TECHNOLOGY TRANSFER OF AQUATIC GENETIC RESOURCES UNDER THE *CONVENTION ON BIOLOGICAL DIVERSITY* AND THE *NAGOYA PROTOCOL*: 'SPONGING' OFF PATENT LAW DEFENCES

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I INTRODUCTION

Many countries are grappling with how to implement their obligations for regulating the access, use and transfer of aquatic genetic resources and technologies under both access and benefit sharing ('ABS') and intellectual property regimes. The urgency for regulation is clear because the aquatic environment is one of the last frontiers for bio-prospecting[1] and the use of its genetic resources in aquaculture is hailed as a key to global food security.[2] However, the details of regulation under the United Nations' *Convention on Biological Diversity* ('*Convention*'),[3] the *Nagoya Protocol* ('*Protocol*')[4] and the World Trade Organization's ('WTO') *Agreement on Trade-Related Aspects of Intellectual Property Rights* ('*TRIPS*')[5] are not clear. This article steps outside the

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1 See, eg, Morten Walløe Tvedt and Ane E Jørem, 'Bioprospecting in the High Seas: Regulatory Options for Benefit Sharing' (2013) 16 *Journal of World Intellectual Property* 150, 151.

2 While industrialised aquaculture was virtually unknown 30 years ago, today aquaculture has become the fastest growing food production sector in the world, accounting for almost half of the seafood products consumed by humans. 'By 2025, aquaculture will have to increase by 350 [per cent] to cover the impending shortage [in seafood products]': Rex A Dunham, *Aquaculture and Fisheries Biotechnology: Genetic Approaches* (CABI, 2nd ed, 2011) 2.

3 *Convention on Biological Diversity*, opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993). The *Convention* is a multilateral treaty providing a framework for national strategies and laws for the conservation and sustainable use of biological diversity.

4 *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 29 October 2010, [2012] ATNIF 3 (entered into force 12 October 2014). The *Protocol* has not yet entered into force for Australia. The *Protocol* is a supplementary agreement to the *Convention* providing a transparent legal framework for the effective implementation of the fair and equitable sharing of benefits arising out of the 'utilization of genetic resources': at art 1.

5 *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1869 UNTS 3 (entered into force 1 January 1995) annex 1C ('*Agreement on Trade-Related Aspects of Intellectual Property Rights*').

recent calls for new mechanisms for ABS of aquatic genetic resources.[6] Instead it provides insight into how uncertainties surrounding obligations for technology transfer and ABS of aquatic genetic resources under the *Convention* and *Protocol* may be influenced by the approach taken in national patent laws on such issues as research defences.[7] This approach recognises the interdependence of *TRIPS*, the *Convention* and *Protocol* regimes which are regulating the same resources and which must necessarily evolve together to avoid legal uncertainty for the transfer of aquatic genetic resource technologies.

The three key uncertainties for discharging technology transfer obligations in relation to aquatic genetic resources for breeding and product development concern: (1) determining the point at which derivatives and technical knowledge are sufficiently removed from the genetic resources on which they are based for technology transfer rules to no longer apply (scope of derivatives); (2) clarifying the temporal scope of 'use' of genetic resources across the research to commercialisation continuum where different rules apply under the *Convention*, *Protocol* and patent regimes (scope of 'use'); and (3) how to address challenges involving the transfer of genetic resources located in multiple jurisdictions from multiple providers, including private parties (extraterritorial challenges).

Both bio-prospecting and aquaculture depend on accessing the genetic resources from wild (and to a lesser extent domesticated) stocks for product development and breeding.[8] To this end, they are likely to be captured within ABS obligations under the *Convention* and *Protocol* if the resources are sourced within national jurisdiction. The interaction with intellectual property regimes is problematic because both the *Convention* and *Protocol* expressly coexist with minimum standard intellectual property measures, such as under *TRIPS*.[9]

Patents are emerging as important economic tools for protecting investment in high-value applications of aquatic genetic resources, particularly

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6 See, eg, *Development of an International Legally-Binding Instrument under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction*, GA Res 69/292, UN GAOR, 69th sess, 96th plen mtg, Agenda Item 74(a), Supp No 49, UN Doc A/RES/69/292 (6 July 2015, adopted 19 June 2015). See also G Kristin Rosendal, Ingrid Olesen and Morten Walløe Tvedt, 'Balancing ABS and IPR Governance in the Aquaculture Sector' in Sebastian Oberthür and G Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, 2014) 196.

7 Secretariat of the Convention on Biological Diversity, *The Role of Intellectual Property Rights in Technology Transfer in the Context of the Convention of Biological Diversity*, Conference of the Parties to the Convention on Biological Diversity, 9th mtg, Agenda Item 4.3, UN Doc UNEP/CBD/COP/9/INF/7 (3 May 2008) 14 [41] ('*The Role of Intellectual Property Right*s').

8 Ninety per cent of the global aquaculture industry is based on wild and undomesticated stocks to prevent inbreeding depression: see Trygve Gjedrem, 'Genetic Improvement for the Development of Efficient Global Aquaculture: A Personal Opinion Review' (2012) 344–9 *Aquaculture* 12, 20. In contrast, practically no terrestrial animal farm production is based on genetically unimproved and undomesticated populations, and crops have been domesticated over thousands of years: Trygve Gjedrem (ed), *Selection and Breeding Programs in Aquaculture* (Springer, 2005) xi.

9 *Convention* art 22(1); *Protocol* art 4(1). However, both agreements provide an exception 'where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity': *Convention* art 22(1); *Protocol* art 4(1). For a discussion on the instruments' relationship with *TRIPS*, see below n 75 and accompanying text.

pharmaceutical applications.[10] At this time, the role of patents in aquaculture is not as significant as in other fields because there are other more prevalent and cost-effective forms of protecting new strains in aquaculture from unauthorised replication.[11] Patents, however, do have the potential to become an important commercial option to protect genetic resource inventions as the private sector increasingly replaces public sector research and commercialisation focuses more on protecting intellectual property.[12]

This article sets out to consider the challenges for interpreting technology transfer rules under patent law and ABS regimes. Part II of this article outlines the *Convention*'s technology transfer obligations and the *Protocol*'s ABS obligations. It argues that while the *Convention* treats technology transfer as an obligation in its own right, the *Protocol* treats technology transfer as a form of contractual benefit sharing. This distinction is significant because the *Convention*'s stronger obligations seem to have been eclipsed by the more topical *Protocol* obligations where technology transfer is optional. The analysis of *TRIPS* in Part III includes a summary of patent law defence options: experimental use, breeding, regulatory approval, compulsory licensing, non-commercial use, exhaustion, innocent bystander and temporary presence of vessels. These defences are available to nations as a mechanism for technology transfer of genetic resources under local patent laws.

Using the farming of sea sponges as an example, Part IV argues that three challenges (scope of derivatives, scope of 'use' and extraterritorial challenges) faced by the patent law, *Convention* and *Protocol* regimes need legal clarification to have a practical effect on technology transfer. This Part argues that the similarities between *TRIPS*, the *Convention* and *Protocol* legal frameworks justify a common approach to interpreting technology transfer rules. This Part gives insight into how patent law's approach to clarifying these three challenges can be used to similarly interpret and develop the *Convention* and *Protocol*'s normative rules around access to and transfer of aquatic genetic resources. In Part V, the article concludes that addressing these three challenges is only the beginning of the benefits that could be gained by 'sponging' off patent law's approach to regulating technology transfer of aquatic genetic resources under its defence framework.

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10 See, eg, Morten Walløe Tvedt, 'Patent Law and Bioprospecting in Antarctica' (2011) 47 *Polar Record* 46, 46–7.

11 These include the use of trade secrets, sex manipulation, the induction of sterility and vertical integration: see, eg, W D Eisbrenner et al, 'Evidence for Multiple Sex-Determining Loci in Tasmanian Atlantic Salmon (*Salmo Salar*)' (2014) 113 *Heredity* 86, 86; World Bank, *Changing the Face of the Waters: The Promise and Challenge of Sustainable Aquaculture* (2007) 3.

12 For example, WorldFish, an international non-profit research organisation that harnesses the potential of fisheries and aquaculture to reduce poverty and hunger, has adopted the *Principles on the Management of Intellectual Assets*, which expressly provide for intellectual property claims to be made over the aquatic genetic resources held in trust by the Consultative Group for International Agricultural Research ('CGIAR'). CGIAR is a global agriculture research partnership of which WorldFish is a member. See CGIAR, *Principles on the Management of Intellectual Assets* (7 March 2012) cl 6.

II TECHNOLOGY TRANSFER OBLIGATIONS UNDER THE *CONVENTION* AND *PROTOCOL*

The *Convention*'s Conference of the Parties recognises that technology transfer will not be effective as a one-off and one-way activity.[13] Rather, it needs to be embedded in a participatory decision-making process as well as in integrated, long-term scientific and technological cooperation, including the joint development of technologies.[14] The framework for technology transfer obligations primarily falls under article 16 of the *Convention* on access to and transfer of technology, in conjunction with articles 12, 17 and 18 on information sharing and cooperation, article 19 on participation and capacity building and article 20 on funding and the transfer of technology.[15] Each of these provisions build scientific, institutional, administrative and legal capacity to adopt and adapt the relevant technology. Article 16(1) provides that:

> Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this *Convention*, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

Parties also have obligations under the *Convention* to:

- facilitate access and transfer of technologies to developing countries under 'fair and most favourable terms';[16]
- provide, on mutually agreed terms, access and transfer to provider states technology (including technology protected by patents) which 'makes use' of their resources;[17]

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13 *Technology Transfer and Co-operation*, Conference of the Parties to the Convention on Biological Diversity, 9th mtg, Agenda Item 4.3, UN Doc UNEP/CBD/COP/DEC/IX/14 (9 October 2008) annex ('*Strategy for the Practical Implementation of the Programme of Work on Technology Transfer and Scientific and Technological Co-operation*') para 4.

14 The *Convention* treats technology transfer as the transfer of a system that includes materials, know-how, procedures and processes, rather than as the mere transfer of a product such as the sale of germplasm: ibid.

15 'The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology': *Convention* art 20(5).

16 *Convention* art 16(2). This sub-article's link with the *Convention*'s financial provisions indicates that the *Convention*'s financial mechanism could be used for the purposes of technology transfer to developing countries, which could provide a means to purchase and transfer technology subject to patents: Lyle Glowka et al, 'A Guide to the *Convention on Biological Diversity*' (Environmental Policy and Law Paper No 30, International Union for Conservation of Nature, 1994) 6, 86–7.

17 *Convention* art 16(3). This must be under mutually agreed terms: Glowka et al, above n 16, 86–7. The use of the term 'aim' in the sub-article indicates that the measures need not require parties to actually transfer the technologies but rather to create a framework permitting technology transfer to take place and to provide the basis through which mutually agreed terms between parties can be achieved. The framework must be consistent with international law, including *TRIPS* obligations. In contrast, other obligations, eg, art 15(4), require 'mutually agreed terms' in the context of the actual negotiation between a user and a provider rather than setting up a framework to achieve it: at 90.

- promote priority access, on mutually agreed terms and on a fair and equitable basis, to the results and benefits arising from biotechnologies 'based on' provider countries' genetic resources;[18]
- facilitate access to and transfer of technology from the private sector;[19] and
- cooperate to make sure that intellectual property rights support the *Convention*'s objectives.[20]

The technology transfer obligations are interconnected with the *Convention*'s obligations for technological cooperation and collaboration,[21] including participation in research and capacity building,[22] as a means of achieving sustainable technology transfer. Where feasible, most of the obligations require activities to be carried out *in* provider countries.[23] This is likely to result in the development of technological infrastructure for flow-on innovation in aquaculture where the aquatic genetic resource is located.

In contrast to the *Convention*'s 'access and technology transfer' obligations above, ABS obligations under the *Protocol* treat technology transfer and collaboration as one of a number of benefits that may flow from the access bargain between the user and the provider of the genetic resource, rather than obligations in their own right. As such, technology transfer under the *Protocol* is optional but encouraged. In short, parties to the *Protocol* have an obligation to

18 *Convention* art 19(2). Glowka et al point out that the undefined terms 'promote and advance' were the result of long negotiation and were carefully chosen to avoid any obligation on the private sector. 'Results and benefits' are undefined and the scope of 'priority access on a fair and equitable basis' is left to be mutually agreed by the parties. The term 'priority access' suggests preferential treatment for the provider country, regardless of their level of development, although developing countries are given special mention: Glowka et al, above n 16, 97.

19 *Convention* art 16(4). The obligation for a framework rather than a direct obligation indicates a reluctance to bind third parties to the *Convention*'s provisions. The Conference of the Parties has acknowledged, however, that

> [i]ntellectual property laws and policies, including … laws governing exceptions and licensing, as well as specific licensing, joint venture, research cooperation and other technology partnership arrangements that deal with intellectual property, are all potentially relevant elements [of measures for the private sector].

