REDEFINING "LIFE": THE CONSTITUTIONAL IMPLICATIONS OF PATENTING IMMORTALITY♦

INTRODUCTION

An indefinite lifespan was far from being a practical concern at the time of the United States Constitution's formation, when the average lifespan in the Americas was thirty to forty years.[1] Not many of the Framers or their families, neighbors, and friends would live past their fifties.[2] Infectious diseases were the leading cause of death before the twentieth century,[3] and, while some people lived to old age and died of natural causes, socioeconomic status played a large role in the access to the sort of health care that enabled longevity.[4]

Since the eighteenth century, the average human lifespan has nearly doubled—the average life expectancy of a person born in 2016 is 78.6 years.[5] Infectious diseases that were sure to cause death upon contraction prior to the twentieth century were rendered practically obsolete by vaccines and other advances in medicine.[6] Consequently, the leading causes of death in 2016 were non-infectious diseases including heart disease, cancer, and chronic lower respiratory diseases.[7] The medical community has been working vigorously on the prevention, treatment, and management of these diseases and has celebrated many successes over the past few decades.

However, a cohort of scientists are committing to a more forward-thinking approach to increasing longevity: instead of curing specific diseases, the scientific community should be focused on curing "the one

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[1] Max Roser, *Life Expectancy*, OUR WORLD IN DATA, https://ourworldindata.org/life-expectancy (last visited Jan. 10, 2019).

[2] *See id.*

[3] *See 10 Leading Causes of Death in 1850 and 2000*, NONPROFIT UPDATE (Oct. 21, 2010, 9:51 AM), https://nonprofitupdate.info/2010/10/21/10-leading-causes-of-death-in-1850-and-2000-2 (listing the top ten causes of death in 1850 as (1) tuberculosis, (2) dysentery/diarrhea, (3) cholera, (4) malaria, (5) typhoid fever, (6) pneumonia, (7) diphtheria, (8) scarlet fever, (9) meningitis, and (10) whooping cough).

[4] *See* Laura Helmuth, *Why Are You Not Dead Yet?*, SLATE (Sept. 5, 2013, 5:18 AM), http://www.slate.com/articles/health_and_science/science_of_longevity/2013/09/life_expectancy_history_public_health_and_medical_advances_that_lead_to.html.

[5] Kenneth D. Kochanek et al., *Mortality in the United States, 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Dec. 2017), https://www.cdc.gov/nchs/data/databriefs/db293.pdf.

[6] Helmuth, *supra* note 4.

[7] Kochanek et al., *supra* note 5 (listing the top ten causes of death in 2016 as (1) heart disease, (2) cancer, (3) unintentional injuries, (4) chronic lower respiratory diseases, (5) stroke, (6) Alzheimer's disease, (7) diabetes, (8) influenza and pneumonia, (9) kidney disease, and (10) suicide).

ailment guaranteed to kill everyone: old age."[8] Proponents of the development of anti-aging therapies reason that many diseases, including Alzheimer's disease, heart disease, and cancer, are caused by senescence,[9] which occurs when the aging of our cells results in their loss of ability to divide.[10] Thus, by preventing senescence, the medical community can prevent the death-causing diseases from developing in our bodies in the first place.[11] The ultimate result of such developments will be a state of peak physical health and mental function for an indefinite lifespan.[12]

This futuristic approach to medicine has received public support from several big investors over the past few years, many of whom have openly expressed their desire to increase longevity by curing aging itself.[13] One of the more well-known projects on this frontier of research is Google's research and development company Calico—California Life

[8] Amy Nicholson, *We'll Cure Death in a Decade, Say the Stars of the SXSW Doc* The Immortalists, L.A. WKLY. (Mar. 17, 2014, 9:31 AM), http://www.laweekly.com/arts/well-cure-death-in-a-decade-say-the-stars-of-the-sxsw-doc-the-immortalists-4514330.

[9] *Common Diseases with Aging*, CTR. FOR CARDIOVASCULAR EDUC., http://www.caregiverresourcecenter.com/disease.pdf (last visited Jan. 10, 2019).

[10] Judith Campisi & Fabrizio d'Adda di Fagagna, *Cellular Senescence: When Bad Things Happen to Good Cells*, 8 NATURE REVS.: MOLECULAR CELL BIO. 729, 729–30 (2007).

[11] This field of study is called senolytics. *See Senolytic Drugs Reverse Damage Caused by Senescent Cells in Mice*, NAT'L INSTS. OF HEALTH (July 9, 2018), https://www.nih.gov/news-events/news-releases/senolytic-drugs-reverse-damage-caused-senescent-cells-mice; Nicholson, *supra* note 8. Some scientists view the cure to aging as a preventative medicine for other age-related illnesses. *See* Leah Samuel, *Can We 'Cure' Aging? Scientists Disagree*, STAT (Dec. 29, 2015), https://www.statnews.com/2015/12/29/aging-disease-cure.

[12] Aubrey de Grey, *A Roadmap to End Aging*, TED (July 2005), https://www.ted.com/talks/aubrey_de_grey_says_we_can_avoid_aging. In addressing the issue of overpopulation as a result of indefinite lifespan, scientist Aubrey de Grey responds, "[w]e will have to decide whether to have a low birth rate, or a high death rate. A high death rate will, of course, arise from simply rejecting these [anti-aging] therapies, in favor of carrying on having a lot of kids. And, I say that that's fine—the future of humanity is entitled to make that choice. What's not fine is for us to make that choice on behalf of the future. If we vacillate, hesitate, and do not actually develop these therapies, then we are condemning a whole cohort of people—who would have been young enough and healthy enough to benefit from those therapies, but will not be, because we haven't developed them as quickly as we could—we'll be denying those people an indefinite lifespan, and I consider that that [sic] is immoral." *Id.*

[13] Laura Lorenzetti, *The Obsession with 'Curing' Aging Is Now Big Business*, FORTUNE (Mar. 7, 2016), http://fortune.com/2016/03/07/aging-cures-research-entrepeneurs. Among the leading entrepreneurial investors in the field of longevity are Peter Thiel, co-founder of PayPal, who gave $3.5 million to Aubrey de Grey and Dave Gobel to start the Methuselah Foundation, which conducts regenerative medicine research; Bill Maris, president of Google Ventures, who invests in companies that slow aging, increase longevity, and reverse disease; Art Levinson, CEO of Calico and a leading name in the field of human longevity due to his research on what controls human lifespan; Dave Gobel, co-founder of the Methuselah Foundation, who has been working to treat aging as a medical condition; Craig Venter, founder of Human Longevity, Inc., who seeks to redefine aging by enhancing lifespan and increasing human performance; and Martine Rothblatt, founder of Sirius Satellite Radio, who redefines indefinite lifespan by using technology and biological measures to store digital files of a person's life in order to recreate her life once the technology to do so is invented. *See, e.g.*, THE METHUSELAH FOUND., https://www.mfoundation.org (last visited Jan. 11, 2019).

Company—which was launched in 2013 with the mission "to harness advanced technologies to increase our understanding of the biology that controls lifespan" and use that knowledge to devise interventions that will increase human longevity.[14] In an interview about the decision to launch Calico, Google co-founder Larry Page expressed his concern that eradicating cancer would only add about three years to average life expectancy, and trying to cure specific diseases in such a way would not be a big enough step in the advancement of human longevity.[15]

This Note will first explore what an indefinite lifespan would look like, according to prominent researchers in the field. Part II of this Note will examine the current patent law system, with a focus on its role in the current medical climate as well as its susceptibility to abuses. Part III of this Note will discuss the evolution of United States patent law and, specifically, its constitutional origins. Additionally, Part III will examine the right to life granted to individuals in the Constitution under the Fifth and Fourteenth Amendments and provide a contextual analysis of the Framers' value of life. This Note will argue that an indefinite lifespan is beyond what the Framers fathomed at the time of the Constitution's formation, and, based on their high regard for an individual's right to life, they did not intend for the Intellectual Property Clause to grant patent protection over the cure to aging. As a result, Part IV of this Note will propose a new legal framework for courts to use when examining whether patent protection should be granted over cutting edge medical developments, such as the cure to aging.

I. INDEFINITE LIFESPAN: HOW WILL IT LOOK AND HOW WILL IT AFFECT HUMANITY?

A. *Recent Developments in Anti-Aging and Longevity Escape Velocity*

With the recent developments in futuristic medicine, such as artificial organs, "designer babies," and cell cloning, it should not come as a surprise that technology to drastically expand human lifespan is on the horizon. Aubrey de Grey, a futurist[16] and one of the scientists at the forefront of the field of anti-aging, predicted that the first large step towards indefinite lifespan would be made within twenty years.[17]

This prediction was generated through the consideration of multiple factors. First, de Grey enumerates all the types of cell damage

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14 CALICO, https://www.calicolabs.com (last visited Jan. 11, 2019).

15 *See TIME Talks to Google CEO Larry Page About Its New Venture to Extend Human Life*, TIME (Sept. 18, 2013), http://business.time.com/2013/09/18/google-extend-human-life.

16 "Futurist" is defined as one who studies and predicts the future, especially on the basis of current trends. *Futurist*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/futurist (last visited Feb. 3, 2018).

