PATENTLY UNFAIR: UNLOCKING ACCESS TO INSULIN THROUGH COMPULSORY LICENSING

*Sioneh Azarian**

Abstract

This article addresses the ongoing and urgent issue of global access to insulin. Insulin's original patent was sold for one dollar to help keep this revolutionary medication open and accessible to those that need it. Unfortunately, pharmaceutical companies are now profiting on the necessity of insulin, driving the cost higher and higher, knowing diabetics have no alternatives. This note proposes the solution of compulsory licensing to help more diabetics worldwide afford the treatment they desperately need. Part One explores the way pharmaceutical companies use patent thickets and evergreening to maintain control over and artificially inflate the price of insulin. Part Two argues that compulsory licensing will facilitate the entry of more biosimilar alternatives to insulin thus providing more affordable options for diabetics. Part Three highlights the devastating consequences of insulin inaccessibility that has forced diabetics to ration their insulin, travel, and participate in underground networks. Diabetics go to such drastic measures because they need insulin to live. High and low blood glucose levels, when left untreated, will cause permanent and severe damage to one's body. Insulin is a lifesaving medication, and there needs to be meaningful reform to ensure access to it.

* Sioneh Azarian received her J.D. from Southwestern Law School in May 2026. She holds a B.A. in English Literature from the University of Southern California. During the 2025-2026 academic year, she served as a Lead Article Editor for the Southwestern Journal of International Law. She is grateful to her family and friends for their consistent support and motivation, and to Professor Thompson-Bell for inspiring her to be a better writer and advocate. Ms. Azarian extends special thanks to the Center for Endocrinology, Diabetes, and Metabolism at Children's Hospital Los Angeles.

I. INTRODUCTION 275
II. INSULIN COMPANIES ABUSE PATENT LAW TO KEEP THE MARKET INSULATED 278
A. Patent Thickets 279
B. Patent Evergreening 280
C. What is Compulsory Licensing? 281
D. How do Compulsory Licenses Help Aid the Insulin Crisis? 282
III. COMPULSORY LICENSING WILL FACILITATE THE ENTRY OF MORE BIOSIMILAR AFFORDABLE ALTERNATIVES TO "BRAND NAME" INSULIN 285
A. Explanation of Biologics and Biosimilars 285
B. The System of Getting Biologics and Biosimilars Approved 286
C. The Consequences of this Ineffective System 286
IV. THE INACCESSIBILITY OF INSULIN HAS FORCED DIABETICS TO RATION THEIR INSULIN, TRAVEL, AND PARTICIPATE IN UNDERGROUND NETWORKS 289
A. Rationing Insulin 289
B. "We are a community, we take care of each other" 291
C. Pharmaceutical Tourism 293
V. CONCLUSION 296

I. INTRODUCTION

Before the discovery of insulin, managing diabetes was a nightmare.[1] French physician Pierre Piorry would advise patients to have a very high calorie diet to counter the calories being lost in urine.[2] Following the failure of these high calorie diets, other French and American physicians started introducing low calorie and low carbohydrate diets.[3] Some of these diets were extremely harsh calling for only 450 calories a day, leaving the patient malnourished and in extreme cases, dead due to starvation.[4] Mitchell Laza, the Director of the Institute for Diabetes, Obesity, and Metabolism at Perelman School of Medicine,

1. *See* The History of a Wonderful Thing We Call Insulin, AM. DIABETES ASS'N (July 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin.

2. *See* Ignazio Vecchio et al., *The Discovery of Insulin: An Important Milestone in the History of Medicine*, 9 FRONT. ENDOCRINOLOGY 1, 2 (Oct. 23, 2018), https://www.frontiersin.org/journals/endocrinology/articles/10.3389/fendo.2018.00613/full.

3. *Id.*

4. The History of a Wonderful Thing We Call Insulin, *supra* note 1.

said that "[f]or most of human history, a diagnosis of diabetes was a death sentence."[5]

In 1910, Sir Edward Albert Sharpey-Schafer theorized that there was a substance secreting from the pancreas that is capable of controlling glucose metabolism, and he called the substance "insulin," from the Latin word "insula" which means island- in reference to the Langhrans island.[6]

In 1921, Dr. Frederick Banting and his junior assistant Charles H. Best performed a pancreatomy on a dog and took the insulin from that dog, purified it, and then shot it back into the animal.[7] That dog experienced a successful decline in blood glucose following the procedure.[8] The first human to be administered insulin was fourteen-year-old Leonard Thompson.[9] Prior to the insulin treatment, Thompson weighed only 65 pounds, and he was in diabetic ketoacidosis.[10] Following the treatment, his blood sugar declined 75 percent and he was able to live thirteen more years.[11] Teddy Ryder was a five-year-old weighing only twenty-six pounds and insulin allowed him to live until seventy-six.[12] The improvement in quality of life is staggering. The new insulin treatment allowed Thompson and Ryder to experience many more years and live those years with significantly better health than they had before. These boys are only two examples of people who were positively impacted by insulin, but diabetics all around the globe were affected positively by this new treatment option.

In 1921, Banting and Best signed an agreement with the University of Toronto's health entity Connaught Antitoxin Laboratories.[13] Due to the rapidly growing demand for insulin, the University of Toronto agreed with Eli Lily and Company, giving Eli Lily the exclusive rights to manufacture and distribute insulin.[14] The scientists did not attempt to profit personally from the discovery until they were forced to when "they became aware that a competitor's patent could interfere

5. Kristen de Groot, *100 years of Insulin,* PENN TODAY (July 26, 2021), https://penntoday.upenn.edu/news/100-years-insulin.

6. Vecchio et al., *supra* note 2.

7. Gary F. Lewis & Patricia L. Brubaker, *The Discovery of Insulin Revisited: Lessons for the Modern Era*, 131 J. CLINICAL INVESTIGATION, 1, 2, 5 (Jan. 4, 2021).

8. *Id.* at 5.

9. *Id.* at 6.

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

with their work in Toronto and could even, potentially shut them down."[15] In December 1922, Banting and Best sold their patent rights the University of Toronto for one dollar each.[16]

In 1923, Banting and MacLeod were awarded the Nobel Prize for Physiology or Medicine.[17] Banting once said, "[i]nsulin does not belong to me, it belongs to the world."[18] Banting's sentiment seemed to resonate with much of the world in the early stages of insulin development. There were urgent actions to make insulin more affordable through price reductions in the United Kingdom and the United States from the 1920s to the 1940s.[19] This, paired with scientists' sale of their patent rights for only one dollar, suggests that the world understood just how important this discovery truly was, and they were committed to maintaining access to this amazing, new medication. Unfortunately, this initial mission and purpose of keeping insulin accessible is now just a faint fantasy.

