THE SECRET'S OUT: THE WHO, WHAT, WHEN, AND HOW OF A CONTEXT-SPECIFIC EXCEPTION TO TRADE SECRET RIGHTS IN BIG PHARMA

Amanda Roberts

I. Trade Secrets and the Hushed Problem of Waste in Pharmaceutical Development

As of March 2022, twenty-eight COVID-19 vaccine candidates have been authorized internationally for public use and over ninety others remain in development pending approval.[1] Many of these vaccines were developed as a result of technological advancements but use the same or similar processes, the same or similar active ingredients, carry the same or similar side effects, and tout the same or similar rates of effectiveness.[2] In a field known for innovative development, such obvious duplicity seems inefficient and raises concerns about the increasingly important role of pharmaceutical actors in global public health.

This dilemma was arguably a byproduct of the current international framework of intellectual property (IP) rights, which seeks to promote innovative development and public access to it by awarding exclusive rights to creators.[3] In the absence of such a framework, competitors could freely copy inventive works and profit from the innovation without acquiring the sunk costs of its

---

[1] Jeff Craven, *COVID-19 Vaccine Tracker*, REGUL. AFFS. PROS. SOC'Y, *available at* https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker (last visited Nov. 8, 2022).

[2] Kathy Katella, *Comparing the COVID-19 Vaccines: How Are They Different?*, YALE MED., *available at* https://www.yalemedicine.org/news/covid-19-vaccine-comparison (last visited Nov. 8, 2022); Juan C. Ravell, *A Simple Breakdown of the Ingredients in the COVID Vaccines*, HACKENSACK MERIDIAN HEALTH, *available at* https://www.hackensackmeridianhealth.org/HealthU/2021/01/11/a-simple-breakdown-of-the-ingredients-in-the-covid-vaccines/ (last visited Nov. 8, 2022); *see also What are the Differences Between the COVID-19 Vaccines?*, YALE NEW HAVEN HEALTH, *available at* https://www.ynhhs.org/patient-care/covid-19/Vaccine/differences-between-the-vaccines (last visited Sept. 11, 2022).

[3] *Intellectual Property Law*, GEO. L., *available at* https://www.law.georgetown.edu/your-life-career/career-exploration-professional-development/for-jd-students/explore-legal-careers/practice-areas/intellectual-property-law/ (last visited Nov. 8, 2022).

development.[4] As a consequence, innovators would be less likely to invest heavily in research and development activities or release their innovation for public use.[5] IP laws thus face the challenge of adequately protecting a creator's efforts against improper use without otherwise restricting the free trade of information or products.[6] Oftentimes, this involves making inventive works available for public consumption, but sometimes the framework functions to suppress proprietary information if the action confers a competitive advantage to its holder. The balance struck is one between general capitalism and social utility.

The pharmaceutical industry (or Big Pharma) offers a unique insight into this balance at work. On the commercial side, drug development is highly research and cost intensive with generally low success rates.[7] This results in a development cycle that constantly faces delays, unexpected expenditures, failed trials, and copious amounts of data collected over time; all in an effort to develop a drug that, more likely than not, will never be approved for human use.[8] As an added challenge for developers, these are costs that must be paid years before a product is made publicly available, if it is at all.[9] A conservative estimate puts the cost to develop a single new drug, when accounting for all capital costs, close to $ 2 billion USD.[10] Against this however, the social utility served by safe and well-researched pharmaceuticals is unquestionable. Albeit time consuming and costly to develop, medicines have the capacity diagnose illnesses as well as treat, halt, prevent, or cure them.[11]

---

[4] Reggie Ash, *Protecting Intellectual Property and the Nation's Economic Security*, 32 AM. BAR ASS'N.: Landslide, 80-1 (2014), *available at* https://www-jstor-org.libezproxy2.syr.edu/stable/pdf/24632564.pdf?refreqid=excelsior%3A82dde61a0352db505dfef4bdc90b91fb&ab_segments=&origin=&acceptTC=1 (last visited Nov. 8, 2022).

[5] *Id.*

[6] *Id.*

[7] Andy Sanderson & Ling Zhuang, *The Value of Secrecy for Big Pharma*, LIFE SCI. INTELL. PROP. REV. (Jun. 23, 2016), *available at* https://www.lifesciencesipreview.com/contributed-article/the-value-of-secrecy-for-big-pharma (last visited Nov. 8, 2022).

[8] *Id.*

[9] *Id.*

[10] *Research and Development in the Pharmaceutical Industry*, CONG. BUDGET OFF. (2021), *available at* https://www.cbo.gov/publication/57126 (last visited Nov. 14, 2022).

[11] Elora Hilmas, *Understanding Medicines and What They Do*, NEMOURS TEENHEALTH (Oct. 2018), *available at* https://kidshealth.org/en/teens/meds.html (last visited Nov. 14, 2022).

Although somewhat nuanced, IP in the form of trade secrets plays an important role in the development of these medicines, particularly as an alternative to patent protection, another subset of IP rights.[12] Things like abstract ideas and experimental data are excluded from the categories of patent eligible subject matter, but nonetheless qualify for trade secret protection and remain valuable assets to pharmaceutical actors if they are the exclusive holder of it.[13] While IP protections generally incentivize an innovator to make their product and information about it publicly available through exclusive market rights, trade secrets function oppositely.[14] Trade secret holders are offered legal recourse against the misappropriation of confidential, proprietary information based on a tort theory of unfair competition.[15] In this way, inter-entity cooperation is diminished and research is kept out of the public domain as businesses protect the byproducts of their corporate investment.[16] This result is desirable only to the limited extent that businesses, including drug developers, have the right to hold a competitive advantage over other actors due to superior research and development efforts.[17] However, as we will see, the standard for conferring a competitive advantage is not a high one.

Trade secrets have a wide range of protectable subject matter and offer its holder flexible protection.[18] This is what makes trade secrets an attractive alternative to patent protection, regardless of whether the information falls within the scope of patent eligible

---

[12] *Id.*

[13] John Hull, *Protecting trade secrets: how organizations can meet the challenge of taking "reasonable steps"* (Oct. 2019), WIPO MAGAZINE, *available at* https://www.wipo.int/wipo_magazine/en/2019/05/article_0006.html (last visited Nov. 14, 2022) ("A report by Forrester Consulting published in 2010 entitled *The value of Corporate Secrets: How Compliance and Collaboration Affect Enterprise Perceptions of Risk*, suggested that '...enterprises in highly knowledge-intensive industries like manufacturing, information services, professional, scientific and technical services and transportation accrue between 70% and 80% of their information portfolio from trade secrets.'").

[14] *See Intellectual Property Enforcement*, U.S. DEP'T STATE (n.d.), *available at* https://www.state.gov/intellectual-property-enforcement/#:~:text=to%20deter%20access%20to%20counterfeit,as%20vital%20for%20economic%20development (last visited Nov. 14, 2022).

[15] *See Trade Secrets*, WIPO (n.d.), *available at* https://www.wipo.int/tradesecrets/en/ (last visited Nov. 14, 2022).

[16] *Id.*

[17] *Id.*

[18] Michael J. Kasdan et al., *Trade Secrets: What You Need to Know*, THE NAT'L L. REV. (Dec. 12, 2019), *available at* https://www.natlawreview.com/article/trade-secrets-what-you-need-to-know (last visited Sept. 5, 2022).

subject matter or not.[19] Multiple studies confirm that businesses on a global scale consider trade secrets to be at least as valuable as patents and other forms intellectual property rights, if not more so.[20] However to balance out their broad scope, the level of protection offered to a trade secret is far lower than that of a patent.[21] Unlike patents, trade secrets do not confer exclusive rights to its holder, who has no recourse against a party who reverse engineers or independently creates the same information or process.[22]

The result can be inefficient: Duplicative innovation and delayed improvements on that innovation. While trade secrets encourage development and maintain standards of commercial morality, it simultaneously suppresses the free flow of information and thereby hinders a major function of a free marketplace.[23] This becomes particularly alarming when applied to Big Pharma and examined in connection with the COVID-19 pandemic, where the world essentially laid in wait until the development of effective vaccination options.