17 De Grey, *supra* note 12.

caused by aging,[18] qualifying that the scientific community has not extended the list since 1982, which is probative of its extensiveness.[19] Second, de Grey asserts that the methods of reversing the effects of each type of cell damage have already been fully or partially developed.[20] Third, de Grey explains, once the therapies[21] to reverse each type of cell damage have been fully developed and tested on mice,[22] clinical trials on humans can begin.[23]

In fact, de Grey was correct in his prediction. In 2014, a team at the Albert Einstein College of Medicine began a human clinical study of the effects of the drug metformin to treat aging. Metformin is a U.S. Food and Drug Administration (FDA)-approved drug used to treat type 2 diabetes, but clinical trials were sought after scientists noticed the drug "may influence metabolic and cellular processes associated with the development of age-related conditions . . . ."[24] In May of 2018, results from the trials were released, demonstrating some anti-aging properties of the drug.[25]

Other developments in the anti-aging field are as recent as July of 2018, when a government-funded research team at the Mayo Clinic published the results of its study on senescent cells in mice—specifically, it concluded that senolytics improve physical function and

[18] *A Reimagined Research Strategy for Aging*, SENS RES. FOUND., http://www.sens.org/research/introduction-to-sens-research (last visited Jan. 25, 2018). The seven types of cell damage caused by aging are (1) cell loss or cell atrophy, (2) division-obsessed cells (i.e., cancerous cells), (3) death-resistant cells, (4) mitochondrial mutations, (5) intracellular aggregates, (6) extracellular aggregates, and (7) extracellular matrix stiffening. *Id.*

[19] *Id.*

[20] *Id.* Use of stem cells, tissue engineering, removal of telomere-lengthening machinery, allotropic expression of proteins, targeted ablation, immunotherapeutic clearance, and novel lysosomal hydrolases are among the biotechnologies which may be used in achieving cell damage reversal. *Id.*

[21] "Therapies" refers to the regeneration of our cells and the reversal of cell damage, which will lead to an arrest of aging. The therapies may be in the form of drugs, medical procedures, or a combination of the two, and both of these forms are currently patentable. *See Patents on Medical Procedures and the Physician Profiteer*, FINDLAW, http://corporate.findlaw.com/intellectual-property/patents-on-medical-procedures-and-the-physician-profiteer.html (last visited Feb. 3, 2018).

[22] Researchers at Mayo Clinic have reversed the negative effects of death-resistant cells, also known as senescent cells, in mice, and the result was an increase in mouse lifespan by seventeen to thirty five percent. Megan Forliti, *Mayo Researchers Extend Lifespan in Mice by as Much as 35 Percent*, MAYO CLINIC (Feb. 3, 2016), https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-researchers-extend-lifespan-by-as-much-as-35-percent-in-mice-2. Further, at the Dana-Farber Cancer Institute at Harvard, damage caused by division-obsessed cells was partially reversed by controlling telomerase enzymes in mice, which prevented senescence and arrested symptoms of aging. Richard Saltus, *Partial Reversal of Aging Achieved in Mice*, HARV. GAZETTE (Nov. 28, 2013), https://news.harvard.edu/gazette/story/2010/11/partial-reversal-of-aging-achieved-in-mice.

[23] De Grey, *supra* note 12. Robust human rejuvenation, also known as longevity escape velocity, can be attained approximately fifteen years after robust mouse rejuvenation is achieved. *Id.*

[24] Erika Brutsaert, *Metformin in Longevity Studies (MILES)*, U.S. NAT'L LIBR. MED., https://clinicaltrials.gov/ct2/show/study/NCT02432287 (last updated May 31, 2018).

[25] *Id.*

increase lifespan in old age.[26] The team transplanted senescent cells into young, healthy mice and found that doing so caused senescence to spread to host tissues and increased physical dysfunction.[27] A transplant of senescent cells to older mice had the same effect as well as reducing lifespan.[28] The scientists further found that administering a "senolytic cocktail"[29] that eliminates senescent cells to the mice alleviated their physical dysfunction and, in the case of older mice, increased their post-treatment survival by 36%.[30] In effect, among other observations, the team found that the cocktail, if proven safe during clinical trials, may be used to lengthen and enhance lifespan in older subjects by preventing frailty, but it also may be used on other individuals, such as cancer survivors whose cells were induced into senescence during chemotherapy or radiation.[31]

To illustrate how anti-aging therapies will develop and affect the population, David Gobel introduced the concept of longevity escape velocity, also known as actuarial escape velocity, which was later popularized by de Grey and Ray Kurzweil.[32] Longevity escape velocity is a predicted hypothetical situation in which lifespan is extended longer than time passes, so for every year that passes, technology is developed to extend lifespan by more than one year.[33] There is no Fountain of Youth, and regenerative therapies that will arrest aging will be developed over a long period of time—for example, the first generation of regenerative therapies may increase lifespan by 30%, adding about twenty to thirty more years to the average lifespan and buying scientists time to develop second-generation regenerative therapies, which may further increase lifespan by 30%, and so on.[34] However, the model is also subject to the consideration that the regenerative therapies will likely benefit younger people more than older people, since the damage to older cells from aging is too vast to be fully reversed by the first few rounds of therapies.[35] If a person has more damaged cells when the regenerative therapies become available, her lifespan will be shorter than a person with young, healthy cells.[36] Thus, longevity escape

[26] James L. Kirkland et al., *Senolytics Improve Physical Function and Increase Lifespan in Old Age*, 24 NAT. MED. 1246 (2018).
[27] *Id.* at 1247–48.
[28] *Id.* at 1248.
[29] The senolytic cocktail comprises dasatinib plus quercetin ("D + Q"). *Id.* at 1246.
[30] *Id.* at 1250–53.
[31] *Id.* at 1254; *see also* NAT'L INSTS. OF HEALTH, *supra* note 11.
[32] *See* Aubrey D.N.J. de Grey, *Escape Velocity: Why the Prospect of Extreme Human Life Extension Matters Now*, 2 PLOS BIOLOGY 723, 725 (2004).
[33] Peter H. Diamandis, *Exponential Wisdom Episode 34: Longevity Escape Velocity*, YOUTUBE (June 5, 2017), https://www.youtube.com/watch?v=4Ouje475718.
[34] The numbers and percentages included in this analysis are hypothetical. De Grey, *supra* note 32.
[35] *Id.*
[36] *Id.*

velocity yields the conclusion that the first 1,000-year-old will only be about ten years younger than the first 150-year-old.[37]

The implications of longevity escape velocity are vast. Under the model, time is more precious than ever, and a ten-year bar on access to cell regeneration therapies may make the difference between an individual living to 1,000 years and living to 150 years.[38] In many ways that will be discussed in Part II, drug and medical procedure patents bar access to the protected good, since the patent holder is granted a limited monopoly over the drug or procedure,[39] and such a monopoly is often unregulated. This raises the important question of how extensive patent rights are, and whether they are extensive enough to grant the inventor of an anti-aging therapy an exclusive right to her invention[40] at the expense of a specific age group's loss of decades of life.

B. *Distinguishing a Cure to Aging from Other Drugs and Therapies*

When thinking about whether patent protection should be granted over the cure to aging, an important inquiry arises: what is the difference between a cure to aging and a cure to any disease, such as cancer, that makes its patentability more questionable? To start, it is important to acknowledge that most scientists who work on research and development of the cure to aging believe aging should be classified as a disease.[41] This group is of the view that aging should be classified as a disease despite the universality of the process, because it is an abnormality of bodily function that is caused by damage at the cellular level.[42] Additionally, it is argued that since aging is the underlying

[37] *Id.*

[38] *See id.*

[39] *Infra* Part II.

[40] Based on the discussion in Part II.B, I will assume that the inventor of the cure to aging will seek patent protection over her invention for similar reasons and motives as other drug and medical procedure patent applicants. *See infra* Part II.B.

[41] Aging is currently not classified as a disease, according to International Classification of Diseases (ICD-11). *See generally International Classification of Diseases*, WORLD HEALTH ORG. (June 18, 2018), https://icd.who.int/browse11/l-m/en. Sven Bulterijs et al., *It Is Time to Classify Biological Aging as a Disease*, 6:205 FRONTIERS GENETICS 1, 1 (June 18, 2015); Alex Zhavoronkov & Bhupinder Bhullar, *Classifying Aging as a Disease in the Context of ICD-11*, 6:326 FRONTIERS GENETICS 1, 1 (Nov. 4, 2015). Also, the FDA does not currently classify aging as a disease or medical condition. *See generally More on Efforts to Lobby the FDA to Accept Aging as a Medical Condition that Can and Should Be Treated*, FIGHTAGING.ORG (June 17, 2015), https://www.fightaging.org/archives/2015/06/more-on-efforts-to-lobby-the-fda-to-accept-aging-as-a-medical-condition-that-can-and-should-be-treated/.

[42] Bulterijs, *supra* note 41, at 1. In an attempt to explain the controversy surrounding whether aging is a disease, researchers for *Frontiers in Genetics Journal* wrote, "stratifying elderly from younger aged adults is not based on any good biological argument but instead masks aging as separate from disease, despite it being apparent that aging represents a deviation of the more desired state of youthful physical and mental capacities. Whilst a statement such as this could be considered ageist, such a conception is based on the misunderstanding of what is meant by youthful. Aging as the passage of time and the accumulation of wisdom is not undesirable; the physiological decline that accompanies the process, however, most certainly is." *Id.* at 2.

cause of many diseases, aging itself should be regarded as a collection of diseases,[43] or at least a treatable risk factor for other conditions.[44]

It is easy to see why scientists in the field of anti-aging want aging to be classified as a disease. With this reclassification, the study of aging will be legitimized, and more funding will be allocated towards the research of it.[45] However, short of the monetary appeal, the arguments for the classification of aging as a disease are not strong.

Scientists who are against classifying aging as a disease argue that since aging is a natural and universal process, it cannot be categorized as a disease, which is defined as a deviation from the normal state.[46] Aging, although a result of cell damage, is in fact a natural, biological process. This distinction is important, since any advancement in the field of anti-aging would universally favor all people and not just a specific class. As such, an increase in longevity should be regarded not as a cure to an individual's cell damage, but rather as lifespan being redefined in our society to be a longer period of time.[47] Thus, to the second class of scientists, the difference between a cure to cancer and a cure to aging is that the former cures a disease and the latter cures a universal and natural biological process—cancer treatments affect the 38.4% of the population that develops cancer in their lifetime,[48] while aging treatments have the ability to affect 100% of the population. With the foregoing distinction in mind, I will proceed to regard the cure to aging differently than the cure to any other medical condition throughout the remainder of this Note, as well as put into question its patentability on the basis of this distinction.

