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THE FOOD MICROBIOME AS TRADITIONAL KNOWLEDGE

JACOB GOLAN*

INTRODUCTION 242
I. SCIENTIFIC AND LEGAL BOUNDARIES OF FERMENTED FOODS' MICROBIOME 244
A. *Issues with Defining "Microbes" and "Fermentation"* 244
B. *Disentangling Biogeography from Geographic Uniqueness* 247
II. GEOGRAPHY AND INTELLECTUAL PROPERTY REGULATORY SYSTEMS 251
A. *Transnational Protection* 251
B. *Branding Microbiota: EU vs. US* 253
III. MICROBIOME, TRADITIONAL KNOWLEDGE, AND TRADE SECRECY 256
A. *The Microbiome as Traditional Knowledge* 257
1. *Defining "Genetic Resources"* 257
2. *Defining "Traditional Knowledge"* 260
3. *Traditional Knowledge as Trade Secret* 261
CONCLUSION 263

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INTRODUCTION

For centuries, bacteria, yeasts, and molds have been used to produce fermented foods and beverages.[1] Throughout the world, fermented products are increasing in popularity in regions where their production has been relatively limited. In the United States, for example, many traditional fermented foods from Europe, Asia, Africa, and South America have become available due to a growing number of large- and small-scale producers.[2] These fermented goods may incorporate novel ingredients, processes, or local microbial communities that differ from those of the places where these products are traditionally made. At the same time, more and more studies are using various genomic and environmental sequencing approaches to uncover the taxonomic, genetic, and functional diversity of many fermented food microbiomes.[3] The confluence of expanded production in new geographic regions and the application of new technologies to traditional products raises important questions not only about how to delimit microbial species' identities, but also about how intellectual property doctrines can account for shifting characterizations of fermented foods' probiotic compositions.

One rapidly emerging practice is to portray the microbial strains and ecosystem within fermented foods as unique to specific production facilities or geographic regions.[4] However, if the same fermented food is made in many different geographic locations, does it possess unique microbes based on location? Do those geographic differences in microbial composition translate into differences in product quality that consumers can reasonably attribute to particular regions? As scientists

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[1] *See* ROBERT W. HUTKINS, MICROBIOLOGY AND TECHNOLOGY OF FERMENTED FOODS 1, 4 (2d ed. 2018) (describing how molecular archaeology has shown that wine has been produced in the Near East regions since the Neolithic Period, 8500 to 4000 B.C.E.).

[2] *Cf.* INNOVATIONS IN TRADITIONAL FOODS 1-51 (Charis M. Galanakis ed. 2019) [hereinafter INNOVATIONS]; Aly Farag El Sheikha, *Revolution in Fermented Foods*, *in* MOLECULAR TECHNIQUES IN FOOD BIOLOGY 239, 239-60 (2018).

[3] *See generally* E.J. Smid & J. Hugenholtz, *Functional Genomics for Food Fermentation Processes*, 1 ANN. REV. FOOD SCI. & TECH. 497 (2010); Mohamed Mannaa et al., *Evolution of Food Fermentation Processes and the Use of Multi-Omics in Deciphering the Roles of the Microbiota*, 10 FOODS 2861 (2021); Meichen Pan & Rodolphe Barrangou, *Combining Omics Technologies with CRISPR-Based Genome Editing to Study Food Microbes*, 61 CURRENT OP. BIOTECHNOLOGY 198 (2020).

[4] *See* Vittorio Capozzi, Pasquale Russo & Giuseppe Spano, *Microbial Information Regimen in EU Geographical Indications*, 34 WORLD PAT. INFO. 229, 229 (2012) (arguing that EC Regulation 510/2006 on EU microbial resource management in "Geographical Indications" production is not unequivocally defined and that regulation should require product information to specify the list of autochthonous microbial strains representing the "virtuous" microbial biodiversity of a specific *terroir* and/or given method of food production).

uncover patterns of microbial diversity in fermented foods, another set of questions emerges about the intellectual property protections available, especially for artisanal producers. Unlike many other foods—for which it is difficult to quickly reproduce unique ingredients from competitors' products—it is relatively straightforward to isolate and propagate microbes from raw fermented foods. What are the legal protections available for the microbial cultures used in fermented foods? Can an American cheese producer legally isolate and use microbes from a French cheese? What national and international laws are available to protect the identity of fermented food microbes? And what novel approaches or technologies might provide new protections of microbial cultures in fermented foods?

In this Article, I explore the intersection of microbial diversity and intellectual property protection for microbial communities of fermented food. I ultimately argue that the "microbiome" should be regarded as a genetic resource and, when its distinctiveness is rooted in geographic origin, should be considered akin to traditional knowledge. I begin by providing an overview of the evidence for unique microbial identities across fermented food producers and production areas. Section I(A) presents an overview of the issues with defining the terms "microbes" and "fermentation," highlighting a lack of clarity not only in the legal sphere but also with regard to what should constitute the scientific bases for a legal definition. In Section I(B), I discuss the relationship between foods' unique characteristics and their geographic origin, and I evaluate the possibility of utilizing patterns of microbial diversity as a basis for intellectual property protections. In this Section, I also discuss the important notion of *terroir* and assess the possibility of expanding its applicability to the whole of microbial patterns that contribute to the taste, odor, and texture of foods.

Section II(A) explores options to protect the intellectual property of fermented foods vis-à-vis their microbial composition. I briefly reconstruct the history of legal appellation systems for the protection of foodstuff based on geographic origin. I highlight the peculiarity of "Geographical Indications" (GIs) as the only kind of intellectual property rights based on collectively held traditions, contrast them to standard trademarks, and discuss challenges to implementing GI protections arising from the global coexistence of different legal and economic traditions. In this context, I discuss US hostility toward European Union institutions of GIs (largely perceived as hindrances to the free market) and the failure of the US to be party to important international agreements. In Section II(B), I reflect on the legal mechanisms already in place through which intellectual property rights may be obtained for fermented foods. While there exists little in the way of legal protections for natural starter cultures, fermented food producers in the US can obtain protections for the fermentation biotechnologies they utilize. I remark that while in the US intellectual property is mostly privately enforced and the system primarily uses trademark law to protect artisanal fermented products geographically, in the EU it is national and supranational bodies that preside over the creation and implementation of GI regulations. I predict that shifts in consumer demand in the US will lead to an increasing quest for EU-style intellectual property protections, albeit through different legal mechanisms.

