TWO BIRDS, TWO STONES: SEPARATING BIODIVERSITY CONSERVATION FROM PATENT LAW

Relinquishing the Origin Disclosure Requirement for Alternative Strategies that Effectuate Biodiversity Conservation and Protect Innovation

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I. INTRODUCTION

The current decline in biodiversity is faster than any other point in human history.[1] Overexploitation is the leading driver of biodiversity loss; species are harvested at unreplenishable rates. Government, non-government, and industry representatives are searching for direction in addressing this rapid species loss. In particular, the World Intellectual Property Organization ("WIPO") is looking to channel biodiversity conservation through patent systems by instituting an origin disclosure requirement within the patent application process. This paper explores the intersection of biodiversity and innovation, contending the origin disclosure requirement is an unjustified, ineffective mechanism to effectuate biodiversity conservation.

Part II describes the biodiversity crisis as it relates to innovation and consequentially, intellectual property ("IP"). This includes an overview of the functioning international conservation laws and patent systems- the legal environment influencing innovation and the context in which an origin disclosure requirement operates. Part III delves into the origin disclosure requirement itself, the logic behind it, and a critique of its operation and compatibility with the legal environment explored in Part II. Finally, accounting for the shortfalls of an origin disclosure requirement described in Part III, Part IV further addresses the barriers to effectuating biodiversity conservation through IP law and explores alternative mechanisms.

II: THE INTERSECTION OF BIODIVERSITY AND INTELLECTUAL PROPERTY

The provided background reveals the relationship between biodiversity and patent law.

[1] *See* Sean L. Maxwell et al., *Biodiversity: The Ravages of Guns, Nets and Bulldozers*, 536 NATURE 143 (2016); Céline Bellard, Clara Marino & Franck Courchamp, *Ranking Threats to Biodiversity and Why It Doesn't Matter*, 13 NAT COMMUN 2616 (2022).

Conceptualizing how biodiversity operates as a resource is necessary to understand how an origin disclosure requirement operates in the larger scheme of patent procurement. This context includes an emphasis on genetic resources and the current legal frameworks shaping biodiversity conservation and patent systems.

A. The Value of Biodiversity

Biological diversity (or "biodiversity") is a panoramic term that encompasses the entire variety of life present on Earth.[2] The Convention on Biological Diversity defines it as "the variability among living organisms from all sources, including *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems."[3] The value of biodiversity is best represented through the benefits that humans derive from life on Earth (i.e., Earth's plants, animals, fungi, microorganisms, etc.). Biodiversity is fundamental for the ecosystems that all living organisms depend upon for food, air, water security, and numerous other benefits.[4] Accordingly, a decline in biodiversity represents a diminution of ecological complexity.[5] FEspecially for the purposes of this paper, the implications of biodiversity loss can be appreciated as a vague, but realistic, threat of option foreclosure.[6] This is the probability of loss

[2] Gaston, Kevin & Spicer, John, Biodiversity: An Introduction (2nd ed. 2004) ("Genetic diversity encompasses the components of the genetic coding that structures organisms (nucleotides, genes, chromosomes) and variation in the genetic make-up between individuals within a population and between populations. Organismal diversity encompasses the taxonomic hierarchy and its components, from individuals upwards to species, genera and beyond. Ecological diversity encompasses the scales of ecological differences from populations, through niches and habitats, on up to biomes. Although presented separately, the groups are intimately linked, and in some cases share elements in common (e.g. populations appear in all three.").
[3] Convention on Biological Diversity art. 2, *opened for signature* June 5, 1992, 1760 U.N.T.S. 79 (entered into force Dec. 29, 1993) [hereinafter CBD].
[4] ORD US EPA, *EnviroAtlas Benefit Category: Biodiversity Conservation*, (2015), https://www.epa.gov/enviroatlas/enviroatlas-benefit-category-biodiversity-conservation (last visited Feb 5, 2024).
[5] Brian H. Walker, *Biodiversity and Ecological Redundancy*, 6 Conservation Biology 18, 19 (1992).
[6] *Id.*

of potential benefits derived from species richness.[7] Essentially, the threat of extinction to both known and unknown biological resources necessarily threatens the ability to derive benefits from them.

Many human activities harm biodiversity[8], and effective conservation requires an understanding of the relationship between biodiversity and ecosystem function.[9] In all, the fate of Earth's biodiversity "depends upon how humanity interacts with natural systems, where human society can act as both custodian and consumer of natural systems."[10] Conceptualizing biodiversity as measurable elements of diversity—genetic, organismal, or ecological—allows for tailored quantification in this complicated field of over one million species (and counting).[11]

1. Genetic Resources

Genetic diversity is focused upon here because of the often-unregarded role it plays in sustaining innovation. Genetic diversity refers broadly to genetic variability- a property that describes the innumerable variations in the genetic code that allows for species' characteristic adaptability to life on Earth.[12] The unique genetic codes and characteristics of living organisms—biological or genetic resources[13]—and the habitats that sustain them may be appreciated as important economic and political assets, essential to modern industrialized society.[14]

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[7] Species richness is a measure of the number of species in a given ecosystem.
[8] *See generally* US EPA, *supra* note 5 (lists the growing human population, land development, overexploitation, overuse of environment, pollution, and invasive species introduction as all having negative effects on biodiversity).
[9] Walker, *supra* note 5.
[10] Joaquín Hortal et al., *Building a Truly Diverse Biodiversity Science*, 1 NPJ BIODIVERS 1 (2022).
[11] GASTON, KEVIN AND SPICER, JOHN, *supra* note 2; John J. Wiens, *How Many Species Are There on Earth? Progress and Problems*, 21 PLOS BIOLOGY e3002388 (2023) (estimating there are 8.75 million species on Earth with 80% of those being hypothetical- yet to be discovered).
[12] GASTON, KEVIN AND SPICER, JOHN, *supra* note 2.
[13] There is some dispute over the definitions of 'biological resource' and 'genetic resource.' Although technically different— 'biological resource' is an encompassing term that includes genetic resources—the two terms are used generally and interchangeably in this paper and should not be construed as limitations to the analysis.
[14] MARGERY L. OLDFIELD, THE VALUE OF CONSERVING GENETIC RESOURCES (1989).

Although unseen, genetic material has commercial value. The information encoded in DNA translates to an organism's distinct properties.[15] Properties that create value when characterized and applied. In this sense, the loss of biological resources (and thus genetic diversity) is the diminishment of a wellspring for "future development of new combinations, new genomes, species, and ecosystems, be it through natural evolution or technological combination [in a lab]."[16] If genetic diversity falls below critical thresholds, the biodiversity at higher levels (species and ecosystems) cannot be sustained.[17]

Adducing material applications founded in genetic resource technology effectively demonstrates the value of biological and genetic resources. To illustrate, animal peptides, like venom compounds, have been utilized to produce a wealth of pharmaceuticals. In fact, society owes one of the greatest advances in cardiovascular medicine, the advent of ACE inhibitor captopril (Capoten), to the Brazilian pit viper (*Bothrops jaraca*). Studying the viper venom's unique property for lowering blood pressure led to Squibb's breakthrough drug Capoten; their first one-billion-dollar drug designed from the template of viper venom.[18]

The pharmaceutical industry has a long-standing practice of sourcing from biodiversity by using a practice termed "bioprospecting."[19] Natural products (like the pit viper's venom) and their genetic precursors are structurally optimized by evolution to serve medicinally relevant

[15] Anna Deplazes-Zemp, *'Genetic Resources', an Analysis of a Multifaceted Concept*, 222 BIOLOGICAL CONSERVATION 86 (2018).
[16] *Id*.
[17] Rajat Panwar, Holly Ober & Jonatan Pinkse, *The Uncomfortable Relationship between Business and Biodiversity: Advancing Research on Business Strategies for Biodiversity Protection*, 32 BUSINESS STRATEGY AND THE ENVIRONMENT 2554 (2023) (citing Laikre et al., Post-2020 goals overlook genetic diversity, 367 Science 1083 (2020)).
[18] João B. Calixto, *The Role of Natural Products in Modern Drug Discovery.*, 91 AN. ACAD. BRAS. CIÊNC. e20190105 (2019).
[19] *See* Javia Mariana, *Biopiracy and Intellectual Property Rights in Bioprospecting: Balancing Innovation and Ethical Concerns*, 9 J BIODIVERS BIOPROS DEV (2023) ("Bioprospecting involves the systematic search for organisms, genes, and bioactive compounds with potential industrial or medicinal applications.").

functions, making them invaluable resources to the advancement of human health.[20] Where high-tech combinatorial chemistry methods are limited (in synthesizing new compounds), Mother Nature provides diverse and continuously evolving structures in natural products.[21] Combining drug design chemistry with the wide structural diversity and biological activity of genetic resources is a no-brainer for industry giants; evidenced by the industries' large-scale utilization of ethnobotanical diversity in drug exploration.[22] Over 50% of currently available FDA-approved drugs are derived from natural products.[23]

Similarly, genetic resources for food and agriculture have proven pivotal to food security and productivity.[24] A well-known representative would be genetically modified organisms ("GMOs"), direct derivatives of genetic resources. Many widely planted crops are genetically vulnerable to certain pests, pathogens, or environmental conditions.[25] Genetic resources like crop wild relatives encode beneficial traits that agricultural geneticists use to modify domesticated crop plants.[26] For example, wild sunflowers have been used to enhance seed production with disease resistance, herbicide resistance, and salt tolerance.[27] USDA reports indicate that 87-96% of corn, 92-99% of cotton, and 91-99% of soybeans planted in the United States are genetically