The Role of Intellectual Property Rights, UN Doc UNEP/CBD/COP/9/INF/7, 8 [19].

20 *Convention* art 16(5).

21 Such cooperation must be promoted with other contracting parties, particularly developing countries, with particular emphasis on strengthening their national capabilities though human resources development and institutional building: *Convention* art 18. Article 14(1) of the *Protocol* establishes an ABS 'clearing-house' as part of the 'clearing-house mechanism' created under *Convention* art 18(3).

22 For example, the obligation on contracting parties to take legislative or other measures 'to provide for the effective participation in biotechnological research activities': *Convention* art 19(1). See also the similar requirements under *Convention* arts 15(7), 16(3), 18(2). Parties are required to promote joint research programs and joint ventures for the development of *Convention*-relevant technologies: *Convention* art 18(5).

23 Under *Convention* art 15(6), parties are obliged to 'endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties'.

develop a framework for benefit sharing.[24] This requires sharing, with provider parties, the benefits arising from the 'utilization of genetic resources'[25] (the research and development phase) as well as 'subsequent applications and commercialization'.[26] Where the providers are indigenous and local communities, any benefits are to be shared with the community that has established rights.[27] Where traditional knowledge associated with genetic resources is used, benefits must be shared with the community holding such knowledge.[28] While traditional knowledge is a key and complex component of the ABS system, it requires more detailed analysis than this article can provide and is therefore beyond its scope.

The *Protocol*'s objective clarifies that benefit sharing includes appropriate access to genetic resources and the transfer of relevant technologies.[29] It also recognises that access and transfer must take into account all rights over those resources and technologies,[30] including intellectual property[31] and rights relating to traditional knowledge associated with genetic resources.[32] Parties have a general obligation to collaborate in research and development programs[33] and an obligation to cooperate in capacity building in developing countries, including 'technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable'.[34] Other requirements directed to actual technology transfer are either couched as general commitments by state Parties to the *Protocol* (encouragement of technology transfer to developing country

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24 *Convention* art 15(7) provides that all parties have an obligation to 'take legislative, administrative or policy measures … with the aim of sharing [with the provider country] in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources'. Where there is benefit sharing there is an obligation for the measures to be on mutually agreed terms. In recognition that many of the benefits contemplated by the provision will be shared by private parties such as corporations, the *Convention*'s obligation is on states to take measures to establish a framework for benefit sharing, rather than an obligation to establish benefit sharing itself: Glowka et al, above n 16, 82; cf *Protocol* art 5(1), which is discussed below.

25 '"Utilization of genetic resources" means to conduct 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*': *Protocol* art 2(c).

26 *Protocol* art 5(1):

> In accordance with Article 15, paragraphs 3 and 7 of the *Convention*, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the *Convention*. Such sharing shall be upon mutually agreed terms.

Parties are obliged to encourage users and providers to direct the benefits towards the conservation of biological diversity and the sustainable use of its components: *Protocol* art 9.

27 *Protocol* art 5(2).

28 *Protocol* art 5(5).

29 *Protocol* art 1.

30 *Protocol* arts 1, 3; see also *Convention* arts 1, 22.

31 *Convention* art 16(2).

32 *Protocol* arts 5(5), 7, 10, 11(2), 12, 16, 18(1). It is beyond the scope of this article to analyse in detail the obligations in the context of traditional knowledge over genetic resources. For an overview of the relationship between the *Convention* and traditional knowledge, see John Scott, 'Protecting Traditional Knowledge and the *Convention on Biological Diversity*' (2006) 6(20) *Indigenous Law Bulletin* 17.

33 *Protocol* art 23.

34 *Protocol* art 22(5)(g).

parties, regardless of whether they are provider countries)[35] or as examples of contractual benefit sharing between individual users and providers (technology transfer[36] and collaboration,[37] sharing research and development results,[38] participation and capacity building).[39] Significantly, technology transfer as a form of benefit sharing to the provider is envisaged 'under fair and most favourable terms, including on concessional and preferential terms where agreed',[40] in contrast to the other forms of benefit sharing which is envisaged only on 'fair and equitable terms'. Table 1 summarises the uncertainties for interpreting technology transfer obligations under the *Convention* and *Protocol*.

III *TRIPS*-COMPLIANT DEFENCES

TRIPS establishes an international legal framework for national patent laws with the objective of promoting 'technological innovation and … the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge'.[41] While this objective is not a legal obligation, it promotes innovation beyond simple inventions as evidenced by the use of the term 'technological innovation' (the whole period of research and development up to implementation, leading to commercial maturity) rather than the narrower term of 'technical invention' (technical knowledge).[42] In this way, patent laws, including defences, should be consistent with objectives for technology transfer along the whole technological change spectrum – from mere dissemination (transfer) to adoption and adaptation (through technological collaboration) of technologies, including genetic resource technologies.

35 *Protocol* art 23. Under *Protocol* art 23 parties have an obligation to 'collaborate and cooperate in technical and scientific research and development programmes'. Unlike its counterpart in *Convention* art 19(1), this obligation is not confined to the transfer to the provider country of the particular genetic resource in question. Rather, obligations for technological cooperation include all types of collaboration leading to the fair and equitable sharing of benefits, although parties are encouraged to undertake such collaborative activities in and with the provider country: see Thomas Greiber et al, 'An Explanatory Guide to the *Nagoya Protocol* on Access and Benefit-Sharing' (Environmental Policy and Law Paper No 83, International Union for Conservation of Nature, 2012) 215 ff.

36 *Protocol* annex para 2(f).

37 *Protocol* annex para 2(b).

38 *Protocol* annex paras 2(a), (e).

39 *Protocol* annex paras 2(c)–(d), (g)–(j); see also *Protocol* art 22(5)(g).

40 *Protocol* annex para 2(f).

41 *TRIPS* art 7. This is to be done 'in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

42 Peter-Tobias Stoll, Jan Busche and Katrin Arend (eds), *WTO – Trade-Related Aspects of Intellectual Property Rights* (Martinus Nijhoff, 2009) 182.

TRIPS provides for a minimum level of patent protection[43] but allows flexibility about the '*means* by which this minimum level of protection is secured in each Member's legal system'.[44] These flexibilities include crafting defences that are consistent with *TRIPS* articles 6 (exhaustion), 27(1) (patent threshold requirements), 30 (exceptions that must be consistent with the 'three step test')[45] and 31 (compulsory licensing). There are many justifications for defences, one of which is to promote technology transfer. Defences under patent law effectively define the circumstances under which patented technological products, such as genetic material, and technological processes, such as breeding techniques, can be transferred to users without the authorisation of the patent holder. In other words, the defences are a mechanism for technology transfer of patented genetic material and its derivatives. There is no consensus, however, about the optimal strength of patents or breadth of defences for maximising technology transfer and innovation.[46]

The most relevant defences under national patent laws for using aquatic genetic resources for breeding and product development in aquaculture include defences for experimental use, breeding, regulatory approval, compulsory licensing, non-commercial use, exhaustion, innocent bystanders and temporary presence summarised below:[47]

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43 All members must, subject to options for exclusion under *TRIPS* arts 27(2)–(3), make exclusive rights available for any invention in any field of technology provided the products or processes are 'new, involve an inventive step [ie, non-obvious] and capable of industrial application [ie, useful]': *TRIPS* art 27(1). '[P]roducts' and 'processes' are not defined under *TRIPS* but they generally relate to physical entities, such as devices and substances, or physical activities, such as methods and uses respectively. An 'invention' is similarly not defined under *TRIPS* and is to be determined under each member's legal system: see Justin Malbon, Charles Lawson and Mark Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights: A Commentary* (Edward Elgar, 2014) 413–15.

44 Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc WT/DS114/R (17 March 2000) [4.30] ('*Canada – Pharmaceutical Products Case*'), citing *TRIPS* art 1(1) (emphasis in original).

45 *TRIPS* art 30 as interpreted by the WTO Panel affirms that WTO members may provide exceptions to the exclusive rights conferred by a patent, provided such exceptions are (1) 'limited' in their impact on rights (2) 'do not unreasonably conflict with a normal exploitation of the patent' and (3) 'do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties': *TRIPS* art 30; see also *Canada- Pharmaceutical Products Case*, WTO Doc WT/DS114/R, [7.20]–[7.21], [7.31], [7.54].

46 See Richard Gold and Yann Joly, *Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, World Intellectual Property Organization Standing Committee on the Law of Patents, 15th sess, WIPO Doc SCP/15/3 (2 September 2010) annex 6 ('*The Patent System and Research Freedom: A Comparative Study*') 50; Health Law Institute, University of Alberta, and Centre for Intellectual Property Policy, McGill University, 'The Research or Experiential Use Exception: A Comparative Analysis' (Research Paper, Health Canada, 2004) 50 <http://www.cipp.mcgill.ca/data/newsletters/00000050.pdf>.

47 For an analysis of the patent defence landscape in the context of aquaculture, see Fran Humphries, 'Shellfish Patents Krill Experimentation: Defences for Sharing Patented Aquatic Genetic Materials in Aquaculture' (2015) 37 *European Intellectual Property Review* 210.

- experimental use defences allow, under certain circumstances, experimental[48] use[49] of a patented genetic resource invention that would otherwise infringe a patent holder's rights;[50]
- evolving breeding defences allow exemptions under specific circumstances for using a patented invention for breeding new biological varieties;[51]
- regulatory approval defences allow the performance of experiments and tests on a patented invention for the purpose of preparing regulatory approval (eg, safety and environmental requirements to commercialise genetically modified organisms) for a limited term before the end of the patent term;[52]

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48 The nature of activities covered vary between countries and range from experiments, research, teaching, development and testing to other technological activities: Lionel Bently, *Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, World Intellectual Property Organization Standing Committee on the Law of Patents, 15th sess, WIPO Doc SCP/15/3 (2 September 2010) annex 1 ('*Introduction*') 39; Secretariat of the World Intellectual Property Organization, *Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels*, World Intellectual Property Organization Committee on Development and Intellectual Property, 5th sess, WIPO Doc CDIP/5/4 (1 March 2010) 21–2 [66]. See also *The Patent System and Research Freedom: A Comparative Study*, WIPO Doc SCP/15/3, annex 6, 20.

49 Key differences between experimental use defences include whether they allow commercial as well as non-commercial uses and whether the defences permit experiments 'with' the invention or only 'on'. See below nn 150–2 and accompanying text.

50 For worldwide examples that treat the defence as either an exception or exemption under patent law, see *The Patent System and Research Freedom: A Comparative Study*, WIPO Doc SCP/15/3, annex 6, 29 ff.

51 Such defences are not widespread and generally relate to terrestrial plant breeding, although they have valuable policy insight for evolving breeding defences in aquaculture. See, eg, *Patentgesetz 1980* [Patent Law 1980] (Germany) § 11(2a); *Code de la propriété intellectuelle* [Intellectual Property Code] (France) art L613-5-3; *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 9(1)(e); *Rijksoctrooiwet 1996* [Patent Law 1995] (Netherlands) art 53C; *Common Provisions on Industrial Property*, Commission of the Andean Community Decision 486 (14 September 2000) art 53(e). The Andean Community is a supranational organisation established by the *Agreement on Andean Subregional Integration*, signed 26 May 1969, 8 ILM 910 (entered into force 16 October 1969) ('*Cartagena Agreement*'). The Commission is an organ of the Andean Community established by *Cartagena Agreement* art 5. It expresses its will through 'Decisions': at art 21. In theory, these 'Decisions' have 'direct effect' in member states and do not require separate incorporation into domestic law: see Thomas Andrew O'Keefe, *Latin American and Caribbean Free Trade Agreements: Keys to a Prosperous Community of the Americas* (Martinus Nijhoff, 2009) 248.

52 For an example of how regulatory approval and patenting processes relate to aquaculture, see Jay Sanderson and Fran Humphries, 'Unnaturally Natural: Inventing and Eating Genetically Engineered AquaAdvantage® Salmon and the Paradox of Nature' in Charles Lawson and Berris Charnley (eds), *Intellectual Property and Genetically Modified Organisms: A Convergence in Laws* (Ashgate, 2015) 185, 187–8. While some countries include the regulatory approval defence as a subset of the experimental use defence, others have standalone defences for regulatory approval: see, eg, 35 USC § 271(e)(1) (2012). Whether a regulatory approval defence would apply to aquaculture varies markedly around the world. For example, a World Intellectual Property Organization report found that (1) 'in some countries, [the defence] covers the regulatory approval of any products, while in some other countries it is limited to certain products' such as pharmaceuticals; (2) 'in some countries, the use of the patented product must take place in the country where the regulatory approval has to be requested, whereas in other cases, it is sufficient that the product be imported'; and (3) the scope of acts covered varies considerably between laws: *Patent Related Flexibilities in the Multilateral Legal Framework*, WIPO Doc CDIP/5/4, 24 [78].

