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Sugar Crash! How Ownership of a Life-Critical Hormone Became a Rare Commodity

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I. INTRODUCTION

Dear reader, I have an important message: You would die without sugar.[1] Sugar is a life giver, as are air and water. It is required for the basic functionality of every organism on our planet. Plants create sugars by taking in carbon dioxide, water, and solar energy.[2] Most bacteria obtain sugars by eating other organisms.[3] And all animals—including lions and tigers and bears, oh my!—obtain sugar from food.[4]

Our cravings for sugar begin at a young age. Every child loves candy, whether it is chocolate, taffy, lollipops, or any other sweet treat.[5] Parents, meanwhile—always leery of their kids becoming hyped up by the infamous "sugar rush"—learn to be cautious about how much candy they permit them to eat. Humans crave fewer sweets as they age, but the need for sugar never goes away.[6] Candy is hardly the only food rich in sugars—apples, carrots, bread, and vegetables, for instance, are all packed with sugars.[7]

There are many types of sugars in nature.[8] Scientists have given them fancy names, including sucralose, fructose, and lactose.[9] Many of these different sugars are important to our health and well-being. The most important sugar in our diet, however, is a tiny, hexagonally-shaped sugar called glucose.[10]

Like other sugars, we get our glucose from food.[11] Glucose is a primary energy source for our bodies; half of our daily

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[1] *Insulin*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/22601-insulin [https://perma.cc/7HXP-9HVX] (last visited Feb. 27, 2024) [hereinafter *Insulin*].

[2] *Photosynthesis*, NAT'L GEOGRAPHIC, https://education.nationalgeographic.org/resource/photosynthesis [https://perma.cc/8S7Y-9WJV] (last visited Feb. 27, 2024).

[3] *Heterotrophic Bacteria*, ENCLYCLOPEDIA.COM, https://www.encyclopedia.com/science/encyclopedias-almanacs-transcripts-and-maps/heterotrophic-bacteria [https://perma.cc/XJD3-6SB6] (last visited Feb. 7, 2024).

[4] *Metabolism of Carbohydrates*, LIBRE TEXTS BIOLOGY, htttps://bio.libretexts.org/Bookshelves/Microbiology/Book%3A_Microbiology_(Boundless)/2%3A_Chemistry/2.6%3A_Energy/2.6.1%3A_Metabolism_of_Carbohydrates#:~:text=Carbohydrates%20are%20one%20of%20the,other%20animals%20to%20obtain%20carbohydrates [https://perma.cc/P4B5-PVQ2] (last visited Feb. 27, 2024).

[5] *Liking Sweets Makes Sense for Kids*, SCI. DAILY (Mar. 20, 2009), https://www.sciencedaily.com/releases/2009/03/090318140624.htm#:~:text=%22The%20relationship%20between%20sweet%20preference,one%20of%20the%20study%20authors [https://perma.cc/6YKX-J84K] [hereinafter *Liking Sweets Makes Sense for Kids*].

[6] *Id.*

[7] *Sugar 101*, AM. HEART ASS'N (Nov. 2, 2021), https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/sugar/sugar-101 [https://perma.cc/DG6K-5RB3].

[8] *Liking Sweets Makes Sense for Kids*, *supra* note 5.

[9] *Id.*

[10] *Blood Sugar*, MEDLINE PLUS, https://medlineplus.gov/bloodsugar.html#:~:text=Blood%20sugar%2C%20or%20glucose%2C%20is,cells%20to%20use%20for%20energy [https://perma.cc/86KZ-EE8D] (last visited Feb. 29, 2024).

[11] *Id.*

intake is utilized to power the brain alone.[12] Glucose is so important to us that our bodies developed a special tool called "insulin" to help us absorb it.[13,14] Without insulin, one could ingest vast amounts of glucose, yet would still die because the body would be unable to move it from the bloodstream into the cells that depend on it. [15]

While most humans can make their own insulin, people with diabetes are either unable to produce insulin or have cells that are unresponsive to insulin.[16, 17] Because of this, many people with diabetes must take insulin as medicine.[18,19] Medicinal insulin is lab-created. Unfortunately, many people living with diabetes have trouble obtaining lab-created insulin; 25% of patients living with diabetes in the United States ration insulin because of its high cost.[20] This can have dire consequences—for example, when people living with diabetes are unable to take insulin, they are at risk of developing hyperglycemia, which occurs when there is too much sugar in their blood.[21] If left untreated, hyperglycemia can, among other things, result in damage to nerves, blood vessels, tissues, and organs.[22]

This paper argues for two options Congress could explore to ease the burden on diabetes patients. First, Congress could make it easier for new insulin products to enter the United States market if it loosens protections on pharmaceutical trade secrets for insulin manufacturing processes and if it limits the ability of pharmaceutical companies to keep clinical trial data secret. Second, Congress could make it easier for diabetes patients to switch insulin brands by requiring insulin delivery devices to have interchangeable parts between devices of different brands.

This paper begins with an overview of intellectual property (IP) practices in the pharmaceutical industry and how those practices apply to human-derived substances. It then explores the history and current trends of insulin-related intellectual properties.

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[12] Scott Edwards, *Sugar and the Brain*, HARVARD MED. SCH., https://hms.harvard.edu/news-events/publications-archive/brain/sugar-brain, [https://perma.cc/4Z5T-NYAQ] (last accessed Feb. 29, 2024).
[13] *Id.*
[14] *Insulin*, *supra* note 1.
[15] *Id.*
[16] *Id.*
[17] *Hyperglycemia: Causes, Symptoms, Treatments, and Prevention*, CLEVELAND CLINIC (Mar. 2, 2023), https://my.clevelandclinic.org/health/diseases/9815-hyperglycemia-high-blood-sugar [https://perma.cc/96ZK-U7M5] [hereinafter *Hyperglycemia*].
[18] *Insulin*, *supra* note 1.
[19] Mallory Locklear, *Insulin Is an Extreme Financial Burden for Over 14% of Americans Who Use It*, YALENEWS (July 5, 2022), https://news.yale.edu/2022/07/05/insulin-extreme-financial-burden-over-14-americans-who-use-it#:~:text=Over%2030%20million%20Americans%20have,of%20them%20require%20daily%20insulin [https://perma.cc/N3X8-FNVR].
[20] S. Vincent Rajkumar, *The High Cost of Insulin In the United States: An Urgent Call to Action*, *95* MAYO CLINIC PROC. 22, 22-28 (Jan. 1, 2020), https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext [https://perma.cc/4F54-CFFG].
[21] *Hyperglycemia*, *supra* note 17.
[22] *Id.*

This paper ends by providing an overview of recent developments in the insulin world and analyzing the implications of these developments on insulin-intellectual-property holders, on the insulin market, and on the ease with which diabetes patients can obtain insulin.

