Shellfish patents krill research: patent law defences and technology transfer of genetic materials and knowledge in aquaculture

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STATEMENT OF ORIGINALITY

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

(Signed): 

(Date): 21 July 2016

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ABSTRACT

The recent rise of access and benefit sharing (ABS) and patent laws concerning the use of aquatic genetic resources is creating increasing legal complexity and uncertainty for the aquaculture sector. The complexity and uncertainty comes at a time when the sector needs unprecedented access and exchange of genetic resources, technologies and knowledge for its early stages of domestication and scientific research and development. Arguably, the complexity largely stems from using the geographical origin of a resource to determine which ABS or stand-alone technology transfer obligations apply. This may suit transactions of terrestrial genetic resources whose origin can be determined within national jurisdiction. It is less suited to self-replicating aquatic genetic resources that can migrate between jurisdictional areas. It is also less suited to regulating derivatives such as the digital (knowledge) resource accessed independently from the physical genetic resource.

This thesis looks beyond the geographical origin to three underlying approaches that generalise how international instruments regulate ABS and technology transfer of genetic resources within three jurisdictional areas – proprietary (within national jurisdiction), stewardship (beyond national jurisdiction or the ‘deep sea’) and cooperative (in the Antarctic Treaty Area) approaches. The benefit of this categorisation is to understand the assumptions and principles underlying each instrument’s approach to technology transfer with a view to finding similarities and compatibilities between three shared legal challenges. First, determining the point at which derivatives and technical knowledge are sufficiently removed from the genetic resource on which they are based for technology transfer rules to no longer apply (derivative challenge). Secondly, the difficulties for distinguishing between commercial and non-commercial uses for which different technology transfer rules apply (commercial use challenge). Thirdly, how to address challenges for implementing technology transfer obligations over genetic resources located in multiple jurisdictions from multiple providers (extra-territoriality challenge).

Patent law plays an increasing role in the balancing of private interests over genetic resource technologies with the public interest in sharing the resources and knowledge
for further innovation in aquaculture. While most literature focuses on the conflicts between patent and ABS regimes, this thesis refocuses the debate on the compatibilities between the regimes, and how they can use consistent approaches to resolve the same challenges that they face. The thesis maps the defences that facilitate the sharing of patented genetic resource technologies for use in aquaculture breeding and research. It also analyses emerging norms for addressing the three legal challenges under the patent law defence framework that is compliant with the World Trade Organisation’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The research question asks whether a TRIPS-compliant patent law defence framework for technology and knowledge transfer can offer certainty and structure for equitably sharing physical and digital genetic resources for use in aquaculture under ABS regimes.

The research found that while patents are proprietary in nature, the defence framework was not limited by the transactional and territorial nature of the proprietary approach under the United Nations’ Convention on Biological Diversity and Nagoya Protocol that regulate in situ and ex situ genetic resources within national jurisdiction. This meant that its approach to resolving the three legal challenges (derivatives, commercial use and extra-territoriality) were also consistent with the stewardship approach under the United Nations Convention on the Law of the Sea (UNCLOS) that facilitates the sharing of deep sea genetic resources for the benefit of the scientific and technological progress of all humankind. The research found that the TRIPS-compliant patent law defence framework was also consistent with the cooperative approach under the Antarctic Treaty System instruments, where private and public interests are balanced with the objective of supporting the collective purpose of freedom of scientific investigation.

Using case studies of genetic resource technologies from sea sponges, tuna, deep sea shrimp, cold ocean pelagic fish and other examples of technologies relevant to product development in aquaculture, the research found TRIPS-compliant norms for addressing derivative, commercial use and extra-territorial challenges that could be applied consistently to the use of genetic resource across the jurisdictional areas. Regarding the derivative challenge, the biological origin (either present or expressed) of the derivative could be the determining factor for whether technology transfer obligations apply and these obligations could only be restricted by patented genetic resource inventions that
are based on the functional origin (expressed, not merely present) of the relevant genetic resource invention. Regarding the commercial use challenge, distinguishing between commercial and non-commercial uses of genetic resources creates unnecessary legal complexity. A more practical guide is determining whether the ultimate goal of the resource’s use is to promote technical or scientific progress. Proprietary interests are still protected by the functional origin approach. Regarding the extra-territorial challenge, states can implement their national obligations in a way that breaks the territorial nexus so that the provider state regulates access but the benefits are directed towards achieving a collective technology transfer goal.

This research concluded that the TRIPS-compliant patent law defence framework is an underutilised but effective mechanism that is currently available for balancing rights and interests in genetic resources across the three jurisdictional areas. As the framework’s normative content evolves to suit new aquatic technologies, it can guide consistent interpretation of obligations under the patchwork of ABS regimes to create certainty for users and providers of genetic resources. This is not only in relation to the three common legal challenges in this thesis, but also to other challenges as they arise, including the unfolding negotiations of the implementing agreement under UNCLOS concerning ABS of deep sea genetic resources. In the meantime, more needs to be done to raise farmers’ and researchers’ awareness about patent law defences available to them. User certainty is a crucial first step towards facilitating the level of exchange of genetic resources, technologies and knowledge that is necessary for sustainably increasing aquaculture production to meet the protein needs of the world’s spiralling human population.
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PUBLISHED/ UNPUBLISHED PAPERS INCLUDED IN THE THESIS

This thesis is published in accordance with Griffith University’s policy on a thesis presented as a series of published and unpublished papers (Appendix). I am the sole author of the published and unpublished papers. Appropriate acknowledgements of those who provided comments on drafts but did not qualify as authors are included in each paper. The bibliographic details for these papers are:

**Chapters 1 & 8:** The following publication draws from content in these chapters:


**Chapter 2:**  

**Chapter 3:**  

**Chapter 4:**  

**Chapter 5:**  

**Chapter 6:**  
GLOSSARY AND ABBREVIATIONS

Access and benefit sharing (or ABS): A legal concept and framework for regulating how genetic resources may be accessed from in situ or ex situ sources and how the benefits arising from their use are equitably shared between the users and the providers of the genetic resource (Convention, art 15).


Antarctic Treaty Area: Antarctic land and waters in the area south of 60° South latitude (Antarctic Treaty, art VI).

Antarctic Treaty System: The entirety of instruments and arrangements that regulate relations among states in Antarctica, including the Antarctic Treaty, Madrid Protocol and CCAMLR (see definitions below).

Aquaculture: The farming of aquatic organisms, including fish, molluscs, crustaceans, invertebrates and aquatic plants.

Area beyond national jurisdiction (also ‘deep sea’): The zone beyond state jurisdiction that comprises the high seas water column (‘the high seas’, UNCLOS arts 86-120) and the seabed and ocean floor and subsoil below the water column (‘the Area’ UNCLOS, arts 133-191).

Biological resources: ‘Includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity’ (Convention, art 15).


Cooperative approach: Cooperative approach to technology transfer underlying the Antarctic Treaty System and the Plant Treaty. It is based on the assumption that technology (including knowledge) transfer achieves a collective purpose that transcends national boundaries. Under this approach, the provider state grants access to the genetic resource but the benefits of its use flow to the collective to achieve a particular goal.

Covenant: See definition for ICESCR below.

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1 For some of the key terms, different abbreviations are used because of the style requirements for different journals and book publishers. Each variation is included below.
Deep sea: See definition for ‘areas beyond national jurisdiction’.

Digital resources: Data, information and knowledge about technologies based on the physical resource as well as other technical, scientific and socio-economic research results including the resources’ characterisation, evaluation and utilisation (Plant Treaty, art 13(2)(a)).

Ex situ genetic resources: Genetic resources outside their habitats, such as genetic resources and derivatives in gene repositories.

Genetic resources: ‘[M]eans genetic material of actual or potential value’ (Convention, art 2). This thesis uses the term ‘genetic resources’ to include both the physical and digital genetic resource.

Genetic material: ‘[M]eans any material of plant, animal, microbial or other origin containing functional units of heredity’ (Convention, art 2).


In situ genetic resources: Genetic resources within ecosystems and natural or manmade habitats.

Jurisdictional area: One of three areas; areas within national jurisdiction, areas beyond national jurisdiction and the Antarctic Treaty Area.


Proprietary approach: The proprietary approach to technology transfer underlying the ABS provisions of the Convention on Biological Diversity and Nagoya Protocol. It is based on assumptions of the transactional nature and territorial approach to sharing
genetic resources, technologies and knowledge. The transactional nature implies that there is a provider of the genetic resource who has legal control over a resource and who is entitled to obtain the benefit of others’ use of the resource. The territorial assumption implies that it is possible to determine the precise geographical origin of a particular genetic resource or derivative.

**Stewardship approach:** The stewardship approach to technology transfer evident under the deep sea provisions of **UNCLOS** and the **International Covenant**. It is based on the assumption that while the physical deep sea genetic resource may become the property of the legal person or entity that obtained them, the cumulative information and knowledge about the use of genetic resources are held in trust for current and future generations of users and producers and for Earth as a system. It transcends the boundaries of the provider/user transactional relationship of the proprietary approach and includes a kind of trust obligation toward the genetic resource knowledge itself.

**Technology transfer:** The transmission, diffusion and up-take of technology, knowledge, expertise, processes and so on, between and across national boundaries that deliver social, economic and environmental benefits.

**Three legal challenges:** The three legal challenges analysed in Chapters 4-7: a) derivatives – determining the point at which derivatives and technical knowledge are sufficiently removed from the genetic resource on which they are based for technology transfer rules to no longer apply; b) commercial use – the difficulties for distinguishing between commercial and non-commercial uses for which different rules apply; and c) extra-territoriality – how to address challenges involving the transfer of genetic resources located in multiple jurisdictions from multiple providers.

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

**TRIPS-compliant patent law defence framework:** Defences against infringement that are consistent with TRIPS articles 6 (exhaustion), 27(1) (non-discrimination), 30 (exceptions) and 31 (mainly compulsory licences).


Aquaculture needs to increase over a thousand fold by 2050 to meet the projected protein needs of the planet’s spiralling human population. Reasons for the urgent increase include capped and declining wild capture fisheries and terrestrial animal protein being mostly beyond the reach of the world’s poor. To reach this production target, farmers and researchers need access to aquatic biological resources and the genetic resources they contain, which are the building blocks for breeding new strains of aquatic animals and plants. Genetic materials are found in a biological resource’s cells and play a fundamental role in determining the structure and nature of cell substances. These materials are capable of variation and self-propagation and their value for farmers and researchers is the materials’ ability for manipulation through selective breeding, for example to create new strains that are resilient to the impacts of disease, intensive farming and climate change. These resources are also increasingly used to develop gene biotechnologies for commercial aquaculture. Current uses mainly concern the development of vaccines, broodstock selection markers and disease diagnostics but other technologies are becoming increasingly important for aquaculture product
development such as bioinformative,\textsuperscript{6} transgenic and embryonic stem cell technologies.\textsuperscript{7}

While access to the physical genetic resource remains crucial for aquaculture’s early stages of domestication and breeding, biotechnology users may increasingly value the knowledge about the resource independently from the physical resource.\textsuperscript{8} An often cited general legal definition of genetic resources means ‘genetic material of actual or potential value’.\textsuperscript{9} Genetic material ‘means any material of plant, animal, microbial or other origin containing functional units of heredity’.\textsuperscript{10} However, the legal concept of genetic resources is flexible and dynamic so that it can cope with the rapid pace of innovation and technological change in sectors such as biotechnology and biology.\textsuperscript{11} State practice has shown that genetic resources include not only the physical material but also the data, information and knowledge on genetic resources\textsuperscript{12} which this thesis calls the ‘digital resource’. The digital resource can include information about technologies based on the physical resource as well as other technical, scientific and socio-economic research results including the resources’ characterisation, evaluation and utilisation.\textsuperscript{13}

Human manipulation of genetic resources requires investment, and users of genetic resources are increasingly protecting their investments in new technologies by claiming patents that might limit others’ use of the resource. However, a range of international obligations and national laws determine the extent to which genetic resources,

\begin{footnotesize}
\textsuperscript{6} Such as genomics and proteomics; see Chapter 5 n 98 and following text.
\textsuperscript{7} Choy L Hew and Garth L Fletcher, ‘The Role of Aquatic Biotechnology in Aquaculture’ (2001) 197(1) \textit{Aquaculture} 191, 192.
\textsuperscript{10} \textit{Convention} art 2.
\end{footnotesize}
technologies and know-how are made available for others to adopt, adapt and modify. The question of whether access to, and sharing the benefits from the use of, genetic resources (called ‘access and benefit sharing’ or ‘ABS’) can be managed sustainably – environmentally, economically and socially – depends on finding a fair balance between the public and private interests protected under the relevant laws. It also depends on navigating the complex ABS and technology transfer regimes for aquatic species that migrate across three jurisdictional areas – within national jurisdiction, beyond national jurisdiction and in Antarctica.

The analysis conducted in this thesis investigates the relationship between patent law’s frameworks on the one hand and ABS frameworks on the other, and the extent to which they mutually facilitate the level of technology, including knowledge, transfer of aquatic genetic resources that is essential for aquaculture to meet its expected food production targets. While the majority of scholarship focuses on the conflict between the relevant laws, this thesis takes a more constructive approach and the research question asks whether the evolving framework for defences against infringement under patent law can offer certainty and structure for fair technology transfer of physical and digital genetic resources for use in aquaculture under ABS regimes.

The thesis has three broad themes: aquaculture, patent law and technology/knowledge transfer within ABS regimes. The significance and importance of each theme is introduced in section 1.1 of this chapter and elaborated in the subsequent chapters of published and unpublished papers. The importance of the research question is outlined in section 1.2 which includes an overview of the key challenges facing the three themes and the legal problems they have in common. These common legal problems form the starting point for answering the research question in relation to the patent law and ABS regimes analysed in each chapter. Section 1.3 lists the aims of the research. These aims are addressed by one or more of the chapters, which is explained in the thesis structure (section 1.4). The linkages between the chapters, aims, themes and concepts are represented in the conceptual model and thesis structure diagram in section 1.5. This thesis is presented in the form of published and unpublished papers in accordance with
the Griffith University Policy on a PhD thesis formatted as published and unpublished papers (Appendix).

1.1 Importance of patent and ABS regimes for technology transfer in aquaculture

Patents
The World Trade Organisation’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)\(^{14}\) provides minimum standards for intellectual property regulation as applied to WTO Member’s nationals. To comply with their obligations under TRIPS, all WTO Members must make exclusive patent rights available for any invention in any field of technology provided that the product or process is new (for example not known to the public before the date of filing an application),\(^{15}\) non-obvious (involving an inventive step) and useful (capable of industrial application).\(^{16}\) This is subject to optional exclusions from patentability including plants and animals (but Members must allow the patenting of microorganisms) and essentially biological processes for the production of plants and animals, in other words, conventional breeding (but they must allow the patenting of the production of plants and animals by non-biological and microbiological processes).\(^{17}\) The effect of a patent is to give the patent holder exclusive use and dealing with the invention for up to 20 years.\(^{18}\)

The question of patentability of genetic resources is beyond the scope of this thesis because the research question concerns defences against infringement of patents once they have already been granted. However, it is relevant to note that the law relating to patentability of genetic resources is rapidly evolving. For example, in 2015 the Australian High Court in *D’Arcy v Myriad Genetics Inc (Myriad)* held that an isolated nucleic acid coding for certain mutations in the human BRACA1 polypeptide (which indicates genetic


\(^{15}\) *Patents Act 1990* (Cth) s 18.

\(^{16}\) TRIPS art 27(1).

\(^{17}\) TRIPS art 27(3)(a).

\(^{18}\) TRIPS art 33.
susceptibility to breast and ovarian cancers) was not a patentable invention within the meaning of s 18(1)(a) of the Patents Act 1990 (Cth).\textsuperscript{19} The Australian Commissioner of Patents has introduced a revised examination practice taking into account the Myriad decision, which among other things specifically excludes claims to isolated naturally occurring human or non-human DNA or RNA and to cDNA in cases where it merely replicates the genetic information of a naturally occurring organism.\textsuperscript{20} In 2013 the United States Supreme Court held that ‘a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.’\textsuperscript{21} It remains to be seen whether US courts will apply this rationale beyond DNA to other naturally occurring molecules.\textsuperscript{22}

This thesis excludes patentability from the scope of this thesis for several reasons. While exclusions from patentability have a lengthy history, the existence of defences is a more recent phenomenon.\textsuperscript{23} Defences are rapidly becoming an important and flexible strategy for reconciling conflicting interests arising from changes in the scientific, technological and economic environment.\textsuperscript{24} Scholars point out that defences are not as blunt as exclusions as they can be conditioned, for example by requiring some remuneration.\textsuperscript{25} They argue that defences are more likely to end up as significant limitations because they are administered primarily by the courts, whereas exclusions tend to be administered in the first instance by patent offices, which, unlike courts, may overlook the public interest of exclusions and tend to grant patents when in doubt.