There is a global crisis in access to insulin.[20] Some countries struggle with affordability, while others grapple with availability.[21] With respect to availability, storing insulin is difficult in developing nations because insulin will go bad if it gets too cold or too hot.[22] Unopened insulin is meant to be stored at 2-8 degrees Celsius, and once it is opened insulin can be stored at room temperature (25-30 degrees Celsius).[23] This is difficult for countries with warmer climates because the room temperature exceeds the requirement. Additionally, it may be difficult to store insulin in a cold space for people with "limited access to refrigeration or reliable electricity."[24] There is recent research that suggests insulin may be able to stay stable if stored in temperatures up to thirty-seven degrees Celsius.[25] Thus, making access to insulin much easier for warmer-climate countries. There is also a push for developing thermostable insulins for the benefit of countries and patients who

15. *Id.*
16. *Id.*
17. *Id.*
18. *Id.*
19. World Health Organization [WHO], *Keeping the 100-year-old Promise: Making Insulin Access Universal*, at 1, (2021), https://iris.who.int/server/api/core/bitstreams/0e4435c6-9f8c-4246-80e1-b2e61a6ae036/content.
20. *Id.* at 2.
21. *See id.* at vii.
22. *Id.* at 10.
23. *Id.*
24. *Id.*
25. *Id.*

struggle with access to cold storage or electricity.[26] New medical developments are great, but they are useless if people are not able to access the new technologies.

The reason this paper highlights the issue with insulin is that there is other scholarship pertaining to the pricing and patenting of other medications. Some other medications also have generic, affordable alternatives that insulin does not have. Furthermore, diabetics' reliance on insulin as a life-saving medication creates this devastating situation of "'grateful victims' who, left without any alternatives, pay the exorbitant prices of the medicines for their survival."[27] Pharmaceutical companies know just how essential insulin is, and they have abused the patent system and hurt diabetics for far too long. Compulsory patent licensing is necessary to aid this issue because it will reduce anticompetitive practice, it will open the doors to more biosimilars, and diabetics around the world deserve better.

II. INSULIN COMPANIES ABUSE PATENT LAW TO KEEP THE MARKET INSULATED

There is tension between patent law and anticompetition law. The Supreme Court of California stated, "[t]o Protect competition in the marketplace, antitrust law prohibits agreements that create or perpetuate monopolies. Patent law, in contrast, grants temporary monopolies to inventors to encourage the development of useful innovations."[28] However, what happens when those monopolies exceed the twenty-year temporary limit they were supposed to be granted? Insulin manufacturers use a variety of methods to prolong their patent protection and sustain their control over the market.[29] There are three large pharmaceutical companies that supply most of the world's insulin: Eli Lily, Novo Nordisk, and Sanofi.[30] The World Health Organization explains one reason why these companies have control on the market, "manufacturing biological medicines (including insulins) requires a higher

26. *Id.* at 31.

27. Rhyea Malik, *Striking a Balance Between Patent Rights and Access to Essential Medicines Through the Use of Compulsory Licenses - Comparative Study of Indian and Malaysian Patent Laws*, 42 J. MALAY. & COMPAR. L. 27, 42 (2015) (citing C. Abboud et al., *The Price of Drugs for Chronic Myeloid Leukemia (CML) is a Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts*, 121 BLOOD FORUM 4439, 4400 (2013)).

28. In re Cipro Cases I & II, 348 P.3d 845, 850 (Cal. 2015).

29. *See* WHO, *supra* note 19.

30. *Id.*

level of engineering and facility requirements."[31] This may explain part of the reason why the market for insulin is dominated by so few companies; however, the various patents that these companies file pose an even greater barrier to accessing insulin. These companies abuse the patent system by filing new patents for small incremental changes, thus increasing the longevity of their control over the product.[32] This abuse of the patent system is also an anticompetitive practice because it keeps other companies from entering the market and allowing consumers a chance to have options. A piece by the California Lawyers Association offers many examples of how companies abuse the patent and market strategies to extend the normal duration of patent exclusivity.[33]

A. Patent Thickets

One way of prolonging patent protection is by creating "patent thickets."[34] A patent thicket is a group of patents that cover a single product. The anticompetitive result of such a thicket is that it deters competitors from trying to challenge it because litigating for a large group of patents costs too much and takes too much time.[35] Drug manufacturers counter this point by arguing that the process of creating a pharmaceutical drug inevitably requires several different innovations, thus requiring several patents.[36] An example of such a dispute was *In Re: Lantus Direct Purchaser Antitrust Litigation*.[37] In this case, FWK Holding, LLC sued Sanofi-Aventis U.S LLC alleging that Sanofi engaged in anticompetitive conduct by improperly listing patents in the FDA Orange Book.[38] There have been similar disputes brought by the Federal Trade Commission (FTC) challenging more than a hundred improper patent listings in the FDA's Orange Book. In 2023, Lina Khan, chair of the FTC spoke to Leila Fadel from NPR about the pending action. Khan said, "[s]o this is a book where firms are able to list patents, and they're only supposed to list patents covering active drug

31. *Id.*

32. *See* Anders Olsen et al., *Patents and Regulatory Exclusivities on FDA-Approved Insulin Products: A Longitudinal Database Study, 1986-2019,* 20 PLOS MED. 1, 12-15 (2023).

33. *See* DeForest McDuff, Mickey Ferri & Noah Brennan, *Patents and Antitrust in the Pharmaceuticals Industry,* 31 CAL. LAW.'S ASS'N 127, 136 (2021).

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

ingredients . . . and instead, we have found that firms are listing device patents that have absolutely nothing to do with the active ingredient."[39] This will be explained in further detail when discussing biosimilars, but one way that insulin manufacturers create thickets is to list device patents, such as the needle or dial on an insulin pen device.

B. Patent Evergreening

Another method for extending patent protection is called evergreening. The strategy of patent evergreening is when a company seeks "additional patents on an already patented product as the existing patents approach expiration."[40] Patents can easily be evergreened if the standard for patent protection is low, therefore companies are able to make minor reformulations that are deemed sufficient to extend the patent life of a medicine.[41] This extension of the patentee's exclusive rights over a product prevents competition.[42]

India's Supreme Court curbed the practice of patent evergreening in *Novartis AG v. Union of India & Others*.[43] In this case, the Indian Supreme Court found that Novartis was seeking to patent a mere modification of a known drug and that Novartis would need to present evidence of a difference in therapeutic efficacy between the different forms of drugs.[44] This case was essentially a win for the generic drug companies in India that wanted to continue producing affordable drugs.[45] The Novartis' court's efficacy standard has served as a model legislation for countries that have difficulty finding a balance between enforceable intellectual property rights and access to medicine. The Philippines' "Cheaper Medicines Act" is nearly identical to section 3(d) of India's Patents Act of 1970, where this efficacy standard stems

39. *The FTC is Threatening Legal Action Against Drugmakers Over Patent Abuses,* NAT'L PUB. NEWS (Nov. 8, 2023), https://www.npr.org/2023/11/08/1211459920/the-ftc-is-threating-legal-action-against-drug-makers-over-patent-abuses.