While the severity and spread of COVID-19 took people and policymakers alike off-guard, future outbreaks of infectious diseases will occur.[24] According to mathematical models based on historic epidemic frequency and geographic distribution data, epidemiological events have been steadily increasing in recent years.[25] One such model places the probability of a pandemic comparable to the severity of COVID-19 at 2.3-2.5% annually.[26] Extrapolated, this means that there is a 47-57% chance that a COVID-analogous event will occur in the next twenty-five years.[27] Advance response planning is therefore a necessary undertaking, and an evaluation of the trade secret

---

[19] *Id.*
[20] Hull, *supra* note 13.
[21] Kasdan, *supra* note 18.
[22] Sanderson & Zhuang, *supra* note 7.
[23] John R. Thomas, *The Role of Trade Secrets in Innovation Policy*, CONG. RSCH. SERV. (January 15, 2014), *available at* https://sgp.fas.org/crs/secrecy/R41391.pdf (last visited Nov. 8, 2022).
[24] Eleni Smitham & Amanda Glassman, *The Next Pandemic Could Come Soon and Be Deadlier*, CTR. FOR GLOB. DEV. (Aug. 25, 2021), *available at* https://www.cgdev.org/blog/the-next-pandemic-could-come-soon-and-be-deadlier (last visited Sept. 5, 2022).
[25] *Id.*
[26] *Id.*
[27] *Id.*

framework's shortcomings as applied to the pharmaceutical industry is a part of this.

In a public health emergency, the general goal is to accelerate the development of viable treatment options. By addressing the problem of waste in the pharmaceutical field and eliminating needless inefficiencies in emergency settings, development timelines can be shortened, lives saved, and the rights of innovators generally preserved. After introducing the international trade secret framework generally, its applicability to Big Pharma will be further analyzed by looking at existing exceptions to the international body of law. With this foundation in mind, the inefficiencies and shortcomings of trade secrecy will be emphasized in connection to a drug's development cycle and the merits of a proposed, pandemic-specific exclusion to traditional trade secrets rights analyzed. More specifically, it is proposed that reducing the scope of trade secret protection in certain circumstances and adding securities to the international IP framework through codified provisions can ensure inter-industry cooperation. Through this, the international community can ensure a swift and focused response to future health emergencies.

II. International Trade Secret Framework

Beforeany meaningful discussion regarding international trade secret legislation can occur, the international IP framework generally must be laid. In modern times, it is based largely on the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement, the Agreement, or TRIPS), which was enacted in 1995 and established the World Trade Organization (the WTO).[28] Although this was the first time trade secret protection was explicitly contemplated in international law, the practice of trade secrecy has existed far longer that its recognition as IP.[29] Broadly viewed, the TRIPS Agreement introduces internationally agreed upon minimum standards to systematically settle IP disputes, which allow a company to engage in advance planning to maximize their rights under the law

[28] Rambod Behboodi, Trade Secrets in International Law: The WTO's Secrets of the Trade, JDSUPRA (Aug. 24, 2018), available at https://www.jdsupra.com/legalnews/trade-secrets-in-international-law-the-26679/ (last visited Dec. 3, 2022).
[29] *Id.*

and position in the marketplace.[30] The TRIPS Agreement remains the most comprehensive international agreement on IP protections to date, which is significant considering that most of the value traded across borders today is done so in the form of information and creativity and not in the form of tangible goods.[31]

Besides its minimum standards, the Agreement affords its members general flexibility in managing their domestic IP legislation, specific to the contracting state's public policy goals.[32] It is therefore up to the member states to strike the balance they deem appropriate between long term progress via creator protections and short term inaccessibility to competitors.[33] Importantly, there has long been recognition that the creator rights conferred under the Agreement can be overcome by domestic authorities in certain compelling circumstances.[34]

In enforcing IP protections, the Agreement generally requires that WTO members grant non-discriminatory treatment to all other WTO members and sets forth principles of fairness, due process, and uniformity in the enforcement of the Agreement's procedures.[35] Trade secrets in specific involve information that is actually [1] secret, [2] commercially valuable, and [3] subject to reasonable steps taken to maintain its secret-status.[36] However, disclosure does not destroy trade secret standing in certain circumstances, like when required to obtain marketing approval for a new drug, pursuant to a complex series of exceptions built into the TRIPS Agreement and reinforced by domestic law.[37] Instead, the implicated information is protected

---

[30] *Intellectual property: protection and enforcement*, WTO, *available at* https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Jan. 7 2023).

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] *See Obligations and exceptions* (Sept. 2006), WTO, *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Jan. 7, 2023) [hereinafter TRIPS Fact Sheet].

[35] *Id.*

[36] Rambod Behboodi, *Trade Secrets in International Law: The WTO's Secrets of the Trade*, JDSUPRA (Aug. 24, 2018), *available at* https://www.jdsupra.com/legalnews/trade-secrets-in-international-law-the-26679/ (last visited Jan. 7, 2023).

[37] *Id.*; TRIPS Fact Sheet.

against unfair use and disclosure that might infringe on the owner's rights in the marketplace.[38]

Such exceptions include Article 8 and Article 40 of the TRIPS Agreement, which broadly allow governments to prevent IP holders from abusing their privileges, including "unreasonably" restricting free trade or "hampering the international transfer of technology."[39] These are often considered negative externalities associated with trade secret overuse, so on some level the Articles' inclusion indicates international distaste for overly suppressive businesses practices and a desire to limit them. Importantly, Article 31 permits "use [of protected IP] without authorization of the right holder," otherwise known as compulsory licensing.[40] Although a significant caveat, compulsory licenses may only be granted under this Article in very limited circumstances and must be used to predominantly serve the domestic market granted in.[41] While Article 31 can apply to any industry's IP, it often implicates Big Pharma's in order to facilitate access to essential drugs during "national emergencies" or times of "extreme urgency," of which the COVID-19 pandemic undoubtedly was.[42]

This evidences a close relationship between public health administration and IP rights of pharmaceutical products, but there is disagreement about how this relationship is to be managed during health emergencies, like that of Covid-19. Some, like the European Union, argue that the TRIPS Agreement as is offers adequate flexibility pertaining to "pandemic health technologies" through its framework of exceptions and minimum standards.[43] Others, including the United States and several other WTO members, have endorsed

---

[38] Behboodi, *supra* note 36; *see also Part II — Standards concerning the availability, scope and use of Intellectual Property Rights*, World Trade Org., *available at* https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm (last visited Jan. 7, 2023).

[39] *Id.*

[40] TRIPS Fact Sheet.

[41] *Id.*

[42] *Id.*

[43] Ellen 't Hoen & Pascale Boulet, *The EU proposed Covid waivers of certain TRIPS rules are mostly meaningless*, MED. L. & POLICY (Oct. 14, 2021), *available at* https://medicineslawandpolicy.org/2021/10/the-eu-proposed-covid-waivers-of-certain-trips-rules-are-mostly-meaningless/ (last visited Nov. 14, 2022) ("At the core of the EU's rejection of the TRIPS waiver has been the argument that the TRIPS agreement offers sufficient flexibility to deal with IP issues around access to pandemic health technologies. The EU in particular . . . takes the position that only some clarification and tweaking may be required.").

either fully or partially waiving TRIPS given intellectual property rights concerning COVID-19 pharmaceuticals.[44] Their argument is that TRIPS lacks "meaningful global policy solutions to ensure access" to the drugs necessary to mitigate the pandemic's effects where it is needed most, usually in less developed countries.[45] It is the opinion of this paper that a waiver to the TRIPS Agreement would be counterproductive considering a pandemic's obvious global effects. TRIPS affords its members uniformity and umbrella leadership under which collaborative international efforts can be posed, and have been before. Considering the broad network of pharmaceutical exceptions already in place in the Agreement, codifying a pandemic and trade secret specific caveat can reinforce the framework's existing provisions and utilize WTO leadership more effectively in future health emergencies.

Although complex, the TRIPS Agreement's framework exists and is enforced generally to promote economic growth, incentivize investment in research and development, and allow creators to recoup their sunk costs. Its effect on public health is not immediately obvious but becomes clearer upon deeper analysis of the framework's exceptions relating to Big Pharma.