- depending on a nation's patent laws, its compulsory licence[53] provisions might apply as a defence under certain circumstances for a breeder using patented genetic resources, including research tools, to create new aquatic strains subject to reasonable remuneration to the patent holder;[54]
- non-commercial use defences[55] and farmer's privilege defences[56] are an option for facilitating, respectively, non-commercial uses of aquatic genetic resources or for saving and reusing reproductive material for personal use;
- the principle of exhaustion can operate as a defence, protecting users from infringement claims concerning the use or sale of a patented genetic resource product after the patent owner has authorised its sale without reservations;[57]
- emerging innocent bystander defences may excuse infringement where patented genetic information is bred into a third party's planting material without his or her knowledge or against his or her will;[58] and

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53 The term 'compulsory licence' is often used as an umbrella term for many types of non-voluntary authorisations to exercise a patentee's rights without his or her authorisation, such as ex officio licenses, government use, licences to remedy anti-competitive practices, mandatory licenses and statutory licenses: Coenraad Visser, *Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*, World Intellectual Property Organization Standing Committee on the Law of Patents, 15th sess, WIPO Doc SCP/15/3 (2 September 2010) annex 5 ('*Patent Exceptions and Limitations in the Health Context*') 10.

54 Even the threat of a compulsory licence may induce patent holders to enter into voluntary licences in these situations: Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004) 613-14 [27.11]-[27.12] ('*Gene Patenting and Human Health*').

55 See, eg, *Patents Act 1977* (UK) c 37, s 60(5)(a).

56 This relates to statutory patent law defences as opposed to the privilege under plant breeder's rights. For example, the United Kingdom allows farmers to save and reuse harvested germplasm (plant and animal) originating from patented germplasm, subject to remuneration to the breeders (other than from small farmers): *Patents Act 1977* (UK) c 37, ss 60(5)(g)–(h); see Christopher Garrison, 'Exceptions to Patent Rights in Developing Countries' (Issues Paper No 17, UNCTAD–ICTSD Project on Intellectual Property Rights and Sustainable Development, October 2006) 65. Germany has a similar farmer's privilege defence under *Patentgesetz 1980* [Patent Law 1980] (Germany) § 9C. See also Steven Zeman and Heike Vogelsang-Wenke, 'Patents for Self-Replicating Products: Not So Exhausting after All', *Life Sciences Intellectual Property Review* (online), 16 October 2013 <http://www.lifesciencesipreview.com/article/patents-for-self-replicating-products-not-so-exhausting-after-all>. See also *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 35A(1), which allows farmers who have acquired reproductive material with the patent owner's consent to replicate it on their own farm. However, they must obtain the consent of a patent owner if they 'wish to give' the material to third parties: at art 35A(3).

57 Some argue, however, that exhaustion is not a defence because the right, as a consequence of the first sale, has been consumed and therefore does not exist: see Garrison, above n 56, 15.

58 Berne Declaration, Submission to Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture, *Views, Experiences and Best Practices on the Implementation of Farmers' Rights Submitted by Contracting Parties and Relevant Organizations*, 8 October 2012, 4 <http://www.planttreaty.org/sites/default/files/Berne%20Declaration%20%20FR_submissions.pdf>. For example, the *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 9(1)(f) provides that 'the effects of the patent do not extend to biological material that is obtained in the field of agriculture by chance or because it is technically unavoidable' [Unofficial Swiss Government trans].

- temporary presence defences prevent a WTO member country from enforcing a patent against a visiting conveyance, such as a vessel belonging to another member country, when that vessel temporarily or accidentally enters its domestic waters.[59] The defence arguably provides a possible approach or model for facilitating breeding technology in open ocean aquaculture.[60]

The focus of this article is not whether *TRIPS* achieves technology transfer. Rather, the focus is how *TRIPS*-compliant defences approach the sharing of genetic resource inventions and whether this approach can help to interpret *Convention* technology transfer obligations over the same resources. This analysis is the converse of the current extensive literature devoted to whether the *Convention* can assist with interpretation of *TRIPS* provisions.[61]

IV ROLE OF PATENT LAW DEFENCES FOR INTERPRETING *CONVENTION* TECHNOLOGY TRANSFER OBLIGATIONS

TRIPS and the *Convention* have a common approach to technology transfer. Both balance sovereignty and the common interest by setting minimum standards for regulation while allowing flexibility for the means by which its members or parties go about achieving them according to their needs and interests. Both *TRIPS* and the *Convention* set up frameworks for technology transfer along the whole technological change spectrum – from mere dissemination (transfer) to collaborative adoption and adaptation of technologies, including aquatic genetic resource technologies. The 'key commodity of genetic resources' within both

59 *TRIPS* art 2(1) provides that 'in respect of Parts II [patents], III and IV of [*TRIPS*], members *shall* comply' (emphasis in original) with the *Paris Convention for the Protection of Industrial Property*, opened for signature 14 July 1967, 828 UNTS 305 (entered into force 26 April 1970), arts 1–12, 19 ('*Paris Convention*'). Article 5ter(1) of the *Paris Convention* provides that

> the following shall not be considered as infringements of the rights of a patentee: … the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel …

60 For example, emerging technologies in open ocean roaming sea cages may create situations where a self-replicating patented invention such as transgenic fish may be 'made' anywhere along the roaming sea cages' route. This may lead to patent infringement if the cages pass through sovereign waters where a patent is claimed, even if that state is not the final destination of the patented product: see Humphries, above n 47, 221.

61 See, eg, Riccardo Pavoni, 'The *Nagoya Protocol* and WTO Law' in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Martinus Nijhoff, 2013) 185, 191, citing Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58/AB/R (12 October 1998) [130], [168].

regimes is not so much 'the physical specimen but rather its biological molecules or the information they contain' (eg, genetic sequences and structures).[62]

While defences are one of many ways to discharge technology transfer obligations through modifications to a patent system,[63] they have several advantages over other *TRIPS*-compliant mechanisms such as exclusions from patentability[64] and have important features in common with technology transfer obligations under the *Convention*. *TRIPS* and the *Convention* both recognise that access, use and transfer cannot simply be open or closed but rather depend on a balancing of rights and obligations according to the circumstances of the case. To this end they both set up frameworks, rather than prescriptive rules, with in-built flexibilities to respond to changing technologies, conditions and interests. The *Convention*'s Conference of the Parties has pointed out that many *Convention*-related technologies are of a proprietary nature and consequently the exercise of intellectual property mechanisms has a potential bearing on technology transfer obligations.[65] Significantly, they flagged that 'options for technology transfer [under the *Convention*] may be influenced by the approach taken in national patent laws on such issues as research exemptions'.[66]

Technology transfer under *TRIPS* and the *Convention* is governed by the concept of fairness but the instruments differ in the way in which they achieve fairness between parties. The concept of fairness under the *Convention*'s obligations is arguably narrower in scope because the standard of fairness changes depending on the beneficiary to whom the technology or benefits flow. Table 1 outlines this complex matrix for *Convention* and *Protocol* obligations. According to Malbon, Lawson and Davison, 'the promotion of technological innovation, transfer and dissemination [under *TRIPS*] should mutually benefit both producers and users. The aim is for a balancing of interests and not the favouring interests of one sector over the other'.[67] *TRIPS* does, however, recognise the 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws' such as defences 'in order to enable them to create a sound and viable technological

62 Bevis Fedder, *Marine Genetic Resources, Access and Benefit Sharing: Legal and Biological Perspectives* (Routledge, 2013) 40.

63 For examples of other mechanisms for discharging obligations, see *The Role of Intellectual Property Rights*, UN Doc UNEP/CBD/COP/9/INF/7, 42–3 [151]. These include construing patent claims literally rather than applying a broad doctrine of functional equivalents; applying a high standard for the 'inventive step' test; and applying a strict standard for industrial applicability for a specific use, rather than general utility for a variety of undefined uses. 'This may prevent the patenting of gene-based research tools such as expression sequence tags (ESTs) and single nucleotide polymorphisms (SNPs)'.

64 First, defences are not as blunt as exclusions and 'can be conditioned, for example by requiring some remuneration': *Introduction*, WIPO Doc SCP/15/3, annex 1, 65. Secondly, they are administered by courts whereas patent officers made decisions on exclusions in the first instance and tend to grant patents when in doubt, overlooking the public interest: at 65. Thirdly, defences are less susceptible to circumvention through clever claim drafting: at 65.

65 *The Role of Intellectual Property Rights*, UN Doc UNEP/CBD/COP/9/INF/7, 7 [18].

66 Ibid 14 [41].

67 Malbon, Lawson and Davison, above n 43, 203.

base'.[68] Ricolfi argues, however, that the goal of preserving access to technical knowledge by subsequent generations under *TRIPS* is to achieve the global economy's long-term efficiency, and not only for the advancement of developing countries' interests.[69]

There are several reasons for considering the effect of patent law's concept of non-discriminatory fairness on the discharge of technology transfer obligations for patented aquatic genetic resources. First, the complex matrix under the *Convention* and *Protocol* obligations outlined in Table 1 below may limit technology transfer in practice, unlike their counterpart patent law defences which may not directly restrict the flow of technology to a particular beneficiary. Further, the approach to 'fairness' under the *Convention* was developed to address the so-called 'north/south conflict' over the use and exchange of *terrestrial* genetic resources, particularly those of plants. Concerns of exploitation arose from the flow of resources from south (developing countries) to north (developed countries), which is not as relevant for current and potential conflict over the use and exchange of *aquatic* genetic resources.[70] Much of the flow of aquatic genetic resources is from south to south or north to south.[71] Conflict in the aquatic sector is more likely to evolve between small and large scale actors in the globalised sector rather than between north and south countries.[72] In any case, it is difficult to ascertain the origin of many aquatic genetic resources which migrate between jurisdictions. This means that non-discriminatory fairness concepts at the heart of patent law defences may be a more powerful tool to effect technology transfer to ensure the flow of genetic material regardless of its uncertain origin.

TRIPS entered into force after the *Convention* but before the *Protocol*. Importantly for the following analysis, the *Convention* and *Protocol* must cede to existing international agreements unless there is likely to be a 'serious damage or threat to biological diversity'.[73] Uncertainty remains, however, about the threshold for harm that would justify the *Protocol*'s overriding effect in such cases.[74] There is also uncertainty about the impact on the *Convention* of later agreements such as *TRIPS*. However, there are emerging norms that where there is inconsistency between the provisions of the two agreements, *TRIPS* is likely to

68 *TRIPS* Preamble para 6.

69 Marco Ricolfi, 'Is There an Antitrust Antidote against IP Overprotection within *TRIPS*?' (2006) 10 *Marquette Intellectual Property Law Review* 305, 327–8.

70 See G Kristin Rosendal, Ingrid Olesen and Morten Walløe Tvedt, 'Evolving Legal Regimes, Market Structures and Biology Affecting Access to and Protection of Aquaculture Genetic Resources' (2013) 402–3 *Aquaculture* 97, 101; Devin M Bartley et al, 'The Use and Exchange of Aquatic Genetic Resources for Food and Agriculture' (Background Study Paper No 45, Commission on Genetic Resources for Food and Agriculture, Food and Agriculture Organization of the United Nations, September 2009) 22–3.

71 See Rosendal, Olesen and Tvedt, *Evolving Legal Regimes*, above n 70, 101; Bartley et al, above n 70, 22–3.

72 Rosendal, Olesen and Tvedt, *Evolving Legal Regimes*, above n 70, 104.

73 *Convention* art 22(1); *Protocol* art 4(1).

74 Charles Lawson, *Regulating Genetic Resources: Access and Benefit Sharing in International Law* (Edward Elgar, 2012) 174.

prevail over the *Convention*.[75] The *Convention* is more explicit in the case of technology obligations, which specifically require that transfers of patented technologies are to be provided on terms consistent with intellectual property protection.[76]

To demonstrate the interaction between the *Convention*, the *Protocol* and *TRIPS*, the following analysis uses sea sponges as an example of where bio-prospecting for biologically active metabolites and breeding in aquaculture converge within patent law defence provisions and obligations for technology transfer. Sponges have been farmed for over 100 years to produce bath sponges and in the past 20 years to produce biologically active metabolites, some of which have pharmaceutical potential.[77] Thousands of sponge-derived chemicals have been isolated and identified.[78] However, many chemical compounds such as Halichondrin B (a polyether macrolide derived from the sponge genus *Halichondria*) and Peloruside A (a macrocyclic lactone derived from the sponge *Mycale hentscheli*) are found only in trace amounts in the biological organism which poses problems for generating enough biomass for research, product development and commercialisation.[79] Aquaculture is a key activity for obtaining enough biomass for preclinical studies[80] and there are several small-scale farming operations producing sponges and metabolites.[81] Alternatively, due to the small amounts of compounds in natural organisms, companies often move toward complete synthesis of the chemical compound.[82]

To illustrate the practical effects of legal uncertainty over the scope of derivatives, commercial provisions and extraterritoriality, this Part refers to examples of Halichondrin B and Peloruside A. Halichondrin B is a pre-*Convention* example of a patented chemical compound from Japanese sea

75 Ibid 174.

76 *Convention* art 16(2). See above n 41 and accompanying text.

