

Journal of Intellectual Property Law

Volume 28 | Issue 2 Article 5

October 2020

Gimme a Break: The Patent Term Restoration Act Should Give Environmental Innovators a Chance to Catch a (Cleaner) Breath

Gabrielle Gravel University of Georgia School of Law

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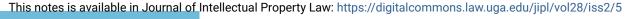
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Gimme a Break: The Patent Term Restoration Act Should Give Environmental Innovators a Chance to Catch a (Cleaner) Breath

Cover Page Footnote

J.D. Candidate, 2022, University of Georgia School of Law. I'd like to use this footnote as an opportunity to thank two individuals that helped me throughout the process of writing this note. My faculty mentor and long-note advisor, Professor Jean Mangan, has been an infallible resource, providing consistent counsel for my ideas and encouraged me to push forward the extra mile. My journal mentor and friend, Taylor Bussey, never left me hanging with sourcing questions and made me believe in my own abilities to write an excellent note.





5/26/2021 4:02 AM

GIMME A BREAK: THE PATENT TERM RESTORATION ACT SHOULD GIVE ENVIRONMENTAL INNOVATORS A CHANCE TO CATCH A (CLEANER) BREATH

Gabrielle Gravel*

^{*} J.D. Candidate, 2022, University of Georgia School of Law. I'd like to use this footnote as an opportunity to thank two individuals that helped me throughout the process of writing this note. My faculty mentor and long-note advisor, Professor Jean Mangan, has been an infallible resource, providing consistent counsel for my ideas and encouraged me to push forward the extra mile. My journal mentor and friend, Taylor Bussey, never left me hanging with sourcing questions and made me believe in my own abilities to write an excellent note.

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I. INTRODUCTION

The natural environment, once pristine and thriving, has taken the brunt of the side effects of human advancement. Around the world, problems with degradation of water, land, and air have become undeniable. There is a policy solution that is relatively simple to implement: expand the Patent Term Restoration Act to include technology addressing environmental issues. The Patent Term Restoration Act (The Act), also nicknamed the Hatch-Waxman Act, preserves the entire life of a designated patent by deferring the clock until the inventor's product actually hits the market.¹ The Act will "reimburse" the inventor up to five years of time lost to the patent life.² This Note addresses these issues and corresponding anecdotes in detail. Further, it will discuss the successes of patented technology that helped solve said pressing issues.

The heart of this Note argues for expanding The Act's terms to include environmental technology to dramatically increase the incentive to innovate in an area whose priority is significant to continued human existence. To illustrate the need for this extension, this Note will explore the vast environmental issues facing the planet due to human activity. Then, this Note will turn to how innovation protected by patents has incentivized and brought about solutions through specific inventions. The Patent Term Restoration Act will be broken down to analyze legislative intent, the application of the Act, and how its benefits have materialized. Next, the discussion section will explore obstacles in the patent world of environmental technology like stagnation, lower incentives for innovation, the massive amount of time and money devoted to one invention, and how not having the benefits of the Patent Term Restoration Act hurts the progress of mitigating and solving these issues.

The analysis section will cover how the Patent Term Restoration Act could and should be applied to environmental technology. This section will explain which steps would need to be taken to make this change at both the legislative and agency level. This Note will address common counterarguments, explain how this extension could positively shape our next generation's future, and outline the potential risks of not implementing this extension.

II. BACKGROUND

The world has no shortage of anthropogenic pollution and disasters affecting both natural and manmade landscapes.³ Globalism and a modern economy have

¹ Pub L. No. 98-417, 98 Stat. 1585.

² *Id*

³ EarthWord: Anthropogenic, UNITED STATES GEOLOGICAL SURVEY (Sept. 1, 2015), https://www.usgs.gov/news/earthword-

anthropogenic#:~:text=Scientists%20use%20the%20word%20%E2%80%9Canthropogenic

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connected populations in different hemispheres as well as increased standards of living.4 This tremendous growth, however, comes at a cost to the planet. Consequently, the same technology that raises standards of living may also emit enough pollution to bring the overall health of the loci in question back to square one.⁵ It has been over thirty years since Americans first became significantly concerned with the state of the environment and climate.⁶ Yet, only minimal progress has been made to rectify the situation, and atmospheric levels of greenhouse gases continue to rise annually. Fortunately, the brilliant thing about technology and innovation as a whole is that there are no limits to their potential. Two hundred years ago, the humans populating the Earth probably would never guess that their descendants would be able to travel the world in a matter of hours via airplane, order takeout on a touchscreen device, or video-chat a friend two states over. Talented human minds have done the impossible, and there is no evidence to believe that we are not able to invent manmade solutions to manmade problems. When "[p]roperly directed, technology can also clean up and control some of the environmental problems it caused in the first place."8 For example, invaluable technology like automobiles came with a side effect of emitting carbon dioxide. In recent years, these same car emissions were reduced by subsequent inventions improving fuel efficiency and the ability to use fuel alternatives.9 Inventions at large have found ways, through evolution, to improve with each new model. The point is that energy efficiency, reduced emissions, and creative solutions to environmental issues have always been a drawing factor of patented innovation.

It is no secret that the world we live in is beginning to change due to anthropogenic vices. Meeting the needs of the world's ever-growing population will very likely be the straw that breaks the very patient camel's back. As of

[,]people%2C%20either%20directly%20or%20indirectly. "Scientists use the word "anthropogenic" in referring to environmental change caused or influenced by people, either directly or indirectly."

⁴ Nina Pavenik, *How Has Globalization Benefitted the Poor?*, YALE INSIGHTS (Apr. 28, 2009), https://insights.som.yale.edu/insights/how-has-globalization-benefited-the-poor#gref.

⁵ Michael A. Gollin, Patent Law and the Environmental/Technology Paradox, 20 ENV*T L. REP. 10171 (1990).

⁶ Andrew Revkin, *Climate Change First Became News 30 Years Ago. Why Haven't We Fixed It?*, NAT'L GEOGRAPHIC, https://www.nationalgeographic.com/magazine/article/embark-essay-climate-change-pollution-revkin?loggedin=true (last visited Apr. 15, 2021).

⁷ Jesse L. Reynolds et al., Solar Climate Engineering and Intellectual Property: Toward a Research Commons, 18 MINN. J.L. Sci. & Tech. 1, 3 (2017).

⁸ Gollin, *supra* note 5, at 10171.

⁹ Alternative Fuels Data Center: Emissions from Hybrid and Plug-In Electric Vehicles, U.S. DEP'T OF ENERGY, https://afdc.energy.gov/vehicles/electric_emissions.html (last visited Apr. 15, 2021).

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November 2020, the United Nations estimated Earth's population at 7.9 billion.¹⁰

A species' carrying capacity is the maximum number of individuals that can be supported by their environment before resources are exhausted.¹¹ While pinpointing the precise number is a challenge, climate scientists believe nine to ten billion people is the human carrying capacity.¹² With that being said, Earth's human population is expected to reach nine billion by 2037 and ten billion by 2057.¹³

Sole reliance on fossil fuels for global energy, while not to mention detrimental, is not a lasting and sustainable solution for the energy demands of the infinite future.¹⁴ In 2017, the Intergovernmental Panel on Climate Change ("IPCC") released data from its Fifth Assessment Report asserting that human-induced global warming post pre-industrial levels had reached an increase of approximately one degree Celsius.¹⁵

Further, the IPCC opines that to combat Earth's increasing temperature, humans cannot ignore the problem but instead must implement "indispensable" mitigation actions. ¹⁶ Finding new ways to reduce human reliance on fossil fuel energy sources, like natural gas, oil, and coal, would reduce the stress on the planet. ¹⁷ The many forms of renewable energy, such as biopower, solar power, geothermal energy, hydropower, and wind energy, ¹⁸ need to be made more accessible to the general population as reliable sources of energy. Society needs



¹⁰ Current World Population, WORLDOMETER, https://www.worldometers.info/world-population/#:~:text=7.8%20Billion%20(2020),currently%20living)%20of%20the%20world (last visited Mar. 25, 2021).

¹¹ How Many People Can Our World Support, WORLD POPULATION HIST., https://worldpopulationhistory.org/carrying-capacity/ (last visited Mar. 25, 2021).

¹² How Many People Can Earth Support?, LIVESCIENCE (Oct. 11, 2011) https://www.livescience.com/16493-people-planet-earth-support.html#:~:text=Earth's%20capacity,billion%20to%2010%20billion%20people.

¹³ See Current World Population, supra note 10.

¹⁴ Samantha Gross, Why Are Fossil Fuels So Hard to Quit?, BROOKINGS INST. (June 2020), https://www.brookings.edu/essay/why-are-fossil-fuels-so-hard-to-quit/.