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[20] Atanas G. Atanasov et al., *Natural Products in Drug Discovery: Advances and Opportunities*, 20 NAT REV DRUG DISCOV 200 (2021).
[21] BIOPROSPECTING OF PLANT BIODIVERSITY FOR INDUSTRIAL MOLECULES, (Santosh Kumar Upadhyay & Sughir P. Singh eds., 2021), https://onlinelibrary.wiley.com/doi/10.1002/9781119718017 (last visited Feb 9, 2024).
[22] *Id.*
[23] David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs over the Nearly Four Decades from 01/1981 to 09/2019*, 83 J. NAT. PROD. 770 (2020) (in a study of new drug sources from January 1981 to September 2019).
[24] Dafydd Pilling et al., *Global Status of Genetic Resources for Food and Agriculture: Challenges and Research Needs: Global Status of Genetic Resources for Food and Agriculture*, 1 GEN. RES. J. 4 (2020).
[25] *Id.*
[26] "Crop wild relative" refers to the plant species that occurs in the "wild" compared to the domesticated crop species. Anne Egelston, *Conserving Biodiversity*, *in* WORTH SAVING: INTERNATIONAL DIPLOMACY TO PROTECT THE ENVIRONMENT 139 (Anne Egelston ed., 2022), https://doi.org/10.1007/978-3-031-06990-1_9 (last visited Feb 8, 2024); Gayle Volk & Patrick Byrne, *Introduction to Crop Wild Relatives* (2020), https://colostate.pressbooks.pub/cropwildrelatives/chapter/introduction-to-crop-wild-relatives/ (last visited Feb 6, 2024).
[27] Volk & Byrne, *supra* note 25.

engineered varieties.[28] Similarly, livestock breeds are routinely enhanced through gene selection and breeding programs. This is illustrated regularly in selecting for heat tolerance in dairy cows; different breeds and populations are analyzed and chosen based on better productivity and/or physiological durability under heat stress.[29]

2. Industry Dependence on Biodiversity

The potential for scientific breakthrough and economic development fuels multi-industry engagement in bioprospecting.[30] Indeed, bioprospecting advances humankind; the progression of science and corresponding industrial, economic, and societal growth cannot be understated. However, there is a less savory practice that mirrors bioprospecting- biopiracy. The concept of biopiracy arose from the illegal exploitation and monopolization of native resources, physically and intellectually.[31] Contemporarily, corporate powers use IP systems to legitimize the taking (i.e., the harvest and potential exploitation) and ownership of biological resources from less developed countries.[32]

The implications of such activity are never solely economic. There are instruments, like IP rights, operating at different levels of the natural world to result in biodiversity degradation

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[28] USDA, *Genetically engineered varieties of corn, upland cotton, and soybeans, by State and for the United States, 2000-23* (last updated Oct. 4, 2023), https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-u-s/.

[29] *See* Abelardo Correa-Calderon et al., *Thermoregulatory Responses of Holstein and Brown Swiss Heat-Stressed Dairy Cows to Two Different Cooling Systems*, 48 INT. J. BIOMETEOROL 142 (2004); S. Dikmen et al., *Heritability of Rectal Temperature and Genetic Correlations with Production and Reproduction Traits in Dairy Cattle*, 95 J DAIRY SCI 3401 (2012).

[30] Mariana, *supra* note 18; Prabhuddha L. Gupta et al., *Eminence of Microbial Products in Cosmetic Industry*, 9 NAT. PROD. BIOPROSPECT 267 (2019) (noting the beauty industry's shift in preference for products derived from biologically natural, rather than synthetic, sources).

[31] The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change | Critical Criminology, https://link.springer.com/article/10.1007/s10612-016-9344-5 (last visited Feb 9, 2024).

[32] *Id.* ("While intellectual property regimes are necessary for technological growth, Western institutions perpetuate and legitimate the exploitation of indigenous knowledge through a biased globalized patent system and specific view of intellectual property. The global patent system has been created by Western developed nations, which recognize only certain forms of 'proof' of knowledge…").

and other related environmental harms.[33] To understand how IP rights may be an instrument used to harm biodiversity, one should properly appreciate genetic resources as a refined product.[34] The distillation of "crude" biodiversity (e.g., plants, animals, etc.) is necessary to extract value: genetic resources. This value (monetized) is shared primarily, if not solely, with non-native corporations holding IP rights rather than the entire worth of these species and their ecosystem/community.[35] In this sense, patents can hamper the degree to which native or local industries can add value to their products.[36] Developing nations, particularly indigenous communities, are less incentivized to preserve native biodiversity when they do not profit or benefit from their own environment/natural resources.[37]

3. Illustrations

a. The African cherry tree (Pygeum africanum)

The African cherry tree, native to the Afromontane regions of Africa, has long been used for its medicinal properties in traditional indigenous medicine systems.[38] In the 1970s, the Western world became aware of these properties when African cherry bark extract was discovered to have pharmacologic benefit in managing benign prostate hyperplasia.[39] A slew of

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[33] Denis Meshaka, *Intellectual Property Rights Are Detrimental to Biodiversity*, INF'OGM (2024), https://www.infogm.org/7849-intellectual-property-rights-are-detrimental-to-biodiversity (last visited Jan 25, 2024).
[34] The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change | Critical Criminology, *supra* note 30.
[35] *Id.* (citing Daniel Robinson, *Locating Biopiracy: Geographically and Culturally Situated Knowledges*, 42 ENV. & PLANNING 38 (2010)); *see also* Panwar, Ober, and Pinkse, *supra* note 15, at 2555-2557 (giving practical illustrations of how corporate activities can affect biodiversity).
[36] Rachel Wynberg, *Biopiracy: Crying Wolf or a Lever for Equity and Conservation?*, 52 RESEARCH POL'Y. 104674 (2023).
[37] The Role of Denial in the 'Theft of Nature': Comparing Biopiracy and Climate Change | Critical Criminology, *supra* note 30.
[38] *See* Emmanuel Rubegeta et al., *The African Cherry: A Review of the Botany, Traditional Uses, Phytochemistry, and Biological Activities of* Prunus Africana *(Hook.*f.*) Kalkman*, 305 J. OF ETHNOPHARMACOLOGY 116004 (2023); Gerard Bodeker, Charlotte van 't Klooster & Emma Weisbord, *Prunus Africana (Hook.f.) Kalkman: The Overexploitation of a Medicinal Plant Species and Its Legal Context*, 20 J. ALTERN COMPLEMENT MED. 810 (2014).
[39] Bodeker, van 't Klooster, and Weisbord, *supra* note 37 ("BPH, a noncancerous enlargement of the prostate that causes discomfort in older men, is present in more than 50% of men older than age 60 years; 15%-30% of these men report lower urinary tract symptoms.").

patents and trademarks were filed based on these therapeutic properties and the tree was quickly commercialized as an effective treatment option.[40]

By the turn of the century, the tree became Africa's most valuable medicinal export plant with over 3,300 tons of bark exported annually, worth over $200 million.[41] However, foreign buyers' exploitative tactics resulted in uncontrolled and destructive harvest.[42] Mass bark exploitation has caused remarkable damage to the African cherry population, leading to worries about long-term species conservation and the sustainability of harvesting.[43] Concerns of genetic erosion surfaced as conservationists noticed the destructive exploitation had also affected endemic wildlife.[44] Poverty, corruption, and poor regulation from importing countries all contributed to overharvest.[45]

African countries would surely benefit from national legislation to conserve the biodiversity of medicinal resources. Despite potential domestic policy or management efforts, the risk of overexploitation in poor countries like Cameroon, the Democratic Republic of Congo, Kenya, Uganda, etc. is still high. This fact has not given pause to Western industry members, as IP trends indicate the bark extract formulations/uses are still being protected and a quick internet search will reveal hundreds of "Pygeum [Africanum]" extract-based supplements.

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[40] *Id.*; Rubegeta et al., *supra* note 37 (noting that bark extract was marketed as a much cheaper, and preferred method of treatment relative to the alternative of surgery).
[41] *See* Bodeker, van 't Klooster, and Weisbord, *supra* note 37; Rubegeta et al., *supra* note 37 ("Wild-harvested P. africana bark from Africa and Madagascar has been internationally traded to a greater extent than any other African medical plant.").
[42] Bodeker, van 't Klooster, and Weisbord, *supra* note 37 ("Buyers encouraged villagers to harvest for them, offering greater rewards than before, but substantially less than Plantecam offered legal suppliers. By 1995, Prunus harvesting was destructive and uncontrolled and had become a major source of cash income for local young men and their households. Trees were felled or totally stripped by villagers to supply bark to illegal buyers, negatively affecting the surrounding ecosystem. Fashing41 reported that 68% of the exploited trees were dead or experiencing canopy dieback.").
[43] *Id.*
[44] A. Cunningham, V.F. Anoncho, & T. Sutherland, *Power, Policy and the Prunus Africana Bark Trade, 1972-2015*, 178 J. ETHNOPHARMACOLOGY 323 (2016) (mentioning the ecological value of *P. africana* for conservation of rare and endemic species like the red colobus and black-and-white colobus monkeys).
[45] Bodeker, van 't Klooster, and Weisbord, *supra* note 37.

b. American horseshoe crab (Limulus polyphemus)

Horseshoe crabs (those of the *Limulidae* family), are widely used in the biomedical sector after the unique properties of their milky-blue blood were discovered in the 1950s.[46] Special immune cells in the crabs' blood are used to detect bacterial endotoxins, a property that translated to an important commercial biomedical product: Limulus amebocyte lysate. This lysate has become a ubiquitous biomedical product; pharmaceutical/biomedical industry members cannot opt out of consumership because any drug, vaccine, device, etc. that may contact blood or cerebrospinal fluid must be tested for the presence of endotoxins before approval.[47]