Section III notes that while patents remain unavailable as a legal resource for the protection of naturally occurring microbiota, trade secret laws could protect biotechnological resources used in the production of fermented foods. This route, however, presents some problems—the use of trade secrecy for microbiome science risks undermining the structure of incentives that constitutes the basis for intellectual property law. In Section III(A), I set forth a definition of *terroir* as collective knowledge possessed over generations by a community. In Section III(A)(1), I include an overview of the most relevant provisions of the Nagoya Protocol and of the difficulties into which one runs when attempting to see the protection of microorganisms as contemplated under the Nagoya Protocol's provisions. In Section III(A)(2), I introduce the notion of "traditional knowledge," commonly defined as a body of knowledge collected and cultivated by a group of people across generations. I argue that the creation of a microbiome in a local context should be understood as a form of traditional knowledge. Thus, in Section III(A)(3), I go on to contend that, for several reasons, the protection of traditional knowledge of local microbiomes through trade secrets constitutes the most reasonable option to provide legal protections in the case of artisanal fermented foods. I conclude by proposing some precautions that can mitigate the weaker exclusionary rights offered by trade secret laws relative to other forms of intellectual property. This Article expands upon a preexisting conversation on the legal protections for fermented foods[5] by incorporating new perspectives emerging from genomic and metagenomic sequencing studies and by adopting a comparative approach for both the United States and Europe.

I
SCIENTIFIC AND LEGAL BOUNDARIES OF FERMENTED FOODS' MICROBIOME

A. Issues with Defining "Microbes" and "Fermentation"

From a legal point of view, the term "microbe" (or equivalently "microorganism") often applies to any biological material that is microscopic in

[5] *See id.*; *see also* Vittorio Capozzi et al., *Genome Sequences of Five* Oenococcus oeni *Strains Isolated from Nero di Troia Wine from the Same Terroir in Apulia, Southern Italy*, 2 GENOME ANNOUNCEMENTS 1, 1-2 (2014).

scale, most commonly including bacteria and fungi, but also viruses, "protozoa," unicellular algae, and so forth.[6] "Microbe" represents an imprecise working definition rather than a scientific term of art. Due to uncertainty as to how organisms qualify as microbes, the EU, for example, has discontinued use of the term "microorganism" in favor of "biological material," defined as any material containing genetic information and capable of replicating itself or of being reproduced in a biological system.[7]

Even a scientific definition of microbial species or strains is somewhat lacking in a theoretical basis, and the extent to which phenotype or genotype should be used to delimit species or strains is still intensely contested.[8] Often a polyphasic approach, at least in bacterial taxonomy, is recommended, whereby strains showing a high degree of phenotypic and/or genotypic similarity to a type of strain are considered to belong to the same species.[9] At the same time, a standardized measure of relatedness (such as degree of genome hybridization or sequence similarity) has yet

[6] *See, e.g.*, 18 U.S.C. § 178(1)-(2); *Definition of "Microorganism,"* NIH NAT'L CANCER INST., https://www.cancer.gov/publications/dictionaries/cancer-terms/def/microorganism (last visited May 16, 2022) (defining a microorganism as "[a]n organism that can be seen only through a microscope. Microorganisms include bacteria, protozoa, algae, and fungi. Although viruses are not considered living organisms, they are sometimes classified as microorganisms"); *see also* Janani Hariharan, *What Counts as a Microbe?*, AM. SOC'Y MICROBIOLOGY (Apr. 11, 2021), https://asm.org/Articles/2021/April/What-Counts-as-a-Microbe ("'Microbe' is a convenient and practical term to introduce novices to the multitudes of the microbial world, but professional microbiologists might want to ask themselves what they mean when they say 'microbe': did they study the fungal community? Or the bacterial community? Or the phages that infect bacteria? In the microbial world, the devil is in the details.").

[7] Soundarapandian Sekar & Dhandayuthapani Kandavel, *The Future of Patent Deposition of Microorganisms?*, 22 TRENDS BIOTECHNOLOGY 213, 214 (2004).

[8] *See* Jeremy R. Dettman et al., *Reproductive Isolation and Phylogenetic Divergence in* Neurospora*: Comparing Methods of Species Recognition in a Model Eukaryote*, 57 EVOLUTION 2721, 2740-41 (2003) (showing that mating type, parental role, and species identity of parental individuals could influence the reproductive success of matings); Ramon Rosselló-Móra & Rudolf Amann, *Past and Future Species Definitions for* Bacteria *and* Archaea, 38 SYSTEMATIC APPLIED MICROBIOLOGY 209, 210 (2015) (arguing that bacteriologists' main point of disagreement over what constitutes a species is definitional, that is, "the way species are circumscribed by means of observable characters," rather than conceptual, that is, "the idea of what a species may be as a unit of biodiversity, the meaning of the patterns of recurrence observed in nature, and the why of their existence").

[9] P. Vandamme et al., *Polyphasic Taxonomy: A Consensus Approach to Bacterial Systematics*, 60 MICROBIOLOGICAL REVS., 407, 408 (1996).

to be agreed upon, and a simple definition of bacterial species remains elusive.[10] Similar difficulties exist for fungi, in which case further confusion arises with regard to the use of such terms as "yeast" and "filamentous."[11] In practice, both bacterial and fungal species' names are mentioned according to their most recently accepted scientific nomenclature, which, especially in the case of microbes, is often under constant revision.[12] More recent advances in environmental DNA sequencing will likely contribute to a more robust understanding of microbes' community composition, strain-level specificity, and geographic uniqueness.[13]

Similar confusion arises from the use of "fermentation," as there exists no apparent phylogenetic trend explaining which bacteria and fungi are useful as starters, or how the chemical process itself should be defined. Scientifically, fermentation relies on the principle of oxidation of carbohydrates and related derivatives to generate acids, alcohol, and/or carbon dioxide, often resulting in improved food preservation, texture, taste, and aroma, in addition to greater nutritional quality and reduced toxicity.[14] Strictly speaking, fermentation as a

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[10] *See* David S. Hibbett & John W. Taylor, *Fungal Systematics: Is a New Age of Enlightenment at Hand?*, 11 NATURE REVS. MICROBIOLOGY 129, 129, 132 (2013); Jongsik Chun & Fred A. Rainey, *Integrating Genomics into the Taxonomy and Systematics of the* Bacteria *and* Archaea, 64 INT'L J. SYSTEMATIC & EVOLUTIONARY MICROBIOLOGY 316, 318 (2014) (discussing the ways in which advances in genomics and computational technology have improved taxonomy methods for identifying *Bacteria* and *Archaea*).

[11] A "yeast" is typically a fungal species consisting of single cells, the most famous of which is baker's yeast, *Saccharomyces cerevisiae*. A "filamentous" fungus produces a hyphal network consisting of hundreds of interconnecting cells. Further confusion arises with some species' alternation between a yeast and filamentous morphology due to different life phases, environmental conditions, or subspecies characteristics. *See* François Bourdichon et al., *Food Fermentations: Microorganisms with Technological Beneficial Use*, 154 INT'L J. FOOD MICROBIOLOGY 87, 90 (2012).

