Drug prices, patents and access to life-saving medicines: *changes are urgently needed in the COVID-19 era*

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by Olga Gurgula*

Abstract

When patented life-saving drugs are inaccessible to patients due to high prices it is evident that the system does not perform its intended function and urgently requires reforming. The paper discusses the evidence recently revealed by the US House Committee on Oversight and Reform that directly contradicts pharmaceutical companies' traditional argument justifying strong patent protection as a vehicle for recouping their R&D investments. It further suggests that structural and comprehensive changes are necessary, including a rigorous investigation into pharmaceutical pricing and patenting practices, ensuring adequate access to the drugs developed with public funds, and assuming the responsibility for public health by governments.

Introduction

The topic of access to affordable medicines has been in the spotlight since the beginning of the COVID-19 pandemic.[1] It is, however, far from new. The inability to provide sufficient access to essential medicines has been traditionally the problem of developing countries.[2] In recent years it has become a critical issue for developed countries as well.[3] The world's wealthiest countries are increasingly

* Dr Olga Gurgula (PhD, LLM) is a Lecturer in Intellectual Property Law at Brunel Law School, Brunel University London. She is also a Visiting Fellow at the Oxford Martin Programme on Affordable Medicines, University of Oxford. Email: Olga.Gurgula@brunel.ac.uk

1 See e.g. Graham Dutfield, 'Coronavirus: it is morally indefensible for a nation to keep life-saving drugs for itself' (*The Conversation*, 1 July 2020) <https://theconversation.com/coronavirus-it-is-morally-indefensible-for-a-nation-to-keep-life-saving-drugs-for-itself-141734> accessed 28 November 2020; Ana Santos Rutschman, 'How 'vaccine nationalism' could block vulnerable populations' access to COVID-19 vaccines' (*The Conversation*, 17 June 2020) <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689> accessed 28 November 2020; UNITAID 'The Medicines Patent Pool and Unitaid respond to access efforts for COVID-19 treatments and technologies' (3 April 2020) <https://unitaid.org/news-blog/medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/#en> accessed 28 November 2020; Chris Morten and Alex Moss, 'Could a patent get in between you and a Covid-19 test? Yes' (*The Guardian*, 20 May 2020) <https://www.theguardian.com/commentisfree/2020/may/20/coronavirus-patents-testing-us-senate> accessed 28 November 2020; Achal Prabhala and Ellen 't Hoen, 'We'll find a treatment for coronavirus – but drug companies will decide who gets it' (*The Guardian*, 15 April 2020) <https://www.theguardian.com/commentisfree/2020/apr/15/coronavirus-treatment-drug-companies> accessed 28 November 2020.

2 WHO, 'Access to medicines: making market forces serve the poor' (2017) <https://www.who.int/publications/10-year-review/chapter-medicines.pdf> accessed 28 November 2020.

3 Aaron S Kesselheim *et al.,* 'The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform' (2016) 316 (8) JAMA 858.

suffering from high drug prices, which puts significant pressure on national healthcare budgets, forcing governments to reconsider their policies in this field. In 2017, the UK National Institute for Health and Care Excellence ('NICE') rejected palbociclib, a drug that slows the progression of advanced cancer, because it was too expensive: a full course of treatment was set at £79,650.[4] It was only after intense negotiations and significant public pressure that Pfizer agreed to lower the price.[5] Similarly, NICE rejected Orkambi, the cystic fibrosis drug, because the price set by its manufacturer Vertex Pharmaceuticals was unaffordably high (£104,000 for a yearly treatment per patient).[6] This caused a tremendous public outcry, leading to three-year-long negotiations that eventually culminated in a deal the terms of which remain confidential.[7] In the US, the situation is no better. Last year, the US FDA approved Zolgensma, a gene therapy developed by Novartis for spinal muscular atrophy, the leading genetic cause of death in infants. The price of the one-time treatment has been set by Novartis at a record $2.125 million, triggering debates about the escalating costs of prescription drugs and access in the US.[8]

This problem of access to affordable medicines stems from a severely distorted system of innovation and access. In theory, the robust system of medical innovation seeks to maintain a delicate balance between private and public interests. It is designed to balance between, on the one hand, the private interests of innovators by stimulating them to engage in innovation and allowing them to recoup R&D investments, and, on the other hand, public interests by providing timely and affordable access to effective life-saving medicines for patients. When the balance is struck at the right level, the system provides sufficient incentives for pharmaceutical companies to engage in genuine innovation that produces new breakthrough medicines, while ensuring timely access for patients at an affordable price. However, for the last several decades the system has been failing to produce the intended results. The pipeline of breakthrough medicines is sharply declining,[9] while the prices for new and existing medicines are constantly rising, making essential medicines inaccessible for millions of people around the world.[10] These deficiencies of the current system prompted various calls from governments,

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4 'Breast cancer drug costs too high in relation to benefits for routine NHS funding' (NICE, 03 February 2017) <https://www.nice.org.uk/news/article/breast-cancer-drug-costs-too-high-in-relation-to-benefits-for-routine-nhs-funding> accessed 28 November 2020.