77 Alan Duckworth, 'Farming Sponges To Supply Bioactive Metabolites and Bath Sponges: A Review' (2009) 11 *Marine Biotechnology* 669, 669–70.

78 Ibid 670.

79 Ibid.

80 Michael J Page et al, 'Successes and Pitfalls of the Aquaculture of the Sponge *Mycale hentscheli*' (2011) 312 *Aquaculture* 52, 52–3. As at 2010, '[a]quaculture of sponges and other benthic invertebrates to generate target metabolites had occurred in over 15 [per cent] of the marine natural product cancer lead developmental programmes': Nicole S Webster et al, 'Bacterial Community Dynamics in the Marine Sponge *Rhopaloeides odorabile* under in situ and ex situ Cultivation' (2011) 13 *Marine Biotechnology* 296, 297.

81 Duckworth, above n 77, 670–6.

82 See, eg, Melvin J Yu, Yoshito Kishi and Bruce A Littlefield, 'Discovery of E7389, a Fully Synthetic Macrocyclic Ketone Analog of Halichondrin B' in Gordon M Cragg, David G I Kingston and David J Newman, *Anticancer Agents from Natural Products* (CRC Press, 2nd ed, 2012) 317, 318.

sponges[83] and a subsequent synthetic chemical compound[84] which involved the use of natural compounds from sponges in New Zealand and Palau, including from farmed stock, as part of early developmental studies.[85] Peloruside A is a post-*Convention* and *Protocol* example of a purely synthetic compound the subject of a patent application[86] produced independently from an invention relating to the natural chemical compound[87] farmed only in New Zealand.[88] Only the Peloruside example may fall within the *Convention*'s technology transfer obligations and *Protocol*'s ABS obligations.[89] However, they are used in this article to demonstrate the practical effects of patent and technology transfer rules. While more mobile fish species may pose additional cross-jurisdictional challenges, sponges were chosen for this article because they are one of the rare examples where patented compounds have been originally accessed from aquatic genetic resources derived from both wild and farmed stocks.

A Scope of Derivatives

The *Convention*'s technology transfer obligations and the *Protocol*'s ABS obligations differ in the way they treat derivatives of genetic resources. However, the extent to which the obligations of both the *Convention* and the *Protocol* apply to different types of derivatives is uncertain. Arguably, technology transfer can be undermined unless there is a legal means of determining the point at which derivatives are sufficiently removed from the genetic resources on which they are based to no longer be considered *Convention*-related technology falling under technology transfer obligations. This section highlights patent law's approach to tackling the same question when determining the extent of a patent holder's control over derivatives of their patented genetic resource inventions. Specifically, it gives insight into how emerging breeding defences can create a legal benchmark for technology transfer of derivatives of self-replicating genetic resources.

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83 Yoshito Kishi et al, 'Synthesis of Halichondrin B and Norhalichondrin B' (United States Patent No 5,338,865, published on 16 August 1994, assigned to President and Fellows of Harvard College). See generally Thomas D Aicher et al, 'Total Synthesis of Halichondrin B and Norhalichondrin B' (1992) 114 *Journal of the American Chemical Society* 3162.The marine sponge is called *Halichondria okadai*: at 3162. The priority date for the patent was 12 March 1992 which indicates that the genetic resource was accessed prior to when the *Convention* came into force on 29 December 1993.

84 Yongbo Hu, 'Halichondrin B Analogs' (United States Patent No 8,598,373 B2, published on 3 December 2013, assigned to Eisai R & D Management Co Ltd) 24.

85 This complex process is explained below at n 129 and accompanying text.

86 See, eg, Johan van der Eycken et al, 'Peloruside Analogs' (International Patent Application No 2015/079009 A1, published on 4 June 2015).

87 Peter T Northcote et al, 'Bioactive Compound' (United States Patent No 6,790,862 B2, issued on 14 September 2004, assigned to Victoria Link Ltd).

88 Page et al, above n 80, 53.

89 This is because international agreements do not have retrospective application: see *Vienna Convention on the Law of Treaties*, opened for signature 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980) art 28.

The scope of technology transfer obligations hinges on the use of 'genetic resources'.[90] It is well established that the meaning of 'genetic resources' needs to be sufficiently flexible to cope with rapid developments in technology and knowledge but sufficiently precise to determine with a degree of legal certainty whether a particular case falls within an obligation.[91] Arguably, the type of derivatives that fall within the *Convention*'s technology transfer obligations are broader in scope than derivatives that fall within the *Protocol*'s ABS obligations. The *Convention*'s technology transfer obligations extend to genetic resources *and* their derivatives but 'derivatives' are undefined.[92] In contrast, the *Protocol* defines a 'derivative' which falls within ABS obligations.[93] While derivatives for the purposes of ABS obligations are confined to 'naturally occurring biochemical compounds',[94] derivatives falling under technology transfer obligations are not similarly confined.

Derivatives, however, may be in a variety of forms with varying connections to the naturally occurring genetic resource. The *Convention*'s Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches ('Group of Legal and Technical Experts') observed that there is a continuum from derivative, to derivative under research and development, to product, noting that all products are derivatives but not all derivatives are products.[95] It found that there is no common understanding of the concept of a derivative but that it could include

- '[d]erivatives understood as the results of an organism's metabolism' (eg, physical natural compounds);

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90 *Convention* art 15 concerns 'access to genetic resources' and benefits arising from the 'utilization of genetic resources'. *Convention* art 19 concerns biotechnologies 'based upon genetic resources'. *Convention* art 16(1) concerns technologies that 'make use of genetic resources'.

91 Morten Walløe Tvedt and Peter Johan Schei, 'The Term "Genetic Resources": Flexible and Dynamic while Providing Legal Certainty?' in Sebastian Oberthür and G Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, 2014) 18, 18.

92 While the *Convention* does not include derivatives in its definition of genetic resources, they are captured by the use of the term 'technology' in each of the *Convention*'s technology transfer obligations. *Convention* art 2 defines 'technology' to include 'biotechnology' which in turn means 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.

93 The *Protocol* applies 'to genetic resources within the scope of Article 15 of the [*Convention*] and to the benefits arising from the utilization of such resources': *Protocol* art 3. 'Utilization of genetic resources' is confined to the 'conduct of research and development … including through the application of biotechnology': at art 2(c). '[B]iotechnology' is defined in a similar manner to *Convention* art 2 as technology 'that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products': at art 2(d) (emphasis added). A 'derivative' means a 'naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity': at art 2(e).

94 *Protocol* art 2(e).

95 *Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 7th mtg, Provisional Agenda Item 3, UN Doc UNEP/CBD/WG-ABS/7/2 (12 December 2008) annex ('*Outcome of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*') [19]–[22].

- '[d]erivatives understood as any result of human activity using a genetic resource' (eg, physical synthetic compounds); and
- '[d]erivatives understood as information on genetic resources' (eg, intangible digitalised information).[96]

Defining the legal status of derivatives of genetic resources under the *Convention* is an increasingly important issue for sharing genetic resources for use in aquaculture and research. In the case of using genetic resources for bio-prospecting and breeding in aquaculture, all three types of derivatives identified above could be involved. The *Mycale hentscheli* example involved the chemical compound Peloruside A derived from the *Mycale hentscheli* genetic resource in New Zealand as well as a purely synthetic form of the compound which was developed in other countries independently of the natural genetic resource.[97] In the context of genomics, proteomics and bio-informatives, ex situ collections or 'gene banks' may include the digitalised form of DNA, RNA or proteins.[98] These kinds of 'omic' technologies or tools are becoming increasingly important for innovation in aquaculture[99] and aquatic-related research.[100] The Group of Legal and Technical Experts also noted that a derivative includes self-replicating material[101] such as from selective breeding in aquaculture.

The decisive criterion for whether a derivative falls within the scope of obligations seems to be the biological origin rather than the biological form.[102] Transfer of genetic information into digital form does not change its genetic character and 'derivatives as information' are likely, as a generalisation, to fall within the scope.[103] Naturally-occurring biochemical compounds clearly fall within the meaning of a derivative.[104] However, those accessed independently of

96 Ibid [20].

97 See above n 87 and accompanying text.

98 Peter Johan Schei and Morten Walløe Tvedt, Fridtjof Nansen Institute, *The Concept of 'Genetic Resources' in the Convention on Biological Diversity and How It Relates to a Functional International Regime on Access and Benefit-Sharing*, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 9th mtg, UN Doc UNEP/CBD/WG-ABS/9/INF/1 (19 March 2010) ('*The Concept of 'Genetic Resources'*') 25.

99 See, eg, Pedro M Rodrigues et al, 'Proteomics in Aquaculture: Applications and Trends' (2012) 75 *Journal of Proteomics* 4325; Marco Saroglia and Zhanjiang (John) Liu (eds), *Functional Genomics in Aquaculture* (Wiley-Blackwell, 2012).

100 See, eg, Paul Oldham, ESRC Centre for Economic and Social Aspects of Genomics, *Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology*, Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing, 3rd mtg, UN Doc UNEP/CBD/WG-ABS/3/INF/4 (11 January 2005).

101 'Something derived from biological and genetic resources such as varieties, strains or breeds … genes, seeds … as well as the products derived from, patterned on, or incorporating manipulated compounds and/or genes': *Outcome of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, UN Doc UNEP/CBD/WG-ABS/7/2, annex [19].

102 Tvedt and Schei, above n 91, 21.

103 Ibid. Tvedt and Schei go further to argue that the 'proteins are expressed by the genes and are thus not objects of heredity themselves but rather a necessary result thereof. This could be taken as an argument that proteomics is a derivative, as has been discussed in the [*Convention*], rather than the resource itself': at 29.

104 *Protocol* art 2(e).

genetic resources fall outside the scope of the obligations.[105] Regarding synthetic derivatives, the link back to the biological material in which the genetic information was found becomes more remote.[106] Synthetic biology has many applications and includes using non-natural components to imitate biological systems on the one hand or extracting natural biological components to create unnatural assemblages on the other.[107] The latter application more easily links back to the original biological material. The former's link may be more difficult to determine. The link would be stronger if there has been some use of genetic material in the process. For example, in the case of Halichondrin B, natural compounds from several species of the *Halichondria* genus were deconstructed to help produce the synthetic fragment for early developmental studies.[108] The link may be weaker in the Peloruside A example where the purely synthetic compound was produced independently from the natural chemical compound derived from *Mycale hentscheli*.[109]

The extent to which derivatives fall within the scope of the *Convention* and *Protocol* is often treated as a political rather than a legal issue.[110] Tvedt and Schei have pointed out that in practice, such a demarcation is often made either through a private law ABS agreement or by a court decision in a dispute over benefit sharing.[111] International transfer of genetic resources for use in aquaculture and pharmaceutical development is increasingly influenced by the concentration of multinational corporations.[112] Leaving demarcation solely to private parties, however, may undermine the fair and equitable sharing of genetic resources, particularly where this creates a power imbalance. Other areas of law, such as patent law, which face similar challenges about determining the scope of derivatives, can provide valuable insight into how a legal, rather than political, point of demarcation can be determined.

As with the ABS system, the patent law system gives private parties the discretion to define the scope of third party use of their patented technologies under a patent claim. Patent law, however, creates added legal

105 Greiber et al, above n 35, 71. Arguably, this is because ABS obligations are limited to the 'utilization of genetic resources' under *Convention* art 15 and *Protocol* art 2(c), and technology transfer obligations are limited to technologies that 'make use' of genetic resources: *Convention* art 16.

106 Tvedt and Schei, above n 91, 29.

107 Steven A Benner and A Michael Sismour, 'Synthetic Biology' (2005) 6 *Nature Reviews: Genetics* 533, 533.

108 Email from Elizabeth Evans-Illidge to Fran Humphries, 20 January 2015 (copy on file with author).

109 See Richard E Taylor, Zhiming Zhao and Sebastian Wünsch, 'Synthetic Efforts towards the Marine Polyketide Peloruside A' (2008) 11 *Comptes rendus: Chimie* 1369, 1379.

110 Tvedt and Schei, above n 91, 24.

111 Ibid. Fedder points out that negotiations for ABS agreements to determine the degree of benefit sharing are based on 'questions of supply and the similarity of the end product in the original resource [the derivative]': above n 62, 65. One consideration which may affect the degree of benefit sharing is 'the relationship between the final product and original sample': at 65. For example, if complete synthesis is not possible without ongoing supply, the share of benefits could be higher. Another consideration is the similarity between the final product and original sample: at 65. Where there is a large modification from the original sample, the share of benefits may be lower: at 65.