\textsuperscript{19} D’Arcy v Myriad Genetics Inc (2015) 89 ALJR 924.
\textsuperscript{21} Association for Molecular Pathology v. Myriad Genetics, Inc. 2013. 133 S. Ct. 2107.
\textsuperscript{23} 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) Executive Summary 5 [3].
\textsuperscript{24} 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’) 65. The changes mean that more basic science is patentable than was previously the case and defences have been introduced to ensure access to the basic building blocks of science that formerly fell outside the patent regime: Ibid 31.
\textsuperscript{25} Ibid 65.
Importantly, while an exclusion can be circumvented through clever claim drafting, defences are less susceptible to such techniques.\textsuperscript{26}

Where patents are granted, holders have exclusive rights over the making, use, sale, offering for sale and importing of the products of an invention.\textsuperscript{27} The types of product claims of relevance to aquaculture that have been patented in the past under various national laws include those concerning actual genetic materials such as lysosome constructs\textsuperscript{28} and DNA vaccines,\textsuperscript{29} as well as the products that are produced by the use of genetic materials, such as synthetic sponge chemical compounds,\textsuperscript{30} antifreeze protein vectors\textsuperscript{31} and recombinant luciferase from the deep sea shrimp.\textsuperscript{32} In the case of a process, patent rights extend to preventing a person from unauthorised use of the process and from using, offering for sale, selling and importing at least the product directly obtained from the process.\textsuperscript{33} Process claims have included tuna germ cell transplantation surrogate technology,\textsuperscript{34} developing transgenic fish,\textsuperscript{35} and breeding methods such as polyploidy and hybridisation.\textsuperscript{36} Some Members may allow the patenting of conventional breeding techniques.\textsuperscript{37} Even Members that do not allow such patenting have found that the products produced from these processes are patentable in principle.\textsuperscript{38} These kinds of products and processes are used in the thesis as practical examples of where private and public interests converge under ABS and patent law frameworks.

\begin{itemize}
  \item \textsuperscript{26} Ibid.
  \item \textsuperscript{27} TRIPS art 28(1)(a).
  \item \textsuperscript{28} Chapter 2 n 74.
  \item \textsuperscript{29} Chapter 2 n 84.
  \item \textsuperscript{30} Chapter 5 n 83 and following text.
  \item \textsuperscript{31} Chapter 7 n 84.
  \item \textsuperscript{32} Chapter 6 n 25 and following text.
  \item \textsuperscript{33} TRIPS art 28(1)(b).
  \item \textsuperscript{34} Chapter 6 n 30 and following text.
  \item \textsuperscript{35} Chapter 2 n 74; Chapter 7 n 83.
  \item \textsuperscript{36} Chapter 2 n 75-76.
  \item \textsuperscript{37} For example the United States of America: see, eg, Michael Blakeney, 'Patenting of Plant Varieties and Plant Breeding Methods’ (2012) 63(3) Journal of Experimental Botany 1069, 1070.
  \item \textsuperscript{38} Plant Bioscience Limited v Syngenta Participants AG and Groupe Limagrain Holding (European Patent Office Enlarged Board of Appeal, G0002/13, 25 March 2015) 66.
\end{itemize}
Generally, patentees emphasise in support of maximising their rights that the role of patent protection is to encourage research and innovation and scientific or technological progress. TRIPS establishes a legal framework for promoting technological innovation and for the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare. In the context of patents, this is achieved through a minimum level of protection and flexibility about the ‘means by which this minimum level of protection is secured in each Member’s legal system.’ In formulating or amending their laws, Members ‘adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of TRIPS. While there is ongoing debate about the scope of the flexibilities under TRIPS, understanding how technology transfer takes place in reality partly depends on how Members use these flexibilities, including articles 6 (exhaustion), 27(1) (non-discrimination), 30 (exceptions) and 31 (mainly compulsory licences). The thesis calls these flexibilities collectively the TRIPS-compliant patent law defence framework that regulates the balancing of private and public interests in the physical and digital genetic resources on which a patented invention is based. Chapter 4 maps the defences of relevance to product development in aquaculture. It examines evolving legal norms for experimental use exceptions, breeding defences, regulatory approval defences, compulsory licensing, non-commercial use exceptions, farmers’ privilege defences, exhaustion, innocent bystander defences, temporary presence defences and some alternative defences based on compensation. These legal norms are further examined in the context of the ABS and technology transfer obligations in Chapters 5, 6 and 7.

41 TRIPS art 7.
42 TRIPS art 27.
44 TRIPS art 8(1).
46 The flexibilities are to be implemented in a manner supportive of the Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001, adopted 14 November 2001) arts 4-5.
Patents are increasingly becoming a more viable option for protecting investment of genetic resource innovations in aquaculture.\textsuperscript{47} This is more the case in industrialised aquaculture where developing fast-growing disease-free fish is very expensive\textsuperscript{48} and risky\textsuperscript{49}, whereas the result can be copied at very low costs.\textsuperscript{50} Although national governments were responsible for much of the initial exchange of aquatic genetic material, commercial breeding centres that seek to protect their proprietary interests now provide the majority of genetic material for the main commercial aquatic species including carp, salmon, tilapia and marine shrimp.\textsuperscript{51} Further, biotechnological innovation in aquaculture may be dependent on protecting investment where the resources are: difficult to obtain for example from areas beyond national jurisdiction; difficult to store, for example, due to the limited effectiveness of cryopreservation of aquatic genetic material for gene banking;\textsuperscript{52} or where the process from research to regulatory approval can take decades.\textsuperscript{53} Patents, however, over food aquatic genetic material are not yet as extensive as those in other fields such as pharmaceutical and terrestrial agriculture.\textsuperscript{54} Nevertheless the rapid rate of technological change in aquaculture\textsuperscript{55} is likely to result in a corresponding increase in patents to protect investment.

\textsuperscript{47} See Chapter 3 n 1 and following text.
\textsuperscript{49} Whereas crop seeds will yield a harvest the same or following year, fish species have a relatively long time interval over a period of years between acquisition of roe and marketing of farmed fish, making fish more vulnerable to market fluctuations: 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) 402-403 \textit{Aquaculture} 97, 100.
\textsuperscript{50} Ibid 102.
\textsuperscript{51} 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) 18.
\textsuperscript{52} For example there is still no technology for gene banking of some species such as crustaceans; John A H Benzie, ‘Use and Exchange of Genetic Resources of Penaeid Shrimps for Food and Aquaculture’ (2009) 1(3-4) \textit{Reviews in Aquaculture} 232, 235.
\textsuperscript{54} While patents are on the increase, at the time of writing, no patented genetically engineered aquatic species has been approved for commercial production. A patent relating to modified salmon (AquAdvantage) is awaiting commercial approval: ibid. However, ‘possibly, transgenic carps have been commercialized in China and transgenic Nile tilapia in Cuba, but this is disputed’; Dunham, Rex A, \textit{Aquaculture and Fisheries Biotechnology: Genetic Approaches} (CAB International, 2004) 247.
\textsuperscript{55} See Didier Montet and Ramesh C Ray, \textit{Aquaculture Microbiology and Biotechnology, Vol. 1} (Science Publishers, 2009).
Conversely, the advent of patented genetic material inventions can be a dampener on technology transfer for the purpose of innovation in the aquaculture sector. The claim of a patent or patent application sets out the scope of the protection by defining the subject matter description of the invention.\textsuperscript{56} Under patent law, protection generally extends to every plant or animal containing the inventive element or resulting from a patented process.\textsuperscript{57} This means that a broad patent claim concerning a gene or gene carrier (vector) of a plant or animal may have the same outcome as patenting the whole plant or animal.\textsuperscript{58} A concern is that broad patent claims relating to aquatic genetic resources could restrict access to the physical and digital resource for further research or use by others.\textsuperscript{59} For example, the holder of a patented strain may be able to prevent others from using it for breeding purposes to create new strains and technologies.\textsuperscript{60}

Biotechnology research is particularly susceptible to patent thickets,\textsuperscript{61} where using one patented genetic resource may require the permission of several patent holders for different product or process inventions over the same resource. For example, patents over fish transgenic technologies can affect access to the genetic resources on which they are based such as luciferase, antifreeze reporter genes and lysozyme constructs.\textsuperscript{62} Permission could be refused or cost prohibitive, and the lost opportunity for using the genetic resources can have a dampening effect on research.\textsuperscript{63} This can lead to Heller and Eisenberg’s often cited ‘tragedy of the anti-commons’ in which people underutilise a scarce resource because multiple owners block each other’s use of the resource.\textsuperscript{64}

Chapter 3 introduces some of the implications for product development in aquaculture as patents concerning aquatic genetic resources become more common. These implications are elaborated further in Chapters 5, 6 and 7.

\textsuperscript{56} Sanderson and Humphries, above n 53, 196.
\textsuperscript{58} Nuffield Council on Bioethics, The Use of Genetically Modified Crops in Developing Countries: A Follow-Up Discussion Paper (Discussion Paper, 2004) 88 [6.10].
\textsuperscript{60} Nuffield Council on Bioethics, above n 58, 88 [6.10].
\textsuperscript{62} Chapter 2 n 85 and following text.
\textsuperscript{63} Mueller, above n 61, 12.
\textsuperscript{64} Michael A Heller and Rebecca S Eisenberg, ‘Can Patents Deter Innovation? The Anticommuns in Biomedical Research’ (1998) 280 (5364) Science 698, 701.
Patents over aquatic genetic resource inventions raise questions of fairness because technological change is the result of the cumulative knowledge of others. It is not easy to determine how much of the returns from the innovation should be credited to the creator of the invention and how much to the use of the global knowledge commons.\textsuperscript{65} In effect this apportionment of credit is what patent law and ABS frameworks attempt to do although they go about achieving it in different ways depending on their approach to technology transfer. It is the similarities and compatibilities of these approaches (proprietary, stewardship and cooperative) to technology transfer that is the subject of this thesis. This thesis does not engage in the moral and legal debates about patenting life forms and biopiracy, which has been done extensively elsewhere.\textsuperscript{66} Rather, it focuses on: (a) some examples of patented genetic resource inventions that are also subject to ABS regimes; (b) how the \textit{TRIPS}-compliant patent law defence framework can balance public and private interests in the physical and digital genetic resource on which a patented invention is based with the objective of generating further technological innovation; and (c) how the \textit{TRIPS}-compliant patent law defence framework can guide normative development of ABS and technology transfer obligations that deal with the same genetic resource technologies. Arguably, legal certainty about the relationship between patent law and ABS law would be a major incentive for further innovation of aquatic genetic resource technologies.\textsuperscript{67}

\textbf{Access and Benefit Sharing}

Access and benefit sharing is a legal concept and framework for regulating how genetic resources may be accessed from \textit{in situ} (within ecosystems and natural or manmade habitats)\textsuperscript{68} or \textit{ex situ} (outside habitats,\textsuperscript{69} such as genetic resources in gene repositories)

\textsuperscript{68} See, eg, \textit{Convention} art 2.
\textsuperscript{69} See, eg, \textit{Convention} art 2.
sources within the control of a provider. It also regulates how the benefits arising from their use are fairly and equitably shared between the users and the providers of the genetic resource.\textsuperscript{70}

The instruments examined in this thesis that influence ABS and technology transfer of genetic resources for biotechnology or breeding use in aquaculture are the United Nations’ \textit{Convention on Biological Diversity} (‘\textit{Convention}’),\textsuperscript{71} the \textit{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} (‘\textit{Nagoya Protocol}’),\textsuperscript{72} \textit{United Nations Convention on the Law of the Sea} (‘\textit{UNCLOS}’),\textsuperscript{73} \textit{International Covenant on Economic, Social and Cultural Rights} (\textit{International Covenant})\textsuperscript{74} the \textit{Antarctic Treaty},\textsuperscript{75} \textit{Protocol on Environmental Protection to the Antarctic Treaty} (‘\textit{Madrid Protocol}’),\textsuperscript{76} \textit{Convention on the Conservation of Antarctic Marine Living Resources} (‘\textit{CCAMLR}’)\textsuperscript{77} and \textit{TRIPS}. Other instruments examined with potential relevance to aquaculture include the \textit{International Treaty on Plant Genetic Resources for Food and Agriculture} (‘\textit{Plant Treaty}’)\textsuperscript{78} and the proposed implementing agreement under \textit{UNCLOS} on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (the New Instrument).\textsuperscript{79} To varying degrees, states have ratified some of the

\textsuperscript{70}\textit{Convention} art 15.

\textsuperscript{71}The \textit{Convention} is a multilateral treaty providing a framework for national strategies and laws for the conservation and sustainable use of biological diversity: \textit{Convention}, above n 9.


\textsuperscript{75}\textit{Antarctic Treaty}, opened for signature 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961) (‘\textit{Antarctic Treaty}’).


above instruments and implemented domestic ABS legislation.\textsuperscript{80} Due to the broad range of instruments examined in this thesis, questions of ratification, implementation and compliance are beyond the scope of the research question, which only focuses on the obligations under ABS regimes if a state has ratified the relevant instrument.

Users and providers of genetic resources and derivatives can be individuals, legal entities or governments. Depending on how a state implements its international obligations, the details of national ABS laws, policies and implementation can vary between countries. ABS rules only apply to the use of a biological resource for its genetic material, for example using the material or knowledge to breed a new strain, rather than for the resource’s other qualities such as using the product (fillet) for human consumption. A key issue for aquaculture is that it is sometimes difficult to distinguish when a particular resource is used for its genetic material or for its biological product.\textsuperscript{81} Some farming operations specialise in producing breeding stock or seed (hatchery facilities), while others may focus on growing out stocks obtained from hatcheries or wild sources (such as farming grow out and sea ranching). While there is some segregation of the industry into seed production and grow-out facilities,\textsuperscript{82} breeding can occur during grow-out unless steps are taken to prevent it. Case studies in Chapters 5 (sponge) and 6 (tuna) provide examples where the demarcation between using a resource for its genetic material and its other attributes may be blurred, causing confusion about whether ABS rules apply.

The ABS concept was originally intended to create economic incentives for conserving and sustainably using biological resources by requiring users to compensate providers who bear the cost of the resources’ physical conservation.\textsuperscript{83} Chapter 2 highlights how this rationale evolved in response to conflict over sharing terrestrial genetic resources between developed and developing countries and does not fit well with the pattern of


\textsuperscript{81} See Chapter 2 n 25 and following text.

\textsuperscript{82} Bartley et al, above n 51, 2.

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exchange of aquatic genetic resources for use in aquaculture.\(^\text{84}\) Chapters 6 and 7 further highlight how the rationale and the jurisdictional assumptions on which ABS are based cause problems for fairly sharing aquatic genetic resources sourced from areas beyond national jurisdiction and the Antarctic Treaty Area. In these jurisdictional areas there are no sovereign rights to grant access, nor a solid legal basis for obtaining benefits as the ‘provider’.

Technology or knowledge transfer can be one of the benefits shared under the ABS framework arising from the utilisation of genetic resources.\(^\text{85}\) It can also arise from stand-alone obligations, which require countries to facilitate the transfer of technologies that make use of genetic resources to other countries.\(^\text{86}\) The technologies and knowledge that fall within the scope of this thesis are those that relate to physical and digital genetic resources, rather than other aquaculture technological innovations such as infrastructure and feed. Technological change is a collective, cultural and evolutionary process where the advanced technologies of a given era are almost always the work of many inventors and developers.\(^\text{87}\) Evidence compiled by the World Bank suggests that for developing countries, technological change is mainly a process of dissemination (transfer, implementation, use) rather than of technological invention.\(^\text{88}\) However, recognising that technology transfer will not be effective as a one-off and one-way activity,\(^\text{89}\) many of the instruments analysed in this thesis treat 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 technology.\(^\text{90}\) This includes technological cooperation, capacity building and joint

\(^{84}\) Chapter 2 n 19 and following text.
\(^{85}\) See Chapter 5 n 36 and following text.
\(^{86}\) See Chapter 5 n 15 and following text.
\(^{90}\) Regarding the Convention see ibid. Regarding UNCLOS see *Intersessional Workshops Aimed at Improving Understanding of the Issues and Clarifying Key Questions as an Input to the Work of the Working Group in Accordance with the Terms of Reference Annexed to General Assembly Resolution 67/78: Summary of Proceedings Prepared by*
development of technologies so that recipients can invent new technologies that suit their local needs. While states have these obligations under the various instruments, they have struggled with their implementation, largely because of the practical difficulties of balancing private interests (such as patents) with the public interest in accessing genetic resource technologies for new inventions.

Proprietary interests under patent law are integral to determining access to and benefit sharing of genetic resources on which the inventions are based. However, patent and ABS regimes have evolved in separate fora – the WTO and the United Nations respectively – and in general states implement their patent and ABS obligations under separate bodies of law. A central problem for this thesis is that the lack of integration of approaches to sharing aquatic genetic resources under patent law and ABS regimes causes a complex system of laws that may apply to a given resource. Such confusion about the circumstances in which the use and exchange of a given genetic resource or derivative is restricted or freely available can deter research, inhibit local inventions and undermine the conservation of genetic diversity in aquaculture. The purpose of this thesis is to find practical solutions to problems for the implementation of both stand-alone technology transfer obligations and those embedded in ABS frameworks. It does this by using the approach, principles and emerging normative content of the TRIPS-compliant patent law defence framework as a starting point for finding common ground between the regimes.

The majority of genetic resources and technologies for breeding in aquaculture are currently freely exchanged or sold without further conditions attached. For some of the major species there is a trend to develop local strains of farmed animals to

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91 See, eg, the implementation gap in relation to UNCLOS technology transfer obligations: Letter Dated 30 June 2011 from the Co-Chairs of the Ad Hoc Open-ended Informal Working Group to the President of the General Assembly, Ad Hoc Open-ended Informal Working Group, 66th sess, Agenda Item 77(a), UN Doc A/66/119 (30 June 2011) [36].


counteract the spread of disease, which may limit the exchange of biological material but increase the need to exchange technology and information.\textsuperscript{94} Aquaculture can rely on technologies including research tools created for general use in other sectors such as the pharmaceutical sector which are more likely to be subject to ABS laws and agreements. Examples include using lysozyme constructs from rainbow trout to improve immunity in other fish (Chapter 2)\textsuperscript{95} and using deep sea shrimp bioluminescence technologies to function as reporter genes to for example, determine expression of other constructs (Chapter 6).\textsuperscript{96} However, ABS agreements for sharing genetic resources for breeding in the aquaculture sector are expected to increase: as countries clarify and implement their ABS obligations under the relevant instruments;\textsuperscript{97} as farmers become aware of their obligations under national ABS laws;\textsuperscript{98} and as the aquaculture sector relies more heavily on biotechnologies.

Determining whether ABS and technology transfer obligations under the various instruments apply to a given genetic resource depends on where the physical sample originated. In other words, geographical origin is emerging as the approach for determining whether a given resource falls within a particular regime.\textsuperscript{99} This geographical origin benchmark might be relatively clear for terrestrial resources within national jurisdiction that have limited independent movement or range and centuries of documentation and research. However aquatic genetic resources are located in two other jurisdictional areas; areas beyond national jurisdiction and in the Antarctic Treaty Area (see below). Figure 1 summarises how these instruments interact in regulating aquatic genetic resources across the three jurisdictional areas. The free movement of aquatic species between jurisdictional areas and the lack of information about the particular accession’s origin challenges whether the geographical approach is appropriate for the exchange and use of aquatic genetic resources. Instead, this thesis drills down beyond the geographical approach to three underlying approaches that

\textsuperscript{94} Bartley et al, above n 51, 3.
\textsuperscript{95} See Chapter 2 n 30 and following text.
\textsuperscript{96} See Chapter 6 n 21 and following text.
\textsuperscript{97} According to Rosendal et al, few countries have implemented their ABS measures although Australia and Norway are more advanced than most: Rosendal, Myhr, and Tvedt, above n 67, 87.
\textsuperscript{98} See Bartley et al, above n 51, 3: ‘there is little awareness among [aquatic genetic resource] stakeholders of ABS issues’.
\textsuperscript{99} See support for this argument in Chapters 2, 6 and 7.
generalise how ABS and technology transfer of genetic resources are regulated within the three jurisdictional areas; proprietary (within national jurisdiction), stewardship (beyond national jurisdiction), and cooperative (in the Antarctic Treaty Area) approaches. While each of the instruments examined can include one or more of these approaches, they have been categorised according to their predominant approach. The benefit of this categorisation is to clearly understand the approach’s assumptions and principles behind the fair allocation of resources with the view to finding similarities and compatibilities with the TRIPS-compliant patent law defence framework for technology transfer. Figure 2 outlines the conceptual framework for the proprietary, stewardship and cooperative approaches to ABS and technology transfer.