II. PATENT LAW TODAY: PRIVILEGES, ABUSES, AND RESPONSE

A. *The Rights of Patent Holders and Requirements for Patents*

Accompanying social, economic, and political climate changes in our country's history, patent law evolved a great deal since it was first

[43] Timothy V. Gladyshev & Vadim N. Gladyshev, *A Disease or Not a Disease? Aging as a Pathology*, 22 TRENDS MOLECULAR MED. 995, 996 (2016).

[44] Samuel, *supra* note 11.

[45] *See* Gladyshev & Gladyshev, *supra* note 43, at 995.

[46] Bulterijs et al., *supra* note 41, at 2.

[47] The universality of aging is an important distinction that is necessary to explain why the social implications of access to a cure to aging are not quite analogous to those of access to medicine, such as a cure to cancer, for sick people. However, from an economics standpoint, I am assuming that access to both treatments is a necessity; as such, the demand for the cure to cancer in a market of people with cancer is identical to the demand for the cure to aging for everyone. Both of these demand curves would be inelastic or perfectly inelastic, which means that people would be willing to pay a lot for the good and are thus more susceptible to price abuse.

[48] *Cancer Stat Facts: Cancer of Any Site*, NAT'L CANCER INST., https://seer.cancer.gov/statfacts/html/all.html (last visited Jan. 31, 2018) (based on 2013–2015 data).

addressed in the Constitution and codified in the Patent Act of 1790.[49] The requirements for an invention to be patentable have become more specific, and these changes are codified in the current U.S. Patent Act. The Act describes patentable inventions by writing, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[50] Specifically, the Act allows patents to be granted for inventions that are of patentable subject matter,[51] novel,[52] useful,[53] non-obvious,[54] and adequately disclosed.[55] The United States Patent and Trademark Office (USPTO) grants patents for a duration of twenty years from the date of first filing the patent application in the United States.[56] Once the patent rights have expired, the invention is in the public domain, and the patent cannot be renewed.[57]

A patent gives the inventor the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States for a limited time.[58] Other than full public disclosure of the invention once the patent is granted,[59] the only additional requirement for a granted patent is maintenance fees, which must be paid in order to keep the patent for the twenty-year period.[60]

B. *The High Cost of Drug Development and Regulation*

The current medical and scientific landscape presents many reasons for the necessity of drug patents. For one, the Tufts Center for the Study of Drug Development recently estimated the average cost of developing a prescription drug is approximately $2.6 billion, based on information from the development cost of 106 randomly selected drugs.[61] Granting a period of exclusivity in the sale of a drug allows for

[49] *Compare* Patent Act of 1790, 1 Stat. 109 (1790), *and* Patent Act, 35 U.S.C. §§ 101 *et seq.*. (1952).
[50] 35 U.S.C. § 101.
[51] *Id.*
[52] 35 U.S.C. § 102.
[53] 35 U.S.C. § 101.
[54] 35 U.S.C. § 103.
[55] 35 U.S.C. § 112.
[56] 35 U.S.C. § 154. This description applies to post-Leahy-Smith America Invents Act (AIA) patents, so it is applicable for patents filed on or after March 16, 2013. JOHN M. GOLDEN ET AL., PRINCIPLES OF PATENT LAW, CASES AND MATERIALS (West Academic 7th ed. 2018).
[57] *Frequently Asked Questions on Patents*, BROWN & MICHAELS, P.C., http://www.bpmlegal.com/patqa.html#2a (last visited Jan. 17, 2019).
[58] 35 U.S.C. § 154.
[59] 35 U.S.C. § 112.
[60] 35 U.S.C. § 41(b). To maintain the patent, maintenance fees must be paid as follows: (1) $980 paid three years and six months after the grant; (2) $2480 paid seven years and six months after the grant; and (3) $4110 paid eleven years and six months after the grant. *Id.*
[61] Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, CHEM. & ENG'G NEWS (Nov. 20, 2014), https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html.

the recovery of some of the costs that the company and its investors sunk into the research, development, and production of that drug.[62]

Prior to being able to market the drug for consumer use, the pharmaceutical company must seek approval from the FDA.[63] The FDA is a regulatory agency within the U.S. Department of Health and Human Services that oversees drugs and medical products and is responsible for "protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices."[64] After drug patent approval, the FDA requires the pharmaceutical company to test the dosage and accumulate data before the drug enters the market, and this period of extensive testing can take up to fourteen years.[65] As a result, on average, pharmaceutical companies only realize the exclusivity and profits from their patent for eleven and a half years.[66] Moreover, once a patent expires, the drug's sales can decrease by as much as 80% within a year as generic competition increases.[67]

A lack of ability to recover the costs of researching and developing drugs creates a lack of incentive for pharmaceutical companies to develop drugs for the market.[68] In fact, it is common practice in the pharmaceutical industry for companies to screen the drugs they are considering developing and to exclude the ones that are unpatentable.[69] According to Massachusetts Institute of Technology Professor Benjamin N. Roin,

> [g]iven the immense investment needed to fund clinical trials on drugs and the ability of generic manufacturers to rely on those tests

The Tufts Center for the Study of Drug Development drew its information from 106 randomly selected drugs provided by ten pharmaceutical companies. *Id.* The average out-of-pocket production costs were estimated at $1.4 billion, and the foregone returns on investments during the period of development were estimated at $1.2 billion. *Id.* Additionally, an estimated $312 million was spent on post-approval development, which includes further testing of formulations and dosage strengths. *Id.*

62 Freya Smale, *Pharmaceutical Patents – What Are the Different Types?*, TOTAL ORPHAN DRUGS (Sept. 9, 2013), http://www.orphan-drugs.org/2013/09/09/pharmaceutical-patents-types (noting that the cost of production is high because the development and release of pharmaceutical drugs can take up to fourteen years).

63 Austin Frakt, *How Patent Law Can Block Even Lifesaving Drugs*, N.Y. TIMES (Sept. 28, 2015), https://www.nytimes.com/2015/09/29/upshot/how-patent-law-can-block-even-lifesaving-drugs.html.

64 *FDA Fundamentals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm (last updated Feb. 9, 2019).

65 Smale, *supra* note 62; Chandra Mohan et al., *Patents – An Important Tool for Pharmaceutical Industry*, 2 RES. & REV.: J. PHARM. & NANOTECH. 12, 13 (2014).

66 Smale, *supra* note 62; Mohan et al., *supra* note 65.

67 Matthew Herper, *Solving the Drug Patent Problem*, FORBES (May 2, 2002, 8:00 AM), https://www.forbes.com/2002/05/02/0502patents.html.

68 Frakt, *supra* note 63.

69 *Id.*

> to secure regulatory approval for their own products, pharmaceutical companies are rarely willing to develop drugs without patent protection . . . . This gap in the patent system for drugs has created a pervasive problem in the pharmaceutical industry, causing firms to regularly screen their drugs during the research-and-development process and discard ones with weak patent protection. The harm to the public from the loss of these drugs is potentially quite significant.[70]

The harmful practice of screening drugs for patentability demonstrates how important patent protection is to pharmaceutical companies and shows that the recovery of investment in a drug is a foremost priority. As such, while the monopoly that patent law grants allows for the recovery of these high costs incurred, it is often abused, usually to the detriment of individuals seeking access to the drugs.

C. *Abuse of Drug Patents: High Prices and Price Gouging*

While patent rights incentivize the development of discoveries and promote the progress of science, drug patent holders often abuse their limited monopoly by engaging in predatory practices such as setting inaccessibly high prices and price gouging.[71]

Instances of prescription drug price abuse are ubiquitous and have recently become a topic of concern in U.S. current events.[72] For example, Gilead Sciences, Inc. stirred up controversy when it set the prices of its drugs Harvoni and Sovaldi, Hepatitis C treatments with a cure rate of over 90%, at $94,500 and $84,000 per course of treatment, respectively.[73] The high price of the drugs caused publicly funded healthcare programs, such as Medicaid, to restrict access to only the sickest patients.[74] Gilead is not alone—most patented cancer treatments are set at exorbitant prices, averaging a cost of about $8,700 per month of treatment.[75] Gleevec, a drug used to treat leukemia, cost patients over $140,000 per year before the expiration of its patent,[76] which is

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[70] Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV., 503, 503 (2009).

[71] *See* Matthew Herper, *Why Did That Drug Price Increase 6,000%? It's the Law*, FORBES (Feb. 10, 2017, 1:52 PM), https://www.forbes.com/sites/matthewherper/2017/02/10/a-6000-price-hike-should-give-drug-companies-a-disgusting-sense-of-deja-vu/#5de2e08071f5.

[72] Gaston Kroub, *The Cost of a Cure: Patent Rights and Drug Prices*, ABOVE LAW (June 6, 2017, 10:03 AM), https://abovethelaw.com/2017/06/the-cost-of-a-cure-patent-rights-and-drug-prices/?rf=1.

[73] Ed Silverman, *Hepatitis C Drugs Remain Unaffordable in Many Countries, Says WHO Study*, STAT NEWS (May 31, 2016), https://www.statnews.com/pharmalot/2016/05/31/gilead-hepatitis-drug-prices-who.

[74] *Id*.

[75] David Crow, *Price of Cancer Drugs Vastly Higher in U.S., According to Study*, FIN. TIMES (June 6, 2016), https://www.ft.com/content/851cd240-2b6f-11e6-bf8d-26294ad519fc.