112 Rosendal, Olesen and Tvedt, 'Balancing ABS and IPR Governance', above n 6, 203.

certainty by building into its defence framework a formula for determining the circumstances in which derivatives of patented genetic resources can be shared and transferred without the authorisation of the patent holder.[113] Under patent law, patent protection on biological material generally extends to every plant and animal 'containing the inventive element or resulting from a patented process'.[114] For example, breeding and selling (without a licence from the patent holder) the offspring of *Mycale hentscheli* containing the patented chemical compound Peloruside A could, depending on the circumstances and the scope of the patent claim, leave a breeder vulnerable to infringement proceedings.[115] This is because the act of breeding is 'making' the invention again by replicating the patented chemical compound in the new product, that is, the offspring. To support public policy objectives for agriculture, France, Switzerland, Germany and the Netherlands have introduced statutory exemptions for using a patented invention for breeding new plant varieties.[116] For example, the German defence provides that 'the effect of a patent shall not extend to … the use of biological material for breeding, discovery and development of a new plant variety type'.[117] Although such defences do not yet extend to the field of aquaculture, they are an important option for creating legal certainty about the reach of patent protection in subsequent generations of genetic resources.

Breeders need clarity, however, on whether a defence would apply if their stock was crossed with a patented variety to develop a new stock without the patented trait, which they subsequently breed or sell.[118] In other words, would the patented strain's trait merely need to be *present* in the new stock or would something more be required such as the *expression* of the trait? Current defences under patent law rarely clarify what has been referred to as the 'functionality

113 Tvedt and Schei have drawn a comparison between the ABS and patent systems. They argue that 'the patent system has married the two virtues of legal certainty and flexibility into the object to those rights': Tvedt and Schei, above n 91, 30. The claimed invention defines the object but 'flexibility is built into the system by each invention being individually determined by the inventor in the "patent claims", which are the elements of the invention to which the inventor claims an exclusive right': at 30. On the other hand, this article argues that defences are an important third element that can be used to define or refine the line between exclusive rights over patented technologies and third party use of its genetic material and derivatives.

114 Viola Prifti, 'The Breeding Exemption in Patent Law: Analysis of Compliance with Article 30 of the *TRIPS* Agreement' (2013) 16 *Journal of World Intellectual Property* 218, 218. For example, patent protection on biological material extends to products of its self-replication, as long as these products have the same characteristics as the parent material: see, eg, *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions* [1998] OJ L 213/13 ('*European Biotechnological Directive*').

115 In other words, proceedings for infringing the patent holder's exclusive rights over the use of a process or the making, use, sale, offering for sale and importing of the products of an invention: *TRIPS* art 28(1).

116 *Patentgesetz 1980* [Patent Law 1980] (Germany) § 11(2a); *Code de la propriété intellectuelle* [Intellectual Property Code] (France) art L613-5-3; *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 9(1)(e); *Rijksoctrooiwet 1995* [Patent Law 1995] (Netherlands) art 53C.

117 *Patentgesetz 1980* [Patent Law 1980] (Germany) § 11(2a). This does not include subsequent commercialisation of the new variety: Prifti, above n 114, 218.

118 See, eg, Nuffield Council on Bioethics, *The Use of Genetically Modified Crops in Developing Countries: A Follow-Up Discussion Paper* (Discussion Paper, 2004) 88 [6.11].

question' in circumstances where subsequent varieties are produced from the self-replicating patent.[119]

There is guidance emerging, however, in the area of patentability.[120] The European Court of Justice has opined that a patented trait may be present in material derived from the invention, but protection may only attract when the patented trait is *performing* its function (ie, expressed and not simply present) *at the time* of the alleged infringement.[121] Depending on a nation's patent law, a breeding defence, an innocent bystander defence[122] or an experimental use defence[123] could apply a similar benchmark so that an infringement could be excused if the patented characteristic is present but not expressed or performing its function at the time of the alleged infringing use.

For example, depending on the specifics of a defence, this could mean that breeders of *Mycale hentscheli* could experiment with subsequent generations until such time as a new stock expresses the original patented element. This could give breeders and researchers the freedom to transfer genetic resources and conduct further breeding and experiments to determine, for example, whether the patented chemical compound is in fact produced by bacteria which is part of *Mycale hentscheli*'s microflora[124] or from the sponge's own genetic material, without fear of infringement proceedings.

The sponge example also highlights the importance of incorporating the *timing* of functionality within the scope of a defence. Functionality is complex and often depends on signals outside the cell to trigger expression of a trait.[125] For example, Peloruside A is only expressed in *Mycale hentscheli* found in particular areas of the Pelorus Sound.[126] Without a defence that excuses infringement where a patented trait is not performing its function at the time of the alleged infringement, a researcher arguably may be able to breed without a licence from a patent holder the *Mycale hentscheli* (which contains but does not expresses the patented compound) outside the Pelorus Sound to investigate its regulatory factors.

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119 See Humphries, above n 47, 213.

120 In other words, exclusions for protection as opposed to defences for infringement.

121 *Monsanto Technology LLC v Cefetra BV* (C-428/08) [2010] ECR I-6765, I-6806–7 [50], citing *European Biotechnological Directive* [1998] OJ L 213/13, art 9.

122 See, eg, *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 9(1)(f), which provides that 'the effects of the patent do not extend to … biological material that is obtained in the field of agriculture due to chance or because it is technically unavoidable'. In effect, a farmer has a defence to patent infringement where the patented genetic information was bred into their planting material without their knowledge or against their will: see Berne Declaration, above n 58, 4.

123 See, eg, Australia's *Patents Act 1990* (Cth) s 119C, which provides that '[a] person may, without infringing a patent for an invention, do an act that would infringe the patent … if the act is done for experimental purposes relating to the subject matter of the invention'.

124 'For many products it is not yet known whether they are produced by the sponge or by a symbiont': Detmer Sipkema et al, 'Marine Sponges as Pharmacy' (2005) 7 *Marine Biotechnology* 142, 154.

125 Tvedt and Schei, above n 91, 28.

126 Page et al, above n 80, 53. Page et al point out that '[t]his highlights the importance of conserving a relatively small genetic resource': at 59.

A similar analysis of functionality could be useful when considering derivatives under technology transfer obligations. Some commentators argue that a derivative could fall within the scope of the *Convention* if it expresses or performs the function of the original genetic resources (the physical and informational elements).[127] The value of the patent law approach is that the benchmark would apply *at the time of its use* (as opposed to the time of accession). Such a benchmark might be more easily applied in cases of natural derivatives and digital information if there is data on how the derivative, such as a chemical compound, is expressed in the genetic resource from which it was derived. The benchmark is more difficult to apply, but may also assist, in cases involving purely synthetic derivatives, as in the Halichondrin B example below.

Halichondrin B illustrates the complexities in determining the extent to which a synthetic compound can be considered a derivative of a genetic resource and therefore falling within technology transfer obligations. Halichondrin B is a natural chemical compound found in *Phakellia carteri*, a Japanese sponge *Halichondria okadai*,[128] Palau sponges of the *Axinella* genus, and New Zealand sponges of the *Lissodendoryx* genus,[129] the latter of which was produced in aquaculture for early developmental studies for a synthetic compound.[130] When it was found that wild sponge could not be produced in sufficient quantities for commercialisation,[131] total synthesis was pursued.[132] Eventually an intermediary synthetic compound (E7389) went on to be developed as eribulin mesylate (now called Halaven®), clinically used to treat metastatic breast cancer.[133] As an added complexity, some of the bulk Halichondrin B (natural chemical compound) was deconstructed to help produce enough E7389 for early developmental studies, however commercial production of Halaven® is now entirely based on synthesis.[134]

If the accessing of the relevant genetic resource had arisen after the *Convention* and if it could be proven that the bulk of Halichondrin B was deconstructed from New Zealand or Palau sponge genetic resources, these countries might have argued that eribulin mesylate was a 'derivative' of their genetic resources because they formed part of the process toward total synthesis. In other words, using the patent law approach for determining derivatives, if *at the time of* using the Japanese synthetic compound, the compound is performing the same function as the natural chemical compound in the New Zealand and Palau sponges, there may be an argument that obligations for technology transfer

127 Tvedt and Schei, above n 91, 20.

128 Murray H G Munro et al, 'The Discovery and Development of Marine Compounds with Pharmaceutical Potential' (1999) 70 *Journal of Biotechnology* 15, 20.

129 Donnette A Dabydeen et al, 'Comparison of the Activities of the Truncated Halichondrin B Analog NSC707389 (E7389) with Those of the Parent Compound and a Proposed Binding Site on Tubulin' (2006) 70 *Molecular Pharmacology* 1866, 1866.

130 Munro et al, above n 128, 20.

131 Aicher et al, above n 83, 3162.

132 Ibid. See also Yu, Kishi and Littlefield, above n 82.

133 Email from Elizabeth Evans-Illidge to Fran Humphries, 20 January 2015 (copy on file with author).

134 Ibid.

and ABS could attach to users and providers of the Japanese (patented) compound. Under this approach, however, synthetic compounds for which no genetic resource can be traced or natural compounds that have been modified to perform unnatural functions in synthetic compounds, might not fall under the technology transfer and ABS obligations because the functional link with the genetic resource may be too remote.

At first glance, there may appear to be inconsistencies in the way such benchmarking works under patent law and the *Convention*. For example, for technology transfer under the *Convention*, a derivative may need to perform the same function as the genetic resource at the time of use. This is to achieve a sufficient link with the genetic resource to which technology transfer obligations apply. Conversely, for technology transfer under a patent defence, the derivative must be *not* performing the same function of the original genetic resource but may be present at the time of infringing use. This is to ensure that a derivative is being used for the purpose of further developing an invention (permitted under *TRIPS*) rather than being used as a tool to incorporate the patented genetic material into a new product that benefits from the patented trait (arguably not permitted under *TRIPS*).[135]

On closer inspection, however, any inconsistencies only relate to genetic resources that fall within a particular patent claim and even then, both obligations and defences may still achieve technology transfer. This is because there is arguably nothing in the *Convention* to preclude a party including in its technology transfer framework derivatives that contain but not necessarily perform the same function of the original genetic resource at the time of its use (ie, consistent with the patent approach). Such an approach would overcome difficulties with including synthetic compounds under technology transfer obligations identified above while at the same time maintaining a traceable link with the original genetic resource for the framework to apply. This would mean that technology transfer could be triggered under both defences and obligations if a derivative contains but does not express the original patented genetic resource. Where patents are *not* in issue, technology transfer under the *Convention* could be triggered where a derivative contains *or* performs the same function as the original genetic resource at the time of use. In the *Mycale hentscheli* example, this may mean that the natural compound, *as well as* the purely synthetic compound created independently of the natural compound could fall within the scope of technology transfer obligations.

Arguably, the definitional challenges for *Convention*-related derivatives could be avoided by using the concept of 'utilization of genetic resources'.[136] In other words, instead of determining whether a chemical compound falls within the definition of a 'derivative', attention could be turned to whether the use of

135 This point is further elaborated below at n 150 and accompanying text which distinguishes experimenting 'with' or 'on' an invention under patent law defences.

136 Tvedt and Schei, above n 91, 23–4; *Outcome of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches*, UN Doc UNEP/CBD/WG-ABS/7/2, annex, [11].

genetic resources in the production of biochemicals falls within the scope of 'utilization of genetic resources'. This approach might have limited benefit because first, the definition of 'utilization of genetic resources', at least under the *Protocol*, does not extend to commercial applications of the derivative. Secondly, the definition does not clarify the temporal scope of the use, which is important for the demarcation between derivatives and the original resource. The advantages of the patent approach connecting derivatives to the temporal function of the patented invention are that it can apply across the use spectrum, including commercial applications, *and* achieves fairness by clarifying that the derivative must be in the relevant form at the time of use, rather than having a potential use at an indeterminate time.

B Scope of Use

Key to understanding the *Convention*'s technology transfer obligations and the *Protocol*'s ABS obligations is the temporal scope of the use of genetic resources. At the time of accessing genetic resources, there may be considerable legal uncertainty as to whether access obligations are triggered because a prospector's intentions are difficult to prove and often change, and the potential of the genetic resources is realised only at a later time.[137] Utilisation, rather than the intent of future use, can be externally verified and enforceable as a legal term and has become the trigger for technology transfer and benefit sharing.[138] This section demonstrates, however, that uncertainty remains about when obligations are triggered across the research to commercialisation continuum and how obligations address changes of intent from non-commercial to commercial uses. It argues that the *Convention* can use similar approaches to patent law to address these issues. In particular, the *Convention* can look to the way experimental use defences deal with uses of a commercial application of genetic resources and how defences for non-commercial purposes deal with changes of intent for subsequent uses.