Proprietary approach

Chapter 5 analyses the Convention and Nagoya Protocol through the lens of a proprietary approach to ABS and technology transfer. The Convention signalled a significant shift from treating genetic resources as a common heritage of humankind when it recognized the sovereign rights of states over those resources and the regulation of their use.100 Under this regime, provider states have sovereign rights to control access to genetic resources sourced from their jurisdiction.101 This is subject to obligations to provide and/or facilitate access to and transfer of technologies that make use of genetic resources to other Contracting Parties to the Convention.102 In return for access, users must share with the provider state, on mutually agreed terms, the results of research and development and the benefits they derive from the commercial and other uses of the genetic resources, which can include technology transfer.103 The Nagoya Protocol is a legally binding supplementary agreement to the Convention and sets out rules, procedures and compliance mechanisms for ABS of genetic resources and traditional knowledge associated with genetic resources. Under this regime, administrative decisions on access are set out in domestic permits, linked to contractual

101 Convention arts 3 and 15(1).
102 Convention art 16(1).
103 Convention arts 15, 16 and 19.
benefit sharing agreements between private parties and supported by an enabling framework of access and benefit sharing national laws in provider and user countries.\textsuperscript{104} It promotes technology transfer\textsuperscript{105} but this is largely done as an optional form of benefit sharing.\textsuperscript{106} The Convention applies to genetic resources within a state’s national jurisdiction and to processes and activities carried out by a state’s nationals that are within its control or beyond the limits of its national jurisdiction.\textsuperscript{107} The Nagoya Protocol, however, only applies to genetic resources within national jurisdiction.\textsuperscript{108}

The assumptions behind the proprietary approach to ABS under the Convention and the Nagoya Protocol include the transactional and territorial nature of technology transfer. The transactional nature implies that there is a provider of the genetic resource who has legal control over a resource and who is entitled to obtain the benefits of others’ use of the resource. The territorial nature implies that it is possible to determine the precise geographical origin of a particular physical and digital genetic resource or derivative to determine which regime applies. This thesis tests the relevance and value of these assumptions in relation to: aquatic genetic resources originally sourced from waters beyond national jurisdiction and in the Antarctic Treaty Area; migratory aquatic genetic resources of unknown or multiple origin; Antarctic ex situ genetic resources; and digital resource used independently from the physical resource.

These assumptions influence the consequent principle of fairness when it comes to the distribution and sharing of the benefits of aquatic genetic resource use under the Convention and Nagoya Protocol’s proprietary approach. This thesis argues that its concept of fairness arose from conflicts between developing and developed countries over terrestrial resources, which does not have the same relevance for aquatic genetic resources.\textsuperscript{109} It finds that the standard of fairness changes depending on the beneficiary

\textsuperscript{105} Nagoya Protocol art 1.
\textsuperscript{106} See Chapter 5 n 24 and following text.
\textsuperscript{107} Convention art 4.
\textsuperscript{108} Nagoya Protocol art 3. See Chapter 7 n 140.
\textsuperscript{109} See Chapter 2 n 19 and following text; Chapter 5 n 70.
to whom the technology or benefits flow\textsuperscript{110} but it effectively ultimately depends on having a provider legally or jurisdictionally entitled to obtain the benefits. The thesis argues that the balancing of public and private interests under this concept of fairness is constrained by the transactional and territorial nature of the proprietary approach to ABS.

Patent law is based on commercial transactions within national laws, however this thesis argues that the TRIPS-compliant patent law defence framework is constrained by neither the same transaction and territorial assumptions nor the same concept of fairness as the Convention and Nagoya Protocol. This thesis outlines the concepts and strategies such as the functional origin and multilateral cooperative approaches that patent law defence frameworks have evolved to overcome the territorial limitations of national law for sharing patented genetic resource inventions that span multiple jurisdictions in the globalised market.\textsuperscript{111} It is beyond the scope of this thesis to examine mechanisms other than the defence framework for the sharing of patented information, such as open source mechanisms under commons theory\textsuperscript{112} or the obligations for disclosure under TRIPS article 29. The thesis does however examine the concept of non-discriminatory fairness under TRIPS-compliant patent law defence frameworks that is aimed at achieving the global economy’s long term efficiency and not only for the advancement of the provider’s interests.\textsuperscript{113}

**Stewardship approach**

The second approach to technology transfer analysed in this thesis is the stewardship approach evident under UNCLOS and the International Covenant. UNCLOS incorporates proprietary,\textsuperscript{114} cooperative\textsuperscript{115} as well as stewardship mechanisms for governance of

\textsuperscript{110}See Chapter 5 table 1.
\textsuperscript{111}See Chapters 4, 5, 6 and 7.
\textsuperscript{113}See Chapter 5 n 67 and following text.
\textsuperscript{114}See, eg, UNCLOS art 2.
\textsuperscript{115}See, eg, UNCLOS art 38.
living resources\textsuperscript{116} depending on where they are located within the relevant zone covered by the Convention.\textsuperscript{117} The purpose of including \textit{UNCLOS}, however, in the analysis of the stewardship approach is to highlight the obligations applicable to marine scientific research and genetic resources located in the zone beyond state jurisdiction, in particular the high seas water column\textsuperscript{118} (‘the high seas’) and the seabed and ocean floor and subsoil below the water column (‘the Area’).\textsuperscript{119} These are the areas beyond national jurisdiction, which are collectively called the ‘deep sea’ in this thesis. Given that these waters make up 40 percent of the surface of the planet, comprising 64 percent of the surface of the oceans and nearly 95 percent of its volume,\textsuperscript{120} over which no state can exercise sovereignty,\textsuperscript{121} it is an important jurisdicitional area to consider for the sharing of aquatic genetic resources. The purpose of including the \textit{International Covenant} in the analysis of the stewardship approach is because its trans-jurisdictional approach means that human rights are applicable in all parts of the world, regardless of country or culture, and should be enjoyed by every human being without discrimination.\textsuperscript{122} Chapter 6 argues that theoretically human rights and obligations can apply to any human activities in the deep sea where there is no state responsibility. In other words, human rights obligations may have extraterritorial application and relate to acts and omissions within and beyond sovereign jurisdictions.

\textit{UNCLOS} establishes a legal order for the seas and oceans and promotes among other things the ‘equitable and efficient utilization of their resources, the conservation of their living resources and the study, protection and preservation of the marine environment’.\textsuperscript{123} Of the parts that are relevant to this thesis, it provides a

\textsuperscript{116} \textit{UNCLOS} does not expressly refer to ‘genetic resources’. Chapter 6 analyses how genetic resource technologies are treated under \textit{UNCLOS}.

\textsuperscript{117} Internal waters (art 8), territorial waters (arts 2-15), archipelagic waters (arts 46-50), contiguous zone (art 33), exclusive economic zone (arts 55-74), continental shelf (arts 76-85), high seas (arts 86-120) and the ‘Area’ (arts 133-191).

\textsuperscript{118} \textit{UNCLOS} arts 86-120.

\textsuperscript{119} \textit{UNCLOS} arts 133-191.


\textsuperscript{121} \textit{UNCLOS} arts 86, 89 and 135.


\textsuperscript{123} \textit{UNCLOS} preamble.
comprehensive legal framework of rights and obligations relating to the conduct of marine scientific research (Part XIII) and the development and transfer of marine technology including capacity building (Part XIV). Part XI (the Area)\(^\text{124}\) and Part XII (Protection and Preservation of Marine Environment)\(^\text{125}\) also have provisions on technology transfer and capacity building. Chapter 6 examines the regulatory vacuum for ABS of deep sea genetic resources used in national jurisdictions as well as the regulatory vacuum surrounding the use of genetic resources in high seas aquaculture. States are currently negotiating a legally binding instrument under UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (the New Instrument)\(^\text{126}\) that may address one or both of these regulatory gaps. Chapter 6 looks at the key question of how to balance the ‘legitimate’ proprietary interests of creators of genetic resource technologies with the public interest in accessing and sharing the knowledge and materials to create other technologies and aquatic strains. It does this by analysing the consistencies between UNCLOS’ stewardship approach to technology transfer and the TRIPS-compliant patent law defence framework.

While there is increasing literature on the relationship between human rights and patent law,\(^\text{127}\) this thesis specifically analyses the stewardship approach to obligations for technology transfer under human rights instruments that are relevant to sharing genetic resources for use in research and breeding in aquaculture. It analyses under the International Covenant, the obligation to respect the freedom indispensable for scientific research and creative activity\(^\text{128}\) and the obligation to take steps necessary for the conservation, development and diffusion of science and culture to achieve realisation of the:\(^\text{129}\)

- the right to benefit from scientific progress and its applications;\(^\text{130}\)

\(^{124}\) UNCLOS arts 143 and 144.
\(^{125}\) UNCLOS art 203.
\(^{126}\) New Instrument Resolution, above n 79.
\(^{128}\) International Covenant art 15(3).
\(^{129}\) International Covenant art 15(2).
\(^{130}\) International Covenant art 15(1)(b).
Chapter 1

- the right to benefit from the protection of the moral and material interests of the creator (of a genetic resource technology for example);\textsuperscript{131} and
- the right to take part in cultural life.\textsuperscript{132}

States Parties are obliged to balance creator’s rights with other human rights, such as those above and the right to adequate food,\textsuperscript{133} and in striking this balance, the private interests of creators ‘should not be unduly favoured and the public interest to enjoying broad access to their productions should be given due consideration’.\textsuperscript{134} States Parties are therefore required to ensure that their legal, or other, regimes for the protection of a creator’s moral and material interests constitute no impediment to their ability to comply with their core obligations in relation to the right to adequate food, the right to take part in cultural life and to enjoy the benefits of scientific progress and its applications.\textsuperscript{135} Chapter 6 analyses the consistencies between the \textit{International Covenant}’s stewardship approach to technology transfer and the \textit{TRIPS}-compliant patent law defence framework.

The assumptions behind the stewardship approach to technology transfer under \textit{UNCLOS} and the \textit{International Covenant} is that while the physical deep sea aquatic genetic resources may become the property of the legal person or entity that obtained them, the cumulative information and knowledge about the use of these resources are held in trust for current and future generations of users and producers and for Earth as a system. In other words, states are obliged to ensure that science is developed and diffused for the benefit of all of humankind, without discrimination.\textsuperscript{136} The distribution and use of the aquatic genetic material under a stewardship approach arguably transcends the boundaries of the provider/user transactional relationship of the

\textsuperscript{131} \textit{International Covenant} art 15(1)(c).
\textsuperscript{132} \textit{International Covenant} art 15(1)(a).
\textsuperscript{133} \textit{International Covenant} art 11.
\textsuperscript{134} Committee on Economic, Social and Cultural Rights, \textit{General Comment No. 17 (2005): The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which he or she is the Author (Article 15, Paragraph 1 (c), of the Covenant)}, 35th Sess. UN Doc E/C.12/GC/17 (12 January 2006) [35] (‘\textit{General Comment No. 17}’).
\textsuperscript{135} Ibid.
proprietary approach and includes a kind of trust obligation towards the genetic resource knowledge itself.

These assumptions influence the principle of fairness when it comes to distributing and sharing the benefits of using aquatic genetic resources under the UNCLOS and International Covenant’s stewardship approach. Arguably the stewardship approach is more akin to the TRIPS concept of non-discriminatory fairness aimed at achieving global long term economic and environmental sustainability and not only for the advancement of the provider’s interests.137 ‘Fairness’ under UNCLOS is realising a just and equitable international economic order which takes into account the interests and needs of human kind as a whole and, in particular, the special interests and needs of developing countries, whether coastal or landlocked.138 ‘Fairness’ under the International Covenant is using the ‘processes, products and applications of science ... for the benefit of all humanity without discrimination, particularly with regard to disadvantaged and marginalised persons and communities’ (emphasis added).139 However, Chapter 6 argues that to achieve fairness, each instrument respects the ‘legitimate’ private interests in the genetic resources that under certain circumstances may override obligations to share the knowledge with the rest of humanity. Chapter 6 analyses what these circumstances are under UNCLOS, the International Covenant and TRIPS and suggests how TRIPS-compliant patent law defence approaches to balancing legitimate interests can provide certainty and structure for implementing current and proposed obligations under UNCLOS.

Cooperative approach

The third approach to obligations for technology transfer is the cooperative approach underlying the Antarctic Treaty System and the Plant Treaty. The reason for analysing the Antarctic Treaty System is to provide an example of an exclusive ‘club’ of nations

137 See above n 113.
138 See, eg, UNCLOS preamble.
cooperatively governing for scientific and peaceful purposes the use and exchange of aquatic genetic material originating from this third jurisdictional area, which is neither fully within nor beyond national jurisdiction. Territorial claims in the Antarctic Treaty Area\(^\text{140}\) are on hold.\(^\text{141}\) While no state has jurisdiction over Antarctica’s \textit{in situ} resources, the activities of observers, scientific personnel and staff in Antarctica are subject to the jurisdiction of their state of nationality\(^\text{142}\) including any applicable national patent and ABS laws. The reason for analysing the \textit{Plant Treaty} is to provide an example of an inclusive ‘club’ of nations (in contrast to the exclusive club in the Antarctic Treaty Area) that sees states and other participants cooperatively using and exchanging plant genetic resources for food and agriculture purposes.

According to some members of the cooperative body in Antarctica, the Antarctic Treaty Consultative Meeting (ATCM), the interest in Antarctic genetic resources is rapidly increasing\(^\text{143}\) (some of which is relevant to product development in aquaculture\(^\text{144}\)), which makes this an important emerging jurisdictional area to consider for technology transfer. The \textit{Antarctic Treaty}, as part of the Antarctic Treaty System\(^\text{145}\) that regulates activities in the Antarctic Treaty Area, came into effect in 1961 well before the existence of technology to conduct large-scale genetic research in Antarctica.\(^\text{146}\) Consequently the \textit{Antarctic Treaty} does not define, nor explicitly govern access and benefit sharing of aquatic genetic resources.\(^\text{147}\) It does, however provide that the primary purpose of

\(^{140}\) Including all ice shelves and land below 60 degrees south latitude: \textit{Antarctic Treaty}, art VI.

\(^{141}\) \textit{Antarctic Treaty} art IV.

\(^{142}\) \textit{Antarctic Treaty} art VIII(1).

\(^{143}\) \textit{Biological Prospecting in Antarctica – the Need for Improved Information}, Antarctic Treaty Consultative Meeting, Agenda Item 17, ATCM XXXVI WP 48 res XXX and see \textit{The Antarctic Biological Prospecting Database}, Antarctic Treaty Consultative Meeting, Agenda Item 17, ATCM XXXII WP1, 13. Some members of the ATCM have said that there is already considerable commercial interest in Antarctic genetic resources, with many already being the subject of patent claims and being marketed by a number of companies: \textit{An Update on Biological Prospecting in Antarctica, Including the Development of the Antarctic Biological Prospecting Database}, Antarctic Treaty Consultative Meeting, Agenda Item 17, ATCM XXXII WP11, 3.

\(^{144}\) See the antifreeze gene technology case study in Chapter 7.

\(^{145}\) The Antarctic Treaty System also includes the \textit{Madrid Protocol} and \textit{CCAMLR} analysed in Chapter 7.

\(^{146}\) Herber, above n 65, 143.

\(^{147}\) Dagmar Lohan and Sam Johnston, ‘The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica’ (UNU/IAS Report, United Nations University, August 2003) 11. ‘There are no instruments in the \textit{Antarctic Treaty} system specifically addressing biological prospecting, but several instruments address activities that may be part, but not exclusively, of biological prospecting’: \textit{Report of the ATCM Intercessional Contact Group to Examine the Issue of Biological Prospecting in the Antarctic Treaty Area}, Antarctic Treaty Consultative Meeting, Agenda Item 17, ATCM XXXIII WP 13, 21.
human presence in Antarctica is to conduct scientific research.\textsuperscript{148} The main obligation for technology transfer is to promote international co-operation in, and freedom of, scientific investigation in Antarctica\textsuperscript{149} for the benefit of all humankind.\textsuperscript{150} This requires to the greatest extent practicable the exchange of plans for scientific programs, personnel and the exchange and free availability of observations and research results.\textsuperscript{151} All parties must establish the same rights and duties under national legislation but these norms can be construed differently by claimant and non-claimant states on the basis of their acknowledgement or denial of sovereign rights in Antarctica.\textsuperscript{152} Chapter 7 outlines the patchwork of access and technology transfer obligations that apply to Antarctica’s \textit{in situ} genetic resources, the absence of regulation under the \textit{Antarctic Treaty} for its \textit{ex situ} genetic resources and the complex and tenuous basis for applying bilateral national ABS laws to Antarctica’s \textit{ex situ} genetic resources.

In contrast to the Antarctic instruments, which are jurisdiction based, the \textit{Plant Treaty} is species based and may have future relevance for \textit{ex situ} Antarctic plant genetic resources.\textsuperscript{153} Many scholars suggest using the multilateral system under the \textit{Plant Treaty} as a model for the exchange and use of aquatic animal genetic material, particularly from areas beyond national jurisdiction.\textsuperscript{154} Under a cooperative approach, the \textit{Plant Treaty} creates a multilateral system of access and benefit sharing for a negotiated selection of plant genetic resources used for food and agriculture.\textsuperscript{155} Members, in exercise of their sovereignty, provide access to each other’s plant genetic resources for research, breeding, conservation and training, subject to benefit-sharing arrangements in the areas of information exchange, technology transfer, capacity

\begin{itemize}
\item \textsuperscript{148} National Research Council, Committee on Antarctic and Science, \textit{Science and Stewardship in the Antarctic}, (National Academies Press, 1993) 2.
\item \textsuperscript{149} \textit{Antarctic Treaty} art II.
\item \textsuperscript{150} \textit{Antarctic Treaty} preamble para 4.
\item \textsuperscript{151} \textit{Antarctic Treaty} art III.
\item \textsuperscript{153} The definition of ‘plant genetic resources for food and agriculture’ under \textit{Plant Treaty} art 2 is broad enough to include aquatic plants and while none are included in Annex 1 to which the multilateral system applies, non-Annex 1 materials may be included in the system (\textit{Plant Treaty} art 15).
\item \textsuperscript{155} \textit{Plant Treaty} art 10(1).
\end{itemize}
building and commercial development. Underlying the obligations is a cooperative commitment to prohibit recipients of genetic material from claiming intellectual property or other rights that prevent others from receiving them in the same form from the multilateral system. If a recipient chooses to prevent others from using for their own research and breeding any product they develop using the materials from the system, they must share a percentage of their commercial benefits to an international fund.