[12] G. Sybren de Hoog et al., *Name Changes in Medically Important Fungi and Their Implications for Clinical Practice*, 53 J. CLINICAL MICROBIOLOGY 1056, 1060 (2015) (identifying issues in the naming conventions of fungi and proposing suggestions to improve the practice); *see also* John W. Taylor et al., *Eukaryotic Microbes, Species Recognition and the Geographic Limits of Species: Examples from the Kingdom Fungi*, 361 PHIL. TRANSACTIONS ROYAL SOC'Y B 1947 (2006) [hereinafter *Eukaryotic Microbes*] (discussing different methods of species recognition in fungi).

[13] Conor J. Doyle, Paul W. O'Toole & Paul D. Cotter, *Metagenome-Based Surveillance and Diagnostic Approaches to Studying the Microbial Ecology of Food Production and Processing Environments*, 19 ENV'T MICROBIOLOGY 4382, 4386 (2017).

[14] HENRY J. PEPPLER & DAVID PERLMAN, MICROBIAL TECHNOLOGY: FERMENTATION TECHNOLOGY (1979).

chemical process applies to an anaerobic system, but the term is commonly applied to both aerobic and anaerobic carbohydrate digestion.[15]

Fermentation is not formally defined under many legal frameworks, although the processes and organisms used therein are explicitly regulated. In the United States, food and food additives are regulated according to the Food Drug and Cosmetic Act. Notably, the Act makes no mention of fermentation, and microbes are instead interpreted to be included under the category of "food additives."[16] In the European Union, microbes are categorized as ingredients and must satisfy the legal requirements of a risk assessment performed by the Scientific Committees assisting the Directorate General for Health and Consumers.[17]

Perhaps due to such definitions, legal practitioners have deferred to inventors' or assignees' innovations by, for example, developing a genetically modified strain of bacteria that improves lactic acid breakdown, or engineering a fermentation process that is both novel and innovative for the production of a given product.[18] Starters are presumed to be ubiquitous in nature, and fermentation is a "natural process." Thus, in the same way in which one could not "own" the rights to a naturally occurring human gene, producers of fermented foods via natural starters and spontaneous chemical processes have limited means of protecting their products using traditional routes, such as through patents.[19]

B. Disentangling Biogeography from Geographic Uniqueness

One framework for defining potential legal protections for fermented food microbes is geographic uniqueness. If both the species and strains within fermented food communities exhibit non-random patterns of diversity for similar food products across a geographic area, these quantifiable patterns could serve as units of intellectual property protection. For example, the French term *terroir* has been used to justify and legally defend the uniqueness of many European wines on a geographic

[15] *Id.*

[16] 21 U.S.C. §§ 301-92 (Suppl. 5 1934).

[17] Theodor Brodmann et al., *Safety of Novel Microbes for Human Consumption: Practical Examples of Assessment in the European Union*, FRONTIERS MICROBIOLOGY 1, 1 (2017).

[18] *E.g.*, Fermentation and Recovery Process for Lactic Acid Prod., U.S. Patent No. 5,464,760 (filed Oct. 23, 1992); Centrifugal Fermentation Process, U.S. Patent No. 6,214,617 B1 (filed Dec. 31, 1998); Probiotic, Lactic Acid-Producing Bacteria and Uses Thereof, U.S. Patent No. 6,461,607 B1 (filed Aug. 5, 1999); Sys. and Method for Making Enhanced Cheese, U.S. Patent No. 6,120,809 (filed Oct. 28, 1998).

[19] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013).

basis and, more recently, on a global scale.[20] For some time now, connoisseurs as well as an increasing number of scientists have been claiming that a given region's signature combination of biotic and abiotic variables imparts a distinctive quality to wine.[21] More recently, these claims have been extended to other fermented products, such as cheese, sourdough breads, and other fermented beverages.[22] This so-called *microbial terroir* has become a buzz term in many food circles, but like its relative, *terroir*, it is still a nebulous and poorly defined concept.[23]

To properly situate debates over *terroir*, it is important to disentangle the term from microbial biogeography more generally. It is now well-established that some microbes can be found throughout the globe, while others can be found only on a limited geographical scale.[24] The notion of *terroir* not only acknowledges the centrality of local microbes in shaping local fermentation but goes one step further by linking microbial biogeography to traditional categories framing perception and practice.[25] As such, an understanding of the relationship between communities and their environments was of fundamental importance in shaping French regionalism during the nineteenth and twentieth centuries.[26] Although *terroir* literally translates as "earth" or "soil," it is more closely related to the notion of territory, derived from

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[20] *See generally* Éric Rouvellac, *Le terroir, essai d'une réflexion géographique à travers la viticulture*, 1 UNIVERSITÉ DE LIMOGES (2013) (Fr.) (discussing the definition of and origins of the term *terroir*); THOMAS PARKER, TASTING FRENCH TERROIR: THE HISTORY OF AN IDEA 15, 15-17 (2015) ("The word *terroir* is today most prevalent among culinary enthusiasts, who use it to map a food or wine to its specific place or origin.").

[21] AMY B. TRUBEK, THE TASTE OF PLACE: A CULTURAL JOURNEY INTO TERROIR 18 (2008).

[22] *See eAmbrosia*, EUR. COMM'N, https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/geographical-indications-register/ (last visited Mar. 19, 2022) (online database of agricultural products and foods registered and protected across the EU).

[23] Daniel Felder et al., *Defining Microbial Terroir: The Use of Native Fungi for the Study of Traditional Fermentative Processes*, 1 INT'L J. GASTRONOMY & FOOD SCI. 64, 69 (2012) (citing Heather Paxson, *Locating Value in Artisan Cheese: Reverse Engineering Terroir for New-World Landscapes*, 112 AM. ANTHROPOLOGIST 444 (2010) ("The importance of terroir is well understood as it relates to cuisine on a number of scientific and cultural levels, the recognition of microbial terroir is less well understood outside of cheese and wine-making.")).

[24] Kabir G. Peay, Martin I. Bidartondo & A. Elizabeth Arnold, *Not Every Fungus Is Everywhere: Scaling to the Biogeography of Fungal-Plant Interactions Across Roots, Shoots and Ecosystems*, 185 NEW PHYTOLOGIST 878 (2010) (emphasizing that some fungal species are highly endemic and disperse only on a local scale); Jennifer B. Hughes Martiny et al., *Microbial Biogeography: Putting Microorganisms on the Map*, 4 NATURE REVS. MICROBIOLOGY 102, 103-04 (2006).

[25] *See generally* TRUBEK, *supra* note 21, at 18.