40. McDuff, Ferri & Brennan, *supra* note 33, at 137.

41. *Id.*

42. *Id.*

43. *See* Joli Patel, *India's Crack Down on the Practice of Pharmaceutical Evergreening: The 2013 Novartis Decision*, 85 UKMC L. REV. 503, 509 (2017).

44. *See id.* at 532-33 (citing *Novartis AG v. Union of India* [2013] 13 S.C.R. 148); *see also id.* at 160.

45. *Id.* at 535 (citing *Indian Supreme Court Decision on Novartis Case a Victory for Access to Medicines in Developing Countries*, DOCTORS WITHOUT BORDERS (Apr. 1, 2013), https://www.doctorswithoutborders.org/latest/indian-supreme-court-decision-novartis-case-victory-access-medicines-developing-countries).

from.[46] As wonderful as this decision is, there is a much simpler solution than leaving every dispute to various countries' judicial systems to review and interpret. Compulsory patent licensing will confront companies that participate in anticompetitive behavior and allow other companies to finally have a chance to compete.

C. What is Compulsory Licensing?

A compulsory license allows other manufacturers to use a patented product without the permission of the patent holder.[47] "It is one of the flexibilities in the field of patent protection included in the World Trade Organization's agreement on intellectual property: the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement).

The TRIPS agreement Section 5, Article 31 is titled "Other Use Without Authorization of the Right Holder" and it sets the terms for compulsory licenses.[48]

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall,

---

46. *See id.* at 537 (first citing Zoee Lynn Turrill, *Finding the Patent Balance: The Novatis Glivec Case and the Trips Compliance of India's Section 3(D) Efficacy Standard*, 44 GEO. J. INT'L L. 1555, 1569 (2013), https://heinonline.org/HOL/P?h=hein.journals/geojintl44&i=1593; Peter Ollier & Emma Barraclough, *Pharma's Indian Challenge*, 172 MANAGING INTELL. PROP. 21, 23 (Sept. 2007), https://heinonline.org/HOL/P?h=hein.journals/manintpr172&i=23; and Edith R. Hechanova *Cheaper Medicines Act Signed into Law,* 181 MANAGING INTELL. PROP. 136, 142 (2008), https://heinonline.org/HOL/P?h=hein.journals/manintpr181&i=142).

47. *Id.* at 524-25 (citing World Trade Organization, *Fact Sheet: TRIPS and Pharmaceutical Patents – Obligations and Exceptions,* (last visited Sep. 30, 2025) https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm).

48. *See Agreement on Trade-Related Aspects of Intellectual Property Rights*, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 319, 333.

nevertheless, be notified as soon as reasonably practicable . . . (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.[49]

D. How do Compulsory Licenses Help Aid the Insulin Crisis?

There are already international examples of compulsory licenses being used in Malaysia and India.[50] Malaysia was the first member state of the World Trade Organization to grant a compulsory license for an AIDS drug.[51] This compulsory license was granted by the Malaysian Ministry of Health due to unsuccessful price negotiations with patent holders.[52] Malaysia also contracted with a generic drug company to import three compulsory licensed drugs from India.[53] As a result of this, the price of the drugs was available for one seventh of the original price, and 2,500 additional HIV patients were able to access treatment.[54] In 2012, India granted its first compulsory license to a generic drug company for the production of an anti-cancer drug.[55] This compulsory license was granted after a large drug company rejected a voluntary license of a patented drug that the generic company was

49. *Id.* at 333-34.
50. Malik, *supra* note 27.
51. *Id.* at 28.
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*

seeking.[56] Due to this, thousands of Indian kidney and liver cancer patients have access to the medicine they need for a fraction of the original price.[57] These are real-life examples of the success of compulsory licenses in helping aid in access to medicine.

The TRIPS Agreement allows, in times of national emergency, member states to waive the requirement of the proposed user making reasonable efforts to obtain authorization from the rights holder.[58] This allows governments to act before a public health crisis becomes an epidemic.[59] The process for compulsory licensing can be lengthy and this is one exception for expediting the process in response to some national emergency.[60] One example of how members have fully utilized this agreement is Malaysia's grant of three "government authorized" compulsory licenses for patented antiretroviral medicines after the 2001 Doha Declaration affirmed that crises related to HIV/AIDS, tuberculosis, malaria, and other epidemics count as national emergencies of extreme urgency.[61]

A recent global example of a public health crisis and emergency is the Coronavirus pandemic. There is an international drug purchasing facility called Unitaid, and Unitaid created the Medicines Patent Pool (MPP), "an independent non-profit foundation . . . with the mission to improve the health of people in low- and middle-income countries by increasing 'access to quality, safe, efficacious, more appropriate and more affordable health products, including through a voluntary patent pool mechanism.'"[62] Pfizer entered into an agreement with MPP to

---

56. *Id.* at 28-29 (citing *Natco Pharma Ltd. v. Bayer Corp.*, Compulsory License Application No. 1 of 2011 (Controller of Patents, Mumbai 2012), available at https://www.globalhealthrights.org/wp-content/uploads/2015/11/Natco-v-Bayer.pdf).

57. *Id.*

58. *See id*. at 40 (citing *see Agreement on Trade-Related Aspects of Intellectual Property Rights*, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 3, 1869 U.N.T.S. 319, 333, available at https://ipindia.gov.in/writereaddata/portal/ipoact/1_31_1_patent-act-1970-11march2015.pdf; The Patents Act, No. 39 of 1970, Imdia Code (1970), § 92(1); Patents Act 1983, Act 291 (Malay.) § 84(1)(a); *id.* at 84(1)(b)).

59. *See id.*

60. *See id.* (citing The Patents Act, No. 39 of 1970, India Code (1970), § 92(1)).

61. *Id*. at 40-41 (citing WTO, *Declaration on the TRIPS Agreement and Public Health*, ¶ 5 (Nov. 14, 2001), WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002), available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf).