An assumption underlying the cooperative approach is that technology transfer achieves a collective purpose that can transcend national boundaries. Unlike the Convention’s proprietary bilateral approach where the provider is responsible for access as well as being the recipient of benefits that flow from their subsequent use, this purpose driven cooperative approach breaks the ABS territorial nexus so that the provider state grants access but the benefits flow to the collective to achieve a particular goal. This assumption shapes the concept of fairness under the Antarctic Treaty System and the Plant Treaty where private and public interests are balanced with the objective of supporting a particular purpose. Chapter 7 offers examples of applying defences under the TRIPS-compliant patent law defence framework for sharing knowledge and technology concerning Antarctica’s ex situ resources in a way that is consistent with fulfilling the objectives of cooperation and freedom of scientific investigation under the Antarctic Treaty.

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156 *Plant Treaty* art 10(2).
157 *Plant Treaty* art 12(3)(d).
Figure 1 Instruments triggered by the geographical origin of aquatic genetic resources

- **Within national jurisdiction**
  - *Convention*
  - *Nagoya Protocol*
  - *UNCLOS*

- **Beyond national jurisdiction (deep sea)**
  - *UNCLOS*
  - *Antarctic Treaty Madrid Protocol CCAMLR*

- **Antarctic Treaty Area**
  - *UNCLOS (high seas, Southern Ocean)*

- **Ex situ**
  - *Convention*#
  - *Nagoya Protocol#*
  - *UNCLOS (repositories in UNCLOS waters)*

- **In situ**
  - *Convention*
  - *Nagoya Protocol*
  - *UNCLOS*

* Not genetic resources and derivatives that were deposited in an *ex situ* facility before the *Convention* entered into force, in non-party state repositories or where the samples were not acquired ‘in accordance with the *Convention*’.

# Not resources deposited before it entered into force and those in non-party state repositories. Arguably not those linked to deep sea or Antarctic Treaty Area origins.
Figure 2 Approaches to technology transfer

- **Proprietary approach**
  - Technology transfer primarily flows...  
  - To benefit the provider

- **Stewardship approach**
  - Transactional and territorial nature of technology and knowledge transfer  
  - Knowledge about resource use is held in trust for current and future users

- **Cooperative approach**
  - To benefit the fulfilment of a purpose
  - Knowledge is shared to fulfil a collective purpose that transcends national boundaries

**Assumptions**

- Concept of fairness for distributions of benefits
  - Standard of fairness changes depending on the beneficiary of benefits but it ultimately depends on having a provider legally entitled to obtain the benefits
  - Non-discriminatory fairness aimed at achieving global long term economic and environmental sustainability and not only for the advancement of the provider’s interests
  - Fairness depends on balancing private and public interests with the objective of supporting a particular purpose
1.2 Importance of the research question

Research question
Can a *TRIPS*-compliant patent law defence framework for technology and knowledge transfer offer certainty and structure for fairly sharing physical and digital genetic resources for use in aquaculture under ABS regimes?

Importance

The research question is both necessary and timely, and identifies a significant gap in patent law and ABS law analysis. Surprisingly, while the costs and benefits of restricting free access to terrestrial food genetic resources by patent claims and ABS laws have been intensely debated over several decades, the same cannot be said for a similar analysis concerning food aquatic (animal and plant) genetic resources. Even less attention has been given to balancing private and public interests in the use of these resources for breeding, product development and research in aquaculture. By focusing specifically on aquatic (rather than terrestrial) species, this thesis will fill some of the gaps in legal analysis and provide important insights into the connection between ABS and technology transfer obligations on the one hand, and the *TRIPS*-compliant patent law defence framework on the other.

The research question and conclusions address the following gaps in current legal scholarship which are elaborated below:

- The role of patent law defences for technology transfer in aquaculture;
- The relationship between ABS regimes under the *Convention/Nagoya Protocol* and (a) patent law defences (b) digital aquatic genetic resources and (c) Antarctica’s *ex situ* genetic resources;
- Benchmarks for balancing ‘legitimate’ interests to implement technology transfer obligations under *UNCLOS*;

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158 Researchers at the Fridtjof Nansen Institute in Norway have, however, produced many recent articles and reports on ABS and patent law in aquaculture. See, eg, G Kristin Rosendal et al, *Strategies and Regulations Pertaining to Access to and Legal Protection of Aquaculture Genetic Resources* (The Fridtjof Nansen Institute 2005).
Chapter 1

- The relationship between ABS of genetic resources for use in aquaculture and human rights obligations;
- A clear analysis of the ABS arrangements under various instruments for Antarctica’s *ex situ* genetic resources; and
- The absence of a multi-jurisdictional approach that brings together aquaculture, patents and ABS within the three jurisdictional areas to identify and resolve the common legal problems preventing the fair sharing of genetic resources for use in aquaculture.

The social and economic role of, and justification for, patent law has been extensively explored in the literature.\(^{159}\) There is also extensive literature devoted to the effects of patents on ABS of *terrestrial* (particularly plant) genetic resources.\(^{160}\) To a far lesser extent, some writers have explored the relationship between patent law and ABS law for the exchange and use of *aquatic* genetic resources\(^{161}\) which is the central theme of this thesis. There is some emerging literature concerning the negative effects of patents on industrial aquaculture development\(^{162}\) but comparatively little about the role of patent law defences to achieve a positive effect on aquaculture development. While there is an abundance of literature about the scope of experimental use defences under national patent laws generally,\(^{163}\) the literature does not map the *TRIPS*-compliant patent law defence framework that applies to using genetic resources in aquaculture specifically. In the first step toward answering the research question, Chapter 4 not only maps the defences available to aquaculture but also offers innovative *TRIPS*-compliant solutions to problems unique to aquaculture.

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\(^{160}\) See [http://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/897.pdf](http://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/897.pdf) for a comprehensive bibliography on access to plant genetic resources and intellectual property.

\(^{161}\) See, eg, articles in the thesis bibliography by G Kirsten Rosendal, Ingrid Olesen and Morten Walløe Tvedt.


\(^{163}\) See, eg, E Richard Gold, Yann Joly and Timothy Caulfield, *'Genetic Research Tools, the Research Defence and Open Science'* (2005) 3 GenEdit 1.
There is an abundance of literature about the relationship between patents and ABS obligations under the *Convention and Nagoya Protocol.* Some of this argues how ABS obligations can modify patent law to achieve ABS objectives, such as requiring disclosure of the origin of the genetic resource on which an invention is based under patent law. The research question uniquely takes the opposite approach to determine whether patent law defences can guide the normative development of ABS laws. The research question also addresses other gaps in legal analysis relating to the *Convention*, including how to provide certainty and structure to obligations for sharing the digital (knowledge) resource separately from the physical resource and for sharing Antarctica’s *ex situ* genetic resources located within national jurisdiction.

Much research is devoted to addressing the lacuna in governance arrangements relating to aquatic genetic material within the *UNCLOS* regime. Relatively little work has found practical ways for determining the ‘legitimate’ interests that are capable of displacing technology transfer obligations over deep sea genetic resource inventions. In Chapter 6, the thesis uniquely uses examples of genetic technologies used in aquaculture to draw comparisons between human rights and patent law defence benchmarks of ‘legitimacy’. The research question investigates practical ways for creating normative content, certainty and structure for current *UNCLOS* technology transfer obligations and proposed obligations under the New Instrument.

While there is an abundance of literature on the relationship between patents, genetic resources for use in agriculture and human rights, few works examine the same relationship for genetic resources used in aquaculture. This is surprising given that

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165 Rosendal, Myhr and Tvedt, above n 67, 95.


developing countries produce over 80 percent of global farmed product\(^{168}\) and the exchange of genetic resources to improve genetic diversity in farming is particularly important for food,\(^{169}\) sustainable livelihoods\(^{170}\) and trade\(^{171}\) in these countries. Arguably, restrictions on access and sharing the benefits of using aquatic genetic resources and resulting technologies have significant human rights implications for the world’s poor. Most literature focuses on the conflict between patent law and human rights.\(^{172}\) The research question instead searches for similarities in normative content between the two regimes that can be applied to the three legal problems for regulating aquatic genetic resources in this thesis.

There is growing literature devoted to the implications of the lack of a comprehensive ABS regime to regulate bioprospecting in Antarctica\(^ {173}\) but surprisingly little about the application of other ABS regimes to Antarctica’s \textit{ex situ} genetic resources. This research fills the gap in navigating the complex arrangements for Antarctica’s \textit{ex situ} genetic resources under the \textit{Convention, Nagoya Protocol} and national ABS laws using Australia as an example. The research question proposes a constructive approach to regulating Antarctica’s \textit{ex situ} genetic resources by looking at ways that the TRIPS-compliant patent law defence framework can fulfil the \textit{Antarctic Treaty}’s purpose.

Most literature focuses on the conflicts between patent law and ABS – for example, the generalisations that patents restrict access and benefits while ABS fairly regulates access and equitably distributes benefits.\(^ {174}\) This thesis refocuses the debate on the compatibilities between the ABS and patent regimes in the three jurisdictional areas

\(^{168}\) Bartley et al, above n 51, 6.
\(^{169}\) Fish is ‘generally the lowest cost animal protein and the world’s growing food fish supply gap has a disproportionate impact on the nutrition and health of the poor’: World Bank, above n 4, 3.
\(^{170}\) In 2012, about 18.9 million people were engaged in fish farming of which more than 96 percent were in Asia: FAO, \textit{The State of World Fisheries and Aquaculture 2014} (Food and Agriculture Organization of the United Nations, Rome, 2014) 6.
\(^{171}\) In some developing countries, the fishery trade accounts for more than half of the total value of traded commodities: ibid 7.
and how they can use consistent approaches to resolve the same challenges that they face. These common challenges are: a) derivatives – determining the point at which derivatives and technical knowledge are sufficiently removed from the genetic resource on which they are based for technology transfer rules to no longer apply; b) commercial use – the difficulties for distinguishing between commercial and non-commercial uses for which different rules apply; and c) extra-territoriality – how to address challenges involving the transfer of genetic resources located in multiple jurisdictions from multiple providers. Figure 3 below identifies where the challenges for the use of aquatic genetic resources in aquaculture, technology/knowledge transfer and patent law intersect. The research question seeks to address the legal uncertainty surrounding these three legal challenges using a TRIPS-compliant patent law defence framework for technology and knowledge transfer.

Resolving these legal challenges is important for creating certainty for researchers and breeders who use genetic resources for product development in aquaculture. Organisations such as WorldFish have already developed policies to navigate the complex obligations. As an international non-profit research organisation, WorldFish ‘harnesses the potential of sustainable fisheries and aquaculture to increase food and nutrition security and promote better livelihoods.’ WorldFish has already implemented a policy on the management of intellectual property and aquatic genetic resources. This research provides further insight for policy development concerning derivatives, commercial use and extraterritoriality across intellectual property and ABS instruments.

175 <http://worldfishcenter.org/what-we-do>
176 <http://worldfishcenter.org/intellectual-property-policy>
Figure 3 Intersecting legal challenges

Timing of the research question

The timing of the research question and conclusions are important for the following reasons:

- Aquaculture is only now starting to connect with patent regimes at a time when its predominantly ‘wild’ aquatic genetic resources and its relatively

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underdeveloped basic scientific knowledge are subject to expanding access and benefit sharing requirements. The research question maps out the relationship between the three themes – aquaculture, patent law and technology transfer or ABS – to analyse whether the assumptions and principles underlying technology transfer obligations concerning the three jurisdictional areas can facilitate the expected expansion in the sector.

- The use of deep sea and Antarctic genetic resources in aquaculture biotechnology is rapidly expanding in a complex and confusing patchwork of ABS regimes from the three jurisdictional areas. The research question navigates these complexities and offers a pathway to legal certainty about the relationship between aquaculture, patent law and ABS law, which may in turn provide an incentive for further innovation of aquatic genetic resource technologies.

- To meet the rapid expansion of interest in deep sea genetic resources, states are currently negotiating the new Instrument under UNCLOS for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction which may also apply to the high seas in Antarctica’s Southern Ocean. The research question and conclusions offer a novel perspective on addressing some of the more controversial aspects of the negotiation including balancing private and public interests, how to regulate the use of ex situ genetic resources as well as derivatives of the physical and digital aquatic genetic resources and changes of intent between commercial and non-commercial research.

- The first *State of the World’s Aquatic Genetic Resources for Food and Agriculture* report is due for consideration by the Food and Agriculture Organisation’s Commission on Genetic Resources for Food and Agriculture in 2017. The scope of the report includes global information on farmed aquatic species and their wild relatives within national jurisdiction. The

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178 FAO Commission on Genetic Resources for Food and Agriculture) *Status of Preparation of the State of the World’s Aquatic Genetic Resources for Food and Agriculture*, 14th Sess, Agenda Item 5.1, CGRFA 14/13/16 (15-19 April 2013) [7].

179 FAO Commission on Genetic Resources for Food and Agriculture, *Status of Preparation of the State of the World’s Aquatic Genetic Resources for Food and Agriculture* (15th sess, CGRFA-15/15/17, 19-23 January 2015) Appendix II.

180 Ibid [1].
Chapter 1

report will include inventories of aquatic genetic resources for food and agriculture, drivers impacting them, in situ and ex situ conservation, institutional capacities, research and international collaboration and relevant legislation and policies.\textsuperscript{181} This thesis includes all of these factors from a patent law and ABS perspective, not only for genetic resources within national jurisdiction (Chapters 2, 3, 4, 5 and 7) but also beyond national jurisdiction (Chapter 6) and in Antarctica (Chapter 7).

- States are only now starting to implement their obligations under the \textit{Nagoya Protocol} that came into effect in 2014. The research question offers a unique aquaculture perspective for ensuring consistency between ABS measures and patent law concerning aquatic genetic resources.

\textsuperscript{181} See <http://www.fao.org/fishery/AquaticGeneticResources/en>
1.3 Research Aims

Aim 1
To identify the extent to which ABS or technology transfer regimes across the three jurisdictional areas (within and beyond national jurisdiction and in the Antarctic Treaty Area) accommodate aquaculture’s special characteristics and challenges for the exchange and use of aquatic genetic resources.

Aim 2
To examine the role of patent law and its TRIPS-compliant patent law defence framework for sharing physical and digital genetic resources for use in aquaculture.

Aim 3
To analyse the relationship between the TRIPS-compliant patent law defence framework and the proprietary approach to ABS and technology transfer of aquatic genetic resources sourced from waters within national jurisdictions.

Aim 4
To analyse the relationship between the TRIPS-compliant patent law defence framework and the stewardship approach to ABS and technology transfer of aquatic genetic resources sourced from waters beyond national jurisdiction.

Aim 5
To analyse the relationship between the TRIPS-compliant patent law defence framework and the cooperative approach to ABS and technology transfer of ex situ aquatic genetic resources originally sourced from the Antarctic Treaty Area.
1.4 Thesis structure

The thesis consists of eight chapters: a general introduction (Chapter 1), five analytical chapters (Chapters 2, 4-7), a descriptive chapter (Chapter 3) and an overall discussion (Chapter 8). The analytical and descriptive chapters are in the form of manuscripts formatted to meet the requirements of the peer reviewed academic publishers to which they were submitted. This structure is in accordance with Griffith University policy on a PhD thesis formatted as published and unpublished papers (Appendix). As a result, there is some repetition in the background of the chapters, including outlines of relevant international instruments and national laws. Each chapter is linked, however, by the thesis research question and each builds upon the preceding chapter to formulate and strengthen the research argument and findings.

The publication and manuscripts stemming from the research presented in this thesis are as follows:

**Chapters 1 & 8:** The following publication draws from content in these chapters:


With the exception of Chapter 3, each of the articles and book chapters were written for an academic and policy audience and contain doctrinal analyses of the legal problems. Chapter 3 was written for a broader audience of aquaculture farmers and researchers and provides a descriptive overview of how patent law applies to breeding in aquaculture and challenges that the sector is likely to face as patents start to take hold.