1 Commercial Applications (Products)

It is clear that technology transfer and ABS obligations only relate to biological resources used for their 'genetic material'[139] and not for their other attributes, for example, as a fish fillet for consumption.[140] An important issue, however, for breeding in aquaculture is that it is often difficult to distinguish when the resource is used as a biological resource, that is, a commodity, or for its

137 *The Concept of 'Genetic Resources'*, UN Doc UNEP/CBD/WG-ABS/9/INF/1, 26.

138 Ibid.

139 Such resources are limited to genetic material with 'actual or potential value' by the definition in *Convention* art 2, but it may be argued that 'all genetic material is potentially valuable at least until proven otherwise': Glowka et al, above n 16, 21–2.

140 Similarly, the *Protocol* only applies to 'genetic resources' when these are accessed with the intention 'to conduct research and development on the genetic and/or biochemical composition of genetic resources': *Protocol* art 2(c). In other words, the *Protocol* does not apply to biological resources traded as commodities.

genetic material. For example, to increase the cultured *Mycale hentscheli* sponge stocks each year, a proportion of the stock was harvested to supply the raw material for Peloruside A extraction for the preclinical trials, while retaining enough raw sponge material to reseed the farm the following year.[141] It would be difficult to definitively determine whether the genetic resource is being used for its genetic material or as a commodity, in this case, broodstock. Conversely, patent law defences do not distinguish between biological and genetic resources but instead focus on the scope of the patent claim and the circumstances of the patent's use under a particular defence.

The *Protocol* defines 'utilization of genetic resources' for the purpose of ABS obligations to mean 'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'.[142] It does not contain a list of specific uses of genetic resources that would be covered, arguably because the drafters considered the definition was comprehensive enough to cover all possible uses of genetic resources, allowing for rapidly evolving technologies.[143] However, the *Protocol* does clarify that ABS obligations connected to the 'utilization of genetic resources' finish when the research and development process ends.[144] Any subsequent application or commercialisation is then covered by the benefit sharing provisions in article 5(1) of the *Protocol*.[145] The distinction between 'utilization' on the one hand and 'subsequent applications and commercialisation' on the other is important. Party obligations to take 'user measures' (eg, ensuring that any use of genetic resources within their jurisdiction respects the legislation of providers)[146] only apply to the 'utilization of genetic resources' whereas benefit sharing, including technology transfer relating to 'subsequent applications and commercialisation', will need to be pursued on the basis of contractual rights.[147]

In contrast to the *Protocol*'s contractual approach to technology transfer, article 19(2) of the Convention, which concerns fair and equitable access to the results and benefits arising from biotechnologies based upon genetic resources, is silent on whether the obligation extends to commercial applications. As the *Protocol* is confined to the scope of *Convention* article 15,[148] arguably *Convention* article 19(2) is not restricted by the *Protocol*'s distinction between utilisation and commercial applications. Support for this view is the wording of

141 Sean Handley, Mike Page and Peter Northcote, 'Anti-cancer Sponge: The Race Is On for Aquaculture Supply' (2006) 14(3) *Water and Atmosphere* 14, 15; Page et al, above n 80, 59.

142 *Protocol* art 2(c).

143 Greiber et al, above n 35, 64.

144 Ibid.

145 Ibid.

146 See *Protocol* arts 15–17. For a more detailed account of the user measures, see below n 202 and accompanying text.

147 Matthias Buck and Clare Hamilton, '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*' (2011) 20 *Review of European Community & International Environmental Law* 47, 52.

148 *Protocol* art 3.

article 19(2), which does not use the phrase 'use of genetic resources' but rather 'based upon genetic resources'. In a temporal sense this could mean the end product of the use to which the genetic resource had been put. In contrast to the technological collaboration obligation in article 19(1), article 19(2) does not restrict the obligation to the research phase, lending further support to the proposition that technology transfer may include biotechnologies that have reached commercialisation. Similarly, the technology transfer obligations in article 16 are restricted to technologies 'which make use of those resources', but use is not confined to the research phase. Arguably, technology transfer obligations could also extend to the commercialisation phase because article 16 specifically includes technologies protected by patents, which in practice are protected throughout the research, development, subsequent application and commercialisation phases.

The breadth of technology collaboration obligations in relation to the use of genetic resources as commercial end products for research has interesting parallels with the scope of sharing patented genetic resources under patent law experimental use defences. The obligation under *Convention* article 19(1) is confined to those genetic resources which will actually be used 'for' the biotechnological research for which the provider provided them. In contrast, the obligations under *Convention* articles 15(6) and 19(2) have a wider scope for research 'based on' the genetic resources provided. Similarly, obligations under article 16 include technologies that 'make use' of genetic resources. In other words, it is not an obligation to make use of the actual genetic resources provided but arguably to make use of any genetic resources. The broader obligations apply not only to the research for which the resources were provided, but also to any research that has a connection with genetic resources provided. In this way, research 'based on' and technologies that 'make use' of genetic resources could include access to and technology transfer of the commercial applications of genetic resources. This means that the extent of technology transfer of genetic resources under the obligations varies depending on whether a narrow ('used for') or broad ('based on' or 'make use') benchmark is used.

Similarly, the extent of technology transfer of aquatic genetic resources under experimental use defences varies depending on whether a nation allows the defence to apply narrowly ('on') or broadly ('with') in relation to a patented invention such as a research tool. Research tools are resources used for experimentation, including genetic material, promoters, biological receptors and transgenic species.[149] Experiments 'on' the invention include investigating the

149 Cook points out that 'the term "research tool" involves an important element of purpose' because 'the subject of a patent claim may be a research tool in one context, and an object of study in its own right in another': Trevor Cook, 'Responding to Concerns about the Scope of the Defence from Patent Infringement for Acts Done for Experimental Purposes Relating to the Subject Matter of the Invention' (2006) 3 *Intellectual Property Quarterly* 193, 210. Research tools that are incorporated physically into a new product that is ultimately marketed may trigger the 'sells' limb of exclusive rights and those that are not physically incorporated but are used to make other products can trigger the 'use' limb: Janice M Mueller, 'No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools' (2001) 76 *Washington Law Review* 1, 14–15.

material for the purposes of testing and further developing the invention,[150] such as experiments on patented aquatic genetic material aimed at discovering another function of a genetic sequence.[151] Experimenting 'with' an invention is where the material itself is not being investigated, but rather is used as a tool to investigate a gene and its expression.[152] In other words, the material is being used as an end product or commercial application of the genetic resource.

For example, if a patented chemical compound for pest resistance is introduced into a new aquaculture stock, the breeder is using the patented invention as a tool for introducing a gene into an animal genome (experimenting 'with' the invention) rather than working on the patented invention to improve the tool (experimenting 'on' the invention).[153] Most countries only allow the more restrictive 'on' the invention approach,[154] while a minority allow experimentation 'with' an invention[155] and a few do not draw a distinction between the two,[156] recognising that the two are often intertwined in practice, particularly in areas such as biotechnology.[157]

The *TRIPS* and *Convention* frameworks both give members and parties the flexibility to tailor defences or obligations to their technological capabilities.[158] In accordance with *TRIPS* article 30, a narrow experimental use defence ('on') would protect investment in research tools for nations with good biotechnological infrastructure.[159] For developing countries seeking to build their technological capabilities, particularly those that depend on aquaculture for income and food

150 *Gene Patenting and Human Health*, above n 54, 339 [13.86]. However, once a technique is validated and becomes routine the defence no longer applies: Cook, above n 149, 218.

151 *Gene Patenting and Human Health*, above n 54, 342 [13.99]. Another common example would be that under the 'on' limb, work to provide an improved polymerase chain reaction ('PCR') methodology would probably qualify as experimental use, but work that simply used PCR as a 'standard procedural step' would not: W R Cornish, M Llewelyn and M Adcock, 'Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector' (Report, Public Health Genetics Unit, Cambridge Genetics Knowledge Park, July 2003) 71–2 <http://www.phgfoundation.org/file/16334/>.

152 *Gene Patenting and Human Health*, above n 54, 339 [13.87].

153 Prifti, above n 114, 219.

154 This is often expressed as 'relating to the subject matter of the invention'. See, eg, *Patents Act 1990* (Cth) s 119C(1): 'A person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention'.

155 See, eg, *Code de droit économique* [Code of Economic Law] (Belgium) book XI art 34(1)(b).

156 See, eg, *Patents Act 1970* (India) s 47(3) which provides that any patented product or process 'may be made or used … by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils'. For a discussion of the breadth of experimental use exceptions, see *The Patent System and Research Freedom: A Comparative Study*, WIPO Doc SCP/15/3, annex 6, 41–2.

157 Advisory Council on Intellectual Property, *Patents and Experimental Use* (Report, October 2005) 19, 52–3 ('*Patents and Experimental Use*').

158 Some commentators argue, however, that the broad 'with' defence may not be compliant with *TRIPS* art 30 because using an invention for its intended purpose (ie, as a tool for research) may 'unreasonably conflict with the normal exploitation of the patent': Chris Dent, 'The *TRIPS* Agreement and an Experimental Use Exception for "Research Tools"' (2011) 44 *Australian Economic Review* 73, 77.

159 However, the defence could not be so narrow that research would be driven offshore: Cook, above n 149, 220.

security, a broad defence ('with') could provide greater access to research tools for breeding and disease control.[160]

Similarly, under the *Convention* framework, a party has the discretion to choose a narrow obligation ('used for' the actual research for which they were provided).[161] This could protect investment in research and patented technologies for nations with good biotechnology infrastructure by only sharing their technology and know-how for the research for which the genetic materials were provided, and not *any* research that happens to be connected with the genetic material. On the other hand, a broad obligation ('based on' the relevant research[162] or 'make use' of the genetic resources)[163] could ensure that developing countries seeking to build their technological capabilities have the opportunity to participate in a broader range of activities associated with the genetic resources they provided. This may be particularly important if there is a long time lag between accession of genetic resources from their jurisdiction and eventual use, as in the Halichondrin B example, which took around 30 years, during which time research intent may change.

An important point to remember is that under the *Protocol*, a country is only required to treat and enforce technology transfer of the commercial *products* of genetic resources as a discretionary contractual obligation within the *Protocol*'s ABS framework. The *Convention* on the other hand imposes a legal obligation on its parties to set up a technology transfer framework for genetic resources which may arguably include subsequent commercial products. This means that a country's technology transfer policies made in accordance with the *Convention* may be frustrated by users and providers of genetic resources effectively opting out through *Protocol*-compliant contractual ABS provisions. Some developments in patent law concerning the overriding of contractual provisions that frustrate policy objectives for technology transfer may be instructive for balancing these ABS and technology transfer obligations. Under a defence in the *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland), farmers who have originally acquired patented reproductive material with the patent owner's consent may replicate it on their own farm, that is, to use the material in a way that would be an infringement but for the defence.[164] Contractual agreements that attempt to limit this defence are void.[165]

160 However, a broad defence could have unintended effects on other biotechnological sectors: see C G Trojan, 'Problem-Solving Approaches to the Issue of the Overlap between Patent Law and Breeders' Rights in the Plant Breeding Sector' (Report, Ministry of Economic Affairs, Agriculture and Innovation (Netherlands), 31 July 2012) 10 ff <http://aiph.org/wp-content/uploads/2015/04/27428-236_engl_report_trojan.pdf>.

161 *Convention* art 19(1).

162 *Convention* arts 15(6), 19(2).

163 *Convention* art 16.

164 *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 35A(1). However, they must obtain the patent owner's consent if they 'wish to give' it to a third party: art 35A(3).

165 *Bundesgesetz über die Erfindungspatente 1954* [Federal Act on Patents for Inventions 1954] (Switzerland) art 35A(4).

Arguably, the *Convention* does not preclude a similar approach to overriding contractual limitations in order to achieve its policy goals relating to technology transfer of commercial applications of genetic resources under specific circumstances.

2 Commercial Uses

Whether technology transfer obligations apply to commercial *research* is a different question to whether they apply to the final commercial application, or end product. Arguably, none of the technology transfer or ABS obligations under discussion in this article limit their scope to non-commercial uses.[166] Under the *Protocol*, parties have an obligation to '[c]reate conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity … including through simplified measures on access for non-commercial research purposes'.[167] This indicates that obligations concerning technology transfer may be stronger in relation to non-commercial uses of *Convention*-related technologies, including research and breeding. It does not, however, indicate that research must not be commercial in nature before obligations apply. Still, clarification is required about how technology transfer and ABS obligations address changes of intent of use so that a country's simplified measures for non-commercial use are not abused.

