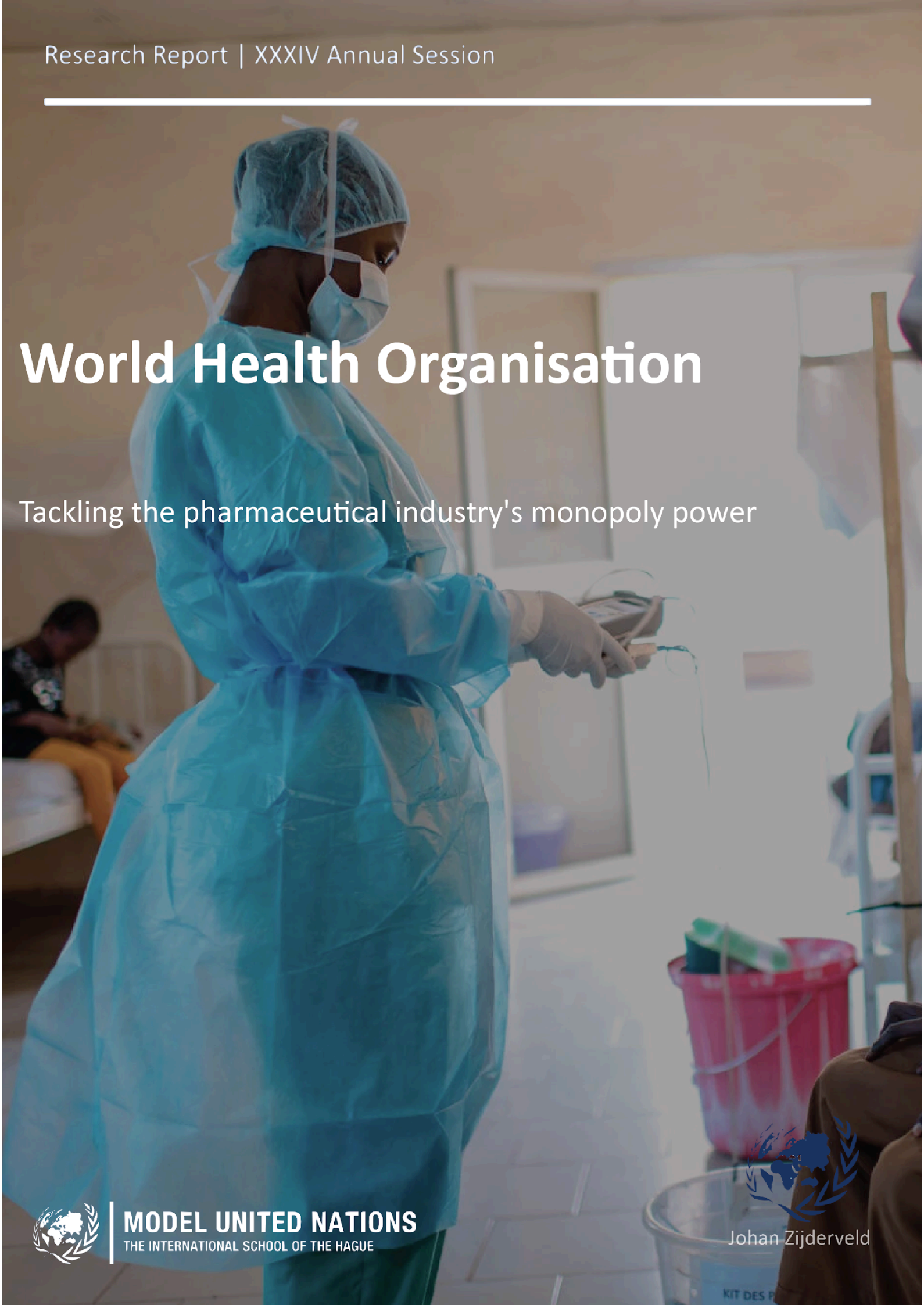

World Health Organisation

Tackling the pharmaceutical industry's monopoly power

MODEL UNITED NATIONS
THE INTERNATIONAL SCHOOL OF THE HAGUE

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Forum	World Health Organisation
Issue:	Tackling the pharmaceutical industry's monopoly power
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Introduction

Tackling the pharmaceutical industry's monopoly power is an enormous issue when it comes to global health. Businesses naturally want to maximise the profits earned in any industry, including the pharmaceutical industry. Even though the pharmaceutical industry thrives on saving people's lives, saving lives is often not profitable. As such, many companies have increased their profits by keeping a monopoly on their products. Finding solutions to this issue may prove challenging due to the nature of needing funding whilst also requiring accessible prices.