At the beginning of each chapter is a statement about how the relevant publication or unpublished paper builds upon the other papers towards reaching an answer to the research question. The statement identifies the thesis aim to which the chapter primarily relates and links the previous chapter. For copyright reasons, the published chapters have been removed from the published version of this thesis and replaced with the citation and abstract. The following section (1.5) provides an overview of how all of the chapters (papers) are linked and how they address the research aims.
## 1.5 Conceptual model and thesis structure diagram

**Figure 4 Conceptual model and thesis structure**

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Primary theme</th>
<th>Jurisdictional area</th>
<th>Primary aim</th>
<th>(Secondary aims)</th>
<th>Question</th>
<th>Technology transfer approach</th>
<th>Defences analysed</th>
<th>Primary case studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Aquaculture</td>
<td>Overview of ABS regimes in all jurisdictional areas</td>
<td>1</td>
<td>-</td>
<td>What are the special challenges that the aquaculture sector faces in the exchange of aquatic genetic resources across the three jurisdictional areas?</td>
<td>All</td>
<td>-</td>
<td>Sponges</td>
</tr>
<tr>
<td>3</td>
<td>Aquaculture</td>
<td>Overview of national patents in aquaculture</td>
<td>2</td>
<td>-</td>
<td>What are some of the implications for aquaculture breeders and researchers of using patented genetic resource inventions in their breeding and research programs?</td>
<td>Proprietary</td>
<td>-</td>
<td>Tuna and Deep Sea Shrimp</td>
</tr>
<tr>
<td>4</td>
<td>Patent Law</td>
<td>National patent defence laws</td>
<td>2</td>
<td>(1 &amp; 2)</td>
<td>Can patent law defences be adapted, or more specific bona fide defences be crafted, to deal with problems that may only exist for breeding new strains in aquaculture?</td>
<td>Proprietary</td>
<td>Experimental use Breeding</td>
<td>Anti-freeze gene promoters (eg tilapia and salmon)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Within national jurisdiction</td>
<td>3</td>
<td>(1 &amp; 2)</td>
<td>How can a TRIPS-compliant patent defence framework be used to interpret and clarify technology transfer obligations under the Convention and Nagoya Protocol?</td>
<td>Stewardship</td>
<td>Experimental use Breeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Beyond national jurisdiction</td>
<td>4</td>
<td>(1 &amp; 2)</td>
<td>How does patent law, law of the sea and human rights balance ‘legitimate’ interests of creators of deep sea genetic resource technologies with the public interest in sharing these resources to create new technologies and aquaculture strains?</td>
<td>Cooperative</td>
<td>Experimental use Regulatory approval</td>
<td></td>
</tr>
<tr>
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<td></td>
<td>Antarctic Treaty Area</td>
<td>5</td>
<td></td>
<td>Can patent law defences offer an approach that clarifies the complex legal arrangements for sharing Antarctica’s ex situ resources in a way that is consistent with the Antarctic Treaty's cooperative objectives?</td>
<td></td>
<td>Breeding</td>
<td></td>
</tr>
</tbody>
</table>

**Chapter 1**
CHAPTER 2 ACCESS AND BENEFIT SHARING IN AQUACULTURE

Chapter 2 addresses the first aim of the thesis – to identify the extent to which access and benefit sharing regimes across the three jurisdictional areas (within and beyond national jurisdiction and in the Antarctic Treaty Area) accommodate aquaculture’s special characteristics and challenges for the exchange and use of aquatic genetic resources. The Chapter gives an overview of the relevant international ABS regimes that apply to the use of genetic resources in aquaculture. It specifically examines the aquaculture sector’s special characteristics that need to be accommodated by ABS regimes to promote long-term sustainability in the sector. It argues that the predominant territorial approach to ABS evolved from the pattern of exchange and conflict over genetic resources in agriculture and does not fully suit aquaculture’s unique characteristics. It clarifies the special challenges that the sector faces for exchanging genetic resources sourced from within national jurisdictions, beyond national jurisdiction and in the Antarctic Treaty Area. The Chapter concludes that clarification across the three jurisdictional areas of the extent to which derivatives of genetic resources, commercial uses and trans-jurisdictional resources are captured by ABS obligations is essential for providing clarity for using genetic resources for breeding and research purposes.

Chapter 2 was peer reviewed and published in October 2016. I am the sole author of the book chapter. I removed the chapter from the published version of my thesis for copyright reasons. The citation is as follows:

Chapter Abstract

Early domestication in the aquaculture sector is unlikely to benefit from the same extent of free exchange of genetic resources that was enjoyed by the agriculture sector. The recent rise of access and benefit sharing (ABS) and patent restrictions concerning aquatic genetic resources are becoming increasingly complex and fragmented. This chapter navigates the main trade, environmental and social international instruments that affect ABS of genetic resources within three jurisdictional areas – waters within national jurisdictions, beyond national jurisdictions and in Antarctic waters. It concludes that the current fragmented geographical approach to ABS will ultimately hinder product development and research in aquaculture. Instead, it offers some practical options for a common approach to implementing the relevant ABS and patent law instruments with the aim of accommodating aquaculture’s special characteristics, namely, its lag in domestication and research, its unique pattern of resource use and exchange and the trans-jurisdictional nature of its biological resources.
(Signed): 
(Date): 21 July 2016
Fran Humphries (author)

(Countersigned): 
(Date): 21 July 2016
Principal Supervisor: Professor Charles Lawson

(Countersigned): 
(Date): 21/7/2016
Supervisor: Dr Chris Butler
CHAPTER 3 ROLE OF PATENT LAW IN AQUACULTURE

The previous chapter outlined the special challenges that the aquaculture sector faces in the exchange of aquatic genetic materials across the three jurisdictional areas. It introduced the relationship between patent law and ABS systems. Chapter 3 addresses the second aim of the thesis – to examine the role of patent law and its TRIPS-compliant patent law defence framework for sharing physical and digital genetic resources for use in aquaculture. This chapter is a general introduction to the issues facing breeders and researchers whereas Chapters 4-7 flesh out the detail of patent law’s role for the exchange and use of aquatic genetic resources within each jurisdictional area.

Chapter 3 was published with the intention of introducing aquaculture farmers and researchers to the issues they may face as patents start to take hold in their industry. It considers the use of patent law for protecting new strains of fish, new varieties of aquatic plants and other patented aquaculture genetic resource products and processes from unauthorised replication. Chapter 3 asks what some of the implications are for aquaculture breeders and researchers of using patented genetic resource inventions in their breeding and research programs. It raises some challenges for breeders as patents become more common over aquatic genetic resources and concludes with some options for sharing genetic material for breeding and research in the sector.

Chapter 3 was peer reviewed and published in the Journal of Aquaculture Research and Development in 2015. I am the sole author of the article. I have removed the chapter from this published version of my thesis for copyright reasons. The citation is as follows:

Patents can have both a positive and negative effect on innovation in aquaculture. On the one hand they may encourage investment in aquatic biotechnology. On the other hand, they may tie up genetic resources and research tools that may have otherwise been freely used by breeders or researchers to develop new breeds. This article considers the role and use of patent law for protecting new strains in aquaculture from unauthorised replication. While patents are not yet as extensive in aquaculture compared with other fields, there are issues that need to be addressed from the outset to protect aquaculture’s increasing role in global food security. Depending on the laws in a particular jurisdiction, patents could be claimed over genetic material products, including those derived from conventional breeding, as well as over processes for example methods of gene research. A central problem for breeders is determining the extent to which a patent holder can control other people’s use of subsequent generations whose breeding line originally incorporated the patented invention. In addressing this problem, the article suggests that exceptions against infringement including experimental use exceptions may be a useful avenue for breeders. It also highlights breeding defences and innocent bystander defences that are emerging in agriculture but which may also have future relevance to aquaculture. The article concludes that as patents start to take hold in aquaculture, breeders need clarity on the circumstances in which they can make a cross with an aquatic strain that includes patented genetic materials (such as a sequence or trait) that are not expressed in their new strain.
(Signed): 

(Date):    21 July 2016
Fran Humphries (author) 

(Countersigned): 

(Date):    21 July 2016
Principal Supervisor: Professor Charles Lawson

(Countersigned): 

(Date):    21/7/2016
Supervisor: Dr Chris Butler
CHAPTER 4 PROPRIETARY APPROACH TO ABS: THE PATENT DEFENCE SEASCAPE FOR AQUACULTURE

The previous Chapter outlined some of the implications for aquaculture breeders and researchers of using patented genetic resource inventions in their breeding and research programs. It raises a key question of how far a patent holder’s control extends to subsequent generations of plants and animals whose breeding line originally incorporated a patented product or process and flags that patent law defences may provide an effective avenue for overcoming these challenges.

Chapter 4 addresses the second aim of the thesis - to examine the role of patent law and its TRIPS-compliant patent law defence framework for sharing physical and digital genetic resources for use in aquaculture. It expands the conclusion in Chapter 3 and provides a doctrinal analysis of the patent law defences that can apply to the use of genetic resources for breeding and product development. It asks the key question of whether defences can be adapted, or more specific bona fide defences can be crafted, to deal with problems that may only exist for breeding new strains in aquaculture. These problems include the three common legal challenges further analysed in Chapters 5-7 of derivatives, commercial use and extraterritorial aspects of patent infringement of aquatic genetic resources that may spontaneously replicate, and thereby infringe rights, in multiple jurisdictions (figure 3, page 33). After highlighting the main limitations of each defence for breeding in aquaculture, it concludes with options for crafting defences to address problems that exist in this particular product area (identified in Chapter 2).

Chapter 4 was peer reviewed and published by the European Intellectual Property Review in 2015. I am the sole author of the article. I have removed the chapter from this published version of my thesis for copyright reasons. The citation is as follows:

Article Abstract
Aquaculture is an emerging field for patents. Defences, however, are a significantly underutilised tool for equitably sharing patented aquatic genetic materials for experimentation and breeding of improved aquatic strains. This article maps the defence landscape, navigates the tensions and gives insight into how defences can resolve difficulties posed by aquatic genetic materials' self-replicating and multi-jurisdictional nature.

(Signed):

(Date): 21 Jul 2016
Fran Humphries (author)

(Countersigned):

(Date): 21 Jul 2016
Principal Supervisor: Professor Charles Lawson

(Countersigned):

(Date): 21 Jul 2016
Supervisor: Dr Chris Butler
CHAPTER 5  PROPRIETARY APPROACH TO ABS: GENETIC RESOURCES OF WATERS WITHIN NATIONAL JURISDICTION

The previous chapter mapped the patent law defences that may be available to breeders and researchers to promote the exchange and use of genetic resources, technologies and knowledge. Chapter 5 addresses the third aim of the thesis – to analyse the relationship between the TRIPS-compliant patent law defence framework and the proprietary approach to ABS and technology transfer of aquatic genetic resources sourced within national jurisdictions.

It further analyses four of the defences mapped in Chapter 4 – experimental use, breeding, exhaustion and temporary presence defences – to answer the question of how a TRIPS-compliant patent law defence framework can be used to interpret and clarify technology transfer obligations under the Convention and Nagoya Protocol. In the context of ABS within national jurisdiction, it further analyses the three legal challenges raised in Chapters 1, 2 and 3 (figure 3, page 33). These uncertainties are: (a) determining the point at which genetic resource derivatives are sufficiently removed from the genetic resources on which they are based for technology transfer rules to no longer apply (derivative challenge); (b) clarifying the temporal scope of ‘use’ of genetic resources across the research to commercialisation continuum where different rules apply under the Convention, Nagoya Protocol and patent regimes (commercial use challenge); and (c) how to address challenges involving the transfer of genetic resources located in multiple jurisdictions from multiple providers, including private parties (extra-territorial challenge). Using sea sponges as an example, it concludes that the TRIPS-compliant patent law defences framework can offer an approach that brings certainty and clarity to overcoming the challenges of the territorial and transactional approach under national ABS regimes. The analysis is timely as States Parties currently grapple with how to implement their obligations under the Nagoya Protocol, which entered into force in 2014.
Chapter 5 was peer reviewed and published by the University of NSW Law Journal in 2015. I am the sole author of the article. I have removed the chapter from this published version of my thesis for copyright reasons. The citation is as follows:


Article Abstract
Aquatic genetic resources are one of the last frontiers for bioprospecting and an important resource for global food security. Genetic resources within national jurisdiction are presently governed by a complex matrix of access and benefit sharing regimes including the United Nations’ Convention on Biological Diversity (Convention) and Nagoya Protocol as well as patent laws under the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This article identifies the legal uncertainties for discharging technology transfer obligations that are shared by all three instruments, including the scope of derivatives falling within the obligations, the scope of ‘use’ along the research to commercialisation continuum and extraterritorial complexities. This article provides an insight into how a TRIPS-compliant patent defence framework can be used to interpret and clarify technology transfer obligations under the Convention and the Nagoya Protocol. Given that developing countries provide the majority of the world’s aquaculture product, the need for a consistent approach to ‘fair and equitable’ technology transfer under patent and ABS regimes will become increasingly important as patents start to take hold in aquaculture.
(Signed): 

(Date): 21 July 2016
Fran Humphries (author)

(Countersigned): 

(Date): 21 July 2016
Principal Supervisor: Professor Charles Lawson

(Countersigned): 

(Date): 21 July 2016
Supervisor: Dr Chris Butler
CHAPTER 7

CHAPTER 6 STEWARDSHIP APPROACH TO ABS: GENETIC RESOURCES OF WATERS BEYOND NATIONAL JURISDICTION

The previous chapter analysed the role of patent law defences for providing clarity about legal challenges facing regimes that regulate the use of aquatic genetic resources sourced from areas within national jurisdiction. Chapter 6 moves to the second jurisdictional area – waters beyond national jurisdiction or the ‘deep sea’ – which includes genetic resources from the high seas water column and in the seabed and ocean floor and subsoil below the water column.

Chapter 6 addresses the fourth aim of the thesis – to analyse the relationship between the TRIPS-compliant patent law defence framework and the stewardship approach to ABS and technology transfer of aquatic genetic resources sourced from waters beyond national jurisdiction. Using tuna and deep sea shrimp as examples, it specifically examines the technology transfer obligations that apply to this jurisdictional area under UNCLOS and TRIPS as well as trans-jurisdictional human rights obligations that were introduced in Chapter 1 under the International Covenant. It asks how the obligations under TRIPS, UNCLOS and the International Covenant each balance the ‘legitimate’ interests of creators of deep sea genetic resource technologies with the public interest in sharing these resources to create new technologies and aquaculture strains. It concludes that TRIPS-compliant defences and the Covenant offer benchmarks that can be used to resolve uncertainty about the extent to which legitimate proprietary interests in derivatives and commercial uses of deep sea genetic resources can override UNCLOS obligations to freely transfer technologies and knowledge for the benefit of humankind.
Chapter 6 was peer reviewed and published during the twelve-month embargo period between thesis approval and publication by the *University of New South Wales Law Journal* in 2017. I am the sole author of the article. I have removed the chapter from this published version of my thesis for copyright reasons. The citation is as follows:


**Article Abstract:**

The aquaculture sector’s interest in areas beyond national jurisdiction (‘deep sea’) is emerging in a regulatory vacuum for accessing aquatic genetic resources and sharing the benefits from their use. A key question is how to balance the ‘legitimate’ interests of creators of deep sea genetic resource technology inventions with the public interest in sharing the genetic materials and knowledge with others to create new technologies and aquaculture strains. This article analyses approaches to ‘legitimacy’ under the World Trade Organisation’s *Agreement on Trade-Related Aspects of Intellectual Property Rights*, and the United Nations’ *International Covenant on Economic, Social and Cultural Rights* and *Convention on the Law of the Sea* (‘UNCLOS’). All three instruments attempt to influence the sharing of genetic resource technologies to varying degrees. Using deep sea shrimp bioluminescence and tuna technologies as examples, the article gives insight into a common stewardship approach under these instruments for fairly balancing public and private interests in deep sea resources. It concludes that this common approach could be a starting point for negotiations over the United Nations’ proposed instrument under *UNCLOS*, which is expected to tackle access and benefit sharing of genetic resources from areas beyond national jurisdiction.
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CHAPTER 7  COOPERATIVE APPROACH TO ABS: EX SITU ANTARCTIC GENETIC RESOURCES

Chapter 5 analysed technology or knowledge transfer obligations for genetic resources from areas within national jurisdiction and Chapter 6 analysed the same for areas beyond national jurisdiction. Building on these analyses, Chapter 7 looks at the complex arrangements for Antarctic ex situ genetic resources that are used within national jurisdiction but originally from the Antarctic Treaty Area. This area is neither within nor beyond national sovereignty but rather, falls within unique cooperative governance arrangements (the third jurisdictional area).

Chapter 7 addresses the fifth aim of the thesis – to analyse the relationship between the TRIPS-compliant patent law defence framework and the cooperative approach to ABS and technology transfer of ex situ aquatic genetic resources originally sourced from the Antarctic Treaty Area. The Chapter navigates the regulation of in situ genetic resources and the absence of regulation of ex situ Antarctic genetic resources under the Antarctic Treaty System. It investigates how the Convention and Nagoya Protocol apply to Antarctica’s ex situ resources. The Chapter argues that the lack of coordination between ex situ repositories together with the confusion about the extent to which national ABS obligations would apply to Antarctic deposits, may undermine the Antarctic Treaty’s objectives of cooperation and freedom of scientific investigation for the benefit of all humankind. States are already regulating access and technology transfer concerning patented Antarctic genetic resource inventions under the TRIPS-compliant patent law defence framework. It concludes that this framework is an underutilised approach to resolving confusion around the three legal challenges (figure 3, page 32) in a way that is consistent with the Antarctic Treaty’s objectives.
Article Abstract

Regulating access and benefit sharing of Antarctica’s ex situ genetic resources is surprisingly complex. While the Antarctic Treaty System is silent on the issue, national access and benefit sharing frameworks may apply on a case-by-case basis depending on the timing, circumstances and nature of the original extraction from Antarctic waters. This article navigates Australia’s legislation applicable to the Australian Antarctic Territory to illustrate the legal complexities. It argues that the lack of coordination between ex situ repositories for exchange of aquatic genetic resources, combined with the complex regulatory arrangements, means there is little legal basis for the benefits from the use of Antarctica’s genetic resources to flow back to the Antarctic Treaty Area or to achieve the Antarctic Treaty’s objectives of cooperation and freedom of scientific investigation in the interests of science and the progress of all humankind. Some Consultative Parties under the Antarctic Treaty seem to be pinning their hopes on the proposed instrument under the United Nations Convention on the Law of the Sea to resolve the legal issues. This article concludes that in the meantime, the evolving system of patent law defences may prove to be an unexpected and underestimated ally for achieving the Antarctic Treaty’s objectives.
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Banking on a patent solution for sharing Antarctica’s ex situ genetic resources

Fran Humphries

I. Introduction

Economic and conservation interests in Antarctica’s ex situ biological and genetic resources\(^1\) are converging to create a perfect regulatory storm. On the one hand, the increasing interest in Antarctica’s genetic resources for commercial purposes\(^2\) could be expected to thrive in the absence of comprehensive access and benefit sharing (ABS)\(^3\) obligations under the Antarctic Treaty System. On the other hand, efforts towards the conservation of migratory aquatic genetic resources\(^4\) are hampered by a lack of

\(^1\) Biological resources include ‘genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.’ ‘Genetic resources’ mean ‘genetic material of actual or potential value’ and ‘genetic material’ means ‘any material of plant, animal, microbial or other origin containing functional units of heredity’. *Convention on Biological Diversity* (CBD), opened for signature on 5 June 1992, 1760 UNTS 79 (entered into force on 29 December 1993) art 2. The CBD is a multilateral treaty providing a framework for national strategies and laws for the conservation and sustainable use of biological diversity.

\(^2\) *An Update on Biological Prospecting in Antarctica, Including the Development of the Antarctic Biological Prospecting Database*, Antarctic Treaty Consultative Meeting, 31\(^{st}\) mtg, Agenda Item 17, WP 011 (June 2008) 3.

\(^3\) ABS refers to how genetic resources may be accessed from in situ or ex situ sources and how the benefits that arise from their use may be shared between users and providers of the genetic resource.