II. IP PRACTICES IN THE PHARMACEUTICAL INDUSTRY

Until recently, only three companies in the United States have supplied insulin products to patients: Novo Nordisk, Sanofi, and Eli Lilly.[23] These companies also make up 90% of the global insulin market.[24] Other companies have had limited success entering the U.S. insulin market, despite the fact that insulin's general manufacturing process is so well known that the basics of it are often taught to high school and undergraduate biology students.[25, 26] Given this, why has it been so difficult for new players to enter the insulin market?

Part of the answer to this lies in the protections insulin manufacturers are given by the U.S. legal system, which recognizes four types of IP: patents, trade secrets, copyrights, and trademarks.[27] Of these, pharmaceutical companies rely most heavily on patents and trade secrets to protect their IP interests[28]

Patents are "government-granted monopolies" for individuals and business entities to build, sell, and use an invention (and prevent others from doing so).[29] Patents are only good in the country where they are granted and are usually good for twenty years, although some types last only fourteen years.[30, 31, 32] Because anyone can copy, build, or sell an invention once its patent expires, patent holders will sometimes look for ways to extend their patent protections.[33] For example, patent holders can try to "evergreen" their patents by making small, incremental changes in their inventions and

[23] Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, 7 OXFORD ACAD. J.L. & BIOSCIENCES 1 (2020), https://academic.oup.com/jlb/article/7/1/lsaa061/5918811 [https://perma.cc/VK46-2KLF].
[24] *Id*.
[25] *See id.* at 3; *see also* Nicholson Price, The Cost of Novelty, 120 COLUM. L. REV. 769, 797-798 (2020).
[26] *See, e.g.*, ROBERT J. BROOKER, GENETICS ANALYSIS AND PRINCIPLES 520 (4th ed. 2009).

[27] Sterling Miller, *Modern General Counsel: Four Types of Intellectual Property*, THOMSON REUTERS LEGAL (Nov. 12, 2021), https://legal.thomsonreuters.com/en/insights/articles/four-types-of-intellectual-property [https://perma.cc/29TM-7SST].
[28] Daniel Gervais, *The Patent Option*, 20 N.C.J.L. & TECH., 359 (2019).
[29] Miller, *supra* note 27.
[30] *Id*.
[31] *Id*.
[32] *Id*.
[33] *Id*.

then refiling for a new patent to extend the life of their control over the invention.[34]

There are several types of patents inventors can apply for, including utility, plant, and design patents.[35] Utility patents last twenty years and are given for new "processes, machines, articles of manufacture, compositions of matter, or any useful improvement thereof."[36] Plant patents also last twenty years and are given for new inventions or discoveries of "distinct and new" plant varieties, which must be able to asexually reproduce.[37] Design patents are given for "new, original, and ornamental designs."[38] Unlike other types of patents, design patents only last fourteen years.[39]

A. Patent Requirements

An invention must meet four requirements to be eligible for patent protection.[40] First, the invention must be patentable subject matter.[41] Second, the idea must be novel, meaning that there are no previous patented inventions that have all the features of the new invention.[42] Third, the idea must be useful.[43] Fourth, the idea must be nonobvious to a "person of ordinary skill in the technical field of the invention."[44]

An invention must meet two sets of criteria to satisfy the subject matter eligibility requirement.[45] First, the invention must be a new process, machine, article of manufacture, or composition of matter.[46] Alternatively, the invention can also be an improvement on an existing patent.[47] Second, the invention must not be a "judicial exception," which is excluded from the four categories of acceptable inventions.[48] Judicial exceptions include laws of nature, natural

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[34] Jeremy Greene & Kevin Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171 (2015).
[35] Miller, *supra* note 27.
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Patent: Overview*, THOMSON REUTERS PRAC. L., https://1.next.westlaw.com/8-509-4160?__lrTS=20210326125405926&transitionType=Default&contextData=(sc.Default)&firstPage=true&OWSessionId=47fe7c3ff7dc439196c4b41dadbcf45d&isplcus=true&fromAnonymous=true&bhcp=1#co_anchor_a000011 [https://perma.cc/CU35-4N7F] (last visited Feb. 29, 2024) [hereinafter *Patent*].
[41] *Id.*
[42] *Id.*
[43] Miller, *supra* note 27.
[44] *Patent*, *supra* note 40.
[45] *2106 Patent Subject Matter Eligibility*, MPEP (8th ed. Rev. 7, Sept. 2008), https://www.uspto.gov/web/offices/pac/mpep/s2106.html [https://perma.cc/3AYB-MMP2] (last visited Feb. 29, 2024) [hereinafter *2106 Patent Subject Matter Eligibility*].
[46] *Patent*, *supra* note 40.
[47] *2106 Patent Subject Matter Eligibility*, *supra* note 45.

[48] *Id.*

phenomena, and abstract ideas.[49] For example, you would not be able to patent your discovery of a new physics equation because physics equations describe laws of nature.

That being said, an invention is not ineligible for a patent just because *part* of it involves a judicial exception.[50] Courts use the *Alice/Mayo* test to determine whether a proposed patent is a judicial exception or whether the proposed patent is a patentable invention that merely uses a judicial exception as a component.[51] This test involves two steps.[52] Step one looks at whether the patent is directed towards a law of nature, natural phenomenon, or an abstract idea.[53] Step two looks at whether the proposed patent contains additional elements that are not judicial exceptions and whether there are more of those additional elements than the elements that are judicial exceptions.[54]

For instance, while in the physics equation example the equation itself is not patentable, a device that uses the equation along with other parts to complete a task may be. Although the device would involve a judicial exception as part of its design, the device could be patentable because it would also have many other parts that are not judicial exceptions, such as circuit boards, wires, and other such things.