[26] Tim Unwin, *Terroir: At the Heart of Geography*, *in* THE GEOGRAPHY OF WINE: REGIONS, TERROIR AND TECHNIQUES 37, 39 (Percy H. Doughtery ed., 2012).

the Latin *territorium*.[27] *Terroir* is more properly viewed as a defined geographic region in which communities have shared and developed their traditional knowledge in relation to the land. This definition goes beyond the more restricted idea that *terroir* is simply the confluence of physical environmental factors that favor the development of a distinctive *goût de terroir* ("taste of the territory").[28] *Terroir* is perhaps best seen as a community's symbiotic relationship with its local environment—a constructed biome favoring not only, for example, the cultivation of a unique grape cultivar, but also the microbial mélange of species that convene and find refuge in the vineyards. Consequently, the soil, plants, and microbiome—but also the traditional knowledge about how to create and care for all of the above—are properly seen as the patrimony of a community, contributing to a perceived *terroir* in the quality of their wine, cheese, shoyu, tequila, and so forth.

A definition of the biogeography and uniqueness of fermented food microbes requires that one define both taxonomic and biogeographic scales of microbial diversity. For some fermented foods such as wine, whose fermentation is dominated by just a few species, biogeographic patterns of microbial strains may matter most. For other fermented foods with more complex communities, both strain-level and community-level biogeographic patterns may emerge. The abovementioned question of the existence of a so-called *microbial terroir*—that is, the spontaneous presence of mainly bacteria and fungi unique to a fermentation process—has sparked further debate, as the geographic ranges of most microbes are unknown and largely depend on the definitions of species that are being employed and on the techniques that are being used to identify them.[29] Even greater difficulties arise from the unknown contributions of unique strains versus unique microbial communities; while some strains may be endemic to a specific region or fermentation process, the degree to which a fermented product's distinctiveness depends on a unique community of geographically-limited microbes is unknown.[30] This further complicates the applicability of geographically-limited intellectual property, as the domain wherein both strain- and community-level characterizations avail has yet to be legally defined, assuming doing so is technologically practical.[31]

Nonetheless, some find that abiotic environmental characteristics permit direct comparisons, and that in some cases there is a nonrandom biogeographic

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[27] *Id.*
[28] *Id.*
[29] *Eukaryotic Microbes*, *supra* note 12, at 1948.
[30] *See* Capozzi et al., *supra* note 4, at 229.
[31] *Id.*

pattern of specific fermenter microbial communities.[32] In their discussion of cheese rind microbial communities, Wolfe et al. show that in a sample of 137 types of cheese rind, 60% of the bacteria and 25% of the fungi are from non-starter culture species and therefore originate from environmental sources.[33] Moreover, species interactions and environmental factors select for communities with similar compositions, resulting in cheeses made in geographically distant parts of the world having strikingly similar rind communities.[34]

However, it is still unknown if microbial communities of the same type of cheese phenotypically differ sufficiently for us to be able to distinguish in them unique qualities that would justify speaking of a "*microbial terroir*." Modern data on strain- and community-level distinctiveness have led many to conclude that the unique qualities of artisanal fermented products are a direct result of unreproducible *terroir* and use them to justify geographically-confined intellectual property.[35] Recent evidence provides glimpses into how fermenter microbes confer a particular combination of characteristics, such as taste, odor, and texture.[36] For the paradigmatic example of wine, in 200 commercial wine fermentations, it is possible to distinguish viticultural areas and individual vineyards by their microbial consortia and unique chemical composition.[37] The diversity and quantity of microbes present in the soil and on the vine determine both the health of the grape and the eventual microbiome introduced during the fermentation and wine maturation processes. Vintners both directly and indirectly select for fungi and bacteria that not only effectively convert sugar and malic acid into wine, but also outcompete undesired microbes that could cause product toxicity or spoilage.

Although there are examples of population structure correlating to product quality among fermenting microbes, many unknowns linger even for the best-studied fermentation processes. Are species abundance and community structure an

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[32] *See* Helder Fraga et al., *Integrated Analysis of Climate, Soil, Topography and Vegetative Growth in Iberian Viticultural Regions*, 9 PLOS ONE 7 (2014); Edna F. Arcuri et al., *Determination of Cheese Origin by Using 16S rDNA Fingerprinting of Bacteria Communities by PCR–DGGE*, 30 FOOD CONTROL 1, 1-6 (2013); Nicholas A. Bokulich et al., *Associations Among Wine Grape Microbiome, Metabolome, and Fermentation Behavior Suggest Microbial Contribution to Regional Wine Characteristics*, MBIO 1 (2016).

[33] Benjamin E. Wolfe et al., *Cheese Rind Communities Provide Tractable Systems for In Situ and In Vitro Studies of Microbial Diversity*, 158 CELL 422 (2014).

[34] *Id.*

[35] Caroline Herody et al., *The Legal Status of Microbial Food Cultures in the European Union: An Overview*, 5 EUR. FOOD & FEED L. REV. 258, 258-59 (2010).

[36] Demarigny Yann & Gerber Pauline, *Usefulness of Natural Starters in Food Industry: The Example of Cheeses and Bread*, 05 FOOD & NUTRITION SCIS. 1679, 1686 (2014).

[37] Bokulich et al., *supra* note 32, at 1, 5.

influence on phenotype and product quality? Or are they simply correlates driven by other causes?[38] Even if some general qualities imparted by endemic phenotypes contribute to a product's overall distinctiveness, the scientific community is still unclear as to which are responsible for this process.[39]

II
GEOGRAPHY AND INTELLECTUAL PROPERTY REGULATORY SYSTEMS

A. Transnational Protection

The World Intellectual Property Organization (WIPO), a division of the United Nations based in Geneva, offers guidelines for the international and national regulation of intellectual property. However, it is the Paris Convention on Trademarks (1883), still in force with 176 members, and the more elaborate provisions contained in the 1958 Lisbon Agreement on the Protection of Appellations of Origin and Their Registration that set the parameters for geographically based intellectual property. The legal structure for appellation registration originated from the French wine industry's concept of *terroir* (that is, the notion that specific locations impart unique qualities on specific products).[40] In the twentieth century, a formal appellation system began to provide a legal basis for protecting products explicitly by their geographic origin.[41] Systems parallel to the French *appellation d'origine contrôlée* (AOC) have since developed across Europe and other regions.[42] Products with controlled appellations are required to adhere to a

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[38] Danilo Ercolini et al., *Microbial Diversity in Natural Whey Cultures Used for the Production of Caciocavallo Silano PDO Cheese*, 124 INT'L J. FOOD MICROBIOLOGY 164, 170 (2008).

[39] Alessandro Martini, *Origin and Domestication of the Wine Yeast* Saccharomyces cerevisiae, 4 J. WINE RSCH. 165, 166 (1993); Jared Diamond, *Evolution, Consequences and Future of Plant and Animal Domestication*, 418 NATURE 700, 704 (2002); Justin C. Fay & Joseph A. Benavides, *Evidence for Domesticated and Wild Populations of* Saccharomyces cerevisiae, 1 PLOS GENETICS 0066 (2005).