The pharmaceutical industry, which has an estimated value of over $1.5 trillion USD, plays a vital role in world health by developing, manufacturing and even distributing medical products in order to save lives worldwide. The industry contains high levels of research and development (R&D), with major companies such as Pfizer, Roche, Johnson & Johnson and Novartis leading the pack. Due to the industry's major contributions during the COVID-19 pandemic, the importance of the pharmaceutical industry has been further underlined in recent years; it is expected to grow significantly in value over the coming decade.

Monopoly power in the pharmaceutical industry alludes to the control over a specific drug or type of drug by one or more companies. The control given to these companies is often due to their exclusive right given by a patent, which allows them to keep the methods of production of the drug confidential. These monopolies are done by companies to reduce competition and prolong increased market share. These exclusive rights to their products enable companies to have high prices for their products without competition, negatively affecting healthcare providers as well as patients in need of these medications.

These monopolies have a profound impact on global health due to healthcare pricing and decreased access to medicines. The increased prices due to monopolies often decrease availability of these essential drugs for a considerable amount of people, particularly in less economically developed countries (LEDC). Take insulin for example, a drug required for diabetes management; it has a high cost leaving 25% of patients reporting there to be a price barrier, even though commercial production began in 1923. Furthermore, these monopolies can further limit the availability of essential, lifesaving drugs in regions where medicinal supplies are already scarce, hindering efforts to achieve global health.

Tackling this issue is essential to increase global health by means of increasing availability for all peoples, especially in LEDCs. Monopolies impose a financial burden on already established health care systems and decrease availability of essential medical products for those in need. Effective solutions should lead to decreased drug prices, whilst not imposing on the supply, allowing for increased availability of these medical products, thereby increasing public healthcare globally.

Definition of Key Terms

Monopoly

The exclusive control by a party over the manufacturing of a service or product, facilitating control over the price and supply of said product or service.

Pharmaceutical industry

The segment of the economy allocated towards medicines.

Intellectual Property (IP) rights

Legal rights, granting control over creations to the creators of original works, such as inventions, symbols, gastronomic products etc.

Patents

A type of IP granting the inventors of products with the right to refrain from sharing details of the creation of their products, typically around 20 years.

Generics

Medications that have the same method of production as that of the branded medication, usually sold at a lower price.

Biosimilars

Biological products which are practically identical to an original product made by a different company, these are made after the patent expires.

Compulsory licencing

A government policy which lets another body manufacture a patented product without consent from the patent holder.

Patent pooling

An alliance between two or more companies agreeing to cross-license patents, usually relating to a specific type of technology.

Orphan drugs

Treatments made in order to treat rare diseases or conditions affecting fewer than 200,000 people, which are often not profitable due to a small number of patients.

Price gouging

The practice of raising prices of essential goods or services to unreasonably high levels.

Evergreening

The practice of making minor modifications to an existing drug in order to renew the patent on the product.

Patent thickets

A multitude of patents on a single product, allowing for IP rights for a greater period.

General Overview

The impact of monopoly power has caused a multitude of smaller issues over the years. However, solving these issues will not be as straightforward due to the dilemma between the requirements of businesses and that of individual patients. Member states should consider both of these requirements in finding solutions to these issues.

