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Supplementary Materials for

Corporate control and global governance of marine genetic resources

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The PDF file includes:

Other Supplementary Material for this manuscript includes the following:
(available at advances.sciencemag.org/cgi/content/full/4/6/eaar5237/DC1)

- data file S1. Raw data, species data, patent registration data, owner data, and data aggregations section (Excel file).

Basics of gene patents

A gene patent is the exclusive rights – or the legal documentation that defines the protection area – to a specific isolated sequence of DNA (a gene), a modified natural genetic sequence, the actual processes and methods for obtaining or utilizing biological material, or a combination of these. Patents are typically granted by a government to an individual, institution, or corporation. Once a gene patent has been granted, patent holders may specify the terms of a given gene's utilization, in commercial (e.g., clinical testing), and noncommercial settings (e.g., research) for 20 years from the date of patent issuance (*45*).

While a sense of standards in patent practice exists worldwide, regulatory principles, including for instance the publication and provision of sequence listings (*46*), vary markedly among countries based on what each nation determines to be an adequate balance between compensating innovation and creativity, and ensuring the community at large benefits from improved technologies. Consequently, gene patents are considered particularly contentious and poorly understood in the intellectual property arena (*47*). The frontiers of genetic research are rapidly expanding, posing a significant challenge to the formulation and processing of corresponding patenting procedures. The constantly evolving legal and regulatory framework serve, in turn, to reinforce the complexity associated with understanding the patent landscape and difficulty of effective monitoring and compliance.

Types of patent applications

Patents can be country-specific or they can provide protection in a number of different countries. In case of the former, a patent obtained in Canada, for instance, applies only in Canada and does not prevent infringement anywhere else. This type of patent is typically obtained when a discovery is of economic interest at national scale only and is associated with less costly and complex filing procedures. If international protection nevertheless becomes of interest, and the original patent was filed in a state that is party to the Paris Convention for the Protection of Industrial Property separate patent applications can be sought in relevant countries within 12 months of the original filing date (www.wipo.int/treaties/en/text.jsp?file_id=288514). Individuals or companies interested in international protection can otherwise also file multiple separate applications at the same time in all of the countries of interest.

Alternatively, for a more cost-effective broad protection, patent applications can be filed with the World Intellectual Property Organisation (WIPO) under the Patent Cooperation Treaty (PCT) – an international patent law treaty that entered into force in 1978 and facilitates protection simultaneously in a large number of countries. Such applications have two phases: the submission of a single claim by a national of a PCT contracting state to a competent patent office or the WIPO; and the transfer of patent claims to contracting states where protection is sought (or the regional European Patent Office (*48*)). While applications are often first filed as PCT applications and subsequently transferred to the European Patent Office (EPO) (*49*) inventors can also directly file for patent protection with the EPO where they undergo one central examination and granting process. This transfer is time-limited – around 30 months with early entry into the national phase possible, if requested – but

provides a delay compared to patent filing under the Paris Convention, granting companies more time to engage in strategic partnerships, seek funding, and find markets, before their invention becomes public. Patents are therefore not granted until the process enters the ‘national phase’, with acceptance or rejection of patent applications remaining under the control of national or regional patent issuing authorities, based on local applicable laws. Paying attention to differences in national-level regulatory requirements among countries at the time of filing is important. For example, in the U.S., Canada and Japan a company can legally file and obtain a patent for an invention up to 12 months after it has disclosed its invention to the public (*50*). However, the majority of patent offices, including the WIPO and the European Patent Office require that a patent application be filed *prior* to any disclosure of the invention.

For further details related to the PCT patent application process, including associated fees, we refer the reader to the WIPO’s website: http://www.wipo.int

What can be patented?

Patents are typically granted on discoveries that satisfy the criteria of functionality (of the genetic sequence itself or the amino acid it encodes); novelty; non-obviousness, also referred to in the literature as ‘inventive step’; enablement; usefulness or industrial applicability (*51*). Accordingly, a number of Latin American countries consider the isolation of genetic material, despite the complexity of the task, a discovery, rather than innovation and therefore natural substances, even when purified, isolated or characterized, cannot be associated with a patent (*52*). The Australian High Court and the United States Supreme Court both ruled in pivotal high

profile cases (*53, 54*) that discovering the location of specific genes or simply isolating a specific sequence from its surrounding genetic material, do not render the genes eligible for patenting. This ruling, in the U.S. at least, does not prevent the patenting of artificial DNA sequences (e.g., complementary DNA) (*55*) or CRISPR (clustered regularly interspaced short palindromic repeats)-modified gene sequences from being associated with patents (*51*).

In Japan, the E.U., the U.K. and Canada, isolated genomic sequences can still be associated with patents (*56*). The European Union directive 98/44/EC (the Biotech Directive) allows for the patenting of natural biological products (*57*), *as long as* they are "isolated from [their] natural environment or produced by means of a technical process." (Rule 23e (2) EPC and 23c(a) EPC). Thus, under the European Patent Convention and individual contracting states, companies may patent naturally occurring gene sequences, without having had to first modify them (Rule 23c(a)).