B. Trade Secret Requirements

In contrast to patents, trade secrets protect business processes rather than inventions.[55] These processes must not be "generally known to the public," the company must use "reasonable efforts" to keep the process secret, and the process must provide "economic value" to the company *because* it is secret.[56]

States and countries vary in what qualifies as a trade secret.[57] Generally, new business models, customer and supplier information, marketing strategies, and company processes can all be trade secrets.[58] Unlike patents—which only expire after a certain amount of time has passed—a business practice can lose trade secret protection if the company does not affirmatively take appropriate steps to keep the business practice secret.[59] On the other hand, if a

[49] *Patent*, *supra* note 40.
[50] *2106 Patent Subject Matter Eligibility*, *supra* note 45.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Miller, *supra* note 27.
[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*

business successfully keeps information secret, a trade secret can protect information for an indefinite amount of time.[60]

Courts consider the following factors to determine whether something is a trade secret: (1) the extent that the process is known outside the company, (2) the measures taken by the company to protect the process, (3) the value of the process to competitors, (4) the extent that the company's employee base knows the process, and (5) the amount of money and effort the company used to develop the process and how easy it would be for others to duplicate it.[61]

C. Shifts In Pharmaceutical IP Practices

Historically, pharmaceutical companies have primarily used patents to protect their IP interests because they provide twenty years of stable protection.[62] Pharmaceutical companies, however, are beginning to favor trade secrets over patents because trade secrets allow them to suppress unfavorable information and are not subject to time limitations, whereas patents are.[63] Patents are also more fragile than trade secrets because they can face challenges to their subject-matter eligibility after they are issued.[64,65] Further, patents are also "one-size-fits-all" because inventions that are more cutting edge or ingenious receive protections identical to inventions that are comparatively straightforward.[66]

In addition to patents and trade secrets, pharmaceutical companies also protect their IP interests by disallowing competitors to use their clinical data.[67] The ability of pharmaceutical companies to keep clinical data secret is essentially an uncodified form of IP protection because it forces competitors to obtain their own clinical data (an expensive and time-consuming process), which makes it more difficult for competitors to create competing products.[68]

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[60] *Trade Secrets /Regulatory Data Protection,* USPTO, https://www.uspto.gov/ip-policy/trade-secret-policy [https://perma.cc/M24G-2NLG] (last visited Feb. 28, 2024).

[61] Miller, *supra* note 27.

[62] Gervais, *supra* note 28, 360 n.5.

[63] *Id.*

[64] *Id*. at 360 n.5.

[65] *E.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, 569 U.S. 576, 576 (2013).

[66] Gervais, *supra* note 28, at 361.

[67] *Id.* at 359.

[68] Clinical data protection is not formally classified by U.S. law as a type of intellectual property protection. *See* Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for A Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 5 (2009). Clinical data obtained by pharmaceutical companies is, however, allowed to be kept secret by the pharmaceutical company for anywhere from three to ten years. *Id.* In some cases, the protection on clinical trial data can outlive relevant patent protections. *Id*. Obtaining new clinical data can be a prohibitive challenge for competing pharmaceutical companies because clinical data can cost hundreds of millions of dollars, requires years to obtain, and carries a high degree of risk — for example, only about twenty percent of drugs that enter clinical trials obtain Federal Drug Administration approval. *Id.* at 5, 9.

III. IP AS RELATED TO THE HUMAN BODY

As is discussed throughout this article, insulin genes and other insulin related technologies are subject to various types of IP protections. But is this not strange? Does it make sense or seem ethical that access to a substance that is normally made by the human body and is necessary for human life is restricted by laws instead intended to incentivize scientific discovery and protect the economic interests of their holders? [69], [70] And, even if the preceding considerations do not conflict, is the current state of the insulin IP universe consistent with how the law has treated similar types of IP in the past?

Ownership of humans and human body parts goes back millennia. In ancient Rome, the law did not consider anyone to be the owner of their own body parts. [71] For example, a person did not own their arms or legs as property. On the other hand, slaves were not recognized as legal persons and thus were classified as property. [72]

Ideas about ownership and IP rights concerning dead bodies also make up an old—although not quite as ancient—area of jurisprudence. Going back to the 17th and 18th centuries, British common law established the principle of "no property" in human corpses.[73] Under the no property principle, dead bodies and biological materials separated from dead bodies cannot be the subject of property rights.[74] Common law exceptions to this exist, however.[75] For example, under the "work or skill exception", a person may gain property rights over a corpse when (1) she lawfully obtained the body (i.e., she did not snag it during a grave robbing spree); (2) she exercised work or skill on the human body or body part; and (3) she caused the body or party part to "[acquire] some attributes differentiating it from a mere corpse awaiting burial through that exercise of work or skill."[76] Modern-day courts have used similar logic to find that individuals can retain property interests in hair clippings if they have used the hair clippings for a specific purpose, such as using them to create something.[77]

While legal thought relating to enslaved individuals and corpses goes back centuries, much of the law relating to human body ownership and relevant IP rights is new and has many unanswered questions. For example, no statutes in the United States classify a

[69] *Patent*, *supra* note 40.
[70] Miller, *supra* note 27.
[71] Rohan Hardcastle & Linda Pearson, LAW AND THE HUMAN BODY: PROPERTY RIGHTS, OWNERSHIP, AND CONTROL 64 (Bloomsbury Publishing Plc 2009).
[72] *Id.*
[73] *Id.* at 25.
[74] *Id.* at 28.
[75] *Id.*
[76] *Id.* at 29.
[77] *Id.* at 94.

person's internal organs as their property.[78] U.S. jurisprudence is also unclear regarding blood ownership; some courts have found that blood and blood products can be "goods" with property characteristics, but other courts disagree.[79] Interestingly, U.S. courts have found that money earned by individuals from the sale of their own blood is taxable income.[80]

It is also unclear whether an individual can own their own gametes. Gametes are a person's reproductive cells which, in humans, includes sperm in people born with testes and eggs in people born with ovaries.[81] While some courts have found that sperm can be a part of a person's estate. there are no federal statutes that regulate the transfer or control of gametes in the U.S., although some state legislatures have passed laws that begin to address these issues. [82, 83] These state laws have focused on stripping gamete providers, such as fertility clinics, of all rights, obligations, or interests with respect to children of artificial insemination. [84] These laws neither classify donated gametes as property nor give gamete providers property rights.[85]

A. Moore V. Regents Of California: Individuals Can Abandon Their Ownership Interest In Their Body Parts

There are a few established modern principles about body-part related IP. For example, a person loses ownership over their cells once the cells removed from their body. In *Moore v. Regents of the University of California*, the California Supreme Court upheld a patent held by Dr. David Golde, which was based on the cells of John Moore, one of Dr. Golde's patients.[86] Moore—who was suffering from leukemia—had his blood and other bodily substances drawn by Dr. Golde as part of Moore's cancer treatment.[87] Dr. Golde then extracted cells from Moore's bodily substances, used them to create a cell line, patented the cell line, and then quickly landed a deal to sell usage rights to the cell line for hundreds of thousands of dollars.[88] None of these actions were done with Moore's knowledge or consent.[89]

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[78] *Id.* at 79.
[79] *Id.* at 85.
[80] *Id.* at 86.
[81] *Gamete*, SCITABLE BY NATURE EDUC., https://www.nature.com/scitable/definition/gamete-gametes-311/ [https://perma.cc/4DWX-ZKC3] (last visited Feb. 28, 2024).
[82] Hardcastle & Pearson, *supra* note 71, at 92.
[83] *Id.* at 91.
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Moore v. Regents of University of California*, 51 Cal. 3d 120, 125 (Cal. 1990).
[88] *Id.* at 127.
[89] HARDCASTLE & PEARSON, *supra* note 71, at 67.