\(^4\) ‘Status and Trends in Aquatic Genetic Resources: A Basis for International Policy’ (Background Study Paper No 37, Commission on Genetic Resources for food and Agriculture, Food and Agriculture Organization of the United Nations, May 2007) 3; see also *Draft State of the World’s Aquatic Genetic Resources for Food and Agriculture*, Ad Hoc Intergovernmental Technical Working Group on Aquatic
coordination between and among ex situ gene banks or repositories. A growing concern is that the genetic resources that the ex situ gene banks hold in physical and digital forms, including the ones that are originally from the Antarctic Treaty Area, may be impacted by a complex array of national ABS regimes. At the heart of the regulatory storm is the global territorial approach to ABS that does not sit comfortably with the unique governance arrangements concerning the Antarctic Treaty Area. Many Consultative Parties to the Antarctic Treaty Consultative Meeting (ATCM)\(^5\) are taking a wait-and-see approach to the possible regulation of Antarctica’s ex situ genetic resources under the proposed United Nations Convention on the Law of the Sea (UNCLOS)\(^6\) on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (New Instrument).\(^7\) Meanwhile, recipients and providers, including gene banks, of Antarctica’s ex situ genetic resources must determine on a case-by-case basis whether a resource is subject to national ABS obligations. This chapter shows that the answer can depend on the location and the purpose of the use of, and the temporal link between, the physical and digital resource in question. This creates a level of confusion and complexity that has the potential to undermine the objectives and principles of the Antarctic Treaty.\(^8\)

There has been surprisingly little debate about whether leaving ABS of Antarctic ex situ genetic resources to multiple ABS systems outside the Antarctic Treaty System undermines the Antarctic Treaty’s principles including international cooperation and

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*Genetic Resources for Food and Agriculture, Commission on Genetic Resources for Food and Agriculture, 1st sess, Provisional Agenda Item 4, CGRFA/AqGR-1/16/Inf.2, (20 – 22 June 2016).*

\(^5\) See n 21 below and accompanying text.


\(^8\) *Antarctic Treaty*, opened for signature 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961) (‘Antarctic Treaty’).
freedom of scientific investigation\textsuperscript{9} that ‘accords with the interests of science and the progress of all [hu]mankind.’\textsuperscript{10} This chapter considers the question by firstly outlining the extent to which the ABS of Antarctica’s \textit{in situ} and \textit{ex situ} genetic resources is regulated under the Antarctic Treaty System. It then argues that the gap in the \textit{ex situ} regulation under the \textit{Antarctic Treaty} is part of a bigger problem that undermines the opportunity for benefits to flow back to Antarctica, namely, the lack of coordination between \textit{ex situ} repositories on aquatic sample, data, information and knowledge exchange. This is followed by an examination of the extent to which ABS regimes outside of the Antarctic Treaty System apply to Antarctic \textit{ex situ} genetic resources. The chapter considers the bilateral territorial approaches to ABS under the United Nations’ \textit{Convention on Biological Diversity} (CBD)\textsuperscript{11} and the \textit{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} (Nagoya Protocol).\textsuperscript{12} The chapter also considers the multilateral cooperative commons approaches under the \textit{International Treaty on Plant Genetic Resources for Food and Agriculture} (Plant Treaty)\textsuperscript{13} and the proposed New Instrument under UNCLOS. The result is a complex matrix of regulation that poses at least two significant challenges for the ABS of Antarctica’s \textit{ex situ} resources. First, the challenge of equitably treating changes of intent for the purpose of a resource’s use. Secondly, the challenge of overcoming jurisdictional problems arising from the CBD’s geographical origin approach to ABS, including the territorial limitations of laws and the

\textsuperscript{9} \textit{Antarctic Treaty} art II.

\textsuperscript{10} \textit{Antarctic Treaty} preamble.

\textsuperscript{11} CBD, above n 1.

\textsuperscript{12} \textit{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} (‘Nagoya Protocol’), opened for signature 29 October 2010, [2012] ATNIF 3 (entered into force 12 October 2014). The \textit{Nagoya Protocol} has not yet entered into force for Australia. It is a supplementary agreement to the CBD 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.

\textsuperscript{13} \textit{International Treaty on Plant Genetic Resources for Food and Agriculture}, opened for signature 3 November 2001, 2400 UNTS 303 (entered into force 26 June 2004) (‘Plant Treaty’).
extent to which physical and digital derivatives of the genetic resources fall within ABS regimes.

Under the *Antarctic Treaty*, sovereignty claims concerning Antarctica’s resources are on hold.\(^{14}\) Despite the perception of an unregulated open access approach to Antarctica’s genetic resources,\(^ {15}\) this chapter shows that some countries appear to be regulating the sharing of Antarctic *ex situ* genetic resources that are located within their national territory. This chapter argues that the legal authority for regulation is tenuous and complicated. It becomes more complex when dealing with the abstract information and knowledge (the digital resources) separate to the physical resource sample. In the light of the increasing interest in commercialising and patenting inventions related to Antarctic genetic resources,\(^ {16}\) an additional layer of national regulation concerns the protection of exclusive rights over genetic resource inventions under patent law. This protection may further restrict access to Antarctic genetic resources on which the inventions are based. A significant difference, however, between ABS and patent law regimes lies in their mechanisms for benefit sharing. This chapter argues that benefits under the bilateral ABS regimes generally flow to the provider country and not Antarctica. It concludes on the other hand that the framework of defences under the World Trade Organization’s *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS)\(^ {17}\) offers a multilateral approach to sharing knowledge and technology concerning Antarctica’s *ex situ* resources in a way that is consistent with fulfilling the objectives of cooperation and freedom of scientific investigation under the *Antarctic Treaty*.

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\(^{14}\) *Antarctic Treaty* art IV.


\(^ {16}\) *Biological Prospecting in Antarctica – the Need for Improved Information*, Antarctic Treaty Consultative Meeting, 36th mtg, Agenda Item 17, WP 48 (April 2013) 4.

II. The framework governing Antarctic genetic resources

The Antarctic Treaty System establishes a distinct international framework for governing activities in waters beyond national jurisdiction of the area south of 60° South latitude. The Antarctic Treaty System includes the Antarctic Treaty, the Protocol on Environmental Protection to the Antarctic Treaty (Madrid Protocol)\(^{18}\) and the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR).\(^{19}\) All claims for sovereignty over Antarctic waters, land and resources are on hold.\(^{20}\) The governance of Antarctic waters, land and resources is dependent on cooperation between representatives of contracting Parties to the Antarctic Treaty through the ATCM.\(^{21}\) The ATCM exchanges information and recommends measures to governments in furtherance of principles and objectives of the Antarctic Treaty including the facilitation of scientific research\(^{22}\) and international scientific cooperation in Antarctica.\(^{23}\)

The ATCM has affirmed that the Antarctic Treaty System is the appropriate framework for managing the collection and use of biological material in the Antarctic Treaty Area.\(^{24}\) Sharing the benefits of Antarctica is an important aim under the Antarctic Treaty System,\(^{25}\) however the system does not directly regulate the ABS of Antarctica’s

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20 Antarctic Treaty art IV.
21 Antarctic Treaty art IX(1).
22 Antarctic Treaty art IX(1)(b).
23 Antarctic Treaty art IX(1)(c).
24 Biological Prospecting in Antarctica, Antarctic Treaty Consultative Meeting Resolution 6, 36\(^{th}\) mtg (adopted on 19 May 2013); and Collection and Use of Antarctic Biological Material Antarctic Treaty Consultative Meeting, 32\(^{nd}\) mtg (adopted on 17 April 2009).
biological resources. Instead there are several provisions that apply to accessing in situ genetic resources and to the sharing of non-monetary benefits that arise from their use. The provisions do not govern the ABS of ex situ Antarctic genetic resources but may arguably be relevant to determining the extent to which national legislation applies to ex situ physical and digital resources outlined later in this chapter.

A. Access Provisions

Access to in situ resources must accord with the principle of freedom of scientific investigation and cooperation. Access must be carried out for peaceful purposes ‘in the interest of all [hu]mankind’ and the preservation of the Antarctic environment. This means, for example, that access to biological resources for developing new biological weapons would not be allowed, but arguably access to develop new aquaculture products would meet these requirements. Contracting Parties are obliged to give prior notification to other Contracting Parties about expedition activities in Antarctica including the collection of biological material, through the Electronic Information Exchange System. While this is not an obligation to seek permission before extraction akin to the CBD’s access obligations of prior informed consent and mutually agreed terms, it provides other Contracting Parties with an opportunity to voice their concerns about the proposed access.

27 Ibid 15 regarding access; ibid 18 regarding benefit sharing.
28 See below n 144 and following text.
29 Antarctic Treaty art II.
30 Antarctic Treaty art I.
31 Antarctic Treaty Preamble.
32 Antarctic Treaty art IX(1)(f); Madrid Protocol art 2.
33 A Gap Analysis, above n 26, 15.
34 Antarctic Treaty art VII(5); and Electronic Information Exchange System, Antarctic Treaty Consultative Meeting Decision 10, 28th mtg, Agenda Item 17 (adopted 17 June 2005).
35 See below n 121 and accompanying text.
Other Antarctic Treaty System instruments have requirements to obtain permits for access under certain circumstances. Under the Madrid Protocol, for example, the ‘taking of native mammals, birds and plants’ is prohibited except with a permit.\(^{36}\) Permits would only be issued to provide specimens for scientific study or information, or to provide specimens for museums, herbaria or other educational or cultural institutions or uses.\(^{37}\) Micro-organisms,\(^{38}\) and arguably invertebrates like molluscs and sponges, fall outside the definition of ‘native mammals, birds and plants’.\(^{39}\) This means there are no requirements for prior authorisation or permit restrictions on taking these organisms (unless domestic legislation provides otherwise)\(^{40}\) other than the general environmental impact assessment obligations on researchers taking samples.\(^{41}\)

Marine living resources under the CCAMLR are also outside the scope of the Madrid Protocol’s permit system.\(^{42}\) The CCAMLR applies to fin fish, molluscs, crustaceans and all other species of living organisms, including birds, found south of the Antarctic Convergence (a wider area than the Madrid Protocol).\(^{43}\) The objective of the CCAMLR is the conservation of marine living resources.\(^{44}\) It is unclear whether it only applies to the harvesting and use of these resources as a source of protein,\(^{45}\) rather than utilisation of the resource for its genetic material value to which ABS regimes apply.\(^{46}\) Members must issue an authorisation (eg permit) to their flagged vessels before they can take the

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\(^{36}\) *Madrid Protocol*, Annex II art 3(1).


\(^{38}\) *A Gap Analysis*, above n 26, 15.

\(^{39}\) *See A Case of Biological Prospecting*, Antarctic Treaty Consultative Meeting, 34\(^{\text{th}}\) mtg, Agenda Item 17, IP62 (July 2011) 3.

\(^{40}\) *A Gap Analysis*, above n 26, 15.

\(^{41}\) *Madrid Protocol* arts 3, 8 and Annex 1.

\(^{42}\) *A Gap Analysis*, above n 26, 15. Under Article 4, the *Madrid Protocol* is subordinate to other instruments within the Antarctic Treaty System and harvesting of marine living resources must comply with measures under the *CCAMLR*.

\(^{43}\) *CCAMLR* art I.

\(^{44}\) *CCAMLR* art II(1) and preamble.

\(^{45}\) *CCAMLR* preamble.

\(^{46}\) *See the definition of genetic resources in CBD art 2.*
relevant resources.\(^{47}\) Recently the Commission declared the world’s largest marine park in the Ross Sea, which will come into effect in December 2017.\(^{48}\) Access restrictions in this area include a ‘no take’ zone in seventy-two percent of the marine park.\(^{49}\)

### B. Knowledge sharing provisions

As with the access provisions above, the benefit sharing of genetic resources accessed from the Antarctic Treaty Area must support the continuance of freedom of scientific investigation and cooperation.\(^{50}\) In other words, benefit sharing would need to accord ‘with the interests of science and the progress of all [hu]mankind’, \(^{51}\) the peaceful use of Antarctica\(^{52}\) and the preservation of the Antarctic environment.\(^{53}\) The *Antarctic Treaty*, which entered into force before TRIPS, does not mention the relationship between these objectives and private interests like intellectual property. While there is no explicit prohibition on claiming intellectual property over Antarctica’s genetic resources, the agreement to put sovereign rights on hold to fulfil a collective purpose of cooperation and scientific investigation that benefits all humankind would suggest that the proprietary interests of users of the resources would not outweigh the public interest in having the resource available in accordance with the *Antarctic Treaty*’s objectives.

The Antarctic Treaty System does not regulate the sharing of monetary benefits but does have provisions for sharing the non-monetary benefits of using Antarctica’s genetic resources.\(^{54}\) These benefits arguably focus on sharing information and knowledge rather

\(^{47}\) See eg permit obligations under Australia’s *Antarctic Marine Living Resources Conservation Act 1981 (Cth)* s 9.


\(^{50}\) *Antarctic Treaty* art II.

\(^{51}\) *Antarctic Treaty* preamble.

\(^{52}\) *Antarctic Treaty* art I.

\(^{53}\) *Antarctic Treaty* art IX(1)(f); *Madrid Protocol* art 2.

\(^{54}\) *A Gap Analysis*, above n 26, 17.
than sharing the physical specimens on which the technologies are based. Contracting Parties to the Antarctic Treaty are obliged to promote international cooperation for scientific investigation in Antarctica. This requires to the greatest extent practicable the exchange of plans for scientific programs, personnel and the exchange and free availability of ‘scientific observations and results’. It is difficult to determine the scope of this obligation because ‘scientific observations and results’ are not defined. The phrase is likely, however, to include observations and results related to biological prospecting of genetic resources.

In 2015, Consultative Parties to the ATCM agreed on a consolidated list of information exchange requirements for science activities including information on the ‘taking and harmful interference with flora and fauna species, location, amount, sex, age and purpose’. The condition to record purpose at the time of taking the resources is relevant for determining the types of benefits that can be shared from their subsequent uses.

The Madrid Protocol and CCAMLR have additional obligations for knowledge sharing within the scope of their jurisdictions. Under the Madrid Protocol, Parties are required to exchange information through annual reports on Protocol activities. Parties are specifically required to exchange records and statistics on the numbers of native mammals, birds and plants taken annually, but this arguably does not apply to invertebrates, fish and microorganisms. The only requirement for invertebrates is to

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55 See examples of non-monetary benefit sharing in A Gap Analysis, ibid, 17.
56 Antarctic Treaty art II.
57 Antarctic Treaty art III.
59 See Biological Prospecting, Antarctic Treaty Consultative Meeting Resolution 7, 28th mtg (adopted 17 June 2005).
63 Madrid Protocol annex II art 6(1)(a).
exchange information on their status but even then it only relates to native invertebrates. Parties must also ‘cooperate in the planning and conduct of activities’. To achieve this goal, Parties must endeavour to among other things undertake joint expeditions and sharing the use of facilities and information that may be helpful in conducting activities. Direct participation in joint marine research is often regarded as a more effective approach to technology transfer than pure information sharing because it promotes sustainable capacity building.

Under the CCAMLR, the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR Commission) must facilitate research of Antarctic marine living resources. Members are obliged to submit statistical, biological and other information, which may include information on the taking of biological resources for use of their genetic resources. Non-parties to the Antarctic Treaty may become members of the CCAMLR. Interestingly they are bound by Articles I, IV, V and VI of the Antarctic Treaty (peaceful purpose objectives and sovereignty arrangements) but not specifically the knowledge sharing provisions under Articles II and III of the Antarctic Treaty.

A recurring theme for the Antarctic Treaty’s access and knowledge sharing rules is its cooperative approach to sharing information, samples, facilities and technical knowhow. It is important to keep in mind that its obligations are only imposed on parties

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64 Madrid Protocol annex II art 6(1)(b).
65 Madrid Protocol annex II art 1(d); see also A Case of Biological Prospecting, above n 39, 3.
69 CCAMLR art IX.
70 CCAMLR art XX.
71 CCAMLR arts III and IV.
to the relevant international instrument. Significantly for the increasingly commercial applications of genetic resources that originated in Antarctica,\textsuperscript{72} the Antarctic Treaty System does not provide guidance on ABS of Antarctic \textit{ex situ} resources, the role of intellectual property,\textsuperscript{73} and how to balance proprietary interests and the interests of humankind.

\section*{III. Gap in Regulating Ex Situ Resources – the Tip of the Iceberg}

Some Contracting Parties to the \textit{Antarctic Treaty} are reluctant to provide for additional or specific ABS regulation\textsuperscript{74} despite the regulatory gap relating to the use and sharing of Antarctic \textit{ex situ} genetic resources, including those that are subsequently patented. The following discussion highlights how this regulatory gap is only the tip of the iceberg for the fair and equitable sharing of Antarctic \textit{ex situ} genetic resources. It is indicative of a bigger problem that is lurking beneath the surface – the lack of coordination between \textit{ex situ} repositories on aquatic sample, data, information and knowledge exchange (outlined in this section) and the confusion about the extent to which national ABS obligations would apply to Antarctic deposits (outlined in the next section). This section outlines some of the uses of Antarctic \textit{ex situ} genetic resources with particular emphasis on aquaculture, which is likely to increasingly become a beneficiary of Antarctica’s genetic resources, making this an important perspective to consider.

Much of the recent commercial and patent activity concerning Antarctic organisms relates to krill while the ‘rest is based on a variety of Antarctic source organisms which include micro-organisms, invertebrates (such sponges, tunicates, corals, sea stars and worms), vertebrates (such as fish) and plants (such as algae and Antarctic hairgrass)’.\textsuperscript{75}

\textsuperscript{72} See below n 75 and accompanying text.


\textsuperscript{74} \textit{Report of the ATCM Intersessional Contact Group to Examine the Issue of Biological Prospecting in the Antarctic Treaty Area}, Antarctic Treaty Consultative Meeting, 33\textsuperscript{rd} mtg, Agenda Item 17, WP 13 (May 2010) 7 [21].

\textsuperscript{75} \textit{The Antarctic Biological Prospecting Database}, Antarctic Treaty Consultative Meeting, 32\textsuperscript{nd} mtg, Agenda Item 17, WP1 (April 2009) 3.
Many uses of genetic material and derivatives concern pharmaceutical and industrial uses.\textsuperscript{76} Although the literature lacks thorough analyses of trends relating specifically to aquaculture, there are some examples of Antarctic genetic resources being used for aquaculture purposes.\textsuperscript{77} A good example is the interest in antifreeze gene technologies. A major issue for aquaculture is unseasonal cold winters which can severely damage production and brood fish stocks.\textsuperscript{78} Further, the inability of fish without antifreeze proteins severely restricts suitable sites for aquaculture operations.\textsuperscript{79} Researchers have focused their attention on antifreeze proteins and glycoproteins that reduce freezing temperatures by preventing ice-crystal growth.\textsuperscript{80} Sources of patented antifreeze proteins and glycoproteins include deep sea cold ocean teleost fish from the Southern Ocean,\textsuperscript{81} including areas covered by the Antarctic Treaty System. Uses of antifreeze protein technologies in breeding include direct injection of purified antifreeze protein into a host species to improve freezing resistance for farming,\textsuperscript{82} or its use in cryopreservation of breeding material,\textsuperscript{83} or the antifreeze gene’s complete integration into the genome of the host species, which might then be expressed in the host’s offspring.\textsuperscript{84} The use of antifreeze genes to develop transgenic fish species such as

\textsuperscript{76} Biological Prospecting in Antarctica, above n 16, 3.