III. The Framework's Side Effects in Big Pharma

Considering that the pharmaceutical field is innovation-driven and research-intensive, secretive development activities are commonplace and represent a commercial interest as a competitive advantage over industry members.[46] In this way, intellectual property rights generally and trade secrets specifically serve an important role in a pharmaceutical firm's business strategy.[47] As has already been established, this phenomenon is not uncommon and stems from a desire to protect the byproduct of company time and resources, regardless of what form it takes.

The reality for pharmaceutical developers is that, more often than not, a drug's clinical trial will yield more information on what

---

[44] Andrew Green, *Where are we on COVID-19 after a year of TRIPS waiver negotiations?*, devex (Oct. 7, 2021), *available at* https://www.devex.com/news/where-are-we-on-covid-19-after-a-year-of-trips-waiver-negotiations-101795 (last visited Nov. 14, 2022).

[45] *Id.*

[46] Sanderson & Zhuang, *supra* note 7.

[47] *Id.*

has failed than what has worked.[48] But that is not to say that this information, aptly called "negative data," is not valuable to the developer who discovered it or to their competitors.[49] Despite the frustration of failure, thorough research and development practices are how health needs are properly addressed and how safe yet effective procedures, medicines, and healthcare products are created.[50] Negative data is a significant part of this process and access to it generally reduces the timeline necessary to produce a viable drug.[51]

In this context, negative data offers a competitive advantage to its exclusive holder; especially if the failure guides the drug development towards a different chemical composition, medical use, or dosage regiment.[52] Because the secret holder has expended time and resources in pursuit of the failed option, the release of such information can guide competitors away from making the same costly mistake, allowing them to both pursue new courses of action and to save costs on research and development.[53] It is for this reason that negative data is often protected as a trade secret.[54]

Although clearly advantageous in the competitive field of pharmaceutical development, the suppression of negative results through trade secrecy has simultaneously been criticized as the primary source of waste and industry inefficiency because it promotes and rewards an incomplete knowledge base.[55] The result is that these

---

[48] *Id.*

[49] *Id.*

[50] *See What is R&D?*, GHTC, *available at* https://www.ghtcoalition.org/why-research-and-development (last visited Nov. 14, 2022).

[51] *See* Linda Peckel, *WHO, NIH, FDA Concerned Negative Data Lacking in Clinical Trial Results,* RHEUMATOLOGY ADVISOR (Mar. 15, 2017), *available at* https://www.rheumatologyadvisor.com/home/topics/practice-management/who-nih-fda-concerned-negative-data-lacking-in-clinical-trial-results/ (last visited Nov. 14, 2022) ("Several objections were specifically raised to the practice of not reporting negative clinical trial results, citing that it . . . results in poor allocation of product development resources and slows drug development.").

[52] *Id.*

[53] *Id.*

[54] *See Trade Secrets*, WORLD INTELL. PROP. ORG., *available at* https://www.wipo.int/tradesecrets/en/ (last visited Nov. 14, 2022) ("In general, any confidential business information which provides an enterprise a competitive edge and is unknown to others may be protected as a trade secret.").

[55] Helen Yu, *Responsible use of negative research outcomes--accelerating the discovery and development of new antibiotics*, J. ANTIBIOTICS (June 8, 2021), *available at* https://www.nature.com/articles/s41429-021-00439-w?proof=t%2Btarget%3D (last visited Nov. 14, 2022); Linda Peckel, *WHO, NIH, FDA Concerned Negative Data Lacking in Clinical Trial Results*, RHEUMATOLOGY ADVISOR (Mar. 15, 2017), *available at*

firms incessantly repeat another's mistakes knowing their resources could be expended pursuing avenues that have not yet been discredited or improving upon promising iterations.[56] The practice further raises ethical concerns considering the fact that the custom indirectly puts clinical trial patients at avoidable risk.[57] Although trade secrets do their part to protect innovative investment, their overuse by pharmaceutical actors ultimately drives up producer and consumer costs alike, and pose significant public interest concerns when connected to current events. Analyzed below in greater detail, these elements demonstrate the consequences posed by trade secret overuse under the current legal regime as well as the opportunities to improve the framework's functionality during future global health emergencies.

A. COSTLY FOR DRUG PRODUCERS

Trade secrets arguably impose their highest costs on drug producers in the form of duplicative innovative efforts.[58] Big Pharma firms often suppress their clinical trial data and virtually all other technical information about a drug's development process under the guise of trade secrecy.[59] This includes subjecting employees to non-disclosure and/or non-compete agreements as well as other policy, physical, and cyber security measures to protect their confidential

---

https://www.rheumatologyadvisor.com/home/topics/practice-management/who-nih-fda-concerned-negative-data-lacking-in-clinical-trial-results/ (last visited Nov. 14, 2022).

[56] Linda Peckel, *WHO, NIH, FDA Concerned Negative Data Lacking in Clinical Trial Results,* RHEUMATOLOGY ADVISOR (Mar. 15, 2017), *available at* https://www.rheumatologyadvisor.com/home/topics/practice-management/who-nih-fda-concerned-negative-data-lacking-in-clinical-trial-results/ (last visited Nov. 14, 2022).

[57] *Id.*

[58] *See* Jake Frankenfield, *Trade Secret*, INVESTOPEDIA (Jan. 5, 2021), *available at* https://www.investopedia.com/terms/t/trade-secret.asp (last visited Sept. 20, 2022).

[59] Laurie Carr Mims & Maya Perelman, *Trade-Secret Vulnerabilities: Recent Hacking Schemes Highlight the Need to Protect Proprietary Pharmaceutical Information* (Apr. 16, 2021), BIOPROCESS INT'L, *available at* https://bioprocessintl.com/business/intellectual-property/recent-hacking-schemes-highlight-the-need-to-protect-pharmaceutical-trade-secrets/ (last visited Nov. 14, 2022) ("[P]harmaceutical trade secrets can include diverse categories of information across a company, including testing procedures and protocols, manufacturing methods, test results, product designs, customized client lists, market analyses, pricing and marketing information, business strategies, and 'negative know-how . . . .'").

corporate investments.[60] While these efforts obviously impose direct costs on the firm, indirectly they create an industry-wide custom that rewards data suppression and lauds independent creation as the only profitable road to public market. Not only does this slow the rate of progress, it also significantly raises production costs for all industry members. According to one report by the European Patent Office, this phenomenon costs the European Union alone a minimum of $ 20 billion annually across all industries.[61] Concerning Big Pharma specifically, up to 85% of drug development expenditures are unnecessary duplicates of another firm's efforts, due in large part to poor data publication practices in the industry.[62]

Companies are motivated to participate in business activities by profit earnings, so it makes little sense that the industry-wide practice is to suppress information even though each firm would likely benefit from the efforts of another at little to no cost.[63] In this context, information is suppressed not with the intention of delaying the development process, but rather with the intention of maintaining a competitive advantage over opposition.[64] Expenditures on research and development are a necessity by each player in this field, so in an offhand way the profit motive is satisfied not through direct earnings of the firm, but by driving up the costs of competitors through the strategic use of IP.[65] This makes sense considering that trade secrets, unlike patents that can be licensed or sold, have limited options for monetization.[66] In order to directly capitalize off of a trade secret, its holder must be the first to bring a product to market and enjoy the

---

[60] Pamela Passman, *Eight steps to secure trade secrets* (Feb. 2016), WIPO MAGAZINE, *available at* https://www.wipo.int/wipo_magazine/en/2016/01/article_0006.html (last visited Sept. 20, 2022).

[61] Yu, *supra* note 55 (citation omitted) (noting that the European Patent Office is a standout regional patent office due to continental industrial relevance and the ability to grant a patent recognized by all European states).

[62] Virginia Minogue & Bill Wells, *Adding value, reducing research waste, the role of NHS research and the development management community*, EMERALD INSIGHT (Apr. 12, 2018), *available at* https://www.emerald.com/insight/content/doi/10.1108/IJHG-08-2017-0043/full/html (last visited Nov. 14, 2022).

