpreted strictly, to accord with the old maxim that “exceptions need to be interpreted restrictively, not expansively”, and with other general principles of EU law such as that rules on property fall within the regulatory jurisdiction of the Member States, not of the EU.”⁶⁴

Meritful as this cautious note might be in a theoretical setting, if intended as a “legal” limitation of the remit of competition law, this approach is not recognized in European jurisprudence which does not insulate the exercise of intellectual property rights from competition law scrutiny.⁶⁵

Furthermore, as consistently held by Court of Justice of the European Union, the European rules on competition supersede national legislation and they are seen as having constitutional value in of themselves. The next section will depict the settled legal approach of European Union in regard to the interface between IPRs and competition law more in detail.

2.1 The Interface of Intellectual Property and Competition Law in the European Union

A conceptual framework related to the anti-competitive exercise of IPRs has long been developed in European law and jurisprudence, making a distinction between lawful existence and unlawful exercise of IPRs, where charging unfair (excessive) pricing is one of the anti-competitive abuses that might arise from exercise of IPRs.

Although the prohibition against excessive pricing entailed in Article 102a TFEU has rarely been used against IPR-protected pharmaceuticals,⁶⁶ there are other cases where the exercise of IPRs were deemed in conflict with European competition law rules on refusal to supply and/or excessive pricing.⁶⁷ The settled case law from the Court of Justice of the European Union (CJEU) clearly mandates competition law to curb anti-competitive exercises of intellectual property rights in general, also during the protection period.⁶⁸

⁶³ Marcel Canoy and Jan Tichem, “Lower Drug Prices Can Improve Innovation”, *European Competition Journal* 14, no. 2–3 (September 2, 2018): 278–304.

⁶⁴ Sven Bostyn and Nicolas Petit, “Patent=Monopoly: A Legal Fiction”, *SSRN Electronic Journal*, 2013, <https://doi.org/10.2139/ssrn.2373471>, accessed February 9, 2022.

⁶⁵ Ioannis Lianos, Valentine Korah, and Paolo Siciliani, “Competition Law and Intellectual Property (IP) Rights: Analysis, Cases and Materials - Chapter 13”, in *Competition Law and Intellectual Property (IP) Rights: Analysis, Cases and Materials* (Hart Publishing, 2017), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2863814.

⁶⁶ European Commission, Case AT.40394 – Aspen, Commission Decision of 10.2.2021, C(2021) 724 final. (n.d.).

⁶⁷ D. Byrne, “Compulsory Licensing of IP Rights: Has EC Competition Law Reached a Clear and Rational Analysis Following the IMS Judgment and the Microsoft Decision?”, *Journal of Intellectual Property Law & Practice* 2, no. 5 (May 1, 2007): 324–30, <https://doi.org/10.1093/jiplp/jpm030>.

⁶⁸ See, e.g., Case T-167/08, *Microsoft Corp. v European Commission*, Judgment of the General Court (Second Chamber), 27 June 2012; Case C-418/01, *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG*, Judgment of the Court (Fifth Chamber) of 29 April 2004; Case 78-70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, Judgment of the Court of 8 June 1971, ECLI:EU:C:1971:59; Case T-151/01,

When the “costs” increase relative the “value”, and when markets are protected by exclusive rights conferred by way of patents and thus shielded from competitive pressure, there is manifest risk for abuse of dominant position, there among imposition of unfair pricing as per Article 102a TFEU.

Indeed, as observed by the Commission in *Parke Davis*, one of the earliest European cases on the interface between IPRs and Competition Law, involving pricing of medicinal products “For patent law does not guarantee the making of a particular profit with certainty, but only the possibility of making a profit.”⁶⁹

As established by this case, involving medicinal products under patent in Netherlands, facing imports of unauthorized versions of the products from Italy, which did not protect patents on medicines at that time (1958), a manifest difference in price between a patented product and an unauthorized, generic copy would not suffice in itself to amount to an abuse of dominance position as per Article 102a on “unfair pricing”.

Nevertheless, as held by the Court “Although the sale price of the protected product may be regarded as a factor to be taken into account in determining the possible existence of an abuse, a higher price for the patented product as compared with the unpatented product does not necessarily constitute an abuse.”⁷⁰

Most importantly, as the CJEU held in *Parke Davis*, in order for Article 102 to apply it is necessary that three elements be present together, these being the existence of a dominant position, the abuse of this position and the possibility that trade between Member States may be affected thereby. As noted by the Court “Although a patent confers on its holder a special protection at national level, it does not follow that the exercise of the rights thus conferred implies the presence together of all three elements in question. It could only do so if the use of the patent were to degenerate into an abuse of the abovementioned protection.”⁷¹

Hence, the distinction between existence and exercise of IPRs builds the basis of European law and jurisprudential approach to the interface between IPRs and Competition Law, where CJEU on numerous occasions⁷² have reiterated that the exercise of IPRs and possible anti-competitive practices arising from such exercise is well within the ambit of European competition law. This view was developed already in the *Consten & Grundig* case,⁷³ where the European Court of Justice elaborated on the distinction between the granting of IPRs and the exercise of the IPRs, and the court has consistently reaffirmed this position ever since.⁷⁴

Der Grüne Punkt - Duales System Deutschland GmbH v Commission of the European Communities, Judgment of the Court of First Instance (First Chamber) of 24 May 2007, ECLI:EU:T:2007:154; European Commission, Case AT.40394 – ASPEN, COMMISSION DECISION of 10.2.2021, C(2021) 724 final.

⁶⁹ Case 24-67, *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, Judgment of the Court of 29 February 1968, ECLI:EU:C:1968:11, page 64.

⁷⁰ Case 24-67, *Parke, Davis*, page 72.

⁷¹ Case 24-67, *Parke, Davis*, page 72.

⁷²See e.g. Joined cases 56 and 58-64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, Judgment of the Court of 13 July 1966, ECLI:EU:C:1966:41; Case 78-70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, Judgment of the Court of 8 June 1971, ECLI:EU:C:1971:59; Case 24-67, *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, Judgment of the Court of 29 February 1968, ECLI:EU:C:1968:11; Case C-372/19, *Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Wearone.World BVBA and Wecandance NV*, Judgment of the Court (Fifth Chamber) of 25 November 2020, ECLI:EU:C:2020:959.

⁷³ Joined cases 56 and 58-64, *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community*, Judgment of the Court of 13 July 1966, ECLI:EU:C:1966:41, see recital 10-11.

⁷⁴ Case 78-70, *Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG*, Judgment of the Court of 8 June 1971, ECLI:EU:C:1971:59; Case 238/87, *AB Volvo v Erik Veng (UK) Ltd*, Judgment of the Court of 5 October 1988, ECLI:EU:C:1988:477; Case 40/70, *Sirena Srl v Eda Srl and others*, Order of the Court of 18 October 1979, ECLI:EU:C:1979:236; Case 24-67, *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, Judgment of the Court of 29 February 1968, ECLI:EU:C:1968:11.

The delicate interaction between competition law and intellectual property law is probably most evident in innovative, high-risk sectors, such as the pharmaceutical sector. As noted by the European Commission:

"In the pharmaceutical sector, the key challenge for competition enforcement is to strike the right balance between, on the one hand, rewarding companies for successful R&D investment activities, and, on the other, enabling a competitive environment which promotes access to less expensive quality medicines."⁷⁵

The Commission also noted in its Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements that:

"The fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention...Nor does it imply that there is an inherent conflict between intellectual property rights and the Community competition rules. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof."⁷⁶

The distinction between the lawful existence and unlawful exercise of property rights and the role and mandate of the EU was highlighted in Opinion of the Advocate General Cosmas in *Masterfoods and HB* case. The AG Cosmas noted:

"There is no doubt that Articles 85 and 86 of the EC Treaty occupy an important position in the system of the Community legal order and serve the general interest which consists in ensuring undistorted competition. Consequently, it is perfectly comprehensible for restrictions to be placed on the right to property ownership pursuant to Articles 85 and 86 of the EC Treaty, to the degree to which they might be necessary to protect competition."⁷⁷

The same reasoning was voiced by the Advocate General Wathelet in the *Huawei v ZTE* case, where he referred to the Enforcement Directive 2004/48 in regard to enforcement of intellectual property rights, noting:

"However, the right to intellectual property is not an absolute right. Accordingly, without making any reference to abuse of rights, recital 12 in the preamble to Directive 2004/48 states that '[t]his Directive should not affect the application of the rules of competition, and in particular Articles [101 TFEU] and [102 TFEU]. The measures provided for in this Directive should not be used to restrict competition unduly in a manner contrary to the Treaty."⁷⁸

As expressed by Hanns Ullrich in regard to the purpose of the granting of the exclusive rights and the ex-post competition law enforcement against the abusive exercise of the granted exclusive rights:

⁷⁵ European Commission, *EU Competition Policy in Action: COMP in Action*, Competition (Luxembourg: Publications Office of the European Union, 2017), p. 31.

⁷⁶ European Commission, "Guidelines on the Application of Article 101 of the Treaty on the Functioning of the European Union to Technology Transfer Agreements(2014/C 89/03)," OJ C 89, 28.3.2014, p. 3–50 §.

⁷⁷ Opinion of Mr. Advocate General Cosmas delivered on 16 May 2000. *Masterfoods Ltd v HB Ice Cream Ltd*. C-344/98, EU:C:2000:249, para 105.

⁷⁸ OPINION OF ADVOCATE GENERAL WATHELET delivered on 20 November 2014 (2) Case C-17013 *Huawei Technologies Co. Ltd v ZTE Corp., ZTE Deutschland GmbH*, ECLI:EU:C:2014:2391, para 63.

"The major concern simply is to minimize the risk that the exclusivity serves only private interests rather than also the public interest, and that it may be put at the service of private interests where protection is not really needed in the first place."⁷⁹

Looking at the annex to the EU Pharmaceutical Sector Inquiry, it is re-affirmed that:

"EC competition rules do not call the existence of intellectual property rights into question. However, for example intellectual property rights are not exempted from the application of competition rules. The exercise by a company of its intellectual property rights can amount to an agreement restricting competition under Article 81 EC or an abuse of a dominant position under Article 82 EC."⁸⁰

As such, actions which are perfectly legal under IP law can be deemed illegal in a competition law setting, as was the case in the seminal AstraZeneca case where AstraZeneca had made use of its legal rights to deregister an established product and its marketing authorization, allegedly as a conscious strategy to delay generic entry. As held by the Court:

...the illegality of abusive conduct under Article 82 EC (now article 102 TFEU, author remark) is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law.⁸¹

Following the standard set by the Court in AstraZeneca, one can conclude that legal and legitimate practices under IP law in some instances can amount to illegal and abuse practices under competition law, provided there is a sound theory of harm. As stated by Rupprecht Podszun:

"If patents are not meritorious and only serve the purpose to exclude competitors (as is common practice in some industries), there is now a clear legal basis for intervention. Such practices, however, are more telling about the deficits of patent law than about the power of competition law."⁸²

As seen from Servier⁸³ and AstraZeneca⁸⁴ cases, the Commission and the CJEU seem to have taken issue with excessive/unfair pricing resulting from different practices by an originator company, at least indirectly. Other cases such as Magill⁸⁵ and Deutsche Grammophon⁸⁶ can also be read in that light. One might point to numerous cases at both EU level⁸⁷ as well as at the Member State level which have dealt with abusive pricing issues related to intellectual property rights, albeit not innovative medicines as such, beyond the cited

⁷⁹ Ulrich, "Intellectual Property: Exclusive Rights for a Purpose – the Case of Technology Protection by Patents and Copyright."

⁸⁰ European Commission, "Annex to Pharmaceutical Sector Inquiry Final Report", 2008, para 13.

⁸¹ C-457/10 P - AstraZeneca v Commission, 2012, ECLI:EU:C:2012:770, para 132.

⁸² Rupprecht Podszun, "Can Competition Law Repair Patent Law and Administrative procedures? AstraZeneca", *Common Market Law Review* 51, no. 1 (2014): 281 – 294.

⁸³ Judgment of the General Court (Ninth Chamber, Extended Composition) of 12 December 2018, Servier SAS and Others v European Commission, T-691/14 – Servier and Others v Commission

⁸⁴ Judgment of the Court (First Chamber), 6 December 2012.

AstraZeneca AB and AstraZeneca plc v European Commission. Case C-457/10 P.

⁸⁵ Joined cases C-241/91 P and C-242/91 P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities, Judgment of the Court of 6 April 1995, ECLI:EU:C:1995:98.

⁸⁶ Case 78-70, Deutsche Grammophon Gesellschaft mbH v Metro-SB-Großmärkte GmbH & Co. KG, Judgment of the Court of 8 June 1971, ECLI:EU:C:1971:59.

⁸⁷ Case 40-70, Judgment of the Court of 18 February 1971 in Sirena S.r.l. v Eda S.r.l. and others, ECLI:EU:C:1971:18; Case 24-67, Judgment of the Court of 29 February 1968 in Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm, ECLI:EU:C:1968:1; Case 238/87, Judgment of the Court of 5 October 1988 in AB Volvo v Erik Veng (UK) Ltd, ECLI:EU:C:1988:477.

AstraZeneca and Servier cases, where the excessive price was result of other practices. As also noted by the EU Report on Competition Enforcement in the Pharmaceutical Sector:

"While competition law enforcement (antitrust and mergers) contributes to securing access to innovative and affordable medicines for patients and healthcare systems, it does not replace or interfere with the legislative and regulatory measures aimed at ensuring that EU patients benefit from state-of-the-art and affordable medicines and healthcare."⁸⁸

The new EU Pharmaceutical Strategy goes even further, in that it seems to envision a revised incentives-regime where "access and affordability" are tied to the granting of intellectual property and marketing rights, where the lack of transparency related to costs of R&D is cited as one major hurdle in pricing and reimbursement decisions. As noted by the Commission in the Strategy:

"Lack of transparency of research costs or return on investment can influence decisions that impact affordability and ultimately access for patients. Drawing on this and wider experience, the Commission will review the system of incentives. This may include greater 'conditionality' of incentives to support broader access for patients and ways to increase competition."⁸⁹

Summing up in the words of Chris Fonteijn et al. from Dutch Competition Authority:

"In our view, it stands to reason that if it turns out that EU based IP rights, or related rights, contribute to excessive pricing of pharmaceuticals by unduly promoting dominant positions across a number of Member States, the relevant incentive structures ought to be revised. Recasting the balance between innovation and competition in that context could further reconcile the two. This does not mean that the application of the competition rules should be suspended until a possible regulatory gap is closed. After all: time waits for no-one."⁹⁰

Competition law has constitutional value in the EU, and it can be presumed that competition law has even greater role to play in young economies in the developing world concerning curbing anti-competitive practices of intellectual property rights.⁹¹

Relatedly, as evident by long-standing research on the matter of fairness in pricing, people do care about fairness in transactions, much more than they would regarding "economic efficiency".⁹² This does not mean that any perceived "excessive" price, even if resulting from intellectual property rights, is a prime target for competition law enforcement, why European competition law ever since the seminal United Brands case have developed a conceptual framework relating to excessiveness and unfairness.⁹³

⁸⁸ European Commission, "REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT - COMPETITION ENFORCEMENT IN THE PHARMACEUTICAL SECTOR (2009-2017) - COM(2019) 17 Final," January 28, 2019.