\textsuperscript{77} Biological Prospecting in Antarctica: Review, Update and Proposed Tool to Support a Way Forward, Antarctic Treaty Consultative Meeting, 30th mtg, Agenda Item 17, IP 67 (May 2007) 8.

\textsuperscript{78} John Beardmore and Joanne Porter, ‘Genetically Modified Organisms and Aquaculture’ (Food and Agriculture Organization of the United Nations, Fisheries Circular No. 989, FIRI/C989(3) 2003)4.


\textsuperscript{80} Beardmore and Porter, above n 78, 4.

\textsuperscript{81} Jong Kyu Lee et al, ‘Molecular and Comparative Analyses of Type IV Antifreeze Proteins (AFPIVs) from Two Antarctic Fishes, Pleuragramma antarcticum and Notothenia coriiceps’ (2011) 159 Comparative Biochemistry and Physiology Part B: Biochemistry and Molecular Biology 197, 204.

\textsuperscript{82} Such as rainbow trout; Garth L Fletcher, Ming H Kao and Ron M Fourney, ‘Antifreeze Peptides Confer Freezing Resistance to Fish’ (1986) 64 Canadian Journal of Zoology 1897, 1898.

\textsuperscript{83} Heather M Young and Garth L Fletcher, ‘Antifreeze Protein Gene Expression in Winter Flounder Pre-hatch Embryos: Implications for Cryopreservation’ (2008) 57 Cryobiology 84, 84.

\textsuperscript{84} Hew et al, above n 7979, 411.
salmon\textsuperscript{85} and tilapia\textsuperscript{86} has attracted much attention. While the use of \textit{ex situ} Antarctic genetic resources may be on the rise, difficulties in pinpointing bioprospecting and patenting trends for their specific use in aquaculture are compounded by the lack of ABS rules documenting intent at the time of extraction, changes of intent and the subsequent use of \textit{ex situ} Antarctic resources. In other words, a genetic resource may be extracted from Antarctic waters for non-commercial research purposes and then later stored in an \textit{ex situ} facility and subsequently used for commercial aquaculture purposes without any benefits flowing back to Antarctica.

\textit{Ex situ} collections are diverse and can include culture collections, germplasm collections, cell banks, stock centres, herbaria, zoos, museum collections and botanic gardens.\textsuperscript{87} Unlike the current extensive system for the exchange of terrestrial plant germplasm collections which began in the early 20\textsuperscript{th} century,\textsuperscript{88} the history of aquatic gene banks only goes back to the past few decades.\textsuperscript{89} Collections of aquatic genetic resources can include living broodstock or cryopreserved collections. Broodstock collections take up space and are more expensive than cryopreserved banks to replenish and maintain.\textsuperscript{90} Storage ranges from simple bacteria strains to more complex organisms. One of the few collections in the world dedicated to the collection of Antarctic bacteria

\begin{thebibliography}{99}
\bibitem{89} David Greer and Brian Harvey, \textit{Blue Genes: Sharing and Conserving the World’s Aquatic Biodiversity} (Earthscan, 2004) 67-68.
\bibitem{90} Ibid 67.
\end{thebibliography}
strains is the Australian Collection of Antarctic Microorganisms (ACAM). There are also growing private and university Antarctic collections including those in the United States, Germany and Belgium. Cryopreservation of sperm from several fish species is also commonly practiced. The same technology, however, for eggs and embryos of aquatic species is not yet viable which severely limits the effectiveness of cryopreservation for aquatic gene banking. Other options for gene banking include androgenesis, cloning, stem cell collections and other future technologies. While there are a number of large state-run collections (for example in Norway, India, Russia and Finland), the bulk of cryopreserved material is held in small private or university-based banks, whose numbers are nowhere near those of plant repositories.

Unlike the plant networks, there is ‘no coordination between aquatic gene banks’. Nor are there generally accepted protocols or regulations governing the access to and use of aquatic resources; rather private law contracts are usually agreed between the providers and users of the resource ‘and very little importance is given to [ABS] considerations’. Similar uncoordinated contractual mechanisms are used for the exchange of aquatic genetic resources from broodstock collections. For example genetic material for marine shrimp or tilapia are improved by private breeding companies and then the genetically improved stocks are ‘multiplied’ by other hatchery facilities in order

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91 See <http://gcmd.nasa.gov/records/AADC_ACAM.html>.
92 Biological Prospecting – A Way Forward, above n 77, 10.
93 Greer and Harvey, above n 89, 67.
96 See ibid 253-4.
97 Greer and Harvey, above n 89, 33 and 68.
98 Ibid 67.
Chapter 7

to provide enough animals to sell to farmers for grow-out.\textsuperscript{100} The multiplier facilities may enter into contractual agreements, usually termed material transfer agreements (MTAs), with the breeding companies that set restrictions on how the multiplier hatcheries may use the genetically improved stocks. The terms of the MTAs often ‘prevent the multiplier stations ... from selling the stock for breeding purposes without compensation’ to the provider breeder.\textsuperscript{101} However, the numerous groups involved in the production process from breed improvement to sale of live fish, combined with the highly fertile nature of many aquatic species, mean that there is substantial scope for failure to adhere to MTAs and for the unauthorised exchange of aquatic genetic material.\textsuperscript{102} This lack of coordination for the exchange of aquatic germplasm has implications for determining which resources may have originated from Antarctica. Even when the origins can be traced back to Antarctica, the gap in regulating \textit{ex situ} resources becomes a significant issue because a substantial proportion of the use of Antarctic specimens takes place in national laboratories.\textsuperscript{103}

In the context of genomics, proteomics, phenomics and bioinformatics, \textit{ex situ} collections may include the digitalised forms of Deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins.\textsuperscript{104} These kinds of ‘omic’ technologies are becoming increasingly

\textsuperscript{100} John A H Benzie, ‘Use and Exchange of Genetic Resources of Penaeid Shrimps for Food and Agriculture’ (2009)\textit{1 Reviews in Aquaculture}, 232, 235.

\textsuperscript{101} Bartley et al, above n 99, 25.

\textsuperscript{102} Ibid.

\textsuperscript{103} A Gap Analysis, above n 26, 18.

\textsuperscript{104} Peter Johan Schei and Morten Walløe Tvedt, Fridtjof Nansen Institute, \textit{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, 9\textsuperscript{th} mtg, UN Doc UNEP/CBD/WG-ABS/9/INF/1 (19 March 2010) (‘\textit{The Concept of ‘Genetic Resources’}’) 25.
important for innovation in aquaculture\textsuperscript{105} and aquatic related research.\textsuperscript{106} There are several global initiatives for storing genetic data, including the information relating to Antarctic genetic resources. The Census of Antarctic Marine Life (CAML) collates DNA barcode data for Antarctic marine species including life from the Southern Ocean and the Sub-Antarctic Islands. DNA barcoding is a technique that uses a short gene sequence from a standardised region of the genome as a diagnostic ‘biomarker’ for species.\textsuperscript{107} There are also separate initiatives for specific species such as the barcode library for Antarctic sponges.\textsuperscript{108} Coordination between depositories is complicated by the different means of entering data. For example, many genetic databases contain DNA sequences such as DNA Data Bank of Japan (DDBJ), European Molecular Biology Laboratory (EMBL) databank and National Institute of Health’s GenBank. However, there are few Antarctic barcodes in Genbank.\textsuperscript{109} These barcodes are held in specially designed databases such as the Barcode of Life Data System (BOLD), which is an online workbench and receptacle for sequence data generated from Barcode of Life projects, such as the CAML project above.\textsuperscript{110} Without proper coordination between databases, however, it is difficult to determine the geographical origin of the data and information for the purposes of ABS.


\textsuperscript{108} For the recent assembly of a barcode library for Antarctic sponges see Sergio Vargas et al, ‘Diversity in a Cold Hot-Spot: DNA-Barcoding Reveals Patterns of Evolution among Antarctic Demosponges (Class Demospongiae, Phylum Porifera)’ (2015) 10 PLOS One: e0127573 DOI: 10.1371/journal.pone.0127573.

\textsuperscript{109} Grant, above n 107, 1631.

\textsuperscript{110} Ibid.
There is no centralised information or knowledge repository for the results of high seas research,\(^{111}\) including the Antarctic waters of the Southern Ocean. The ATCM has called for ‘further development of linked databases and geographically referenced maps, which can serve to improve the informational basis for discussions at the ATCM’.\(^{112}\) ATCM parties set up a database for bioprospecting in Antarctica that included patenting information, effectively linking data, information and knowledge relating to Antarctic genetic resources. The Antarctic Biological Prospecting Database ‘provides a searchable interface allowing the user to obtain information about research and commercial products arising from biological samples that were sourced from the Antarctic region’.\(^{113}\) However, at the time of writing this chapter, the database had been taken offline. Other broader initiatives incorporate Antarctic information such as the Global Biodiversity Information Facility,\(^ {114}\) which was set up to make primary global biodiversity information more widely available, and the Ocean Biogeographic Information System,\(^ {115}\) which publishes information on the distribution of marine species.\(^ {116}\) The Marine Biodiversity Information Network (SCAR-MarBIN) compiles and manages information on Antarctic marine biodiversity by coordinating database networking.\(^ {117}\)

In summary, the regulatory vacuum outlined in the previous section combined with the lack of coordination between \textit{ex situ} repositories and the subsequent loss of control over resources that originated from Antarctic waters make it difficult to pinpoint the extent to which physical and digital Antarctic genetic resources contribute to aquatic research and development generally and aquaculture in particular. Significantly, the lack of coordination impedes the collection and exchange of detailed information needed to

\(^{111}\) \textit{IWG Intersessional Workshops}, above n 68 [121].

\(^{112}\) \textit{Biological Prospecting in Antarctica}, above n 16, 4.

\(^{113}\) \textit{The Antarctic Biological Prospecting Database}, above n 75, 3.

\(^{114}\) See <www.gbif.org>.

\(^{115}\) See <www.iobis.org>.

\(^{116}\) Grant and Linse, above n 107, 1630.

\(^{117}\) See <http://www.scarmarbin.be>.
trace the origin of a given genetic resource to determine its status for the purpose of ABS under national laws as outlined in the following section.

IV. The Tidal Wave of Applicable ABS-related Instruments

Private benefit sharing agreements and patent protection concerning Antarctic genetic resources have already begun despite the regulatory gaps in the Antarctic Treaty System. ATCM Parties have reported that some companies using Antarctic resources offer benefit sharing on an ad hoc basis in return for access. This may include a mix of monetary benefits like fees per sample and licensing agreements, as well as non-monetary benefits, for example through training, capacity-building, research exchanges, and technology transfer. Given that no country has control over Antarctic resources and the Antarctic Treaty System has no ABS mechanism, it would be interesting to know to whom or to what the benefits in these private agreements flow. The ABS of Antarctic ex situ resources is being influenced by a growing matrix of ABS-related international instruments including the CBD, the Nagoya Protocol, the Plant Treaty and the New Instrument under UNCLOS. This section explores the extent to which other ABS regimes apply to Antarctic genetic resources.

A. CBD’s Territorial Approach

The CBD and the Nagoya Protocol provide a framework for a bilateral territorial approach to ABS of genetic resources. The CBD’s significant shift from treating genetic resources as a common heritage of humankind toward recognising the sovereign rights of countries over their resources has created spatial and temporal complexities for the legal status of Antarctic genetic resources. The following discussion highlights that spatially, the reach of the ABS rules depends on whether Antarctic genetic resources are located in situ or ex situ (geographical origin) which may depend on the timing and

118 Sarah A Laird, Rachel Wynberg and Sam Johnston, Recent Trends in the Biological Prospecting (Antarctic Treaty Consultative Meeting, 29th mtg, Agenda Item 18, IP 116) 23.
119 Ibid.
circumstances of their extraction. Other temporal complexities arise in cases where derivatives of the genetic resource such as the abstract digital resource and synthetic derivatives are being used independently from the physical in situ or ex situ resource, at different points in time and for different purposes of extraction and subsequent use.

Under the framework of the CBD and the Nagoya Protocol, Parties have sovereign rights to control access to in situ and ex situ genetic resources within their jurisdiction (subject to exceptions addressed below), as well as control over their nationals’ activities in relation to genetic resources located outside their territories.\(^{121}\) This is subject to obligations to facilitate access for, and transfer to, other Contracting Parties’ relevant technologies that make use of (in situ or ex situ) genetic resources.\(^{122}\) In return for access, users must share with the provider country, on mutually agreed terms, the benefits ultimately gained from the subsequent use of the genetic resources. The benefits include the resource provider’s participation in scientific and biotechnology research based on the genetic resources supplied\(^ {123}\) as well as the fair and equitable sharing of the results of research, development, commercial and biotechnological use of the resources.\(^ {124}\) More specifically, the CBD’s supplementary agreement, the Nagoya Protocol, sets out the rules, procedures and compliance mechanisms for ABS. This more detailed system is based on access conditions set out in domestic permits issued by a contracting party to the CBD\(^ {125}\) that are linked to contractual benefit sharing agreements between users and providers,\(^ {126}\) all of which operate within a compliance framework of national laws in user and provider countries.\(^ {127}\)

\(^{121}\) CBD arts 3, 4 and 15(1).

\(^{122}\) CBD art 16(1).

\(^{123}\) CBD art 19(1).

\(^{124}\) CBD art 15(7) and 19(2).

\(^{125}\) Nagoya Protocol arts 6(3)(e), 14(2)(c) and 17(2).

\(^{126}\) Referred to as ‘mutually agreed terms’ in the Nagoya Protocol; at arts 5, 6(3)(g), 7, 12(3)(b) and 19.

The ABS framework applies to genetic resources that are (a) provided by the country of origin, or (b) parties that have ‘acquired’ genetic resources ‘in accordance with the [CBD].’ Antarctica does not fall within the definition of a ‘country of origin’. The question therefore becomes whether Antarctica’s genetic resources located in a national ex situ facility have been ‘acquired ... in accordance with the [CBD]’ – a term that is not defined under the CBD. Glowka argues that genetic resources are not acquired in accordance with the CBD if they are taken illegally from a country of origin, for example, without prior informed consent (if required by the country of origin). Other circumstances may include acquiring genetic resources that were deposited in an ex situ facility before the CBD entered into force, or those in repositories within the jurisdiction of nations that are not party to the CBD. The meaning or the timing of the term ‘acquired’ is also not defined in the CBD and may need clarification in national legislation. As the following discussion highlights, the clarification may depend on the circumstances of the original accession of the relevant genetic resource from the Antarctic Treaty Area.

While the CBD is based on the principle of territorial sovereignty, it also applies to processes and activities carried out by a party’s nationals within its control beyond the limits of the national jurisdiction. Even though there is no territorial application of laws to genetic resources in the Antarctic Treaty Area, the people located in Antarctica including scientific personnel, staff and observers in Antarctica are subject to the jurisdiction of their country of nationality. The Nagoya Protocol does not have similar extra-territorial application because its scope is limited to ABS under Article 15 of the

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128 CBD arts 2 and 15(3).
129 CBD art 2.
131 Ibid 77.
132 Glowka above n 130, 79.
133 CBD art 4(b).
134 Antarctic Treaty art VIII(1).
CBD\textsuperscript{135} and not the CBD’s extended scope in Article 4.\textsuperscript{136} This means that the CBD’s obligations may apply to users of Antarctica’s \textit{in situ} resources but not the Nagoya Protocol’s obligations.\textsuperscript{137}

1. \textbf{Argument that the CBD does not apply}

Some commentators argue that the Antarctic Treaty Area is not a sovereign state and therefore cannot be a Contracting Party to the CBD within the meaning of the ABS framework that can enter into mutually agreed terms, require prior informed consent and be afforded benefits for subsequent uses of the genetic resources.\textsuperscript{138} Under the CBD:

\begin{quote}
access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.\textsuperscript{139}
\end{quote}

The ATCM is a forum rather than a decision making body authorised with sovereign rights and would not similarly be deemed a Contracting Party with sovereign powers. The CCAMLR Commission does have a legal personality\textsuperscript{140} but there is uncertainty about whether its mandate is limited to the use of genetic resources for consumption rather than for their genetic material potential.\textsuperscript{141} One interpretation of Article 15(5) of the CBD is that in the absence of a ‘state’ with sovereign rights over the resources, there is no provider to whom prior informed consent is owed. The consequence is that the genetic resources cannot be taken ‘in accordance with’ the CBD and so the ABS

\textsuperscript{135} Nagoya Protocol art 3.
\textsuperscript{136} Greiber, above n 25, 74.
\textsuperscript{137} Ibid.
\textsuperscript{139} CBD art 15(5).
\textsuperscript{140} CCAMLR art VIII.
\textsuperscript{141} See above n 46 and accompanying text.
provisions are not triggered (in effect a free access scenario). Once a commons resource has been extracted by a Contracting Party to the CBD, the extractor may then become the party from whom consent is required and benefits are afforded under the ABS framework. This is because, although the requirement to provide prior informed consent does not clarify the phrase ‘the Contracting Party providing such resources’, it is likely to have a similar meaning to the ‘country providing genetic resources’ under Article 2 of the CBD. In other words:

the country supplying genetic resources collected from in situ sources, including populations of both wild and domesticated species, or taken from ex situ sources, which may or may not have originated in that country.\textsuperscript{142}

Under this ‘res nullius scenario’,\textsuperscript{143} the CBD’s ABS obligations would not apply. The Antarctic genetic resource would be treated the same way as a country’s territorial genetic resources. In this case, the benefits of using the genetic resources flow back to the country taking the resource, and not for the benefit of the Antarctic Treaty System’s collective purpose.