[76] Hagop Kantarjian, *The Arrival of Generic Imatinib Into the U.S. Market: An Educational Event*, ASCO POST (May 25, 2016), http://www.ascopost.com/issues/may-25-2016/the-arrival-of-

reflective of a common practice in the pharmaceutical industry.[77]

Companies marketing orphan drugs, meaning drugs aimed to treat rare diseases affecting fewer than 200,000 people in the U.S. population, also partake in price abuse.[78] Orphan drug treatments, such as Cerezyme,[79] can cost up to $300,000 per year, and "once an orphan [drug] gains FDA approval, the agency guarantees it will not approve another version to treat that specific disease for seven years, even if the brand name company's patent has run out."[80] The extremely high prices of life-or-death medicines are reflective of a lack of regulation of patent holders, and the result is a bar on access to these drugs for many people who cannot afford them or whose healthcare providers do not find sufficient need for the treatment.

In addition to price abuse of patent-protected drugs, drugs with expired patents are also subject to such price abuse—this practice is known as price gouging.[81] Price gouging of prescription drugs is a common practice where the seller dramatically hikes up the price of a drug that is in demand to a price that is unfair and, for many, inaccessible.[82] Martin Shkreli, former CEO of Turing Pharmaceuticals, recently gained infamy for engaging in this predatory practice. Shkreli is known for increasing the price of Daraprim, an anti-parasitic drug commonly used in the treatment of HIV/AIDS, from $13.50 a pill to $750 a pill.[83] Other companies have participated in this practice as well.

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generic-imatinib-into-the-us-market-an-educational-event.

[77] Hagop Kantarjian et al., *High Cancer Drug Prices in the United States: Reasons and Proposed Solutions*, 10 J. ONCOLOGY PRAC. 208, 208 (2014). On the price spike of cancer medications, researchers for the Journal of Oncology Practice wrote,

> [c]ancer drug prices in the United States follow their own economic rules that have little to do with what the market will bear. Oncology drugs have become synonymous with extremely high cost. The prices of patented cancer drugs in the United States have increased 5- to 10-fold from before 2000 until now, and the cost of new drugs continues to grow far ahead of inflation. The average cancer drug price for approximately 1 year of therapy or a total treatment duration was less than $10,000 before 2000, and had increased to $30,000 to $50,000 [sic] by 2005. In 2012, 12 of the 13 new drugs approved for cancer indications were priced above $100,000 per year of therapy.

Id.

[78] Sara Jane Tribble & Sydney Lupkin, *High Prices for Orphan Drugs Strain Families and Insurers*, NAT'L PUB. RADIO (Jan. 17, 2017, 1:36 PM), https://www.npr.org/sections/health-shots/2017/01/17/509507035/high-prices-for-orphan-drugs-strain-families-and-insurers.

[79] *Id.* Cerezyme is a drug that treats Gaucher Disease, a rare genetic condition that affects about 6,000 people in the U.S.

[80] *Id.* The average annual cost of orphan drugs in the U.S. in 2014 was $111,820.

[81] *See* A. Gordon Smith, *Price Gouging and the Dangerous New Breed of Pharma Companies*, HARV. BUS. REV. (July 6, 2016), https://hbr.org/2016/07/price-gouging-and-the-dangerous-new-breed-of-pharma companies?referral=03759&cm_vc=rr_item_page.bottom.

[82] *See id.*

[83] Ariana Eunjung Cha, *CEO Martin Shkreli: 4,000 Percent Drug Price Hike Is 'Altruistic', Not Greedy*, WASH. POST (Sept. 22, 2015), https://www.washingtonpost.com/news/to-your-health/wp/2015/09/22/turing-ceo-martin-shkreli-explains-that-4000-percent-drug-price-hike-is-altruistic-not-greedy/?utm_term=.89cc0be13b5b; Carolyn Y. Johnson, *What Happened to the*

In 2015, Valeant Pharmaceuticals increased the price of isoproterenol, a drug used to treat heart attacks, from $440 to about $2,700 per dose.[84] In 2016, Lannett Co., Inc. raised the price of fluphenazine, a drug used to treat symptoms of schizophrenia, by 1,650%.[85] The apparently common practice of drug price gouging brings an important question to mind: if an exorbitantly high priced drug is not patent protected, why is generic competition not saving consumers from price gouging by lowering the overall market price of the drug?

According to Erin Fox, the Director of Drug Information at the University of Utah Health, branded drug manufacturers are engaging in a variety of practices to thwart generic competition.[86] One of these tactics is a "pay for delay" agreement, where a branded pharmaceutical company pays off a generic company to not develop a generic version of the drug.[87] Another practice is known as "citizen petitions," in which the branded pharmaceutical company petitions the FDA, usually near the time of its patent expiration, to delay pending generic drug applications for 150 days.[88] Branded pharmaceutical companies also take advantage of "authorized generics," which occurs when the company makes a generic version of its own drug and receives an exclusivity period of 180 days, by law, for being the first to market the drug after the patent expires.[89] Such practices demonstrate why price gouging poses a real threat to a consumer's access to many drugs, and why a lack of consumer access, both with and without patent protection in place, remains a large issue.

The foregoing issues demonstrate the necessity of patents as well as their drawbacks. Like almost all other drug developers, the developer of the cure to aging, if it is in the form of a drug, will seek to secure patent protection.[90] Consequently, barring access to the cure to aging may become very real, as reflected in our current pharmaceutical climate of high drug prices and price gouging.

$750 Pill that Catapulted Martin Shkreli to Infamy, WASH. POST (Aug. 1, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/08/01/what-happened-to-the-750-pill-that-catapulted-pharma-bro-martin-shkreli-to-infamy/?utm_term=.cfefae3614e7. The patent for Daraprim expired over sixty years ago. *Id.*

[84] Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive.

[85] Nathan Vardi, *Another Drug Company that Raises Prices Like Crazy*, FORBES (Oct. 6, 2016, 8:31 AM), https://www.forbes.com/sites/nathanvardi/2016/10/06/another-drug-company-that-raises-prices-like crazy/#7113f821e0d0.

[86] Fox, *supra* note 84.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] For an analysis of the cure to aging if it is in the form of a medical procedure, see *infra* Part II.D.

D. *Medical Procedures: Different Regulations, Same Effects*

Although the cure to aging may be in the form of a drug, de Grey suggests that cell damage may be reversed by a series of regenerative therapies, which create the possibility that the cure to aging could be in the form of a medical procedure.[91] Like pharmaceuticals, medical procedures may also receive patent protection by the USPTO.[92] Medical procedures are defined as "procedures for the purpose of treatment or diagnosis of a human or animal condition, whether or not the condition is medically defined as a disease."[93] However, medical procedure patents differ from drug patents in two fundamental ways: medical procedures are usually[94] not regulated by the FDA, and although medical procedures are patentable, their patent is unenforceable.[95]

There are many possible explanations for the lack of federal regulation pertaining to medical procedures. Foremost is the explanation that state medical boards, codes of professional responsibility, and nongovernmental organizations in specific areas of practice (i.e., the American Board of Surgery) regulate the administration of medical procedures.[96] However, a lack of federal regulatory approval for the specific procedures themselves may be attributed to the difficulty of conducting randomized controlled trials.[97] For instance, a surgeon performing a surgery on Patient A's foot may be using the same exact medical procedure as he used on Patient B, but many factors that cannot be adequately controlled will cause a large variation in the outcome of the two surgeries; such a gap makes regulation of the procedure difficult. Moreover, while the FDA does not regulate the medical procedures themselves, it does in fact regulate any drugs and medical devices used during the course of the procedures.[98]

However, the cell regeneration therapies suggested for curing aging fall into a niche class of procedures that are subject to FDA regulation[99]: human cells, tissues, and cellular- and tissue-based

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91 De Grey, *supra* note 12.

92 *Patents on Medical Procedures and the Physician Profiteer*, *supra* note 21.

93 *Id.* Medical procedures that have been granted patents include the administration of insulin, skin grafting, and transferring surrogate embryos.

94 An exception is HCT/Ps, which are regulated by the FDA. *See Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, *infra* note 103.

95 Mossinghoff, *infra* note 104.

96 Jonathan J. Darrow, *Explaining the Absence of Surgical Procedure Regulation*, 27 CORNELL J.L. & PUB. POL'Y 189, 192 (2017). These boards require surgeons to possess specific certifications prior to performing certain procedures.

97 *Id.* at 196–97.

98 *FDA Fundamentals*, *supra* note 64.

99 Recently, the U.S. District Court for the District of Columbia expanded the traditional role of the FDA by holding that a procedure in which an orthopedic doctor uses stem cell therapy to treat her patients is subject to FDA regulation as an HCT/P under 21 C.F.R. § 1271. In the case *United States v. Regenerative Scis., LLC*, the defendants were permanently enjoined from employing

products (HCT/Ps).[100] The purpose of FDA regulation of HCT/Ps is "to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps."[101] HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."[102]

The regulation of HCT/Ps comes in the form of FDA requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery, processing and process controls, labeling controls, storage, shipment and distribution, and donor eligibility determinations of HCT/Ps; these requirements are referred to as Current Good Tissue Practice.[103] Like drug regulations, these requirements are quite stringent and costly to meet. Consequently, patents in medical procedures involving HCT/Ps—like the proposed procedures to cure aging—will result in similar price abuse as that which is created by drug patents, due to the similar motivation as recovery of incurred costs during development and regulation of the procedure.