⁸⁹ COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS "Pharmaceutical Strategy for Europe", COM/2020/761 final, 2020.

⁹⁰ Chris Fonteijn, Ilan Akker, and Wolf Sauter, "Reconciling Competition and IP Law: The Case of Patented Pharmaceuticals and Dominance Abuse", in *The Interplay between Competition Law and Intellectual Property - An International Perspective*, ed. Gabriella Muscolo and Tavassi Mariaanna (Kluwer Law International, 2016).

⁹¹ Frederick Abbott et al., "Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries", (United Nations Development Programme, 2014).

⁹² Klaus Mathis, *Efficiency Instead of Justice? Searching for the Philosophical Foundations of the Economic Analysis of Law*, trans. Deborah Shannon, Law and Philosophy Library (New York: Springer, 2009).

⁹³ Behrang Kianzad, "Excessive Pricing", chapter in "Encyclopedia of Law and Economics", edited by Alain Marciano and Giovanni Battista Ramello, Springer, 2021.

The next section firstly depicts the law and economics arguments pro and against excessive pricing in general, before moving on to the prohibition of excessive pricing in European competition law.

2.2 Excessive Pricing of IPRs as an Anti-Competitive Practice in Law and Economics

The hands-off approach found in a major part of the doctrine on excessive pricing, mainly written by economists from neoclassical and marginalist schools, will forever be in direct conflict with the black letter law and the legislative history of the prohibition against excessive and unfair pricing.

This is due to the fact that the law, and the economic theory underlying the legal prohibition, operates around manifestly different presumptions and inherent values codified since 3000 years.⁹⁴

The neoclassical opposition to excessive pricing enforcement against intellectual property rights as an anti-competitive practice can be summed by the following statement:

“Requiring by law that prices be “fair” or “reasonable,” or prohibiting a firm from charging “unfairly high” prices risks punishing vigorous competition. In general, competition policy should not prohibit a monopolist from charging whatever price for its products, including its IPRs, that it believes will maximize its profits.”⁹⁵

The above claim forwards the supposed harm to innovation, asserting that if risky and costly innovations are not able to be rewarded with manifestly excessive pricing, which should be excluded from competition law scrutiny, long-term innovation and thus consumer welfare would be harmed. This is a claim which is yet to be qualified and demonstrated, as evidence points to other direction, where there is no causal relationship between an increase in profits matched by an increase in R&D.⁹⁶

The R&D assertion still needs to be qualified along empirical lines,⁹⁷ let alone be normatively substantiated,⁹⁸ as empirical evidence that enforcing the legal prohibition against excessive pricing would harm innovation per se is all but conclusive, as seen from studies cited above. Granting a free pass to monopolistic profits seems indeed to be the antithesis to competition law, at least in the European tradition.⁹⁹

Further, this position also exposes the main divide between certain strands of economic analysis of law. As noted by Ernst-Joachim Mestmäcker, one of the chief architects behind European competition law and policy:

⁹⁴ Michal S. Gal, “Monopoly Pricing as an Antitrust Offense in the U.S. and the EC: Two Systems of Belief about Monopoly?”, *The Antitrust Bulletin* 49, no. 1–2 (March 2004): 343–84.

⁹⁵ Jorge Padilla, Douglas H. Ginsburg, and Koren Wong-Ervin, “Antitrust Analysis Involving Intellectual Property and Standards: Implications from Economics”, *Harvard Journal of Law & Technology* 33, no. 1 (2019).

⁹⁶ Kiu Tay-Teo, André Ilbawi, and Suzanne R. Hill, “Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies”, *JAMA Network Open* 2, no. 1 (January 4, 2019).

⁹⁷ G. A. Manne and J. D. Wright, “Innovation and the limits of Antitrust”, *Journal of Competition Law and Economics* 6, no. 1 (March 1, 2010): 153–202.

⁹⁸ Timothy J Brennan, “Should Innovation Rationalize Supra-Competitive Prices? A Skeptical Speculation”, in *The Pros and Cons of High Prices* (Swedish Competition Authority, 2007), 88–127.

⁹⁹ David Giló, “A Coherent Approach to the Antitrust Prohibition of Excessive Pricing by Dominant Firms”, in *Excessive Pricing and Competition Law Enforcement*, ed. Yannis Katsoulacos and Frédéric Jenny (Cham: Springer International Publishing, 2018), 99–126, https://doi.org/10.1007/978-3-319-92831-9_4.

“Cost-benefit analysis is end-neutral. It can be applied to any given purpose. Constitutions, statutes and precedents, however, are as a rule not end-neutral. The question then is how to accommodate the normative implications of economic analysis with diverse non-economic legal purposes.”¹⁰⁰

The main opposition by neoclassical and welfarist economics to enforcement against excessive pricing resulting from IPRs concerns the elevation of the risk of Type I errors, explained as:

“Type I errors may have serious consequences. Such intervention may reduce prices in the short run, but may also affect a company’s ability to recoup its investment if the price was, in fact, not excessive. Furthermore, unwarranted intervention risks chilling innovation and reducing the incentive for other companies (branded or generic) to enter the market, thereby stifling dynamic competition.”¹⁰¹

This view re-connects with the Schumpeterian position on competition in dynamic settings, as well as positing monopolistic or supra-competitive profits (at least during the patent term) as necessary for innovation and investments. This theoretical framework is in turn countered by the sheer number of empirical industrial organisation research, pointing to counter-intuitive results, where few causal links are found between an increase in profitability and an increase in R&D investments or actual innovation in the number of patents obtained, for example.

But the Type I claim also faces normative and theoretical shortcomings. The simplified normative position citing supra-competitive profits as rational for innovation has been contested by others such as Tim Brennan, analysing the model proposed by Segal and Whinston.¹⁰²

Segal and Whinston propose a model where they “posit an incumbent and an entrant. At any given period, the entrant (but not the incumbent) decides how much R&D to undertake, with the probability of success a concave function of the expenditure. If the entrant succeeds, it first gets to compete with the monopolist in the present period, and gets to be the monopolist in the next period, with the game starting over, retaining the same parameters for R&D cost and monopoly profit.”¹⁰³ Tim Brennan correctly points to the inherent limitations in the model, noting:

“It is highly stylized, with innovation doing little more than switch the identity of the incumbent and entrant. Product pricing and consumer welfare are not modelled, so the model provides no insight as to whether additional innovation is worth the cost or is more akin to a wasteful patent race”.¹⁰⁴

Indeed, the gravest problem plaguing the position advancing the potential innovation being harmed as result of excessive pricing intervention is the matter of un-accounted counterfactuals, decreasing the robustness of the claims considerably. What costs are associated with Type II errors, i.e., underenforcement, are not caught by the claim that Type I errors always are more costly, as such claim needs to be made in context, and when the

¹⁰⁰ Ernst-Joachim Mestmäcker, *A Legal Theory without Law* (Mohr Siebeck, 2007), <https://doi.org/10.1628/978-3-16-151072-4>.

¹⁰¹ Claudio Calcagno, Antoine Chapsal, and Joshua White, “Economics of Excessive Pricing: An Application to the Pharmaceutical Industry”, *Journal of European Competition Law & Practice*, February 22, 2019, <https://doi.org/10.1093/jeclap/lpy083>.

¹⁰² Ilya Segal and Michael D Whinston, “Antitrust in Innovative Industries”, *THE AMERICAN ECONOMIC REVIEW* 97, no. 5 (2007): 28.

¹⁰³ Timothy J Brennan, “Should Innovation Rationalize Supra-Competitive Prices? A Skeptical Speculation”, in *Pros and Cons of High Prices* (Swedish Competition Authority, 2007), p. 98.

¹⁰⁴ Brennan, 2007, p. 99.

context concerns goods such as lifesaving, essential treatments or vaccines, other values than pure efficiency become evident.¹⁰⁵

Furthermore, distorting competition law enforcement to encourage innovation contradicts the "sanity check" that must be placed on the normative goals of both competition law and intellectual property law respectively, as this would task competition law to account for deficiencies in incentives awarded by the intellectual property regime.

In the words of Tim Brennan, citing the works of Coase¹⁰⁶ as well as Buchanan and Stubblebine,¹⁰⁷ IP laws could provide optimal incentives to innovate, while distorting competition:

"will not only produce static inefficiency, but will over-reward innovation. Ideally, IP laws provide incentives so that the expected marginal social benefit from more innovation just equals its marginal cost. If antitrust is weakened to stimulate more innovation, an economy will end up with too much of its resources devoted to innovative activity."¹⁰⁸

The risk of irrelevance of neoclassical approach in such analytical settings is also addressed by Eli Salzberger, stating:

"Mainstream Law and Economics ignores the deficiencies of the shift from assuming self-maximization of utility to assuming self-maximization of wealth, such as ignoring the decreasing marginal utility of wealth, or the endowment effect. The insistence of most scholars to continue the Chicago path in this realm too, therefore, makes their work of little contribution to the real world of law."¹⁰⁹

Enforcement against unfair, excessive pricing is thus by many neoclassical-welfare minded economists described as a "highly controversial" tool and topic in competition law and economics. Even more so when the IPRs and sector regulation are present, introducing complicating layers into the analysis.

This "controversy" is not entirely surprising, as the enforcement against unfair, excessive pricing stand in direct opposition to "wealth maximisation" and "total welfare" as an inherent value and object of law advanced by Richard Posner,¹¹⁰ Robert Bork¹¹¹ et al., many times framed as "conventional wisdom" regarding competition law and policy by many mainstream texts.¹¹²

Much of the "controversy" thus revolves around the exclusion of fairness as an inherent "value" and objective by a certain strand of orthodox neoclassical and welfarist economics, assuming the role of normative legal rulemaking beyond a positive economic analysis of law.¹¹³

¹⁰⁵ Behrang Kianzad, "Beyond Justice versus Efficiency – Reconciling Law and Economics Approaches to Fairness," in *Law and Economics of Justice: Efficiency, Reciprocity, Meritocracy*, ed. Klaus Mathis and Avishalom Tor, New Developments in Competition Law and Economics Series (Springer, 2024).

¹⁰⁶ Ronald Coase, "The Problem of Social Cost", *Journal of Law and Economics* October 1960, vol. 3: p. 1-44

¹⁰⁷ James Buchanan and W. C. Stubblebine, "Externality", 1962, *Economica* 29, p. 371-84.

¹⁰⁸ Timothy J Brennan, "Should Innovation Rationalize Supra-Competitive Prices? A Skeptical Speculation", in *Pros and Cons of High Prices* (Swedish Competition Authority, 2007), p. 112.

¹⁰⁹ Eli M. Salzberger, "The Economic Analysis of Law – The Dominant Methodology for Legal Research?!", *University of Haifa Faculty of Law Legal Studies Research Paper No. 1044382*, 2007, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1044382.

¹¹⁰ Richard A Posner, "The Ethical and Political Basis of the Efficiency Norm in Common Law Adjudication", *Hofstra Law Review* 8 (1980).

¹¹¹ Robert H Bork, *The Antitrust Paradox: A Policy at War with Itself* (New York: Basic Books, 1978).

¹¹² David S. Evans and A. Jorge Padilla, "Excessive Prices: Using Economics to Define Administrable Legal Rules", *Journal of Competition Law & Economics* 1, no. 1 (January 1, 2005): 97–122.

¹¹³ Louis Kaplow and Steven Shavell, "Fairness versus Welfare: Notes on the Pareto Principle, Preferences, and Distributive Justice", *Journal of Legal Studies* 32, no. 1 (January 2003); Marc Fleurbaey, Bertil Tungodden, and

This stands in direct ontological opposition to not only the black letter of law, settled jurisprudence and legislative history and intent, but also to the economics of Adam Smith, who was not a utilitarian, and being a professor of Moral Philosophy, noted that “Justice...is the main pillar that upholds the whole edifice”.¹¹⁴

The supposed economic "conventional wisdom" asserted in some part of the literature on excessive pricing has been referred to by legal councils in many cases, and questioned and rejected by judges and courts.¹¹⁵

The literature on excessive pricing is ripe with countless references of the kind, alluding to a supposed "general consensus" or "conventional wisdom", mostly describing an "efficiency-orientated" approach to the object of competition law and rationales for enforcement, espousing a monolithic view of economics of competition law.¹¹⁶ Many of such writings rely on manifestly erroneous claims, such as the “scarcity of cases”, where in fact no less than 28 cases at the Commission and CJEU level and another 95 cases at the Member State level in EU dealt with excessive pricing between 1971-2021.¹¹⁷

The perceived unfairness in taking undue advantage of an economically dependent position, especially in times of crisis such as war or pandemic, constitutes the *ratio legis* informing the prohibition of excessive pricing from its inception centuries ago and onwards.¹¹⁸

Seen in that legislative light, what would constitute “economic sense” is rather irrelevant from the perspective of a European legal order,¹¹⁹ which is not solely oriented by “economic sanity” or “welfare maximizing” attributes of a certain legal code in order for the code to be applied in a coherent and uniform fashion.¹²⁰

Whereas the neoclassical economics find their root in the utilitarian and welfarist perspectives, focusing on economic efficiency and total welfare, the Keynesian, neo-Keynesian, and the behavioural schools allow more room for other public policy rationales and collective preferences beyond economic efficiency, such as the right to health.¹²¹

Neoclassical, marginalist, and welfarist law and economics schools do not recognize the position expressed in European law as per Article 102 TFE, nor the settled case law,¹²² neither

Howard F. Chang, “Any Non-welfarist Method of Policy Assessment Violates the Pareto Principle: A Comment”, *Journal of Political Economy* 111, no. 6 (December 2003).