High medical prices

The prices of medical treatments have been noticeably high when considering them as essential goods. This can largely be related to IP rights and more specifically patents. These patents allow for companies to create temporary monopolies (usually 20 years) over products which they have developed. For drugs, this creates a lack of generic drugs and biosimilars to act as competition, even after the R&D costs are made back. Furthermore, some companies participate in evergreening, allowing them to renew a patent on the existing product. Extending patents may be done through minor modifications to the drug; combining existing drugs to create a new one; finding new uses for the same drug; reformulations of the drug (for example: from a pill to an injectable form) and patent thickets, where multiple patents are given to the same product.

An example of patent thickets is Humira, used to treat autoimmune diseases; 247 patent applications have been filed for it. These patents allow the manufacturer of Humira to prevent competition from entering the market for 39 years, instead of the usual 20 years. This also allowed for the doubling of the average spending on Humira per person from $16000 to $33000 USD between 2012 and 2016. This monopoly alone has been estimated to cost US payers and taxpayers an excess of $14.4 billion USD. On top of that, 89% of the total patent applications were filed after the drug was first patented and on the market.

Another drug seeing high prices is insulin, with 25% of users seeing a price barrier, not allowing them to use it. This is largely due to the insulin market being dominated by three companies: Eli Lilly, Sanofi, and Novo Nordisk. Without any other competition, these companies have been excessively price gouging this product. It should be noted that the costs of one vial of insulin can rise to upwards of 100 times the manufacturing costs.

Access to medicines

It is important to note that these high medical costs have major impacts on the accessibility of medical treatment. Higher prices often make medical treatment unaffordable for individuals in LEDCs as well as countries with limited healthcare budgets. Moreover, monopolies on medical products can lead to a decrease in availability of these medical products in rural areas, due to there being little need for them in the area. Market exclusivity, due to companies only providing in certain markets, can also lead to a delay in availability of life saving medication in LEDCs. Take hepatitis C medications for example, which have particularly low availability in LEDCs. The high costs of branded medicines as well as diagnostic tests have led to low availability for many lower income patients. These disparities in accessibility due to the level of economic development, have contributed significantly to health inequities around the globe.

Innovation vs access

Even though all these issues arise from these monopolies causing high drug prices, it is important for member states to note that this allows for increased innovation in the pharmaceutical industry. Patents are necessary to incentivise pharmaceutical innovation as they insure returns on research and development investments, essentially allowing for a profitable business model. In the pharmaceutical industry, there tends to be high costs of innovation, as development and testing of new products requires a significant financial investment and time. Thus, the difficulty is balancing the innovation versus the access of pharmaceutical products. There must be an incentive to create new products, yet these products must still be accessible to as many people as possible.

This issue is particularly noticeable with orphan drugs. Being drugs which are inherently rare in use, these become even less profitable than large scale medical products. Many governments already provide incentives to pharmaceutical companies for the creation of such products, such as tax credits, grant funding and market exclusivity extensions. The United States of America (USA) provides 7 years of market exclusivity for approved orphan drugs and the EU offers ten years. Often these small patient populations lead to exceedingly high prices for companies to make returns on their R&D investments. An example of this can be seen in spinraza, used to treat spinal muscular atrophy, where costs for the first year of treatment are estimated at $805,000 USD and $380,000 USD per year thereafter.

Regulatory challenges

Whilst patents incentivise companies to innovate, they can also directly lead to challenges of availability. There are often variations in legal enforcement of patents across different countries and as a result, products may only come to light in certain countries where there are greater benefits in IP rights. On top of that, applications and approvals of patents often take lengthy amounts of time, delaying the products' market entry. Furthermore, certain countries require compulsory licences allowing for local generic production. For example, Thailand's compulsory licences for cancer drugs. Nevertheless, market exclusive rights given to companies can prevent the creation of generics even after the patent expires.

Case studies of monopoly power and its effects

There are some specific cases where access to medicinal products was limited due to monopoly power over specific products.

EpiPen pricing

EpiPens are an emergency treatment for severe allergic reactions. From 2007 to 2016 the price of EpiPens increased by over 400%, from around $100 USD to $600 USD for a two-pack. This was largely due to Survival Technology Inc., the manufacturer of EpiPens, having little competition due to its patent protection. However, in this particular case, there was a public outcry on the matter due to harsh backlash and criticism, they were forced to introduce a generic version, although the branded version was still used at a high price.