An additional distinction between drug patents and medical procedure patents is that although medical procedures may receive patent protection, they are subject to a patent infringement liability exception, which means that the plaintiff cannot recover in a medical procedure patent infringement suit.[104] As a result, where patents in the drugs and HCT/Ps themselves have the appeal of patent protection,[105] patents in medical procedures, namely the process or administration of the regenerative therapies, have less appeal to patent applicants. The

their procedure, which involved a doctor using a syringe to extract a patient's bone marrow from her hipbone, cultivating the stem cells from the extraction, and re-injecting the cells into the patient with a syringe. United States v. Regenerative Scis. LLC, 878 F. Supp. 2d 248, 252, 256 (D.D.C. 2012). Stem cell therapy is one of de Grey's proposed methods of cell damage reversal; it therefore falls into the class of FDA-regulated HCT/Ps. *See* De Grey, *supra* note 12.

[100] *See Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, U.S. FOOD & DRUG ADMIN. (Aug. 2007), https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm062592.pdf.

[101] 21 C.F.R. § 1271.1 (2018).

[102] 21 C.F.R. § 1271.3 (2018) (Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, and hematopoietic stem cells derived from peripheral and cord blood.).

[103] 21 C.F.R. § 1271.145 (2018).

[104] Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, 110 Stat. 3009 § 616 (1996) (This amendment to 35 U.S.C. § 287 came shortly after a patent infringement case before the District Court for the District of Vermont. Pallin v. Singer, Civ. No. 5:93–202, 1995 WL 608365 (D. Vt. May 1, 1995). In that case, plaintiff Dr. Pallin sued defendant Dr. Singer and his practice for an alleged infringement of Dr. Pallin's surgical technique for a cataract surgery. After the lawsuit, the parties signed a Consent Order and Dr. Pallin was enjoined from enforcing his patent; *see also* Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PATENT & TRADEMARK OFF. SOC'Y 789 (1996).

[105] *Supra* Part II.C.

applicant of the cure to aging will probably seek patents over the medical procedure anyway, but such patents yield little room for recovery due to their unenforceable nature.

E. *Drug Prices in Politics and How the Issues Are Addressed Today*

As a result of the pervasiveness of price gouging in the pharmaceutical industry, some states are starting to take measures against price gouging by proposing bills against the practice. In Washington State, SB 5995 has been proposed, which would allow the Health Commission to declare a price increase in generic medication to be excessive if the increase follows a rise in wholesale acquisition cost of more than 100%.[106] In Rhode Island, H 7022 has been proposed, which would make price gouging of brand or generic drugs in times of market shortages punishable by felony charges, imprisonment, and fines and injunctive relief.[107] Despite these efforts, drug companies and their executives are still a threat to the accessibility of drugs. It is clear that the policies still have a long way to go.[108]

In addition to efforts to combat inaccessibly high drug prices at the state level, President Donald Trump has expressed his desire "to make fixing the injustice of high drug prices one of [his Administration's] top priorities."[109] Although his ability to effectively follow through on that promise is in question, it is true that the FDA has approved more new generic drugs and medical devices during his first year in office than ever before.[110] To combat steep drug prices, the Administration has recently taken a few steps. In October of 2018, Trump announced that the government would be requiring pharmaceutical companies show their drug list prices in their television advertisements—the hope is that increased price transparency will increase competition, make consumers aware of cheaper alternatives, and "shame" drug companies into lowering their prices.[111]

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106 *State Legislative Action on Pharmaceutical Prices*, NAT'L ACADEMY FOR STATE HEALTH POL'Y, https://nashp.org/state-legislative-action-on-pharmaceutical-prices (last updated Jan. 24, 2019).

107 *Id.*

108 Jeremy A. Greene, *Don't Let Pharma Take Down a New Maryland Price Gouging Law*, WASH. POST (Sept. 8, 2017), https://www.washingtonpost.com/opinions/dont-let-big-pharma-take-down-a-new-maryland-price-gouging-law/2017/09/08/73a50630-8d99-11e7-84c0-02cc069f2c37_story.html?utm_term=.68a12a7b229a.

109 Paul R. La Monica, *Trump Wants to Fix 'Injustice' of High Drug Prices. But Can He?* CNN: MONEY (Jan. 31, 2018, 11:34 AM), http://money.cnn.com/2018/01/31/investing/trump-state-of-the-union-drug-prices/index.html.

110 Jayne O'Donnell, *State of the Union Fact Check: Feds Did Approve More New and Generic Drugs, Devices in 2017*, USA TODAY (Jan. 30, 2018, 10:43 PM), https://www.usatoday.com/story/news/politics/2018/01/30/state-union-fact-check-feds-did-approve-more-new-and-generic-drugs-devices-2017/1081460001.

111 Ezekiel Emanuel, *The Trump Administration's Latest Plan to Lower Drug Prices Is Hollow—And Maybe Counterproductive*, WASH. POST (Oct. 18, 2018),

The patent law landscape is constantly evolving as new breakthroughs in medicine and science are developed; it is up to courts to regularly expand patent law to encompass these new technologies without compromising the Framers' intent in granting the power to issue patents in the Constitution.[112] However, as science and medicine advance to levels beyond what the Framers could have imagined when forming the Constitution, an issue that is unique to our time is presented: what if granting an inventor a limited exclusive right to her discovery violates another person's constitutional right—namely, an individual's right to life?

III. CONSTITUTIONAL PATENT POWERS AND THEIR LIMITATIONS

A. *Patent Law in the Constitution*

The United States Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[113] This constitutional language is known as the Intellectual Property Clause; it gives inventors a limited monopoly over their discoveries in order to incentivize innovation and promote scientific progress to better the public good.[114] The clause was the subject of little debate during the Constitutional Convention and Debate over Ratification prior to its adoption into the Constitution.[115]

The Intellectual Property Clause reflected the Framers' belief that it is the job of the government to encourage the advancement of science and the useful arts and establish a uniform system of copyright law and patent law, respectively.[116] In *Federalist No. 43*, James Madison briefly addressed the twofold justification of the Intellectual Property Clause, which was to grant protection to authors and inventors similar to the protection granted to authors under Great Britain common law and to create a uniform system of intellectual property regulation.[117]

https://www.washingtonpost.com/opinions/the-trump-administrations-latest-plan-to-lower-drug-prices-is-hollow--and-maybe-counterproductive/2018/10/18/f7ea5a16-d30d-11e8-a275-81c671a50422_story.html?utm_term=.502f6ebc3d36.

112 *Infra* Part III.

113 U.S. CONST. art. I, § 8, cl. 8.

114 *The Heritage Guide to the Constitution*, HERITAGE FOUND. http://www.heritage.org/constitution/#!/articles/1/essays/46/patent-and-copyright-clause (last visited Oct. 25, 2017).

115 Edward C. Walterscheid, *Conforming the General Welfare Clause and the Intellectual Property Clause*, 13 HARV. J.L. & TECH. 88, 92–93 (1999).

116 *Id.* at 94.

117 *The Heritage Guide to the Constitution*, *supra* note 114. In *Federalist No. 43*, Madison explained the purpose of the Intellectual Property Clause by writing, "[t]he utility of this power will scarcely be questioned. The copyright of authors has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of

Ultimately, Madison explained, the Intellectual Property Clause would promote the public good.[118] With this purpose in mind, the first United States patent statute, the Patent Act of 1790, was enacted shortly after the Constitution was ratified.[119]

B. *How Valuable Is Life?: Due Process and the Right to Life*

The Fourteenth Amendment of the U.S. Constitution states,

> [a]ll persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the state wherein they reside. No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; *nor shall any state deprive any person of life, liberty, or property, without due process of law*; nor deny to any person within its jurisdiction the equal protection of the laws.[120]

Arguably one of the most important clauses in the Constitution, the Due Process Clause was created to ensure procedural due process[121] and has been interpreted by courts to grant substantive due process to citizens as well.[122] The clause is structured to read that due process of law must accompany the deprivation of life, liberty, or property, and it does not need to accompany the deprivation of interests other than those three.[123] When using the language "life, liberty, or property" in the Fifth and Fourteenth Amendments of the Constitution, the Framers were heavily influenced by Sir William Blackstone, who addressed these

individuals. The States cannot separately make effectual provisions for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress." THE FEDERALIST NO. 43 (James Madison).

118 THE FEDERALIST NO. 43, *supra* note 117.

119 *See* Patent Act of 1790, 1 Stat. 109 (1790). The Patent Act of 1790 granted patent rights to persons who have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used. *Id.* If the invention or discovery was sufficiently useful and important, the patent holder was granted "the sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery," and the rights lasted for a term of fourteen years). *Id.*

120 U.S. CONST. amend. XIV (emphasis added). Similar language can also be found in the Fifth Amendment: "[n]o person shall . . . *be deprived of life, liberty, or property, without due process of law* . . . ." U.S. CONST. amend. V (emphasis added).