The raw material, crab blood, is required to create this product. Regulation of crab harvest is lenient because the animals are captured, bled, and returned alive to the ocean.[48] However, the established mortality associated with this practice is at least 15-30%, and spawning surveys indicate even greater morbidity in female crabs.[49] The decline in spawning females has resulted in the near-elimination of entire horseshoe crab populations along the Massachusetts and Delaware coastline, and lower numbers affect the entire ecosystem surrounding horseshoe crabs.[50] The fear is that American horseshoe crabs, a vulnerable species, could meet the same

[46] Glenn A. Gauvry, Thomas Uhlig & Karolina Heed, *LAL/TAL and Animal-Free rFC-Based Endotoxin Tests: Their Characteristics and Impact on the Horseshoe Crab Populations in the United States and Asia*, *in* INT'L. HORSESHOE CRAB CONSERVATION AND RESEARCH EFFORTS: 2007- 2020 369 (John T. Tanacredi et al. eds., 2022).
[47] Jolie Crunelle & Kristoffer Whitney, *Regulating Horseshoe Crabs: Sustainability and Public Health*, (2023). Bacterial endotoxins can contaminate products and cause fever, anaphylactic shock, and other diseases.
[48] Thomas J. Novitsky, *Biomedical Implications for Managing the Limulus Polyphemus Harvest Along the Northeast Coast of the United States*, *in* CHANGING GLOBAL PERSPECTIVES ON HORSESHOE CRAB BIOLOGY, CONSERVATION AND MANAGEMENT 483 (Ruth H. Carmichael et al. eds., 2015), https://doi.org/10.1007/978-3-319-19542-1_28 (last visited Feb. 12, 2024).
[49] *Id.*
[50] *Id.* (explaining how the endangered Red knot bird was threatened due to lower horseshoe crab numbers, its major food source).

fate as Asian horseshoe crabs- a spot on the International Union for Conservation of Nature's endangered list.[51]

Furthermore, a synthetic alternative to the horseshoe crab-derived lysate (recombinant factor C, "rFC") was developed twenty years ago. The original rFC patent, owned by Lonza, has also expired now (as of 2024), meaning other suppliers can produce rFC at a much lower cost, an event that would theoretically funnel the alternative into mainstream use. Studies show rFC is just as efficacious and conversion to rFC would result in a 90% reduction in the demand for LAL, equal to 100,000 less horseshoe crab bleedings per year.[52]

So what is preventing widespread adoption of rFC or alternatives? The three major market players, Lonza, Charles River, and Associates of Cape Cod, still have major investments in IP for crab blood testing-related consumables (e.g., testing kits, instruments, services, reagents, assays, etc.)[53] These derivative products and their associated IP instruments may not directly implicate horseshoe crab-derived genetic resources, but their commercial success depends upon the continuing use of crab blood.

[51] Chris Iovenko, *The Fight to Save Horseshoe Crabs from the Biomedical Industry*, THE VERGE (2021), https://www.theverge.com/2021/12/17/22840263/horseshoe-crab-blood-medical-industry-controversy (last visited Feb. 12, 2024).
[52] Tom Maloney, Ryan Phelan & Naira Simmons, *Saving the Horseshoe Crab: A Synthetic Alternative to Horseshoe Crab Blood for Endotoxin Detection*, 16 PLOS BIOL e2006607 (2018).
[53] BCC Library - Report View - BIO238A, https://tto.bccresearch.com/market-research/biotechnology/pyrogen-testing-market.html (last visited Feb. 12, 2024) ("The consumables segment dominates the pyrogen testing market by products and services. The companies in this segment provide assay kits, reagents, controls and other consumables based on the test. Consumables such as pipettes and multi-well plates must be pre-screened and certified for pyrogen testing. Many companies, including Charles River, Lonza and ACC, provide consumables for all three types of tests. The segment accounts for 57.1% of the market and is forecast to reach $1.2 billion by the end of 2027.").

B. Intellectual Property and Biodiversity: The Legal Landscape

1. Patenting Genetic Resources

Inventions that incorporate biological/genetic resources present a unique type of subject matter for IP protection.[54] Genetic resources themselves are not subject to protection because they are a product of nature- unpatentable subject matter.[55] The logic behind this distinction is that naturally occurring sequences of DNA are like stars—discoverable and naturally occurring—thus they belong to the public domain.[56] However, inventions that are based upon or developed using genetic resources are eligible for patent protection.[57]

For example, U.S. Patent No. 7,906,146, *Lyophilized formulations of exendins and exendin agonist analogs,* claims different weight/volume formulations of exendin-4.[58] Briefly mentioned in the patent's background section, "exendins are peptides found in salivary secretions of the Gila Monster and Mexican Bearded Lizard, reptiles endogenous to Arizona and Northern Mexico."[59] The use of Gila Monster peptides is rooted in the reptile's ability to slow its metabolism and maintain constant blood sugar- a trait that was appealing to scientists looking to mitigate diabetes.[60] Note, the inventors and assignee (Amylin Pharmaceuticals L.L.C.) could not patent the Gila Monster's venom, the exendin peptide itself, or even the genetic code of the

[54] WIPO, *Intellectual Property and Genetic Resources* (2023), https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-5-10-en-intellectual-property-and-genetic-resources.pdf.
[55] *See* Association for Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 576 (2013) (holding that naturally occurring DNA is not patentable, but DNA manipulated in a lab, like complementary DNA or "cDNA" is eligible to be patented because the DNA sequences are altered by humans); *see also* Aaron S. Kesselheim et al., *Gene Patenting—The Supreme Court Finally Speaks*, 369 N Engl. J. Med. 869 (2013).
[56] Yun-Han Huang, *Gene Patents: A Broken Incentives System*, 52 J. Relig. Health 1079 (2013).
[57] WIPO, *supra* note 53.
[58] U.S. Patent No. 7,906,146 (issued Mar. 15, 2011).
[59] *Id.*
[60] Exendin-4: From lizard to laboratory...and beyond, Nat'l. Inst. on Aging (2012), https://www.nia.nih.gov/news/exendin-4-lizard-laboratory-and-beyond (last visited Feb. 7, 2024).

exendin peptide- those are all products of nature that constitute unpatentable subject matter. However, they were able to patent *compositions* that included those genetic resources.

2. Commodifying Biodiversity: The Scope and Value of Genetic Patents

Restrictions in patenting genetic material have not lessened their utilization. Industries have simply shifted towards patenting applied genetics that still utilize and enhance the value of such biological resources- colloquially termed biotechnology ("biotech"). The scope of biotech patents, what they include and protect, commonly incorporates genetic material falling into three broad categories: (1) DNA, RNA, amino acid sequences, and metabolic pathways with specific functions or products, (2) chemical compounds (compound structure both characterized and uncharacterized), and (3) raw extracts or byproducts.[61] These categories are helpful in understanding the connection between a given genetic resource and how it may be patented for purposes of commercialization. Resources from the first category are the paradigmatic genetic resources, including biotechnologies such as industrial enzymes and research, diagnostic, or therapeutic tools expressed in sequence data.[62] Resources from the second category are commonly associated with quintessential biotech—pharmaceuticals and medical technologies—where compound functionality may be emphasized over the particular genetic structure.[63] The last category is associated with commercial harvesting, typical for nutraceuticals and cosmetics.[64]

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[61] PAUL OLDHAM, ET AL., VALUING THE DEEP: MARINE GENETIC RESOURCES IN AREAS BEYOND NATIONAL JURISDICTION (2014), https://bookdown.org/poldham/valuingthedeep/the-value-of-marine-genetic-resources.html (last visited Feb. 8, 2024).
[62] *Id.*
[63] *Id.*
[64] *Id.* "Nutraceutical" is a term that describes dietary compounds, like a supplement or additive, with potential pharmaceutical effects, although they are largely unregulated and effects are unconfirmed.

Corporations worldwide invest heavily in research and development ("R&D") to create biotechnology. This is particularly true for "northern" countries (i.e., "western nations" like the United States, Canada, Japan, Australia, and European countries) as they represent the chief users of genetic material, the basis for biotechnology development.[65] This contrasts the areas where biodiversity is greatest, many developing "southern" nations like Brazil, Colombia, Indonesia, and India. The overlapping result is non-native biotech developers targeting tropical developing countries, often with poor and rapidly growing populations, that are increasingly dependent upon external assistance to address food and economic development needs, much less biodiversity conservation.[66] Socioeconomic dynamics aside, the natural relationship between genetic resources and scientific/technological advancement suggests patent rights are inextricable from society's use and development of biological resources.

3. International Patent Governance

A patent grants the owner exclusive rights for a period of time. This means that the owner (whether it be the inventor(s) or an assignee) can stop anyone from using, making, or selling their invention without permission.[67] In granting these rights, the patent system aims to promote innovation and progress by rewarding inventors. At the same time, obtaining a patent requires disclosure of the invention- publication of the data and specifics regarding that invention, meant to enable further research and awareness regarding the body of knowledge.[68] Countries vary in the legal requirements for patent obtainment, but an applicant is generally required to describe the invention clearly and with sufficient detail to allow the average person in that technical field

[65] Egelston, *supra* note 25.
[66] E. O. Wilson & Frances M. Peter, *International Development and the Protection of Biological Diversity*, *in* BIODIVERSITY (1988), https://www.ncbi.nlm.nih.gov/books/NBK219293/ (last visited Feb 9, 2024).
[67] WORLD INTELLECTUAL PROPERTY ASSOCIATION, *What Is Intellectual Property? 2020*, WIPO PUBLICATION NO. 450E/20. at 4. Patent rights are generally for a period of 20 years.
[68] *Id.*

to use or reproduce it.[69] Additionally, all countries require the invention to be useful and novel (although nations differ on what those terms mean). The United States, for example, has both codified and established judicial precedents that outline what subject matter is patentable, and what it means for an invention to be novel and non-obvious.[70]

Patent law is jurisdictional, meaning protections are territorially limited to the country that issues the patent. Consequently, an inventor or business has to file applications in multiple, individual jurisdictions to obtain broad-scale protection. To address this arduous and expensive process, various treaties have been employed to facilitate more efficient means of obtaining multi-national IP rights. The two main routes for achieving multi-national patent rights are facilitated under the Paris Convention and the Patent Cooperation Treaty.