HIV/AIDS drug pricing

In the early 2000s, antiretroviral drugs (ARVs), which treated HIV/AIDS, were remarkably expensive, costing up to $10,000 per patient per year. Pharmaceutical companies had patents on ARVs, prohibiting any generic versions of ARVs to be manufactured, thus monopolising the product. In turn, this ensured that prices were kept high, limiting accessibility in LEDCs. This contributed to millions of deaths from HIV/AIDS, especially in sub-Saharan Africa. This led to an outcry of global campaigns, like Médecins San Frontières (MSF) and the Clinton Health Access Initiative. Due to this, compulsory licensing of ARV was enforced, allowing for generic versions of ARV to hit the market, causing the prices of branded ARV to drop.

Major Parties Involved

World Trade Organisation

The World Trade Organisation (WTO) is an organisation run by member governments overseeing global trade. WTO creates agreements to facilitate international trade between all 164 member states. Whilst the organisation tends to focus on trade, rather than health affairs, the WTO affirms that businesses are allowed the rights to monopolies in article VIII of the General Agreement on Trade in Services (GATS), given that there is clear transparency under article II of GATS. As such, the WTO stands for monopoly rights, given that they are consistent with its transparency policies.

World Health Organisation

The World Health Organisation (WHO) is an organisation run by the United Nations (UN) aiming to aid with global health. WHO as an organisation wishes to promote global health efforts with methods including but not limited by tracking diseases; aiding with access to medicines through transportation to locations where medicines are scarce; and creating treaties and resolutions to enable governments to aid their public health. As such, the WHO aims to end the abuse of monopoly power, ensuring that there is access to medicines globally.

Médecins Sans Frontières

MSF, French for doctors without borders, is an international non-government organization which provides medical humanitarian aid around the world. It is an organisation with nearly 68,000 members of staff, providing medical assistance to those in need in 75 countries. MSF is firmly against all abuses of monopoly power within the pharmaceutical industry.

Pfizer Inc.

Pfizer is among the largest pharmaceutical companies globally. They have innovated a large number of medications including Lipitor, Viagra, and the COVID-19 vaccine. They have had issues with lawsuits in the past due to alleged fraud, misbranding and unspecified side effects of its drugs. Pfizer as a company also tends to keep prices high if possible, has been subject to underhanded patent practices, and has kept market control for essential medications.

Roche F. Hoffmann-La Roche AG

F. Hoffmann-La Roche AG, often called Roche, is another company among the largest pharmaceutical innovators around the world. It is the largest investor in pharmaceutical research and development, developing products for: cancer treatment, for virus diseases and metabolic disease. Roche has been found price gouging in order to increase its profits.

Gilead Sciences Inc.

Gilead Sciences is another large pharmaceutical innovator globally. It created products such as Truvada and Harvoni used to treat HIV as well as Remdesivir used to treat COVID-19. Whilst being one of the largest innovators, it has been criticised for keeping high prices and abusing patent extensions.

Novartis

Novartis is a major company in the pharmaceutical industry, creating innovations as well as generics through its Sandoz division. Whilst Novartis is a medical company which is only sold on prescription, it has been known to keep high prices for drugs such as Gleevec. Novartis has developed cardiovascular treatments, oncological treatments (such as Gleevec), respiratory disease treatment, etc.

Teva Pharmaceutical Industry Ltd.

Teva is one of the largest generic drug manufacturers globally. They provide cheaper generic versions of many essential drugs including but not limited to injectable drugs for cancer, treatments for respiratory conditions, like asthma and treatments for the central nervous system. As such, Teva is largely against monopolies in the pharmaceutical sector.

Mylan N. V.

Mylan is another large provider of generic medications. Mylan has merged with Upjohn, a division of Pfizer. Similarly to Teva, they provide cheaper generic versions of essential drugs and medications. Mylan is responsible for generic versions of products such as: the EpiPen, ARV, treatments for epilepsy, nasal sprays etc. Similarly to Teva, Mylan relies on innovations of other companies, and as such is against monopolies.