121 Jonathan Kim, *Fifth Amendment*, CORNELL L. SCH. LEGAL INFO. INST. (June 2017), https://www.law.cornell.edu/wex/fifth_amendment. Procedural due process aims to prevent the government from unfairly and unjustly denying a citizen a right and opportunity to be heard in court. The purpose is to prevent citizens from being deprived of their life, liberty, or property interests without a fair and timely legal process. *Id.*

122 *Id.* Substantive due process is a controversial doctrine and generates many of split court opinions. The idea behind substantive due process is that the Due Process Clause, in addition to guaranteeing procedural due process, also protects certain fundamental rights of citizens. *Id.*

123 *Due Process Clause*, HERITAGE FOUND., http://www.heritage.org/constitution/#!/amendments/5/essays/150/due-process-clause (last visited Feb. 2, 2018).

concepts in his *Commentaries on the Laws of England* in 1765.[124]

In his *Commentaries*, Blackstone defines and thoroughly explains the fundamental rights of life, liberty, and property, thus providing the context that influenced the Framers to mimic his language.[125] The right to life, which Blackstone refers to as the right of personal security, is a right granted by God and inherent in every individual, and it is foundational to all other rights.[126] The right to life consists of a person's legal and uninterrupted enjoyment of her life, limbs, body, health, and reputation.[127] Further, the right encompasses "[t]he preservation of a man's health from such practices as may prejudice or annoy it . . . ."[128] Blackstone writes that natural life "cannot legally be disposed of or destroyed by any individual, neither by the person himself nor by any other of his fellow creatures, merely upon their own authority," with the exception of forfeiting life in the context of capital punishment as a consequence of breaching certain laws of society.[129]

To illustrate how invaluable our right to life is, Blackstone highlights the high value with which the law of England regards life. For instance, Blackstone explains, life is so valuable that the law pardons homicide if committed in self-defense in order to preserve one's own life.[130] Further, the law not only regards life and protects every person in their enjoyment of it, but also furnishes people with everything necessary to support life, "[f]or there is no man so indigent or wretched, but he may demand a supply sufficient for all the necessities of life, from the more opulent part of the community, by means of the several statutes enacted for the relief of the poor, of which in their proper places."[131] Blackstone concludes that a government

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124 *See id.*; Kent Schmidt, *Blackstone's View of Natural Law and Its Influence on the Formation of American Declaration of Independence and the Constitution*, U. ARK., http://www.sullivan-county.com/deism/blackstone.htm (last visited Nov. 19, 2017); William Blackstone, *Commentaries on the Laws of England: A Facsimile of the First Edition of 1765–1769*, U. CHI. (1979), http://press-pubs.uchicago.edu/founders/documents/amendIXs1.html.

125 Blackstone, *supra* note 124.

126 *See id.*; Schmidt, *supra* note 124.

127 Blackstone, *supra* note 124.

128 *Id.*

129 *Id.*

130 *Id.* In United States criminal law, use of deadly force in self-defense is an affirmative defense under the Model Penal Code, and over thirty states have adopted similar doctrines into their criminal statutes. Christopher Allen, *Montana Shooter Found Guilty Despite State's 'Castle Doctrine'*, NAT'L PUB. RADIO (Dec. 20, 2014, 5:05 PM), https://www.npr.org/2014/12/20/372136054/montana-shooter-found-guilty-despite-states-castle-doctrine; *see* MODEL PENAL CODE § 3.04 (AM. LAW INST. 1962) ("(1) Use of Force Justifiable for Protection of the Person. Subject to the provisions of this Section and of Section 3.09, the use of force upon or toward another person is justifiable when the actor believes that such force is immediately necessary for the purpose of protecting himself against the use of unlawful force by such other person on the present occasion . . . . (b) The use of deadly force is not justifiable under this Section unless the actor believes that such force is necessary to protect himself against death, serious bodily harm, kidnapping or sexual intercourse compelled by force or threat . . . .").

131 Blackstone, *supra* note 124.

cannot, under any circumstances, wrongly deprive individuals of their right to life because it would be a gross act of despotism.[132]

With Blackstone's analysis of the fundamental notions of life, liberty, and property in mind, the Framers incorporated this language into the Fifth and Fourteenth Amendments of the Constitution and forbade any person from being deprived of life, liberty, or property without due process of law.[133] The justification of the Due Process Clause is that these fundamental rights of an individual are so important, that arbitrarily depriving her of the rights is against the principles on which the United States is built on.[134] In fact, the rights to life and liberty were so essential to the Founders of the United States that they were termed "unalienable rights" and incorporated into the Declaration of Independence in 1776, where Thomas Jefferson wrote, "[w]e hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty[,] and the pursuit of Happiness."[135] Evidently, the Framers believed that a person's right to life is an inalienable and inherent right that cannot be curtailed by any person or entity and must be granted the highest deference.[136] From this proposition it can be concluded that any statute or regulation, whether state or federal, that deprives an individual of her right to life is one that must be evaluated as a statute implicating the individual's utmost fundamental right.[137]

C. *Protection of Human Life in Patent Case Law*

Patent case law further bolsters the belief that it is necessary to regulate access to patents and protect the public good. In the landmark case of *eBay Inc. v. MercExchange, LLC*, the Supreme Court held that permanent injunctions should not be automatically granted in patent infringement cases, and the Court established a four-factor test to determine whether a permanent injunction is appropriate.[138] For the injunction to be granted, the plaintiff must show:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law . . . are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and

132 *Id.*

133 *Due Process Clause*, *supra* note 123; U.S. CONST. amend. V; U.S. CONST. amend. XIV.

134 *See* Peter Strauss, *Due Process*, CORNELL L. SCH. LEGAL INFO. INST., https://www.law.cornell.edu/wex/due_process (last visited Nov. 19, 2017); *see also The Due Process and Equal Protection Clauses*, U. MINN., http://open.lib.umn.edu/criminallaw/chapter/3-2-the-due-process-and-equal-protection-clauses (last visited Nov. 19, 2017).

135 THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

136 *See id.*

137 *See id.*

138 *See* eBay v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006).

> defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[139]

The public interest prong of the *eBay* test gives courts a great deal of discretion over whether an injunction should be issued,[140] and this played out favorably for the public in a number of cases. In *Bard Peripheral Vascular, Inc. v. W.L. Gore & Associates, Inc.*, the U.S. District Court for the District of Arizona denied injunctive relief against the defendant on the grounds that the public interest would be disserved if the public did not have access to the defendant's vascular graft technology.[141] In *Edwards Lifesciences AG v. CoreValve, Inc.*, although the District Court of Delaware enjoined the defendant from selling its devices, which functioned as a mechanism that was akin to open heart surgery, the court, in weighing the public interest, allowed for the defendant to sell its devices to those patients who could not be helped by the plaintiff's devices.[142] The courts' hesitance to bar access to potentially life-saving procedures and devices post-*eBay* demonstrates an adherence to one of the most fundamental principles that our nation is built on: our system of law should do all that it can to prevent the unjust deprivation of an individual's right to life.

The human lifespan has nearly doubled since the Constitution's formation,[143] and yet the importance of life and the Framers' high regard for it has not been reinterpreted or given any less protection by lawmakers and the courts than it was given in the eighteenth century. Even if the cure to aging redefines lifespan to mean 1,000 years on average,[144] there is no reason to believe that the Framers would have thought about protecting life differently. As such, lawmakers and courts would continue to be influenced by the Constitution to protect this right.[145]

With this in mind, it can be concluded that the Framers neither anticipated nor intended for the Intellectual Property Clause to allow patent rights to be granted in the cure to aging by operation of law, as they are granted in any other drug or procedure. This conclusion is based on the premise that granting a patent in the cure to aging and giving the patent holder a limited monopoly blatantly defies the Framers' belief that the right to life is an inalienable right that may not

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139 *Id.*

140 *See id.*

141 Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., No. CV-03-597-PHX-MHM, 2010 WL 11484420, at *7 (D. Ariz. Sept. 9, 2010).

142 Edwards Lifesciences AG v. CoreValve, Inc., No. 08-91-GMS, 2014 WL 1493187, at *11 (D. Del. Apr. 15, 2014).

143 *See* Kochanek, *supra* note 5.

144 This figure is hypothetical and is not based on scientific data.

145 Evidently, patent law has already demonstrated that the public's interest in its health is not subject to any less legal protection as longevity increases.

be compromised by any individual or institution.[146] Therefore, the Intellectual Property Clause and the "life, liberty, or property" language of the Constitution cannot be reconciled in this context, resulting in the need for an alternative means of determining whether a patent should be afforded in the cure to aging.

D. *The Impact of Patenting a Cure to Aging on Our Inalienable Right to Life*

The constitutional right to life of individuals is in danger of being violated by the Intellectual Property Clause of the Constitution with the potential patent of drugs or therapies to cure aging, which will potentially redefine a human life term to eventually mean an indefinite lifespan.[147] Further, under de Grey, Kurzweil, and Gobel's hypothetical longevity escape velocity model, the time at which an individual may access the first few generations of cell regeneration therapy may determine whether the anti-aging therapy will allow that person to live to 1,000 years or to 150 years.[148] This means every second of access, or lack thereof, counts. A bar to access on these therapies that lasts even a few years can be responsible for depriving an individual of many potential years of lifespan.[149]

The right to life was intended by the Framers to be fundamental and foundational, and it cannot legally be disposed of or destroyed.[150] By granting a twenty-year monopoly to the company that first files for a patent over an anti-aging drug or therapy,[151] individuals who cannot access the cure to aging during the patent's duration will be deprived of additional years of life under the longevity escape velocity model,[152] as their cells may deteriorate beyond a point of substantial damage reversal in that time.[153] This scenario works under the assumption that but for not being able to access the cure to aging during the years in which it is patent protected, the person who lives to be 150 years old would have otherwise been able to live to the "normal" life expectancy of 1,000. Thus, the situation targets an age group of people who were young enough to fully benefit from the first few rounds of regenerative therapies at the time of their availability to the public, but, due to the

146 Blackstone, *supra* note 124.
147 *See* de Grey, *supra* note 12.
148 De Grey, *supra* note 32 (Chart, Figure 1).
149 *See id.*
150 Blackstone, *supra* note 124. The exception is the deprivation of life through capital punishment as a result of the individual breaking certain laws. *See id.*
151 I am not arguing that the drug or therapy should not pass through the proper FDA approval process, however long that may take. The duration of the bar to access that is unconstitutional is the twenty years less the number of years the drug or therapy takes to obtain regulatory approval.
152 The reasons why the individuals would be unable to access the patented medicine are discussed *supra* Part II.C.
153 *See* de Grey, *supra* note 12.

individuals' lack of access to the medicine until the patent term expires and generics drive the medicine's price down, the class can no longer fully benefit, because their cell damage has progressed too much.[154] Ultimately, granting patent rights in a cure to aging, although rooted in the Intellectual Property Clause of the Constitution, would not serve the clause's main goal of promoting the public good in accordance with the Framers' intent.[155] Further, in a future where living to 1,000 years is the norm, only being able to live to 150 years, as a result of the patent barring access to the therapies that would arrest aging, would be gravely unjust and would blatantly defy that individual's right to life.