¹⁵ Myles R. Allen et al., *Framing and Context, in* INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, GLOBAL WARMING OF 1.5°C, at 31 (Valérie Masson-Delmotte et al. eds., 2018), https://www.ipcc.ch/site/assets/uploads/sites/2/2019/06/SR15_Full_Report_Low_Res.pdf ("Human-induced warming reached approximately 1°C (*likely* between 0.8°C and 1.2°C) above pre-industrial levels in 2017, increasing at 0.2°C (*likely* between 0.1°C and 0.3°C) per decade (*high confidence*).").

¹⁶ *Id*.

¹⁷ Benefits of Renewable Energy Use, UNION OF CONCERNED SCIENTISTS, (Dec. 20, 2017) https://www.ucsusa.org/resources/benefits-renewable-energy-use ("[A] 2009 UCS analysis found that a 25 percent by 2025 national renewable electricity standard would lower power plant CO2 emissions 277 million metric tons annually by 2025—the equivalent of the annual output from 70 typical (600 MW) new coal plants.").

¹⁸ *Id*.

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inventors and engineers to make this possible. Thus, society should incentivize such innovation in renewable energy by adopting more enticing patent policies.

To address the growing problems of environmental degradation and the need for more efficient renewable energy for a growing population, the United States could consider looking to existing statutory schemes that might be adapted to benefit inventors, the government, and the public. With helpful tweaks to this system, the answer to all energy problems would be on their way to being solved. Like the many phases of common technology, American patent law is no stranger to evolution. Patent origins date back to England as early as the sixteenth century before being officially codified into English law in the Statute of Monopolies of 1624, giving the owner of new products a fourteen-year monopoly.¹⁹

Patent rights were used in America long before 1790 when President George Washington signed the first American patent bill.²⁰ States were issuing their own patents and assigning various patent lives to America's earliest inventions.²¹ Article I, Section 8, Clause 8 of the U.S. Constitution "grants Congress the enumerated power 'to 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." The original patent bill protected novel ideas for a maximum of fourteen years and cost applicants between \$4 and \$5.²³ The basis of this first intellectual property clause was the British Statute of Monopolies.²⁴ Later nicknamed "the cornerstone of American Patent Law," fourteen years was automatically assumed to be an adequate patent life as no discussion was held on the topic at the First Federal Congress.²⁵ Later, in an 1836 amendment, under certain circumstances, patents could be granted an extension for seven years, making the full patent life twenty-one years for some

¹⁹ Simon Lester & Huan Zhu, Rethinking the Length of Patent Terms, 34 Am. U. INT'L L. REV. 787, 788-89 (2019).

²⁰ Id. at 791.

²¹ *Id.* ("After the revolution, several states took over the role of issuing patents. For instance, between 1779 and 1791, there were twenty-three state patents granted, without enactment of a dedicated patent law. The only state that formally addressed patent rights prior to the U.S. Constitution was South Carolina in the Copyright Statute of 1784.").

²² Legal Info. Inst., *Intellectual Property Clause*, CORNELL L. SCH., https://www.law.cornell.edu/wex/intellectual_property_clause#:~:text=Article%20I%2C%20Section%208%2C

^{%20} Clause, their %20 respective %20 writings %20 and %20 discoveries. %22 (last visited Mar., 25, 2021) (quoting U.S. CONST. art. I, § 8, cl. 8.).

²³ P. J. Federico, Operation of the Patent Act of 1790, 85 J. PAT. & TRADEMARK OFF. SOC'Y 33, 33-34 (2003).

²⁴ Lester & Zhu, supra note 19, at 792.

²⁵ Id.

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inventions.²⁶ At a cost of \$40, this first swing at extending the patent life required inventors to present to the Secretary of State, the Commissioner of the Patent Office, and the Solicitor of the Treasury good faith evidence for why the extension is justified.²⁷ In the Patent Act of 1861, the patent life was amended again to a happy medium of seventeen years without the possibility of an extension.²⁸ More changes came in 1994, 1999, and 2012, all seeking to improve the profitability and protections for innovators.²⁹ Patents come in three forms: first, utility patents, protecting functional aspects of products and processes; second, design patents, protecting the ornamental design of useful objects; and lastly, plant patents, protecting a new variety of a living plant.³⁰

Quite obviously, amendments to the U.S. patent system are not radical and instead have been the historical norm to meet the demands of an evolving modern society. "Through legislative debate and compromise," Congress has an enumerated role to research and develop laws that affect our daily lives to make the country run more smoothly and meet the demands of Americans.³¹ There are certainly ways for U.S. patent law to evolve to meet the demands of environmental inventors. For inventors, patents guarantee that their invention is granted an "exclusionary right" for a specified period of time.³² For the government and the public, these "new inventions propel technological inventions,"³³ which can spawn new works after the patent has expired.

Outside of extending the term of patents, all forms of environmental technology currently receive preferential treatment from the U.S. Patent and Trademark Office due to a 1982 regulatory amendment.³⁴ According to this

²⁶ Id.; see also Patent Act of 1836, ch. 357, § 18, 5 Stat. 117. ("An Act to promote the progress of useful arts, and to repeal all acts and parts of acts heretofore made for that purpose," which amended the original statute to provide a patent life extension.).

²⁷ Patent Act of 1836, ch. 357, § 18, 5 Stat. 117, 124. ("The patentee shall furnish to said board a statement, in writing, under oath, of the ascertained value of the invention, and of his receipts and expenditures, sufficiently in detail to exhibit a true and faithful account of loss and profit in any manner accruing to him from and by reason of said invention.").

²⁸ Patent Act of 1861, ch. 230, § 22, 5 Stat. 198, 201.

²⁹ 17 U.S.C. § 154 (2012)

³⁰ Gene Quinn, *The Constitutional Underpinnings of Patent Law*, IP WATCHDOG (Nov. 14, 2017), https://www.ipwatchdog.com/2017/11/14/constitutional-underpinnings-patent-law/id=90190/.

³¹ About Congress, U.S. CAPITOL VISITOR CTR., https://www.visitthecapitol.gov/about-congress#:~:text=Through%20legislative%20debate%20and%20compromise,states%20in%20the%20federal%20government (last visited Mar. 25, 2021).

³² James Yang, *Purpose of the Patent System*, OC PATENT LAWYER (Apr. 11, 2018), https://ocpatentlawyer.com/lesson/purpose-benefits-patent-system/#:~:text=The%20purpose%20of%20the%20patent,the%20United%20States%2C% 20their%20invention.

³³ Id.

³⁴ Gollin, *supra* note 5, at 10172.

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amendment, known as the Green Technology Pilot Program, an invention that "will materially enhance the quality of environment or materially contribute to the development or conservation of energy resources" will be granted fast-tracked patent approval.³⁵ However, under the Amendment's language, any invention contributing to the development of energy sources, would receive special treatment.³⁶ Even with this benefit applied to inventions materially enhancing environmental quality or conservation of resources, this amendment only accelerates the timeline of patent approval, one would have to pursue patent prosecution to regain lost profits.³⁷ The Act also was put into law thirty-eight years ago.³⁸ Since, many unprecedented environmental issues like climate change, rapid biodiversity loss, and overuse of critical natural resources have come to be.³⁹

This system is fundamentally flawed and could use improvements. As it stands, the U.S. patent system does not sufficiently recognize environmental consequences of the technology it seeks to promote, and the U.S. patent system should be doing more.⁴⁰ If the patent system is designed to protect all inventions, both environmentally harmful and beneficial technology, it could offer attractive subsidies to beneficial technology alone as a way to increase protections for our planet.

Inventing complex environmental technology is not equivalent to a summer's stay at science camp. It's no small ask of a person. Committing to producing new technology of value might require years of an inventor's life as well as funding to support their research and livelihood along the way.⁴¹ Further, patentable innovations cannot be slightly adapted known technology, but must promote a "nonobvious advance."⁴² Something patentable will become the solution to a problem presented or fill in some gap—may that be yet known or unknown.⁴³ In addition, when applying for a patent, the inventor must have already made a working product or have an air-tight design plan ready to

³⁵ Id.

³⁶ *Id*.

³⁷ Id.

³⁸ *Id*.

³⁹ Erik Lundberg, Facing Our Global Environmental Challenges Requires Efficient International Cooperation, UNITED NATIONS ENV'T PROGRAMME (July 4, 2019), https://www.unep.org/news-and-stories/editorial/facing-our-global-environmental-challenges-requires-efficient

⁴⁰ Gollin, *supra* note 5.

⁴¹ May Wong, Big Ideas Are Getting Harder to Find, STAN. BUS. (Sept. 25, 2017), https://www.gsb.stanford.edu/insights/big-ideas-are-getting-harder-find.