Timeline of Key Events

Date	Description of event
January 4th, 1983	The Orphan Drug Act is adopted by the United States, incentivising the creation of treatments of rare diseases. Despite this, it left much to be desired regarding regulations on monopoly power.
April 15th, 1994	The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed, setting the bar for standard of intellectual property regulations, which include pharmaceutical patents.
January 1st, 1995	The General Agreement on Trade in Services Rights (GATS) was adopted by the WTO. Article VIII of which affirms monopoly rights given certain specifications of transparency.
May 10th, 2001	Novartis released Gleevec, a new cancer drug, at a high price ($26000 USD annually).
November 14th, 2001	The Doha Declaration is signed, affirming WTO member states to prioritise public health and access to medicines for all peoples.
May 4th, 2007	Brazil creates a compulsory licence for ARVs, setting a precedent for this compulsory licence.
September 20th, 2015	Turing Pharmaceuticals acquires a drug called Daraprim and increases its price from $13.50 USD to $750 USD overnight.
August 25th, 2016	Survival Technology Inc faces harsh criticism after increasing prices of EpiPens by five times in fewer than 10 years.
December 23rd, 2016	Spinraza is launched at $750,000 USD for the first year of treatment, alarming concerns of the affordability of orphan drugs.
March 12th, 2020	COVID-19 pandemic causes lockdowns globally, this emphasises the need for global cooperation in the development of treatment, also leading to initiatives such as COVAX.

UN involvement, Relevant Resolutions, Treaties and Events

- Patent Cooperation Treaty, 19 June 1970 (PCT)
- Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994 (TRIPS)
- The General Agreement on Trade in Services, 1 January 1995 (GATS)
- Doha Declaration on the TRIPS agreement and public health, 14 November 2001 (WT/MIN(01)/DEC/2)
- Enhancing capacity-building in global public health, 17 November 2003 (A/RES/58/3)
- Global strategy and plan of action on public health, innovation and intellectual property, 24 May 2008 (WHA61.21)
- Global health and foreign policy, 14 March 2013 (A/RES/67/81)
- Transforming our world: the 2030 Agenda for Sustainable Development, 25 September 2015 (A/RES/70/1)
- Addressing the global shortage of medicines and vaccines, 28 May 2016 (WHA69.25)
- Improving the transparency of markets for medicines, vaccines, and other health products, 28 May 2019 (WHA72.8)
- Universal health coverage: moving together to build a healthier world, 10 October 2019 (A/RES/74/2)

Previous Attempts to solve the Issue

Orphan Drug Act

The orphan drug act, adopted by US congress in 1983, was an act which incentivised the production of orphan drugs. This was done through increasing tax benefits for companies which produce such drugs, as well as prolonging the patent length. These incentives led to an increase in production of orphan drugs, such as Gleevec and Spinraza. Nevertheless, the increased benefits from the act led to unreasonable prices and elongated the time without generic versions of the drugs. As such, the Orphan Drug Act failed to properly address the pharmaceutical industry's monopoly power, rather it increased it at the cost of more innovations.

Doha Declaration

The Doha declaration was an addition to the TRIPS agreement; the declaration aimed to ensure access to medicines globally and affirmed support for compulsory licensing to combat monopoly power within the pharmaceutical industry. Clause 2 of the declaration explicitly states that access to medicines for all is a right all member states should have. The declaration affirmed the importance of public health over that of commercial interest. Moreover, it allowed for a clear legal path for such member states to implement compulsory licences, as seen with Thailand earlier in this report. Furthermore, it lowered the expectations for LEDCs as they may not be able to comply with these clauses due to lack of finance.

This attempted solution to the issue did still come with limits. The first being that many countries are reluctant to implement compulsory licensing due to economic pressures from the pharmaceutical industry. Furthermore, the declaration's language is vague, this means it can be up for interpretation, hence, different member states had different interpretations of the policies involved. This can be seen with clause 5c, where what constitutes a 'national emergency' is up for interpretation of the member states. Moreover, the compulsory licences involved may not even allow for sufficient supply of generic drugs or medication as the manufacturers have found little to gain from supplying to small markets. Even though the Doha declaration pushed the effort for global health forward, it left much to be desired when it comes to directly tackling the issue at its core.