IV. AN ALTERNATIVE FRAMEWORK FOR EVALUATING WHETHER PATENT PROTECTION SHOULD BE GRANTED IN THE CURE TO AGING

Based on the historical context of the "right to life" language used in the Fifth and Fourteenth Amendments, the Framers of the Constitution could not have anticipated or intended for the Intellectual Property Clause to grant systematic patent protection over the cure to aging just as it does over other drugs and therapies, since granting a patent for the cure to aging and the Framers' belief that individuals have an inalienable right to life cannot be reconciled.[156] This is not to say that patent protection should not be granted over the cure to aging—rather, that the U.S. patent law system, which is rooted in the Constitution, never intended for a drug or therapy that would redefine lifespan across the entire population to be granted a patent by operation of law through the USPTO.[157] Evaluating whether the cure to aging should be granted patent protection under the current requirements set by our federal patent statute would not give enough deference to the Framers' regard for life.[158] Consequently, there should be an alternative test to determine whether inventors should be granted a patent for the cure to aging, and the test must be a more comprehensive solution that weighs the interests of individuals and drug or medical procedure developers, while respecting the Framers' intent with regard to patent protection.

In light of the foregoing conclusion, this Note proposes a modified *Mathews v. Eldridge* balancing test ("Modified *Mathews* Test").[159] This test will weigh (1) the private interest of individuals in their right to life, or specifically in indefinite lifespan, which will be affected if patent rights are granted; (2) the interest of the inventor of the cure to aging in having a patent over its invention; and (3) the "risk of erroneous

154 Likely, this will be a group of people around fifty years old. *See* de Grey, *supra* note 12.
155 *The Heritage Guide to the Constitution*, *supra* note 114.
156 *See supra* Part III.D.
157 *See supra* Part III.C.
158 *See supra* Part III.C.
159 Mathews v. Eldridge, 424 U.S. 319 (1976).

deprivation" by granting patent protection, plus the costs and benefits of putting additional safeguards in place.

A. *A Due Process Test as an Adequate Means of Addressing the Right to Life*

"How do we know whether due process is met?" is a similar inquiry to "how do we know whether we unfairly deprived an individual of her right to life?" Facially, these inquiries are comparable, because an individual's right to due process and her right to life are both regarded as fundamental rights.[160] An even stronger argument that these two inquiries are comparable to each other is that the Fifth and Fourteenth Amendments are written to encompass the right to life within the Due Process Clause.[161] Based on the intertwined nature of the Due Process Clause and an individual's right to life, a test that sufficiently measures whether due process is met may be applied to assess whether a person's right to life is being deprived unfairly, since due process seeks to protect a citizen's interest in her life, liberty, and property.

Mathews v. Eldridge is one of many due process cases heard by the Supreme Court, and it is best known for establishing a multi-factor balancing test used by the courts to determine whether an individual was unfairly deprived of her due process rights.[162] In *Mathews*, a disabled employee was given notice by his employer that his disability benefits would be terminated.[163] The employee did not receive an evidentiary hearing prior to the termination of his benefits, and he brought an action alleging that his Fifth Amendment due process rights were violated.[164] In its holding, the Supreme Court established a balancing test for courts to use when determining whether an individual's due process rights were met.[165] Justice Powell explained,

> due process generally requires consideration of three distinct factors: [f]irst, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the [g]overnment's interest, including the function involved and the fiscal and

[160] *See, e.g.*, Wash. v. Glucksberg, 521 U.S. 702, 720 (1997) ("The Due Process Clause guarantees more than fair process, and the 'liberty' it protects includes more than the absence of physical restraint. The Clause also provides heightened protection against government interference with certain fundamental rights and liberty interests.") (internal citations omitted); *id.* at 714 ("The right to life and to personal security is not only sacred in the estimation of the common law, but it is inalienable.") (internal quotations omitted).

[161] *See* U.S. CONST. amend. V; *see also* U.S. CONST. amend. XIV.

[162] *See Mathews*, 424 U.S. 319.

[163] *Id.* at 324.

[164] *Id.* at 324–25.

[165] *Id.* at 335.

> administrative burdens that the additional or substitute procedural requirement would entail.[166]

The *Mathews* test has been used in many subsequent cases[167] and has become well ingrained in courts' assessments of whether due process and liberty rights were violated, and thus it serves as the perfect blueprint for the instant inquiry.

B. *The Modified* Mathews *Test*

A modified *Mathews* test would balance similar factors as the original test but would adjust what is being balanced to reflect the important considerations regarding whether the cure to aging should be patented.

First, the Modified *Mathews* Test will consider the private interest of individuals in their right to life and the effects of patenting the cure to aging on those interests.[168] This refers to the individuals' interest in being able to receive regenerative drugs or therapies and being able to live for the duration of the redefined lifespan with the rest of society.

Second, the Modified *Mathews* Test will weigh the first factor against the interest of the inventor of the cure to aging in having a patent over its invention. This will be an analysis of the benefit of patenting combined with the cost of not patenting to the inventor.[169]

Third, the Modified *Mathews* Test will consider what the *Mathews* test calls the "risk of erroneous deprivation" of the private interest.[170] In the case of the cure to aging, the risk of erroneous deprivation would be the effect of affording patent protection and thus hindering access to the cohort of individuals who cannot afford the medication for up to twenty years. Along with the risk of error, the test will also look to the costs and benefits of adding or substituting the safeguards that are in place.[171]

Weighing these factors against each other will pave the way for determining whether the cure to aging should ultimately be patented, and this Note will conclude that it should be.

C. *Application of the Modified* Mathews *Test to the Cure to Aging*

i. The Private Interests of Individuals in Their Right to Life

It is a universally accepted proposition that almost all individuals

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166 *Id.*

167 *See, e.g.*, Hamdi v. Rumsfeld, 542 U.S. 507 (2004); Bowen v. City of N.Y., 476 U.S. 467 (1986); Lassiter v. Dep't of Soc. Servs., 452 U.S. 18 (1981).

168 The individuals that this inquiry refers to are those who are a part of the class of people who cannot access the cure to aging during the duration of its patent. *See generally Hamdi*, 542 U.S. at 528–30.

169 *See id.*

170 *Mathews*, 424 U.S. at 335.

171 *Hamdi*, 542 U.S. at 528–30.

highly regard their own right to life. In fact, the protection of this right is predominant in the moral beliefs of all individuals[172] and is consequently ingrained into our system of law.[173] In Blackstone's *Commentaries on the Laws of England*, Blackstone brings to view people's value of life, or personal security, and the ways in which it has influenced the system of law in England.[174] Specifically, he addresses (1) the law allowing a person to get away with murder if it is done in self-defense, and (2) the law having many mechanisms in place to supply for the indigent all of the necessities to maintain life.[175] The same laws and policies addressed by Blackstone are prevalent in the U.S. today—for instance, many states have doctrines imbedded within their criminal law codes for justifiable homicide, which is usually a homicide done in self-defense after perceived risk of death.[176] The U.S. government also dedicates a portion of our national budget to provide programs for the indigent[177] and has systems of incentives to donate to charity ingrained in its policies.[178]

Based on the high value of an individual's right to life, it must be strongly considered when weighing the private interests of her right to life under the Modified *Mathews* Test. If the cure to aging redefines lifespan by drastically increasing its duration, everyone would seek to obtain regenerative therapies and live in a state of peak physical and mental function. The private interest in the redefined lifespan of the class of people who cannot access the cure to aging and must wait years for generic availability of the drug or therapy is great.[179] These people will be surrounded by family, friends, and neighbors who all experience the full effects of the cure to aging, while the group who lacks access

172 *See, e.g.*, PETER SINGER, THE LIFE YOU CAN SAVE (2009). Peter Singer is a moral philosopher most known for his thought experiment that compares failure to save a drowning child to failure to donate money to help people suffering from preventable disease and poverty. Although some of his arguments generate controversy among philosophers, very few doubt the underlying proposition that it is immoral to deprive another of their life.

173 *See, e.g.*, Allen, *supra* note 130.

174 *See* Blackstone, *supra* note 124.

175 *Id.*

176 For example, Stand Your Ground laws remove the duty to retreat from a situation before using deadly force in self-defense. *States That Have Stand Your Ground Laws*, FINDLAW, http://criminal.findlaw.com/criminal-law-basics/states-that-have-stand-your-ground-laws.html (last visited Feb. 3, 2018). Although these laws are extremely controversial, especially in recent years, the doctrine of justifiable homicide is not.

177 *See, e.g.*, *Financing*, MEDICAID, https://www.medicaid.gov/chip/financing/index.html (last visited Feb. 3, 2018).

178 *See, e.g.*, *Tax Benefits of Giving*, CHARITY NAVIGATOR, https://www.charitynavigator.org/index.cfm?bay=content.view&cpid=31 (last visited Feb. 3, 2018) (describing the way in which an individual can make her charitable contribution count as an itemized deduction when filing her annual federal income tax report).

179 This assumes that the presence of generic alternatives in the market would make the drug more accessible. As is evident in Part II.C, generic competition does not always save consumers from high drug prices.

can be gravely deprived of up to hundreds of extra years of life.