[40] Rouvellac, *supra* note 20; Fraga et al., *supra* note 32, at 9; PARKER, *supra* note 20; Ignacio Belda et al., *From Vineyard Soil to Wine Fermentation: Microbiome Approximations to Explain the "Terroir" Concept*, 8 FRONTIERS MICROBIOLOGY 821 (2017); Mark A. Matthews, *The Terroir Explanation*, *in* TERROIR & OTHER MYTHS OF WINEGROWING 146, 146-206 (1st ed. 2015); Unwin, *supra* note 26.

[41] Loi du 6 mai 1919 relative à la protection des appellations d'origine [Law of May 6, 1919 Relating to the Protection of Designations of Origin], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE, May 8, 1919, p. 4725.

[42] *See, e.g.*, Lei n.˚ 8/85 de 4 de junho [Act no. 8/85 of 4 June], igf.gov.pt/leggeraldocs/LEI_008_85.htm, amended by Decreto-Lei n.º 212/2004 de 23 de Agosto [Decree-Law no. 212/2004 23 August], https://www.igf.gov.pt/leggeraldocs/DL_212_2004.htm#ARTIGO_23 (Portuguese legal

set of rigorous and clearly-defined standards, failure to comply with which results in a prohibition against manufacturing and selling a product under, for example, AOC control.

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the current principal basis for the international protection of goods. "Geographical indications" (GIs) mark goods "originating in the territory of a member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographic origin."[43] In practice, there exist two categories of registered GIs, namely Protected Designation of Origin (PDOs), whereby the entire product must be traditionally and entirely manufactured (prepared, processed, and produced) within a specific region, and Protected Geographical Indications (PGIs), for cases in which at least one of the stages of production, processing, or preparation takes place in a given region.[44] Among the most famous products within the context of fermented foods are Champagne (PDO, AO 243), Comté Cheese (PGO, AO 455), Stilton Blue Cheese (PGI), and Parma Ham (PDO, WIPO AO 843).[45] In 2015, the Geneva Act to the Lisbon Agreement was adopted, formally recognizing GIs as extending certain property rights to producers on a geographic basis.[46]

The main characteristic that distinguishes GIs from other intellectual property rights is that they are based on traditions held by communities of people, owned and exercised collectively. The main advantage of GIs is the "relative impersonality" of

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framework indicating requirements for the labelling of wine to indicate designations of origin and geographical indications). In addition, the European Union introduced the protection of geographical indications and designations of origins in 1992. *See* Council Regulation 2081/92 of 14 July 1992 on the Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs, 1992 O.J. (L 208) 1, 1-8. One example of this protection is in Greece: "Protected Designation of Origin (PDO) Wines" of Greece are required to display certain geographical indications and information on their labels; in essence, the wines originate in "the historical winegrowing and winemaking areas of Greece." *Wine categories*, WINES OF GREECE, https://winesofgreece.org/articles/wine-categories/ (last visited Apr. 12, 2022).

[43] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 22, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].

[44] *Quality Schemes Explained*, EUR. COMM'N, https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/quality-schemes-explained_en#pdo (last visited Mar. 22, 2022).

[45] Dominique Barjolle & Bertil Sylvander, *PDO and PGI Products: Market, Supply Chains and Institutions* (2000).

[46] Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms, Oct. 29, 1971, 866 U.N.T.S. 67.

the right; the subject matter is first and foremost protected (for example, an orange for "Florida Oranges") and therefore not dependent on a specific rights-holder.[47] Much like trademarks, GIs confer the exclusive right to use the designation, albeit within a certain geographic area. However, while a trademark is not inherently capable of being descriptive of the goods or services,[48] a GI is descriptive by definition as its very purpose is to distinguish a product or service from competitors by its geographical origin. Therefore, one shortcoming of GIs is that in many countries they cannot be registered as a trademark in a jurisdiction that would insufficiently distinguish the product or where GIs as such are unrecognized.

B. Branding Microbiota: EU vs. US

Due to national differences in regulation and standards, international disputes pertaining to name usage have developed between the EU and US.[49] Linking food products to specific environmental conditions remains a contentious practice of international trade, and the European and US approaches to the matter markedly contrast. The results of the Uruguay round of the General Agreement on Tariffs and Trade (GATT), later incorporated into TRIPS legislation, set a framework for regulating GIs internationally with the WTO arbitrating disputes. However, the WTO has proven inconsequential in significantly penalizing what the EU denounces as US, Australian, and New Zealand's violations of TRIPS. Specifically, Article 23 of TRIPS stipulates that each signing member must enact laws preventing the use of GIs that do not originate from a designated geographical location, focusing mainly on wines and spirits.[50] Nonetheless, many US producers continue to legally use European GIs due to an exception, outlined in Article 24, to Article 23's general prohibition of the continued use of geographical indications. As many US producers have used European GIs for decades, producers who began production 10 years before TRIPS (April 15, 1984) are authorized to use generic names, such as "Burgundy" or "Chianti." As a result, a regulatory disparity between New- and Old-World wines or other fermented food products remains unaddressed. Despite international efforts to harmonize intellectual property on a global scale, dissonance

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[47] Felix Addor & Alexandra Graziol, *Geographical Indications Beyond Wines and Spirits: A Roadmap for a Better Protection for Geographical Indications in the WTO/TRIPS Agreement*, 5 J. WORLD INTELL. PROP. 865, 894 (2002).

[48] *See* TRIPS Agreement, *supra* note 43, at art. 15.1.

[49] *Cf.* Michael Handler, *The WTO Geographical Indications Dispute*, 69 MOD. L. REV. 70 (2006).

[50] TRIPS Art. 23. For a discussion of the geographical provisions of the TRIPS agreement, see generally Leigh Ann Lindquist, *Champagne or Champagne? An Examination of U.S. Failure to Comply with the Geographical Provisions of the TRIPS Agreement*, 27 GA. J. INT'L & COMP. L. 309 (2014).

among national GI doctrines continues to make their cross-border enforcement more precarious than that of most other forms of intellectual property.

Notably, the US is party neither to the original Lisbon Agreement nor to the more recent Geneva Act. Additionally, there has been considerable difficulty in regulating such appellations on an international scale, despite trade agreements such as the Lisbon Agreement and TRIPS. The predominantly EU institutions of GI are regarded in the US more as hindrances to the free market—inasmuch as they narrow competition and fix capital on a geographic basis—although a reduced appellation system has been enforced in some cases—for example, in certain US wine-growing regions, for which 85% of the wine must have been produced from grapes grown in one of 239 American Viticultural Areas (AVA).[51] The principal means by which products are recognized in the US is instead trademarks, identifying a good or service as originating from a particular company or individual. Unlike GIs, which are usually predetermined by the name of a geographical area, trademark law has no explicit geographic component. A trademark can make reference to a place with or without an actual association to said location, for example the Idaho Potato Commission's "Idaho Potatoes" and "Grown in Idaho" registered trademarks for potatoes.[52] Various standards of identity are also in place in the US (for example, for dairy products) under the United States Code of Federal Regulations, which are essentially quality standards for products to be labeled under specific categories. Examples include US products such as "Munster (133.160)," "Gorgonzola (133.141)," and "Parmesan and Reggiano (133.165)" cheeses—brands otherwise protected in the EU (under AO 505, 927, 513).