Possible Solutions

One possible solution to this issue is to enforce a price limit on each product, relative to the cost of manufacturing. Such a solution would impose a price limit on each product, as such the products would become affordable for people in LEDCs. However, according to economic theory, this would require subsidies on the products to compensate for lower revenue on the producer side. As such, this solution would require large investments from governments around the world. Moreover, orphan products already tend to lead to deficits due to little return on research and development investments hence, implementing these price ceilings on all pharmaceutical products would not lead to a suitable outcome. Perhaps the resolution could incorporate this policy into products with high consumption rates.

Implementing compulsory licensing to companies which produce generics may be another possibility. Having generic versions of every medical product would allow for other companies to produce at a lower price as they do not need to return on research and development investments. However, this too may come at the expense of incentive of innovation; it is imperative that incentives are maintained whilst decreasing monopoly power. It is possible to incentivise innovation through means outside of fiscal policies, such policies may include tax credits, tax abatements, low interest rates, etc. Accessibility in LEDCs and rural areas is also a great concern in this issue. Possible resolutions may ensure that given quantities of products are within a given distance of homes, or that travel to locations with necessary medication is accessible to all peoples in order to ensure global health.

Enforcing regulations on patents, ensuring they are issued only once for new discoveries is another noteworthy solution. The creation of a committee enforcing patent regulation, setting up consequences for attempted abuses such as mentioned earlier in the report would allow for the rewards for life saving innovations to be justified and not handed off to slight modifications of existing products. Furthermore, initiating patent pooling may aid to improve access and decrease monopoly power as there will be multiple bodies with the ability to create the same product. It is important to note the importance of international cooperation, as if one member state does not agree with given solutions, this may cause issues with accessibility in that member state due to differences in policies causing differences in profit for businesses.

Bibliography

Ali, Salamat, et al. "Improving Access to the Treatment of Hepatitis c in Low- and Middle-Income Countries: Evaluation of a Patient Assistance Programme." *International Journal of Clinical Pharmacy*, Nov. 2020, https://doi.org/10.1007/s11096-020-01202-1. Accessed 14 June 2024.

Bayoumi, Ahmed M., et al. "Cost-Effectiveness of Newer Antiretroviral Drugs in Treatment-Experienced Patients with Multi-Drug Resistant HIV Disease." *Journal of Acquired Immune Deficiency Syndromes (1999)*, vol. 64, no. 4, Dec. 2013, pp. 382–91, https://doi.org/10.1097/QAI.0000000000000002. Accessed 12 June 2024.

BBC. "Drug Company Stung by Criticism of 'Outrageous' EpiPen Price Rises." *BBC News*, 25 Aug. 2016, www.bbc.com/news/blogs-trending-37179158. Accessed 11 June 2024.

Cassier, Maurice, and Marilena Correa. "Nationalizing Efavirenz: Compulsory Licence, Collective Invention and Neo-Developmentalism in Brazil." *Nationalizing Efavirenz: Compulsory Licence, Collective Invention and Neo–Developmentalism in Brazil*, Feb. 2023, p. 6, https://shs.hal.science/halshs-03975575/document. Accessed 10 June 2024.

CBS News. "EpiPen Price Hike Controversy: Mylan CEO Heather Bresch Speaks out - CBS News - Norah O'Donnell Interview." *Cbsnews.com*, 27 Jan. 2017, www.cbsnews.com/news/epipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out/. Accessed 11 June 2024.

Cockburn, Iain. *THE ECONOMICS of INTELLECTUAL PROPERTY INTELLECTUAL PROPERTY RIGHTS and PHARMACEUTICALS: CHALLENGES and OPPORTUNITIES for ECONOMIC RESEARCH*. WIPO, www.wipo.int/edocs/pubdocs/en/wipo_pub_1012-chapter5.pdf. Accessed 7 June 2024.