The Paris Convention is effectuated through the United Nations and WIPO.[71] For contracting nations, it provides national treatment-member states afford international patent applicants the same rights as a national patent holder.[72] This prevents different countries from treating foreign applicants unfavorably. Under the "Paris [Convention] route" (for obtaining protection in several countries), an applicant can file an initial application in any member country and receive twelve months priority. This means the applicant has one year to subsequently file any other individual applications to protect that same invention in another member country without forfeiting the novelty of the invention.[73]

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[69] *Id.* at 6.
[70] *See* 35 U.S.C. §101-103 for United States patent law requirements.
[71] Summary of the Paris Convention for the Protection of Industrial Property (1883), https://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Jan 29, 2024).
[72] Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.S.T. 305.
[73] "Paris" refers to the Paris Convention for the Protection of Industrial Property. *See* 21 U.S.T. 1583; 828 U.N.T.S. 305. "Priority" is a term used in patent law to describe the time-limited right for a person to file a patent application.

A sort of "extension" of the Paris Convention, also administered by WIPO, is the Patent Cooperation Treaty ("PCT"). To become a contracting state of the PCT, one must first join the Paris Convention. The 1883 Paris Convention is one of the most widely adopted treaties worldwide, with 180 contracting member countries[74], the PCT is a similarly wide-scale union including the major industrialized nations.[75] The alternative "PCT route" for filing allows the applicant to simultaneously seek protection from any of 155 contracting nations with just one, *single* application.[76] While a PCT application doesn't give rise to a single "international patent" it provides an applicant international priority for all member nations designated in the initial application and eighteen additional months of priority (on top of the twelve months, for thirty months total). This extra time to file means applicants have more time to collect the funds for multi-national filing- an unavoidably expensive process. Both routes have advantages for different types of applicants with different goals or budgets.[77]

4. International Law affecting Biological Resources: TRIPS and the CBD

If one visualizes the PCT as a "world patent office" processing "world patent applications", the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS") would be the overarching instrument establishing "global patent law" (more like an extension of the Paris Convention).[78] Naturally, TRIPS guides technology flow by regulating multilateral trade as well. This is where it overlaps with the Convention on Biological Diversity ("CBD")- another

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[74] World International Property Organization, *Contracting Parties*, (status on Oct. 23, 2023), https://www.wipo.int/export/sites/www/treaties/en/docs/pdf/paris.pdf.
[75] *See* The PCT now has 157 Contracting States, https://www.wipo.int/pct/en/pct_contracting_states.html (last visited Feb 16, 2024).
[76] *PCT FAQs, https://www.wipo.int/pct/en/faqs/faqs.html (last visited Feb 7, 2024).* (emphasis added).
[77] The PCT route is more efficient for those who wish to file in a large number of countries. On the other hand, filing individually under the Paris route may be the better choice for applicants filing in a few countries. *See* PCT or Paris Convention?, https://www.ip-coster.com/academy/details/pct_or_paris_convention (last visited Feb 16, 2024).
[78] MARKUS NOLFF, TRIPS, PCT & GLOBAL PATENT PROCUREMENT (2001); TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

agreement touching international technology flow, although motivated by different objectives. Hence, both agreements—TRIPS and the CBD—are relevant to patent rights and the use of biological resources.

World Trade Organization members concluded the TRIPS agreement in 1994- an effort to unify trade regulation through the establishment of minimum IP protection standards.[79] Put simply, TRIPS creates the universal bottom floor of patent protections and allows member nations to decide the upper level.[80] In a sense, it expanded on the Paris Convention by further nationalizing patent law with the impact of creating even enforcement mechanisms and requiring a 20-year term.[81] Notably, TRIPS requires patents to be granted in all subject-matter fields, including genetic material, so member countries cannot wholly exclude patents implicating genetic resources without violating the agreement.[82]

Around the same time TRIPS was being negotiated, the United Nations Environment Program, noticing the alarming extinction rate, initiated the CBD. The CBD was an attempt to fill the gaps in global biodiversity conservation that left biological resources exposed to the whims of countries, corporations, and individuals.[83] This conservation gap could be an economic problem; some countries undervalue, and thus under-conserve, their natural resources.[84] The resulting principle, which guides the CBD, is one of "common concern for humankind" that

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[79] Santanu Mukherjee, *TRIPS Agreement: The Negotiating History of the TRIPS Agreement and Patent Exhaustion*, *in* PATENT EXHAUSTION AND INTERNATIONAL TRADE REGULATION 115 (2023), https://brill.com/display/book/9789004542815/BP000009.xml (last visited Feb. 16, 2024).
[80] *Id.* (Prior to TRIPS being signed many member countries restricted patent protection only to processes, not products, protection was less than 20 years, and many did not provide protection for pharmaceuticals.).
[81] TRIPS Agreement, *supra* note 77, art. 33, 41; Egelston, *supra* note 25.
[82] TRIPS Agreement, *supra* note 77, art. 27.
[83] Stuart Harrop & Diana Pritchard, *A Hard Instrument Goes Soft: The Implications of the Convention on Biological Diversity's Current Trajectory*, 21 GLOBAL ENVIRONMENTAL CHANGE 474 (2011) (noting that predecessors to the CBD, like CITES, Ramsar, or Bonn, were narrowly focused mandates and thus a comprehensive, global approach was lacking).
[84] *Id.* (citing Timothy Swanson, *Why is there a biodiversity convention? The international interest in centralized development planning,* 75 INT'L. AFFAIRS 2 (1999) 307–331).

emphasizes state sovereignty over biological resources.[85] To this end, member countries are mandated to protect their biodiversity (and cooperate if need be). Principally, this obligates the creation of national strategies to research, monitor, and protect biodiversity, restoration and maintenance of protected habitats, and governance over access and equitable benefit-sharing.[86]

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the "Nagoya Protocol") is a supplementary agreement to the CBD. The Nagoya Protocol is aimed at effectuating one particular CBD objective: the fair and equitable sharing of benefits arising from genetic resource use. That is, the exploitation of poorer, biodiversity-rich states by developed countries. But like the CBD, the Nagoya Protocol's success depends upon effective implementation at the domestic level. Contracting parties are further obligated to create measures for access, benefit-sharing, and compliance, but this is not without criticism of redundancy and research hampering.[87]

Notably, The U.S. is the only U.N. member state that has not ratified the CBD or the Nagoya Protocol. Despite the flexibility in their technology transfer provision, the U.S. (particularly the pharmaceutical industry) is unwilling to put IP rights on the table when it comes to promoting biodiversity sustainability.[88] The U.S. position is not necessarily unreasonable;

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[85] *See Id.*; CBD, *supra* note 2 (referring to text of the preamble); RETHINKING INTERNATIONAL INTELLECTUAL PROPERTY, (Kraig M. Hill, Toshiko Takenaka, & Kevin Takeuchi eds., 2000), at 146.

[86] LYLE GLOWKA, FRANCOISE BURHENNE-GUILMIN, & HUGH SYNGE, A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY (1994); Stuart Harrop and Diana Pritchard, *supra* note 82.

[87] *See* K. Divakaran Prathapan et al., *When the Cure Kills-CBD Limits Biodiversity Research*, 360 SCIENCE, Jun. 2018, at 1405 ("Although NP Article 8(a) appears to encourage regulations that do not impede bona fide scientific research, the NP's definition of the 'utilization of genetic resources' as the 'means to conduct research and development on the genetic and/or bio-chemical composition of genetic resources' (Article 2c) makes no exceptions for purely academic or conservation-related biodiversity research, such as taxonomic studies").

[88] RETHINKING INTERNATIONAL INTELLECTUAL PROPERTY, *supra* note 84, at 152 ("In the U.S. view, the principle that it is appropriate or necessary to restrict intellectual property rights to encourage the transfer of technology form the private sector was unacceptable.").

commercially viable products won't make it to market without effective patent protections for the investor/developer.[89] To ratify, the U.S. would prefer rigorous foreign patent protection for inventions implicating biological resources, contracting parties to voluntarily accept distribution and tech transfer conditions, and space clear of restrictions on technology development, sale, or commercialization.[90]

TRIPS' institution of universal mandatory patent protection standards should have lessened the U.S.' resistance to ratify the CBD, given that TRIPS "standards constitute the *international law* to be observed under Art. 16 of the CBD, whenever access to and transfer of a patented…technology is at hand."[91] However, conflict between the two regulations is ever-looming as countries can choose which treaty they want to emphasize in their domestic policies.[92] The World Trade Organization is the more influential regime; membership benefits, like robust compliance and enforcement mechanisms, are economically and geopolitically valuable for any country.[93] However, members are limited in their ability to leverage IP protections for biodiversity conversation. Consequently, a developing nation that is a World Trade Organization member is bound to implement TRIPS in its legal framework, despite potential conflict with their domestic environmental interests.[94] In this sense, the CBD's encouragement of sovereign policymaking may be pointless. If countries can't properly enforce

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[89] Cheryl D Hardy, *Patent Protection and Raw Materials: The Convention on Biological Diversity and Its Implications for U.S. Policy on the Development and Commercialization of Biotechnology*, 15 U. PA. J. INT'L L. 299 (1995).
[90] RETHINKING INTERNATIONAL INTELLECTUAL PROPERTY, *supra* note 84.
[91] RETHINKING INTERNATIONAL INTELLECTUAL PROPERTY, *supra* note 84, at 152 (emphasis in original).
[92] Egelston, *supra* note 25 (pointing out that "TRIPS created exclusive rights to genetic resources through the use of a patent system while the CBD sought to ensure equitable sharing and benefits, thereby ending the exclusive nature of the same set of patents").
[93] *See* Elias Dinopoulos & Paul Segerstrom, *Intellectual Property Rights, Multinational Firms and Economic Growth*, 92 J. OF DEVELOPMENT ECON. 13 (2010) (discussing how stronger IP right protections, namely the implementation of TRIPS, in the global South leads to greater technology transfer and adaptive R&D spending in the South)
[94] C.L. Akurugoda, *Bio Piracy and its Impact on Biodiversity: A Critical Analysis with Special Reference to Sri Lanka*, 2 (2013) (using Sri Lanka as an example of this conflict).

existing domestic regulations, or policy measures are null and inadequate in light of TRIPS requirements, there is no significant advancement towards biodiversity conservation.