62. Chenglin Liu*, Beyond Compulsory Licensing: Pfizer Shares Its COVID-19 Medicines with the Patent Pool*, 25 N.Y.U. J. LEGIS. & PUB. POL'Y 1, 24 (2023) (first citing Unitaid, *Impact Story - Medicines Patent Pool: Voluntary Licenses Can Make Medicines More Accessible* (Dec. 2007), available at https://unitaid.org/assets/impact-story_medicines-patent-pool.pdf; then citing Medicines Patent Pool Foundation, *Statutes of 8 July 2010*, art. 3 (last visited Mar. 19, 2025), https://medicinespatentpool.org/who-we-are/statutes-by-laws-policies).

license the intellectual property rights for Paxlovid, a medication used to treat COVID-19.[63] Leading up to this decision by Pfizer, shareholder activities were pushing Pfizer to "broaden access to COVID-19 vaccines."[64] Oxfam and other global health activities were able to place some pressure on Pfizer through Rule 14a-8, from the SEC Act of 1934.[65] The rule allows "shareholders who have continuously held at least $2,000 in market value of the company's securities for at least three years to submit a proposal to be included in the company's proxy card."[66] The activists were successful in getting their proposal on Pfizer's proxy card bringing it to the attention of other shareholders.[67] Pfizer also requested that the SEC exclude the proposal, which brought this activist movement to the general public's attention.[68] The public pressure, paired with the activist's persistence, played a role in Pfizer entering into the voluntary agreement with MPP.[69] As great as this agreement is, voluntary licensing is not enough to meet the global demand for medications or vaccines. Voluntary licensing is certainly a step in the right direction, but compulsory licensing would push more companies to share their technologies.[70]

Through the TRIPS agreement, compulsory licensing is a greater threat that countries can wield over rights-holders.[71] The word "threat"

63. *Id.* at 2 (citing *Nirmatrelvir*, PUBCHEM NAT'L LIBR. OF MED. (2025), https://pubchem.ncbi.nlm.nih.gov/compound/Nirmatrelvir).

64. *Id.* at 35 (citing Peter Loftus, *Pfizer, Moderna and J&J Face Shareholder Pressure to Broaden COVID-19 Vaccine Access*, WALL ST. J. (Mar. 27, 2022), https://www.wsj.com/articles/pfizer-moderna-and-j-j-face-shareholder-pressure-to-broaden-covid-19-vaccine-access-11648373402).

65. *See id.* at 35-36 (citing Peter Loftus, *supra* note 64; 17 C.F.R. § 240.14a-8 pmbl. (2021); *id.* § 240.14a-8(b)(1)(i)(A)–(D); *id.* §240.14a–8(d); Letter from Rule 14a-8 Review Team, U.S. Sec. & Exch. Comm'n, to Margaret M. Madden, Sr. Vice President & Corporate Secretary, Chief Governance Counsel, Pfizer Inc. (Feb. 23, 2022), https://www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2022/oxfampfizer022322-14a8.pdf); Pfizer Inc., *Breakthroughs That Change Patients' Lives: Proxy Statement for 2022 Annual Meeting of Shareholders and 2021 Annual Report on Form 10-K* (Mar. 17, 2022), https://s206.q4cdn.com/795948973/files/doc_financials/2021/sr/Pfizer-Proxy-2022.pdf.

66. *Id*. (citing 17 C.F.R. § 240.14a-8 (2021)).

67. *Id.* at 37.

68. *Id.*

69. *Id.* at 38 (citing *Bolivia Outlines Vaccine Import Needs in Use of WTO Flexibilities to Tackle Pandemic,* WTO (May 12, 2021), https://www.wto.org/english/news_e/news21_e/dgno_10may21_e.htm).

70. *See id.* at 40.

71. *See id.* (citing Siva Thambisetty et al., *The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to End the COVID-19 Pandemic,* LSE Law, Society and Economy Working Paper No. 06/2021*,* at 27, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3851737).

has a negative connotation, but the companies alone cannot be trusted to do the right thing. In the face of a global pandemic, Pfizer had to face criticism from shareholders and the public just to enter a voluntary agreement that has multiple limitations. It is not as if the agreement with MPP requires Pfizer allow any facility that wants to make Paxlovid to make it. The agreement is narrowly tailored to certain countries, certain facilities, and Pfizer has the final word on whether a company can use the license or not.[72] The unfortunate reality is that companies need to be faced with the threat of compulsory licensing to guide them towards helping ensure public welfare in times of emergency.

Compulsory licenses can also reduce anticompetitive practices in the insulin industry by introducing more biosimilar options for consumers.

III. COMPULSORY LICENSING WILL FACILITATE THE ENTRY OF MORE BIOSIMILAR AFFORDABLE ALTERNATIVES TO "BRAND NAME" INSULIN

A. Explanation of Biologics and Biosimilars

Biologics often come from living organisms so they have a complex structure.[73] "A biosimilar is a biologic that is highly similar to another biologic that is already FDA-approved (known as the original biologic).[74] The FDA started treating insulin as a biologic in 2020, thus opening the door for insulin biosimilars and interchangeable insulins to develop and be approved by the FDA.[75] Despite the difference between generics and biosimilars defined below, it is easy to consider a biosimilar like a generic drug. Biosimilars are just as effective as the original biologic, with perhaps a few minor differences.[76] There is an additional requirement for a drug to be considered an "interchangeable biosimilar."[77]

---

72. *See id.* at 27-29.

73. *Biosimilar and Interchangeable Biologics: More Treatment Choices*, U.S. FOOD & DRUG ADMIN. (2023), https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices.

74. *Id.*

75. Robin Feldman & Gideon Schor, *Purple is the New Orange: A Comparison of Competitive Information (?) in Generics and Biologics*, 2024 U. ILL. L. REV. 1075, 1077.

76. *Biosimilar and Interchangeable Biologics: More Treatment Choice, supra* note 73.

77. *Id.*

B. The System for Getting Biologics and Biosimilars Approved

Under the Hatch-Waxman act, a non-biologic company "must identify all patents it owns that could be reasonably asserted in protection of the drug" upon approval by the FDA.[78] The FDA then includes that information in the publicly available Orange Book.[79] However, companies that manufacture biologics need not disclose this kind of information.[80] Instead of mandating transparency of patent ownership, the biosimilar system simply hopes that the information will become available once a biosimilar drug tries to enter the market and runs into patent law disputes.[81] Once that information reveals itself in litigation, it is publicly released in the Purple Book.[82] This is incredibly ineffective. It is also very unfair to the company that takes the time to manufacture a biosimilar (already an arduous process), and then they must encounter a patent dispute to reveal information. If companies were made to disclose their patents, then smaller companies would know what to avoid. The counterargument is that this system, which only requires information once needed, actually saves time.[83] But the extra time that it takes for large multinational pharmaceutical companies and the FDA to publish this information saves time later because there will be less litigation.