The way in which patent law defences treat commercial and non-commercial uses of patented genetic material may provide valuable guidance for changes of intent in this regard. Many nations have patent law defences for private and non-commercial uses of patented inventions.[168] Courts, however, have experienced difficulties in distinguishing between 'pure' non-commercial research and research whose purpose it is to produce a commercial outcome.[169] This distinction is particularly blurred in the area of biotechnology.[170] In cases where an activity has both commercial and non-commercial benefits, some laws require the subjective intention of the users to be ascertained.[171] If the intention was non-commercial at the time of use, the user could rely on a non-commercial use defence even if the resulting information has a commercial benefit.[172] Emerging norms in the European Union seek to strike a fairer balance between the

166 *Convention* art 15(7) expressly includes commercial use in its scope.

167 *Protocol* art 8(a).

168 See, eg, *Patents Act 1977* (UK) c 37, s 60(5)(a), which provides that an 'act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if … it is done privately and for purposes which are not commercial'.

169 *Gene Patenting and Human Health*, above n 54, 329 [13.49].

170 *Patents and Experimental Use*, above n 157, 19.

171 *Introduction*, WIPO Doc SCP/15/3, annex 1, 56.

172 See *SKF Laboratories v Evans Medical* [1989] FSR 513, 518 (Aldous J), cited in *Introduction*, WIPO Doc SCP/15/3, annex 1, 56 n 165.

commercial and non-commercial phases of research.[173] To this end, some laws do not distinguish between commercial and non-commercial uses, as long as the ultimate goal is to promote technical or scientific progress.[174] These emerging norms could be similarly applied to technology transfer obligations when it comes to pinpointing the temporal scope between commercial and non-commercial uses of aquatic genetic resources.

C Extraterritoriality

The trans-jurisdictional nature of aquatic stocks and the multi-jurisdictional nature of corporations, which are increasingly involved in biotechnological uses of aquatic genetic resources,[175] pose key challenges for certainty and enforcement of technology transfer across national boundaries. Both ABS and patent law regimes can only operate within national jurisdiction and therefore face the same extraterritorial challenges. This section identifies the *Convention* and *Protocol*'s optional and contractual forms for multilateral technology transfer and contrasts this with patent law's legislative approach to achieving multilateral objectives under its defence framework. Specifically, this section highlights how exhaustion and temporary presence defences under patent law can achieve multilateral objectives within national regimes.

The *Convention* and *Protocol* provisions apply to areas within the limits of national jurisdiction.[176] In areas beyond national jurisdiction – the high seas and deep seabed – a *Convention* party has no sovereign jurisdiction over the *products* (actual aquatic genetic resources) but it does have technology transfer obligations toward *activities* carried out under its jurisdiction or control.[177] *Protocol* ABS

173 'The WTO Panel decision [*Canada – Pharmaceutical Products Case*, WTO Doc WT/DS114/R] suggests that a European-type provision is more likely to be considered to be in accord with the *TRIPS* Agreement than other types': Advisory Council on Intellectual Property, above n 157, 3. See also Matthew Rimmer, *Intellectual Property and Biotechnology: Biological Inventions* (Edward Elgar, 2008) 182; Tim Sampson, 'Madey, Integra and the Wealth of Nations' (2004) 26 *European Intellectual Property Review* 1, 6.

174 *Clinical Trials II*, Bundesgerichtshof [German Federal Court of Justice], X ZR 68/94, 17 April 1997 reported in (1997) 135 BGHZ 217, quoted in Annette Kur and Thomas Dreier, *European Intellectual Property Law: Text, Cases and Materials* (Edward Elgar, 2013) 120.

175 Organisation for Economic Co-operation and Development, *Globalisation in Fisheries and Aquaculture: Opportunities and Challenges* (2010) 48.

176 *Convention* art 4(a); *Protocol* art 3. These agreements must be consistent with the rights and obligations under the 'law of the sea' by *Convention* art 22(2) and parties' obligations extend to genetic material in zones within national jurisdiction – internal waters, territorial waters, contiguous zone, archipelagic waters, exclusive economic zones and extended continental shelves: *United Nations Convention on the Law of the Sea*, opened for signature 10 December 1982, 1833 UNTS 3 (entered into force 16 November 1994) arts 2–15, 33, 46–50, 55–74, 76–85.

177 *Convention* arts 4(a)–(b). For example, the exploitation of genetic resources in the high seas carried out by a party's nationals and vessels operating under its flag could be considered activities that fall within the scope of art 4(b): see Greiber et al, above n 35, 73. Similarly, Antarctica is not subject to foreign control but observers, scientific personnel and staff located there are subject to the jurisdiction of their state of nationality: *Antarctic Treaty*, signed 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961) arts IV, VIII(1) ('*Antarctic Treaty*').

obligations apply to neither products nor activities carried out in areas beyond national jurisdiction[178] or in Antarctica.[179]

The implications of the geographical limitations of the *Convention* and *Protocol* for the effective sharing of genetic resource technologies and their benefits are becoming increasingly documented.[180] Wild sponges have commonly been accessed and used as source organisms for bio-prospecting in areas beyond national jurisdiction and Antarctica, particularly for pharmaceuticals. For example, a derivative of Variolin B sourced from the Antarctic sponge *Kirkpatricka varialosa*[181] is the subject of various patents.[182] Such aquatic genetic resources would not fall within the scope of technology transfer or ABS obligations because claims of sovereignty within the Antarctic Treaty Area are on hold.[183]

Given that the majority of aquaculture programs require regular inputs from migratory wild stocks,[184] it is crucial for the future of the industry to address the challenges of meeting patent law defence criteria and technology transfer obligations in transboundary situations. Under the *Protocol*'s bilateral approach, benefits from using aquatic genetic resources flow to the country of origin that is in fact providing the genetic resources rather than all the countries that possess those genetic resources in situ.[185] This raises questions of equity and competition between different provider parties sharing genetic resources and may lead to a 'race to the bottom' regarding ABS and technology transfer requirements.[186]

Under the *Convention*, parties have an obligation to cooperate with other parties in respect of areas beyond national jurisdiction and on other matters of mutual interest, such as transboundary stocks, 'for the conservation and sustainable use of biological diversity'.[187] Further, the *Protocol* recognises the need for innovative solutions to address the fair and equitable sharing of benefits

178 Veit Koester, 'The *Nagoya Protocol* on ABS: Ratification by the EU and Its Member States and Implementation Challenges' (Study No 03/12, Institut du développement durable et des relations internationales [Institute for Sustainable Development and International Relations], June 2012) 16 <http://www.iddri.org/Publications/The-Nagoya-Protocol-on-ABS-ratification-by-the-EU-and-its-Member-States-and-implementation-challenges>.

179 This is because the scope of the *Protocol* is confined to the scope of *Convention* art 15 dealing with products, in contrast to the *Convention*'s general scope in art 4 which includes activities beyond state jurisdiction: see Greiber et al above n 35, 73–4.

180 See, eg, Ane Jørem and Morten Walløe Tvedt, 'Bioprospecting in the High Seas: Existing Rights and Obligations in View of a New Legal Regime for Marine Areas beyond National Jurisdiction' (2014) 29 *International Journal of Marine and Coastal Law* 321.

181 *An Update on Biological Prospecting in Antarctica, Including the Development of the Antarctic Biological Prospecting Database*, Antarctic Treaty Consultative Meeting, 31st mtg, Agenda Item 17, WP 011 (June 2008) 9.

182 See, eg, Mercedes Alvarez, José Luis Fernández Puentes and David Ferández Bleda, 'Derivatives of Variolin B' (United States Patent No 7,329,666 B2, published on 12 February 2008, assigned to Pharma Mar SA).

183 *Antarctic Treaty* art IV.

184 This is to prevent inbreeding depression: Gjedrem, 'Genetic Improvement', above n 8, 20.

185 Greiber et al, above n 35, 128–9.

186 Ibid 17–18.

187 *Convention* art 5.

from using transboundary genetic resources.[188] To this end, the *Protocol* requires parties to consider the possible development of a 'global multilateral benefit-sharing mechanism' for resources in 'transboundary situations or for which it is not possible to grant or obtain prior informed consent'.[189] It also reaffirms the need for cooperation over transboundary genetic resources.[190]

The sea sponge example demonstrates that there are both pros and cons of taking a multilateral approach to sharing aquatic genetic resources. It may be advantageous for discharging technology transfer obligations in certain situations. First, it may be useful where a user that was not involved in the original acquisition of the genetic resources is using them without being able to trace the provider country among the several countries of origin.[191] Secondly, it might assist where genetic resources are obtained from a country that has not yet established ABS requirements, as would have been the case for New Zealand and Palau in the *Halichondria* genus sea sponge example. Thirdly, it might assist where genetic resources from ex situ collections such as gene banks are used in the absence of information on country or countries of origin.

Unlike the current extensive system for the exchange of terrestrial plant germplasm collections, which began in the early 20th century,[192] the history of aquatic gene banks goes back two decades.[193] The numbers of aquatic banks[194] and coordination between banks lag behind similar repositories for plants.[195] Nor are there generally accepted protocols or regulations governing the access to and use of aquatic resources.[196] Rather, private law contracts are usually agreed between the providers and users of aquatic resource, and 'very little importance is given to access and benefit sharing considerations'.[197] A

188 The *Protocol* preamble states

> that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent.

189 *Protocol* art 10.

190 *Protocol* art 11.

191 Greiber et al, above n 35, 129–30.

192 According to Koo, Pardey and Wright:

> Recent estimates quantified existing global ex situ collections at over 6 million accessions in more than 1300 genebanks worldwide. About 10 [per cent] of these accessions are maintained within the centres of the Consultative Group on International Agricultural Research (CGIAR), most of them as 'in trust' accessions for the international community under the auspices of the Food and Agriculture Organization of the United Nations.'

Bonwoo Koo, Philip G Pardey and Brian D Wright, 'Introduction' in Bonwoo Koo, Philip G Pardey and Brian D Wright (eds), *Saving Seeds: The Economics of Conserving Crop Genetic Ex Situ in the Future Harvest Centres of the CGIAR* (CABI Publishing, 2004) 2 (citations omitted).

193 See David Greer and Brian Harvey, *Blue Genes: Sharing & Conserving the World's Aquatic Biodiversity* (Earthscan, 2004) 67–8.

194 Ibid 33, 68. For examples of governmental and non-governmental collections, see Bartley et al, above n 70, 24–5.

195 Greer and Harvey, above n 193, 67.

196 Bartley et al, above n 70, 24.

197 Ibid.

multilateral mechanism could assist with a more coordinated approach to sharing aquatic genetic resources that are sourced globally.

On the other hand, parties with ABS systems may feel aggrieved if other countries effectively 'sponge' off their research and obtain a share in benefits simply because they happen to have the same species occurring in situ, particularly in instances of polymorphism.[198] For example, the chemical compound Peloruside A is only expressed in *Mycale hentscheli* sponges found in particular areas of the Pelorus Sound.[199] It may not be considered fair and equitable if benefits from the use of the technology flow to the custodians of any waters in which the species is located.

One step toward a multilateral approach is the *Protocol*'s innovative tools to tackle the access and use of genetic material from multiple providers within multiple jurisdictions. The *Protocol* goes beyond traditional public international law because it not only regulates relations between states, but also relations between states and non-state actors.[200] However, there are problems with leaving technology transfer obligations to the discretion of individual parties. For example, unfairness arising from uneven bargaining power of increasingly multinational corporations that are involved in using genetic resources for biotechnology or aquaculture purposes.[201]

The *Protocol* does offer an innovative legislative solution to tackle cross-jurisdictional compliance with user measures for accessing genetic resources. Here, parties are required to take measures to comply with provider country measures concerning prior informed consent and mutually agreed terms, to address noncompliance with those measures and to cooperate with other parties in cases of alleged noncompliance.[202] Every party has these obligations, regardless of whether it requires prior informed consent for access to its own genetic resources. This innovation does not extend, however, to the cross-jurisdictional enforcement of technology transfer as a form of benefit sharing. Instead, cross-jurisdictional enforcement is addressed contractually between

198 The presence of polymorphism in a given sponge species means that 'the economic value may lie in the internal genetic differences between examples of the same species (local adaptations, for example)': Greiber et al, above n 35, 18.

199 Page et al, above n 80, 53.

200 Non-state parties include the private sector, research and indigenous communities: Elisa Morgera, Matthias Buck and Elsa Tsioumani, 'Introduction' in Elisa Morgera, Matthias Buck and Elsa Tsioumani (eds), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective: Implications for International Law and Implementation Challenges* (Martinus Nijhoff, 2013) 1, 10. For example, the *Protocol*'s provisions on capacity building in art 22 explicitly address a broad range of non-state actors.