What needs to be included in a patent application?

Patent applications are complex and typically require a qualified attorney to successfully navigate the relevant regulatory and format rules. A number of Chief Justices in the U.S. have stated that “drafting the specification and claims of a patent application constitutes one of the most difficult legal instruments to draw with accuracy” (*58, p. 9-12*). Depending on the chosen filing procedure, patent applicants will have to check with relevant authorities and qualified personnel how to draft a claim. In all instances, as claims delineate exactly the subject matter over which the applicant is entitled to exclude others from developing, using, or selling, they will need to be detailed, showcase novelty, non-obviousness and industrial utility, and in

the case of marine genetic resources (MGRs) typically contain a description of the gene's protein sequence and its specific role or function (*59*). Any industrial application must also be disclosed when filing with the European Patent Office (Rule 23c (3), T 0870/04 (BDP1)).

Benefits associated with gene patents

Direct benefits to the inventor associated with the utilization of gene patents are commonly financial in nature and can also include the opportunity to lead in a given research and development field without competition. However, some argue that on balance, patents linked to genetic resources hinder innovation and that promoting unrestricted access to genetic sequences, especially in the health and medical arena, contributes to the public good (*60*). Once a gene or process is associated with a patent, users of the patented technology or its commercial application will need to license or pay for it, providing returns on initial investments for the patent holder. The latter tend to be considerable given that accessing genetic resources, especially in areas beyond national jurisdiction (ABNJ), and processing biological material are extremely costly. It requires the deployment of complex instrumentation as well as the application of advanced technological capacity. The monopoly that gene patents create can also stimulate research and development in the private sector and is critical to attracting investments fostering innovation.

The monetary and non-monetary benefits arising from the utilization of MGRs, in the context of the Nagoya Protocol to the Convention on Biological Diversity, can be manifold and are to be mutually agreed upon through negotiations between the user and the provider. They can include access to research results; employment of local

staff; joint promotion of intellectual property; capacity building as well as knowledge and technology transfer at provider level; and a percentage of royalty payments derived from the commercialization of transferred biological resources (including profits earned by third parties under license arrangements) (*10*). In Papua New Guinea, for instance, some of the benefits the University of Minnesota and Utah have committed to provide to their local counterparts through the 'Sustainable Use of Biodiversity in Papua New Guinea' Project, include: education and training through projects for locally registered university students; workshops; updated laboratory facilities and equipment; improved or new infrastructure; co-authorship of publications; financial support (e.g., travel costs, field supplies) for collection expeditions and herbaria activities; postgraduate fellowships; and direct financial compensation to the University of Papua New Guinea (*61*).