¹¹⁴ ¹¹⁴ Adam Smith, “The theory of moral sentiments. To which is added a dissertation on the origin of languages”, London: printed for A. Millar, A. Kincaid and J. Bell in Edinburgh; and sold by T. Cadell in the Strand, MDCCLXVII [1767], The third edition, p. 148.

¹¹⁵ See e.g. UK Competition Appeals Tribunal Case No. 1274/1/12/16 (IR), transcript of hearing for application of interim relief, 17 January 2017, para 17-26.

¹¹⁶ Stucke, “Reconsidering Antitrust’s Goals.”

¹¹⁷ Behrang Kianzad, Are excessive pricing cases few and far between? A quantitative analysis of fifty years of European jurisprudence 1971–2021, September 2023, Concurrences N° 3-2023, Art. N° 113222, www.concurrences.com

¹¹⁸ Edgar Watkins, “The Law and the Profits”, *The Yale Law Journal* 32, no. 1 (November 1922), <https://doi.org/10.2307/789272>.

¹¹⁹ Wouter P J Wils, “The Judgment of the EU General Court in Intel and the So-Called ‘more Economic Approach’ to Abuse of Dominance”, *World Competition* 37, no. 4 (2014): 405–34; Ioannis Lianos, “Competition Law as a Form of Social Regulation,” *The Antitrust Bulletin* 65, no. 1 (March 2020): 3–86.

¹²⁰ Pablo Ibanez Colomo, “Beyond the ‘More Economics-Based Approach’: A Legal Perspective on Article 102 TFEU Case Law”, *SSRN Electronic Journal*, 2016, <https://doi.org/10.2139/ssrn.2755656>.

¹²¹ Robert D. Atkinson and David B. Audretsch, “Economic Doctrines and Approaches to Antitrust”, *Indiana University-Bloomington: School of Public & Environmental Affairs Research Paper Series No. 2011-01-02*, 2011.

¹²² Case 27/76 United Brands Company and United Brands Continentaal BV v Commission of the European Communities, ECLI:EU:C:1978:22; Case 26–75, General Motors Continental NV v Commission of the European Communities, Judgment of the Court of 13 November 1975, ECLI:EU:C:1975:150; Case 226/84, British Leyland Public Limited Company v Commission of the European Communities, Judgment of the Court (Fifth Chamber) of

normatively nor empirically. They thus point to what they perceive as normative and empirical fallacies of the legal prohibition, in turn characterising excessive pricing as being "... not only not unlawful" but "also an important element of the free market system."¹²³

The latter being a quote from US Supreme Court judgement in *Trinko*, a ruling which has been heavily criticised by US Antitrust scholars.¹²⁴ The opinion by Justice Scalia has nonetheless been described as:

"...wrong on the law, wrong on the facts, wrong as a matter of procedure, wrong as a matter of economics, wrong as a matter of institutional competencies, and a poor contrast with the way Section 2 legal standards have been articulated by courts in antitrust cases since the passage of the Sherman Act."¹²⁵

Indeed, *Trinko* did not concern excessive pricing in the European competition law sense, but rather refusal to deal in a US context, as the efficiency-oriented approach lacks the legal basis in European competition law when addressing the matter of excessive pricing, as such an approach would define away any excessive prices, even more so during a pandemic or crisis. As noted by Giorgio Monti on Advocate General Wahl quoting the *Trinko* case in a European case on excessive pricing:¹²⁶

"...it is remarkable that in interpreting EU Law, AG Wahl should make reference to a judgment of the US Supreme Court, *Verizon v Trinko*, a judgment so conservative that even some in the US have distanced themselves from it. But the surprise at the favourable reference to this case is also for two other reasons. First because US antitrust law does not prohibit excessive pricing...but also because in a judgment restating this, Justice Scalia took the view that 'charging... monopoly prices... is an important element of the free-market system.' Since the express prohibition of excessive pricing in Article 102 suggests a diametrically opposite attitude to the one expressed here, it is hard to see why one should see *Trinko* as a helpful discussion for the purposes of EU Law, but it reveals the trend to assimilate much of the thinking (ideology?) that underpins Scalia's thinking into EU antitrust even when, as here, it runs against the statutory text."¹²⁷

The above point holds great relevance for a developing country approach to competition law enforcement in general and excessive pricing prohibition in particular. As many of the developing countries' competition law regimes are modelled after the European, and not the US approach to competition law, the neoclassical and marginalist approaches in light of a Chicago doctrine on antitrust would be wholly in conflict with the black letter law and overall competition policy in the European Union but also in many developing countries.

11 November 1986, ECLI:EU:C:1986:421; Case C-177/16 – Biedrība 'Autortiesību Un Komunicēšanās Konsultāciju Aģentūra – Latvijas Autoru Apvienība' Konkurences Padome, ECLI:EU:C:2017:689.

¹²³ Justice Antonin Scalia in *Verizon Communications, Inc v Law Offices of Curtis v Trinko, LLP* 157 L Ed 2d 823, 836 (2004).

¹²⁴ Eleanor M Fox, "THE TROUBLE WITH TRINKO - American Bar Association Antitrust Section Spring Meeting 2004"; Spencer Weber Waller, "Microsoft and *Trinko*: A Tale of Two Courts.," *UTAH LAW REVIEW* 901, no. No 3 (2006): 741–59; Harry First, "Excessive Drug Pricing as an Antitrust Violation", *Antitrust Law Journal* 82, no. 2 (2019): 59.

¹²⁵ Spencer Weber Waller, "Microsoft and *Trinko*: A Tale of Two Courts", *UTAH LAW REVIEW*, 901, No 3 (2006):, p. 742.: see also Fox, "THE TROUBLE WITH TRINKO - American Bar Association Antitrust Section Spring Meeting 2004."

¹²⁶ "Opinion of the Advocate General Wahl, 6 April 2017, C-177/16 - Biedrība 'Autortiesību Un Komunicēšanās Konsultāciju Aģentūra - Latvijas Autoru Apvienība' Konkurences Padome, EU:C:2017:286," n.d.

¹²⁷ Giorgio Monti, "Excessive Pricing: Competition Law in Shared Regulatory Space" (Tilburg University Working Paper, 2019), <https://www.tilburguniversity.edu/sites/tiu/files/download/Monti%20Excessive%20pricing.pdf>.

Regarding the criticism from the neoclassical, marginalist and welfarist schools, as Jenny summarises in regard to the Kanal 5 case:

"The ECJ, following the precedent of *United Brands*, assessed whether the royalties were reasonable in relation to the economic value of the service provided by STIM. In doing so, it struck a balance between the interests of composers of music protected by copyright and those of the television broadcasting companies, whereas economists, if they had to consider both the consumer surplus and the producer surplus, would have chosen a total welfare criterion... Thus the concept of "unfair" price also lacks a conceptual basis in economics. Altogether, not only do the concepts of "excessive" or "unfair" price lack a sound economic basis, but their use to sanction pricing practices of dominant firms may cause serious economic harm."¹²⁸

Contrarily, it can be claimed that the concept of unfair prices has a rather solid "conceptual basis" in economics, as the matter of unfair pricing has laid the groundwork of Nobel Prize in Economics, following the work of Kahneman et al.¹²⁹ who demonstrated that people hold strong fairness in transaction preferences. As it is evident from their work, people do forego an increase in utility if they perceive the transaction as being unfair, or when they are faced with manifest price increases without any objective reasons such as an increase in costs of supplying the product.¹³⁰

It is simply a testament to the intellectual poverty of a certain strands of economics that it has no capability to come to terms with one of the most robust findings regarding human preferences and transactions, which is also evidently the *ratio legis* as well as the *ratio oeconomica* of the prohibition against excessive pricing and price gouging since time immemorial.

There are three main problems with the line of reasoning which rejects "any conceptual basis" regarding excessive/unfair pricing (under European law these concepts are interchangeable), on both normative and empirical lines. Firstly, total welfare is not the object of European competition law, and never has been, as seen from the legal-history and jurisprudence of CJEU, which is geared towards consumer welfare.¹³¹

Secondly, the definition of "economists" or "economics" in a monolithic sense is not a correct framing of the discipline and its practitioners, rather, enforcement against undue rent transfer and profiteering can indeed be seen as the *prima facie* function of competition law, in preventing undue wealth transfer, creation of market power and preventing in-efficiencies.

The conceptual basis of human aversion against unfair pricing is rather solid from both behavioural and neuro-economics studies. In comparison, empirical and neurological evidence for utilitarianism, rational choice and Homo Oeconomicus are yet to be

¹²⁸ Jenny, "Abuse of Dominance by Firms Charging Excessive or Unfair Prices".

¹²⁹ Daniel Kahneman, Jack L. Knetsch, and Richard H. Thaler, "Fairness and the Assumptions of Economics", *The Journal of Business* 59, no. S4 (January 1986): S285, <https://doi.org/10.1086/296367>.

¹³⁰ Daniel Kahneman, Jack L. Knetsch, and Richard H. Thaler, "Fairness and the Assumptions of Economics", *The Journal of Business* 59, no. S4 (January 1986): S285; see also Robert Piron and Luis Fernandez, "Are Fairness Constraints on Profit-Seeking Important?", *Journal of Economic Psychology* 16, no. 1 (March 1995): 73–96, [https://doi.org/10.1016/0167-4870\(94\)00037-B](https://doi.org/10.1016/0167-4870(94)00037-B).

¹³¹ Doris Hildebrand, "The Equality and Social Fairness Objective in EU Competition Law: The European School of Thought", *Concurrences* No 1 (2017): 1–10. ;Ioannis Lianos, "Some Reflections on the Question of the Goals of EU Competition Law", in *HANDBOOK ON EUROPEAN COMPETITION LAW*, Edited by Ioannis Lianos and Damien Geradin (Edward Elgar, 2013), 1–84; See also Konstantinos Stylianou and Marios Iacovides, "The Goals of EU Competition Law - A Comprehensive Empirical Investigation", *SSRN Electronic Journal*, 2020, <https://www.ssrn.com/abstract=3735795>.

substantiated. Fairness is further able to be aggregated and modelled in a strict economic sense.¹³²

Thirdly, the assertion of "serious economic harm" being a risk associated with vigorous enforcement against excessive pricing must be qualified in a case-by-case approach, in the light of an empirical reality demonstrating the opposite, i.e., the absence of a causal relationship between excessive profits and innovation as the evidence examined rather points to less innovation and wealth and not being able to create "welfare", if this latter is defined on a societal and not individual level.¹³³

The next section depicts the excessive/unfair pricing prohibition in European competition law, including an overview of various assessment tests employed by the European Commission, CJEU and some Member States.

¹³² Stefan Wintein and Conrad Heilmann, "Theories of Fairness and Aggregation", *Erkenntnis* 85, no. 3 (June 2020); Jan Boone, "Pricing above Value: Selling to an Adverse Selection Market", *CentER Discussion Paper, 2020-023*, September 2020; Marcel Canoy and Jan Tichem, "Lower Drug Prices Can Improve Innovation", *European Competition Journal* 14, no. 2–3 (September 2, 2018); Daniel Kahneman, Jack L. Knetsch, and Richard H. Thaler, "Fairness and the Assumptions of Economics," *The Journal of Business* 59, no. S4 (January 1986); Daniel Kahneman, Jack L. Knetsch, and Richard H. Thaler, "Fairness as a Constraint on Profit Seeking: Entitlements in the Market", *The American Economic Review* 76, no. 4 (1986); Ernst Fehr and Colin F. Camerer, "Social Neuroeconomics: The Neural Circuitry of Social Preferences", *Trends in Cognitive Sciences* 11, no. 10 (October 2007).

¹³³ General Secretariat OECD, "Beyond Growth: Towards a New Economic Approach - Report of the Secretary General's Advisory Group on a New Growth Narrative", September 12, 2019.

3. EXCESSIVE/UNFAIR PHARMACEUTICAL PRICING IN EUROPEAN COMPETITION LAW

Excessive pharmaceutical pricing as an anti-competitive practice had a revival during the recent decade following a string of cases at Member State level¹³⁴ as well at the Commission level,¹³⁵ creating headlines far beyond the legal community.

The historically unique excessive pricing investigation by European Commission into Aspen Pharmaceutical price hike of 1500 percent of certain long off-patent cancer drugs for Leukaemia and Multiple Myeloma ended by Aspen offering commitments to drastically reduce its EU-wide prices by 73 percent.¹³⁶ The commitments offered by Aspen were the result of the preliminary assessment by the Commission using Aspen's accounting data on revenues and costs demonstrating considerable profits without added therapeutic benefits to a long off-patent drug.¹³⁷

The string of cases has relied on the prohibition of imposing "unfair prices" by a dominant company under Article 102a TFEU, as well as on the assessment-method developed in the seminal *United Brands* case.¹³⁸ In this case, it was held by the CJEU that it would be possible to compare the economic value of the products with the actual prices charged, in the first limb, and if a manifest excess is found, moving on to a second limb, to investigate whether the disclosed excess is "unfair in itself" or "unfair when compared" with equivalent products in equivalent markets and consumer segments.

As held by the Court in the seminal *United Brands* case:

"The questions therefore to be determined are whether the differences between the costs actually incurred and the price 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."¹³⁹

In the case at hand regarding pharmaceuticals, the analysis would also be compelled to take note of the therapeutic benefit actually offered, the actual costs for R&D and related product development costs such as clinical trials etc. Whether or not and how costs of failures and opportunity costs can be accounted for is also a relevant and an equally important question. Nevertheless, the economic value of the products in the context of lifesaving, essential medicines must invariably be tied to their therapeutic efficacy.¹⁴⁰

¹³⁴ B. Kianzad and T. Minssen, "How Much Is Too Much? Defining the Metes and Bounds of Excessive Pricing in the Pharmaceutical Sector", *European Pharmaceutical Law Review* 2, no. 3 (2018): 133–48.

¹³⁵ European Commission, Press Release "Commission Opens Formal Investigation into Aspen Pharma's Pricing Practices for Cancer Medicines - IP/17/1323," May 15, 2017.

¹³⁶ European Commission, Antitrust: Commission accepts commitments by Aspen to reduce prices for six off-patent cancer medicines by 73% addressing excessive pricing concerns – IP/21/524 – Brussels, 10 February 2021.

¹³⁷ European Commission, Case AT.40394 – Aspen, Commission Decision of 10.2.2021, C(2021) 724 final.

¹³⁸ Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, ECLI:EU:C:1978:22.