5 Robert Hart, 'Drugs are too expensive for the NHS – and people are paying with their lives' (*The Guardian*, 20 December 2017) <https://www.theguardian.com/science/2017/dec/20/drug-giants-hefty-prices-nhs-vital-medication-pharma-profits> accessed 28 November 2020.

6 Sarah Boseley, 'NHS England agrees price for 'unaffordable' cystic fibrosis drug' (*The Guardian*, 24 October 2019) <https://www.theguardian.com/society/2019/oct/24/nhs-england-vertex-agrees-price-for-orkambi-unaffordable-cystic-fibrosis-drug> accessed 28 November 2020.

7 'NHS England concludes wide-ranging deal for cystic fibrosis drugs' (NHS, 24 October 2019) <https://www.england.nhs.uk/2019/10/nhs-england-concludes-wide-ranging-deal-for-cystic-fibrosis-drugs/> accessed 28 November 2020; Lizzie Roberts, 'Cystic fibrosis 'wonder drug' to be provided on the NHS after three-year fight' (*The Telegraph*, 24 October 2019) <https://www.telegraph.co.uk/news/2019/10/24/cystic-fibrosis-wonder-drug-provided-nhs-three-year-fight/> accessed 28 November 2020.

8 Nat Biotechnol Editorial 'Gene therapy's next installment' (2019) 37 Nat Biotechnol 697.

9 Fabio Pammolli *et al*, 'The Productivity Crisis in Pharmaceutical R&D. Nature reviews' (2011) 10(6) Drug Discovery 428; Jack Scannell *et al*, 'Diagnosing the decline in pharmaceutical R&D efficiency' (2012) 11(3) Nature Reviews 191; Donald W Light and Joel R Lexchin 'Pharmaceutical R&D - What Do We Get for All That Money?' (2012) 345(7869) BMJ 22.

10 WHO, 'Ten Years in Public Health, 2007-2017. Access to Medicines: Making Market Forces Serve the Poor' (2017) ('Nearly 2 billion people have no access to basic medicines, causing a cascade of preventable misery and suffering') <https://www.who.int/publications/10-year-review/chapter-medicines.pdf? ua=1> accessed 28 November 2020; WHO 'Access To Medicines, Vaccines And Pharmaceuticals. Technical Report. Pricing of cancer medicines and its impacts' (2018) ('In the absence of insurance coverage, cancer treatment is unaffordable for many patients…Even

international organisations, civil society and academics that are aimed at controlling prices, facilitating access and stimulating genuine innovation.[11] However, no tangible changes in the operation of this system have occurred.

When life-saving drugs are inaccessible to patients due to exorbitantly high prices, and when the development of new medicines is on the decline, it is evident that the system does not perform its intended function and urgently requires changes. The aim of this article, therefore, is to discuss the roots of the problem in the current system of medical innovation and access to medicines, and to provide certain recommendations on how this issue can be resolved. It will start with the rationale of the existing system of innovation, explaining the justification for strong patent protection traditionally put forward by pharmaceutical companies, and the effect it has on drug prices. It will then discuss recent evidence produced by the US House Committee on Oversight and Reform that was gathered during its two-year investigation into pricing practices of pharmaceutical companies, which was revealed during its hearings in September/October 2020. The Committee's evidence directly contradicts pharmaceutical companies' traditional argument justifying strong patent protection as a vehicle for recouping their R&D investments. The article will further explain why it is crucial to urgently solve the problem of effective medical innovation and access to affordable medicines, as well as providing some recommendations on how to improve the operation of the system. These include more rigorous attention to pricing and patenting practices by pharmaceutical companies, ensuring adequate access to medicines developed with the use of public funding, and assuming the responsibility for public health by governments, instead of exclusively relying on private pharmaceutical companies. It is believed that these recommendations will allow enhanced accessibility to medicines, stimulate genuine innovation, and will enable countries to ensure timely and affordable access to life-saving medicines, including for COVID-19.

1. Why are drugs so expensive?

The ability to charge high prices on medicines stems from the legal protection provided by intellectual property rights, and patents in particular. Patents provide exclusive rights to their owners. This means that patent holders have the right to prevent others from using their patent-protected invention, and thus control the manufacture and distribution of such products, including their prices.[12] While patents often lead to unaffordably high prices, pharmaceutical companies claim that they need strong patent protection to recoup their investments in R&D.[13] The traditional argument put forward by

with insurance coverage, patients living with cancer in many countries have reported financial stress, to the extent that they may lower the treatment dose, partially fill prescriptions or even forego treatment altogether') <https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf> accessed 28 November 2020; Sachiko Ozawa *et al.* 'Access to medicines through health systems in low- and middle-income countries' (2019) 34(3) Health Policy and Planning iii1.