The court found that Moore had not retained ownership interest in his cells after they were removed because the laws governing biological materials did not exist to establish or protect any personal property rights in such materials; rather, these laws solely existed to achieve policy goals that were not related to personal property rights.[90] Further, the court—apparently applying the previously discussed "work or skill exception"—also said that Moore did not have a claim to the patented cell line or products derived from it because it was a product of invention.[91] In short, the court found that cell lines were chattels capable of being converted because they were created from property that their original owner abandoned.[92] In this sense, the court analyzed human cell ownership similarly to how it analyzes ownership of human waste products. Concerning these substances, courts have found that, while an individual may assert continuing property rights in such bodily substances after the substances leave the body, it is also the universal human custom and experience that such things are discarded (i.e. legally abandoned).[93]

B. Ass'n For Molecular Pathology V. Myriad Genetics: Some Types Of Genetic Information Can Be Patented

Interestingly, until recently courts considered DNA segments to be ownable and patentable substances.[94] In a 2013 decision, the United States Supreme Court found in *Ass'n for Molecular Pathology v. Myriad Genetics* that naturally occurring DNA segments are not patentable because they are products of nature.[95] In this case, Myriad Genetics, Inc., a biotech company, had patented two genes—BRCA1 and BRCA2—that were associated with an increased risk of breast cancer.[96] Women could be genetically tested to determine whether they had the version of BRCA1 or BRCA2 that would make them susceptible to breast cancer later in life.[97] Women could use the information from these genetic tests to determine whether they needed to take steps to reduce their likelihood of getting breast cancer, such as by getting a preemptory mastectomy (removal of the breast tissue).[98]

Myriad's patents gave it the exclusive right to isolate these genes in an individual, meaning that if a person wanted to find out whether she had a version of these genes that made her more

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[90] 51 Cal. 3d at 137.
[91] *Id.*
[92] *Id.* at 88.
[93] *Id.* at 95; *Ass'n for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576, 576 (2013).
[94] *Ass'n for Molecular Pathology*, 569 U.S. at 567.
[95] *Id.*
[96] *Id.*
[97] *BRCA Gene Mutations: Cancer Risk and Genetic Testing*, NIH: NAT'L CANCER INST. (Nov. 19, 2020), https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet [https://perma.cc/88CL-6JM9].
[98] *Id.*

susceptible to cancer, she could only get tested by Myriad.[99] Prior to the lawsuit, Myriad had sued and shut down several third-party clinics that had provided BRCA1 and BRCA2 genetic testing services to women.[100]

The Court held that Myriad's patents on these genes were invalid.[101] This was because Myriad's patents did not involve altered versions of the genes, so the genes were thus products of nature.[102] All Myriad had done was identify the genetic sequences of these genes and where these genes appear in the human genome.[103] While Myriad had also come up with a way to isolate these genes, "separating the gene from its surrounding genetic material" was "not an act of invention."[104] Further, while Myriad had also undertaken extensive efforts to find the genes, this in and of itself was not enough to make the genes patent-eligible.[105] In short, the Court found that Myriad had not applied the necessary "work or skill" to claim it had an invention in the gene.

The Court, however, also said that complementary DNA sequences were still patentable.[106] Complementary DNA ("cDNA") is made by scientists by using human DNA as a template.[107] Any cDNA made from human DNA will have the same information as the original human DNA; both carry complete sets of information about a person's genetic makeup.[108]

The information in the cDNA, however, is more refined than the information in human DNA and appears in a different form than human DNA.[109, 110] The information in cDNA could be thought of as being in French while the information in human DNA could be thought of as being in Spanish. While cDNA and DNA appear differently at the molecular level and present the information in different "languages", the gene-related information they contain is identical.

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[99] *Ass'n for Molecular Pathology*, 569 U.S. at 567.
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] *Id.*
[107] *Complementary DNA*, BIOLOGY ONLINE (Jul. 23, 2021), https://www.biologyonline.com/dictionary/complementary-dna [https://perma.cc/T9RY-DM47].
[108] *Id.*
[109] *Id.*
[110] *See generally cDNA vs Genomic DNA: The Relationship and Differences in Genomic DNA and Complimentary DNA*, BIOCHAIN, https://www.biochain.com/blog/cdna-vs-genomic-dna/#:~:text=cDNA%20can%20be%20described%20as,t%20have%20any%20coding%20sequences [https://perma.cc/XE6W-B4T3] (last visited Feb. 12, 2024) (Contains more information about DNA and cDNA that is beyond the scope of this article).

Certain organisms do naturally make cDNA, including some single-celled organisms.[111] It is not, however, naturally made in the human body.[112] The *Myriad* court reasoned that, while the information contained in DNA sequences and cDNA sequences was the same, cDNA was patentable because it did not occur naturally in the human body.[113]

Myriad ended a decades long practice of patenting DNA sequences.[114] You can no longer isolate a DNA sequence and claim that you are the only person with the right to use it in research or technology—unless you use common laboratory processes to convert it to cDNA.

IV. IP MEETS INSULIN

Insulin's discoverers made a deliberate choice to not profit from it.[115] In 1921, Dr. Frederick Banting, Charles Best (his assistant), and James Collop came across a substance that prolonged dogs' lives after removal of their pancreases.[116] The men named the substance "insulin," which is Latin for "island," a reference to the part of the pancreas that makes insulin, which is called the "islets of Langerhans."[117]

In 1922, the first successful administration of insulin was given to a fourteen-year-old boy named Leonard Thompson.[118] Thompson was diabetic and near death; he weighed only sixty-five pounds and was severely ill.[119] His condition immediately improved after receiving the insulin.[120] Insulin was subsequently given to several other children who were in similarly dire straits, and all of them showed the same improvement as Thompson.[121]

Two days after the test on Thompson, Banting, Best, and Collop signed an agreement with the University of Toronto's Connaught Antitoxin Laboratories—a noncommercial public healthy entity—to produce insulin.[122] Dr. Banting had been reluctant to patent his discovery because he was concerned about patients being unable