In conclusion, the weight of the individual interest prong of the Modified *Mathews* Test is high and must be seriously considered.

ii. The Interests of Inventors in Patent Protection

Absent patent protection for the cure to aging, pharmaceutical companies will lack incentive to develop the drugs or therapies that would bring about cell regeneration.[180] Researching, developing, and marketing the cure to aging will be costly.[181] Without giving patent protection to pharmaceutical companies over their drug inventions, competing generic companies will be able to enter that market with nearly identical drugs, and, thus, drive down the market price.[182] The result would be that the large investment of pharmaceutical companies discussed in Part II-B would not be fully recoverable, and the inventor of the cure could lose billions of dollars. The direct result of the lack of patent protection and failure to recoup investments would be the industry continuing to engage in its already common practice of not pursuing the development of non-patentable drugs.[183]

This profitless climate would be further aggravated by the fact that a cure to aging will bring about the eradication of many age-related diseases.[184] As previously mentioned, nearly all of the top ten causes of death in the U.S. are age-related diseases caused by senescence.[185] Curing aging creates an extremely high cost to pharmaceutical companies; by preventing many of the death-causing diseases that our population suffers from with a cure to aging,[186] the pharmaceutical companies are preventing numerous diseases for which people need medications.[187] In fact, there is a strong likelihood of pharmaceutical companies, as they develop cures for aging, factoring their foregone revenue into the cost of the cure to aging. Consequently, there is potential for the cost of the cure to aging to be even higher than the

[180] For the duration of this Section, I will assume the inventor of the cure to aging is a pharmaceutical company, unless otherwise stated. As mentioned *supra* Section II.D, the cure to aging may be a drug, medical procedure, or a combination thereof—it is not limited to drugs.

[181] *See* Mullin, *supra* note 61 and accompanying text (concluding the process of developing a drug that gets market approval costs up to $2.6 billion).

[182] *See* Herper, *supra* note 71 (concluding that generic competition may drive a brand drug's prices down by up to eighty percent).

[183] *See* Frakt, *supra* note 63.

[184] *See, e.g.*, *10 Leading Causes of Death in 1850 and 2000*, *supra* note 3.

[185] *See id.*

[186] *See id.*

[187] A cure to aging will cause some individuals who would have otherwise suffered from an illness, such as cancer or heart disease, to not become ill in the first place and have no need to seek medication or treatment for the ailment. The result will be an overall market decrease in demand for treatments for all age-related diseases. The market decrease will cause the pharmaceutical companies to lose almost all of their revenue from age-related disease treatments.

current $2.6 billion.[188]

This is a big enough reason for pharmaceutical companies to be discouraged from developing the cure to aging, even with patent protection. It is probable that one of the only motivating forces behind the development of the cure to aging is the prospect of making an enormous profit from the limited monopoly over the drug or therapy due to the novelty of the invention and an overwhelming demand for it by the population.

The next issue is the following: if pharmaceutical companies refuse to develop the cure to aging because of the absence of patent protection, is there anyone who would develop the cure to aging, knowing that she would not receive patent protection over the drug? The short answer is yes. The cure to aging would still be developed, but it would be developed by inventors who are motivated by factors other than making a profit. Other possible incentives include the fame and recognition accompanied by being credited as the inventor of the cure to aging and the desire to have the actual cure itself—maybe the inventor would want an indefinite lifespan for herself or for her loved ones.[189]

Unlike, for instance, big pharmaceutical companies, freelance inventors do not have access to the resources and capital necessary to develop the cure to aging in a reasonable amount of time, if at all. Companies such as Johnson & Johnson,[190] Gilead Sciences,[191] Roche,[192] and Bayer[193] are multi-billion-dollar titans in the industry with eleven-figure annual revenues. On the other hand, any person or company willing to develop the cure to aging absent patent protection would not be able to incur the (potential) billion-dollar cost of the development in a reasonable period of time. Likely, finding the capital to invest would take decades, if not centuries.[194] In the time it would take for the capital to be raised and the cure for aging to be developed and approved for the market, exponentially more people would be deprived of their right to the redefined lifespan than would be if big pharmaceutical companies would develop and patent the drugs. Thus, the result will inevitably cut against public interest. Ultimately, it is a choice between high drug prices barring access to a class of individuals for a limited time, and

188 Frakt, *supra* note 63.

189 *See, e.g.*, THE IMMORTALISTS (Structure Films 2014).

190 Peter Hogg, *Who Are the Top 10 Pharmaceutical Companies in the World?*, PROCLINICAL (June 15, 2015, 3:47 PM), https://blog.proclinical.com/who-are-the-top-10-pharmaceutical-companies-in-the-world (stating Johnson & Johnson had an annual revenue of $74.331 billion in 2015).

191 *Id.* (stating Gilead Sciences had an annual revenue of $25.65 billion in 2015).

192 *Id.* (stating Roche had an annual revenue of $44.36 billion in 2015).

193 *Id.* (stating Bayer had an annual revenue of $25.47 billion in 2015).

194 Although the Introduction suggests that many large investors are funding research and development companies that study aging, the investors are in most cases motivated by the desire for a return on their investment as well as access to the cure itself. *See* Lorenzetti, *supra* note 13.

accessible prices barring access to all individuals for an even longer time. The second factor of the Modified *Mathews* Test weighs even more heavily in favor of patent protection than the first factor weighs against it.

iii. Risk of Erroneous Deprivation

The risk of erroneous deprivation is a factor of the *Mathews* Test and the Modified *Mathews* Test that is strongly related to the interests of the individual factor.[195] This requires asking what the results would be if the policy—in this case, patent protection over the cure to aging—were implemented.[196] Specifically, it is a question of the harm to an individual's due process and fundamental rights that may result from the policy.[197]

The erroneous deprivation of the individual's interest in her right to life has a high cost: it is unfair, unjust, and against Framers' intent.[198] However, when looking at the alternative—not granting a patent and allowing for at least decades to pass before the cure to aging is developed—the risk is clearly mitigated. In his Ted Talk on why the cure to aging should be developed now, de Grey briefly addressed this issue and stated,

> [i]f we vacillate, hesitate, and do not actually develop these therapies, then we are condemning a whole cohort of people—who would have been young enough and healthy enough to benefit from those therapies, but will not be, because we haven't developed them as quickly as we could—we'll be denying those people an indefinite lifespan, and I consider that that [sic] is immoral.[199]

With patent protection, the cohort of people is a group that cannot access the cure to aging for up to twenty years due to its high costs. Without patent protection, the cohort of people is the entire population for years and years to come. The conclusion of the Modified *Mathews* Test is clear: the public good will best be served if the cure to aging is developed and is eligible for patent protection.

iv. Costs and Benefits of Additional or Substitute Procedures

A discussion of some costs and benefits of implementing additional procedures is worthwhile, although it will not likely change the ultimate outcome of the Modified *Mathews* Test. This factor of the

195 Hamdi v. Rumsfeld, 124 S. Ct. 2633, 2646 (2004).
196 *See id.*
197 *Id.*
198 *Supra* Part III.C.
199 De Grey, *supra* note 12.

balancing test is a consideration of the value of adding or changing procedures to make the overall scales more equivalent.

One idea is to allow loans to be granted to individuals who are in the cohort of people that would lack access to the cure to aging and would otherwise be able to enjoy the therapies fully, but for their lack of access. These loans would be low-risk, since a person who will probably live for hundreds of more years would have a lot of time to work and accumulate the money to pay off the loan.

Another idea is to implement strict price regulation for the cure to aging at the federal and state levels. Prices can be regulated by setting caps on what suppliers of the cure to aging may charge, similar to the proposed legislation of Washington SB 5995 and Rhode Island H 7022.[200] Moreover, a failure to abide by the regulations may be punishable by charges, fines, injunctive relief, and loss of patent.[201] In light of the fact that a cure to aging will likely eradicate a big portion of the pharmaceutical company's revenue from age-related disease treatments, substantial price regulation may be unfair to the patent holder. Although some price regulation may be necessary and beneficial, any sort of meaningful price cap that would allow the cure to aging to be accessible to everyone would too severely undercut the company's ability to survive in a world without age-related disease.

CONCLUSION

The current climate in the medical and pharmaceutical industries illustrates the many benefits and costs of drug and medical procedure patents. Due to the high cost of researching and developing a drug or therapy, in addition to the supplemental cost of bringing the drug or therapy through the elaborate, years-long process of FDA approval and the costs incurred by the developer, patent protection is a necessity. Besides its constitutional goals to incentivize scientific progress and promote public welfare, patent law is essential for any company seeking a return on its million- or billion-dollar investment in a drug or therapy. However, there is a fine line between seeking a return on an investment, or even a substantial profit, and seeking billion-dollar revenues through the exercise of unfair price practices. In the pharmaceutical industry, the pervasiveness of inaccessibly high drug prices of patented drugs, combined with the price gouging of patent-expired drugs, creates a hostile environment for consumers who want treatments for a reasonable price. As for medical procedure patents, while they are not enforced due to a 1996 amendment of the Patent Act, they are still commonplace, and their combination with drugs or HCT/Ps creates an

[200] *Supra* Part II.E.

[201] *See State Legislative Action on Pharmaceutical Prices*, *supra* note 106.

environment similar to that of the drug industry.

Despite the difficulties of reconciling patent protection for the cure to aging in the current patent law climate with the importance of individuals' right to life, a balancing test must be conducted to determine whether a patent should be granted. Although the right to life, as explained by Blackstone and relied upon by the Framers of the Constitution, is fundamental and foundational, an analysis of a patent-less world reveals that a lot more lives are at stake without patent protection over the cure to aging. Ultimately, the best choice is not the most just choice—rather, it is the *more* just one. Perhaps federal and state regulations can someday fix the injustice, but until that day, we must be content with redefining life and harnessing its benefits in the current system of patent law.

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[*] Julia Spivak, Editor-in-Chief, CARDOZO ARTS & ENT. L.J. Vol. 37, J.D., Benjamin N. Cardozo School of Law, Class of 2019. Thank you to everyone who helped me research and write this Note—whether through sending articles to read, coffee, or support!