11 The United Nations Secretary-General's High-Level Panel On Access To Medicines Report, 'Promoting Innovation and Access to Health Technologies' (2016) 22 <http://www.unsgaccessmeds.org/final-report> accessed 28 November 2020.

12 Carlos M. Correa**,** **'**Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents' (April 2020) Research Paper 107, The South Centre 13.

13 European Commission, 'Pharmaceutical Sector Inquiry Final Report' (8 July 2009) para 253 citing EFPIA ('Given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation') <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.> accessed 28 November 2020; IFPMA Statement on the 'Solidarity Call to Action to realize equitable global access to COVID-19

pharmaceutical companies is that there will be no incentives to engage in R&D of important life-saving drugs if there is no strong patent protection.[14] To support this claim they typically refer to industry figures placing the cost of developing a single drug above $2.6 billion.[15] To incentivise pharmaceutical companies to innovate, the patent system in Europe and the US provides a broad opportunity for strong patent protection by setting a low bar for patentability.[16] This enables them to procure numerous patents around a single medicine, thus prolonging its protection well beyond the expiration of a primary patent that protects its active ingredient.[17]

While relying on patents to extract a competitive edge is not a new practice,[18] Walsh *et al.*, reviewing the studies in the field of strategic patenting, argue that the last several decades have shown a significant increase in patenting,[19] with a growing emphasis on strategic or pre-emptive patents. Such patents are

health technologies through pooling of knowledge, intellectual property and data' (28 May 2020) <https://www.ifpma.org/resource-centre/ifpma-statement-on-the-solidarity-call-to-action-to-realize-equitable-global-access-to-covid-19-health-technologies-through-pooling-of-knowledge-intellectual-property-and-data/> accessed 28 November 2020.

14 ibid; Thomas Cueni, 'Intellectual property is not a hindrance but a help to end Covid-19' (*The Financial Times*, 17 May 2020) ('Now, of all times, is not the moment to undermine IP. It would create uncertainty and send the wrong message to pharma companies that have taken risks on huge investments to repurpose medicines for Covid-19 treatment and scale up manufacturing') <https://www.ft.com/content/e82dd07c-95c5-11ea-899a-f62a20d54625> accessed 28 November 2020; see also, the response to this letter by Ellen 't Hoen, 'Letter: Finding a treatment for Covid-19 is linked to IP (*The Financial Times*, 20 May 2020) ('The IP monopoly pharmaceutical model has served the industry and its shareholders well, but is not the model to deliver the products now needed to respond to the Covid-19 pandemic') <https://www.ft.com/content/d6d258e2-9a86-47fd-949d-14784b585063> accessed 28 November 2020.

15 Avorn J, 'The $2.6 billion pill - methodologic and policy considerations' (2015) N Engl J Med 372:1877-9. doi:10.1056/NEJMp1500848 pmid:25970049; EFPIA, 'The Pharmaceutical Industry in Figures. Key Data 2018' (2018) 6 <https://efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf> accessed 28 November 2020; Salomeh Keyhani *et al*, 'Do Drug Prices Reflect Development Time and Government Investment?' (2005) 43(8) Medical Care 753, 753; PHARMA, 'The High Cost Of Inventing New Drugs – And Of Not Inventing Them' (2015) <http://www.fromhopetocures.org/the-high-cost-of-inventing-new-drugs-and-of-not-inventing-them> accessed 28 November 2020; Joseph. A. DiMasi *et al.*, 'Innovation in the pharmaceutical industry: New estimates of R&D costs' (2016) 47 Journal of Health Economics 20, 26; See, however, Wouters et al., 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018' (2020) 323(9) JAMA 844, ('the median capitalized research and development investment to bring a new drug to market was estimated at $985.3 million …, and the mean investment was estimated at $1335.9 million … in the base case analysis').

16 Christopher M. Holman *et al*., 'Patentability Standards for Follow-On Pharmaceutical Innovation' (2018) 37(3) Biotechnology Law Report 131,133 (arguing that the current permissive patentability standard is set to provide this incentive to the pharmaceutical industry by providing means of protecting its investments); Christopher M. Holman, 'In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination' (2017) 50 Ind. L. Rev. (2017) 759, 781; Eric M. Solovy and Pavan S. Krishnamurthy, 'TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines' (2017) 50(1) Geo. Wash. Int'l L. Rev. 69; Benjamin N. Roin, 'Unpatentable Drugs and the Standards of Patentability'(2009) 87 Tex. L. Rev. 503; Robert Merges, 'Uncertainty and the Standard of Patentability' (1992) 7(1) High Tech. L.J. 1 (suggesting 'a moderate lowering of patentability standards for very high-cost research').