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[111] *Id.*
[112] *Ass'n for Molecular Pathology*, 569 U.S. at 595.
[113] *Id.* at 576.
[114] Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM. GENETICS 383, 396 (2010).
[115] Gary F. Lewis & Patricia L. Brubaker, *The Discovery of Insulin Revisited: Lessons for the Modern Era,* 131 J. CLINICAL INVESTIGATION 1, 1 (2021).
[116] *Id.* at 3.
[117] *Id.* at 5.
[118] *Id.* at 6.
[119] *Id.*
[120] *Id.*
[121] *Id.*
[122] *Id.*

to access insulin due to its cost.[123] He famously declared, "Insulin does not belong to me, it belongs to the world."[124] Banting and his colleagues, however, were forced to patent their discovery after it became clear that their work could be shut down if they did not.[125] In December 1922, Banting, Best, and Collop sold their pending insulin patent rights to the University of Toronto for $1 apiece.[126] A month later, the men filed a patent for preparing insulin extracted from the pancreas. [127]

Unfortunately, the Connaught Laboratory was not able to produce enough insulin to meet the demand, so the University of Toronto signed an agreement with the pharmaceutical company Eli Lily that gave Eli Lily exclusive rights to manufacture and distribute insulin.[128] Per the agreement Eli Lily was to give insulin to physicians and hospitals free of charge for one year.[129] After that time, Eli Lily was free to charge for insulin and patent any changes to the drug. [130]

During the mid-20th century, pharmaceutical companies began to patent processes for obtaining insulin from discarded pig and cow pancreases.[131,132] Many different processes for preparing insulin for diabetic patients also received patent protections during this time.[133] In 1978, a method of creating "biosynthetic insulin"—which is insulin formed by genetically-altered bacteria—was developed, ending the need to use animal pancreases during the manufacturing process.[134] Eli Lilly put the first biosynthetic insulin, called "Humulin," on the market in 1982.[135] While many newer types of biosynthetic insulins are on the market today, all are still made using microscopic organisms such as bacteria, just as they were in 1982. [136, 137]

Many biosynthetic insulins have properties not found in naturally occurring human insulin. Insulins with special properties are generally referred to as "analog insulins" and are made using a

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[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] *Id.*
[127] Extract Obtainable from the Mammalian Pancreas or from the Related Glands in Fishes, Useful for the Treatment of Diabetes Mellitus, and a Method of Preparing it, U.S. Patent No. 1,469,994 (filed Jan. 12, 1923).
[128] Lewis & Brubaker, *supra* note 115.
[129] *Id.*
[130] *Id.*
[131] *The History of a Wonderful Thing We Call Insulin*, AM. DIABETES ASS'N (July 1, 2019), https://diabetes.org/blog/history-wonderful-thing-we-call-insulin [https://perma.cc/2KWG-M729].
[132] Protein Purification Process & Proteinaceous Product, U.S. Patent No. 2,576,066 (filed Aug. 11, 1948) (issued Nov. 20, 1951).
[133] Process for Purifying Insulin, U.S. Patent No. 3,907,676 (filed May 14, 1973) (issued Sept. 23, 1975).
[134] Lewis and Brubaker, *supra* note 115.
[135] *Id.*
[136] *Id.*
[137] Irl Hirsch et al., *The Evolution of Insulin and How It Informs Therapy and Treatment Choices*, ENDOCRINE REVS. (May 12, 2020), https://academic.oup.com/edrv/article/41/5/733/5836295 [https://perma.cc/7TAW-CKXZ].

slightly modified version of the human insulin gene. Because of these modifications, analog insulins have specific enhancements.[138] There are four types of analog insulins: rapid-acting short-acting, intermediate-acting, and long-acting. [139] They are categorized based on how long it takes them to work; rapid- and short-acting insulins provide patients with rapid effects, long-acting insulins take longer to take an effect but can last longer, and intermediate-acting insulins fall somewhere in the middle.[140]

There are also many new ways diabetes patients can administer insulin. While in the past patients had to take insulin via an injection, today patients can also take insulin by using an insulin pump or by inhaling it as a powder.[141] Many—if not all—of these insulin administration technologies are currently patent protected.[142]

V. CURRENT ISSUES WITH INSULIN RELATED IP

Insulin prices have skyrocketed over the past few decades and have gone from a few dollars per vial to hundreds of dollars per vial.[143] For example, between 1999 and 2019, the price of one type of insulin increased over 1000%.[144] Meanwhile, a vial of insulin still costs only a few dollars to manufacture.[145] In contrast, the price of insulin in other developed countries—such as Canada— has stayed the same during this time period.[146]

Legal challenges posed by insulin IP holders' challenges holders are partly to blame for this. [147] Until 2014, only three companies held insulin-related patents in the United States: Novo Nordisk (holding fifty-three percent of these patents), Sanofi Aventis (holding thirty-two percent of these patents), and Eli Lilly (holding sixteen percent of these patents).[148]

Initially, most intellectual properties related to insulin were patents on insulin genes.[149] The recent *Myriad* decision calls the stability of these patents into question, although the number of

[138] David Morris, *Biosimilar Insulins: An in-depth Guide*, 26 J. OF DIABETES NURSING 1, 2 (2022).
[139] Knox, *supra* note 23.
[140] *Id.*
[141] *Supra* note 1.
[142] *See, e.g.*, Rapid Acting Drug Delivery Compositions, U.S. Patent No. 7,279,457 (issued Oct. 9, 2007); *see also* Medical Injection System with Dose Capturing, U.S. Patent No. 10,117,999 (issued Nov. 6, 2018); *see also* Peristaltic Micropump with Exchangeable Pump Head, U.S. Patent No. 2009/0292247 (issued Nov. 26, 2009).
[143] Rajkumar, *supra* note 20.
[144] *Id.*
[145] *Id.*
[146] *Id.*
[147] Jing Luo & Aaron Kesselheim, *Evolution of Insulin Patent and Market Exclusivities in the USA*, 3 LANCET DIABETES & ENDOCRINOLOGY 835, 836 (2015).

[148] *Id.*
[149] Knox, *supra* note 23.

existing patents on insulin DNA sequences had begun to taper off well before *Myriad*.[150] Most human and analog insulin patents have expired or are about to expire. [151]

Pharmaceutical companies have shifted their focus from patenting new forms of insulin to patenting new insulin delivery devices. Between 2004 and 2014, the number of insulin-related patents in the U.S. increased from eight patents to nineteen patents.[152] Most of these patents were for new devices to administer insulin and were not for patents on the insulin gene itself.[153] Of the active insulin-related patents in the U.S., more than half are for insulin devices and less than a quarter are for actual insulins, a disparity that has only increased since 2014.[154]

Insulin manufacturers are likely focusing their patent endeavors on insulin delivery devices because these are less likely to face legal challenges than are actual insulins. For example, insulin-gene patents must contend with the question of whether they are a product of nature as opposed to an actual invention, whereas insulin devices are entirely man made and thus have a lesser risk of later being invalidated by a court. The lessons learned from *Myriad* will likely perpetuate this change.