¹³⁹ Case 27/76, *United Brands*, para 252.

¹⁴⁰ Behrang Kianzad, "What makes a price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law", PhD Dissertation, Copenhagen University, November 2022; See also Ezekiel J. Emanuel, "When Is The Price Of A Drug Unjust? The Average Lifetime Earnings Standard", *Health Affairs* 38, no. 4 (April 2019): 604–12; and Marcel Canoy and Jan Tichem, "Lower Drug Prices Can Improve Innovation", *European Competition Journal* 14, no. 2–3 (September 2, 2018).

The United Brands framework departs from the notion of “Cost Plus” in its approach to value, price and profit, i.e., departing from the costs involved in the production of the good, moving on to the “competitive market price”, and allowing for a “competitive profit”, again all conditioned towards the structure of the market, the product in question, and the prevalent demand structure.

De-coupling the value entirely from its costs of production and conditioning the value alongside non-economic values have seldom if ever have been recognized in the jurisprudence of the Commission and the CJEU.¹⁴¹

In the case of “public goods”, such as water,¹⁴² energy¹⁴³ and life-saving medicines,¹⁴⁴ an approach to value by way of willingness-to-pay as the core determinant of value stands in bright contrast to both law and logic, as such an approach would negate demand-related issues such as inelasticity, nullity of choice as well as other public rationales such as public authority legal obligations, e.g., regarding affordable healthcare.

Indeed, much of the aforementioned sectors are also subject to sector regulation, but such regulation does not negate the importance of competition law in curbing anti-competitive practices of IPRs.¹⁴⁴ As noted by the European Commission in the *Deutsche Telekom* case:

“the Court of Justice of the European Communities and the Court of First Instance of the European Communities have consistently held that the competition rules may apply where the sector-specific legislation does not preclude the undertakings it governs from engaging in autonomous conduct that prevents, restricts or distorts competition.”¹⁴⁵

As established by *United Brands*, charging an excessive price describes a price which is excessive because it has no “reasonable relation to the economic value of the product supplied”, if the undertaking in question holds a dominant position on the relevant market, in the meaning of Article 102a TFEU.

To distinguish if this is the case, the Court offered a conceptual framework which is still the most used test in regard to assessment of alleged excessive pricing. As noted by the Court:

“...this excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin.”¹⁴⁶

¹⁴¹ See European Commission, Amicus brief in case no. c3/2018/1847 and c3/2018/1874, UK Court of Appeals; Flynn Pharma limited Flynn Pharma (holdings) limited and Pfizer inc. Pfizer limited v. the Competition and Markets Authority; 14 June 2019, for hearing on 26-28 November 2019; the Commission distances itself in blunt words from the reasoning in *Scandlines* case, to date one of the few examples of an approach to value which does not depart from the Cost Plus approach.

¹⁴² See German Competition Authority report on enforcement in the drinking water sector, *Bundeskartellamt*, “Bericht Über Die Großstädtische Trinkwasserversorgung in Deutschland”, June 2016.

¹⁴³ Marc van der Woude, “Unfair and Excessive Prices in the Energy Sector”, *European Review of Energy Markets* 2, no. 3 (May 2008); See also Marco Botta and R. Karova, “Sanctioning Excessive Energy Prices as Abuse of Dominance: Are the EU Commission and the National Competition Authorities on the Same Frequency?”, in *Abuse of Dominance in EU Competition Law*, Pier Parcu and Giorgio Monti, eds. (Edward Elgar Publishing, 2017).

¹⁴⁴ Behrang Kianzad, “The Limits of Control – Competition law versus Sector Regulation in the wake of the European Commission Excessive Pricing Decision in Aspen”, *European Competition and Regulatory Law Review (CORE)*, October 2022.

¹⁴⁵ Case COMP/C-1/37.451, 37.578, 37.579 — *Deutsche Telekom AG*, Commission Decision of 21 May 2003; the Commission Decision was on appeal upheld by both the General Court as well as CJEU; Case C-280/08 P, *Deutsche Telekom AG v European Commission*, Judgment of the Court (Second Chamber) of 14 October 2010.

¹⁴⁶ Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, No. Case 27/76, ECLI:EU:C:1978:22 (1978), dictum, point 9.

United Brands thus established the seminal test for assessment of excessive/unfair prices in European competition law which to-date remains the “golden standard” for assessment in such cases, with recent cases refining the test further.¹⁴⁷

The European Commission has examined excessive pricing in a total of 14 decisions between 1971 and 2021,¹⁴⁸ ending with fines, commitments, rejection of the claim of excessive pricing and annulment as well as confirmation of a Commission’s decision upon appeal to the CJEU. A total of five cases were resolved by way of settlements and commitments, and the Commission issued a rejection decision in three other cases.

A total of five cases where the Commission had found an infringement were appealed to the CJEU, whereof the Commission succeeded in three cases and the appellants prevailed in two other cases against the Commission’s decision. The Commission’s decision in one case finding an infringement and imposing fines was not appealed.¹⁴⁹

The other cases reviewed by the CJEU were initiated by way of preliminary questions referred to the Court by national courts, with a total number of 13 cases, where the Court clarified the content of Article 102a and the application of the United Brands test.

More recently the CJEU ruling on a preliminary question from a Latvian court regarding allegedly excessive royalties charged by a royalty-collecting society reiterated that several methods and benchmarks can be deemed valid for assessment of the excessiveness of a price, including a comparison of prices between Member States, provided that the reference Member States are selected in accordance with “objective, appropriate and verifiable criteria”.¹⁵⁰

These points were later reiterated in the case on excessive pricing handled by the CJEU at the time of writing, namely the SABAM case which also concerned a royalty-collecting society.¹⁵¹

¹⁴⁷ Case C-177/16 - Biedrība ‘Autortiesību Un Komunicēšanās Konsultāciju Aģentūra - Latvijas Autoru Apvienība’ Konkurences Padome, ECLI:EU:C:2017:689; Case C-372/19, Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Weareone.World BVBA and Wecandance NV, Judgment of the Court (Fifth Chamber) of 25 November 2020, ECLI:EU:C:2020:959.

¹⁴⁸ Case 75/75/EEC, Commission Decision of 19 December 1974 relating to a proceeding under Article 86 of the EEC Treaty (IV/28.851 - General Motors Continental); Case 76/353/EEC, Commission Decision of 17 December 1975 relating to a proceeding under Article 86 of the EEC Treaty (IV/26699 — Chiquita; Sterling Airways, commitment decision, referred in European Commission, “Tenth Report on Competition Policy”, 1981, Brussels, p. 95; Case 84/379/EEC, British Leyland, Commission Decision of 2 July 1984 relating to a proceeding under Article 86 of the EEC Treaty (IV/30.615 - BL); Belgacom case, commitment decision, European Commission, “Settlement Reached with Belgacom on the Publication of Telephone Directories - ITT Withdraws Complaint, IP/97/292,” April 11, 1997; COMP/C-1/36.915 — Deutsche Post AG, Commission Decision of 25 July 2001 relating to a proceeding under Article 82 of the EC Treaty (COMP/C-1/36.915 — Deutsche Post AG — Interception of cross-border mail); Case COMP/A.36.568/D3 — Scandlines Sverige AB v Port of Helsingborg, Commission of the European Communities, Brussels, 23 July 2004; Case C-159/08 P, Isabella Scippacercola and Ioannis Terezakis v Commission of the European Communities, Order of the Court (Fifth Chamber) of 25 March 2009, ECLI:EU:C:2009:188; Case COMP_D3/34493 - DSD / Der Grüne Punkt, Commission Decision of 20 April 2001; Case COMP/C-1/37.451, 37.578, 37.579 — Deutsche Telekom AG, Commission Decision of 21 May 2003; Case COMP/39.592 - Standard & Poor’s, Commission Decision of 15.11.2011; Case COMP C-2/37/761 Euromax/IMAX, Commission rejection decision, 25.03.2014; Case AT.39816—Upstream gas supplies in Central and Eastern Europe (Gazprom), Commission decision of 24 May 2018; Case at.40394 — Aspen — commitments to the European Commission — 28 January 2021.

¹⁴⁹ For a detailed view of the cases and the outcomes, see the table of cases in this thesis related to cases pursued by the Commission, General Court and CJEU.

¹⁵⁰ Case C-177/16 - Biedrība ‘Autortiesību Un Komunicēšanās Konsultāciju Aģentūra - Latvijas Autoru Apvienība’ Konkurences Padome, ECLI:EU:C:2017:689.

¹⁵¹ Case C-372/19, Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Weareone.World BVBA and Wecandance NV, Judgment of the Court (Fifth Chamber) of 25 November 2020, ECLI:EU:C:2020:959.

Of importance is also the opinion of Advocate General Wahl, noting:

“In particular, there is simply no need to apply that provision in a free and competitive market: with no barriers to entry, high prices should normally attract new entrants. The market would accordingly self-correct. It may however be different in markets with legal barriers to entry or expansion and, in particular, in those in which there is a legal monopoly. Indeed, there may be markets which, because of their particular features, are not run efficiently when open to competition.”¹⁵²

The market of patented, life-saving vaccines fits well into this latter category. To the contrary, the endorsing of self-correcting markets as hindrance to applying black letter law comes close to a Posnerian Economic Analysis of Law and is not without inherent limitations and conceptual challenges.¹⁵³ Relevant for the present inquiry on excessive pharmaceutical pricing is also the already mentioned and most recent case reviewed by CJEU concerning excessive royalties by a Belgian royalty collecting society, SABAM.¹⁵⁴ The Advocate General Pitruzzella in his opinion noted that:

“Moreover, it is not always the case that there is a maximum price that the consumer is willing to pay for a product, with a result that, in those situations, there are no obstacles to the introduction of excessive prices. In the case of a life-saving medicine, for example, the only spending limit is the financial capacity of the purchaser (whether the patient or the national health service).”¹⁵⁵

The above is also addressed by the European Commission in its 2018 submission to OECD on the matter of excessive pharmaceutical pricing, noting the in-elastic demand, price-insensitivity, high pressure on health systems to pay for certain medicines even at high prices, limited bargaining power in face of essential medicines and lack of substitute products – which combined “...make the pharmaceutical sector more prone to unfair pricing practices or concerns than other sectors.”¹⁵⁶

How the actual assessment and finding of a competitive price is construed represents another matter entirely, posing more empirical than normative considerations, although some of those considerations entail a normative aspect, by asserting that enforcement would harm innovation if in the form of “price cap”.¹⁵⁷

Nevertheless, the normative position denying the prohibition of excessive pricing can only be sustained if one ignores the overall economic effects of excessive pricing and the ratio legis of the prohibition. As noted by Michal Gal:

“ If taken to its logical conclusion, this would suggest that axiomatically any price paid in a voluntary transaction is equal or even lower than the product’s economic value to

¹⁵² Opinion of the Advocate General Wahl, 6 April 2017, C-177/16 - Biedrība ‘Autortiesību Un Komunicēšanās Konsultāciju Aģentūra - Latvijas Autoru Apvienība’ Konkurences Padome, EU:C:2017:286.

¹⁵³ A. Ezrachi and D. Gilo, “Are Excessive Prices Really Self-Correcting?”, *Journal of Competition Law and Economics* 5, no. 2 (June 1, 2009): 249–68, <https://doi.org/10.1093/joclec/nhn033>.

¹⁵⁴ Case C-372/19, Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Weareone.World BVBA and Wecandance NV, Judgment of the Court (Fifth Chamber) of 25 November 2020; For a comment and analysis of the case see: Behrang Kianzad, “Let’s Dance! Excessive Royalties and the Economic Value of Music”, *European Competition and Regulatory Law Review* 5, no. 2 (2021): 172–76.

¹⁵⁵ Opinion of advocate general pitruzzella in case c-372/19 belgische vereniging van auteurs, componisten en uitgevers cvba (sabam) v weareone.world bvba, wecandance nv, No. ECLI:EU:C:2020:598 (July 16, 2020).

¹⁵⁶ European Union, “Excessive Pricing in Pharmaceutical Markets - Note by the European Union - OECD Roundtable on Excessive Pharmaceutical Pricing - DAF/COMP/WD(2018)112”, November 23, 2018, para 15.

¹⁵⁷ J. Hoekstra and W. Sauter, “What Standard for Excessive Pricing in EU Law? A Discussion of the Competition Appeal Tribunal’s Judgment in the Pfizer/Flynn v CMA Case”, *European Pharmaceutical Law Review* 2, no. 4 (2018): 215–21.

the buyer, and thus no price is ever abusive in itself. Yet this conclusion is correct only with regard to those who bought the product, and not to those excluded from buying it because of the monopolistic price."¹⁵⁸

In summary, approaching the pricing dynamics in markets such as that of life-saving medicines and vaccines by way of a willingness-to-pay understanding of economic value stand not only in direct opposition to European legal tradition, but also to sound economics.¹⁵⁹

3.1 The European Commission and the Case of Aspen

Probably the most important case on excessive/unfair pharmaceutical pricing concerns, is the recent Aspen commitment decision, where a South African company was found to have imposed excessive prices across EU.

The case emanated from the Italian Competition Authority, which investigated and subsequently fined Aspen for its excessive prices and aggressive negotiation strategy, with Aspen being unsuccessful in its later appeals against the judgement.¹⁶⁰

As other European countries also started to investigate the Aspen prices and behaviour, the European Commission made use of its powers under Regulation 1/2003¹⁶¹ and took over the investigations. In May 2017, following the previous investigation by the Italian Competition Authority, the EU Directorate General on Competition decided to open a formal investigation into Aspen Pharma's pricing practices regarding some oncology drugs across the EU, alleging significant price increases for products containing the active pharmaceutical ingredients chlorambucil, melphalan, mercaptopurine, busulfan and tioguanine.

The Commission announced its intention to investigate the case as it had received information that the practices by Aspen across EU took the form of unfair, abusive negotiation practices with national authorities and/or hindered parallel trade between the Member States.¹⁶²

The Commission investigated the alleged unfair pricing practices by Aspen by way of applying the United Brands test, after securing source data regarding costs by way of dawn raid and request for assistance from national competition authorities. The Commission's analysis of Aspen cost structure as per the accounting data obtained demonstrated that Aspen had consistently earned:

"Very high profits from its sale of these medicines in Europe, both in absolute terms and when compared to the profit levels of similar companies in the industry. Aspen's prices exceeded its relevant costs by almost three hundred percent on average, including when accounting for a reasonable rate of return, although differences did exist between products and countries. The Commission's investigation did not reveal any legitimate reasons for Aspen's very high profit levels. In particular, Aspen's

¹⁵⁸ Michal Gal, "Abuse of Dominance - exploitative abuses", 2013, p. 410.