17 European Commission, 'Pharmaceutical Sector Inquiry Final Report' (n 13), para 486; IMAK, 'Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices' (2018) 3 <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> accessed 28 November 2020; Mark A. Lemley, 'Expecting the Unexpected' (2017) 92 Notre Dame L. Rev. 1369, 1393 ('later-filed patents on enantiomers, delayed-release versions, and other modifications of existing drugs arguably do more harm than good to society. They permit a practice known as "evergreening" – making minor modifications to existing drug patents in order to avoid facing generic competition as the basic patent on a drug expires').

18 Richard J. Gilbert, 'Patents, sleeping patents, and entry deterrence' (1987) 17 J. Reprints Antitrust L. & Econ. 205; Kurt M. Saunders, 'Patent nonuse and the role of public interest as a deterrent to technology suppression' (2001) 15 Harv. J. Law Technol. 389.

19 John Walsh *et al*., 'Win, lose or draw? The fate of patented inventions' (2016) 45(7) Res. Policy 1-2.

filed with strategic purposes to block competitors, creating protection around a technology.[20] This could be observed in the pharmaceutical industry, where a low bar for patentability coupled with the strategic motives by pharmaceutical companies has led to a significant increase in patenting in the pharmaceutical industry.[21] The European Commission found during its Pharmaceutical Sector Inquiry that while before the 1980s pharmaceutical companies tended to protect their products by one patent,[22] nowadays they move towards broader and more numerous patents[23] 'surrounding the first patents of a successful compound and its product in order to protect their position'.[24] Several recent studies provide evidence of the abusive nature of strategic patenting by pharmaceutical companies. The IMAK analysis of the top blockbusters in the US reveals that '[f]our of the top twelve drugs have already been on the market for 20 years and have pending patent applications seeking to extend patent life to 2033 (Herceptin, Genentech), 2030 (Rituxan, Biogen/Genentech), 2029 (Enbrel, Amgen), and 2025 (Remicade, Janssen)'.[25] They conclude that 'patents are used by drug makers for the purpose of forestalling generic competition while continuing to increase the price of these drugs'.[26] Another study found that 'pharmaceutical companies are recycling and repurposing old [drugs].[27] On average, '78% of the drugs associated with new patents were not new drugs coming on the market, but existing drugs' and that '[a]dding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once'.[28]

Such extensive patent protection enables pharmaceutical companies to prevent competition for a significant period and to continue charging monopoly prices for their products, making them inaccessible for many patients.[29] To date, a lack of transparency as to how the pharmaceutical profits are spent has not allowed us to fully examine the justifications for such strong patent protection put

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20 Walsh *et al.* (n 19) 3 ('A significant share of non-commercialized patents is used for preemption, with 34% for "Blocking other firms" and 23% for "Preventing inventing around'); similarly, Paola Giuri *et al,* 'Inventors and invention processes in Europe' (2007) 36 Res. Policy 1107, 1119 (found that 'large firms use 50% of their patents internally… and about 40% are not used. More than half of the unused inventions aim at blocking competitors').

21 Carlos M. Correa, 'Pharmaceutical innovation, incremental patenting and compulsory licensing' (South Centre, 2011) Research Papers 41, 7; Amy Kapczynski et al., 'Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents' (2012) 7 (12) PLOS ONE. 1; Carsten Fink *et al.*, 'Exploring the worldwide patent surge' (2013) WIPO Economic Research Working Paper No. 12 <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_econstat_wp_12.pdf> accessed 28 November 2020.

22 European Commission, 'Pharmaceutical Sector Inquiry Final Report' (n 13), para 486.

23 ibid.

24 ibid, para 487.

25 IMAK, 'Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices' (2018) 3 <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf> accessed 28 November 2020.

26 ibid 2.

27 Robin Feldman, 'May Your Drug Price Be Ever Green' (October 29, 2017) UC Hastings Research Paper No. 256, 3 <https://ssrn.com/abstract=3061567> accessed 28 November 2020.

28 ibid.

29 European Commission, 'Pharmaceutical Sector Inquiry Final Report' (n 13) 201, para 525; UNCTAD, 'The role of competition in the pharmaceutical sector and its benefits for consumers' (2015) TD/RBP/CONF.8/3, 7; María José Abud *et al*, 'An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile' (2015) 10(4) PLoS ONE, 2; Cynthia M. Ho,'Should All Drugs Be Patentable?: A Comparative Perspective' (2015) 17 (2) Vanderbilt Journal of Entertainment & Technology Law 29, 314.

forward by pharmaceutical companies.[30] Recent developments, however, shed light on the internal processes of price setting by some of the leading pharmaceutical companies and provide fresh insights on the strategies they use to protect their revenue streams.