C. The Consequences of this Ineffective System

Due to the disastrous system described above, biosimilars have only been launched by the same three large pharmaceutical companies within the United States.[84] This essentially expands their oligarchy and prevents other companies from developing biosimilars and granting more options to the consumer. These large companies act like petulant children when faced with a slight revenue decrease as more options

78. Feldman & Schor*, supra* note 75 (citing 21 U.S.C. § 355(b)(1)(A)(viii)).

79. *Id.* at 1079 (citing 21 U.S.C. § 355 Subsection IV.B.1. at 1103-04; Michael J. Schellhous*, Improving Access to Emerging Lifesaving Drugs: Solving the Disclosure Problem Within the Patent Dance*, 15 ST. LOUIS U. J. HEALTH L. & POL'Y 201, 209 (2021)).

80. *Id.* (citing Subsection IV.B.1, *supra* note 79; 42 U.S.C. § 262(i) (2021)).

81. *Id.* (citing Kurt R. Karst, *The "Purple Book" Makes Its Debut!*, FDA L. BLOG (Sep. 9, 2014), https://www.thefdalawblog.com/2014/09/the-purple-book-makes-its-debut).

82. *Id.*

83. *Id.*

84. WHO, *supra* note 19, at 8.

enter the market. Sanofi is a prime example.[85] The company relies on the judicial system anytime it wants to block a potential competitor.[86] Sanofi filed a lawsuit alleging infringement against Merck & Co when that company filed for approval of a biosimilar version of Lantus. Just the simple action of filing the lawsuit triggered a pause on FDA approval of Merck's drug "for up to 30 months unless a court rules in favor of Merck earlier."[87] Running to the courthouse allows the major companies to temporarily bar smaller companies from receiving FDA approval. Sanofi even went as far as to sue a fellow large, multinational corporation: Eli Lilly.[88] Eli Lily and Sanofi eventually reached a settlement agreement and kept the dispute from being litigated.[89] The settlement allowed Lily to keep going with drug development so long as they paid Sanofi royalties. If Eli Lily, a major international pharmaceutical company that is arguably on the same level as Sanofi, cannot afford to go to court and fight, then who can? How can this ineffective system for facilitating biosimilars work when no company dares to litigate against the big three? Despite the resources large pharmaceutical companies have, it is hard to believe that the constant litigation is an effective or enjoyable use of their time. Smaller companies that are trying to create biosimilars do not have the money or time to litigate. Hence, lengthy and pricey patent litigation is a deterrent to most companies that do not dare try to file for approval of a biosimilar in fear of an impending lawsuit.

A common counterargument is why don't companies just create biosimilars once the patents for insulin expire. That is because of the various other patents on insulin pen delivery devices.[90] Insulin needs to be administered somehow, and pharmaceutical companies trying to compete with the big three companies would need to put in money, time, and resources to "designing and manufacturing a pen device and/or related cartridge that does not infringe on any patent for any existing pen device or cartridge."[91] There are only so many ways to

85. *See* Joe Cantlupe, *Sanofi aims to block Merck's Lantus Biosimilar*, BIOPHARMA DIVE (Sep. 20, 2016), https://www.biopharmadive.com/news/sanofi-aims-to-block-mercks-lantus-biosimilar/426644/.

86. *Id.*

87. *FDA tentatively approves Merck's copycat of Sanofi's Lantus*, REUTERS (July 24, 2017), https://www.reuters.com/article/us-merck-co-fda idUSKBN1A52BN/.

88. Cantlupe, *supra* note 85.

89. *Id.*

90. Feldman & Schor, *supra* note 75, at 1088 (citing Markus Reitzig, *Strategic Management of Intellectual Property*, 45 MIT SLOAN MGMT. REV. 35, 39 (2004)).

91. *Id.*

make a dial that spins on an insulin pen. This is yet again another example of how patent thickets discussed above bar other companies from entering the market. Similar patent thickets are created with other medications and medical devices such as inhalers and eyedroppers. An FTC challenge to improper listing included device patents such as "the dispenser cap on a multidose eye dropper or the cap strap on an inhaler, which just keeps the inhalers in place."[92] The FTC Chair, Khan, said that these improper listings of device patents "may in fact be resulting in Americans having to pay hundreds, if not thousands, of dollars more than they should be."[93]

Even if companies were able to create brand new devices that do not infringe on any of the patents within the thicket, there is also no guarantee that diabetics who are used to one delivery device will immediately switch to another.[94] Diabetics get comfortable using what they know how to use- it's human nature. Type one diabetes is a chronic condition, meaning that from the age a diabetic is diagnosed, they must live with the condition until the day they die. Diabetes technology is evolving constantly. Insulin pumps are undoubtedly more convenient than using syringes and pens to constantly poke oneself, but older type one diabetics cannot be expected to learn how to use a brand-new piece of technology at the rapid rate at which they are evolving. Some elders struggle with adapting to new smartphones and computers. Some newer insulin pumps look and work like smartphones, so it is dangerous to give them to people who are not accustomed to newer technology, because if they hit the wrong button, they could deliver too many doses of insulin and end their life.

The current system for biosimilars and biologics is meant to release information about relevant patents once a biosimilar drug begins entering patent rights disputes. That information is meant to be published in the publicly available Purple Book. However, two biosimilar insulin drugs have emerged, and yet there is still no patent or exclusivity information available for any of the thirty insulin products listed in

92. *The FTC is Threatening Legal Action Against Drugmakers Over Patent Abuses*, *supra* note 39.

93. *Id.*

94. *See* Feldman & Schor, *supra* note 75, at 1088 (citing Michael S. Sinha, *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*, 23 MINN. J.L. SCI. & TECH. 293, 312–13 (2022); Jing Luo & Aaron S. Kesselheim, *Evolution of Insulin Patents and Market Exclusivities in the USA*, 3 LANCET DIABETES & ENDOCRINOLOGY 835, 837 (2015)).

the Purple Book.[95] How have two biosimilars emerged and there is no more information in the book than there was before they emerged? What is the point of this arduous, annoying process if the FDA still fails to give future competitors a chance to know about potential patent disputes?

The current system for facilitating biosimilars is riddled with ineffective FDA publications and patent law disputes dominated by lucrative, international pharmaceutical companies. Compulsory patent licensing will create a more streamlined pathway for affordable biosimilars to enter the market and grant diabetics fair options.

IV. THE INACCESSIBILITY OF INSULIN HAS FORCED DIABETICS TO RATION THEIR INSULIN, TRAVEL, AND PARTICIPATE IN UNDERGROUND NETWORKS.

Compulsory licensing is necessary to aiding this issue because diabetics deserve better.