⁴² Gollin, supra note 5.

⁴³ *Id*.

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implement.⁴⁴ The time and effort going into this requirement alone can be a significant expense.⁴⁵

Although patents protect novel ideas for twenty years, much of this time is eroded while inventors await permitting and testing. ⁴⁶ For example, while the clock is running, FDA testing may require animal testing and multiple phases of clinical trials. ⁴⁷ Obtaining a patent does nothing but protect the invention from copyists. It also does not convey the right to the patent owner to commercialize the product or plan. ⁴⁸ Another stamp of approval via regulatory testing will be required. ⁴⁹ As a result, the incentive to innovate nonmedical inventions is diluted by time lost, and a portion of inventors' profiting potential is permanently nixed.

A. WE'VE MADE OUR BED, NOW IT'S TIME TO LIE IN IT

The air we breathe has a carbon dioxide concentration unknown to any of our ancestors, and this concentration would be enough to stave off the next ice age for millennia. Beginning in Mauna Loa, Hawaii in 1959, researchers tested atmospheric air quality for carbon dioxide concentrations. What they found is referred to as the "Keeling Curve", and it represents the unprecedented exponential growth of atmospheric carbon in parts per million (ppm). This curve, developed through daily records, perfectly aligns with fossil fuel emissions (in percentage of carbon per year). A notable observation occurred while writing this Note: atmospheric carbon dioxide increased by 6.8 ppm between October 29, 2020 (411.36 ppm) and April 22, 2021 (418.16 ppm).



⁴⁴ *Id*.

⁴⁵ Wong, supra note 41.

⁴⁶ Erika Lietzan, *The History and Political Economy of the Hatch-Waxman Amendments*, 49 SETON HALL L. REV. 53, 65 (2018) ("Today a patent lasts for twenty years, starting when the inventor files the patent application.").

⁴⁷ *Id.* ("If the inventor spends a decade testing embodiments for regulatory purposes—animal testing to justify a clinical program, followed by three phases of clinical trials—only ten years of patent life remain when the FDA (Food and Drug Administration) approves the finished product for the market. This is the product's 'effective patent life,' meaning the portion of the patent term during which the patent owner may lawfully sell embodiments of the invention while excluding others from doing so.").

⁴⁸ Gollin, *supra* note 5, at 10171-72.

⁴⁹ *Id*.

⁵⁰ K.G. Orphanides, *Human CO2 Emissions Could Hold Off the Next Ice Age*, WIRED, (Jan. 14, 2016) https://www.wired.co.uk/article/human-co2-emissions-prevent-ice-age.

⁵¹ The Keeling Curve, SCRIPPS INST. OF OCEANOGRAPHY, UC SAN DIEGO, https://sioweb.ucsd.edu/programs/keelingcurve/ (last visited Apr. 25, 2021).

⁵² Id.

⁵³ *Id*.

⁵⁴ *Id*.

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As our populations grow and we continue to rely on natural resources for survival and economic welfare, mitigation of harmful toxins from industrial waste and day-to-day human life is more important than ever. Humans worldwide have better access to healthcare and food, lower infant mortality rates, and increased life expectancy that would have been difficult for our ancestors to fathom 300 years ago.⁵⁵ Improvements in public health and medical technology receive much of this credit.⁵⁶ All of these improvements, however, have come at a steep price. Experts suggest that we are currently living in the Anthropocene Epoch, "an unofficial unit of geologic time, used to describe the most recent period in Earth's history when human activity started to have a significant impact on the planet's climate and ecosystems."57 Humanity's profound impact on the planet characterizes the Anthropocene Epoch.⁵⁸ Our geological layer will be marked by "the radioactive elements dispersed across the planet by nuclear bomb tests, and an array of other signals, including plastic pollution, soot from power stations, concrete, and even bones left by the global proliferation of the domestic chicken. . . . "59

1. All we are is dust in the wind

Burning fossil fuels, deforestation, and industrial activities, atmospheric carbon dioxide concentrations have contributed to the unprecedented jump in atmospheric carbon levels.⁶⁰ Starting at 280 ppm 200 years ago during pre-Industrial Revolution times, the levels have jumped to approximately 400 ppm today.⁶¹ This atmospheric carbon dioxide overload not only degrades the natural

⁵⁵ John V.C. Nye, *Standards of Living and Modern Economic* Growth, THE LIBR. OF ECON. & LIBERTY, https://www.econlib.org/library/Enc/StandardsofLivingandModernEconomic Growth.html (last visited Mar. 25, 2021).

⁵⁶ Claire Ninde, 200 Years of Public Health Has Doubled Our Life Expectancy, SAN JUAN BASIN PUB. HEALTH, https://sjbpublichealth.org/200-years-public-health-doubled-life-expectancy/ (last visited Mar. 25, 2021) ("Over the last 200 years, U.S. life expectancy has more than doubled to almost 80 years (78.8 in 2015), with vast improvements in health and quality of life. However, while most people imagine medical advancements to be the reason for this increase, the largest gain in life expectancy occurred between 1880 and 1920 due to public health improvements such as control of infectious diseases, more abundant and safer foods, cleaner water, and other nonmedical social improvements.").

⁵⁷ Anthropocene, NAT'L GEOGRAPHIC, https://www.nationalgeographic.org/encyclopedia/anthropocene/ (last visited Mar. 25, 2021) (defining the "Anthropocene Epoch").

⁵⁸ *Id*.

⁵⁹ Damien Carrington, *The Anthropocene Epoch: Scientists Declare Dawn of Human-Influenced* Age, The Guardian (Sept. 4, 2019, 11:10 AM) https://www.theguardian.com/environment/2016/aug/29/declare-anthropocene-epoch-experts-urge-geological-congress-human-impact-earth.

⁶⁰ Nils Zimmerman, Five of the World's Biggest Environmental Problems, DW (Nov. 10, 2016), https://www.dw.com/en/five-of-the-worlds-biggest-environmental-problems/a-35915705.

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balance of the air we breathe, but also contributes to severe health problems for the human population.⁶² According to the World Health Organization, outdoor air pollution is directly linked to premature deaths from ischemic heart disease, stroke, chronic obstructive pulmonary disease, lung cancer, and acute lower respiratory infections in children.⁶³ Many cities around the world, such as Beijing, Dhaka, New Delhi, Moscow, and Mexico City, have sacrificed air quality for development and industry.⁶⁴ Consequently, the World Health Organization suggests that seven million people die each year from exposure to air pollution.⁶⁵

2. Come on in, the water's warm

In the words of the British poet, W.H. Auden, "[t]housands have lived without love, not one without water." Humans laud water as their most precious and scarce natural resource, yet continuously and unapologetically degraded it with wastewater and other anthropogenic activity, both legal and illegal. About eighty percent of wastewater is not properly recycled back into municipal systems. Instead, it goes right back into natural waterways, primarily untreated, where humans and wildlife can easily come into contact with toxins.

While humans must find safe ways to dispose of wastewater, certain localities lack the funding, infrastructure, or technology to perform this task adequately. Drinking contaminated water is more dangerous to humanity than any war or man-on-man violence. The World Wildlife Fund estimates that more than one billion people do not have access to clean water and more than double that amount do not have proper sanitation infrastructure in their locality. To ensure that human populations across the globe have access to clean drinking water for years to come, creative solutions are essential. Business as usual cannot continue.

^{62 7} Million Premature Deaths Annually Linked to Air Pollution, WORLD HEALTH ORG. (Mar. 25, 2014), https://www.who.int/mediacentre/news/releases/2014/air-pollution/en/.

⁶³ *Id*.

⁶⁴ *Id*.

⁶⁵ WHO, Ambient Air Pollution: A Global Assessment of Exposure and Burden of Disease, WORLD HEALTH ORGANIZATION (2016) at 40 http://apps.who.int/iris/bitstream/handle/10665/250141/9789241511353-eng.pdf?sequence=1&isAllowed=y.

⁶⁶ Melissa Denchak, *Water Pollution: Everything You Need to* Know, NRDC (May 14, 2018), https://www.nrdc.org/stories/water-pollution-everything-you-need-know.

⁶⁷ Id.

⁶⁸ Id.

⁶⁹ Id. ("80 percent of the world's wastewater is dumped–largely untreated–back into the environment, polluting rivers, lakes, and oceans.").

⁷⁰ Ninde, supra note 56.

⁷¹ Denchak, *supra* note 66 ("Unsafe water kills more people each year than war and all other forms of violence combined.").

 $^{^{72}}$ Pollution, WORLD WILDLIFE FUND, https://www.worldwildlife.org/threats/pollution (last visited Mar. 25, 2021).

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3. Can we ever go back to the land before time?