2. New insights into the pharmaceutical companies' pricing practice

The 'skyrocketing' prices of medicines have prompted the investigation in the US by the House Committee on Oversight and Reform, which held its first hearing on 30 September 2020 with top executives of major drug companies to examine their pricing practices for some of the most expensive drugs in the US.[31] The Committee cited a recent report, which found that 'drug companies have raised the list prices of more than 600 single-source brand name drugs by a median 21.4% between January 2018 and June 2020'.[32] At the hearing, the representatives of the pharmaceutical industry were arguing that the increases in drug prices were necessary to fund R&D research, and any cap on price increases would stifle innovation. Some of the members of the Committee even suggested prolonging the term of patent protection to incentivise pharmaceutical innovation.[33]

However, the evidence uncovered during a two-year investigation by the Committee, that has reviewed internal documents of a number of pharmaceutical companies, suggests a completely different picture. One of the drugs investigated by the Committee is Copaxone, a drug used in the treatment of multiple sclerosis produced by Teva. The price of Copaxone was increased 27 times since its launch in 1997.[34] As a result 'the price of an annual course of Copaxone 20 mg/ml has jumped from $9,230 in 1997 to $85,368 today.'[35] The investigation by the Committee showed that while Teva has made more than $34 billion from Copaxone, it spent only 2% of that profit on R&D expenditures.[36] Teva also could not report any single R&D expenditure that took place after 2015, and yet there have been multiple price increases since 2015.[37]

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30 Steven G Morgan *et al*., 'Pricing of pharmaceuticals is becoming a major challenge for health systems' (2020) BMJ 2020;368:l4627 ('Manufacturers do not disclose their research and development costs, however, when claiming that high prices are needed to recoup investments. Instead, they often cite hypothetical average drug development costs based on opaque, self-reported data') <https://www.bmj.com/content/368/bmj.l4627> accessed 28 November 2020.

31 The Committee on Oversight and Reform U.S. House of Representatives hearings 'Unsustainable Drug Prices: Testimony from the CEOs (Part I)' (30 September 2020) <https://www.youtube.com/watch?v=om7mvkQ8P0Q&feature=youtu.be> accessed 28 November 2020.

32 Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid' (September 2020) <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf> accessed 28 November 2020.

33 The Committee on Oversight and Reform U.S. House of Representatives hearings 'Unsustainable Drug Prices: Testimony from the CEOs (Part I)' (n 31).

34 Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Teva—Copaxone' (September 2020) 1 <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf> accessed 28 November 2020.

35 ibid.

36 ibid 43.

37 ibid.

Another drug under investigation is Revlimid, a critical drug for treating multiple myeloma and other forms of cancer.[38] It was manufactured by Celgene, until in 2019 the company was acquired by Bristol Myers Squibb (BMS). The documents revealed that since the launch of this drug in 2005, the price was raised 22 times, from $215 per pill to $719 per pill. After BMS obtained the rights to Revlimid in 2019, it raised its price again to $763 per pill.[39] As a result, a monthly course of Revlimid in the US is currently priced at $16,023.[40] The company's internal communications showed that pricing decisions were driven almost exclusively by the need to meet company revenue targets and shareholder earnings goals.[41] Among the practices that the company employed to protect and extend its market monopoly is strategic patenting. The first patent protecting the active ingredient in Revlimid was filed by Celgene in 1996 and expired in October 2019.[42] This would potentially mean that from the date of patent expiration, generic companies would be able to enter the market, leading to a reduction of prices for the patients. However, Celgene has filed an astonishing 196 patent applications on Revlimid in the US, 109 of which have been granted.[43] These multiple patents, according to the Initiative for Medicine, Access, and Knowledge, will enable Celgene to extend its monopoly until at least 2026 and will directly increase US health care costs by $45 billion.[44] This is appalling especially given that the company did not invent the active ingredient in Revlimid. The drug's origins begin in the 1950s from the infamous thalidomide, a medicine prescribed for treating morning sickness during pregnancy that caused serious birth defects.[45] The Committee found that while the company earned more than '$53 billion in net worldwide revenue from Revlimid since 2005, the company contributed very little to the science first establishing that drugs like Revlimid could be an effective treatment for multiple myeloma'.[46] It also revealed that Celgene 'benefited from the acquisition of a decades-old product, academic and non-profit research, and at least eight federally funded studies'.[47] The Committee concluded that 'its internal pricing decisions appear to have been unrelated to past or future investment in research and development.'[48]

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38 Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid' (September 2020) <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf> accessed 28 November 2020.

39 ibid, 1.

40 ibid.

41 ibid, 7.

42 ibid 22.

43 Tahir Amin, 'Celgene didn't invent Revlimid. But it has made billions from overpatenting' (*Medium*, 1 October 2020) <https://medium.com/@tahir_5675/celgene-didnt-invent-revlimid-but-it-has-made-billions-from-overpatenting-7b71876ad0> accessed 28 November 2020.

44 'Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid' (n 38) 22; Initiative for Medicine, Access, and Knowledge, 'America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices' (25 October 2017) <https://www.i-mak.org/americas-overspend/> accessed 28 November 2020.

45 Tahir Amin, 'Celgene didn't invent Revlimid. But it has made billions from overpatenting' (*Medium*, 1 October 2020) <https://medium.com/@tahir_5675/celgene-didnt-invent-revlimid-but-it-has-made-billions-from-overpatenting-7b71876ad0> accessed 28 November 2020.