A. Rationing Insulin

A report from the Human Rights Watch aptly titled, "If I'm Out of Insulin, I'm Going to Die" has a section on the human cost of unaffordable insulin.[96] Diabetics around the world have been forced to go through dire measures to stay alive. Many diabetics ration their supply of insulin by taking less than they should to stretch the supply.[97] Travis Paulson, a forty-eight-year-old diabetic from Minnesota, rationed his insulin for a dangerous amount of time.[98] Paulson had no choice but to ration because he had lost his job during the economic recession in 2007.[99] Rationing insulin can have various harmful consequences on

95. *Id.* at 1081 (citing *Orange Book Data Files*, U.S. FOOD & DRUG ADMIN. (Dec. 12, 2019), https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files; *See* Skylar Jeremias, *Lilly Plans to Launch Insulin Biosimilar at 78% Discount to Lantus*, AJMC CTR. FOR BIOSIMILARS (Mar. 2, 2023), https://www.centerforbiosimilars.com/view/lilly-plans-to-launch-insulin-biosimilar-at-78-discount-to-lantus).

96. *If I'm Out of Insulin, I'm Going to Die: United States' Lack of Regulation Fuels Crisis of Unaffordable Insulin*, HUM. RTS. WATCH 1, 4 (Apr. 12, 2022), https://www.hrw.org/sites/default/files/media_2022/04/us_insulin0422_web.pdf.

97. *Id.* at 5.

98. *Id.* at 36, 41 (citing Telephone Interview with Travis Paulson (Apr. 29, 2021)).

99. *Id.* at 41.

one's body.[100] Paulson had to have dozens of eye surgeries over the past decade to repair the damage.[101]

The Human Rights Watch also notes that economically vulnerable individuals are disproportionately impacted by the high out of pocket costs.[102] This then negatively impacts their standard of life because "the money needed to acquire this lifesaving medicine can come at the expense of food, rent, and secure living conditions."[103] The disproportionate impact is also unfortunately reflected in the prevalence and severity of diabetes in racial and ethnic minorities.[104] Black adults are more than twice as likely as white adults to be hospitalized for diabetic ketoacidosis.[105] A study also revealed that white respondents were eighteen percent less likely to ration insulin than the average, meanwhile Black respondents were twenty percent more likely to ration insulin than the average.[106] Latino respondents were about ten percent more likely to ration than the average.[107]

As a result of this rationing, there have been emergency access laws granted in parts of the United States of America.[108] This includes Kevin's Law and the Alec Smith Insulin Affordability Act. Kevin Houdeshell was a diabetic that passed in 2014 because he ran out of his prescription for insulin refills, he could not contact his doctor during the holiday season to refill the prescription, and the pharmacy he went to did nothing to help.[109] Thus, Kevin was forced to ration his insulin and experienced diabetic ketoacidosis.[110] Kevin died in his apartment alone at the age of 36.[111] This death could have been avoided if the pharmacist gave Kevin an emergency vial or other supplies to last him until his doctor was back in office. Kevin's law "allows a pharmacist to use their professional judgement if a doctor cannot be reached to authorize a prescription and dispense an emergency supply

100. *Id.*

101. *Id.*

102. *Id.* at 45.

103. *Id.* at 5.

104. *Id.* at 6.

105. *Id.* at 47 (citing *Factors Contributing to Higher Incidence of Diabetes for Black Americans,* NAT'L INSIT. OF HEALTH (Jan. 18, 2018), https://www.nih.gov/news-events/nih-research-matters/factors-contributing-higher- incidence-diabetes-black-americans).

106. *Id.* at 6.

107. *Id.*

108. *Kevin's Law*, T1INTERNATIONAL, (Dec. 23, 2024), https://www.t1international.com/media/assets/file/Kevins_Law_Fact_Sheet.pdf.

109. *Id.*

110. *Id.*

111. *Id.*

of a chronic maintenance drug."[112] Eighteen states have passed some version of Kevin's law.[113] State legislation varies with what kinds of medications are covered and what quantity of medication the pharmacist can give.[114] The Alec Smith Insulin Affordability Act has a safety net program within it to allow qualifying diabetics access to emergency supplies if they are in urgent need of them.[115] "Under the law, eligible individuals in urgent need of insulin can go to their pharmacy once in a 12-month period and receive a one-time, 30-day supply of insulin for a $35 co-pay."[116] The law's name comes from Alec Smith, a 26-year-old man from Minneapolis.[117] Alec died because he was uninsured and could not afford to pay out of pocket, so he was forced to ration his insulin.[118] This state legislation is inspiring but devastating. These laws were triggered by two young diabetics suffering horrible consequences for simply not being able to afford the medicine they need. These two young men are among thousands of other diabetics across the nation and across the globe who have been forced to take smaller doses of insulin than they need. Insulin is not a drug you can stretch out because the effects of rationing are so severe. Dr. Laura Nally, a pediatric endocrinologist, stated, "[i]nsulin isn't the type of medication you can go two to three days without. People have to get insulin somehow."[119] When diabetics are in need of insulin, they turn to one another.

B. "We are a community, we take care of each other"[120]

There is an avid underground network of diabetics helping one another access the life-saving medicine they need.[121] A research study

112. *Id.*

113. *Id.*

114. *Id.*

115. *See No One Should Have to Choose Between Affording their Lives and Affording to Live*, OFFICE OF MINN. ATT'Y GEN. (Mar. 15, 2021), https://www.ag.state.mn.us/Office/Communications/2021/03/15_InsulinAffordabilityAct.asp.

116. *Id.*

117. *See id.*

118. *Id.*

119. Kaitlin Sullivan, *The High Cost of Diabetes Drugs has Led to a Flourishing Black Market*, NBC NEWS (Feb. 9, 2023), https://www.nbcnews.com/health/health-news/diabetes-medications-high-costs-flourishing-black-market-rcna67480.

120. Michelle L. Litchman et al., *The Underground Exchange of Diabetes Medications and Supplies: Donating, Trading, and Borrowing, Oh My!,* 14 J. DIABETES SCI. AND TECH., 1000, 1003 (2020).

121. *See id.* at 1006-07.

observing the prevalence of and factors surrounding the underground exchange of diabetic supplies.[122] These activities include: donating, trading, borrowing, and purchasing.[123] The research noted that participants felt compelled to donate because they did not want to see fellow diabetics suffering and stressing "due to inability to access basic diabetic needs."[124] People find these networks of other diabetics that share their surplus supplies through social media.[125] There are also mutual aid groups such as Mutual Aid Diabetes (MAD).[126] MAD's website states that the group was "formed in response to the insulin crisis"[127]

Michelle Litchman, the medical director of the Intensive Diabetes Education and Support Program at the University of Utah, was shocked that some participants in the underground networks are insured. Perhaps the image of someone that participates in the "black market" of diabetic supplies does not line up with the typical image of an individual that has health insurance. People like to assume that this issue could never exist for them or someone like them. They assume this only applies to the absolute poorest person they could imagine so it doesn't affect them in any shape or form. However, one should care about an issue even if it does not directly affect them because we should have empathy for our fellow humans. Also, the issue does indeed affect middle-class, insured individuals that think it could never apply to them. The actual number of people that have participated in these networks is hard to determine because of the secretive nature of trading supplies. I, myself, have had to rely on a diabetic friend to loan me a continuous glucose monitor sensor because of issues regarding physician authorization and how many sensors my insurance allowed per month. I have had type-two diabetics in my family give me surplus insulin pens that are extremely useful when my insulin pump malfunctions, and I still need to manage my glucose. It is no exaggeration to say that without these donations, I would not be alive.