Crawford, Serena. "The Price of Insulin: A Q&a with Kasia Lipska." *Medicine.yale.edu*, 27 Apr. 2023, medicine.yale.edu/news-article/the-price-of-insulin-a-qanda-with-kasia-lipska/. Accessed 11

June 2024.

Dickson, Sean, et al. “Estimated Changes in Insulin Prices and Discounts after Entry of New Insulin Products, 2012-2019.” *JAMA Health Forum*, vol. 4, no. 6, American Medical Association, June 2023, pp. e231430–30, https://doi.org/10.1001/jamahealthforum.2023.1430. Accessed 11 June 2024.

EPO. “The Role of Patents in the Pharmaceutical Sector | Epo.org.” EPO, 22 Sept. 2023, www.epo.org/en/news-events/news/role-patents-pharmaceutical-sector. Accessed 6 June 2024.

GlobalData. “Pharma - Top 10 Pharmaceutical Companies in the World in 2022 by Market Capitalization.” Globaldata, 31 Mar. 2023, www.globaldata.com/companies/top-companies-by-sector/healthcare/global-companies-by-market-cap/. Accessed 8 June 2024.

Herder, Matthew. “What Is the Purpose of the Orphan Drug Act?” *PLOS Medicine*, vol. 14, no. 1, Jan. 2017, p. e1002191, https://doi.org/10.1371/journal.pmed.1002191. Accessed 15 June 2024.

Hogerzeil, Hans. *Access to Medicine Index 2022*. 9 Nov. 2022, accesstomedicinefoundation.org/resource/2022-access-to-medicine-index. Accessed 16 June 2024.

I-Mak. “Overpatented, Overpriced Humira.” *I-Mak*, Sept. 2021, www.i-mak.org/humira/. Accessed 16 June 2024.

Jacobsen, Grant D., and Kathryn H. Jacobsen. “Statewide COVID-19 Stay-At-Home Orders and Population Mobility in the United States.” *World Medical & Health Policy*, vol. 12, no. 4, July 2020, https://doi.org/10.1002/wmh3.350. Accessed 17 June 2024.

Kirshner, Ghily, et al. *The Impact of an “Evergreening” Strategy Nearing Patent Expiration on the Uptake of Biosimilars and Public Healthcare Costs a Case Study on the Introduction of a Second*

Administration Form of Trastuzumab in the Netherlands. 2023, www.eur.nl/en/media/2023-07-2023001-kirshner-et-al-trastuzumabescherworking-paper. Accessed 13 June 2024.

Kuanpoth, Jakkrit. "Compulsory Licences: Law and Practice in Thailand." *MPI Studies on Intellectual Property and Competition Law*, Sept. 2014, pp. 61–77, https://doi.org/10.1007/978-3-642-54704-1_4. Accessed 16 June 2024.

Lieberman, Steven M., et al. "Balancing Lower U.S. Prescription Drug Prices and Innovation – Part 1." *Brookings*, 25 Nov. 2020, www.brookings.edu/articles/balancing-lower-u-s-prescription-drug-prices-and-innovation-part-1/. Accessed 12 June 2024.

"Market Exclusivity: Orphan Medicines | European Medicines Agency." EMA, www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/orphan-designation-post-authorisation/market-exclusivity-orphan-medicines. Accessed 15 June 2024.

Maybarduk, Peter. "Access to Medicine - Learn More." *Public Citizen*, 2 Mar. 2016, www.citizen.org/article/access-to-medicine-learn-more/. Accessed 16 June 2024.

Mulcahy, Andrew, et al. *International Prescription Drug Price Comparisons Current Empirical Estimates and Comparisons with Previous Studies*. 2021, aspe.hhs.gov/sites/default/files/documents/ca08ebf0d93dbc0faf270f35bbecf28b/international-prescription-drug-price-comparisons.pdf. Accessed 10 June 2024.

National Cancer Institute. "How Gleevec Transformed Leukemia Treatment." *National Cancer Institute*, Cancer.gov, 11 Apr. 2018, www.cancer.gov/research/progress/discovery/gleevec. Accessed 16 June 2024.