III. UNRAVELING THE ORIGIN DISCLOSURE REQUIREMENT

Reconciling the objectives of TRIPS, the CBD, and patent rights within the overarching North-South conflict is a challenge. Amongst other proposed strategies[95], the specific measure critiqued here allocates the role of resource gatekeeper to already-burdened patent offices. Decades of growing tension over the accessibility and exploitation of biological resources have prompted intergovernmental efforts to alter the conventional disclosure obligations by creating a mandatory source/country of origin disclosure requirement (the "disclosure requirement").[96]

The disclosure requirement has been debated since 1997 and nearly thirty jurisdictions have already imposed an origin disclosure requirement in domestic legislation.[97] So why is exploration of this requirement still relevant? Those decades of negotiation have finally come to fruition in the form of a "groundbreaking" new treaty on genetic resources- WIPO's first treaty to "address the interface between intellectual property, genetic resources, and traditional knowledge".[98] Adopting the CBD's definition of genetic resources, Article 3 of the WIPO Treaty

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[95] Egelston, *supra* note 25 (citing Sahai and Morgera et al.) Proposed solutions have recommended amending TRIPS to promote the CBD, removing biodiversity from TRIPS, or utilizing the WTO's dispute resolution process to strengthen the CBD.

[96] WORLD INTELLECTUAL PROPERTY ORGANIZATION, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge*, (2020) https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047_19.pdf.

[97] International fora have investigated and been pushing for global implementation of this requirement for over twenty years without successful international adoption. Previous attempts to incorporate a similar disclosure requirement were seen in negotiations for the 2008 TRIPS agreement and later the Nagoya Protocol. RETHINKING INTERNATIONAL INTELLECTUAL PROPERTY, *supra* note 84, at 160 (noting that the European Parliament attempted, without success, to introduce the obligation in 1997).

[98] WIPO, *WIPO Member States Adopt Historic New Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge*, WIPO Press Release PR/2024/919, www.wipo.int/pressroom/en/articles/2024/article_0007.html (last accessed Sept. 26, 2024); *see* WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge art. 3.1 (May 24, 2024) www.wipo.int/edocs/mdocs/tk/en/gratk_dc/gratk_dc_7.pdf [hereinafter GRATK Treaty].

on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (the "GRATK Treaty") provides the following disclosure requirement:

> 3.1 Where the claimed invention in a patent application is based on genetic resources, each Contracting Party shall require applicants to disclose:
> (a) the country of origin of the genetic resources, or
> (b) in cases where the information in Article 3.1(a) is not known to the applicant, or Article 3.1(a) does not apply, the source of the genetic resources.

GRATK Treaty art. 3.1, May 24, 2024, WIPO edoc GRATK/DC/7.

Although WIPO's legal instrument is "soft law", the new treaty obligations, operating within the inherently global context of patent protection, could result in real changes to the requirements for filing patent applications and challenging patents.[99] For example, a GRATK Treaty footnote explicitly requests the International Patent Cooperation Union (PCT application policymakers) to incorporate the origin disclosure requirement into their regulations.[100] Considering patent protections are a launch pad for prosperity and opportunity worldwide, even the slightest change in policy implicates the global innovation economy.

A. Purpose, Intent, and Operation of the Disclosure Requirement

The disclosure requirement forces patent applicants to specify the original source of any biological/genetic material or any associated traditional knowledge[101] upon which the claimed invention was derived. This requirement is supposedly the answer to curbing biopiracy and resource misappropriation- originally posed to compliment and empower the CBD's access and

[99] WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge [Docket No.: PTO-C-2023-0019] 88 Fed. Reg. 204 (Oct. 24, 2023), https://www.regulations.gov/document/PTO-C-2023-0019-0001 (last visited Feb. 21, 2024).
[100] GRATK Treaty art. 7, footnote 4.
[101] Although traditional (indigenous) knowledge is also a focus of the origin disclosure requirement for the purposes of access and benefit sharing, this paper focuses on the biodiversity and intellectual property-related implications of such a requirement as it relates to genetic resources.

benefit-sharing requirements, thus protecting genetic resources.[102] However, the final, narrowed GRATK Treaty text merely recognizes the "*potential* role of the patent system in contributing to the protection of genetic resources".[103]

The logic behind the requirement is that patent disclosures can be a tool for identifying situations where access to biological/genetic resources has been obtained without proper consent or benefit-sharing. From that point, a nation could facilitate corrective actions.[104] However, this logic requires much more than just an origin disclosure to function properly. WIPO knows this as well, but still only specifies that contracting parties *may* establish a genetic resource database system to accompany their mandatory disclosure requirement.[105] As such, biodiversity conservation under the GRATK Treaty relies on the assumption that a product incorporating genetic resources would be correctly indicated in the application process *and* the country of origin has established the necessary benefit-sharing systems to facilitate economic renumeration for conservation- a tall order for even the most developed countries.[106]

B. AD NAUSEAM: THE PROBLEMS WITH ORIGIN DISCLOSURE OBLIGATIONS

In the wake of WIPO's disclosure requirement revival, one should question why the origin disclosure requirement has been pursued ad nauseam. Decades of failed negotiations and

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[102] Alison L. Hoare & Richard G. Tarasofsky, *Asking and Telling: Can "Disclosure of Origin" Requirements in Patent Applications Make a Difference?*, 10 THE J. OF WORLD INTELLECTUAL PROPERTY 149 (2007).
[103] GRATK Treaty, page 2 (emphasis added).
[104] Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing The TRIPS Agreement: The Problem and The Solution*, 2 WASH. U. J. OF L. & POL'Y. 371 (2000); Mas Rahmah, *Disclosure of Origin of Plant Genetic Resources: Challenges for Supporting Food Security in Indonesia*, 21 INTERNATIONAL JOURNAL OF BUSINESS & SOCIETY 95 (2020) (claiming that the most critical function of origin disclosure is ensuring transparency by allowing national authorities to grant access to genetic resources to track use).
[105] GRATK Treaty art. 6.
[106] *See also* Kriti Sharma, *Missed Opportunities: WIPO Treaty falls short of protecting Traditional Knowledge*, CIL DIALOGUES: AN INT'L. L. BLOG (July 15, 2024), https://cil.nus.edu.sg/blogs/missed-opportunities-wipo-treaty-falls-short-of-protecting-traditional-knowledge/.

inconsistent implementation raise a valid question of whether WIPO's new treaty, and the disclosure requirement in general, is the right tool for the job. Not only does the GRATK Treaty lack the teeth to effectively protect genetic resources[107], but biodiversity depletion associated with exploitative patented technologies is arguably better served through other systems. Effective conservation is better monitored and served through a lens on commodification or commercialization (i.e., monitoring different stages of the value chain such as harvest, trade (import/export), manufacturing, and monetization) rather than patent prosecution. This contention is supported by (1) the overwhelming evidence of burden upon patent systems, (2) the serious potential to chill innovation, and (3) divergence from the foundational objectives of patent law.

1. Evidence of Burden

The burdens implicated by WIPO's new disclosure requirement are not offset by verifiable evidence that they will ameliorate systemic inefficiencies in biodiversity conservation. Creating IP policy that responds to verifiable interests, like conserving biodiversity, should incorporate the concerns of all jurisdictions and industries, especially those that depend upon both the biosphere and patent protections to support their value chain (e.g., the pharmaceutical sector).[108] Furthermore, the far-reaching reverberations of both international and domestic IP policies demand a focus on evidence-based policymaking.[109] For the disclosure requirement, the

[107] *See Id.*
[108] Luka Brown, *Nature's Medicine: The Link between the Pharmaceutical Industry and Biodiversity*, NATURE POSITIVE (2022), https://naturepositive.com/natures-medicine-the-link-between-the-pharmaceutical-industry-and-biodiversity/ (last visited Jan. 29, 2024).
[109] WHY THE PATENT SYSTEM SHOULD LOOK MORE LIKE INDIANA AND LESS LIKE KENTUCKY |ALAN MARCO | TEDXTYSONS, (2017), https://www.youtube.com/watch?v=HJhSD8ABt3s (last visited Feb 24, 2024). Alan Marco is the former Chief Economist of the USPTO.

lack of supportive evidence is an unavoidable snag WIPO policymakers failed to adequately address.

Numerous jurisdictions have already adopted a voluntary or mandatory disclosure requirement. These nations are the optimal experimental models for establishing evidence of the requirement's effectiveness. Jurisdictions with mandatory disclosure requirements- meaning failure to comply may result in sanction, rejection, or revocation- include (but are not limited to) the Andean Community[110], Indonesia, India, China, Brazil, Costa Rica, Turkey, and Switzerland.