¹⁵⁹ Robert H Lande, "Wealth Transfers as the Original and Primary Concern of Antitrust: The Efficiency Interpretation Challenged", *Hastings Law Journal* 34, no. 1 (1982); Antonio J. Trujillo et al., "Fairness in Drug Prices: Do Economists Think Differently from the Public?", *Health Economics, Policy and Law*, December 4, 2018, 1–12.

¹⁶⁰ Michela Angeli, "The TAR Lazio's Judgement in the Italian Aspen Case on the Imposition of Unfair Prices under Art. 102(a) TFEU", *Rivista Italiana Di Antitrust / Italian Antitrust Review* 4, no. 2 (March 2, 2018).

¹⁶¹ European Commission, "Council Regulation 1/2003/EC of 16 December 2002 on the Implementation of the Rules on Competition Laid down in Articles 81 and 82 of the Treaty (OJ L 1/1, 4.1.2003 p. 1-25) Amended by Council Regulation 411/2004/EC of 26 February 2004 (OJ L 68/1, 6.3.2004) and Council Regulation 1419/2006/EC of 25 September 2006 (OJ L 269/1 28.9.2006) – Consolidated Version of 18 October 2006" (n.d.).

¹⁶² European Commission, "European Commission - Press Release - Antitrust: Commission Opens Formal Investigation into Aspen Pharma's Pricing Practices for Cancer Medicines - IP/17/1323", May 15, 2017; Opening of Proceedings.

medicines have been off-patent for 50 years, which means that any R&D investment on the medicines has long been recouped."¹⁶³

Regarding the unfairness of the prices, focusing on the demand-side in-elasticities and Aspen overall strategy, the Commission noted that Aspen could earn such profits due to the nature of the products in question, lack of comparable alternatives as well as the aggressive negotiation strategy employed by Aspen towards the sector price regulator.

The strategy consisted of Aspen threatening to withdraw the medicines from the national market, and Aspen had also employed an EU wide pricing strategy to defeat parallel imports as well as international price reference systems.¹⁶⁴ All of these latter issues relate to the "intent" of Aspen to exploit the reimbursement systems by way of excessive and unfair pricing.

On 19 June 2020, the Commission adopted a Preliminary Assessment as referred to in Article 9(1) of Regulation 1/2003 which set out the Commission's competition concerns of excessive/unfair pricing by Aspen in relation to the products across the European Economic Area (EEA), minus Italy as Aspen already had been subject of an enforcement decision related to its pricing practices in that national jurisdiction.

On 9 July 2020, Aspen submitted commitments to the Commission to meet the concerns expressed in the Preliminary Assessment. Following publication of the commitments and comments received, on 9 December 2020, the Commission informed Aspen of the observations received from interested third parties following the publication of the notice. On 28 January 2021, Aspen submitted revised, final commitments.¹⁶⁵

The commitments consisted in Aspen reducing prices across Europe by approximately 73% (reverting to prices in 2012 before the price hike), and further that these reduced prices would be in effect for the coming 10 years taking effect as of 1 October 2019, and finally that Aspen would guarantee the supply of the medicines for the next five years, and, for an additional five-year period either continue to supply or make its marketing authorisation available to other suppliers.¹⁶⁶

This case represented a historical milestone where the Commission took issue with excessive/unfair pricing in the pharmaceutical market, and given the theme of the present study, the approach of the Commission in defining the relevant market, dominance, and the approach to applying United Brands test will be depicted in greater detail.

In approaching the first limb of the United Brands, the Commission by way of investigating the accounting data of Aspen sought firstly to determine the actual revenues, given that Aspen was a multi-product, multi-geographic firm, a point which has been considered in the doctrine as being particularly complex and translating by some into an "impossibility theorem".¹⁶⁷

The Commission set out to determine what costs (direct and indirect) should be allocated to each product. Nevertheless, a value-based cost-allocation method would not serve the analysis, as this would be inflated by the nature of the alleged infringement regarding the

¹⁶³ Commission Press Release, 2021.

¹⁶⁴ Commission Press Release, 2021.

¹⁶⁵ European Commission, Case AT.40394 – Aspen, Commission Decision of 10.2.2021, C (2021) 724 final.

¹⁶⁶ European Commission, Antitrust: Commission accepts commitments by Aspen to reduce prices for six off-patent cancer medicines by 73% addressing excessive pricing concerns – IP/21/524 – Brussels, 10 February 2021; Case at.40394 – Aspen – commitments to the European Commission – 28 January 2021.

¹⁶⁷ See David S. Evans and A. Jorge Padilla, "Excessive Prices: Using Economics to Define Administrable Legal Rules", *Journal of Competition Law & Economics* 1, no. 1 (January 1, 2005):p. 101; as seen by the string of case law and doctrinal development, there exists no such "impossibility theorem" more than in the minds of neoclassical economists.

imposition of excessive pricing. Following this, the profit range could then be determined using two profit metrics: i) gross profits and ii) Earnings Before Interest, Taxes, Depreciation, and Amortization (EBITDA). Regarding the direct and indirect costs taken into account, as noted by the Commission:

“Direct costs are all costs incurred in the production, supply and distribution of the Products, which can be directly attributed to their sales. Indirect costs are common costs (for example, operating costs) that Aspen incurred in the supply of more than one product.”¹⁶⁸

In the Aspen case, the definition given to EBITDA by the Commission was one of “Net Sales of the Relevant Product in the Relevant Country, less Direct Costs and an allocation of Indirect Costs” where indirect costs had been defined as marketing authorisation costs and indirect costs excluding marketing authorisation costs, also including overheads costs.¹⁶⁹

Following the EBITDA-method and deductions, dictated by the specifics of the case, profits according to this method could be calculated. This was in turn compared to the overall profitability of the sector and firms with similar product portfolios, using different industry databases. This latter point —relying on the prevailing profit range in the sector— has also been a point of contention in the doctrine but the jurisprudence of both the Commission and the CJEU have consistently availed themselves of such metrics.

This does not mean that no (dominant) company can earn profits widely surpassing the “competitive profit range” without being target of excessive pricing scrutiny, but the question of relevance is how the supra-competitive profits were earned by the (dominant) company, if by way of superiority of quality, reputation, efficiencies and other objective justifications, or rather enabled by the nature of the products being characterized by in-elastic demand, lack of competitive pressure and payer-insensitivity, where life-saving essential medicines provide an apt example.

The Commission’s analysis thus demonstrated that Aspen in the period 2013-2019 had persistently earned “very high profits” both in absolute and relative terms, where prices had exceeded disclosed indirect and direct costs by almost 300% on average, i.e., prices being almost four times higher than the costs, including a reasonable rate of return. Adding to this finding, Aspen’s average EEA-wide profit range were more than three times higher than the average profitability prevailing in comparable firms in the pharmaceutical industry, surpassing any of these firms’ profitability also on the individual level.

This should also be contrasted to the fact that when Aspen acquired the drug portfolio from GlaxoSmithKline (GSK) in 2012, the portfolio was already making profits almost double the industry average. Nonetheless, as noted by the Commission, Aspen decided to proceed with a drastic increase of its prices “although at portfolio level, that is, all Products taken together, the Products were profitable, with an overall EBITDA margin at [40-50] per cent and therefore significantly higher than the 23 per cent EBITDA margin of the industry.”¹⁷⁰ Aspen had further outsourced the production, and this is why the higher prices could not be seen as resulting from superior efficiency on part of Aspen.¹⁷¹

Using the Cost-Plus approach, with “plus” being the 23 per cent median, and “excess” defined as significant deviation from this proxy, the profits earned by Aspen were found to lie 280-300

¹⁶⁸ Aspen Commission Decision, paras 108, 109 and 111.

¹⁶⁹ Case at.40394 – Aspen – commitments to the European Commission – 28 January 2021, see Annex 2 regarding methodology of allocation of indirect costs.

¹⁷⁰ Aspen Commission Decision, para 180.

¹⁷¹ Aspen Commission Decision, para 174.

per cent in excess of the Cost-Plus benchmark, meaning that Aspen, on top of a reasonable return, had earned additional profits roughly three times the level of cost-plus.

On that basis, i.e., the average profitability at product level and the products' total profitability over time at portfolio level in the EEA, the Commission expressed concerns that Aspen made profits significantly exceeding industry levels. Overall, the excess levels for individual products in individual member states were at times as high as 900 per cent (the case of Purinethol in Malta).

As the results demonstrated considerable excess profits on part of Aspen, the Commission thus went on to the second limb of *United Brands*, regarding if the disclosed excess also was "unfair in itself" or "unfair when compared". As the relevant markets regarding pricing practices of Aspen were considered to consist of all national markets within the EEA where Aspen sold the products (minus Italy where Aspen already had been found liable of excessive pricing), there would not be meaningful to undertake a geographic comparison.

The Commission anchored its determination of "unfairness" by mainly four points:

"Whether Aspen had carried out any particular activity in relation to the Products (such as potential innovations or commercial risk-taking). It further considered the characteristics of the Products as medicines that had been off-patent for decades, but on which a number of cancer patients still depend. In addition, the Preliminary Assessment considered the stark disproportion between the (limited) increases in the costs of the Products and the (very high) price increases leading to a very high level of Aspen's profits and prices. Finally, the Preliminary Assessment considered the strategy and means that Aspen employed when implementing the high price increases."¹⁷²

As seen from the above, two points of anchorage regarding the unfairness assessment relate to rather static and quantitative matters such as demonstrable innovation activity as well as the "stark disproportion" between the costs and prices increases, while two other points of anchorage relate to qualitative matters such as the dependence of patients and the "strategy and means" employed by Aspen.

The legal takeaway from this case is manifold. Firstly, the approach of the Commission in the first limb is of utmost importance and relevance in contrast to much of the literature on the subject. The approach was consistent with settled case law regarding Cost Plus (costs plus reasonable profits) as per *United Brands*, but did involve some benchmarking, although not an exercise in developing counterfactuals.

This is to be undertaken under the second alternative under limb two, i.e., "unfair when compared". Prevailing profit ranges in the industry and companies having similar product portfolios sufficed to reveal the excess in the first limb of analysis, thus not requiring pricing benchmarks.

Secondly, as the drugs were long-off patent, the presumption was that the sunk costs had been recouped by another entity, thus the case did not involve sunk costs in the form of R&D costs on part of Aspen, although Aspen brought some defences regarding other indirect costs, which were taken into account to some degree.

Thirdly, the matter of demand-side dynamics of willingness-to-pay and "economic value" was correctly treated in a holistic manner by way of references to inelasticity of demand, indispensability of the product as well as the negotiation strategy by Aspen given the fact that

¹⁷² Aspen Commission Decision, para 165.

the authorities in question had no choice but to procure the medicines, no matter the costs, i.e., manifest payer insensitivity. In this context, indispensability and inelasticity are to be seen as an argument towards demonstrating the normatively unfair element in the exploitation and the abuse of dominant position per Article 102a TFEU.

Fourthly, as is often the case in pharmaceutical sector, the product's temporal, geographical elements do not constitute suitable comparators per se. This finding affects the analysis regarding the relevant market definition, the choice of suitable "products" to be compared if found, the choice of suitable "competitors", the difficulty of equating off-patent and on-patent pricing (presumption being recoupment of R&D during the patent term, and thus reduced prices for off-patent products) and so on.

As the case did not end with a formal assessment and infringement decision, which could be appealed to the General Court and the CJEU, but rather by a preliminary assessment and commitment decision, an opportunity was lost to create a more solid legal ground relating to the analysis of excessive/unfair pricing in the context of pharmaceutical pricing. Some important lessons and guidance for future cases can nevertheless be extracted from the rich analysis done by the Commission in this case.

The next section depicts various assessment tests in the previous case law of in the European Union.

3.2 Various Assessment Tests in Previous Case Law in the European Union

As seen from the foundational case law from the Commission, General Court and the Court of Justice of European Union, no less than eight different assessment methods have been established which can be summarized as follows:

1. Comparison of the dominant undertaking's costs and prices / profits regarding the products and services in question in the relevant market, where this calculation targets both current and past cost-price relationship, as such also adding a temporal element to the analysis. Least objective and justifiable increases in the costs incurred, excess can be indicative of abuse but needs to be analysed whether the disclosed excess is also unfair.
2. Comparison of the dominant undertaking's prices for other comparable products in the same market, if applicable to the case at hand where there are comparable products or services provided by the same undertaking in the same relevant market investigated.
3. Comparison of the dominant undertaking's price to other customers and consumer groups in the same market, if applicable to the case at hand where there would exist other customers in the same market regarding same products or services.
4. Comparison of the dominant undertaking's competitors' prices in the same market, if applicable to the case at hand, where comparable products and services must be first identified to serve as comparators. There is manifest risk of a faulty comparator in the case of inflated prices across a whole market where few undertakings are active and there are high barriers to entry, mindfulness of Cellophane Fallacy is thus warranted.
5. Comparison of the dominant undertaking's prices/profits in other geographical markets, if applicable to the case at hand, and provided comparisons are done on a consistent and objective basis, taking PPP-index, differences in willingness to pay and other relevant criteria into account. Also, here the Cellophane Fallacy must be observed.

6. Comparison of the dominant undertaking's competitors' prices/profits in other geographical markets regarding comparable products/services, if applicable to the case at hand, provided comparators are selected on a consistent and objective basis.
7. Comparison of prices imposed by the dominant undertaking with prices it had previously charged in other markets. The markets can be comprised of geographical ditto, or other product markets, which bear resemblance to the products or services in question. However, the markets must be "competitive", and relevant differences in product quality and incurred costs due to the structure of the markets examined must also be taken into account.
8. Comparison of the prices imposed by the dominant undertaking with prices other undertakings charge in other markets. The products or services must be rather identical in nature or highly comparable. The competitiveness of markets in question must be examined in order to provide an appropriate comparison regarding product quality and incurred costs due to the structure of the markets, to be assessed on a case by case basis.

The first step in the assessment consists of a Cost-Plus approach, if the United Brands test is the chosen methodology, but as the CJEU already noted in *United Brands*, other tests might also be devised which can fulfil the purposes of Article 102a TFEU.