Nonetheless, some legal mechanisms are already in place in the US by which producers of fermented foods can obtain intellectual property rights within the context of fermentation biotechnologies in lieu of securing direct protection of their microbiota. Trademark law is the most established legal framework for producers to secure intellectual property protection for artisanal fermented foodstuffs on a geographic basis. While the US Patent and Trademark Office generally prohibits the registration of place names as part of a trademark, geographic signs may be protected if "it is clear that they are meant to convey some meaning other than geographic origin."[53] Examples relevant to fermented foods include WISCONSIN DAIRIES

[51] *See* 27 U.S.C. § 9 (2022).

[52] IDAHO POTATOES, Registration No. 2,934,385; GROWN IN IDAHO, Registration No. 2,914,309.

[53] *See* K. William Watson, *Reign of Terroir: How to Resist Europe's Efforts to Control Common Food Names as Geographical Indications*, CATO INSTITUTE, Feb. 16, 2016, at 1, 2, https://www.cato.org/policy-analysis/reign-terroir-how-resist-europes-efforts-control-common-food-names-geographical.

(Registration No. 1298995) and JEFFERSON'S RESERVE VERY OLD KENTUCKY STRAIGHT BOURBON WHISKEY (Registration No. 3505374). In the case of many natural starters, trademarks that specify both the product (such as cheese) and the region (such as "Vermont Alehouse Cheddar," Serial No. 85221576) provide a straightforward method by which fermented food producers can secure intellectual property rights for both the quality of their products and the microbial communities presumably unique to their production methods, materials, and facilities.

Regional cooperatives can also register products using "Collective Marks" or a "Certification Mark," which differ slightly from the more traditional trademark. The owner of a Certification Mark cannot produce the product or use the mark itself; rather, the Certification Mark regulates its usage on behalf of a given consortium or guild in order to certify, among other things, a product's regional origin and quality.[54] Among the most cited examples of the ability of Collective Marks to confer geographic attribution in the US are MISSOURI WINES and NAPA VALLEY.[55] Similarly, Collective Marks indicate that the user is a member of a particular organization without indicating the origin of goods or services.[56] Thus, depending on the nature of intellectual property protection sought by businesses dependent on natural starters, product-specific cooperatives could be formed on a geographic basis, ensuring that a brand's quality goes hand in hand with its geographic origin.

In the US, intellectual property law concerning GIs is mostly privately enforced (that is, litigating infringement is at the discretion of private holders of, for example, a given trademark). European legislation, more keen to uphold the concept of *terroir* and national patrimony, delegates regulation of GIs to both national and supranational regulating bodies.[57] While the US initiated the development of the TRIPS Agreement, the EU has since been the greatest advocate for Article 23 and the international protection of GIs.[58] While GIs are criticized as protectionism and an attempt to limit commerce on a geographic basis, the EU contends that strict government protection of GIs ensures that producers not only be located in a specific region but also conform to highly-controlled production directives and quality standards.[59] Among the most common examples of such products are Parmigiano-

[54] 15 U.S.C. § 1054.

[55] MISSOURI WINES, Registration No. 3606768; NAPA VALLEY, Registration No. 4853438.

[56] *See* Lanham Act, 15 U.S.C. §1127.

[57] *See* Watson, *supra* note 53, at 1.

[58] Lindquist, *supra* note 50, at 310-11, 343.

[59] *Id.*

Reggiano cheese and Champagne,[60] for which European law stipulates not only the specific methods that must be employed in order to qualify as a given GI product (such as exact cheese ripening time, specific pasteurization techniques, and precise additive measures), but also the regions in which a product can be produced.[61]

In the case of European fermenter microbes, the microbial communities unique to a region are implicitly protected by a given GI. Nonetheless, the recent interest of American consumers in locally produced and fermented foods, paired with the booming US intellectual property market, set the stage for expanded use of existing US legal protection for industries that rely on microbial fermentation.[62] Since the 1990s, more than one-third of all milk produced by volume in the US has diverted to cheese production, in contrast with just 11% during the period between 1953 and 1960.[63] Likewise, regional craft beer production in terms of total barrels produced has increased by over 300% from 2004 to 2016, while contract breweries have decreased by over 60%.[64] Consumer demand in the US will likely cause a major shift among producers, who will increasingly seek intellectual property protections more in line with a European model. However, they will most likely look to trademarks and similar branding options.

III
MICROBIOME, TRADITIONAL KNOWLEDGE, AND TRADE SECRECY

The burgeoning field of microbiome technologies offers a challenging context for traditional notions of intellectual property protection. Patents are often unavailable, with the US Patent and Trademark Office maintaining that a mixture of otherwise unaltered bacteria is patent ineligible as a "manifestation of laws of nature."[65] Moreover, GIs and trademarks are often unenforceable. However, trade

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[60] *See* Deborah J. Kemp & Lynn M. Forsythe, *Trademarks and Geographical Indications: A Case of California Champagne*, 10 CHAPMAN L. REV. 257, 258, 274, 279-80 (2007).

[61] *See, e.g.*, Décret 2010-1441 du 22 novembre 2010 relatif à l'appellation d'origine contrôlée «Champagne» [Decree 2010-1441 of November 22, 2010 related to the controlled designation of origin "Champagne"]; Légifrance: Le Service Public de la Diffusion du Droit, Apr. 6, 2022; 2018 O.J. (C 132) 7, (product specification of "Parmegiano Reggiano," published in the *Official Journal of the European Union*).

[62] *See* INNOVATIONS, *supra* note 2; Sheikha, *supra* note 2.

[63] INT'L DAIRY FOODS ASS'N, DAIRY FACTS 4 (2003).

[64] *National Beer Sales & Production Data*, BREWERS ASS'N, https://www.brewersassociation.org/statistics-and-data/national-beer-stats/ (last visited Apr. 8, 2022).

[65] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

secret law offers both a promising and perilous alternative route for protecting technologies associated with environmental nucleotide sequencing.

A. The Microbiome as Traditional Knowledge

To the definitions of *terroir* provided above, there may be added the view according to which *terroir* is collective knowledge held by a community over generations. As a result, requirements such as time limitations and author attributions demanded by most intellectual property systems appear to be poorly suited for protecting *terroir*. In particular, the microbial components of *terroir* pose a special challenge for intellectual property doctrines, as many would characterize the assorted fungi and bacteria inhabiting traditional fermented foods as naturally occurring.[66] Fortunately, recent international initiatives have begun to emphasize the importance of protecting "traditional knowledge," either by grafting it onto conventional notions of intellectual property or by proposing *sui generis* systems by which local communities' knowledge can be protected.