Eric Douds, a type one diabetic, participated in these online groups of diabetics donating and trading supplies.[128] Douds has had difficulty

122. *Id.* at 1000.

123. *Id.*

124. *Id.* at 1003.

125. *See* Markian Hawryluk, *Diabetes patients turn to underground insulin networks as Covid-19 exposes limits of copay caps*, CNN HEALTH (Oct. 1, 2020), https://www.cnn.com/2020/10/01/health/insulin-copay-caps-sharing/index.html.

126. *See About MAD*, MUTUAL AID DIABETES (Dec. 23, 2024), https://mutualaiddiabetes.com/about-mad/.

127. *Id.*

128. Sullivan, *supra* note 119.

finding an affordable health insurance because he freelances as a videographer.[129] Douds said, "[r]ight now, it's easier for me to get medicine from the diabetes community than it is for me to figure out America's insurance system."[130] This statement is bittersweet in its emphasis on the strength of the diabetic community and its critique of the complexity of the health insurance system. Annalisa Van den Bergh, a diabetic in the same groups as Douds, shared his sentiment and said, "[t]he diabetes mutual aid community is more reliable than [any] insurance or doctor I've had. We're literally keeping each other alive."[131]

In a report, the World Health Organization said that "As a major and complex public health problem, diabetes cannot be addressed simply through a top-down approach in the absence of community involvement."[132] It is cruel to put the weight of this massive issue on the diabetics who are suffering as a result of the issue. Diabetics are not at fault for this crisis, so why should they be the ones responsible for solving it? Massive, international pharmaceutical companies are responsible for keeping the patents under lock and key; thus, restricting people's access to cheaper, more readily accessible alternatives. The companies that have insulated the insulin market should be the ones being held responsible for aiding this crisis. Diabetics have created these mutual aid groups and social media networks out of necessity. These generous diabetics are not the solution to the problem; if anything, they demonstrate just how much compulsory licensing is necessary to put an end to this crisis.

C. Pharmaceutical Tourism

Another way diabetics try to help themselves and others access insulin is by travelling abroad where insulin is cheaper. Paulson consistently travels to Canada to be able to afford his own supply and purchase a surplus of vials to donate to diabetics in need.[133] Paulson crossing the border to buy insulin has helped him avoid rationing his insulin.[134] A six-month supply costs around $700 USD in Canada, that

129. *Id.*

130. *Id.*

131. *Id.*

132. WHO, *supra* note 19, at 36.

133. *If I'm Out of Insulin, I'm Going to Die: United States' Lack of Regulation Fuels Crisis of Unaffordable Insulin*, *supra* note 96, at 36 (citing Telephone Interview with Travis Paulson (Apr. 29, 2021)).

134. *Id.* (citing *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, H. COMM. ON WAYS AND MEANS COMM. STAFF 1, 52 (Sept. 2019), https://democrats-

same amount of money would only cover two vials in the United States.[135] Novolog is more than 92 percent cheaper per dose than in the U.S.[136] But, many diabetics cannot travel elsewhere to access cheaper medicine so unfortunately, they are forced to reckon with the high prices in the United States. Quinn Nystrom, a diabetic who organized a trip to Canada, acknowledged that she was lucky to be able to make the trip because many other diabetics couldn't afford to miss work.[137] Forcing diabetics to choose between life-sustaining medicine they so desperately need and the job that provides them the income to keep purchasing that medicine is a major indicator of how horrendous the insulin crisis truly is. Like the mutual aid groups and emergency access litigation described above, pharmaceutical tourism is not a long-term solution to the insulin access crisis. Nystrom also says, "Coming to Canada is not a long-term solution; coming to Canada is putting a Band-Aid on a gunshot wound."[138] The economic impact of pharmaceutical tourism also demonstrates just how widespread the crisis is. The global medical tourism market is projected to grow from $13.98 billion in 2021 to a $53.51 billion in 2028 at a compound annual growth rate of 21.1% in 2021-2028.[139]

Pharmaceutical tourism has become so mainstream that some states have programs to help citizens that plan on travelling abroad for the purpose of purchasing medication. The Public Employee Health Plan (PEHP) in Utah includes a voluntary Pharmacy Tourism Program. This program allows certain members "who use any of 13 costly prescription medications . . . the insurer will foot the bill to fly the patient and a companion to San Diego, then drive them to a hospital in

waysandmeans.house.gov/sites/evo-subsites/democrats-waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf).

135. *Id.* at 36 (citing Telephone Interview with Travis Paulson (Apr. 29, 2021)).

136. *Id.* (citing *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*, H. COMM. ON WAYS AND MEANS COMM. STAFF 1, 52 (Sept. 2019), https://democrats-waysandmeans.house.gov/sites/evo-subsites/democrats-waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf).

137. *Caravan of Americans Battling Diabetes Heads to Canada for Affordable Insulin*, CBS NEWS (July 2, 2019), https://www.cbsnews.com/news/insulin-caravan-battling-high-drug-prices-in-the-us-diabetes/.

138. *Id.*

139. Michael R. Agostino, *Travel-for-Treatment Provides Access to Cost-Effective Prescription Drugs*, PHARMACY TIMES (June 19, 2023), https://www.pharmacytimes.com/view/travel-for-treatment-provides-access-to-cost-effective-prescription-drugs (citing Jignesh Rawal*, U.S. Medical Tourism Market*, FORTUNE BUS. INSIGHTS (Sep. 1, 2025), https://www.fortunebusinessinsights.com/u-s-medical-tourism-market-108968).

Tijuana, Mexico, to pick up a 90-day supply of medicine."[140] The program is probably very helpful to the members that use any of the thirteen medications covered in the program. However, there is something deeply unsettling about a state committing that much money and time to a program that effectively just takes the underlying issue of pharmaceutical unaffordability and ships it elsewhere. Instead of passing local measures to combat this issue, it is as if the state has just made peace with the fact that drugs are expensive in the United States.