In the first limb of *United Brands*, actual costs incurred are compared to actual prices charged, in order to disclose an appreciable excess in the profit margin, where the "excess" might be corroborated by overall profit margins prevailing in the sector by comparable firms offering comparable products, but also by way of a temporal element on the part of the investigated undertaking regarding previous prices charged, or prices charged in other markets or to other consumer segments.

The necessary, in-depth benchmarking as per the alternative approaches listed above are chiefly to be undertaken in the second limb of *United Brands*, either by way of "unfair in itself" or by way of "unfair when compared". Demanding benchmarking in the first limb if cost-price range can be disclosed by way of other methods (internal documents, previous prices etc.) is not recognised under European competition law, as also evident from the Amicus Brief by the Commission in the *Pfizer/Flynn* case, detailing the European jurisprudence on the matter.¹⁷³

Certain sectors and products/services by their nature cannot be subjugated to the above method of calculating the costs, such as the case of copyrighted works and other individual creations of the mind which are difficult to monetize and compare in a sensible way. In those cases, benchmarking might be needed already in the first step, which is the lesson from the royalty collecting cases such as *SACEM*,¹⁷⁴ *Tournier*,¹⁷⁵ *AKKA/LAA*,¹⁷⁶ *SABAM*,¹⁷⁷ etc.

As also re-affirmed by case law of the CJEU, the Competition Authority enjoys a margin of discretion in what method(s) would be most suitable in the individual case, and further, the two alternatives in the second limb (unfair when compared versus unfair in itself) are not cumulative in nature but stand-alone alternatives.¹⁷⁸

¹⁷³ European Commission, Amicus brief in case no. c3/2018/1847 and c3/2018/1874, UK Court of Appeals; *Flynn Pharma limited Flynn Pharma (holdings) limited and Pfizer inc. Pfizer limited v. the Competition and Markets Authority*; 14 June 2019, for hearing on 26-28 November 2019.

¹⁷⁴ Case 402/85, *G. Basset v Société des auteurs, compositeurs et éditeurs de musique (SACEM I)*, Judgment of the Court of 9 April 1987; Joined cases 110/88, 241/88 and 242/88, *François Lucazeau and others v Société des Auteurs, compositeurs et éditeurs de musique (SACEM II) and others*, Judgment of the Court of 13 July 1989.

¹⁷⁵ Case 395/87, *Ministère public v Jean-Louis Tournier*, Reference for a preliminary ruling: Cour d'appel d'Aix-en-Provence - France, Judgment of the Court of 13 July 1989.

¹⁷⁶ Case C-177/16 - *AKKA / LAA*.

¹⁷⁷ Case C-372/19, *Belgische Vereniging van Auteurs, Componisten en Uitgevers CVBA (SABAM) v Weareone.World BVBA and Wecandance NV*, Judgment of the Court (Fifth Chamber) of 25 November 2020.

¹⁷⁸ Case C-159/08 P, *Isabella Scippaccola*.

The recent cases in the pharmaceutical sector have employed a preponderance of evidence approach,¹⁷⁹ combining several of the eight different assessment methods to create a “sanity check” on the excess and unfairness. It is nevertheless of utmost importance to note the function of comparisons and benchmarking, where the first limb serves to establish the “excess”, while under the second limb the benchmarking has the function of establishing the “unfairness”.

That is also why if there is a manifest excess found in the first limb, and as per settled jurisprudence, the excess in some cases “in itself” can be indicative of abuse, why the analysis can proceed to the second limb of “sanity check”, whether the manifest and appreciable excess is also “unfair”. Otherwise, one would have to prove the “excessiveness” of “excessiveness” which would make little conceptual sense.¹⁸⁰

The next section will connect the excessive pricing legislation with the compulsory licensing framework entailed in TRIPS, making the case that excessively priced life-saving medicines can be targeted by the compulsory licensing instrument.

¹⁷⁹ See Kianzad, “What makes a Price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law”, University of Copenhagen, 2022, Chapter 10.

¹⁸⁰ Gilo, “A Coherent Approach to the Antitrust Prohibition of Excessive Pricing by Dominant Firms”.

4. EXCESSIVE PRICING AS A RATIONALE FOR COMPULSORY LICENSING

Looking at the globally most important codification of IPRs, the TRIPS Agreement,¹⁸¹ one can note that balancing between conflicting policy interests and different *ratio legis* of intellectual property law, competition law and right to health is expressed throughout the agreement.¹⁸² Articles 7 and 8 of the TRIPS agreement firmly establishes such a balanced approach. Article 7 states:

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

The connection to public health is addressed in Article 8 of the Agreement:

“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health... , provided that such measures are consistent with the provisions of this Agreement” and further that “Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade”.

Finally, Article 40 of the TRIPS Agreement creates the legal basis for curbing anti-competitive practices arising from IPRs in licensing agreements:

“Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.”¹⁸³

The legal basis for compulsory licensing in the TRIPS Agreement is found in Article 31 on “other use without authorization of right holder”, and previously rules on compulsory licensing were also found in Article 5.A of the Paris Convention for the Protection of Industrial Property.¹⁸⁴ Generally, compulsory licensing defines a situation where the public authority grants a non-exclusive license to a third party, without the consent of the rightsholder, who retains its rights to license to others, and also the right to receive adequate remuneration.

Compulsory licensing further requires previous attempts to license on voluntary / commercial basis except in the case of government use, due judicial or administrative review with the right to appeal, and the license should be predominantly granted for the domestic market, a matter which was addressed through amendment of the TRIPS agreement (Article 31*bis*) so that countries lacking sufficient manufacturing capacity could rely on other countries having such

¹⁸¹ Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, 1869 UNTS 299; 33 ILM 1197 (1994).

¹⁸² See for European context the Joined Cases 56 and 58-64 *Établissements Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community* [1964] ECLI:EU:C:1966:41; Compare to Case C-307/18 *Generics (UK) Ltd and Others v Competition and Markets Authority*, where same principles in regard to the relationship between IPRs and Competition Law is expressed and re-affirmed.

¹⁸³ Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, 1869 UNTS 299; 33 ILM 1197 (1994), Article 40 (1) and (2).

¹⁸⁴ Paris Convention for the Protection of Industrial Property, 1883, available from <https://www.wipo.int/treaties/en/ip/paris/>, accessed 2022-02-10.

capacity to get access to pharmaceuticals.¹⁸⁵ Nevertheless, this so-called “paragraph 6 system”, has been under-used due to the barrage of requirements for both importing and exporting countries. A testament to this fact is the meagre number of cases in the twenty years since the 30 August 2003 Decision that granted a waiver later transformed in article 31bis.

Actually, the system was only used in one case in Rwanda¹⁸⁶ as importing country, notifying the TRIPS Council in July 2007, and Canada as exporting country¹⁸⁷ notifying the TRIPS Council in October 2007 of its willingness to supply a fixed-dose combination of the generic HIV/AIDS medicine ApoTriAvir.

The shipments commenced in September 2008 from the Canadian manufacturer Apotex. The system was heavily criticized for not allowing production efficiency (being on a case-by-case basis and specific quantities) and hence making it unprofitable for any potential exporter, also costing Canada a lot of money in the process.

The possibility of some developing countries to “pool together” and realize economies of scale, by requesting an exporting country to produce a medicine needed in all these importing countries is further severely limited, due to the complex rules regulating this process. According to Paragraph 3 of the Protocol amending the TRIPS agreement, in order to supply more than one country the receiving country must be a member of a WTO recognized regional trade agreement (RTA), and at least half of the countries parties to that RTA must be on the United Nations list of least developed countries. Furthermore, the country seeking to issue the compulsory license would be the main responsible for importation and re-exportation of the medicines to the other participating members of the RTA.

By contrast, using the approach envisaged below in this paper, by reference to TRIPS article 31(k), a speedier compulsory licensing process could be facilitated, given that the competition law of most WTO member States prohibits excessive pricing (this is the case in most jurisdictions around the world minus US, Canada, Mexico, Australia and New Zealand, with both Canada and Mexico prohibiting excessive pharmaceutical pricing albeit in their patent law).

But where are the boundaries of intellectual property law and competition law? A statement by the European Commission in the Council for TRIPS can be illuminating to that end, where the discussion between the members of the Council centred around a proposal by South Africa¹⁸⁸ in regard to using competition law to address and correct abuses of IPRs in the field of pharmaceuticals so as to ensure access to affordable medicines, one such abuse being charging of excessive prices.

The submission by the South African delegation which was subsequently co-sponsored by Brazil, China and India, put forth some questions to the Council on how to employ competition law in regard to perceived abuses of intellectual property rights.¹⁸⁹ This submission did not find a response from the Council as it was referred to other international bodies more concerned with competition law per se.¹⁹⁰

¹⁸⁵ Behrang Kianzad, “Excessive Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law”, in *New Developments in Competition Law and Economics*, Klaus Mathis and Avshalom Tor, eds. (Cham: Springer International Publishing, 2019), 197–220.

¹⁸⁶ IP/N/9/RWA/1 19 July 2007.

¹⁸⁷ IP/N/10/CAN/1 8 October 2007.

¹⁸⁸ “Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy - Communication from South Africa - Ip/c/w/649” (Council for Trade-Related Aspects of Intellectual Property Rights, October 29, 2018).

¹⁸⁹ “Intellectual Property and the Public Interest: Promoting Public Health through Competition Law and Policy - Communication from South Africa - Ip/c/w/649.”

¹⁹⁰ Minutes of the Meeting - Council For Trade-Related Aspects Of Intellectual Property Rights - 13 February 2019” (World Trade Organization, April 2, 2019. Available from

The European Commission, while alluding to its report released in 2019¹⁹¹ in regard to competition law issues in the pharmaceutical sector targeting abuses of IPRs, such as pay for delay and misuse of regulatory systems, stated that **“However, in the EU, there were no competition cases of excessive prices related to intellectual property rights...the European Commission has never reached the conclusion that the pricing of an innovative medicine was excessive.”**¹⁹²

This statement from European Commission is rather challenging to interpret. Is it an articulation of a policy position, i.e., that the European Commission is not inclined to pursue excessive price cases resulting from monopolist prices by an IPRs holder during their patent term, or is it to be seen as a mere statement of the facts, that hitherto there has not been any such cases purely related to excessive prices resulting from an abuse of a dominant position by way of intellectual property rights ?

As seen from the Servier and AstraZeneca cases, the Commission and the CJEU seem indeed to have taken issue with excessive pricing resulting from different practices by an originator company. As such, if the statement is made as a factual statement, one might point to numerous cases on both EU level¹⁹³ as well as on the Member State level which have dealt with abusive pricing issues related to intellectual property rights, albeit not innovative medicines as such, beyond the cited AstraZeneca and Servier cases, where the excessive pricing was a result of other practices. Recently there has also been a case surrounding excessive pricing by an orphan medicine still under IPRs protection.¹⁹⁴

Nevertheless, the TRIPS agreement explicitly elevates the matter of anti-competitive practices as grounds for limiting the exercise of the granted IPRs in order to satisfy other publicly desirable goals and values. As Article 7 regarding objectives, and Article 8 regarding principles provide for, the protection of IPRs must not collide with other economic and social considerations, and WTO members are allowed to take action to prevent abuses of IPRs, as long as these measures are consistent with the obligations set forth in the TRIPS agreement. Article 40 (1) and (2) of the TRIPS Agreement reads as follows:

**“1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2.Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member”.**

https://docs.wto.org/dol2fe/Pages/FE_Search/ExportFile.aspx?id=252827&filename=q/IP/C/M91A1.pdf. Accessed 2020-10-10.

¹⁹¹ European Commission, “Competition Enforcement in the Pharmaceutical Sector (2009-2017) – Report from the Commission to the Council and the European Parliament - Com(2019) 17 Final”, (European Commission, January 28, 2019).

¹⁹² “Minutes of the Meeting – Council for Trade-Related Aspects of Intellectual Property Rights – 13 February 2019” (World Trade Organization, April 2, 2019) , p. 55, emphasis added.

¹⁹³ Case 40-70, Judgment of the Court of 18 February 1971 in Sirena S.r.l. v Eda S.r.l. and others, ECLI:EU:C:1971:18; Case 24-67, Judgment of the Court of 29 February 1968 in Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm, ECLI:EU:C:1968:1; Case 238/87, Judgment of the Court of 5 October 1988 in AB Volvo v Erik Veng (UK) Ltd, ECLI:EU:C:1988:477.

¹⁹⁴ The Leadiant case, see Dutch Authority for Consumer and Markets, Case ACM/20/041239.

At the same time, the TRIPS agreement offers other, more effective provisions that can be utilized to ensure access to affordable essential medicines, using the competition rules entailed in articles 7, 8, 31(k) and 40(2) of the TRIPS agreement. Relying on this approach presupposes that excessive prices can be determined as an anti-competitive practice in the national legislation of the member wishing to make use of the suggested approach, in the same vein as of Article 102 TFEU.¹⁹⁵

As many developing countries have modelled their competition law in general, and the prohibition of unfair pricing in particular, as per the European competition law articulated in Article 102 TFEU, the assessment and benchmarks applied in the European context carry immense implications also in the global context, but do not limit the right of other countries to adopt different approaches.¹⁹⁶ This re-connects to the questions posed by the South African delegation when asking the TRIPS Council to offer guidance on both examples of excessive pricing approaches and appropriate benchmarks. A request which was denied by the TRIPS Council in referring to other international bodies more concerned with competition law per se.

This reluctance to debate the issue can be seen in light of the recent decade of Compulsory Licensing cases, where countries such as Germany, Switzerland, United Kingdom, Israel, Russia and US have made use of compulsory licensing under TRIPS Agreement to procure expensive treatments and therapies such as those relating to Hepatitis C. In all cases the medicines were available, but expensively priced, thus it is more a matter of anti-competitive practice of excessive pricing, than refusal to license, in those cases, even if the cases were not framed in this light.

Already in 2014 in a report by UNDP gathering scholars such as Carlos Correa and Frederick Abbot, the case was made for using the competition law flexibilities in the TRIPS agreement to promote development.¹⁹⁷ As noted by Frederick Abbott "If a pharmaceutical company has a dominant position in the market and can effectively foreclose competition, it should not be able to charge any prices it wishes."¹⁹⁸

Importantly, Article 31(k) TRIPS agreement states:

"Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be considered in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur".

Hence, there are some clear advantages with Article 31(k) of the TRIPS agreement when compared to the many and onerous obligations under Article 31(f) of the TRIPS agreement:

- 1. No need for prior negotiation with the patent holder.**
- 2. Both domestic and external markets are allowed with no restrictions on where the compulsory licensed products can be exported to.**

¹⁹⁵ This part on TRIPS flexibilities and competition law has previously been discussed in Behrang Kianzad, "Excessive Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European competition law.", 2018, Springer Verlag.