1. Defining "Genetic Resources"

Local communities often live in close association with other species, using them in agriculture, medicine, craft, and religious or spiritual practices. As a result, communities often seek protection for so-called "genetic resources," especially in the face of increasing bioprospecting, which deprives them not only of components of their cultural heritage but also of the fair and equitable sharing of benefits derived from the increasingly industrial production of resources cultivated locally over generations.

International and national leaders struggle with defining protections for "genetic resources" in the context of traditional knowledge. The United Nations Conference on Environment and Development (more commonly referred to as the Rio Earth Summit) brought 178 nations together in Rio de Janeiro, Brazil in 1992. While the summit focused on the environmental and resource issues facing world economies, its most lasting effect with respect to intellectual property was arguably the signing of the Convention on Biological Diversity (CBD).[67] In addition to sounding a global call to conserve biodiversity and promote the sustainable use of biological resources, the CBD explicitly demands the fair and equitable sharing of benefits arising from the utilization of genetic resources.[68] The protocol currently

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[66] *Id.*

[67] Convention on Biological Diversity, *opened for signature* June 5, 1992, 1760 U.N.T.S. 69 (entered into force Dec. 29, 1993), https://www.cbd.int/convention/text/.

[68] *Id.* at arts. 15, 16, 19.

has 105 parties (with the United States notably absent), 92 of which are signatories committed to implementing national-level benefit sharing policies.

Article 2 of the CBD defines "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity." Genetic materials include "genetic resources," which are defined as "genetic material of actual or potential value," and include isolated and/or sequences of DNA, RNA, and proteins.[69] Notably, human genetic resources do not fall within the scope of the CBD nor the Nagoya Protocol.[70] Though being an important first step toward protecting genetic resources, the CBD did not implement any formal language recognizing the rights of local communities, nor any that easily facilitated the integration of their knowledge within national and international intellectual property regimes.[71]

It would be another 18 years before further UN discussions took form as a supplementary text to the original CBD: 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, or simply the "Nagoya Protocol." The Nagoya Protocol establishes roles and mechanisms protecting traditional knowledge of genetic resources while also supporting the fair and equitable sharing of benefits for their utilization.[72]

Crucially, the Nagoya Protocol sets out clearer guidelines for the "utilization" of genetic resources, as defined in Article 2(c) as "research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."[73] This definition effectively expands the interpretation of genetic resources to all forms of biotechnology, which is also defined in Article 2(d) as "any technological

[69] *Id.* at art. 2.

[70] *See* Decision II/11, "Access to Genetic Resources," as published in Conference of the Parties to the Convention on Biological Diversity, *Report of the Second Meeting of the Conference of the Parties to the Convention on Biological Diversity*, p. 64, U.N. Doc. UNEP/CBD/COP/2/19 (Nov. 6-17, 1995); 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, *opened for signature* Feb. 2, 2011, U.N.T.S. A-30619 (entered into force Oct. 12, 2014), https://www.cbd.int/abs/text/ [hereinafter Nagoya Protocol].

[71] Libby Liggins, Māui Hudson & Jane Anderson, *Creating Space for Indigenous Perspectives on Access and Benefit-Sharing: Encouraging Researcher Use of the Local Contexts Notices*, 30 MOLECULAR ECOLOGY 2477, 2477 (2021).

[72] *Id. See also* Michael Heinrich et al., *Access and Benefit Sharing Under the Nagoya Protocol — Quo Vadis? Six Latin American Case Studies Assessing Opportunities and Risk*, 11 FRONTIERS PHARMACOLOGY 765, 776 (2020).

[73] Nagoya Protocol, *supra* note 70.

application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." Interestingly, "derivatives" are further defined in Article 2(e) to include any naturally occurring biochemical compound, even if they do not contain "functional units of heredity."[74]

While Article 16 of the CBD recognizes the impact of intellectual property policy on access to benefit sharing, detailed mention of intellectual property is surprisingly absent from the Nagoya Protocol. Nonetheless, the Protocol does require signatories to formulate fair and non-arbitrary procedures for access to genetic resources, as well as guidelines when applying policy related to Free, Prior, and Informed Consent (FPIC) within the context of trade deals and permit applications.[75]

The microbiome is composed of the bacteria, archaea, fungi, viruses, and microscopic eukaryotes present in any given environment—groups of organisms rarely visible to the naked eye and consequently less readily imagined than goats or corn. Although such microbes contain genetic material, whether they are considered as genetic resources according to the Nagoya Protocol is somewhat unclear. Part of the uncertainty has to do with whether the Nagoya Protocol included digital sequence information, which includes digital sequences of DNA, RNA, proteins, metabolites, the epigenome, and so forth. Environmental DNA sequencing techniques, whereby all the microbes present in a single sample can be sequenced at once, are typically employed to identify organisms present in a microbiome. Once identified, the organism itself seems to fit easily within Nagoya's definition of "genetic material" (that is, "any material of plant, animal, microbial or other origin containing functional units of heredity").[76] More difficult, however, is the not uncommon occurrence of an unnamed and undescribed species whose presence in a microbiome is only represented by digital sequence information. This issue may be especially poignant in the context of traditional fermented products, as years of evolutionary divergence from "natural" source populations paired with a strongly-selective environment—for example, saline dried meat skin or very acidic balsamic vinegar—will often result in sequences that poorly match named sequences in preexisting databases. Nevertheless, once the key players in a microbiome are identified, their isolation and use are presumably encompassed by the same

[74] *Id.*

[75] U.N. Conference on Trade and Development, *The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications*, 14-15, U.N. Doc. UNCTAD/DIAE/PCB/2014/3 (2014).

[76] Convention on Biological Diversity, *supra* note 67, at 3 (Article 2 defines the term "genetic material" as it is to be used for the purposes of the Convention on Biological Diversity, including use in the Nagoya Protocol).

definition of genetic material as when the definition is applied to the familiar non-microscopic animal or plant.