Humans not only put stressors on Earth's water and air, but also on its land. Land surfaces face degradation as a result of litter from various human sources, such as waste washed ashore from boats and oil rigs, and toxic agricultural runoff.⁷³ Human waste and thus, anthropogenic land pollution, fits into three distinct groups: municipal solid waste, construction and demolition waste, and hazardous waste.⁷⁴ Hazardous waste in particular must be dealt with in a unique way: "[i]ts disposal requires special attention because it can cause serious illnesses or injuries and can pose immediate and significant threats to environmental quality."⁷⁵

The difficulties presented with disposing of hazardous waste are reflected in its frequent illegal disposal. For Superfund sites illustrate the difficulty of waste disposal in the United States. Due to improper management of hazardous waste, Superfund sites include former processing plants, mines, and manufacturing facilities. Such illegal "midnight dumping" seriously degrades land quality at thousands of industrial sites and puts public health and environmental quality at extreme risk.

The need for more cutting edge, state of the art environmental technology to address the issues of hazardous waste disposal is apparent upon reviewing the data.⁸⁰ Instead of playing the fiddle while the world burns, it is vital that capable

⁷³ Land Pollution, LONGDOM, https://www.longdom.org/scholarly/land-pollution-journals-articles-ppts-list-2721.html#:~:text=Land%20pollution%20is%20a%20result,oil% 20rigs%2C%20and%20sewage%20outlets (last visited Mar. 25, 2021).

⁷⁴ Jerry A. Nathanson, *Land Pollution*, BRITANNICA https://www.britannica.com/science/land-pollution (last visited Mar. 25, 2021).

⁷⁵ I.d

⁷⁶ Claire Wolters, *Toxic Waste, Explained*, NAT¹L GEOGRAPHIC (June 26, 2019), https://www.nationalgeographic.com/environment/global-warming/toxic-waste/#:~:text = Violations%20of%20the%20law%2C%20like,the%20era%20prior%20to%201976.

Through CERCLA or Superfund -- provides a Federal "Superfund" to clean up uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment. Through CERCLA, EPA was given power to seek out those parties responsible for any release and assure their cooperation in the cleanup.").

⁷⁸ What is Superfund?, ENV'T PROT. AGENCY, https://www.epa.gov/superfund/what-superfund (last visited Mar. 25, 2021).

⁷⁹ Nathanson, *supra* note 74.

⁸⁰ Richard Espinoza, *How Hazardous Waste Disposal Affects the Environment*, IDR ENV'T SERVICES, (Nov. 24, 2020) https://blog.idrenvironmental.com/how-hazardous-waste-disposal-affects-the-environment.

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minds have the proper incentive to devote years of their time and money to develop the technology our environment so desperately needs.

B. IT'S NOT THAT BIG OF AN ASK

It is easy to hammer home the need for fresh takes and complicated mathematical equations to solve the world's major environmental issues. However, those equipped with the mental dexterity to untangle such a web need a metaphorical carrot in order to find the motivation for such a daunting commitment. Historically, standard patents were the answer to this issue.⁸¹

Those who obtain patents for their intellectual property "reap greater profits if protected from direct competition." For example, the patent holder of the barcode won "over \$450 million in royalties and judgments," so there is a lot of money at stake with competitors. While environmental degradation worsened after the Industrial Revolution, patent law motivated talented minds to innovate, and led some to thoughtful solutions to environmental problems. 84

The Clean Air Act was promulgated in 1970 under President Nixon to regulate air emissions and protect public health.⁸⁵ After the 1990 amendments, stricter regulations required industries to greatly reduce fossil fuel emissions of stationary sources to certain lower levels by 2010.⁸⁶

One of the most promising pieces of technology inventors were able to work with, gracefully named flue gas desulphurization systems, also known as "scrubbers," already existed.⁸⁷ These scrubbers remove particulate matter, sulphur dioxide, hydrochloric acid, and other air toxins from atmospheric

⁸¹ Joe Hadzima, *The Importance of Patents: It Pays to Know Patent Rules*, BOSTON BUS. J. 1, 1 (Dec. 7, 2006), http://web.mit.edu/e-club/hadzima/pdf/the-importance-of-patents.pdf ("A patent is an exclusive right granted by a country to an inventor, allowing the inventor to exclude others from making, using or selling his or her invention in that country during the life of the patent.").

⁸² Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program (last visited Mar. 25, 2021) [hereinafter Small Business Assistance].

⁸³ Hadzima, supra note 81, at 2.

⁸⁴ Gollin, supra note 5.

^{85 40}th Anniversary of the Clean Air Act, ENV'T PROT. AGENCY, https://www.epa.gov/clean-air-act-overview/40th-anniversary-clean-air-act#:~:text=The%20Clean%20Air%20Act%20 was,human%20health%20and%20the%20environment (last visited Mar. 25, 2021).

⁸⁶ Joseph Cotruvo, *Smokestack Scrubbers: How They Work and How They are Used,* WATER TECH. (Oct. 22, 2018) https://www.watertechonline.com/wastewater/article/15550703/smokestack-scrubbers-how-they-work-and-why-they-are-used.

⁸⁷ Sulfur Dioxide Scrubbers, DUKE ENERGY, https://www.duke-energy.com/Our-Company/Environment/Air-Quality/Sulfur-Dioxide-Scrubbers (last visited Apr. 15, 2021).

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output.⁸⁸ The patent system incentivized inventors to improve existing technology so industries could efficiently meet administrative regulations.⁸⁹ The EPA itself owned about 100 patents around the time of the 1990 Amendments mainly for air pollution, wastewater management technology, and environmental sampling devices.⁹⁰ This anecdotal evidence lends credence to the success of the patent system in solving air quality issues in the 1990s, but the need did not stop there.

Over a thirty-year period, between General Electric's two New York plants, over 500,000 pounds of polychlorinated biphenyls ("PCBs") were dumped into the Hudson River.⁹¹ PCBs, "used by many industries as insulation fluids in capacitators, transformers and electrical systems," are suspected carcinogens and endocrine disruptors that have been linked to many severe health and reproductive issues in wildlife.⁹² From human consumption of affected wildlife, PCBs made their way up the food chain through biomagnification and will exist in our bodies for the remainder of our lives.⁹³ Upon connecting the toxic dots, New York State ordered General Electric to stop dumping into the Hudson in 1977; thus, General Electric turned to environmental engineers for help.94 General Electric soon realized that naturally occurring bacteria in the Hudson's sediment were able to break down PCBs into less harmful components through biodegradation.⁹⁵ General Electric then elected to fund scientists and engineers to find a solution stemming from this natural occurrence instead of the other costly option of dredging PCBs from the Hudson. 96 Eventually, General Electric patented its own "PCB-digesting bacteria," and the Hudson began to heal from the effects of PCBs.97

Just as the atmosphere and water bodies of the world have their share of environmental issues, the land is no different. Many municipalities utilize landfills to dispose of and store municipal solid waste, and the combined capacity

⁸⁸ Id.

⁸⁹ Anetta Caplanova, *Intellectual Property*, START-UP CREATION, 2nd Ed., 2020, https://www.sciencedirect.com/topics/engineering/patent-system.

⁹⁰ Gollin, supra note 5, at 10173.

⁹¹ Hudson River Sloop Clearwater, Inc., PCB Contamination of the Hudson: Is the River Cleaning Itself?, RENSSELAER POLYTECHNIC INST., https://www.rpi.edu/dept/environ/orgs/Clearwater/cleaning .itself.html#:~:text=According%20to%20GE%2C%20bacteria%20which,process%20known%20as%20%22biodegradation%22.&text=It%20is%20generally%20believed %20that,PCBs%20with%20fewer%20chlorine%20atoms (last visited Mar. 25, 2021).

⁹² Id.

⁹³ Id.

⁹⁴ *Id*.

⁹⁵ Id.

⁹⁶ Id.

⁹⁷ Gollin, supra note 5.

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of the two largest U.S. landfills in 2019 equated to 9.9 billion cubic yards. These landfills may have hidden human waste well, but this cover-all solution is not a catch-all solution. When precipitation seeps into the hilly landscape and filters through the landfill's debris, a toxic liquid byproduct called leachate forms. 99

As populations increased, so did the amount of waste, and thus the size of landfills grew. ¹⁰⁰ Leachate could no longer be ignored, as it was percolating through the bedrock and contaminating groundwater reservoirs. ¹⁰¹ In came patent law and environmental technology to the rescue. Engineers developed impermeable polymeric barriers to line the bottoms of landfills to catch leachate as it materialized and then properly dispose of the toxin. ¹⁰² Others found ways to employ treating the leachate with chlorine-based oxidant and filtering the leachate by reverse osmosis. ¹⁰³ The presence of the patent system to protect ideas kept pushing innovators to chase new leads and develop new processes in hopes of finding the ultimate solution.