¹⁹⁶ This section is partly extracted from Excessive prices and access to medicines – Compulsory licensing as an anticompetitive remedy under the TRIPS Agreement: <http://lup.lub.lu.se/student-papers/record/5432497>.

¹⁹⁷ Abbott et al. 2014, p 35 ff.

¹⁹⁸ <http://www.ip-watch.org/2014/05/19/undp-report-promotes-competition-law-to-boost-access-to-medicines/>. Accessed 2018-06-06.

3. The need for correcting the anticompetitive practice can be taken into account in determining the remuneration paid to the patent holder, eventually nullifying the remuneration altogether.¹⁹⁹

Taken together. Articles 7, 8(2), 31(k) and 40.2 provide a solid legal argument to restrict the exercise of IPRs due to anticompetitive practice within the framework of the TRIPS agreement. This approach can be used in order to address public health issues and correct anticompetitive behaviour which harms competition and consumer welfare.

The key concept here is “anticompetitive practices” and, in this regard, treating excessive prices as such a practice, where as shown in previous sections there exists a solid case law and conceptual framework under article 102a TFEU. As noted by the OECD note on excessive pharmaceutical pricing:

“To minimise the impact of excessive pricing cases against IP protected products on innovation and investments, it was argued that agencies should take incentives to innovate into account in any competition enforcement action. As regards excessive pricing, this can be achieved by considering the probability of a medicine’s success during the research stage, or by comparing research costs or other relevant benchmarks for similar products.”²⁰⁰

This is perfectly in line with some recent doctrinal approaches,²⁰¹ where the balance between supply and demand interest (incentives to innovate and affordable access) can be reconciled, e.g., by way of QALY and HTA,²⁰² or by way of constructing a benchmark targeting Average Lifetime Earnings Standard as per the suggestion by Emanuel,²⁰³ or the Fair Pricing model suggested by Moon et al.²⁰⁴

Looking at the matter of value, as mentioned above, many factors hinder an approach alongside “willingness-to-pay” as such an approach that would ignore the characteristics of the market and the goods, namely inelastic demand, nullity of choice, buyer insensitivity, legal mandates and so on.

Interestingly, these are all matters which have been seized upon by the European competition authorities in Italy,²⁰⁵ Denmark²⁰⁶ and UK²⁰⁷ as well as the European Commission in their recent approaches to excessive pharmaceutical pricing cases handled by these authorities.

¹⁹⁹ Abbott et al., 2014, p. 51 ff; See also Kianzad, “Excessive Pharmaceutical Prices as an Anticompetitive Practice in TRIPS and European Competition Law”, 2019; and Burton Ong, *Compulsory Licensing of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines in Reto M. Hilty et al., Compulsory Licensing – Practical Experiences and Ways Forward*, 2015.

²⁰⁰ OECD, “Executive Summary of the Roundtable on Excessive Prices in Pharmaceutical Markets, DAF/COMP/M(2018)2/ANN5/FINAL”, 2018.

²⁰¹ Behrang Kianzad, *What Makes A Price (Un)Fair? Excessive Pharmaceutical Pricing in European Competition Law* (Copenhagen: Det Juridiske Fakultet, København, 2022).

²⁰² Canoy and Tichem, “Lower Drug Prices Can Improve Innovation”, September 2, 2018.

²⁰³ Emanuel, “When Is The Price Of A Drug Unjust?”.

²⁰⁴ Suerie Moon et al., “Defining the Concept of Fair Pricing for Medicines”, *BMJ*, January 13, 2020, I4726, <https://doi.org/10.1136/bmj.l4726>.

²⁰⁵ Case N. 01832/2020, Aspen, Consiglio di Stato, 13/03/2020.

²⁰⁶ Case BS-3038/2019-SHR, CD Pharma v Danish Competition and Consumer Authority, Judgement of Maritime and Commercial Court, March 2, 2020; See also Behrang Kianzad, “Temporary Dominance and Excessive Pharmaceutical Pricing – CD Pharma (Denmark)”, in *EU Competition Law and Pharmaceuticals*, Wolf Sauter, Marcel Canoy and Jotte Mulder, eds., Edward Elgar Publishing, forthcoming 2022.

²⁰⁷ Case [2020] EWCA Civ 339, Competition and Market Authority v Flynn Pharma and Pfizer, UK Court of Appeal (Civil Division), 10/03/2020.

As regards adequate remuneration paid to rights-holders under a compulsory licensing regime, there is a substantial case law as well as some guidelines on how to assess the correct level of remuneration.²⁰⁸

While the possibility²⁰⁹ to correct anticompetitive behaviour are explicit and well-established parts of the TRIPS agreement²¹⁰ and competition law can be advanced as a credible option,²¹¹ several criteria must be fulfilled before theory can be translated into practice.

First and foremost, since application of the Article 31(k) presupposes the existence of competition rules in the national legislations, which in turn would prohibit anti-competitive practices (in our case excessive prices of patented pharmaceutical products), it requires developing countries to prohibit excessive pricing under their domestic legislations, which is almost universally the case.

The grant of a compulsory license would require a two-fold analytical process. First, unless excessive pricing is considered a per-se anti-competitive practice (a possibility not excluded by the TRIPS Agreement or any other international instrument), it must be established by the competition agency that the patent holder has a position of dominance in the relevant market of the patented pharmaceutical product, and secondly, that the conduct of the patent holder is amounting to what can constitute as an abuse of such a position.²¹²

The anticompetitive practice in the context of the TRIPS Agreement can also be established if a generic company has sought, and has been denied, a voluntary license from the patent holder to address an apparent demand, as the excessive prices charged by the patent holder denies the consumer access to a needed medical product. Indeed, there have been many instances during the COVID-19 pandemic where voluntary licensing has been refused by innovator companies holding IPRs on vaccines.^{213 214}

Regarding the impact of compulsory licensing on innovation and total welfare, as noted earlier the inherent research challenges complicate a comprehensive analysis as multitude of factors interact. In one analysis offering a formal model regarding the Global South use of compulsory licensing it was shown that:

“While a compulsory license improves access to essential drugs, pharmaceutical companies believe that, if broadly used, compulsory licensing might undermine their incentives for innovation. Indeed, this is what we find. Nonetheless, the welfare effects do not necessarily go in the same direction. In fact, we have shown how welfare

²⁰⁸ James Love, “Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies”, WHO/UNDP, accessed February 9, 2022, https://apps.who.int/iris/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf; see also Maura Nuno, “A Fair Return Approach to Pharmaceutical Compulsory Licensing,” *Case Western Reserve Journal of International Law*, 2016, 22; for a criticism of the proposed approach, see Eric M Solovy and Deepak Raju, “The UNDP/WHO Remuneration Guidelines: A Proposed Formula for Inadequate Remuneration for Compulsory Licensing in Violation of the TRIPS Agreement”, *Journal of Intellectual Property Law & Practice* 16, no. 11 (November 1, 2021): 1192–1202.

²¹⁰ Burton Ong, “Compulsory Licensing of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines”, *Compulsory Licensing – Practical Experiences and Ways Forward*, in Reto M. Hilty et al., 2015, p. 246.

²¹¹ Frederick M. Abbott and Rudolf V. Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Papers (The World Bank, 2005); Abbott et al., “Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries”.

²¹² Ong 2015, p. 258.

²¹³ Jorge L. Contreras et al., “Pledging Intellectual Property for COVID-19”, *Nature Biotechnology* 38, no. 10 (October 2020): 1146–49, <https://doi.org/10.1038/s41587-020-0682-1>.

increases globally in many circumstances, which should cast a much more positive light on compulsory licensing.”²¹⁵

Finally, as noted by UNDP, the excessiveness in price of a needed medicine can be presumed if the price set by a dominant supplier “does not make the benefit of the patented invention available at reasonably affordable prices to the public”.²¹⁶ What would constitute “reasonable” and “fair” must logically remain a case-by-case exercise, although the general benchmarks and assessment method(s) should be known ex ante.

²¹⁵ Charitini Stavropoulou and Tommaso Valletti, “Compulsory Licensing and Access to Drugs”, *The European Journal of Health Economics* 16, no. 1 (January 2015): 83–94.

²¹⁶ Abbott et al. 2014, p 146.

5. FINAL REMARKS AND RECOMMENDATIONS

As it has been examined in this paper, it is of fundamental importance to recognise the limits on economic freedom that Article 102a TFEU (and its counterpart in other countries' competition regimes) imposes on dominant undertakings, following the Scholastic-Kantian tradition underlying the competition law prohibition of excessive/unfair pricing.

As noted by Carl Shapiro "Profits necessary to induce risky investments are one thing; incumbency rents are quite another."²¹⁷ This conceptual note is of fundamental importance in understanding the *ratio legis* but also *ratio oeconomica* of the prohibition against unfair / excessive pricing.

The task of competition law in this (European but also universally recognised) tradition is to distinguish between economically sound and legally valid monopolist prices (i.e. prices exceeding the competitive price in equilibrium) on the one hand; and economically harmful and legally invalid excessive prices (i.e., prices exceeding the competitive benchmark and having no reasonable connection to neither the cost structure nor economic value, with undue profit maximization as the end result).

The function of the prohibition of excessive pricing is not, and has never been, to prevent prices set above competitive levels, as high profit margins can also prevail in competitive markets, but to create a distinct border between these prices and excessive, unfair prices enabled by a dominant position and faulty market/demand/entry mechanisms.

Invoking the wording of the US Supreme Court *Trinko* judgement "monopolistic profits being what attracts business acumen in the first place" does not advance our knowledge in this context and is, as demonstrated earlier, in direct conflict with the conception of competition law in Europe and other countries that follows its legal approach regarding competition law.

Interestingly, the TRIPS agreement closely mirrors this European approach in its Article 31(k) as well as Article 40(2), alongside Articles 7 and 8 on the objectives and principles of the TRIPS Agreement, thereby promoting a mutually beneficial relationship between society and innovators.

The assertion that excessive profits are both the pre-condition and end-result of innovation does further conflict with the overarching goal of intellectual property law—which allows for the creation of a legal monopolist dominant position in the first place—and ignores how and why innovation is facilitated. Such a position also stands in conflict with basic mainstream economics supporting the view that the competitive outcome is efficient.

The grant of patent rights is a cost on the society as a whole. The cost is borne against the expectation that the result of innovation will benefit the society as a whole. The question is whether, how and to what extent intellectual property and competition law ought to take policy notions and values into account such as the right-to-health, which should inform the overall consumer welfare standard policy and approach regarding the design of those laws, beyond a strict and monolith focus on economic efficiency in the case of competition law.²¹⁸

²¹⁷ Carl Shapiro, "Antitrust in a Time of Populism", *International Journal of Industrial Organization* 61 (2018).

²¹⁸ Vitor Henrique Pinto Ido, *Designing Pro-Health Competition Policies in Developing Countries*, Research Paper No. 125, (Geneva, South Centre, December 2020). Available from <https://www.southcentre.int/research-paper-125-december-2020/>; Abbott et al., "Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries."

As noted by the Nobel Laureate in Economics, Joseph Stiglitz, in his call for new approaches to competition law:

“Over the past third of a century...the scope and effectiveness of competition policy has been narrowed, under the influence of certain ideas about the functioning of the market economy—ideas which have subsequently been widely discredited within the economics profession, but whose influence within antitrust law remains significant.”²¹⁹

This rather simple fact, i.e., the vacuity of ideas assuming the role of “conventional wisdom” in dictating the appropriate competition law and policy, seems to have been somewhat lost in the debate on the subject of competition law in general, and on excessive pricing, in particular.

This is evident from the distinctively monolithic body of commentary on excessive pricing and competition law, claiming a certain “consensus” or “conventional wisdom”, grounded on neoclassical-welfarist economic analysis of law, as opposed to the more cohabitant Law and Economics movement in the tradition of Guido Calabresi.

There is a need to vigorously challenge and reform the orthodox view emanating from the Chicago School approach to antitrust led by Robert Bork, Richard Posner et. al., a matter which was also noted on the OECD Global Competition Day in 2022, where other approaches seeking to broaden the scope of competition law and policy were discussed.²²⁰

Applying the neoclassical notion of price and value theory in its textbook form, departing from marginal price theory and equating this to the economic value centred around exchange value and exchange value only, one would never locate an excessive price. This also explains why the vast body of academic literature on excessive pricing, mostly written by neoclassical and neoliberal minded economists, are as repetitive as they are wholly irrelevant as they stand in bright contrast not only to the black letter law, but also the legal history and legal-economic philosophy underpinning the prohibition. The quoting of Trinko is the first sign of this illness.

At least not if a buyer would be willing to pay the price charged, and not at least during a significant period of time, simply because “Under conditions of perfect competition, a firm always maximizes profits (or minimizes losses) which its marginal cost equals the market price.”²²¹

There would simply not exist any durable excessive prices in such an idealized, perfect market, due to the prospect of entry by competitors who would challenge the “excessive” price if it existed in the first place. Markets with high barriers to entry (patents, considerable ex ante investments, demand-side characteristics, etc.) are not able to self-correct and the need for competition law intervention is rather manifest. Therefore, the European legal prohibition of excessive pricing has been applied rather consistently since 1971 in a wide variety of sectors.²²²

Looking at behavioural economic research and its implications for law and economics of IP law, we are further compelled to transcend the neoclassical approach to this area of law. The insights into “endowment effect”, i.e., “that the least amount of money that owners of goods

²¹⁹ Joseph Stiglitz, “Towards a Broader View of Competition Policy”, in *Competition Policy for the New Era: Insights from the BRICS Countries*, ed. Tembinkosi Bonakele, Eleanor M. Fox, and Liberty Mncube (Oxford University Press, 2017).

²²⁰ OECD Global Competition Day 2022, <https://www.oecd.org/competition/globalforum/>.

²²¹ Philip Areeda and Donald F. Turner, “Predatory Pricing and Related Practices under Section 2 of the Sherman Act”, *Harvard Law Review* 88 (75 1974): 679–733.

²²² Behrang Kianzad, “What makes a Price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law”, 2022, University of Copenhagen, Table of Cases; demonstrating that there are 27 cases on European level and another 95 cases on Member state level as located by the author. A Non-exhaustive list.

are willing to accept to part with their possessions is often far greater than the amount that purchasers would be willing to pay to obtain them"²²³ have certain implications for our understanding of the *ratio legis* and economic analysis of IP Law, as well.