201 See Rosendal, Olesen and Tvedt, 'Evolving Legal Regimes', above n 70, 104.

202 *Protocol* arts 15–16.

parties under mutually agreed terms [203] and enforced through compliance obligations requiring parties to ensure opportunities for dispute resolution.[204]

Legislative solutions to cross-jurisdictional technology transfer, such as those under patent law defences, have the advantage of increasing legal certainty for users and providers by developing a framework for technology transfer and collaboration. The patent law principle of exhaustion and its practical effects on technology transfer of patented genetic inventions through parallel importation is one such example. Exhaustion operates as a defence, protecting users from infringement claims concerning the use or sale of a patented product after the patent owner has authorised its sale without reservations.[205] The rationale behind the doctrine is that the patent owner has received full benefit of the patent from the first sale so they should not be able to restrain the resale of products in which their patents are embedded.[206] The significance of exhaustion is that a nation may regulate the extent of a patent holder's control over a patented product once it has been sold, depending on whether it allows regional or international exhaustion.[207]

Where national exhaustion is prescribed, the patent is exhausted by the unreserved domestic sale of the patented product, but importations are still infringements. If a country allows regional or international exhaustion, the patent is exhausted by the unreserved sale of the patented product in the region (eg, the European Union) or in any foreign country respectively, so that importations are not infringements.[208] This is when parallel importation becomes relevant. Patented products can only be parallel imported when the patent embodied in them has been exhausted.[209] Parallel importation means that a third party can purchase a patented aquatic genetic material product from the patent holder on the market in one country and then import into another country for resale there, but the third party cannot make and sell the product themselves.[210] In other words, exact replication of the genetic invention is not allowed but modification might

203 To support compliance with contractual obligations (as opposed to user measures), parties are obliged to 'encourage' users and providers of genetic resources or traditional knowledge to cover dispute resolution measures in their mutually agreed terms, 'ensure' opportunities for legal recourse under their legal systems and take 'effective measures' for mutual recognition of foreign judgments and awards: *Protocol* art 18. See Greiber et al, above n 35, 162.

204 *Protocol* art 18.

205 See Garrison, above n 56, 15.

206 Olasupo Owoeye, 'Access to Medicines and Parallel Trade in Patented Pharmaceuticals' (2015) 37 *European Intellectual Property Review* 359, 360.

207 See Garrison, above n 56, 16.

208 See, eg, *Ley de Patentes de Invención y Modelos de Utilidad 1995* [Law on Patents and Utility Models 1995] (Argentina) art 36(c), which provides that the rights conferred by a patent shall have no effect against 'any person who ... imports or in any way deals in the product patented or obtained by the patented process once the said product has been lawfully placed on the market in any country; placing on the market shall be considered lawful if it conforms to Section 4 of Part III of the *TRIPs* Agreement' [Carlos M Correa trans, 'Intellectual Property Rights and the Protection of Public Health in Developing Countries in World Bank' in *The World Bank Legal Review: Law and Justice for Development* (World Bank, 2003) vol 1, 161, 191 n 98].

209 Christopher J Clugston, 'International Exhaustion, Parallel Imports, and the Conflict between the Patent and Copyright Laws of the United States' (2013) 4 *Beijing Law Review* 95, 95.

210 See Garrison, above n 56, 16.

be allowed under certain circumstances.[211] In effect, this achieves technology transfer by having less costly patented aquatic genetic resources available for experimental and breeding uses than those in other jurisdictions.[212]

A similar approach could be taken to discharge the *Convention*'s technology transfer obligations. Those genetic resources accessed in accordance with the *Convention* that are patented are already subject to the principle of exhaustion. Even for those resources that are not patented, a country could arguably create a system of international exhaustion connected with the unreserved sale of genetic resources. This would mean that where aquatic genetic resources have been sold in any country, a provider country with international exhaustion would be entitled to use the genetic resource – not to produce exact replicas, but to use or modify the resources for research or breeding purposes. This may achieve a legal framework for fair and equitable sharing of benefits between providers and users. *TRIPS* leaves it up to WTO members to decide the extent to which exhaustion applies in their country,[213] which is consistent with the exercise of sovereign rights over resources under the *Convention*. This means that if a nation, such as a developing country wants to attract technology transfer of genetic resources, it could choose a system of international exhaustion, rather than national exhaustion for the sale of genetic resources.

Another example of a patent law defence that has multi-jurisdictional reach is the temporary presence defence. Unlike all other defences which are discretionary, all WTO members are obliged to include a defence preventing a member country from enforcing a patent against a visiting conveyance (eg, a vessel containing a patented product) belonging to another member country when that vessel temporarily or accidentally enters its domestic waters.[214] Without the defence, the unauthorised importation and use of the patented invention would infringe a patent holder's rights. While the purpose of the defence is to facilitate uninterrupted international travel,[215] arguably, it could be indirectly used to facilitate experimental use of self-replicating patented genetic resources in roaming open ocean cages if such devices fall within the defence's requirements.[216] Such multilateral approaches to defences under patent law could give valuable insight into how technology transfer obligations can similarly apply to multiple parties in multiple jurisdictions under the *Convention* and *Protocol*.

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211 See Humphries, above n 47, 220. This raises the same issues as those in Part IV(A) above concerning the extent to which a derivative would need to be different from the patented original for exhaustion to apply.

212 Ibid 219.

213 *TRIPS* art 6. This is subject to *TRIPS* provisions on national treatment in art 3 and most favoured nation treatment in art 4. See also *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001, adopted 14 November 2001) art 5(d).

214 See *TRIPS* art 2(1) and above n 59 and accompanying text.

215 See Garrison, above n 56, 9.

216 The requirements are that: (1) the temporary entrants must be vessels; (2) they must enter another country on a temporary or accidental basis; and (3) the patented product must be used exclusively for the needs of the vessel: J Jonas Anderson, 'Hiding Behind Nationality: The Temporary Presence Exception and Patent Infringement Avoidance' (2008) 15 *Michigan Telecommunications Technology Law Review* 1, 3. For arguments on the relevance of the exception for breeding, see Humphries, above n 47, 221–2.

V CONCLUSION

The interrelationship and the similarities between frameworks for *TRIPS*-consistent patent law defences, *Convention* technology transfer obligations and *Protocol* ABS obligations means that patent law could be an important influence on the approach taken to technology transfer under the *Convention*.[217] All frameworks aim to achieve the transfer and dissemination of technology to the mutual advantage of providers, producers and users of technological knowledge.[218] Each also faces interesting questions about how to discharge their respective technology transfer obligations in a fair and equitable manner. It is important to remember, however, that the *Convention*'s 'access and technology transfer' obligations treat technology transfer as an obligation in its own right, whereas the *Protocol*'s ABS obligations treat technology transfer only as a form of contractual benefit sharing. The difference in approaches raises challenges for three concepts that they have in common and that need legal clarification to achieve technology transfer: the scope of derivatives of genetic resources, the temporal scope of use across the research to commercialisation continuum and extraterritorial technology transfer.

Regarding the scope of derivatives, patent law defences provide a temporal approach to clarifying the point at which the derivative is sufficiently removed from the genetic resource on which it is based to no longer be considered *Convention*-related technology falling under technology transfer or ABS obligations. The patent law approach also gives insight into how legal certainty can be achieved for clarifying the temporal scope of 'use', the point at which technology transfer obligations attach to users and providers along the research to commercialisation continuum. Here, experimental use defences and non-commercial use defences provide an approach to tackling technology transfer of commercial applications of genetic resources and changes of intent for use. Finally, patent law defences of exhaustion and temporary presence indicate how national legal regimes can tackle similar extraterritorial issues to those faced by ABS regimes when it comes to the transfer of genetic resource technologies from multiple jurisdictions.

Patent and ABS regimes are faced with similar challenges when it comes to regulating aquatic genetic resources. Analysis of the three challenges in this article is only the first step towards identifying the areas in which patent law defences could assist in the interpretation of the *Convention*'s technology transfer obligations and *Protocol*'s ABS obligations. The interdependence between patent and ABS frameworks means that their legal norms should evolve together to avoid legal uncertainty. Given that developing countries provide over 80 per cent of the world's aquaculture products,[219] the need for a coherent approach to 'fair

217 See *The Role of Intellectual Property Rights*, UN Doc UNEP/CBD/COP/9/INF/7, 7 [18].
218 *TRIPS* art 7; *Convention* art 1; *Protocol* art 1.
219 Bartley et al, above n 70, 6.

and equitable' technology transfer under patent and ABS regimes will become increasingly important as patents start to take hold in aquaculture.

Table 1: The *Convention* and *Protocol*'s Main Technology Transfer and Collaboration Obligations

Article	**Purpose**	**Connection to Genetic Resources ('GRs')**	**Nature or Terms for Transfer**	**Main beneficiaries of Technology Transfer**	**Uncertainties for Legal Interpretation**
Convention art 15(6)	Technological collaboration	'[B]ased on' GRs	Silent	Contracting Parties who provide the GRs	Meaning of 'based on' GRs and the types of derivatives it could cover
Convention art 15(7)	Sharing results of research and development, and other benefits	'[C]ommercial and other utilization' of GRs	'[F]air and equitable way … upon mutually agreed terms'	Contracting Parties who provide the GRs	Distinction between 'commercial' and 'other utilization'
Convention art 16(1)	Access to and transfer of technology	'[M]ake use' of GRs	Silent	All Contracting Parties	Meaning of 'make use' of GRs, and the types of derivatives and commercial applications it could cover
Convention art 16(2)	Access to and transfer of technology	'[M]ake use' of GRs	'[F]air and most favourable terms, including on concessional or preferential terms where mutually agreed'	'[D]eveloping countries', even if not provider countries	Meaning of 'make use' of GRs, and the types of derivatives and commercial applications it could cover
Convention art 16(3)	Access to and transfer of technology	'[M]ake use' of GRs	'[M]utually agreed terms'	Contracting Parties who provide the GRs, 'in particular those that are developing countries'	Meaning of 'make use' of GRs, and the types of derivatives and commercial applications it could cover

Article	Purpose	Connection to Genetic Resources ('GRs')	Nature or Terms for Transfer	Main beneficiaries of Technology Transfer	Uncertainties for Legal Interpretation
Convention art 16(4)	Access to, joint development and transfer of technology	'[M]ake use' of GRs	Silent	'[G]overnmental institutions and the private sector of developing countries'	Meaning of 'make use' of GRs, and the types of derivatives and commercial applications it could cover
Convention art 19(1)	Participation in biotechnological research activities	'[P]rovide the [GRs] for such research'	Silent	Contracting Parties who provide the GRs, 'especially developing countries'	Connection with GRs and their derivatives and whether it extends to non-commercial research
Convention art 19(2)	Priority access to the results and benefits arising from biotechnologies	'[B]ased upon' GRs	'[F]air and equitable basis … on mutually agreed terms'	Contracting Parties who provide the GRs, 'especially developing countries'	Meaning of 'based upon', and the types of derivatives and commercial applications it could cover
Convention art 20(4)	Financial resources and transfer of technology	Silent	'[T]ake fully into account the fact that economic and social development and eradication of poverty are the first and overriding priorities'	'Developing countr[ies]'	No uncertainties raised in this article's analysis (included for completeness)
Convention art 20(5)	Financial resources and transfer of technology	Silent	'[T]ake full account of the specific needs and special situation of least developed countries'	'Least developed countries'	No uncertainties raised in this article's analysis (included for completeness)

Article	**Purpose**	**Connection to Genetic Resources ('GRs')**	**Nature or Terms for Transfer**	**Main beneficiaries of Technology Transfer**	**Uncertainties for Legal Interpretation**
Protocol art 22	Capacity-building	Silent	Silent	'[D]eveloping country Parties, in particular the least developed country Parties and small island developing states … and Parties with economies in transition'	Whether it includes technology transfer of genetic resource applications (end products)
Protocol art 23	Collaboration and cooperation in technical and scientific research	Silent	'Fair and equitable' (reference to objective stated in *Protocol* art 1)	'Where possible and appropriate … collaborative activities' should take place in and with the provider country	Whether connection to GRs is 'based on', 'used for' or 'make use of' and whether it relates to commercial applications (given reference to *Convention* arts 15–16, 17–18)
Protocol art 23	Access to and transfer of technology	Silent	'Fair and equitable' (reference to *Convention* and *Protocol* objectives)	'[D]eveloping country Parties, in particular the least developed country Parties and small island developing states … and Parties with economies in transition'	Whether a legal obligation or general commitment, and whether connection to GRs is 'based on', 'used for' or 'make use of' and whether it relates to commercial applications (given reference to *Convention* arts 15–16, 17–18)

Article	**Purpose**	**Connection to Genetic Resources ('GRs')**	**Nature or Terms for Transfer**	**Main beneficiaries of Technology Transfer**	**Uncertainties for Legal Interpretation**
Protocol annex	Benefit-sharing	'[M]ake use' of GRs	'[F]air and most favourable terms, including on concessional and preferential terms where agreed'	'[P]rovider of the [GRs]'	Relationship between 'make use' of GRs, and general *Protocol* benefit-sharing obligations relating to 'utilization of' GRs