Investment, both intellectual and monetary, in environmental technology to prevent and curtail the impacts of human activity is essential to keep natural, healthy balances in our atmosphere, land, and waterways. The world depends on the sharp minds of innovators to find ways to undo the damage from human activity. Through patents,

[t]echnological progress is promoted by guaranteeing inventors the exclusive right to their inventions long enough for them to reap a just reward without competition from a copyist. By granting the exclusive rights conveyed by a patent, the federal government provides an economic incentive to innovate ¹⁰⁴

⁹⁸ Ctr. for Sustainable Sys., *Municipal Solid Waste Factsheet*, UNIV. OF MICH., http://css.umich.edu/factsheets/municipal-solid-waste-factsheet (last visited Mar. 25, 2021).

⁹⁹ Safaa M. Raghab, Ahmed M. Abd El Meguid & Hala A. Hegazi, Treatment of Leachate from Municipal Solid Waste Landfill, 9 HOUS. & BLDG. NAT'L RSCH. CTR. J. 187, 187 (2013), https://www.sciencedirect.com/science/article/pii/S168740481300031X.

¹⁰⁰ Municipal Solid Waste Fact Sheet, supra note 98 ("Landfills were the third largest source of U.S. anthropogenic CH₄ emissions in 2018, accounting for 111 million metric tons CO₂-equivalent emissions, about 1.7% of total GHG emissions.").

¹⁰¹ Richard Espinoza, How Does Leachate Contaminate Our Water Supply?, IDR ENV'T SERVS. (Sept. 29, 2020) https://blog.idrenvironmental.com/how-does-leachate-contaminate-our-water-

 $supply \#: \sim : text = The \%20 leach ate \%20 from \%20 Municipal \%20 Solid, unsuitable \%20 for \%20 domestic \%20 water \%20 use.$

¹⁰² U.S. Patent No. 4,790,688A (issued Dec. 13, 1988).

¹⁰³ U.S. Patent No. 7,517,456B2 (issued Apr. 14, 2009).

¹⁰⁴ Gollin, supra note 5.

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Such investments in environmental technology, however, are costly and timely. The General Accounting Office released a report in 2002 announcing that the cost of obtaining a patent applicable to ten countries outside the U.S. will cost between \$160,000 to \$330,000. The Further, it is estimated that a single U.S. patent will cost the inventor between \$10,000 to \$25,000, excluding maintenance and foreign filing fees. The current patent life on new technologies post-1995 is generally twenty years, and that clock starts running before this technology even hits the marketplace and is available to consumers. When the patent's shelf life has already begun, innovators are still working to get their products permitted and can spend months to years before their work is in the hands of consumers.

Inventors can spend eighteen to twenty-four months just waiting for their patent application. Patents no longer provide adequate incentive to innovate complex environmental technology because so much of the protected time is lost during the permitting and testing period. Because the effective term of these patents is affectively eroded through waiting time for proper permitting and testing, it is more important than ever that environmental technologies be awarded the same grace that the pharmaceutical industry receives through the Drug Price Competition and Patent Term Restoration Act of 1984. Passed by the 98th Congress and signed by President Reagan, the purpose of the Food and Drug Administration's patent term restoration privilege was to extend the benefits of the patent life for the holder to make up for marketing time lost. This Act is hailed "as [] one of the most important pieces of legislation affecting the drug industry" and would be helpful for any sector of inventors.

Title II of the Act, the patent term restoration or patent term extension portion, gave certain patent holders the opportunity to extend the terms of patents claiming human drug products, including antibiotics and biologics, medical devices, food

¹⁰⁵ Wong, supra note 41.

¹⁰⁶ Hadzima, *supra* note 81, at 2.

¹⁰⁷ Id.

¹⁰⁸ *Id*.

¹⁰⁹ Small Business Assistance, supra note 82.

¹¹⁰ Hadzima, supra note 81.

¹¹¹ Small Business Assistance, supra note 82.

¹¹² Pub L. No. 98-417, 98 Stat. 1585.

¹¹³ Small Business Assistance, supra note 82.

¹¹⁴ Drug Price Competition and Patent Term Restoration Act, FINDLAW, https://corporate.findlaw.com/intellectual-property/drug-price-competition-and-patent-term-restoration-

act.html#:~:text=Title%20II%20of%20the%20Act,food%20additives%20and%20color%20additives (last visited Mar. 25, 2021) [hereinafter *Drug Price Competition*].

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additives and color additives. By giving inventors a portion of the patent term lost to federal regulatory review, Congress sought to: "restore to our domestic drug companies some of the incentive for innovation which has weakened as Federal premarket approval requirements have become more expensive and time consuming. That incentive will produce both the investment and the commitment to research and development that will again place the United States in unquestioned leadership in the field. And it will generate an increase in the number of important new drugs, among the most vital causes for this century's dramatic increase in the length and quality of life." 115

Title II of the Drug Price Competition and Patent Term Restoration Act was enacted by Congress in 1984 "to extend patent life to compensate patent holders for marketing time lost while developing the product and awaiting government approval."116 Further, Title II enables patent holders whose invention relates to the medical field, or a food or color additive, to gain back up to five years of time lost.¹¹⁷ Through the Act, newly patented drugs do not start their then seventeenyear patent life clock until the drug had FDA approval.¹¹⁸ The congressional intent behind The Act, was to address the growing costs of American healthcare and increase in medical innovation.¹¹⁹ Not only did the Act aim to extend the patent life of medically related inventions, but it sought to create an expedited pathway for pharmaceutical companies to obtain approval by the Food and Drug Administration. 120 To meet these ends, the Act has several safeguards to protect both patented and unpatented inventions. "[The Act] also created a statutory 'safe harbor' that shields generic applicants from charges of patent infringement until such time as they request approval to market their products from the FDA."121

The Act provides ample support to companies introducing new patents. 122 For example, the Act pushes "brand-name" pharmaceutical companies to inform the FDA of their patents, which the FDA will list in "the Orange Book" —a publication that identifies approved drugs and the intellectual property rights

¹¹⁵ *Id*.

¹¹⁶ Small Business Assistance, supra note 82.

¹¹⁷ Id.

¹¹⁸ Id. (The seventeen-year patent life clock has since become a twenty-year patent life clock after the signing of the Uruguay Rounds Agreements Act of 1994).

¹¹⁹ CONG. RSCH. SERV., THE HATCH-WAXMAN ACT: A PRIMER 1 (Sept. 28, 2016), https://www.everycrsreport.com/files/20160928_R44643_1c2fafad2efe96d4c0fe44f2f233 08dcfc059f83.pdf [hereinafter PRIMER].

¹²⁰ Id.

¹²¹ Id. at i.

¹²² Id.

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associated with them."¹²³ Off-brand companies awaiting FDA approval for marketing must check the Orange Book.¹²⁴ These companies will likely delay any marketing of their new products until the patented product listed in the Orange Book has expired, unless they can dispute the patent's validity or distinguish their product from the brand-name product.¹²⁵

This grant promotes intellectual property innovation in the drug industry by ensuring that ideas are protected for the full patent lifespan, making innovators more inclined to spend time and energy developing. This time extension is not to be understated. Before market approval, one must employ extensive testing for safety and implementation. As of the 2021 Patent Term Restoration Act, the only products granted this patent life extension are human drug products, medical devices, food additives, color additives, and animal drug products. Under the Act, a maximum of five years can be restored to the patent, which provides the potential for enormous profits to be saved from years lost to direct competition. These five years, or a portion thereof, would otherwise be lost in the shuffling of paperwork and wading through bureaucratic red tape, benefitting no one but any direct competitors waiting to implement the patented idea into their own product.

The Act has been credited with "foster[ing] innovation, spurr[ing] competition[,] and help[ing] the United States remain a leader in biopharmaceutical research and development." ¹³⁰ As it stands, developing a new drug will take between ten and fifteen years and cost the developer around \$2.6 billion. ¹³¹



¹²³ *Id*.

¹²⁴ Id.

¹²⁵ Id.

¹²⁶ *Id*.

¹²⁷ *Id*.

¹²⁸ *Id*.

¹³⁰ Tom Wilbur, IP Explained: How Hatch-Waxman Successfully Balances Affordability and Innovation, THE CATALYST (May 22, 2019) https://catalyst.phrma.org/ip-explained-how-hatch-waxman-successfully-balances-affordability-and-

 $innovation\#:\sim: text=In\%20 addition\%20 to\%20 fostering\%20 biopharmaceutical, approval\%20 path\%20 for\%20 generic\%20 products. \& text=With\%20 this\%20 increase\%20 in\%20 brand, savings\%20 from\%20 2007\%20 to\%20 2016.$

¹³¹ *Id*.