46 'Drug Pricing Investigation Celgene and Bristol Myers Squibb—Revlimid' (n 38) 24.

47 ibid, 25.

48 ibid, ii. Similar conclusions have been reached by other studies. See e.g. WHO 'Access To Medicines, Vaccines And Pharmaceuticals. Technical Report. Pricing of cancer medicines and its impacts' (n 10) ('the analysis suggests that the costs of R&D and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines. Pharmaceutical companies set prices according to their commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine. This pricing approach often makes cancer medicines unaffordable, preventing the full benefit of the medicines from being realized.'); Aaron Berman *et al*, 'Curbing Unfair Drug Prices, A Primer for States' (2017) Yale Global Health Justice Partnership Policy Paper 3 ('Evidence has unequivocally shown that high drug prices are not linked to the actual costs of research, development and manufacturing. Instead, inflated drug prices are a result of drug manufacturers' power to charge whatever price

Similar conclusions were revealed by the Commission in relation to other life-saving drugs under their investigation.[49] This includes, for example, the cancer drug Gleevec owned by Novartis. The company has raised the price of the drug 22 times since launching its 400 mg tablet in 2003.[50] This has resulted in an increase of more than 395%, from $25,000 in 2003 for a yearly course to more than $123,000 today.[51] Along with other aggressive practices that were aimed at maintaining its market exclusivity, Novartis strategically exploited the patent system by filing for multiple patents around Gleevec active ingredient imatinib,[52] suing for patent infringement[53] and striking pay-for-delay agreements with generic companies.[54] As with other life-saving medicines under investigation, the Commission concluded that Novartis' pricing decisions were not intended to recoup R&D expenditures,[55] but were 'based on meeting revenue goals, particularly as the drug approached the loss of its patent exclusivity.'[56]

The evidence uncovered by the Committee directly contradicts the traditional argument put forward by pharmaceutical companies that strong patent protection and the ability to set high drug prices is necessary to recoup their investments into R&D. On the contrary, it shows that the patent system is used strategically to prevent competition and extend market monopoly for as long as possible, enabling pharmaceutical companies to charge excessive prices on life-saving medicines well beyond their R&D investments 'to meet company revenue targets and shareholder earnings goals'.[57] Moreover, such practices often relate to inventions that were developed by public institutions and with the support of

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the market will bear') <https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf> accessed 28 November 2020; Steven G Morgan *et al*., 'Pricing of pharmaceuticals is becoming a major challenge for health systems' (2020) BMJ 2020;368:l4627 ('In addition to the potential for bias in such data, average estimates are not specific to any company's case for the price of a particular drug. Furthermore, the trend towards developing more specialised drugs—particularly orphan drugs—implies that many new drugs are being approved based on smaller trials and, consequently, lower development costs').

49 For example, in relation to the two drugs marketed by Amgen, i.e. Enbrel (used in treatment of rheumatoid arthritis and other painful inflammatory diseases) and Sensipar (used in treatment the effects of kidney failure and parathyroid cancer) (Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Amgen—Enbrel and Sensipar' (October 2020) i <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf> accessed 28 November 2020; see also the Committee's findings in relation to Acthar Gel, a drug used in treatment a rare infant seizure disorder, marketed by Mallinckrodt (Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Mallinckrodt—H.P. Acthar Gel' (October 2020) <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Mallinckrodt%20Staff%20Report%2010-01-20%20PDF.pdf > accessed 28 November 2020.

50 Staff Report Committee on Oversight and Reform U.S. House of Representatives, 'Drug Pricing Investigation Novartis—Gleevec' (October 2020) i <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Novartis%20Staff%20Report%2010-1-2020.pdf > accessed 28 November 2020.

51 ibid.

52 ibid 18 ('According to experts at the Initiative for Medicines, Access, and Knowledge, Novartis has filed a total of 73 patents related to Gleevec. Out of 29 granted patents, 28 are secondary patents, covering alternative forms of the same drug such as the formulation of the drug and methods of treatment.)

53 ibid 19. This led to a class action lawsuit alleging that Novartis was engaging in sham litigation (Class Action Complaint, *United Food and Commercial Workers Union v. Novartis*, Case 1:15-cv-12732-ADB (filed 6/22/2015) <https://www.wexlerwallace.com/wp-content/uploads/2016/08/Gleevec-Antitrust-Litigation-Class-Action-Complaint.pdf> accessed 28 November 2020.

54 'Drug Pricing Investigation Novartis—Gleevec' (n 50) 18.

55 ibid 32.

56 ibid 4.