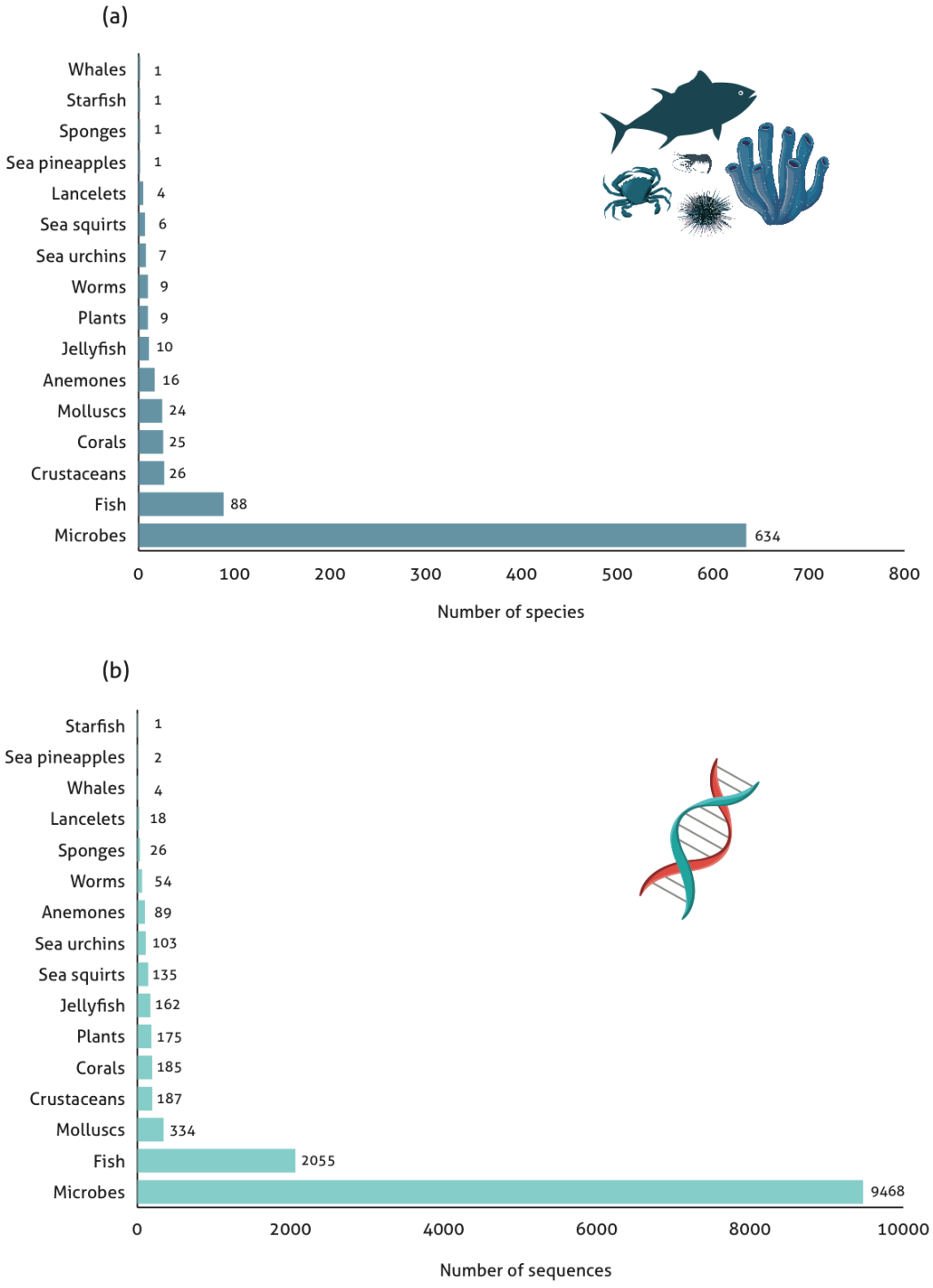

fig. S1. Number of marine species and marine sequences associated with patents. Number of (**A**) marine species with patent sequences; and (**B**) patent sequences from marine species, classified within broad categories inspired from Costello and Chaudhary 2017 (see Supplementary Materials for species within each category).

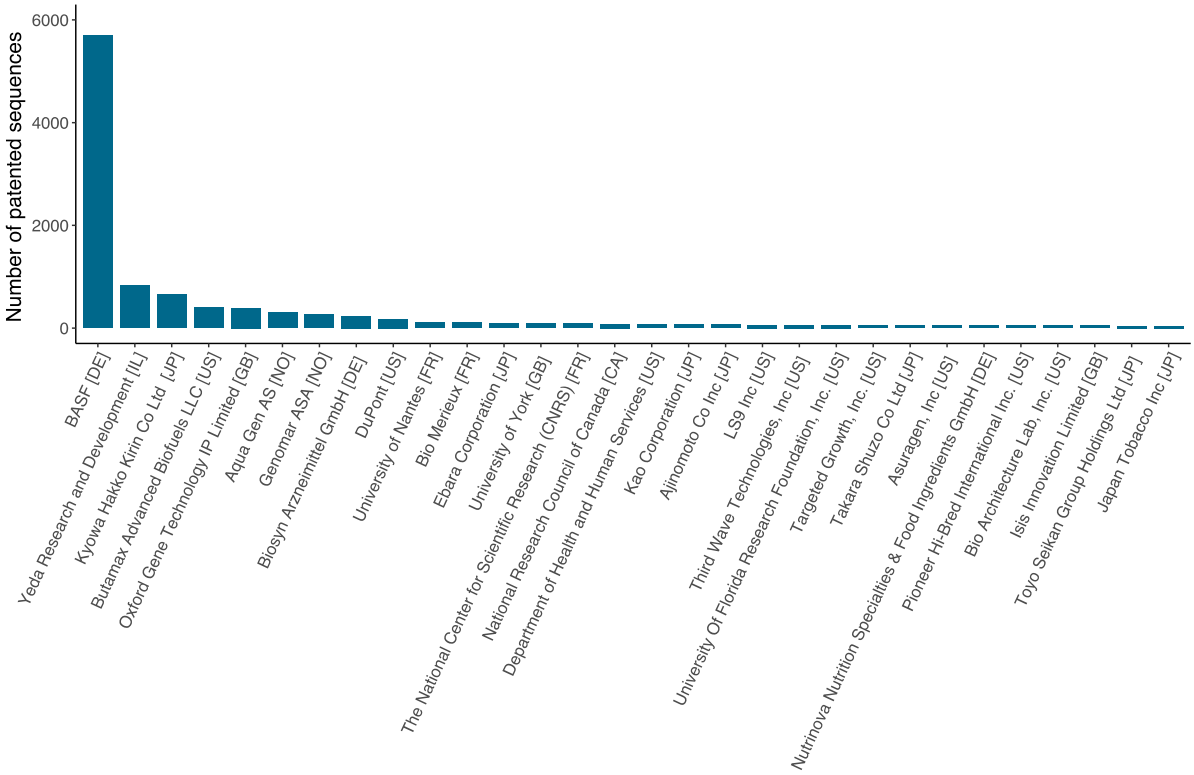

fig. S2. Top 30 largest patent holders. The top 30 largest patent owners, who together account for 84.4% of patents for which international protection was obtained between 1988 and 2017. US: United States; GB: Great Britain; DE: Germany; FR: France; IL: Israel; JP: Japan; NO: Norway; CA: Canada.