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C. THE LEGAL NEXUS

In 1970, Congress granted the Food and Drug Administration the benefit of the Patent Term Restoration Act to protect and increase the output of inventions with "life-saving impact[s]." ¹³²

1. Legislative History

In the pharmaceutical world, there are two types of drugs at play: pioneer drugs, being that they are the first of their kind, and generic drugs, the less expensive redevelopment of a pioneer drug after it is no longer patent protected.¹³³ The testing process for FDA approval is considerable for any type of drug.¹³⁴ Congress established the Hatch-Waxman Act while pharmaceutical prices were soaring, generic drug companies were jumping through hoops to avoid patent infringement and obtain FDA approval, and "to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."¹³⁵ Title II discusses the duration of the patent term.¹³⁶

2. Title II: The Basics

Legislators designed Title II of the Patent Term Restoration Act to grant an extension of the patent life for the time lost by the pioneer between patent issuance and FDA approval.¹³⁷ In order to receive an extension, the pharmaceutical inventor must satisfy five requirements: (1) the patent term must still be valid before an extension application is submitted; (2) the patent term seeking an extension must never have been extended; (3) the extension application needs to have been submitted by the patent holder or an agent of the patent holder; (4) the invention itself has already gone through regulatory review before being available to the commercial market; and (5) after the regulatory

¹³² Pamela Fuentes, *Nipping the Bad in the Bud: Using Hatch-Waxman to Renew Monsanto's Cmp*, 30 TEMP. J. SCI. TECH. & ENV'T. L. 81, 87 (2011) (arguing that the life-saving properties of the agricultural biotechnology are akin to the life-saving properties of the pharmaceutical industry and that this nexus should enable the Hatch-Waxman legislation to apply to agricultural biotechnological inventions).

¹³³ Id. at 88.

¹³⁴ Hatch-Waxman: Carefully Balancing the Need for Innovation and Drug Competition, BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/sites/default/files/legacy/bio org/docs/Hatch_Waxman.pdf (last visited Mar. 25, 2021) ("The time it takes for a generic medicine to come to market has remained steady at approximately 13.5 years for over two decades.").

¹³⁵ Fuentes, *supra* note 132, at 89.

¹³⁶ Id, at 89-90.

¹³⁷ *Id.* at 92.

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review, the permitted marketing occurring thereafter was the first time the product was marketed or used. 138 Once granted, the extended patent retains all the same rights it had under its original patent life. 139

These five requirements noted above to achieve eligibility under the Patent Term Restoration Act are painted with a broad brush. They are applicable to industries other than pharmaceutical considering the language does not specifically reflect a pharmaceutical invention. These broad requirements could match with many forms of innovation, especially those that require an assessment of safety.

In addition, the Patent Term Restoration Act is no stranger to expansion and amendment. In 1990, the U.S. Supreme Court expanded the scope of the Act to cover medical devices in addition to pharmaceuticals. 140 In 1988, the Generic Animal Drug and Patent Term Restoration Act lent the same restoration of time lost to veterinary drugs.¹⁴¹ As mentioned earlier in this Note, the very essence of the U.S. House of Representatives and the Senate is to ensure our current laws are well-adapted to the needs of modern society. 142 When Congress wants to improve a statute to better line-up with these needs, an amendment is researched, written, and proposed before going up for a vote in its respective legislature before going up for another vote in the other. 143 The U.S. Constitution has seventeen amendments itself, excluding the Bill of Rights. 144

D. LANGUAGE OF THE STATUTE

The original language of Title II of the Drug Price Competition and Patent Term Restoration Act relating to patent term extension is as follows:

(a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent if—"(1) the term of the patent has not expired before an application is submitted under subsection

(d) for its extension; "(2) the term of the patent has never been

¹³⁸ Id.

¹⁴⁰ Eyal H. Barash, Experimental Uses, Patents, and Scientific Progress, 91 Nw. U. L. REV. 667, 691 (1997) (citing the holding in Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990)).

¹⁴¹ Drug Price Competition, supra note 114.

¹⁴² The Legislative Branch, THE WHITE HOUSE, https://www.whitehouse.gov/about-thewhite-house/our-government/the-legislative-branch/ (last visited Mar. 25, 2021).

¹⁴³ The Legislative Process, U.S. REPRESENTATIVE BILL KEATING, https://keating.house.gov /policy-work/legislative-process (last visited Mar. 25, 2021).

¹⁴⁴ The United States Constitution, TEXAS A&M SCH. OF L., https://law.tamu.libguides .com/c.php?g=513904&p=3510977 (last visited Mar. 25, 2021).

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extended; "(3) an application for extension is submitted by the owner of record of the patent or its agent and in accordance with the requirements of subsection (d); "(4) the product has been subject to a regulatory review period before its commercial marketing or use; "(5)(A) except as provided in subparagraph (B), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; or "(B) in the case of a patent which claims a method of manufacturing the product which primarily uses recombinant DNA technology in the manufacture of the product, the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of a product manufactured under the process claimed in the patent.¹⁴⁵

It is clear from the broad language used in Title II that the extension to include environmental technology that has some positive effect is easily workable into the legislative schema. Legislators would barely have to lift a finger to incorporate a new exception. In fact, proposing a simple addendum would be sufficient.

III. ANALYSIS

Translating this generous grant to the environmental sphere would provide the same incentive to environmental engineers to tackle the growing number of environmental issues facing humanity. The legislative intent behind the Patent Term Restoration Act was sufficiently tailored to meet the government's ends in that it aimed to improve healthcare and increase innovation. This same legislative intent must be applied to the environmental sector of innovation.

Aside from directly benefiting patent holders, new inventions can improve quality of life, stimulate economies, promote high rates of entrepreneurship, create career opportunities for skilled labor, and protect and preserve natural resources.¹⁴⁷ With many minds working on many problems at once, each diverse

¹⁴⁵ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 201, 98 Stat. 1585, 1598.

¹⁴⁶ Legislative History of the Drug Price Competition and Patent Term Restoration Act of 1984 – PL 98 – 417, IPMALL, https://ipmall.law.unh.edu/content/legislative-history-drug-price-competition-and-patent-term-restoration-act-1984-pl-98-417 (last visited Apr. 15, 2021).

¹⁴⁷ Andrew Reamer, *The Impacts of Technological Innovation on Economic Growth – A Review of the Literature*, THE GEORGE WASHINGTON INST. OF PUB. POLICY (Feb. 28, 2014), https://

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issue attracts critical problem solving through inventions. One could see the number of lives saved by introducing new drugs via the Patent Term Restoration Act as minuscule compared to the future generations saved by improvements in the air, water, and land quality worldwide.¹⁴⁸

Following an inventor's logic, "the stronger the patent right and the easier it is to obtain a patent, the more incentive there is to innovate and disclose inventions." To build off this argument, the idea of a stronger patent begins with restoring its relate-back date and starting the patent life clock at twenty years only when the product is available for consumers.

A. IN REAL TIME

Imagine you are a highly skilled engineer. You have spent considerable time studying and racking your brain on an invention that could change the world for the better. You land on a more efficient way to capture methane gas emitted from landfills. There is a process in place already, but you think you can improve it by removing moisture, impurities, and carbon dioxide simultaneously instead of in three separate processes. 150 You work on the design for several years, build a prototype over the course of months, test it for months, and spend time making productive changes. You believe that this invention is one of a kind and that you have a right to protect it as intellectual property.

What follows below are your next steps under the current patent system. Step one is to determine the type of intellectual property needed.¹⁵¹ For the sake of

gwipp.gwu.edu/sites/g/files/zaxdzs2181/f/downloads/Reamer_The_Impacts_of_Invention_on_Economic_Growth_02-28-14.pdf.

¹⁴⁸ Mandy Warner, Cleaning the Air Saves Lives and Creates an Engine for Job Growth, ENV'T DEF. FUND (June 27, 2017), http://blogs.edf.org/energyexchange/2017/06/27/cleaning-the-air-saves-lives-and-creates-an-engine-for-job-growth/ ("Cleaner air saves lives and protects the health of American families. According to a landmark analysis, in 2010 alone the Clean Air Act prevented 160,000 deaths. It also prevented 13 million lost workdays and 3.2 million lost school days because of illnesses and diseases caused or exacerbated by air pollution. The value of avoiding those lost work and school days in 2010 was approximately \$2 billion."). For the "landmark analysis" Warner refers to in her article, see U.S. EPA, OFF. OF AIR AND RADIATION, THE BENEFITS AND COSTS OF THE CLEAN AIR ACT FROM 1990 TO 2020: FINAL REPORT 9, 11 tbls. 5 & 6 (2011). This study is the third in a series of studies mandated by Congress in the Clean Air Act Amendments of 1990. The report received extensive review and input from the Council on Clean Air Compliance Analysis, an independent panel of distinguished economists, scientists and public health experts established by Congress in 1991.