57 ibid, i.

public funding.[58] While this fact should, in theory, facilitate access to life-saving medicines and make them more affordable to patients, in reality, this is not the case. Instead, the design of the current system of medical innovation and access to medicines places a unilateral control over access to life-saving medicines into the hands of private pharmaceutical businesses. As a result, the system, the initial aim of which is to facilitate genuine innovation and access, in fact provides ample opportunities for its strategic exploitation for the benefit of private corporations and to the detriment of public interests. As this system does not produce its intended results with the declining breakthrough innovation and inaccessible life-saving drugs, it is evident that it requires urgent changes.

3. Policy recommendations to improve access to medicines in the COVID-19 era

The current system of medicinal innovation and access to medicines has been failing to fulfil its intended purposes for decades. Yet, what is disturbing today is that we are relying on this very system to provide the solution to the global COVID-19 pandemic by developing breakthrough medicines and providing affordable and equal access worldwide.[59] Billions of people across the globe are eagerly waiting for new medicines that will be able to cure and prevent the further spread of this coronavirus. These therapies must not only be safe and effective, they must also be distributed at an affordable price to all. With respect to the latter, there is a justifiable fear that the system that has been incapable of producing adequate access to medicines in the past will not be able to ensure the affordability and equitable access to COVID-19 medicines worldwide.[60] As pharmaceutical companies are currently in a race to develop COVID-19 treatment and vaccines,[61] they are also actively patenting the results of their research.[62] These patents will provide private pharmaceutical companies with full control over access. This is even though the research and development of the COVID-19 medicines have been

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58 Steven G Morgan *et al*., 'Pricing of pharmaceuticals is becoming a major challenge for health systems' (2020) BMJ 2020;368:l4627 ('Cited costs of drug development also fail to acknowledge the critical role of public and non-profit financing of research and development'); Galkina Cleary E *et al*., 'Contribution of NIH funding to new drug approvals 2010-2016' (2018) 115(10) Proc Natl Acad Sci USA, DOI:10.1073/pnas.1715368115 (this study found that the US National Institutes of Health contributed an average of $839m for basic or applied research for each of the 210 first-in-class drugs approved in the US between 2010 and 2016); Dzintars Gotham *et al*., 'Pills and profits. How drug companies make a killing out of public research' (2017) Global Justice Now 9.

59 Olga Gurgula and Wen Hwa Lee, 'COVID-19, IP and Access: Will the Current System of Medical Innovation and Access to Medicines Meet Global Expectations?' (2021) forthcoming in the Journal of Generic Medicines <https://ssrn.com/abstract=3771935>.

60 See references in (n 1); Achal Prabhala and Ellen 't Hoen, 'We'll find a treatment for coronavirus – but drug companies will decide who gets it' (n 1) (' …there is every indication that treatments for coronavirus may soon emerge, the mere fact of their existence is no guarantee that people will be able to access them. In fact, Covid-19 is more likely to end in the same way that every pandemic ends: treatments and vaccines will be buried in a thicket of patents – and pharmaceutical companies will ultimately make the decisions about who lives and who dies').

61 'Covid-19 Vaccine Tracker' (as of the time of writing 237 vaccines are in development and 40 are now in clinical testing) <https://www.covid-19vaccinetracker.org/> accessed 29 November 2020; 'Covid-19 Treatment And Vaccine Tracker' <https://milken-institute-covid-19-tracker.webflow.io/#vaccines_intro> accessed 29 November 2020.

62 Cynthia Koons, 'The Vaccine Scramble Is Also a Scramble for Patents' (*Bloomberg,* 12 August 2020) <https://www.bloomberg.com/features/2020-covid-vaccine-patent-price/> accessed 29 November 2020; Achal Prabhala and Ellen 't Hoen, 'We'll find a treatment for coronavirus – but drug companies will decide who gets it' (n 1).

heavily supported by public funding.[63] As a result, while governments transfer billions to pharmaceutical companies, they have failed to establish proper control over access to such medicines, remaining dependent on private business and the decisions of their shareholders. This, in turn, may significantly impact on the affordability and equitable distribution of COVID-19 therapeutics and we are starting to experience this effect today.[64]

The new reality we are living in today demands the new rules. The current pandemic has exposed a fundamental failure of our system, calling us to reconsider approaches to access to COVID-19 medicines, as well as putting a new perspective on access to life-saving drugs in general. It is, therefore, crucial that practices that were tolerated in the past are restricted, and more stringent control is undertaken. In particular, practices that enable pharmaceutical companies to unjustifiably extend their market monopoly and continue charging unaffordable prices should be rigorously investigated. This includes such practices as strategic patenting[65] and other patent-related strategies that prevent competition.[66] Competition authorities should be more active in pursuing these practices. Moreover, the bar for patentability of pharmaceutical inventions may need to be reconsidered, setting it at a level which would, on the one hand, provide pharmaceutical companies with sufficient incentive to engage in genuine innovation, while on the other hand, preventing the patenting of trivial modifications of existing drugs that are aimed at extending market monopoly.[67] Furthermore, where a medicine was developed with the support of public funds, strict safeguards must be put in place, which would ensure that its further commercialisation takes into account, first and foremost, public interests in accessibility and affordability of such a medicine. Such public funding and terms of commercialisation of the result of publicly funded research must be transparent and available for monitoring by independent authorities and civil society.[68]