[63] Julia Kagan, *Profit Motive*, INVESTOPEDIA, *available at* https://www.investopedia.com/terms/p/profit-motive.asp (last visited Sept. 23, 2022).

[64] Yu, *supra* note 55.

[65] *See* Carr Mims & Perelman, *supra* note 59 ("Given the high costs that come with researching, developing, and commercializing lifesaving drugs, pharmaceutical companies are poised to suffer unique risks as targets of trade-secret misappropriation.").

[66] *The Pros and Cons of Trade Secrets*, IP.COM, *available at* https://ip.com/blog/the-pros-and-cons-of-trade-secrets/ (last visited Sept. 23, 2022).

advantage of being the only producer until a rival independently develops a competitive product, which could take years even in the absence of strong data protection practices.[67] Surprisingly, this method is often favored by corporate entities over more robust forms of IP protection.[68] A study of US process and product innovations confirms that secrecy and lead-time to market is usually preferred over patent protection by industry players.[69]

It is in this way that trade secrets create barriers to market entry that include limited labor mobility, restricted research and development collaboration, longer development timelines, reduced productivity growth, and stifled competition in general.[70] Although a firm's market share may be better protected through these efforts, the use of trade secrets in Big Pharma creates inefficiencies inevitably to be imputed to patients and consumers. Industry players do bear some of the brunt of these inefficiencies in the form of raised production costs, but it is the public that that suffers most severely.

B. COSTLY TO CONSUMERS

High pharmaceutical prices almost always raise public accessibility concerns. This is a genuine issue considered by IP laws and speaking broadly, is a large reason that IP protections exist at all. Governments around the world have recognized a societal benefit in ensuring public access to medicines and healthcare. In the context of pharmaceuticals, IP protections are how well-researched products reach the public market and, ideally, result in higher quality drugs at affordable prices overall.[71] The international IP framework facilitates

---

[67] *Id.*

[68] *The economic and innovation impacts of trade secrets*, GOV.UK (April 19, 2021), *available at* https://www.gov.uk/government/publications/economic-and-innovation-impacts-of-trade-secrets/the-economic-and-innovation-impacts-of-trade-secrets (last visited Jan. 7, 2023) (citation omitted).

[69] *Id.*

[70] *Id.* ("Stronger policy benefits existing trade secrets holders and encourages investment in R&D, yet reduces future innovation and creates barriers to entry. There is a balance to be struck between trade secrecy that encourages innovation, and trade secrecy that blocks innovation.").

[71] Tom Wilbur, *IP Explained: Three forms of IP protections for medicines*, PhRMA (Aug. 27, 2019), *available at* https://catalyst.phrma.org/ip-explained-three-forms-of-ip-protections-for-medicines (last visited Sept. 23, 2022). ("Intellectual property (IP) protections for the biopharmaceutical sector provide incentives that help to promote the

this end by providing incentives for pharmaceutical firms to invest in new drug development while at the same time encouraging a competitive market for the benefit of consumers.[72]

Competition between firms is necessary because it generally reduces the costs to consumers by "detecting, halting, and correcting anticompetitive practices."[73] But too strong of IP protections undermines this basic economic theory, resulting in inefficiencies.[74] Trade secrets in specific were created to address concerns about unfair competition.[75] Theoretically, trade secrets promote innovation by ensuring that the market functions fairly and innovative investments are protected against improper use.[76] In practice however, their overuse contributes to higher development costs, which are often supplemented with public funds collected from tax revenue, and delayed progress.[77] Consumers of pharmaceutical products thus face higher drug prices, higher taxes, and developmental delays/drug inaccessibility as a result, especially in the United States.[78]

This result is ironic because, annually, the largest single investor in pharmaceutical research is the American public.[79] Each year, over $ 20 billion of American taxpayer money is invested in health related development.[80] Regardless, this population faces

---

discovery and development of life-saving medicines for patients and foster a competitive market for generic and biosimilar medicines.").

[72] *Id.*

[73] *The role of competition in the pharmaceutical sector and its benefits for consumers*, TD/RBP/CONF.8/3, U.N. CONFERENCE ON TRADE AND DEV. (Apr. 27, 2015), *available at* https://unctad.org/system/files/official-document/tdrbpconf8d3_en.pdf (last visited Nov. 14, 2022).

[74] *See* Jason Wiens & Chris Jackson, *How Intellectual Property Can Help or Hinder Innovation*, EWING MARION KAUFFMAN FOUND. (Apr. 6, 2015), *available at* https://www.kauffman.org/resources/entrepreneurship-policy-digest/how-intellectual-property-can-help-or-hinder-innovation/ (last visited Nov. 14, 2022).

[75] *See* Jake Frankenfield, *Trade Secret*, INVESTOPEDIA (Jan. 5, 2021), *available at* https://www.investopedia.com/terms/t/trade-secret.asp (last visited Nov. 14, 2022).

[76] *Frequently Asked Questions: Trade Secrets*, WIPO, *available at* https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html (last visited Nov. 14, 2022).

[77] Yu *supra* note 55.

[78] Kevin J. Hickey Et. Al., *Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress*, CONG. RESEARCH SERV., R46741, (2021) ("[P]harmaceutical products are frequently protected by IP rights, and IP rights are often among the most important factors driving high drug prices.").

[79] Peter Arno & Michael Davis, *Paying Twice for the Same Drug*, WASH. POST (Mar. 27, 2002), *available at* https://www.washingtonpost.com/archive/opinions/2002/03/27/paying-twice-for-the-same-drugs/c031aa41-caaf-450d-a95f-c072f6998931/ (last visited Nov. 14, 2022).

[80] *Id.*

soaring prescription drug costs prices, regardless of the fact that they have technically paid for part of the research.[81] This is called "double spending" and involves contributing funds to a product's development then being charged to purchase said product once developed.[82] It is an inefficient result that treats consumers unfairly.

Along with issues of efficiency and fairness, the data concealing practices of drug developers also raise heightened consumer safety concerns. Because clinical trial and negative data is often treated as a trade secret, it is not fully disclosed to regulatory officials during the drug approval process.[83] Without this information, a drug's claimed benefits or side effects cannot be fully verified by researchers prior to giving it market approval.[84] As a consequence, serious side effects are often not discovered until a drug has been on the market for years, and often not until consumers have been seriously harmed or killed by the product.[85] This is so well accepted that "post-approval monitoring," monitoring a drug's efficacy and side effects after it has been approved for public consumption, is considered an implied final phase of the clinical trial process.[86] Such a safety concern, even if it affects only a small fraction of the pharmaceutical products on the market, clearly undermines the significant interest of consumer safety and is but one example of the IP framework's undesirable effect on public health.[87]

---

[81] *Id.*

[82] *Id.*

[83] *See* Allison Durkin et. al., *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, HEALTH AND HUMAN RIGHTS JOURNAL (June 2021), *available at* https://www.hhrjournal.org/2021/06/addressing-the-risks-that-trade-secret-protections-pose-for-health-and-rights/#:~:text=Pharmaceutical%20companies%20have%20invoked%20trade,and%20details%20regarding%20financial%20arrangements (last visited Nov. 9, 2022).

[84] *Id.*

[85] *Id.* ("Prominent examples include rofecoxib (Vioxx), estrogen hormone therapy (Prempro), and extended-release oxycodone (OxyContin).").

[86] *Steps of a Clinical Trial*, PHA, *available at* https://phassociation.org/research/steps-in-clinical-trials/ (last visited Sept. 12, 2022).

[87] *Intellectual Property*, COURSE HERO, *available at* https://courses.lumenlearning.com/wmopen-introductiontobusiness/chapter/intellectual-property-2/#:~:text=The%20purpose%20of%20intellectual%20property%20law%20is%20to%20create%20a,to%20the%20good%20or%20service (last visited Nov. 9, 2022).