¹⁴⁹ Gollin, supra note 5.

¹⁵⁰ See Basic Information About Landfill Gas, ENV'T PROT. AGENCY, https://www.epa.gov/lmop/basic-information-about-landfill-gas#:~:text=LFG%20is%20nextracted%20from%20landfills,in%20an%20LFG%20energy%20project (last visited Mar. 25, 2021) (describing how landfill gas is collected and treated in three separate processes).

¹⁵¹ Patent Process Overview, U.S. PAT. & TRADEMARK OFF. (Jan. 31, 2019, 07:13 AM EST), https://www.uspto.gov/patents/basics/patent-process-overview.

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this hypothetical, you determine that a patent is required. Step two requires you to verify that your invention has not been publicly disclosed by anyone else. ¹⁵² If you are not sure how to conduct this search, you will need to pay an agent, or a patent attorney registered with the USPTO. ¹⁵³ This alone is a significant expense and can cost between \$300-\$700 per hour in major metropolitan areas. ¹⁵⁴

The third step is to determine which type of patent you need.¹⁵⁵ Based on your methane-capturing invention, your patent attorney determines you need a utility patent because your invention is the combination of a machine and a new and useful process.¹⁵⁶ Step four is getting ready to apply; this process requires you to consider time and cost, as well as whether to continue to retain an attorney or agent.¹⁵⁷ Given that you are a novice in patent law (you prefer physics exercises over torts hypos), you continue to use your patent attorney's expertise. Keep in mind your attorney is logging her hours spent working for you. As for the cost of applying, "[a] patent application is subject to the payment of a basic fee and additional fees that include a search fee, an examination fee, and issue fee. Depending on your application, there may also be excess claims fees." ¹⁵⁸

Step five is actually submitting your initial application.¹⁵⁹ To better illustrate the likely timeline from initial research and development, to USPTO application, to patent granted, it is helpful to look to a similar patent already registered with the USPTO (although yours is much better). This other patent is for a "Landfill methane enhancement process," and the inventors, Russell and Xiomara Chianelli, incorporated inventions from as early as 1994 and 2001 in their research and development.¹⁶⁰ The Chianellis filed their patent application on March 3, 2010 with the USPTO and received their patent on February 17, 2015, almost five years later.¹⁶¹ The numerous fees that come along with filing are not insignificant. The filing fee for a utility patent alone is \$320, \$700 for a utility

¹⁵² *Id*.

¹⁵³ *Id*.

¹⁵⁴ Gene Quinn, Patent Cost: Understanding Patent Attorney Fees, IP WATCHDOG (Apr. 18, 2015), https://www.ipwatchdog.com/2015/04/18/patent-cost-understanding-patent-attorney-

fees/id=56970/#:~:text=If%20you%20are%20looking%20for,hour%20in%20major%20m etropolitan%20areas ("If you are looking for experienced patent attorneys at a reputable firm you should anticipate hourly rates to be a minimum of \$300 per hour in areas outside major metropolitan areas and somewhere between \$400 to \$700+ per hour in major metropolitan areas.").

¹⁵⁵ Patent Process Overview, supra note 151.

¹⁵⁶ *Id*.

¹⁵⁷ *Id*.

¹⁵⁸ *Id*.

¹⁵⁹ Id.

¹⁶⁰ U.S. Patent No. 8,956,854B2.

¹⁶¹ *Id*.

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search fee, \$800 for a utility examination fee, and \$1,200 for a utility patent postallowance fee. 162

Step six requires you to work with your patent examiner and work through any issues in your application.¹⁶³ Steps seven and eight are receiving your patent and maintaining its status.¹⁶⁴ As you can see, this is a lengthy process that stretches out over the course of years, while also costing a pretty penny.¹⁶⁵

You, like the Chianellis, 166 have a worthwhile invention that can preserve atmospheric integrity and keep excess methane out of living lungs. Because your invention is environmentally beneficial, you should be granted any time lost in your application and testing process back to your patent life automatically, without wading through the bureaucratic paperwork at the USPTO. If the Patent Term Restoration Act had been applied to the Chianellis's "Landfill methane enhancement process," the lifetime of the Chianelli patent would be extended by the amount of time the Chianellis spent in patent prosecution. Thus, the Chianellis would be awarded five more years of patent protection for their enhanced process. This is just one factual pathway of how the amended Act could help an inventor.

B. JUSTIFICATION FOR PATENT EXPIRATION IN GENERAL

With all great ideas, comes counterarguments attempting to pick apart their sound reasoning. Undeniably, there are legitimate policy reasons for limiting patent lives. Once a patent expires, the invention or idea becomes available to the public to "stimulate a wide range of invention and innovation." As is apparent from a broad look at technological evolution, old technology lends insight to the development of newer technology. For example, cell phones have changed dramatically through the years. The many phases and updates reflected through these inventions would not have accelerated the rate they did

¹⁶² USPTO Fee Schedule, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule#Patent%20Fees (last visited Mar. 26, 2021).

¹⁶³ Patent Process Overview, supra note 151.

¹⁶⁴ *Id*.

 $^{^{165}}$ Id. (for maintaining an original patent, \$2,000 is due at 3.5 years, \$3,760 is due at 7.5 years, and \$7,700 is due at 11.5 years).

¹⁶⁶ The inventors of Landfill Methane Enhancement Process, U.S. Patent No. 8,956,854B2 (filed Mar. 3, 2011) (issued Feb. 17, 2015).

¹⁶⁷ Id

¹⁶⁸ Amanda Ray, *The History and Evolution of Cell Phones*, THE ART INSTITUTE, Jan. 22, 2015, https://www.artinstitutes.edu/about/blog/the-history-and-evolution-of-cell-phones.
¹⁶⁹ Id.

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without limits on patent-lives and early releases of patent rights.¹⁷⁰ A patent without an expiration date would stand in the way of others improving and expanding on the idea.¹⁷¹ As explained earlier, the entire point of the patent system is to reward extensive research and time put into inventions for the common good.¹⁷² While this is true, too lengthy of a patent life has the potential to stifle creativity.¹⁷³

Still, there is the argument of true necessity. Pharmaceuticals and other medical-related devices must pass rigorous testing before gaining FDA approval, yet the testing of other industries, such as the agricultural biotechnological industry, are "subject to a much more lenient and, frankly, easy approval process." The response is simple. Any practice of formal regulatory testing, no matter how lenient or nonchalant, reduces the invention's profitability for the patent holder by eating up some quantity of time.

Stifling the development of inventions beneficial to the public at large prevents the possibility of improvements in quality of life and standards of living.¹⁷⁵ There are, however, specifically curated safeguards put in place to protect against overexploitation of patents. Patent holders must pay the United States Patent and Trademark Office ("USPTO") maintenance fees and renew annually to keep their patents in place.¹⁷⁶ Fees to the USPTO increase as the patent life approaches the twenty-year mark.¹⁷⁷ The whole aim is to ensure that the patent holder's monopoly over the invention is economically justifiable to the inventor.¹⁷⁸ An invention no longer making the inventor substantial profits would incentivize the patent holder to release the patent rights before the maximum time allowance.¹⁷⁹ After release, the invention is free to be used and altered by the public, and new ideas may emerge.¹⁸⁰

While these counterarguments are rooted in logic, the grips of their reasoning are made weaker in light of the global climate, both literal and political. The

r%20designs (last visited Mar. 25, 2021).

¹⁷⁰ Tom Nicholas, Are Patents Creative or Destructive?, HARVARD BUS. SCH. (Nov. 12, 2013), https://www.hbs.edu/ris/Publication%20Files/14-036_88022f59-a293-4a6f-b643-b205304 bce91.pdf.

¹⁷¹ *Id*.

¹⁷² *Id.* at 2.

¹⁷³ *Id.* at 7.

¹⁷⁴ Fuentes, *supra* note 132, at 103.

¹⁷⁵ Why Do Patents Expire: Everything You Need to Know, UPCOUNSEL, https://www.upcounsel.com/why-do-patents-expire#:~:text=The%20reason%20for%20putting%20a,create%20similar%20products%20o

¹⁷⁶ Id.

¹⁷⁷ Id.

¹⁷⁸ *Id*.

¹⁷⁹ *Id*.

¹⁸⁰ Id.

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potential of environmental devices to be successful and make a positive difference should be worth its weight in gold. To encourage the technology so desperately needed, eliminating all deterrents, like loss of profitability through patent life wasted, can only increase the preferred output.