Switzerland, which actively supports adding an origin disclosure requirement to the PCT, implemented a domestic disclosure requirement in 2008.[111] Article 49a of Switzerland's Patents Act requires all patent applicants to include information regarding the source of the genetic resource and associated traditional knowledge (for inventions based upon it).[112] The invention has to make "immediate use of the genetic resource, that is, depend on the specific properties of this resource" and the inventor must have physical access to the resource before the obligation to disclose is triggered.[113] In a similar fashion to the GRATK Treaty, Switzerland's provision purports to use patent disclosures as the starting point for corresponding authorities in the provider country. However, other industrialized nations have criticized the Swiss law's lack of clarity, and post-disclosure control frameworks are generally absent from consideration.[114] Like

[110] The Andean Community is a regional trade group consisting of Bolivia, Colombia, Ecuador, and Peru.
[111] *See* Switzerland's Proposals Regarding The Declaration Of The Source Of Genetic Resources And Traditional Knowledge In Patent Applications And Switzerland's Views On The Declaration Of Evidence Of Prior Informed Consent And Benefit Sharing In Patent Applications, , *in* ICTSD/CIEL/IDDRI/IUCN/QUNO DIALOGUE ON DISCLOSURE REQUIREMENTS: INCORPORATING THE CBD PRINCIPLES IN THE TRIPS AGREEMENT ON THE ROAD TO HONG KONG 7 (2005), https://www.iprsonline.org/ictsd/docs/DOO6_Addor.pdf (last visited Feb. 25, 2024).
[112] BUNDESGESETZ UBER DIE ERFINDUNGSPATEN [PATG] [PATENTS ACT] JUNE 25, 1954, SR 232.14, ART. 49A (*in force since* July 1, 2008) (Switz.).
[113] *Id.*
[114] Paraskevi Kollia, *Disclosure of Origin in Patent Law: How to Enforce It Best?*, (2013) https://papers.ssrn.com/abstract=2407321 (last visited Feb. 21, 2024) ("It was deemed that the mention of geographical origin enables monitoring whether.. arrangements exist; requiring additional proof for these is superfluous and places too heavy a burden on applicants and patent offices.").

the GRATK Treaty, Switzerland's disclosure requirement functions more as a superfluous filter to patent issuance rather than means to facilitate resource tracking or conservation.

Furthermore, European countries like Switzerland and Norway, are unconvincing proponents and poor examples of the disclosure requirement in action. For these countries, adopting the requirement is low-risk and low-impact to their patent system.[115] They can easily tout the disclosure requirement's feasibility because it poses such minimal demands on their patent office.[116] Adopting the origin disclosure requirement is essentially a formality- nothing more than a signal of political support for the issue, rather than having any meaningful impact on actually improving access and benefit sharing.[117]

Another example of the requirement at play in a developed country, with a relatively advanced patent regime, is the Republic of Korea (South Korea). In 2012 the Korean IP Office spent six months analyzing genetic resources used in Korean patent applications before concluding that the sheer number of genetic resources implicated in patent applications demanded a systematical database.[118] The varying styles of origin disclosure (e.g., academic Latin terms, typical names, local community names, etc.) meant that Korean patent examiners had to search over 5,000 genetic resources one by one to clarify what was actually used. The resources required was far greater than expected and caused South Korea concern over the

[115] Hoare and Tarasofsky, *supra* note 102 (explaining that the requirement only impacts national biotechnology applications, which constitutes less than 25% of total applications and Sweden, for example, only receives about 300 biotech applications a year total).
[116] *See* IPI Database - Patents | Swiss Federal Institute of Intellectual Property, https://database.ipi.ch/database-client/search/query/patents (last visited Apr. 8, 2024) (where only 40 of the 1,920,135 patents in the database were marked for "genetic resources and traditional knowledge").
[117] Hoare and Tarasofsky, *supra* note 102.
[118] WIPO SECRETARIAT, *Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, at 26 (2013).

practicality of a mandatory disclosure requirement- an attention-worthy reaction considering South Korea's IP office is one of the largest in the world with nearly one thousand examiners.[119]

Mirroring these sentiments, New Zealand, a growing innovation leader, investigated the feasibility of the disclosure requirement in three different forms.[120] The 30-year projection of administrative and compliance costs was estimated to be a minimum of $1,390,000 and up to $7,464,000 for the most resource-intensive form of the disclosure requirement (roughly $46,300 to $248,800 per year).[121] The greatest source of cost was attributed to additional application processing time- the seemingly unavoidable result of putting access and benefit-sharing compliance on the plate of patent offices.

A candidly supportive study of Indonesia's origin disclosure requirement further supports this dilemma, recognizing that adoption of such a requirement in patent law "can be technically complex, particularly for developing countries with inadequate human resources," due to the lack of adequate policy/regulatory frameworks to implement the obligation.[122] This acknowledgment echoes a pattern of concern for conservation in developing countries—hollow conservation structures with missing links to facilitate law/policy like the GRATK Treaty.

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[119] *Id.* ("Public disclosure requirements adopted in Brazil or India have proven equally problematic with significant costs created for innovators without any measurable corresponding progress in innovation or economic growth to balance these additional costs. These requirements "delayed patent applications from months to over 2 years" in Brazil and by four years in India. The available evidence demonstrates that genetic resource-based patent disclosure requirements create uncertainty, delay patent grants, and slow the pace of innovation. They also will drown the USPTO and officials in compliance scrutiny. There are no clear benefits that offset these costs."). The Korean IP Office is one of the "IP5"- a forum of the five largest IP offices in the world.

[120] CASTALIA STRATEGIC ADVISORS, *Economic Evaluation of Disclosure of Origin Requirements*, (2018), https://www.mbie.govt.nz/assets/137b70a333/castalia-economic-assessment-evaluation-disclosure-origin-requirements.pdf (last visited Apr. 8, 2024) (the three implementation scenarios investigated being (1) disclosure of origin alone, (2) disclosure plus a source, and (3) disclosure plus evidence of access and benefit sharing arrangements).

[121] *Id.*

[122] Rahmah, *supra* note 105. Mas Rahmah, Nurul Barizah, & Sam Blay, *Ensuring Disclosure of Origin of Genetic Resources in Patent Applications: Indonesia's Efforts to Combat Biopiracy*, 25 J. INTELLECTUAL PROPERTY RIGHTS 40, at 50 (2020).

To mitigate concerns of overburdening the patent office, and likely ease the minds of potential signatories, WIPO policy drafters put "no obligations on patent offices to verify the authenticity" of an origin disclosure.[123] This addition supposedly minimizes the "transactional cost/burden on patent offices and ensur[es] [the disclosure requirement] does not create unreasonable processing delays for patent applicants."[124] However, the treaty certainly does not prevent patent systems from conducting verification and affirmatively expects patent offices to provide guidance on meeting the disclosure requirement.[125] Even if one assumes the disclosure submission itself is all that patent offices have to ensure, who or what agency has the expertise to subsequently verify the origin? Isn't verification necessary to monitor for fraud and any postliminary benefit sharing and conservation? The gaps left downstream, largely unguided by the GRATK Treaty, leave patent offices with nothing more than extra paperwork to handle.

2. Chilling Effect

Patent applicants already wait at least 12 months (longer in most jurisdictions) for a response from the patent office- any extra hurdle only furthering the delay. Extra hurdles also equate to extra time and money spent on patent prosecution- resources many small and medium-sized enterprises don't have. Even though applications cannot be outright rejected based on failure to adequately disclose, the potential for hiccups in a realm of brand-new law is discouraging to applicants, large and small.

Countries with robust origin disclosure requirements, like India and Brazil, already have the longest average pendency times, reaching an average of 156 to 179 months, respectively,

[123] GRATK Treaty art. 3.5.
[124] WIPO, 47th Sess., Doc. WIPO/GRTKF/IC/43/5, *Chair's Text of a Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources*, page 10 (May, 1, 2023).
[125] GRATK Treaty art. 3.4.

between filing and final decision.[126] Any extra cost and delay is notable given patent rights "more than double [a startup's] chances of securing venture capital financing" and statistically increase a startup's overall chance of success in the marketplace.[127]

This will inevitably chill innovation and the global innovation economy as private R&D investments, those which foster market-ready innovation, are abated.[128] The losers in this situation are not only the inventors, relying on patents to gain capital or recoup R&D and commercialization expenditures, but also a worldwide population that may have significantly benefitted from that innovation.[129] Without predictable and effective patent protections, investors would shift capital towards less risky endeavors. This possibility is especially detrimental to sectors like biotechnology or pharmaceuticals, which offer some of the greatest value to society.[130]

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[126] WIPO, *Patent Office Operations: Application Processing Times, Examination Capacity and Examination Outcomes*, (2017), https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2017-chapter1.pdf (last visited Apr. 8, 2024).

[127] Letter from Adam Mossoff, Professor of Law, George Mason Univ. Antonin Scalia Law School, to Honorable Katherine Vidal, Director of the USPTO (Jan. 22, 2024) (on file with the Federal eRulemaking Portal as a Comment to Docket ID No. PTO-C-2023-0019, Re: WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge) (citing Joan Farre-Mensa, et al., *What Is a Patent Worth? Evidence from the U.S. Patent "Lottery*,*"* 75 J. FINANCE 639 (2019), https://doi.org/10.1111/jofi.12867).

[128] Letter from Adam Mossoff, *supra* note 123 ("Only a fraction of commercial firms have the financial and institutional wherewithal to identify every chemical and biological compound relied on or included in the extensive and lengthy R&D process underlying a new discovery or invention").