As noted by Buccafusco and Sprigman on the neoclassical model "...economic theory posits that when making decisions, people rationally weigh the utility they will derive from different choices and assign monetary values to the options by anticipating the utility these choices will provide. This supposition, which has been labelled the 'rational choice model', is so fundamental to the structure of IP law that it is often simply taken for granted".²²⁴

This approach simply does not hold in the context of lifesaving, essential medicines and vaccines, where the "choice" and "utility" elements operate under entirely different dynamics as examined in previous sections. As the empirical link between higher profits and higher rate of innovation is yet to be substantiated, and since the prohibition against excessive/unfair pricing predates economics by some 2000 years,²²⁵ the normative basis for the prohibition is rather found in the inherent human aversion to unfairness in pricing,²²⁶ as well as in the Ordoliberal School and its approach to social responsibility of property.

Thus, the economic analysis of law, in its marginalist, welfarist and Chicagoan forms, cannot be de-coupled from assumptions of rationality, perfect markets, voluntary transactions and resultant supply and demand equilibrium. Therefore, such (normative) analysis is ill-suited in regard to what the optimal competition law policy should do in respect of unfair pricing, due to the one-sided focus on wealth maximization advanced as the sole purpose of the law.²²⁷

It should be noted that the very nature of lifesaving, essential medicines make such goods impossible to analyse by way of neoclassical, marginalist and welfarist perspectives. This is due to the in-elastic demand side, payer-insensitivity as the result of the public obligation relating to the provision of lifesaving medicines, as well as the intricate interaction between intellectual property law and competition law.

As aptly noted by Besen and Raskind "For as long as laws have aimed at protecting intellectual property, disputes have raged over which works to protect, for how long, and to what extent."²²⁸ The law and economic policy governing intellectual property rights, requires a delicate balancing of competing interests and trade-offs.

The spirited disagreements regarding if economic efficiency or equity should guide competition law enforcement are perhaps nowhere more prevalent than in the area of excessive pricing. Even more so, in the context of the pharmaceutical sector, where patients rarely have a choice (making the demand-side inelastic) and do not pay out of pocket (due to

²²³ Christopher J. Buccafusco and Christopher Jon Sprigman, "The Creativity Effect", *SSRN Electronic Journal*, 2010, <https://doi.org/10.2139/ssrn.1631900>.

²²⁴ Christopher J. Buccafusco and Christopher Jon Sprigman, "Valuing Intellectual Property: An Experiment", *Cornell Law Review* 96, no. 1 (2010), <https://doi.org/10.2139/ssrn.1568962>.

²²⁵ Watkins, "The Law and the Profits".

²²⁶ Ernst Fehr and Klaus M. Schmidt, "Chapter 8 The Economics of Fairness, Reciprocity and Altruism – Experimental Evidence and New Theories", in *Handbook of the Economics of Giving, Altruism and Reciprocity*, vol. 1 (Elsevier, 2006), 615–91; Daniel Kahneman, Jack L. Knetsch, and Richard H. Thaler, "Fairness as a Constraint on Profit Seeking: Entitlements in the Market", *The American Economic Review* 76, no. 4 (1986): 728–74; Robert Piron and Luis Fernandez, "Are Fairness Constraints on Profit-Seeking Important?", *Journal of Economic Psychology* 16, no. 1 (March 1995): 73–96; Robert J. Bies, Thomas M. Tripp, and Margaret A. Neale, "Procedural Fairness and Profit Seeking: The Perceived Legitimacy of Market Exploitation", *Journal of Behavioral Decision Making* 6, no. 4 (December 1993): 243–56.

²²⁷ Richard A Posner, "Utilitarianism, Economics, and Legal Theory". *The Journal of Legal Studies* 8, no. 1 (1979).

²²⁸ Stanley M Besen and Leo J Raskind, "An Introduction to the Law and Economics of Intellectual Property", *Journal of Economic Perspectives* 5, no. 1 (February 1, 1991): 3–27.

universal healthcare coverage in most OECD-countries),²²⁹ or simply lack the resources to pay as it is the situation in low and middle income countries.

Indeed, despite the re-occurring criticism in the neoclassical, marginalist, and welfarist law and economics literature, both the European Commission as well as EU Member States and their competition authorities have time and again demonstrated their commitments to apply the law against excessive/unfair pricing of pharmaceuticals.

The United Brands judgement further refers to the fact (or hope) that economists will have a role to play to develop a more coherent test for excessiveness in the future. The often repeated notion that there would exist some form of conceptual consensus "among economists" and the proposition that the *ratio legis* of the prohibition against excessive pricing would be "economically flawed" is rather exaggerated and another sign of the chronic illness plaguing much of academic literature on competition law in this context.²³⁰

In the words of David Gilo "The rhetoric regarding reluctance of competition authorities to enforce the prohibition of excessive pricing by dominant firms is surprising, given the ultimate aim of antitrust law of preventing precisely this occurrence".²³¹

Indeed, the matter of mergers, margin squeeze, predatory pricing, the ban against cartels and price fixing have all the same object, preventing undue wealth transfer from consumers to undertakings through gaming of the competitive process and "unfair business practices" – a matter highlighted not only in European competition law, but also in US Antitrust Law.²³²

The intricacies of the pharmaceutical markets is another element complicating the legal and economic analysis of excessive pricing. As noted by the European Commission in its 2018 submission to OECD on the matter of excessive pharmaceutical pricing, the demand-side inelasticity and the payment being made on the part of health systems under pressure to reimburse even highly costly medicines for patients, negate the strict static competition analysis, making the pharma sector "more prone to unfair pricing practices or concerns than other sectors."²³³

On the matter of whether the sector regulation would preclude competition law enforcement, the settled case law of European Union shows that this is not the case. In fact, competition law is the necessary complementary tool where regulation fails or is faulty, depending on a myriad of factors, with the regulator being unable or "captured" being a prime example. As also noted by Giorgio Monti, there is a need to:

"challenge the restrictive vision embraced by the courts not by lamenting the degeneration of EU competition law, but by showing that instances when competition agencies raise concerns about excessive prices are less rare than assumed, not any more difficult to bring than other kinds of antitrust action, and do not necessarily require the agency to act as a price regulator. Rather, cases of excessive prices are instances where the application of competition law responds to, or helps to shape, the regulatory framework"²³⁴

²²⁹ The Single Payer System has a high willingness to pay (due to collective preferences and the right to health creating both a legal obligation and public pressure.

²³⁰ Jenny, "Abuse of Dominance by Firms Charging Excessive or Unfair Prices".

²³¹ Gilo, "A Coherent Approach to the Antitrust Prohibition of Excessive Pricing by Dominant Firms".

²³² John B Kirkwood and Robert H Lande, "The Fundamental Goal of Antitrust: Protecting Consumers, Not Increasing Efficiency", *Notre Dame Law Review* 84, no. 1 (2008): 55.

²³³ European Union, "Excessive Pricing in Pharmaceutical Markets - Note by the European Union - OECD Roundtable on Excessive Pharmaceutical Pricing - DAF/COMP/WD(2018)112", November 23, 2018, para 15.

²³⁴ Giorgio Monti, "Excessive Pricing: Competition Law in Shared Regulatory Space", (Tilburg University Working Paper, 2018), accessed February 2, 2021, <https://www.tilburguniversity.edu/sites/default/files/download/Monti%20Excessive%20pricing.pdf>.

This approach could have been applied to suspected cases of excessive pricing of lifesaving, essential medicines and treatments during COVID-19,²³⁵ provided a set of requirements such as dominance (as per European competition law), a sound law and economics assessment of excessiveness and unfairness as well as other aspects of the intersection of IPRs and competition law are present.

Economic theory is not monolithic, and judges are increasingly aware of this fact. Although economic theories rightly influence a body of jurisprudence concerned with the economic behaviour of undertakings and its impact on society in general, there are other law and policy interests at stake as well.

As stated by the European Commission on the interaction between economic theories and the legal discipline:

“... it should be made clear that economic theory cannot be the only factor in the design of policy for several reasons. Firstly, strict economic theory is just one of the sources of policy. In practice, the application of economic theory must take place in the context of the existing legal texts and jurisprudence. Secondly, economic theories are necessarily based on simplifying assumptions often obtained in the context of stylised theoretical models that cannot take into account all the complexities of real-life cases.”²³⁶

Seen against the above, it would be counter-intuitive if the developing countries would opt for a restrictive approach to excessive pricing enforcement and the granting of compulsory licensing against manifest abuses of IPRs. To combat the problem of access to medicines, compulsory licensing (alongside voluntary licensing, patent pools, etc.) has been advanced as one solution, though hitherto mainly discussed from the human rights and right to health perspectives. Less attention has been focused on excessive prices of patented medicines as an anticompetitive practice in and of itself, and how competition law and legal-economics theories and models can inform this deadlocked issue.

Such a treatment of excessive prices under competition law would provide a sound legal basis for anti-competitive enforcement through compulsory licensing but also make other tools available to competition authorities such as retroactive fines, where such are allowed in the respective jurisdiction. This could be done by making use of the flexibilities entailed in this regard in the TRIPS agreement, mainly through article 31(k) in accordance with national competition laws.

Based on the above analysis, the following law and policy recommendations relating to compulsory licensing based on excessive pricing can be made:

- First and foremost, in order to be able to ground compulsory licensing for anti-competitive practices, provisions relating to excessive pricing constituting an abuse must be provided in the national law. Further, a set procedural steps including right to appeal, and a sound law and economics assessment must underpin the decision to grant a compulsory license.
- Secondly, despite the longstanding doctrinal adversity to prohibition of excessive pricing, it has not been heeded by neither competition authorities, nor courts tasked

²³⁵ For a general treatment of excessive pricing and price gouging during COVID-19 pandemic, see: Behrang Kianzad, “The Giant Awakens - Law and Economics of Excessive Pricing during COVID-19 Crisis”, in *Law and Economics of the Coronavirus Crisis: New Developments in Competition Law and Economics*, Klaus Mathis and Avshalom Tor, Springer, eds. forthcoming 2022; see also Behrang Kianzad, “Excessive Pricing during the COVID-19 Crisis in the EU: An Empirical Inquiry”, *Concurrences* 2021, no. 1 (February 15, 2021).

²³⁶ European Commission, “Green Paper on Vertical Restraints in EC Competition Policy - COM (96) 721 Final”, January 22, 1997, https://europa.eu/documents/comm/green_papers/pdf/com96_721_en.pdf.

with applying the law “as is”, in the tradition of *de lege lata*. Looking at recent pharmaceutical excessive pricing cases in the European Union, there is a vast and rich source of law and economics approaches to the calculation of excess and the allocation of costs and profits, as well as regarding how excessiveness and unfairness could be defined in such cases.

- Thirdly, as the developing world represents a meagre 10-20 per cent of the pharmaceutical companies main markets, enforcement against excessive and unfair pricing in such countries is not capable of jeopardizing overall investments in pharmaceutical R&D, as their markets will never be able to allow those companies to recoup R&D investments in the first place, and theoretically the products could be licensed away to generic companies. There are further few empirical causal links found between increased profitability and an increase in R&D activity.
- Fourthly, the TRIPS Agreement as well as the Doha Declaration on the TRIPS Agreement and Public Health manifestly require a balance between the protection of IPRs and other objectives such as the protection of public health and, hence, the protection of IPRs must be pursued in a manner conducive with social interests. In this perspective compulsory licensing is the most apt approach when time is an issue and there is no or little room for voluntary negotiations.
- Fifthly, sector regulation does not preclude competition law enforcement.²³⁷ In case of “public goods”, such as water,²³⁸ energy²³⁹ and life-saving medicines, an approach to value by way of willingness-to-pay as the core determinant of value stand in bright contrast to both law and logic, as such approach would negate demand-related issues such as inelasticity, nullity of choice as well as other public rationales such as public authority legal obligations, e.g. regarding affordable healthcare.
- Sixthly, an approach departing from welfare economics views of competition law simply does not hold in the context of lifesaving, essential medicines, where the “choice” and “utility” elements operate under entirely different dynamics. The envisaged approach in the present paper is perfectly in line with some recent doctrinal approaches, where the balance between supply and demand interest (incentives to innovate and affordable access) can be reconciled, e.g. by way of QALY and HTA,²⁴⁰ or by way of constructing a benchmark targeting Average Lifetime Earnings Standard as per the suggestion by Emanuel,²⁴¹ or the Fair Pricing model suggested by Moon et al.²⁴²

²³⁷ Behrang Kianzad, “The Limits of Control – Competition law versus Sector Regulation in the wake of the European Commission Excessive Pricing Decision in Aspen,” *European Competition and Regulatory Law Review (CORE)*, October 2022.

²³⁸ See German Competition Authority report on enforcement in the drinking water sector, Bundeskartellamt, “Bericht Über Die Großstädtische Trinkwasserversorgung in Deutschland”.

²³⁹ Marc van der Woude, “Unfair and Excessive Prices in the Energy Sector”, *European Review of Energy Markets* 2, no. 3 (May 2008); See also Marco Botta and R. Karova, “Sanctioning Excessive Energy Prices as Abuse of Dominance: Are the EU Commission and the National Competition Authorities on the Same Frequency?”, in *Abuse of Dominance in EU Competition Law*, ed. Pier Parcu and Giorgio Monti (Edward Elgar Publishing, 2017).

²⁴⁰ Canoy and Tichem, “Lower Drug Prices Can Improve Innovation”, September 2, 2018; See also Behrang Kianzad, “What is an unfair price for medicine? Excessive pharmaceutical pricing as an anti-competitive practice in European competition law”, presenting a unique model relating to definition of unfairness in light of the United Brands, Phd Dissertation, November 2022.

²⁴¹ Emanuel, “When Is The Price Of A Drug Unjust?”

²⁴² Moon et al., “Defining the Concept of Fair Pricing for Medicines”; See also Behrang Kianzad, “What Makes a price (un)Fair? Excessive Pharmaceutical Pricing in European Competition Law”, Phd dissertation, 2022, and here a detailed model for assessment of excessive and unfair pharmaceutical pricing is offered.

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International Environment House 2
Chemin de Balexert 7-9
POB 228, 1211 Geneva 19
Switzerland

Telephone: (41) 022 791 8050
E-mail: south@southcentre.int

Website:
<http://www.southcentre.int>

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