The intersectionality between IP interests in both insulin and insulin delivery devices has added additional complications to the insulin market. While pharmaceutical companies have shifted their focus from insulin genes to insulin devices, this shift will not significantly alleviate the current insulin oligopoly because the existence of insulin-device patents is a barrier new types of insulin must overcome to enter the market.[155] Even if a company creates a new insulin, the new insulin is useless to patients if they have no way to administer it.

Insulin delivery devices require that the patient learn how to use them.[156] Even if a pharmaceutical company develops a new delivery device to go along with its new insulin medication, a patient may be unwilling to switch to the new device—even if doing so would allow them to use cheaper insulins—if this would require them to use a delivery device they are unfamiliar with. [157] While it is possible for pharmaceutical companies to create new compatible insulin products and devices, doing this is a very expensive and time-consuming process that requires extensive testing to receive Food and

[150] Michael Hopkins et al., *DNA Patenting: The end of an Era?*, 25 NATURE BIOTECHNOLOGY 185 (2007).
[151] Knox, *supra* note 23.
[152] Luo & Kesselheim, *supra* note 147.
[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] John White & Jennifer Goldman, *Biosimilar and Follow-On Insulin: The Ins, Outs, and Interchangeability*, 35 J. PHARMACY TECH. 1 (2019).
[157] *Id.*

Drug Administration (FDA) approval.[158] Unless the pharmaceutical company is well established or has another way of obtaining the necessary funds, these challenges make it difficult to enter the U.S. insulin market.[159]

Further, pharmaceutical companies are financially incentivized to develop and patent insulin products that are deliberately and unnecessarily incompatible with their competitors' insulin products because this forces patients to lock in with a particular brand.[160] The story of the insulin pump market highlights the issues this can cause.[161] Insulin pumps are devices that help diabetes patients administer insulin more easily than they can with manual injections.[162] For many years, insulin pumps could be connected to an industry standard insulin kit.[163] This meant that patients could use any brand of pump without having to worry about the availability of brand-specific parts.[164] Pharmaceutical companies, however, began making and obtaining patents on new insulin pumps and kits.[165] These new devices were not any more functional than older models and were designed to be incompatible with competitors' insulin pumps[166] In short, pharmaceutical companies were creating new kits solely to obtain new patents and to incentivize patients to use only their devices.[167]

The practice of making brand-specific, non-standardized parts has spread throughout the insulin industry and has been to the detriment of diabetes patients.[168] Patients must be retrained to switch between insulin pumps with different connectors, which increases the risk of medical error.[169] Further, patients who use insulin pumps cannot use parts from other brands if something breaks and have fewer devices to choose from than if they had access to standardized kits. Additionally, non-standardized devices also make it difficult for new insulin manufacturers to enter the market, as those manufacturers must now create a new insulin delivery device to accompany any new insulin they make.

To be sure, there are some societal benefits to having insulin-related IP. For one, the existence of insulin-related patents can help promote the invention of new insulin products because only new insulin products can get patent protection.[170] Arguably, this has

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[158] *Id.*
[159] *Id.*
[160] Nicholson Price, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 804 (2020).
[161] *Id.*
[162] *Id.*
[163] *Id.*
[164] *Id.* at 804.
[165] *Id.* at 805.
[166] *Id.*
[167] *Id.*
[168] *Id.*
[169] *Id.* at 805-06.
[170] *Id.* at 788.

helped facilitate the development of insulin products with special features, such as long-acting and short-acting insulin analogs and has thus given patients access to a wider variety of products to choose from.

Overall, however, the existence of and enforcement of insulin-related patents has highlighted some of the troubles that can arise from patenting human genes and related technologies. Fortunately, new technological and political developments are beginning to alleviate some of these troubles.[171] The lessons learned from insulin show us that IP interests in life-critical medications can direly impact the patients who need them.

VI. *MYRIAD* DISCOURAGES INSULIN GENE IP PROTECTION

While most new insulin-related IP has focused on insulin delivery devices instead of insulin genes, is there any reason to think this trend will continue? The answer to this question is important because it will provide information about the types of legislation that could meaningfully improve insulin access.

Commercially available insulin differs from some types of human-derived IP in that it does not come from an identifiable individual. On the other hand, it is like other human-derived IP in it is made using instructions available in all humans and concerns a substance that is necessary for human life. Further, all versions of insulin given to diabetes patients are created using genes originally derived from the naturally occurring human insulin gene. For these reasons, we should consider how insulin related IPs fit into the scheme of IP as related to the human body.

As previously discussed, the historical reasoning for allowing ownership interests in human bodies and body parts has relied on one of two theories: (1) that the body or body part had been abandoned or (2) that the new holder of the body or body part had applied work or skill sufficient to give the body or body part new qualities. Of these possibilities, the work-or-skill line of reasoning is the only one that could grant individuals IP protections for insulin genes.

Insulin is a "biologic" —a drug derived from living materials.[172] Biologics are larger and more complicated than drugs that are not derived from living materials, such as aspirin. [173]

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[171] Benita Lee, *How Much Does Insulin Cost? Here's How 28 Brands and Generics Compare*, GOODRX HEALTH (Jan. 26, 2022), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands [https://perma.cc/32PY-FJUP].

[172] Knox, *supra* note 23, at 13.

[173] *Building Biologics*, GENENTECH (Feb. 8, 2016), https://www.gene.com/stories/building-biologics [https://perma.cc/KFW8-D8K9].

Compared to insulin and other biologics, aspirin is a very small drug.[174] It is made of only twenty-one atoms, whereas a biologic such as insulin can be made of tens of thousands of atoms.[175] Because of their size and complex structure, biologics are much more difficult to manufacture and manipulate than non-biologic drugs.[176]

The first commercially available insulin, Humulin, was made using the original human insulin gene.[177] While isolating the gene was a labor-intensive process for its discoverers, intensive labor is insufficient to grant patent rights.[178] Because no work or skill is used to make Humulin different from naturally occurring insulin, a patent for Humulin would not likely be valid under *Myriad.*

Analog insulins, however, are different from naturally occurring insulins because scientists create them by cultivating insulins with special characteristics.[179] Because at least some work and skill is used to develop analog insulins, under *Myriad* the case for granting patents for them is stronger than the case for granting a patent to a non-altered form of insulin. Even so, *Myriad* still discourages pharmaceutical companies from focusing their efforts on patenting genes because *Myriad* establishes that gene patents can fail the subject-matter requirements for patents. It is likely that pharmaceutical companies will continue to focus their efforts on protecting their interests in insulin delivery devices because these are less likely to face legal challenges.