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63 See e.g. James Love, 'DARPA letter to KEI confirming investigation of Moderna for failure to report government funding in patent applications' (*KEI*, 18 September 2020) < https://www.keionline.org/33970> accessed 29 November 2020; Donato Paolo Macini, 'US government's Darpa probes Moderna's vaccine patents' (*The Financial Times*, 29 August 2020) ('Researchers accuse biotech company of failing to disclose federal grants in patents which also cover Covid-19 candidate') <https://www.ft.com/content/2be1f87e-9e96-4e23-9cc5-33ba35e50586> accessed 29 November 2020; The Public Citizen, 'The Real Story of Remdesivir. Taxpayers are spending at least $70.5 million to develop the drug' (2020) (explaining that 'Remdesivir, an experimental COVID-19 treatment, has benefited significantly from public funding'. Despite this the patents protecting remdesivir are owned by Gilead> <https://www.citizen.org/article/the-real-story-of-remdesivir/> accessed 29 November 2020.

64 Miles Johnson *et al*, 'Moderna cuts deliveries to Italy and France in new blow to EU vaccination plans' (*The Financial Times*, 29 January 2021) < https://www.ft.com/content/bb514eed-3be8-411a-b1c4-255dc569bae5> accessed 06 February 2021.

65 Olga Gurgula, 'Strategic Patenting by Pharmaceutical Companies: Should Competition Law Intervene?' (2020) 51 IIC - International Review of Intellectual Property and Competition Law 1062.

66 Duncan Matthews and Olga Gurgula, 'Patent Strategies and Competition Law in the Pharmaceutical Sector: Implications for Access to Medicines' (2016) 38 European Intellectual Property Review 661.

67 Lemley (n 17) 1370; European Commission, 'Pharmaceutical Sector Inquiry Final Report' (n 13), para 1324 ('in those cases where such patent applications, if granted, could serve to prolong the income stream from a medicine well beyond the expiry of the original patent protection, it is crucial that such an application be scrutinised very carefully and that a patent be awarded only where a true inventive contribution is made'); Olga Gurgula, The '"Obvious to Try" Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines' (2019) South Centre, Policy Brief 59 <https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf> accessed 28 November 2020.

68 Dzintars Gotham *et al.,* 'Pills and profits: How drug companies make a killing out of public research' (2017) Global Justice Now 11.

Finally, and more fundamentally, the current global pandemic has exposed our pervasive dependence on private pharmaceutical companies. While in some sectors of the economy this may be appropriate, it has become obvious today that the protection of public health, especially during pandemics and with regards to life-threatening diseases, cannot be solely dependent upon private companies. There is no doubt that pharmaceutical companies undertake an important role in the healthcare system. However, we must not forget that they are profit-oriented businesses, the main goal of which is to increase their revenues for the benefit of their shareholders. While these companies should be encouraged and motivated to continue engaging in genuine innovation, they should not be the only solution in ensuring access to essential medicines, but rather merely be a part of it. It is time for the state to assume its responsibility for the protection of public health, treating it as a matter of national security. Therefore, governments should urgently reconsider the healthcare system by designing a new model of innovation with a more open and collaborative approach, as well as by establishing designated infrastructures for drug research, development and production.[69] This will allow the state to finally resume control over the issue of access to life-saving drugs, as well as ensuring our full preparedness for the pandemics of the future.

Conclusions

Access to life-saving medicines has been a matter of significant concern for several decades. Millions of people worldwide have been denied access to essential medicines due to their excessive prices. While in the past this was mainly the problem of developing countries, today developed countries suffer from an inability to provide their populations with sufficient access to medicines as well. The existing system, which is intended to encourage genuine innovation and ensure access, instead creates pharmaceutical monopolies. This allows private pharmaceutical companies to perpetuate their market exclusivity by acquiring multiple patents around a single medicine and controlling access to such medicines. While the development of many life-saving medicines is undertaken by public institutions and supported by public funding, private companies retain control over access to such medicines and are able to charge high drug prices, making them inaccessible to many. With the COVID-19 pandemic threatening the lives of thousands of people every day, our pervasive dependence on private pharmaceutical companies has become apparent. It is clear today that the current system requires fundamental changes in the way medicinal innovation is conducted, as well as how access to life-saving medicines is secured. Therefore, structural and comprehensive changes will help to facilitate genuine innovation and access to affordable medicines to all. This should include a rigorous investigation into pharmaceutical pricing and patenting practices, ensuring adequate access to the drugs developed with public funds, as well as assuming the responsibility for public health by governments, making pharmaceutical business part of the solution, rather than the only solution.

[69] Olga Gurgula and Wen Hwa Lee (n 59).