C. PUBLIC INTEREST CONCERNS AND CURRENT EVENTS

Along with increasing the risk of dangerous drugs getting to market, an incomplete knowledge base in Big Pharma, authorized by the IP framework, raises serious public interest concerns, especially when analyzed in connection with current world events. More specifically, the suppression of clinical trial data in the context of drug development has been criticized both as needlessly dangerous and unnecessarily wasteful.[88] The problem of waste is a problem of efficiency—resources or methods not being utilized in the most effective way. In the pharmaceutical industry, this manifests as anti-collaborative practices and duplicative research efforts in pursuit of a single solution.[89]

Upon closer examination, many trade secret claims are actually discovered to be inappropriate applications of the law, especially as they pertain to healthcare.[90] In reality, trade secret law does not protect many categories of information in this field.[91] For example, data pertaining to drug pricing, safety, and efficacy, often ascertained through clinical trials, does not actually confer a competitive advantage to its holder.[92] This relates to the commercially valuable requirement for trade secret protection. Because this data alone cannot be used to reduce the costs of a competitor or aid in the marketing or development of another product, it cannot be *commercially* valuable, although it may hold value internal to the discovering firm.[93] Even so, this data remains confidential since there are no statutory requirements that must be demonstrated before information can be treated as a trade secret, and therefore a firm is under no obligation to disclose it to the public or competitors for the purpose of creating a more robust knowledge base.

However, the public has compelling interests in accessing this data and suffers harm because of its suppression. Pricing information, for example, is essential for consumers and regulators to gage how fairly drug prices are being set, especially when they are set by a sole

---

[88] Yu, *supra* note 55; Durkin et. al., *supra* note 83.
[89] *See* Yu *supra* note 55.
[90] Durkin Et. Al., *supra* note 83.
[91] *Id.*
[92] *Id.*
[93] *Id.*

drug producer.[94] Concealment of this data further contributes to higher drug prices, with the United States consistently having the highest per capita pharmaceutical expenditures worldwide.[95] Such high costs reduce medicine accessibility as it prices consumers out of healthcare or reduces their options, sometimes depriving patients of their ability to make meaningful decisions regarding their treatment.[96] These concerns and others become even more troubling when analyzed in connection with current world events. The COVID-19 pandemic began in late 2019 and was declared a pandemic by the World Health Organization in March of 2020.[97] COVID-19 causes in most people mild to moderate symptoms like the common cold including a runny nose, cough, headache, and fever; but to others it causes debilitating respiratory illness.[98] As of February 2022, there have been over 400 million reported COVID-19 cases and over 5 million COVID-related deaths worldwide.[99] These figures, although staggering, are based only on reported information and are, in reality, much higher.

Under normal circumstances, it takes years to develop a vaccine from start to finish.[100] However it was just under a year after the pandemic began in late 2019 that the Pfizer vaccine became the first to receive emergency use approval from the Federal Drug Administration (FDA) in the United States.[101] This extraordinary feat can be at least partially explained by the fact that researchers had been

---

[94] *See* Yu *supra* note 55; *See also* Genevieve M. Halpenny, *High Drug Prices Hurt Everyone*, NCBI (May 3, 2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4904249/ (last visited Dec. 4, 2022). ("Pharmaceutical companies refuse to substantiate their arguments by providing information about the cost of developing new medicines.").

[95] Halpenny, *supra* note 94.

[96] *Id.*

[97] *Covid-19 Pandemic Timeline Fast Facts*, CNN HEALTH (Feb. 1, 2022), *available at* https://www.cnn.com/2021/08/09/health/covid-19-pandemic-timeline-fast-facts/index.html (last visited Nov. 8, 2022).

[98] *Id.*

[99] Henrik Pettersson, Byron Manley & Sergio Hernandez, *Tracking Covid-19's global spread*, CNN HEALTH (Feb. 9, 2022), *available at* https://edition.cnn.com/interactive/2020/health/coronavirus-maps-and-cases/ (last visited Nov. 8, 2022).

[100] Jocelyn Solis-Moreira, *How did we develop a COVID-19 vaccine so quickly?*, MEDICAL NEWS TODAY (Nov. 13, 2021), *available at* https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly (last visited Nov. 8, 2022).

[101] *Id.*

studying other coronaviruses, the family of viruses from which the pandemic stems, for over half a century.[102] Yet curiously, it was not until a pandemic negatively affected the global economy that researchers were willing to forego some trade secrecy in collaboration with others in the field to fast-track viable results.[103]

During this time, it was decided that the public interest in pandemic mitigation was more important than the IP rights of crucial drug researchers and developers. As a result, and with the help of government funded research and development, multiple COVID-19 vaccines were developed in under one year and have been broadly distributed around the world.[104] The accomplishment is attributed to the collaborative efforts of private and public actors but because of the urgency required, was imperfectly executed and legal ambiguities remain between the parties. Scientists from the National Institute of Health (NIH), a governmental entity funded by US taxpayers, helped develop the base that biotech company and drug developer Moderna relied on for their COVID-19 vaccine iteration.[105] This fact has become the source of a patent conflict between the two parties, with the NIH arguing that their name should be listed on the patent application and Moderna arguing the opposite.[106] Accounting for research as well as advance payments for the final vaccine, Moderna received billions in funding from the US government and its citizens.[107] Such action, although extreme, was deemed and proven to be essential to the accelerated development of the COVID-19 vaccine and similar efforts will likely be necessary again in future

---

[102] *Id.* ("[S]cientists have been studying coronaviruses for more than 50 years. This meant that scientists had existing data on the structure, genome, and life cycle of this type of virus.").

[103] *Id.*

[104] *Covid-19 Pandemic Timeline Fast Facts*, CNN health (Feb. 1, 2022), *available at* https://www.cnn.com/2021/08/09/health/covid-19-pandemic-timeline-fast-facts/index.html (last visited Nov. 8, 2022).

[105] Judy Stone, *The People's Vaccine - Moderna's Coronavirus Vaccine Was Largely Funded by Taxpayer Dollars*, FORBES (Dec. 3, 2020), *available at* https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=ee0b59a63039 (last visited Nov. 9, 2022).

[106] *See* Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, NY TIMES (Nov. 9, 2021), *available at* https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html (last visited Nov. 9, 2022).

[107] Stone, *supra* note 105.

epidemiological emergencies.[108] By engaging in advance legal planning, the roles and rights of implicated parties (governments and pharmaceutical firms) can be clarified and a foundation laid for meaningful and effective cooperation between the parties when called for.

Clearly the IP framework imperfectly applies to the pharmaceutical industry. Although a relatively quick response to the COVID-19 pandemic was achieved by the pharmaceutical industry, the role of public funding and inter-entity cooperation in lieu of suppressive practices cannot be understated. Greater security and clarity regarding said cooperation in times of pharmaceutical need, like during future pandemics, must therefore be integrated into the legal IP framework.

IV. The Treatment Plan

Due to the domestic deference offered by the TRIPS Agreement, a solution that places a greater emphasis on collaborative efforts and data sharing between pharmaceutical firms in necessary circumstances aligns with the Agreement's flexible nature.[109] By reducing the scope of trade secret protection in certain conditions and adding securities to the international IP framework to guarantee inter-entity cooperation within the drug development industry, the international community can better ensure a swift and concerted response to future health emergencies.

A. SOLUTION DETAILS: WHAT, WHEN, WHO

To combat the inefficiencies in the IP framework and mitigate the concerns associated with data suppression in Big Pharma, an exception creating a tiered system of mandatory government

---

[108] Michael Penn, *Statistics Say Large Pandemics Are More Likely Than We Thought*, DUKE GLOBAL HEALTH INST. (Aug. 23, 2021), *available at* https://globalhealth.duke.edu/news/statistics-say-large-pandemics-are-more-likely-we-thought#:~:text=next%20400%20years.-,The%20most%20important%20takeaway%20is%20that%20large%20pandemics%20like%20COVID,Spanish%20flu%20are%20relatively%20likely.&text=time%20period%20studied.-,Taken%20another%20way%2C%20those%20figures%20mean%20it%20is%20statistically%20likely,within%20the%20next%20400%20years (last visited Nov. 9, 2022)

[109] *See Obligations and Exceptions* (Sept. 2006), WORLD TRADE ORG., *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Nov. 9, 2022)

disclosure regarding relevant drug research during international health emergencies should be codified in the TRIPS Agreement. Such a system would create conditions ripe for breakthroughs in research, and likely develop safe and effective vaccine or treatment options significantly faster than independent creation would allow.[110] It would require pharmaceutical firms to disclose relevant research and development activities related to a pressing health concern to government actors, who then would assist with further development and act as an oversight authority over implicated firms and a liaison to international authorities. In the interest of fairness and cooperation, such disclosures should be compensated monetarily and how the IP rights of completed products are to be split between the public and private actors negotiated in advance. This will preserve judicial resources and add predictability to the relations between entities.