[129] Letter from Adam Mossoff, *supra* note 123 ("Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky – without regard to the great value that biotechnology offers society"); *see also* Graham, Stuart J. H. and Sichelman, Ted M., *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L. J. (Sept. 6, 2008) ("Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe that there will be an attractive return on their investment. Patents and regulatory data protection provide this assurance. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs reported that potential funders, such as venture capitalists, angel investors, and commercial banks, indicated patents were an important factor in their investment decisions.").

[130] Letter from Biotechnology Innovation Organization, to the Office of Policy and International Affairs, USPTO (on file with the Federal eRulemaking Portal as a Comment to Docket ID No. PTO-C-2023-0019, Re: WIPO IGC Negotiations on Genetic Resources and Associated Traditional Knowledge) ("Legal certainty in the acquisition and enforcement of patents is therefore critical to research and development efforts needed to deliver promising biotechnology solutions to humanity").

One can also speculate the chilling effect may be jurisdiction-specific. Depending upon the technology, the existence of an origin disclosure requirement may be a consideration in the decision to pursue patent protection for a certain jurisdiction. Large enterprises may indicate biodiverse countries for development and/or manufacturing of their patentable products. This translates to economic flow for countries whose patents generally have limited demand in the international market. However, if the additional compliance burdens aren't met with proportionate benefits, economic development is easily directed elsewhere.

3. Contrary to the Fundamental Purposes of Patent Law

Proponents of the origin disclosure requirement assert that such obligations are necessary to enforce benefit sharing and sustainable utilization in the face of biopiracy associated with exploitation from patent-holders. They argue that the transparency generated via the disclosure requirement improves the function of the patent system as well.[131] Evidence supporting this is slim and particularized.[132] Simply put, patent law is the wrong medium for effectuating biodiversity conservation.

The growing necessity and effort to protect genetic resources have already resulted in global regulation systems (collectively referred to as "access-benefit sharing systems"). These systems, particularly the Nagoya Protocol, are meaningful regulatory mechanisms in their own right, but fundamentally incompatible with the purpose of patents. Patents and technology

[131] The idea is that greater disclosure requirements, more transparency regarding the origins of an invention, would help filter out inventions that are obvious or not novel and prevent the granting of erroneous patents, thus increasing patent quality.

[132] *See* Donna Perdue, *Patent Disclosure Requirements Related to Genetic Resources: The Right Tool for the Job?*, 36 BIOTECHNOLOGY L. REPORT 285 (2017) ("No new disclosure requirement is needed to prevent grant of erroneous patents… existing disclosure requirements function very well by establishing clear standards for technical information that may be disclosed in the form of text ,figures, sequence data, geographical data, or a biological deposit.").

transfer may have overlapping subject matter (genetic and biological resources), but patents strictly encourage innovation and serve as tools for industry development.

Patents are based upon technical information specifically provided to fulfill the objective requirements for patentability. Accordingly, all of the information provided in a patent application is generally behavior-neutral. Adding a new disclosure requirement to track and monitor the inherently non-neutral behaviors of a party pursuing access or rights to a certain biological resource is thus inappropriate.[133] While conservation is a noble pursuit, the origin disclosure requirement can easily alter and effectively undermine the neutrality of patent procurement. Moreover, adding a new requirement opens up patent law to a potentially inexhaustible demand for further information that is irrelevant to the foundationally objective application requirements- utility, novelty, and non-obviousness.

Any benefit from the origin disclosure requirement is negligible compared to the far-reaching effects a requirement imposes on international patent rights. The value of a steady and predictable patent system cannot be understated. IP allows for the cultivation of partnerships worldwide, complements information sharing, and ultimately serves as a pillar for innovation development.

IV. Alternative Mechanisms to Promote Innovation and Biodiversity Conservation

Within the operational model of conservation, an origin disclosure requirement, necessarily simplified, serves a narrow purpose: to identify what is being commodified using genetic/biological resources. This makes sense in theory; it is logical to see how disclosure could

[133] *Id.*

provide an entry point to address misappropriation. Given the CBD and Nagoya Protocol's weak compliance, it is similarly logical to try and "mainstream biodiversity"- that is, integrate biodiversity issues into all policy sectors, including IP.[134] This paper is not necessarily in opposition to integrating biodiversity and IP policy, but there are other less burdensome mechanisms to protect biological resources through patent law.[135]

Proponents of the disclosure requirement unrealistically assume a level of simplicity and tangibility in the task of identifying a biological/genetic resource. Biological and genetic resources can be easily studied and incorporated into technology without any physical access to the resource. Unfortunately, nothing in the GRATK Treaty prevents contracting nations from applying disclosure requirements to digital sequence information (DSI).[136] Moreover, genetic resources are used, combined, and altered in increasingly complex ways that complicate the identification of a resource or allocation of rights. How "much" of a certain gene or protein is enough to warrant access and benefit sharing?[137]

When genetic resources are functionally just bio-information, there is no physical resource to be misappropriated. A sovereign's assertion of ownership, and demand for benefit sharing, over that information is essentially the licensing of naturally occurring DNA- clearly unpatentable subject matter. These considerations muddy and distract from the goal of protecting physical, raw biological resources. Reproducing DNA or compounds in a lab (i.e., using synthetic or abundant materials) is not threatening biodiversity. Physical changes to an

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[134] Niak Sian Koh, Claudia Ituarte-Lima & Thomas Hahn, *Mind the Compliance Gap: How Insights from International Human Rights Mechanisms Can Help to Implement the Convention on Biological Diversity*, 11 TRANSNATIONAL ENVIRONMENTAL L. 39 (2022).
[135] *See infra* Part IV.B.
[136] Nirmalya Syam & Carlos Correa, Understanding the New WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, South Centre (July 3, 2014) https://www.southcentre.int/wp-content/uploads/2024/07/PB131_Understanding-the-New-WIPO-Treaty-on-Intellectual-Property-Genetic-Resources-and-Associated-Traditional-Knowledge_EN.pdf.
[137] *See* discussion *infra* Part IV.A.1.

ecosystem are where biological, and thus genetic, resources are being affected. Accordingly, efforts to monitor and track those resources should be focused on a phase of the value chain where overexploitation and habitat alternations (the main threats to biodiversity) occur.[138]

A. Shifting the Focus to a Different Stage in the Value Chain: Commercialization

Considering the narrow conservational purpose served by an origin disclosure requirement—to identify and trace genetic/biological resources that are *commodified* through innovation—the alternatives explored are specific to that goal. A *de minimis* standard, applicable to identification and monitoring activities at any stage, is a legal mechanism that would improve the efficiency of conservation by directing focus to higher-risk activities. More broadly, responsibility (for monitoring) could be shifted to better-suited regulatory bodies, like trade control, or even private sectors.

1. A De Minimis Requirement is Essential to Effectuating Biodiversity Conservation

A lack of clarity regarding what activities constitute access and/or use of a genetic or biological resource in the governing law (the Nagoya Protocol) is one major reason these models lack effectiveness in facilitating biodiversity conservation. Proponents of the origin disclosure requirement have oversimplified the R&D process by asking for the source of every genetic or biological influence incorporated in an invention. Theoretically, this would allow patent systems to trace each influencing resource back to its origin country/region for some other unallocated party to then facilitate sharing agreements and any conservation measures. Besides the numerous unclarities and assumptions in this theory, a major pitfall of this mechanism is that it does not address the activities that are actually threatening biodiversity- namely overexploitation. This is

[138] *See* discussion *infra* Part IV.A., Maxwell et al., *supra* note 1.

why a de minimis standard is necessary to narrow the scope of what resources are focused on and to ensure disclosure requirements are consistent with conservation objectives.

A 1991 patent involving a glufosinate herbicide-resistant gene is a good example of the necessity for a de minimis standard.[139] The gene was isolated from *Streptomyces viridochromogenes*, a bacterium native to Cameroonian soil, and then incorporated into the gene structure of plants for herbicide resistance. The question becomes does Bayer Crop Sciences, the owner of this patent, owe Cameroon for the gene derived from bacteria that inhabit soil in their country. It is arguable given the massive commercial success of this technology, but it still seems like a stretch, especially considering the technology only involves the gene sequence itself. Post-research (which itself hardly requires more than an initial sample to culture the bacteria), neither the native bacterium, the soil, nor any sort of tangible resource are being used to create this commercial product. Thus, there is virtually no effect on Cameroon's biodiversity. In this case, requiring extra disclosures and potentially imposing further legalities (i.e., access and benefit sharing or resource monitoring) in the name of biodiversity conservation would be a waste of time and resources for all parties involved.

Notwithstanding the fact that genetic resources greatly contribute to innovation—a principle driving biodiversity protection in and of itself—their use in R&D does not always translate to resource consumption that rises to a threat to biodiversity. In many cases, development involves numerous genes derived from any number of species, any of which are likely manipulated before derivation results in an end product. In all, a genetic resource's overall contribution to the final innovation is usually less substantial in the grand scheme of technological development. The exclusion of minimal (*de minimis*) contributions from legalities

[139] *See* U.S. Patent No. 5,276,268A (issued Jan. 4, 1994).

surrounding genetic and biological resources would greatly increase the efficiency of systems aiming to identify and trace these resources for biodiversity conservation.[140] Shifting away from the idea of a patent disclosure-driven monitoring regime, and towards an alternative forum for monitoring and tracing resource consumption is the efficient path to allow both R&D and sustainable consumption of resources.