2. Defining "Traditional Knowledge"

"Traditional knowledge" is by necessity a general term given the diversity of Indigenous and local communities across the globe. It is typically defined as a body of knowledge collected and cultivated by a group of people across generations.[77] In the context of communities' living surroundings, traditional knowledge often includes a classification of organisms, observations about the local environment, and details on its stewardship.[78] Analogous to, yet distinct from, Western notions of science, traditional knowledge represents a unique body of knowledge that is often transmitted orally, compiled in qualitative terms, rooted in a community's social context, and collected.[79]

From an intellectual property point of view, traditional knowledge is defined by the World Intellectual Property Organization as "tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[80] Knowledge may be considered "traditional" as long as, at its creation and use, it is alive as part of a community's cultural traditions; the term does not need to imply that the knowledge itself is ancient or fixed.[81]

Given accepted definitions of genetic resources and traditional knowledge, it is appropriate to consider the former as a subset of the latter, especially in the context of artisanal fermented products. The unique composition of organisms present in a microbiome goes hand in hand with the distinctive qualities of a fermented product. These qualities are the direct product of generations of a community managing and

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[77] Jacob Golan et al., *Intellectual Property Rights and Ethnobiology: An Update on Posey's Call to Action*, 39 ETHNOBIOLOGY 90, 104 (2019); Daniel Gervais, *Traditional Knowledge & Intellectual Property: A TRIPS-Compatible Approach*, 2005 MICH. STATE L. REV. 137, 140-41 (2005).

[78] Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RSRV. J. INT'L L. 233, 240 (2001).

[79] *Id.* at 241.

[80] WORLD INTELL. PROP. ORG., INTELLECTUAL PROPERTY NEEDS AND EXPECTATIONS OF TRADITIONAL KNOWLEDGE HOLDERS 25 (2001) ("'[T]radition-based' refers to knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment.").

[81] Gervais, *supra* note 77, at 140.

selecting for favorable strains indirectly through collective observation, sharing, and building of communal knowledge. Properly understood, the fostering of a traditional microbiome is the very essence of traditional knowledge, no different from the transmission of knowledge on shamanism or midwifery from one generation to the next.

3. Traditional Knowledge as Trade Secret

Having argued that the microbiome should be viewed as a genetic resource, and as such can be reinterpreted as a form of traditional knowledge in the context of local communities, legal protection for the microbiome enters into sight. Trade secrets emerge as the most versatile option for protecting the naturally occurring yet meticulously cultivated microbiome found within local fermentation processes. Trade secrets appear as a sensible option in part due to their relatively less rigid requirements when compared to other forms of intellectual property protection: the information need not be novel or nonobvious, and even slight improvements to established methods or know-how qualify. Furthermore, a local community is not necessarily required to have commercialized the information, but merely to show potential economic value.[82]

More specifically, trade secret law functions without patent law's rigid requirements. The microbiome as traditional knowledge fails on multiple requirements of patentability: the microbiome is naturally occurring, despite local communities' cultivation of specific conditions, and consequently it fails the novelty requirement of patentability. Furthermore, as the local microbiome has been kept by many over generations, patent law's requirement that there be identifiable inventors could not be fulfilled.[83] Trade secrets, on the other hand, are well-suited for information that is intermutually held, whether by a corporation or a local community. Despite trade secret law applying only to relatively secret, rather than publicly available, information, communities are free to share information among themselves as well as operationalize the information with "outsiders," provided explicit understandings exist that the information is to remain a secret.[84] One seeming limitation is that, for example, Indigenous and local communities cannot point to contracts or other written instruments to demonstrate efforts to keep knowledge secret. However, "reasonable secrecy" is treated by courts as a flexible

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[82] Jorge L. Contreras, *Genetic Property*, 105 GEO. L.J. 1, 43-44 (2016).

[83] Iraj Daizadeh et al., *A General Approach for Determining When to Patent, Publish, or Protect Information as a Trade Secret*, 20 NATURE BIOTECHNOLOGY 1053, 1053-54 (2002).

[84] Deepa Varadarajan, *A Trade Secret Approach to Protecting Traditional Knowledge*, 36 YALE J. INT'L L. 371, 397, 401, 405 (2011).

standard, and one that importantly relies on factual circumstances, including evidence of custom.[85]

Temporal limitations of exclusivity also render other forms of intellectual property inappropriate, as not only does the local microbiome require decades to develop, but traditional knowledge is also something to which a community often desires entitlement indefinitely. Trade secrecy operates indefinitely and is therefore well-suited for protecting inter-generational knowledge. Such indefinite protection also follows from the lack of formal registration for trade secrets, at least in the US. In contrast to patents—the application process for which is arduous and requires ample financial and technical resources—trade secrets are created simply by an entity keeping a given pool of information secret. Enforcement of the trade secret flows from misappropriation of the knowledge. For example, local Shoyu producers can informally maintain trade secrecy over the microbiome cultivated in their soybean fermentation vats; were a party to misappropriate an unauthorized culture of the vat microbiome, these producers could enforce trade secrecy rights over the microbiome.[86]

Despite its breadth and flexibility, trade secret law offers weaker exclusionary rights than, for example, patent law. In particular, the property entitlement that trade secrets offer extends only to improper obtainment of information, in contrast to other forms of intellectual property whose exclusionary attributes extend further.[87] Moreover, neither independent creation by another party nor reverse engineering are protected under trade secret law. In the context of the fermentation microbiome, several precautions can help mitigate these gaps in protection. First, limiting access to fermentation facilities obviously prevents non-traditional-knowledge-holders from sampling genetic material. Even though the microbiome may go hand in hand with the cultivated product—allowing parties to directly appropriate the microbiome from the product itself—this risk can be avoided through sterilization or pasteurization of fermented products prior to making them available to the public. Although sterilization and pasteurization do not completely prevent outside parties from identifying species present in the microbiome (for example, through environmental DNA sampling of dead cells), this process substantially reduces the ease with which the microbiome can be propagated and reproduced.[88] Furthermore,

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[85] *See, e.g.*, 18 U.S.C. § 1839(3)(A)–(B); Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 277 n.161 (1998).

[86] *See, e.g.*, Nicholas A. Bokulich et al., *Indigenous Bacteria and Fungi Drive Traditional Kimoto Sake Fermentations*, 80 APPLIED ENV'T MICROBIOLOGY 5522 (2014).

[87] Varadarajan, *supra* note 84, at 397.

[88] Golan et al., *supra* note 77, at 90.

mere knowledge of which species are present is unlikely to enable full reproduction of the microbiome, as the unique environment and substrate on which fermenter microbes are cultivated will be unknown to potential usurpers.

CONCLUSION

The production of artisanal, small-batch fermented foods has expanded worldwide, highlighting critical issues of how best to identify and legally protect the microbial ecosystems that make them unique. However, traditional forms of intellectual property are poorly suited for protecting these microbial communities.

Instead, trade secrets provide the most practical and versatile means of addressing ownership of the microbiome of artisanal fermented foods. Moreover, the microbiome itself should be viewed as a genetic resource, understood in several contexts as a form of traditional knowledge. The ongoing global initiative to recognize traditional knowledge as the patrimony of local communities, deserving of some form of property entitlement—whether by existing intellectual property mechanisms or *sui generis* systems—suggests a general willingness of national and international governing bodies to recognize the microbial constituents of artisanal fermented products protectable as trade secrets. It is through trade secrets that the law can properly bridge the intersection of microbial diversity and the intellectual property therein, providing protection for the ever-expanding technology of artisanal fermented foods.