The premise of this solution is neither untested nor groundbreaking. Generally speaking, collaborative efforts reduce the time it takes to resolve unexpected problems and is commonplace in modern business.[111] *Network collaboration* in particular occurs when multiple businesses work together to benefit their shared interests, often times gaining access to each other's resources even though they may be competitors.[112] Successful business collaboration benefits all parties involved and is "fostered through open, honest, and productive communication."[113] Contrasted with the highly secretive world of pharmaceutical development, it may be necessary to legally compel network collaboration for public benefit. This is the essence that underlies the proposal.

---

[110] *Sharing Clinical Trial Data*, NAT. ACADEMIES OF SCI. ENGINEERING MED. (2015), *available at* https://www.nap.edu/catalog/18998/sharing-clinical-trial-data-maximizing-benefits-minimizing-risk (last visited Nov. 9, 2022) ("Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators.").

[111] *See* Katrina Dessavre, *Top 5 Benefits of Collaboration in Business*, BEEKEEPER (April 1, 2021), *available at* https://www.beekeeper.io/blog/benefits-collaboration-business/ (last visited Nov. 9, 2022).

[112] *What is Business Collaboration? Benefits, Types & Collaboration Ideas,* RINGCENTRAL (July 20, 2021), *available at* https://www.ringcentral.co.uk/gb/en/blog/business-collaboration/ (last visited Nov. 9, 2022).

[113] *Id.*

A variation of this solution is already in effect on an international scale through the FDA's Project Orbis.[114] Designed to promote faster access to innovative cancer therapies, the partnership between the US, Australia, Brazil, Canada, Singapore, Switzerland, and the United Kingdom has improved efficiency in cancer treatment development by improving data sharing practices across many countries.[115] Although simple in premise, Project Orbis is largely regarded as a success.[116] In its first year alone, the project led to thirty-eight approvals of formerly unprecedented cancer treatments.[117] In many essential ways, the proposal outlined in this paper seeks only to recreate these outcomes using specialized international policy to improve data sharing practices in times of global need.

It should also be mentioned that there is a longstanding relationship between government funding and pharmaceutical research.[118] COVID-19 vaccines in specific were routinely well-funded by government investment in research and development and advance payments, not to mention the supply of federal scientists and external research to vaccine projects.[119] This is appropriate considering that pandemics manifest largely as domestic issues with overarching international consequences. This system meant that vaccine candidates were approved for public use faster than they would have in the absence of government involvement, which is a significant benefit sought to be codified here for future healthcare emergencies.[120]

---

[114] Kevin Rudd, *Global Cooperation on Vaccines Barely Exists. Here's a Way for the World to Work Together*, TIME (Aug. 11, 2021), *available at* https://time.com/6088896/vaccine-cooperation-global-idea/ (last visited Dec. 2, 2022).

[115] *Id.*

[116] *Id.*

[117] Chen Li, *First year of Project Orbis leads to 38 approvals of cancer therapies, including 8 by Health Canada*, SMART & BIGGAR (Jan. 13, 2021), *available at* https://www.smartbiggar.ca/insights/publication/first-year-of-project-orbis-leads-to-38-approvals-of-cancer-therapies-including-8-by-health-canada (last visited Dec. 2, 2022).

[118] *See Research and Development in the Pharmaceutical Industry*, Cong. Budget Office (April 2021), *available at* https://www.cbo.gov/publication/57126 (last visited Dec. 2, 2022) ("The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand.").

[119] Gabor David Kelen & Lisa Maragakis, *COVID-19 Vaccines: Myth Versus Fact*, JOHNS HOPKINS MED., *available at* https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-19-vaccines-myth-versus-fact (last visited Dec. 2, 2022).

[120] *See id.*

Even still, the interests protected by trade secrets are important and therefore should only be overcome in well-defined and necessary circumstances. After all, it is necessary that innovators recoup their financial investment in research and development and feel recognized and compensated in the marketplace.[121] Relating to trade secrets, innovators seek to feel protected against unfairly competitive practices and improper use of corporate investments.[122] As such, objective boundaries of epidemiological events must be established to determine when the pharmaceutical firms are to be compelled to cooperate with government actors.

From the COVID-19 pandemic, as well as others including the Spanish Flu, large amounts of data have been collected regarding a virus's severity and spread.[123] With entities already in place to collect this information, mathematical modeling of future infectious diseases is possible and can be used in developing the categorical boundaries called for by the proposal.[124] Limiting the circumstances of application in this way make the proposal more palatable to those implicated by it while still serving the primary purpose of accelerating treatment development. Further, having acute disease transmission models in place can aid in early detection and project intervention induced changes, potentially to the extent that the event never escalates to pandemic level.[125]

If it does however, international cooperation and oversight will again be necessary and is contemplated by the proposal here. Pandemics are unique in that they simultaneously create a public health emergency and, less obviously, an economic crisis.[126] The

---

[121] *What is Intellectual Property?*, WORLD INTELL. PROP. ORG, *available at* https://www.wipo.int/about-ip/en/ (last visited Nov. 7, 2022).

[122] *See Trade Secrets,* WORLD INTELL. PROP. ORG., *available at* https://www.wipo.int/tradesecrets/en/ (last visited Nov. 7, 2022).

[123] *See* WORLDOMETER, *available at* https://www.worldometers.info/coronavirus/ (last visited Nov. 7, 2022).

[124] *See* Amy Barret, *New Mathematical Models may help us Predict the Spread of Future Epidemics*, Science Focus (April 12, 2020), *available at* https://www.sciencefocus.com/news/new-mathematical-models-may-help-us-predict-the-spread-of-future-epidemics/ (last visited Nov. 7, 2022).

[125] Amit Huppert & Guy Katriel, *Mathematical modelling and prediction in infectious disease epidemiology*, 19 CLIN. MICROBOL INFECT 999, 999-1005 (June 25, 2013), *available at* https://doi.org/10.1111/1469-0691.12308 (last visited Nov. 7, 2022).

[126] *See* Daniel Kurt, *The Special Economic Impact of Pandemics*, INVESTOPEDIA (Dec. 17, 2021), *available at* https://www.investopedia.com/special-economic-impact-of-pandemics-4800597 (last visited Nov. 7, 2022) ("As necessary as these steps were to bring the

initial downturn of the economy at the onset of COVID-19 has been compared to the beginning of the Great Depression.[127] Because of this significant dual impact, dual international oversight from the World Health Organization (WHO) and World Trade Organization (WTO) is appropriate.

Considering the obvious ties of pandemics to public health, the United Nation's WHO sits poised as a prime candidate to implement the proposed policy exception. In their own words, the WHO "direct[s] and coordinate[s] the world's response to health emergencies."[128] This includes spearheading the COVID-19 pandemic response.[129] As such, the WHO is the entity under which future pandemic responses are likely to be lead, making them a necessary partner in the implementation of the IP exception proposed here.

The ties between IP and public health are less obvious, but not less compelling. The WHO has already taken an interest in the IP field prior to the outbreak of COVID-19. Their report labeled "Research and Development to Meet Health Needs in Developing Countries" considered a global research and development framework and explored other open approaches to data sharing.[130] Essentially, the report recognized a need for flexible IP rights in order to reduce artificial barriers to innovation, reduce duplicative research, and contribute to the general knowledge base of drug development sciences overall.[131] Because of this, it is likely that they will amenable to the reform proposed here.

Just as the WHO has taken an interest in matters related to IP, the WTO has taken an interest in public health by closely tracking

---

coronavirus outbreak under control from a medical standpoint, there was a flip side: Large swaths of the economy ground to a halt.").