2. Alternative Mechanisms for Monitoring and Traceability

Compared to patent procurement, logic favors the creation of biological resource monitorization frameworks at a different place in the value chain- where there is actually "harvest" or a revenue-generating product. Commercial consumption (use) and trade controls are essentially inseparable, so monitoring for activities that implicate biodiversity threats at these stages may be a better choice for actually identifying and facilitating conservation.[141] Furthermore, characterizing threats to biodiversity is a context-specific task, as illustrated above[142], and species are affected differently.[143]

A specific alternative would be requiring biodiversity disclosures from the private sector (e.g., businesses, companies, research institutions, etc.), similar to the demands made in the Global Biodiversity Framework's Target 15.[144] Adopting a measure like Target 15[145] would make private parties ("businesses") disclose their production patterns in the context of biodiversity. These disclosures or biodiversity "risk assessments" would help a business identify opportunities

[140] *See* EVANSON KAMAU, IMPLEMENTATION OF THE NAGOYA PROTOCOL FULFILLING NEW OBLIGATIONS AMONG EMERGING ISSUES (2021) at 109.
[141] Cyrille de Klemm & Clare Shine, *Biological Diversity Conservation and the Law*, No. 29 xix, 95, https://portals.iucn.org/library/sites/library/files/documents/EPLP-029.pdf.
[142] See Cameroonian example above *supra* Part IV.A.1.
[143] *See* Bellard, Marino, and Courchamp, *supra* note 1.
[144] Kunming-Montreal Global Biodiversity Framework, (2022), https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-04-en.pdf; Biosafety Unit, *Target 15*, https://www.cbd.int/gbf/targets/15 (last visited Apr 13, 2024).
[145] Government signatories or members would be expected to update national biodiversity strategies or action plans that include disclosure requirements for the private sector.

for generating a positive impact on biodiversity, like collaboration with source countries to promote sustainable practices, cultivation, community development, and even further R&D.[146]

Although this alternative currently relies upon voluntary participation from businesses in many countries, an obvious limitation, this type of engagement is contagious and greatly benefits companies.[147] In-house monitoring allows businesses to cater mitigation strategies without risking the loss of important proprietary rights, like a patent. They also get to use such disclosures as an opportunity for sustainable marketing. Meanwhile, biodiversity conservation efforts benefit from the clarity in disclosing supply chain(s) and/or business portfolios- data that would indicate where (geographically) and how significantly a company is using bioresources.

B. Pro-Biodiversity Changes within the Patent System

There is no reason to expect any industry or area of law should be completely exempt from the efforts to mainstream biodiversity, including IP. Still, there are less contentious and less burdensome initiatives that would support biodiversity conservation through the patent system(s). One such route would employ a strategy of focusing on extinct and threatened species implicated in patent applications. Potentially working in tandem, the institution of resource databases would lessen pressure on both applicants and patent offices worldwide.

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[146] *See* Rodolfo Jaffe & Lawson Fite, *Biodiversity Conservation and the Problem of Extraterritoriality*, 38 ABA NAT. RES. & ENV. (2023); WEBINAR SLIDES : HOW AI IS TRANSFORMING BIODIVERSITY..., https://video.ramboll.com/webinar-slides-how-ai-is (last visited Mar. 19, 2024); Anastasia Balova, *What is Target 15 and why is it important* , Ramboll Group, https://www.ramboll.com/galago/what-is-target-15-and-why-is-it-important (July 26, 2023) (last visited Mar 19, 2024).

[147] Matteo Tonello, *2023 Biodiversity Disclosures in the Russell 3000 and S&P 500*, HARV. L. SCHOOL FORUM ON CORPORATE GOVERNANCE (2023), https://corpgov.law.harvard.edu/2024/01/09/2023-biodiversity-disclosures-in-the-russell-3000-and-sp-500/ (last visited Apr 13, 2024) (demonstrating the increase in company disclosures).

1. An Extinction Bar and Threatened Species Disclosure

The *quid pro quo* of patent rights is the exchange between society, receiving an enabling disclosure of the invention, and the inventor, receiving monopoly rights.[148] Thus, if an invention's disclosure becomes non-enabling, it follows that the inventor should lose monopoly rights. In the most extreme scenario, where a biological resource required to practice the invention becomes extinct, the invention is no longer "available to the public without undue experimentation."[149] Although the value of a patent may vary, the loss of patent rights upon species extinction—an extinction bar—is a strong incentive for respective owners to conserve the biological resources implicated by their innovation.[150] Granted, *de minimis* limitations are also an important consideration for such a bar for the same reasons noted above.

Within the workings of an extinction bar, there are also incentives for disclosing at-risk species in a patent application. If an invention implicates a biological resource (species) that is considered at-risk (e.g., labeled as vulnerable, endangered, or critically endangered) under a uniform body like the International Union for Conservation of Nature ("IUCN"), it should be disclosed in the patent application. This disclosure would put patent offices on notice of the at-risk biological resource for any necessary further action or monitoring. For example, they may flag the application for further review by a conservation-focused administration or pass that information on to an origin-specific administrative body.

Similarly, a patent applicant could benefit from the disclosure by gaining immunity from the extinction bar when they show good faith effort to conserve the disclosed resource(s). These

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[148] Patent law requires a disclosure that is sufficient enough to "enable" a person skilled in the art to practice the technical invention. The public should be able to understand what the invention is and reproduce it using the knowledge given in the disclosure for the inventor to gain monopoly rights.

[149] *Ex parte Rinehart*, 10 U.S.P.Q.2d at 1720.

[150] See Andrew W. Torrance, *An Extinction Bar to Patentability*, 20 GEO. INT'L ENVTL. L. REV. 237 (2007) for a thorough discussion of an extinction bar in the American patent system.

conservation efforts could be in the form of synthetic biology, acquiring conservation easements to resource-native lands, compensating locals to protect the species/habitat, negotiating with the local government or organizations to ensure protection—whatever strategies necessary to show a legitimate effort towards conservation.[151] For example, a patent application for a method of screening with horseshoe crab blood would require the applicant to disclose that their invention implicated a biological resource from *Limulus polyphemus* (American horseshoe crab), an IUCN vulnerable species, and pursue conservation efforts accordingly.[152]

An easy integration strategy could require reporting of these efforts and the resource's conservation status with post-grant patent maintenance fees. For example, in the U.S., reporting could be required (along with the usual maintenance payments) at 3.5, 7.5, and 11.5 years after a patent is granted. Notably, to avoid an overload of future "good faith effort" confusion and litigation, patent systems would benefit from compiling a guideline of adequate conservation strategies. An advanced form of this requirement may even assess the adequacy of conservation efforts according to the patent's economic value or the assignee's (the entity owner's) size.

2. A Global Database for Biological Resources

An organization system in which threat-focused disclosure requirements (as discussed above) could operate would further facilitate effective international conservation through the patent system. A major concern plaguing both patent offices and applicants lies in the capacity to properly disclose and assess the origins of a resource, and perhaps the most improvident policy

[151] *Id.* at 266.
[152] The IUCN Red List of Threatened Species, IUCN RED LIST OF THREATENED SPECIES, https://www.iucnredlist.org/en (last visited Apr. 13, 2024); Martin Reeves, *Economic Factors Underlying Biodiversity Loss with Partha Dasgupta, Simon Levin and Georg Kell*, https://bcghendersoninstitute.com/economic-factors-underlying-biodiversity-loss-with-partha-dasgupta-simon-levin-and-georg-kell/ (emphasizing that locals generally know more about caring for their local ecology than studied ecologists do, and business would greatly benefit from using that local knowledge in their conservation efforts).

failure of the GRATK Treaty is the absence of mandatory information system establishment. It would serve all parties, including local authorities or access and benefit sharing systems, to make a database that combines all the information an applicant needs: instructions, guidelines, identification information, resource logs, etc. Applicants would have an all-encompassing resource to help them identify at-risk resources that they should disclose or the nation-specific legalities associated with the use of a certain resource in the event of commodification. Furthermore, patent offices would be able to easily confirm required origin disclosures based on this database, and automatically connect applicants with local administrative bodies for any further compliance.

A working model of this database, on a national scale, is seen in Australia's Genetic Resources Information Database ("GRID"). As the Australian government eloquently explains, "confidence by parties in the biodiversity commercialization chain is essential for investment in natural product recovery."[153] The database provides private parties with information to help them verify the legal origins of an Australian biological resource and access associated permits or records. The ability to search a database and find legal certainty greatly uncomplicates the compliance process for companies/applicants and any necessary verification for patent offices.[154] Eliminating the risks and burdens behind disclosure requirements and compliance violations would better effectuate resource identification and monitoring on a global scale.

[153] Australian Government, Department of the Environment and Heritage, *Australia: The Right Environment for Biodiversity*, https://www.dcceew.gov.au/sites/default/files/env/pages/f9446036-7ce9-47aa-a239-79376d3f285b/files/biodiscovery.pdf (last visited Apr 13, 2024).
[154] Zhengyuan Liao, *Disclosure Requirement of Origins in Patent Law: The Pros and Cons of the "Layer" between Patents and Genetic Resources and Traditional Knowledge*, 10 J. OF CIVIL LEGAL SCIENCES 261 (2021).

V. CONCLUSION

The relationship between biodiversity and innovation suggests patent rights are inextricable from society's use and development of biological resources. Protecting the traditional incentives of the patent system is necessary to sustain the biotechnological advancements that are vital to mankind. Yet at the world stage, integrating biodiversity conservation into patent systems has been relatively unfruitful. The solution to mainstreaming biodiversity requires a bird's-eye view of the entire innovation value chain. Realistic, efficient policy changes should focus on high-risk activities for overexploitation, particularly where patents are translated to products that depend upon the exploitation of biological resources. Relinquishing the contentious and burdensome origin disclosure requirement for conservation policies that employ monitorization at the commercialization stage, and focus on high-risk species implicated in patent applications, would better serve the goals of the CBD—biodiversity preservation—and allow innovation to flourish through the patent systems.