Odell, John S., and Susan K. Sell. *THE WTO COALITION on INTELLECTUAL PROPERTY and PUBLIC HEALTH*. 2001,

www.researchgate.net/profile/John-Odell/publication/228125366_Reframing_the_Issue_The_Coalition_on_Intellectual_Property_and_Public_Health_in_the_WTO_2001/links/5400b6200cf23d9765a4188b/Reframing-the-Issue-The-Coalition-on-Intellectual-Property-and-Public. Accessed 9 June 2024.

Pollack, Andrew. "Drug Goes from $13.50 a Tablet to $750, Overnight." *The New York Times*, 20 Sept. 2015, www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html. Accessed 16 June 2024.

Scherer, F. *Patents, Monopoly Power, and the Pricing of Pharmaceuticals in Low-Income Nations Faculty Research Working Paper Series*. 2013, research.hks.harvard.edu/publications/getFile.aspx?Id=5175. Accessed 5 June 2024.

Starner, Catherine I., and Patrick P. Gleason. "Spinal Muscular Atrophy Therapies: ICER Grounds the Price to Value Conversation in Facts." *Journal of Managed Care & Specialty Pharmacy*, vol. 25, no. 12, Dec. 2019, pp. 1306–8, https://doi.org/10.18553/jmcp.2019.25.12.1306. Accessed 16 June 2024.

Vaughan, Don. "Pfizer, Inc.." *Encyclopedia Britannica*, 15 Jun. 2024, https://www.britannica.com/money/Pfizer-Inc. Accessed 18 June 2024.

Vision Research Reports. "Pharmaceutical Market Size to Hit around USD 2,832.66 Bn by 2033." *BioSpace*, 28 Mar. 2024, www.biospace.com/article/releases/pharmaceutical-market-size-to-hit-around-usd-2-832-66-bn-by-2033/. Accessed 6 June 2024.

Waxman, Henry A. "H.R.5238 - 97th Congress (1981-1982): Orphan Drug Act." *Www.congress.gov*, 4 Jan. 1983, www.congress.gov/bill/97th-congress/house-bill/5238. Accessed 18 June 2024.

Wikipedia Contributors. "Gilead Sciences." *Wikipedia*, 13 June 2021, en.wikipedia.org/wiki/Gilead_Sciences. Accessed 18 June 2024.

---. "Novartis." *Wikipedia*, Wikimedia Foundation, 12 June 2019, en.wikipedia.org/wiki/Novartis. Accessed 18 June 2024.

---. "Roche." *Wikipedia*, Wikimedia Foundation, 10 July 2019, en.wikipedia.org/wiki/Roche. Accessed 18 June 2024.

World Trade Organisation. "WTO | Intellectual Property (TRIPS) - TRIPS and Public Health." *Wto.org*, 2017, www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm. Accessed 6 June 2024.

WTO. "WTO | Ministerial Conferences - Doha 4th Ministerial - TRIPS Declaration." *Wto.org*, 2001, www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed 16 June 2024.

---. "WTO | Services - the GATS: Objectives, Coverage and Disciplines." *Wto.org*, 2019, www.wto.org/english/tratop_e/serv_e/gatsqa_e.htm. Accessed 15 June 2024.

Yenet, Aderaw, et al. "Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review." *ClinicoEconomics and Outcomes Research*, vol. 15, June 2023, pp. 443–58, https://doi.org/10.2147/CEOR.S413546. Accessed 16 June 2024.

Appendices

Appendix I

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm

Appendix II

Improving the transparency of markets for medicines, vaccines, and other health products (WHA72.8)
https://www.who.int/publications/m/item/wha72.8

Appendix III

WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA-PHI) https://www.who.int/publications/m/item/gspa-phi-final-implementation

Appendix IV

UNDP Good Practice Guide: Improving Access to Treatment with Flexibilities in TRIPS https://www.undp.org/publications/good-practice-guide-improving-access-treatment-flexibilities-trips

Appendix V

Human Rights Watch: Health Care Access https://www.hrw.org/topic/health/health-care-access