VII. NON-TRADITIONAL INSULIN TECHNOLOGIES: BIOSIMILARS CHANGE THE GAME

Biosimilar insulins are another of insulin available in the U.S. [180] Biosimilar insulins—also referred to as "follow-on" insulins—are a copy-version of an existing insulin product, which is referred to as the "reference product."[181] They are made using the same DNA sequences as the reference insulin and thus have no meaningful differences.[182] The manufacturing processes for existing biologic products, however, are trade secrets owned by the original insulin manufacturers.[183] The quality of biologics such as insulin is very sensitive to changes in the manufacturing process, and for this

[174] *See id.*
[175] *See id.*
[176] *See id.*
[177] Morris, *supra* note 138.
[178] Kat Arney, *From Insulin to Humulin — The Story of the First Genetically Engineered Drug*, GENETICS UNZIPPED (June 3, 2021), https://geneticsunzipped.com/transcripts/2021/6/3/from-insulin-to-humulin-the-story-of-the-first-genetically-engineered-drug [https://perma.cc/4J4X-EM6A].
[179] Knox, *supra* note 23, at 6.
[180] White and Goldman, *supra* note 156, at 25.
[181] *Id.* at 26.
[182] *Id.*
[183] *Id.*

reason, it is impossible for biosimilars to be identical to the reference product, although any changes are not clinically meaningful.[184]

Biosimilar insulins are often inaccurately equated with generic drugs.[185] Generic drugs are replicas of relatively simple, small, and stable molecules, whereas biosimilars are replicas of complicated, large, and unstable molecules.[186] Further, biosimilar insulins are not inherently interchangeable with the reference insulin.[187] This means that a patient cannot go to a pharmacy with a prescription for a reference insulin and receive the equivalent biosimilar insulin if the biosimilar insulin is not listed on their prescription.[188, 189] In contrast, a patient could get a generic version of a drug in lieu of the specific type named on their prescription without needing additional prescriber approval.

For a biosimilar insulin to be available to patients without them needing an additional prescription, the FDA must approve the interchangeability between the biosimilar insulin and its reference insulin.[190] The first insulin biosimilar was approved in the United States in 2019.[191] This insulin, called Lispro, is manufactured by Eli Lilly and is the counterpart to an analog insulin—also manufactured by Eli Lilly—called Humalog.[192] Since then, the FDA has approved several other biosimilar insulins.[193] These biosimilar insulins all retail for about half the price of their reference products.[194]

It was not until July 28, 2021, however, that the FDA approved the first *interchangeable* biosimilar insulin.[195] This biosimilar insulin, called Semglee, is interchangeable with Lantus, a

[184] *Id.*
[185] *Id.*
[186] *Id.* at 26.
[187] *Id.*
[188] *Id.* at 30; *See also* Jing Luo et al., *Insulin Access and Affordability in the U.S.: Anticipating the First Interchangeable Insulin Product*, 8 LANCET DIABETES & ENDOCRINOLOGY 360, 361 (2020).
[189] *See also* Jing Luo et al., *Insulin Access and Affordability in the U.S.: Anticipating the First Interchangeable Insulin Product*, 8 LANCET DIABETES & ENDOCRINOLOGY 360, 361 (2020).
[190] White and Goldman, *supra* note 156, at 31.
[191] Lee, *supra* note 171.
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] *FDA Approves First Interchangeable Biosimilar Insulin Product For Treatment of Diabetes*, FOOD & DRUG ADMIN. (July 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes [https://perma.cc/BN8Q-MHWF].

type of analog insulin.[196] This means that a pharmacy can substitute Lantus with Semglee without prescriber intervention.[197,198, 199]

It is unclear whether *Myriad* precludes patenting biosimilar insulins.[200] Because biosimilar insulins only differ from reference insulins in their manufacturing process and not in their DNA sequences, their patentability may hinge on whether their reference insulin is still patent-protected and whether the DNA sequence has been meaningfully changed from the original human insulin gene. Overall, it is more likely that the therapeutic processes for using biosimilars will be patentable than the biosimilars themselves.[201]

Insulin biosimilars have been available in Europe since 2014.[202] IP litigation brought by pharmaceutical companies is a major reason why it took five additional years for biosimilar insulins to hit the U.S. market. Biosimilars faced a high cost of entry partly due to patent infringement litigation and trade secrets protecting insulin manufacturing processes.[203] Pharmaceutical companies have also used evergreening tactics—making small, incremental changes to their existing insulin gene patents—to extend the lives of their patent protections well beyond their intended twenty-year expiration date.

Notably, the first biosimilar insulin to be approved in the U.S.—Lispro—is manufactured by Eli Lilly, one of the three major U.S. insulin manufacturers. Further, the biosimilar version of Lispro is also made by Eli Lilly. From this, we can infer that the major insulin players are trying to maintain their shares of the insulin market by staying ahead of the changes biosimilars could bring. By doing this, pharmaceutical companies may retain their oligopoly over the insulin market by establishing new proprietary interests over biosimilar manufacturing processes.

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[196] *Id.*
[197] *Id.*
[198] *Discover Semglee – The First FDA-Approved, Long-Acting Insulin Glargine that is Interchangeable with Lantus (Insuline Glargine) Injection*, BIOCON BIOLOGICS, https://www.semgleehcp.com/#:~:text=SEMGLEE%20and%20the%20Semglee%20Logo,Inc.%2C%20a%20Viatris%20Company [https://perma.cc/D928-H9D2] (last visited Nov. 21, 2022).
[199] *Once-Daily Lantus Is the Most Prescribed Long-Acting Insulin*, SANOFI-AVENTIS, https://www.lantus.com/#:~:text=And%20Lantus%20is%20only%20one,diabetes%20medicines%20made%20by%20Sanofi [https://perma.cc/EX6Z-SPX2] (last visited Nov. 21, 2022).
[200] Nicolas Arkells, *Patentable Subject Matter Barriers for Biosimilars – And How to Overcome Them*, BIOSIMILAR DEV. (July 17, 2018), https://www.biosimilardevelopment.com/doc/patentable-subject-matter-barriers-for-biosimilars-and-how-to-overcome-them-0001 [https://perma.cc/4LHM-URKU].
[201] *Id.*
[202] M. Davies et al., *Introduction of Biosimilar Insulins to Europe*, 34 DIABETIC MED. 1340, 1340 (2017).
[203] Luo & Kesselheim, *supra* note 147, at 836-37.