According to the FDA, it is technically "illegal for individuals to import drugs into the United States for personal use."[141] There is debate on whether there is any true risk of being arrested for participating in pharmaceutical tourism.[142] The act of travelling for medication has become so widespread and normalized. "The U.S. government estimates that close to one million people in California alone cross to Mexico annually for health care, including to buy prescription drugs. And between 150,000 and 320,000 Americans list health care as a reason for traveling abroad each year."[143] Utah state representative, Norm Thurstone, is not worried about potential prosecution and he says, "this sort of purchase for personal use is a widely established practice."[144] Nathan Cortez, a law professor at Southern Methodist University, also acknowledges that the FDA typically doesn't care about people bringing back small amounts of medication; however, Cortez warns that the FDA could change its mind on a whim and become much stricter.[145]

There is tension between patent law and public welfare. On one hand, it is devastating and horrific to see diabetics suffering because they cannot access insulin. On the other hand, developing life-saving medicine takes a lot of time and resources so the people that go through all that effort should be granted protection via patent rights. There is a belief in intellectual property law that without the safety net of intellectual property protection and rights, people will no longer create. Though this may be true for some people who seek out intellectual property protection, the scientists that originally discovered insulin serve as an excellent example of people that do not need money or

140. Bram Sable-Smith, *American Travelers Seek Cheaper Prescription Drugs in Mexico and Beyond*, NPR (Feb. 11, 2019), https://www.npr.org/sections/health-shots/2019/02/11/691467587/americans-seek-cheaper-meds-in-mexico.

141. *Id.*

142. *See id.*

143. *Id.*

144. *See id.*

145. *Id.*

credit as an incentive to create. Banting and the other scientists sold their patent rights for only one dollar.[146] They gave up their intellectual property protection in support of greater access to insulin. There is no way to fully appease either side, but compulsory licenses balance public welfare and intellectual property concerns. Compulsory licenses, under the TRIPS agreement, require adequate renumeration to the original patent owner.[147] Thus, compulsory licenses compensate the patent owner while still increasing the availability of insulin. The rights holder is happy because they receive some royalties, the licensee is happy because they receive the license to create, and the person consuming the patented product is happy because they have greater access to the medicine they need to survive. Compulsory licensing will help fix this global crisis harming diabetics.

Diabetics going through dire measures just to survive and help one another deserve better than the current state of insulin accessibility, and compulsory licenses are necessary to help fix this issue.

V. CONCLUSION

There are multiple factors that contribute to the issue of insulin accessibility. There are also multiple actors in the line of people from manufacturer to patient. Insulin manufacturers, insurance companies, prescription drug benefit managers (PBMs), pharmacists, endocrinologists, and patients are among many others. Recently, the Federal Trade Commission (FTC) has brought action against the three largest PBMS.[148] The FTC says that the action is brought against these groups for "engaging in anticompetitive and unfair rebating practices that have artificially inflated the list price of insulin drugs, impaired patients' access to lower list products, and shifted the cost of high insulin list prices to vulnerable patients."[149] Other administrative agencies like the FDA and the United State Patent and Trademark Office are other administrative agencies that can hold companies accountable. This is

146. Lewis & Brubaker, *supra* note 7, at 6.

147. Malik, *supra* note 27, at 28 (citing Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 3, 1869 U.N.T.S. 319, 333; TRIPS Agreement, art. 31; Martin Khor, Compulsory License and Government Use to Promote Access to Medicines: Some Examples, (Third World Network 2014), https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf).

148. *FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices*, F.T.C. (Sept. 20, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices.

149. *Id.*

one avenue for the United States to begin chipping away at the issue of insulin accessibility. While that is hopeful, the issue still exists globally outside of just the United States.

Additionally, insulin is only the tip of the iceberg. Diabetes management includes insulin delivery devices that vary from a simple syringe and vial to an insulin pump that you charge and update like a smartphone. Diabetes management also includes blood glucose surveillance and that requires a glucose meter with test trips, lancets, and a poking device or some kind of continuous glucose monitor. The more advanced technology like the insulin pump and continuous glucose monitors have their own supplies including cartridges, sensors, transmitters, etc. Safe to say, diabetics require lots of moving parts to manage their blood sugar and stay healthy. Each product has a price and a patent barrier to it. As mentioned before, some of the devices even have patents on miniscule parts of the device so companies cannot create any kind of pen device.[150] Putting aside the expansive range of diabetic supplies, the issue of accessibility exists for many other lifesaving medications. India and Malaysia have already utilized compulsory licensing to help broaden access to HIV/AIDS treatment.[151] Compulsory licensing has been and can be used a helpful tool for various other medications. It is shown to help more people gain access to life-saving treatment. Insulin just happens to be the focus of this paper because it is essential to many diabetics, and there is not enough scholarship about insulin patent licensing.

Over 420,000,000 people are living with diabetes.[152] Three in four people with diabetes live in low- and middle-income countries.[153] The United States spent $760 billion in total diabetes-related health expenditures in 2019.[154] This is not an issue that can go away on its own. There must be some action taken to help the diabetics around the world that are finding a way to survive despite the growing difficulty of

150. *See* Feldman & Schor*, supra* note 75, at 1088 (citing Marcus Reitzig*, Strategic Management of Intellectual Property*, 45 MIT SLOAN MGMT. REV. 35, 38-39 (2004)).

151. Malik, *supra* note 27, at 28 (citing Marcus Meland*, Malaysia Issues World's First Compulsory License*, LAW360 (Feb. 26, 2004), https://www.law360.com/articles/1035; Khor, *supra* note 147, at 1, 9).

152. WHO, *supra* note 19, at 3.

153. *See id.* (citing *Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants*, 387 LANCET 1513, 1521 (2016), https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2900618-8); IDF Diabetes Atlas 1, 34 (Int'l Diabetes Fed'n 2019), https://diabetesatlas.org/resources/previous-editions/.

154. *Id.* (citing IDF Diabetes Atlas, *supra* note 153).

accessing insulin. Three major companies engage in anticompetitive behavior bending the rules of patent law to keep other companies from entering the market. In addition to this, the current system for allowing biosimilars protects large biologic-producing companies from being transparent about what patent rights they currently possess so smaller companies must enter the arena of drug manufacturing blind and susceptible to lawsuits. This is extremely unfair to diabetics that are desperately seeking out less expensive insulin. Diabetics of all socioeconomic backgrounds deserve access to the insulin their body needs. The diabetics that are travelling, rationing, and donating their surplus supplies deserve better than the current oligarchy of companies controlling the price of insulin.

There are various solutions that could potentially combat the issue of insulin accessibility, but an increase in compulsory licensing strikes at the very heart of the problem with companies maintaining control over the market.