C. ADDRESSING COUNTERARGUMENTS

Generally, economists are against lengthening the federal patent life. 181 Their reasonings suggest that a longer life stifles creativity by locking up simple innovations, such as software, for too long. 182 While a lengthy and restored patent life does afford the inventor more time and more protection to profit from their costs in research and development, it does not necessarily equate to less innovation. In fact, the opposite is true. FDA trends have shown that the more protection promised to an inventor, the more likely they are to invest the time, money, and research into a patentable invention. 183 Without the incentive of adequate protection and a sizeable duration, the inventor may choose to focus their energy elsewhere and not invent at all. By providing this added incentive, the U.S. government has the power to encourage powerful innovation from those that may have been on the fence on whether or not to get started. This facet can be the difference from having a life-saving device that cleans wastewater while using half the energy and chemicals as the standard process versus not having it at all. Hypothetically, one could go on and on dreaming up amazing inventions that the world needs, but until unnecessary barriers in the U.S. patent system are brought down, society may never know what it is missing.

Alternatively, and mentioned earlier in this Note, large portions of that twenty-year patent are eaten up waiting for a patent to be issued.¹⁸⁴ No exclusive rights to the invention vest in the holder until issuance.¹⁸⁵ Further, inventors are

¹⁸¹ Lester & Zhu, *supra* note 19, at 800 (explaining how economist William Nordhaus "who looked at the 'optimal patent life' and found that there was little effect on welfare from extending patent terms beyond ten years.").

¹⁸² Gene Quinn, Rebutting the Myth that Patents Last Too Long, IP WATCHDOG, (Feb. 12, 2010), https://www.ipwatchdog.com/2010/02/22/rebutting-the-myth-that-patents-last-too-long/id=9268/.

¹⁸³ Hatch-Waxman: Carefully Balancing the Need for Innovation and Drug Competition, supra note 134 ("The U.S. leads the world in innovation AND has the most robust generic market in the developed world."); *id.* ("The U.S. produces more new drugs than the rest of the world combined."); *id.* (explaining that the U.S. produces 57% of the world's drugs).

¹⁸⁴ *Id.* ("As a general rule the patent term can extend all the way to 20 years after the filing of a patent application, but you obtain no exclusive rights until a patent is issued, which is usually a minimum of several years after filing, sometimes much longer, as in the case of the recently issued TiVo patent that was issued more than 10 years after it was filed. On top of that, to keep a patent in force you need to make additional payments over the course of the life of the patent, which is frequently not done.").

¹⁸⁵ *Id*.

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pushed by the Patent and Trademark Office to file for a patent as soon as humanly possible. ¹⁸⁶ If the system is built to incentivize early patent filing, it should also take into account the sacrifices inventors are making just to satisfy the USPTO. Other alternatives pale in comparison to the ease of expanding the Patent Term Restoration Act. ¹⁸⁷

However, other economists have suggested that a better patent system altogether would consist of a "flexible system of compulsory licensing" in which inventors must make arguments for the length of the patent life deserved. Going by this economist's philosophy, any environmental inventor could take a shot in the dark and hit a surplus of data pointing to a climate change doomsday. Studies and data that paint the picture of how life as we know is going to change for the worse unless humanity makes major changes are the best possible evidence for a party carrying the burden of proof for this dire need. Pollowing this exhibition, even the stingiest economist would agree that of all inventions to be given deference, environmental solution inventions make an incredibly compelling argument for themselves.

Opponents of extending patent-lives in general argue that inventors can become too powerful by cornering markets with monopolies on certain

¹⁸⁶ Lietzan, *supra* note 46, at 61-62 (2018)("Various doctrines of patent law provide a strong incentive to file for a patent as soon as possible after invention. For instance, the PTO will generally deny a patent if the invention was described in a printed publication, or in public use, more than a year before the patent application was filed. Today, the PTO awards the patent to the first to file a patent application, which also pushes inventors into filing as soon as possible so that another person does not secure the patent first. In some cases, this early patenting occurs well before the invention takes the form of a product that will be commercially successful. As Professor Sichelman shows, transforming a prototype into a commercially viable product can require years of experimentation with product features as well as extensive market testing. The nature and extent of the testing is a business judgment, as the inventor focuses on identifying features that will cost-effectively attract customers and minimize liability.").

¹⁸⁷ Kristina M. L. Acri née Lybecker, *How to Promote Innovation: The Economics of Incentives*, IP WATCHDOG (July 21, 2014), https://www.ipwatchdog.com/2014/07/21/promote-inno vation-the-economics-of-incentives/id=50428/ ("Historically, societies have incentivized and rewarded research in a variety of ways, including patents, prizes, and direct government funding and grants. The primary mechanisms utilized today are patents and government grants.").

¹⁸⁸ Lester & Zhu, supra note 19, at 801 (quoting F.M. Scherer, Nordhaus' Theory of Optimal Patent Life: A Geometric Reinterpretation, 62 Am. ECON. REV. 422, 427 (1972)).

¹⁸⁹ *Id.* at 800-01 (discussing how Economist F.M. Scherer "noted that a good policy 'would tailor the life of each patent to the economic characteristics of its underlying invention,' which could be achieved 'through a flexible system of compulsory licensing, under which the patent recipient bears the burden of showing why his patent should not expire or be licensed at modest royalties to all applicants three or five years after its issue."").

¹⁹⁰ For an example of such a study, see Allen et al., *supra* note 15 (explaining the drastic impact of temperature rise world-wide).

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products.¹⁹¹ Competitors and consumers alike are wary of patent life "evergreening," which, in the pharmaceutical industry is "when brand-name companies patent 'new inventions' that are really just slight modifications of old drugs And it's a practice that, according to some who have looked into it, isn't doing a whole lot to improve people's health."¹⁹² There is also the argument that continuing the enforceability and opportunity for patent prosecution does not provide any additional benefit to the public and "inches toward a commonlaw property right, departing from the Constitution's express limitation on intellectual property rights."¹⁹³

Others argue that there is no evidence that even with a diminished patent life that innovation rates have suffered. Some might assert that there is no evidence that applying the Patent Term Restoration Act to this industry would affirmatively lead to life-savings gadgets. In response, this Note argues that there is also no evidence that expanding the Act would be futile. What is there to lose in an industry that is not necessarily booming in the first place? We are at a point in the Anthropocene where we need to aggressively use any tools available to spark innovation in the environmental tech arena. In short, the negatives of extending a patent life through restoration of time lost outweigh the positives by the probability that it brings inventions needed by society as a whole.

IV. CONCLUSION

The U.S. Patent system holds the key to unlocking the precious incentive needed to jumpstart more environmental technology. With only sixteen more years until 2037 when we reach the lower threshold of Earth's carrying capacity, 194 the time to develop solutions to reduce human impact is ripe. With the right technology, we could produce less waste, find smart ways to dispose of waste, recycle and generate renewable energy, introduce new protein sources to reduce dependency on livestock, and the list goes on and on. There are infinite possibilities for niche inventions to improve human quality of life while also being kind to our host planet. Even inventions that do not seem totally

¹⁹¹ Why Do Patents Expire: Everything You Need to Know, supra note 175, https://blog.idrenvironmental.com/how-hazardous-waste-disposal-affects-the-environment ("The reason for putting a time limit on patents is to prevent the building of unlimited monopolies. If patents were to have no expiration date then large corporations could corner the market by securing numerous patents to push out the competition by never allowing them to create similar products or designs.").

¹⁹² Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CANADIAN MED. ASS'N J., at E385 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/pdf/185e385.pdf.

¹⁹³ Taylor Bussey, "You Got Too Much Dip on Your Chip!" How Stagnant Copyright Law Is Stifling Creativity, 27 J. INTELL. PROP. L. 277, 290-91 (2020).

¹⁹⁴ Current World Population, supra note 10.

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environmentally focused may be enough to shift lifestyle trends in an eco-friendlier direction.

The Godsend of the pharmaceutical industry, the Patent Term Restoration Act, is the most simple and cost-efficient solution. Following the philosophy of Occam's razor, the best solution is never the most complex and intricate, but instead the most simplistic and easy. ¹⁹⁵ Instead of legislating more federal and state regulations, restricting businesses and industries, or taxing corporations, implementing this Act in the environmental industry would require very little sunk costs in development and research on the legislative side, and this incentive boost can have only positive impacts on inventors and the world-wide public.

¹⁹⁵ Occam's Razor, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/Occam%27s%20razor#:~:text=%3A%20a%20scientific%20and%20philosophical%20rule,in%20terms%20of%20known%20quantities (last visited Mar. 25, 2021).

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