VIII. PROPOSALS FOR THE FUTURE

Dr. Frederick Banting wanted insulin to be easily accessible to those who need it. His wish has not come to be, but there is still hope. The first *interchangeable* biosimilar approved in the U.S., Semglee, is manufactured by Mylan Pharmaceuticals, and is interchangeable with Lantus, which is manufactured by Sanofi-Aventis.[204] Sanofi-Aventis is one of the three major, classic insulin manufacturers in the United States, whereas Mylan Pharmaceuticals is the first new player to enter the U.S. insulin market in decades.[205]

Further, various nonprofits are also developing additional competing biosimilar insulin products. For example, the nonprofit Civica is creating three new interchangeable biosimilar insulins and plans to introduce them to the U.S. market by 2024.[206] If the FDA approves them, Civica's biosimilar insulins will join the first approved interchangeable biosimilar insulin from 2021.[207]

There is also room for Congress to alleviate the burdens of new insulin manufacturers. For example, in the past, Congress has implemented legislation to shorten the approval pathway—and thus lower prices—for various types of drugs.[208] These past legislative efforts, however, have not been successful in lowering insulin prices because they do not account for the unique difficulties biologic manufacturers face in the manufacturing process.[209] Other past Congressional actions—such as the recent Inflation Reduction Act passed by the Biden administration—include measures that are specifically meant to reduce insulin prices.[210] This last measure has

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[204] BIOCON BIOLOGICS, *supra* note 198; SANOFI-AVENTIS, *supra* note 199.

[205] Todd Boudreaux, *Fourth Major Insulin Manufacturer Enters US Market with Semglee Launch*, BEYOND TYPE 1 (Aug. 31, 2020), https://beyondtype1.org/semglee-available-us-market/ [https://perma.cc/9DRR-DSVJ].

[206] Amruta Khandekar & Bhanvi Satija, *Civica Aims to Launch Low-Cost Insulin in U.S. by 2024*, REUTERS (Mar. 3, 2022, 4:19 AM) https://www.reuters.com/business/healthcare-pharmaceuticals/civica-aims-launch-low-cost-insulin-us-by-2024-2022-03-03/ [https://perma.cc/M387-BYQ2]; FAQ, CIVICA, https://www.civicainsulin.org/faq/#:~:text=Civica%20will%20produce%20three%20insulins,Humalog%20and%20Novolog%2C%20respectively [https://perma.cc/7ANX-D3Y6] (last visited Nov. 21, 2022).

[207] FOOD & DRUG ADMIN., *supra* note 195.

[208] Emily Hanson, *The Economic Burdens of Life: Trade Secrecy and The Insulin Pricing Crisis in The United States*, 27 J. INTELL. PROP. L. 251, 265-70 (2020).

[209] *Id.* at 270

[210] Simmone Shah, *Why Insulin Is so Expensive in The U.S. — and What the Inflation Reduction Act Does About It*, TIME (Aug. 16, 2022, 4:58 PM), https://time.com/6206569/insulin-prices-inflation-reduction-act/ [https://perma.cc/Q86V-7APJ].

successfully led to significant savings for diabetes patients in the U.S.[211]

Congress could take additional actions to increase insulin access. For example, Congress could mandate that insulin delivery devices be compatible with those of other insulin brands. This would give patients flexibility to try different types of insulin and to take advantage of some of the lower priced insulins that are beginning to enter the market without them having to learn how to use a new insulin administration device. This would also make it easier for new insulin manufacturers to enter the market because they would not have to spend funds developing new insulin delivery devices.

Further, Congress could limit the types of IP protections that are available to pharmaceutical companies. Currently, certain patented pharmaceutical technologies are eligible for additional market exclusivity protections after they receive FDA approval.[212] Many insulin technologies have benefitted from these extra protections in the past, which have received an average of two extra years of market protection compared to other similarly classified drugs.[213] Recent studies have indicated that drug companies—including developers of insulin technologies—have abused these extra protections in the past by mischaracterizing their patents.[214] These abuses have likely contributed to the difficulties new insulin manufacturers face when trying to enter the U.S. market.[215] While rules already exist about which pharmaceutical technologies qualify for extra protections, the complicated interrelationship between pharmaceutical patents makes violations of these rules difficult to spot and enforce.[216] Congress could respond by further restricting the types of pharmaceuticals that qualify for extra exclusivity protections. By shrinking the pool of technologies that are eligible for extra protections, Congress could make it easier for regulators to spot abuses of the protections.

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[211] *New HHS Report Finds Major Savings for Americans Who Use Insulin Thanks to President Biden's Inflation Reduction Act*, U.S. DEP'T HEALTH & HUMAN SERVS. (Jan. 24, 2023), https://www.hhs.gov/about/news/2023/01/24/new-hhs-report-finds-major-savings-americans-who-use-insulin-thanks-president-bidens-inflation-reduction-act.html#:~:text=The%20report%20shows%20that%20if,on%20insulin%20for%20the%20year [https://perma.cc/6QYC-682D].

[212] Haley Weiss, *How Drug Makers Manipulate Patents to Keep Insulin Prices High*, TIME (Nov. 17, 2023, 11:45 AM), https://time.com/6336840/patent-manipulation-insulin-prices/ [https://perma.cc/M38J-ZYPX].

[213] *Id.*

[214] *Id.*

[215] *Id.*

[216] *Id.*

IX. CONCLUSION

For years, diabetes patients have had to contend with a severely overpriced insulin market and a confusing array of insulin-related products. This has been partly due to the highly insulated state of the U.S. insulin market and the incentive for pharmaceutical companies to patent brand-specific insulin products to lock patients to their brand. New forms of insulin products have already begun to alleviate burdens on diabetes patients. Since the first insulin biosimilar was introduced in the United States in 2019, the average cost of insulin has dropped by 5% and is expected to drop further as more interchangeable biosimilar insulins enter the market.[217]

To be sure, these changes alone will not be enough to eliminate excessive insulin prices. For example, in addition to issues caused by the oppressive insulin IP landscape, the cost of insulin has remained high also due to middlemen negotiating higher prices.[218] Still, biosimilars are a good first step for bringing insulin back to the people. It is unclear whether biosimilar insulins will face the same or similar patent-related restrictions that past insulin products have encountered. The good news is that the *Myriad* decision makes this a less likely eventuality. Biosimilar products may raise their own set of interesting patent-related questions in the future, but for now, they are already alleviating the burden on insulin patients by providing them with lower prices and more options.

[217] Lee, *supra* note 171.
[218] Shah, *supra* note 210.