[127] *Id.*

[128] World Health Organization, *What we do*, WHO, *available at* https://www.who.int/about (last visited Nov. 7, 2022).

[129] *See Timeline: WHO's COVID-19 response*, WHO, *available at* https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline (last visited Nov. 18, 2022).

[130] Hilde Stevens & Isabelle Huys, *Innovative Approaches to Increased Access to Medicines in Developing Countries*, FRONTIERS IN MED. (Dec. 7, 2017), *available at* https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full (last visited Nov. 18, 2022).

[131] *Id.*

COVID-19's impact on world trade.[132] According to the WTO, the COVID-19 pandemic was a devastating disruption to the global economy and world trade.[133] This demonstrates an interest in managing world health catastrophes and makes participation with the WHO more likely.

The WTO's endorsement is nearly necessary for any meaningful IP reform to take place because their work is directly relevant to the enforcement of IP rights through the TRIPS Agreement, the appropriate body of law in which to embed the proposal.[134] Since the proposed reform involves procedures that directly contradict an innovator's TRIPS given IP rights concerning trade secrecy, WTO cooperation is essential for the proposal's feasibility. But this is not out of character with the Agreement. Since the TRIPS Agreement builds in such a high degree of flexibility for contracting states, the proposed measures are appropriate under the Agreement and stay in line with the Agreement's principles of fairness, due process, and uniformity.[135]

The solution proposed here is neither untested, complicated, or unrealistic. It has been limited in scope to encourage pharmaceutical firm and international organization participation and is a realistic option for future pandemic management and mitigation. Especially considering that the proposal is supported by legal exceptions and protocols on both a domestic and international scale.

B. SOLUTION FOUNDATION

Around the world and long before the times of COVID-19, there has been enduring legal recognition that public health crises call for special treatment of intellectual property rights. Once again, this is reflected in the flexible nature of the TRIPS Agreement's system of

---

[132] *See COVID-19 and world trade*, WTO, *available at* https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm (Nov. 18, 2022).

[133] *Id.*

[134] *WTO Activities*, WTO, *available at* https://www.wto.org/english/tratop_e/trips_e/ipenforcement_e.htm (last visited Nov. 18, 2022).

[135] *See Obligations and exceptions* (Sept. 2006), WTO, *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Nov. 18, 2022).

minimum standards and special exceptions, which will now be examined in closer detail.[136]

The Doha Declaration is but one example of such an exception.[137] It grants compulsory licenses to allow for the production and exportation of low-cost generic drugs to countries who do not possess the means to manufacture those products themselves.[138] This language directly impacts the "domestic market" limitation in Article 31 and recognizes that the limitation can hinder efficient use and public health interests, further demonstrating both the WTO's interest in effective healthcare management and the role of IP protections to that end.[139] The proposed solution therefore falls within existing categories of IP flexibilities and for the same global health purpose as those already enacted.

Similar legislation has been adopted on domestic scales as well. Italy for example, has amended their Code of Industrial Property to entitle their government to grant compulsory licenses in public health emergencies "in order to overcome proven difficulties in supplying essential medicines or medical devices and in compliance with international and European obligations."[140] The capacity for a government to grant compulsory licenses of drugs for domestic use has always been enabled by the TRIPS Agreement's Doha Declaration and other exceptions, but the adoption of parallel legislation in a

---

[136] *Advice on Flexibilities under the TRIPS Agreement*, WIPO, *available at* https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html (last visited Nov. 18, 2022) ("[T]he TRIPS Agreement incorporates certain 'flexibilities.' These aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally . . . .").

[137] *Pharmaceutical patents and the TRIPS Agreement,* WTO (Sept. 21, 2006), *available at* https://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm (last visited Nov. 18, 2022).

[138] *Id.*

[139] *Id.*

[140] Elena Mannini, *Compulsory Licensing: amendment approved by Italian Parliament for health emergencies*, TREVISAN & CUONZO (July 22, 2021), *available at* https://www.ipinitalia.com/licensing/compulsory-licensing-amendment-approved-by-italian-parliament-for-health-emergencies/#:~:text=Compulsory%20licensing%3A%20amendment%20approved%20by%20Italian%20Parliament%20for%20health%20emergencies,-By%20Elena%20Mannini&text=If%20a%20national%20health%20emergency,with%20international%20and%20European%20obligations (last visited Nov. 18, 2022).

country's domestic law signals a deeper regional commitment to resolving public health related issues using IP reform as a tool.[141]

It must be noted that the use of the word "reform" may be misleading when used in connection with the solution proposed here. As has already been mentioned, proposed system of mandatory disclosure and cooperation has a strong basis in existing protocols in recognition of pharmaceutical products' unique importance to humanitarian efforts. Government disclosure and approval, for example, is already often required before pharmaceutical products can be sold to the public market.[142]

In the United States, the FDA's drug approval process requires submission of a New Drug Application that includes all data collected from animal and human trials and analysis of that data, including how the drug reacts in the body.[143] This stage of the approval process also requires disclosure of the drug's manufacturing process, but it is highly limited in recognition of a firm's trade secret rights.[144] Although the FDA requires disclosure of sensitive information, the approval process is not public, and the FDA will not even confirm the existence of a specific application.[145] However Confidentiality Commitments do allow the FDA to share non-public information with foreign counterparts for narrow regulatory and legal purposes.[146] All disclosures are required to further the FDA's mission: To protect and advance public health by fostering innovative and safe drug development, although this cannot always accomplished due to

---

[141] This amendment comes after Italy suffered severely at the onset of the COVID-19 pandemic, with the country ranking fourth worldwide in COVID-related deaths per capita. *See* Angelo Amante & Crispian Balmer, *Why has Italy suffered so badly during the pandemic?* WORLD ECO. F. (Dec. 17, 2020), *available at* https://www.weforum.org/agenda/2020/12/italy-death-toll-pandemic-covid-coronavirus-health-population-europe/ (last visited Nov. 18, 2022).

[142] *See* Emily Miller, *FDA Approval Process, DRUGWATCH (*Sept. 1, 2021*), available at* https://www.drugwatch.com/fda/approval-process/#:~:text=FDA%20Drug%2DApproval%20Process,FDA%20post%2Dmarket%20safety%20monitoring (last visited Nov. 18, 2022).

[143] *FDA Drug Approval Process Infographic (Horizontal)*, FDA (Feb. 26, 2016), *available at* https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fda-drug-approval-process-infographic-horizontal (last visited Nov. 18, 2022).

[144] *Id.*

[145] Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process,* 4 N.Y. UNIV. L. REV. 1210, 1221 (2007).

[146] *International Arrangements,* FDA (July 12, 2019), *available at* https://www.fda.gov/international-programs/international-arrangements (last visited Nov. 18, 2022).

submittal of incomplete information.[147] Though an American institution, the FDA's international partnerships with organizations and foreign governments work in tandem with the existing international IP framework to enhance the free flow of information and pharmaceuticals across international borders.[148]

The European Union's FDA equivalent, the European Medicines Agency, similarly requires data disclosure in order to evaluate, supervise, and approve new pharmaceutical products for the Union's twenty-seven member states and the three members of the European Economic Area.[149] Beyond this, most Asian countries have their own regulatory authorities for pharmaceutical products, and in 2019, the African Union Assembly voted unanimously to create an Africans Medicines Agency, a crucial step towards increasing medical access on the continent.[150]

Clearly, the similarities between international law, domestic law, and the solution proposed by this paper are numerous and serve as the foundation establishing its feasibility. The analogous rationales behind existing compulsory licensing and regulatory infrastructures and this proposal perhaps provides the greatest support. Whether part of a currently enacted or the proposed legal framework, flexibilities in IP law connected to drug development and public health serve the same social purpose: Facilitating access to affordable, effective pharmaceuticals in a timeline that makes ethical and fiscal sense.

---

[147] *What We Do,* FDA (Mar. 28, 2019), *available at* https://www.fda.gov/about-fda/what-we-do#:~:text=FDA%20is%20responsible%20for%20advancing,maintain%20and%20improve%20their%20health (last visited Nov. 18, 2022).

[148] *Id.*

[149] Julia Kagan, *European Medicines Agency*, INVESTOPEDIA (Sept. 17, 2021), *available at* https://www.investopedia.com/terms/e/european-medicines-agency-ema.asp#:~:text=Key%20Takeaways-,The%20European%20Medicines%20Agency%20(EMA)%20is%20a%20decentralized%20agency%20of,Iceland%2C%20Norway%2C%20and%20Liechtenstein. (last visited Sept. 8, 2022).

[150] *See* Michael Mezher, *The Essential List of Regulatory Authorities in Asia*, RAPS (Jan. 7, 2020), *available at* https://www.raps.org/regulatory-focus/news-articles/2015/4/the-essential-list-of-regulatory-authorities-in-asia (last visited Nov. 18, 2022); *Strengthening Regulatory Systems: African Medicines Agency*, IFPMA, *available at* https://www.ifpma.org/subtopics/african-medicines-agency/ (last visited Nov. 18, 2022).

C. A HARD PILL TO SWALLOW . . .

Although mechanisms mandating pharmaceutical cooperation and disclosure in limited circumstances exist already, memorializing an international pandemic-specific exception to trade secret protection is sure to be met with opposition from both pharmaceutical and government actors. Because this proposal includes the use of proprietary information, data, and effort for public purposes, rather than private profit, drug developers are unlikely to endorse this solution enthusiastically. But this narrow view fails to recognize the various balancing elements of the proposal or the protections that are maintained. First and foremost, absolute patent protection and ownership is preserved. Like the compulsory licensing exceptions that already exist, the proposal here respects the role that patents play in promoting innovative development but recognizes that some public interests overcome the a single firm's rights to exclusivity.[151] Similarly, information that properly qualifies as a trade secret will not lose protection as such after a mandated disclosure, and will be protected against unauthorized use or disclosure so long as the information remains in the custody of an entity other than the originator. In this way, the proposal mirrors the FDA drug approval process in the US as well as that of regulatory authorities worldwide.[152]

However, since the proposal dictates *mandatory* disclosure, rather than voluntary as in the case of submitting data for drug approval, it must go further than simple data protection. Pharmaceutical firms implicated by the exception, if enacted, must be fairly compensated in recognition of their intellectual property contributions. This may take the form of monetary gains, public recognition, appropriate intellectual property rights, or any combination thereof.

The compensation element will likely be the greatest source of proposal pushback from government actors. It is a consequence that the proposal will be unavoidably expensive as drug developers must be compensated and any government involvement staffed.[153] The US

---

[151] *See Obligations and Exceptions,* WTO (Sept. 2006), *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Nov. 18, 2022).

[152] *What We Do, supra* note 147.

[153] *See* Julia Kagan, *Profit Motive*, INVESTOPEDIA (Nov. 23, 2020), *available at* https://www.investopedia.com/terms/p/profit-motive.asp (last visited Nov. 18, 2022)

government for example paid over $6 billion USD to biotech company Moderna to develop and test a viable COVID-19 vaccine.[154] This large figure is further exasperated by the fact that Moderna is but one of several pharmaceutical companies to receive government funding for this same purpose.[155] Beyond funding research and development activities, the proposal also instills on the public entity the affirmative obligation to secure and protect the data gathered from pharmaceutical actors, including taking "reasonable efforts" to secure work product through physical and electronic means in much the same way as the firm itself would undertake.[156]

Even so, the proposed solution stays within the boundaries of appropriate government action in emergency settings. Although the global economy is based off the premise of a free market, the interest in preserving capitalistic competition has before been overcome for the sake of more pressing public interests. The US nationalization of the rubber and metal industries during World War II serves as a semi analogous example to the COVID-19 response just witnessed.[157]

Simply put, whether from the perspective of the pharmaceutical or the government actor, this proposal goes no further than the current framework allows. Rather, the solution proposed here seeks to clarify the legal rights available to public entities and empower them to act quickly in the event of another global health emergency, irrespective of relevant trade secrets protected. Through

---

("Profit motive can also be construed as the underlying reason why a taxpayer or company participates in business activities of any kind.").

[154] Johnathon Saltzman, *The US government has now paid Moderna $6b for vaccine effort*, BOS. GLOBE (Apr. 29, 2021), *available at* https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/ (last visited Nov. 18, 2022).

[155] Richard G. Frank et al., *It Was The Government That Produced COVID-19 Vaccine Success*, HEALTH AFF. (May 14, 2021), *available at* https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/#:~:text=Pre%2DClinical%20Investment%20And%20Scientific,Sanofi%2C%20Merck%2C%20and%20Moderna (last visited Nov. 18, 2022).

[156] *Intellectual property: protection and enforcement*, WTO, *available at* https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Nov. 18, 2022).

[157] Gillian Brunet, *5 lessons from World War II for the coronavirus response*, VOX (Apr. 10, 2020), *available at* https://www.vox.com/2020/4/10/21214980/coronavirus-economy-jobs-ppe (last visited Nov. 18, 2022) ("Although the country avoided nationalizing most industries during WWII, the federal government did take direct control of the production of rubber and metals.").

these efforts, duplicative research between firms can be mitigated leading to a more efficient use of scientific resources.

V. The Secret's Out

COVID-19 was an essential pressure test on the international IP framework as applied to Big Pharma. Being the only pandemic handled under the TRIPS Agreement, it highlighted the harsh side effects of trade secrecy in the field of drug development in a time where cooperation was essential. The 100+ COVID-19 vaccine candidates are but one example of the duplicity promogulated by data-suppression and signals a need to consolidate and focus the response efforts by pharmaceutical entities in future health emergencies.[158]
While trade secrets are afforded intellectual property protection in recognition of their commercial value, even if in the form of negative data, there has been a longstanding tradition of setting these interests aside in favor of more urgent matters related to the public good, particularly in relation to public health.[159]
The COVID-19 vaccine efforts built upon the existing relationship between government funding and pharmaceutical development with private and public entities cooperating under a series of complex exceptions under the TRIPS Agreement and domestic law.[160] In time sensitive circumstances, like pandemics, overly complex legal solutions spur litigation and run contrary to the spirit of the exceptions themselves, which is so facilitate public access to safe and essential pharmaceutical products.[161] By reducing the scope of trade secret protection in certain circumstances and adding securities to the international IP framework to ensure inter-industry cooperation, the

---

[158] Jeff Craven, *COVID-19 vaccine tracker*, REGUL. AFF. PRO. SOC'Y (June 24, 2022), *available at* https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker (last visited Nov. 18, 2022).
[159] *See Obligations and exceptions*, WTO (Sept. 2006), *available at* https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm (last visited Nov. 18, 2022).
[160] *See* Gabor David Kelen & Lisa Maragakis, *COVID-19 Vaccines: Myth Versus Fact*, JOHNS HOPKINS MED. (Mar. 10, 2022), *available at* https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid-19-vaccines-myth-versus-fact (last visited Nov. 18, 2022); *see also* WTO, *supra* note 159.
[161] *See* Sheryl Gay Stolberg & Rebecca Robbins, *Moderna and U.S. at Odds Over Vaccine Patent Rights*, N.Y. TIMES (Nov. 9, 2021), *available at* https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html (last visited Nov. 18, 2022).

international community can ensure a swift yet focused response to future epidemiological emergencies.

The primary elements of the proposed solution are not eccentric nor likely to fail and remain within the spirit of the law. Public health related exceptions to intellectual property rights already exist in the form of compulsory licenses and government disclosure and is an essential aspect of the drug approval and regulatory processes.[162] With international agencies appropriately poised to codify and implement a pandemic-specific exception to the trade secret framework, which includes appropriate balancing factors to offset the commercial interests given up by the private actor, the world can better respond to future health emergencies.

---

[162] *See Advice on Flexibilities under the TRIPS Agreement,* WIPO, *available at* https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html (last visited Nov. 18, 2022); *see also FDA Drug Approval Process Infographic (Horizontal),* FDA (Feb. 26, 2016), *available at* https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fda-drug-approval-process-infographic-horizontal (last visited Nov. 18, 2022).