2. Argument that the CBD does apply

A second ‘collective scenario’ is based on the unique governing arrangements of the Antarctic Treaty System where the genetic resources are subject to neither national sovereignty nor free access. Under this scenario, although Consultative Parties to the ATCM cannot exercise sovereign powers over resources within the Antarctic Treaty Area, collectively they have contracted to put into effect their access and knowledge sharing obligations under the Antarctic Treaty System within their national laws on behalf of one another. So for a Contracting Party to the CBD that is also a Consultative Party to the Antarctic Treaty System, the ‘res nullius’ scenario above would not apply. In effect there is a reciprocal arrangement where prior informed consent is given on

\textsuperscript{142} CBD art 2.

\textsuperscript{143} Where the genetic resources are available to the first person with the capacity and technology to exploit them, who also receives the benefits from their use to the exclusion of others; Charles Lawson, \textit{Regulating Genetic Resources: Access and Benefit Sharing in International Law} (Edward Elgar, 2012) p 242.
behalf of other parties and resources are capable of being acquired ‘in accordance with’ the CBD.

For example, Australia is a party to the Antarctic Treaty, Madrid Protocol and CCAMLR. The Antarctic Treaty Act 1960 (Cth) gives effect to the Antarctic Treaty in Australia and applies to observers, scientific personnel and accompanying staff within the meaning of the Antarctic Treaty who are nationals of a Contracting Party to the Antarctic Treaty. Australia’s obligations under the Madrid Protocol, including permit approvals and environmental impact assessments, are implemented through the Antarctic Treaty (Environmental Protection) Act 1980 (Cth) (ATEP Act). These laws (that effectively put into effect the Antarctic Treaty’s access provisions) apply to any activity proposed to be undertaken by Australian citizens, organisations, expeditions and tour operators in any waters south of 60 degrees South including all waters. Australia’s obligations under CCAMLR including permit approvals are implemented through the Antarctic Marine Living Resources Conservation Act 1981 (Cth) (AMLRC Act) that applies to the CCAMLR ‘Convention Area’ (marine areas south of the Antarctic Convergence). These Acts apply to Australian citizens and organisations so foreign nationals and organisations based outside Australia need to contact their respective country’s Antarctic administrative organisations for approval, unless their activity is part of the Australian Antarctic programme. The Australian government has advised that ‘in accordance with the principles of the Antarctic Treaty, Parties are responsible for their own nationals and other Antarctic programmes will recognise approvals granted by Australia.’ Under this reciprocal ‘collective scenario’, the extracting party has an obligation for prior informed consent of the permitting country on behalf of the other parties to the Antarctic Treaty System. This means the genetic resources can be ‘taken in accordance with’ the CBD and therefore Antarctica’s in situ and subsequent ex situ

144 Antarctic Treaty Act 1960 (Cth) s 3.
145 Antarctic Treaty (Environmental Protection) Act 1980 (Cth) (‘ATEP Act’).
146 Antarctic Marine Living Resources Conservation Act 1981 (Cth) s 3 (‘AMLRC Act’).
147 ‘Guide to Administering Environmental Approvals’ (Australian Antarctic Division, Department of the Environment, June 2014) 5.
148 Ibid. See ATEP Act s 7(1).
genetic resources may fall within the CBD’s framework. The Nagoya Protocol’s framework will not apply to Antarctic in situ resources but may apply to its ex situ resources depending on how a country implements its obligations.

While this reasoning may offer legal authority to regulate Antarctica’s ex situ genetic resources under the CBD, the territorial application of laws means that benefits still flow to the provider country, unless otherwise negotiated under mutually agreed terms. To use the Australian example, the Environment Protection and Biodiversity Conservation Act 1999 (Cth) (EPBC Act) puts into effect Australia’s ABS obligations under the CBD. The EPBC Act only applies to the physical genetic resources in Commonwealth Areas, which includes the Australian Antarctic Territory, generally the area south of 60 degrees South and between 45 degrees East and 160 degrees East. This area largely represents Australia’s claim that has been put on hold by the Antarctic Treaty. It does not apply to physical genetic resources or Australian nationals dealing with genetic resources in the broader Antarctic Treaty Area or CCAMLR waters outside Commonwealth Areas. Biological resources in land and waters administered by the Australian Antarctic Division are exempt from the ABS obligations under the EPBC Act. This means that a permit is required to access Antarctic genetic resources but administratively, access is governed in accordance with the ATEP Act or the AMLRC Act. While these acts do not have specific benefit sharing laws, it is likely that government decision-makers will follow the process under the EPBC Act. If a party wishes to access an Antarctic genetic resource for non-commercial purposes, they must have written permission from the provider to use the resource in return for giving the provider the results of any research on the biological resource and a taxonomic duplicate of the sample. If a party wishes to access a genetic resource for actual or potential

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150 Australian Antarctic Territory Acceptance Act 1933 (Cth) s 2.
152 EPBC Regulation reg 8A.13.
commercial purposes, a benefit sharing agreement must be negotiated with the Commonwealth government’s relevant delegate.\(^{153}\) Among other things, the benefit sharing agreement must set out the purpose of access\(^{154}\) and details of benefits to the access provider who in this case is the Australian government.\(^{155}\) The only concession to the Antarctic Treaty Area is to include the details of any proposals of the user to benefit biodiscovery conservation ‘in the area’ if access is granted.\(^{156}\) Arguably, this requirement is at the contractual discretion of the user, rather than a legislative obligation for benefits to flow to the Antarctic Treaty Area.

In summary, whether or not the CBD applies to Antarctica’s \textit{in situ} and \textit{ex situ} genetic resources, the territorial application of laws means that there are no positive requirements for benefits to flow to the Antarctic Treaty Area in support of its knowledge sharing provisions, unless agreed between the parties that negotiate a contract over a specific genetic resource.

3. The CBD’s spatial and temporal complexities

The Australian example highlights the spatial and temporal complexities caused by the territorial approach to ABS laws that apply to collecting \textit{in situ} Antarctic genetic resources and the subsequent taking of the same resources from \textit{ex situ} facilities. This is because in keeping with the Antarctic Treaty System, the ATEP Act and the AMLRC Act apply to \textit{in situ} Antarctic resources and not \textit{ex situ} genetic resources of Antarctica.\(^{157}\) Australian ABS obligations apply to genetic resources within Commonwealth Areas which might include \textit{in situ} resources in the Australian Antarctic Territory as well as Antarctica’s \textit{ex situ} resources that are stored in government-owned storage facilities on the Australian mainland, but not those held in private facilities within Australia or any

\(^{153}\) \textit{EPBC Regulation} reg 8A.04(1) and div 8A.2.

\(^{154}\) \textit{EPBC Regulation} reg 8A.08(e).

\(^{155}\) \textit{EPBC Regulation} reg 8A.08(l).

\(^{156}\) \textit{EPBC Regulation} reg 8A.08(k).

\(^{157}\) See above n 27 and accompanying text.
facilities outside Australia’s jurisdiction.\textsuperscript{158} However, the ownership of each collection would need to be considered on its own merits, taking into account a range of factors including ownership prior to entering the repository, the circumstances under which the material passed into the possession of the \textit{ex situ} holder (including contractual agreements), and any relevant legislation.\textsuperscript{159}

Temporal complexities arise in the context of the purpose of use. These complexities could be overcome to a certain extent by requiring that if resources extracted from Australian Antarctic Territory waters for a non-commercial purpose are later used for a commercial purpose, a benefit sharing agreement will need to be negotiated with the original provider. Without effective coordination between \textit{ex situ} facilities though, it may be difficult to determine the original provider and track the benefit sharing obligations connected with the physical sample once the temporal link between \textit{in situ} access and subsequent \textit{ex situ} use is severed (for example, by passing through different private and public facilities that are subject to different ABS laws).

A similar temporal complexity arises in the context of the purpose of extraction. The EPBC Act does not apply to the taking of public resources for collecting broodstock for aquaculture.\textsuperscript{160} In aquaculture, however, it is often difficult to distinguish when the resource is used as a commodity, such as broodstock for grow out, or for its genetic material, such as using the biological resource’s antifreeze gene promoters to breed cold tolerant fish, the latter of which does fall within the CBD’s\textsuperscript{161} and EPBC Act’s ABS regime. Wild broodstock may be collected without an ABS agreement, stored in an \textit{ex situ} facility and subsequently used for a different purpose – for its genetic material – but


\textsuperscript{159} Ibid [4.37].

\textsuperscript{160} \textit{EPBC Regulation} reg 8A.03(4)(a).

the opportunity for sharing the benefits in accordance with the Antarctic Treaty System may be lost by the temporal disconnect.

A third temporal and spatial complexity arises if the ex situ derivative such as the chemical compounds and the information or knowledge component of the genetic resource (the digital resource) are used independently of the physical sample in Antarctic waters to which the derivative relates. While it is clear that derivatives of the physical genetic resource fall within CBD and Nagoya Protocol obligations, there is legal uncertainty about the type of derivatives to which their obligations apply.162 The CBD’s Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches observed that there was no common understanding of the concept of a derivative but that it could include: (a) derivatives understood as the result of an organism’s metabolism (eg natural chemical compounds); (b) derivatives understood as the result of human activity using the genetic resource (eg synthetic compounds); or (c) derivatives understood as information on genetic resources (eg the abstract digital resource).163 Naturally occurring biochemical compounds clearly fall within the meaning of a derivative,164 however derivatives accessed independently of genetic resources fall outside of the scope of the obligations.165 This is because Article 15 of the CBD is limited to the ‘utilization of genetic resources’ and Article 2 of the Nagoya Protocol links utilization to the genetic and/or biochemical composition of the genetic resources.166 Further, the CBD’s technology transfer obligations under Article 16 are limited to technologies that ‘make use’ of genetic resources.167 The criterion therefore for

162 Ibid 248.
164 Protocol art 2(e).
165 Greiber et al, above n 25, 71.
166 Ibid.
167 CBD art 16.
whether other types of derivatives fall within the scope of obligations appears to be the biological origin rather than the biological form.\textsuperscript{168} This means that digital resources are likely to fall within the scope because transfer of genetic information into digital form does not change its genetic character.\textsuperscript{169} Whether a synthetic derivative falls within the scope may depend on its link with the original material.\textsuperscript{170} The link would be stronger if there has been some use of genetic material in the developmental phase of the synthetic compound.\textsuperscript{171}

Complexities for benefit sharing arise where a derivative is derived from the abstract digital resource that relates to an Antarctic genetic resource under an access agreement. In the example above, digital resources are not specifically regulated under the EPBC Act, the ATEP Act or the AMLRC Act. However, the terms of access (mutually agreed terms) might include benefit sharing obligations concerning the digital resource. The issue is how to ensure that subsequent uses of \textit{ex situ} Antarctic digital resources, such as those that are part of the DNA barcode project example above\textsuperscript{172} that do not depend on access to the physical sample, are held accountable to benefit sharing obligations for the original accession. The emphasis under the \textit{Antarctic Treaty} of information and knowledge sharing for freedom and cooperation of scientific investigation that ‘accords with the interests of science and the progress of all [hu]mankind’ demonstrates the value it holds for the digital resource independently of the physical resource. Research results on the original genetic resource can, however, easily be lost in the dissemination process, for example through databases, media and

\textsuperscript{168} 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), \textit{Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol} (Routledge, 2014) 18, 21.

\textsuperscript{169} Ibid.

\textsuperscript{170} Ibid 29.

\textsuperscript{171} Humphries, above n 161, 251.

\textsuperscript{172} See above n 107 and accompanying text.
Leaving the ABS of Antarctica’s *ex situ* genetic resources up to the bilateral territorial approach undermines the *Antarctic Treaty’s* objectives unless this temporal disconnect is effectively addressed.

Growing awareness of the importance of ABS concerning subsequent uses of the digital resource and the time lag between accessing the original physical resource have led to initiatives such as the *Micro B3 Model Agreement on Access to Marine Microorganisms and Benefit Sharing* (Micro B3 Agreement). This agreement:

sets out the terms for the access to genetic resources found in/on the Provider State’s marine internal waters, territorial sea, exclusive economic zone or continental shelf, for the utilization and transfer to third parties of the accessed genetic resources, for the management and transfer to third parties of associated knowledge and for the sharing of benefits drawn from the same.\(^ {174}\)

While this clause would need modification if it were to apply to Antarctic genetic resources, the Micro B3 Agreement is a good example of how benefit sharing obligations can travel with the digital resource separately from the physical sample. The Commentary on the Micro B3 Agreement explains that it applies to three scenarios – full non-commercial (public domain), hybrid and full commercial use at the point of access with differing benefit sharing obligations.\(^ {175}\) It allows for changes of intent by both the provider and the recipient of the genetic resource so that conditions are renegotiated at the time of change of intent.\(^ {176}\) Significantly, it sets out the conditions under which the recipient is allowed to transfer the accessed genetic resources and/or


\(^{176}\) *Micro B3 Agreement* arts 4.4 and 4.5.
the associated genetic knowledge to third parties through a ‘viral licence clause’.\textsuperscript{177} In other words, subsequent recipients are bound by the same obligations that were imposed on the first recipient in the contract concluded with the provider.\textsuperscript{178} The digital resource which may include not only data and information but also knowledge does not need to remain connected with the original sample for the obligations to apply. If a similar model applied to Antarctic genetic and digital resources, there would need to be a way to overcome the reality of the highly migratory nature of aquatic genetic resources where those extracted from the high seas may also be extracted from waters within national jurisdictions.\textsuperscript{179} In other words, recipients may claim that the digital resource originated from a physical sample within national jurisdictions and the benefits may not flow back to Antarctica.

In summary, the CBD’s bilateral territorial approach to ABS may regulate Antarctica’s \textit{ex situ} genetic resources physically located within national jurisdictions, but not genetic resources and derivatives that were deposited in an \textit{ex situ} facility before the CBD entered into force,\textsuperscript{180} in repositories within the jurisdiction of nations that are not party to the CBD, or where the samples were not acquired ‘in accordance with’ the CBD. Depending on how a country has implemented its CBD obligations, its regulation may extend to Antarctic \textit{ex situ} genetic resources in private facilities. The benefits flow back to the country that has jurisdiction over the \textit{ex situ} facility in which the Antarctic genetic resource is based. Whether or not subsequent uses of the \textit{ex situ} physical and digital resources benefit Antarctica depends on the discretion of the parties negotiating a contract over a particular resource and how they deal with matters like changes of intent and subsequent third parties to the agreement. The tension between the CBD’s and Nagoya Protocol’s bilateral territorial approach and the Antarctic Treaty System’s cooperative commons approach to sharing genetic resources makes it difficult for the

\textsuperscript{177} Micro B3 Agreement arts S. Micro B3 Commentary, above n 175, 14.

\textsuperscript{178} Ibid.


\textsuperscript{180} Glowka, above n 130, 6.
former approach to uphold the *Antarctic Treaty’s* overarching principle of cooperation and freedom of scientific investigation.

### B. Multilateral Cooperative Commons Approaches

Various multilateral cooperative commons approaches do not yet regulate the use of Antarctic *ex situ* genetic resources but they may provide insights into how an ABS framework could achieve the *Antarctic Treaty’s* overarching principle of cooperation and freedom of scientific investigation. The Nagoya Protocol recognises 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’.\(^{181}\) To this end, the Nagoya Protocol requires parties to consider the possible development of a global multilateral ABS mechanism for these resources.\(^{182}\) Such a mechanism may be achieved through the New Instrument under UNCLOS. It is too early to tell what the final model will be so this section outlines a similar mechanism under the Plant Treaty that might also serve as a guide.

#### 1. UNCLOS implementing agreement for areas beyond national jurisdiction

Some participants of the ATCM have suggested that further regulation under the Antarctic Treaty System to fill ABS gaps should be dealt with under a New Instrument.\(^{183}\) The regulatory vacuum for a comprehensive ABS regime under UNCLOS for genetic resources from areas beyond national jurisdictions, or the ‘deep sea’ is well

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\(^{181}\) *Protocol* preamble.

\(^{182}\) *Protocol* art 10.

\(^{183}\) *Biological Prospecting in Antarctica*, above n 16, 5.
The deep sea includes the high seas water column and the Area – the seabed and ocean floor and subsoil below the water column. This includes the high seas in the Southern Ocean surrounding Antarctica. The technology transfer obligations under UNCLOS include technological cooperation and collaboration, participation in research activities, information sharing and capacity building. Marine Scientific Research obligations include promoting the flow of data and information and the transfer of knowledge resulting from marine scientific research. The provisions concerning technology transfer and knowledge sharing of deep sea genetic resources do not necessarily override those under the Antarctic Treaty System because UNCLOS:

\[
\text{shall not alter the rights and obligations of States Parties which arise from other agreements compatible with this [UNCLOS] and which do not affect the enjoyment by other States Parties of their rights or the performance of their obligations under this [UNCLOS].}
\]

The New Instrument will, however, fill the regulatory gaps concerning the sharing of benefits of the use of deep sea genetic resources, capacity building and the transfer of

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185 *UNCLOS* arts 86-120.

186 *UNCLOS* arts 133-191.

187 ‘[N]othing in the present Treaty shall prejudice or in any way affect the rights, or the exercise of the rights, of any State under international law with regard to the high seas within that area’; *Antarctic Treaty* art VI.

188 *UNCLOS* arts 268(e), 270, 271, 272, 273 and 274.

189 *UNCLOS* arts 269 (d) and (e).

190 *UNCLOS* art 268(a).

191 *UNCLOS* arts 266(2), 268(d) and 269(d).

192 *UNCLOS* art 244(2).

193 *UNCLOS* art 311(2).
marine technology. The Nagoya Protocol would cede to a specialised instrument regarding the specific genetic resources it covers. An important issue to resolve will be whether the New Instrument will deal with *ex situ* high seas resources or only *in situ* resources. It is unclear whether it would apply to all of Antarctica’s genetic resources (land and sea). Also, it is unclear whether it will tailor the benefits arising from Antarctica’s genetic resources to support the *Antarctic Treaty*’s collective purpose ‘in the interests of science and the progress of all [h]umankind’. If the benefits flow toward a purpose (similar to the Plant Treaty framework below), it will be interesting to see if they flow to a broader purpose concerning the whole of the world’s oceans under UNCLOS or only the Antarctic Treaty System’s more narrow knowledge sharing, conservation and peaceful purposes.

2. The FAO’s Plant Treaty model

The Plant Treaty creates a Multilateral System for a negotiated selection of plant genetic resources used for food and agriculture using a Standard Material Transfer Agreement (SMTA) for all exchanges and removing the need for bilateral negotiations between parties for each resource. It does not apply to genetic resources used for other purposes such as pharmaceuticals, which continue to require negotiation on a bilateral basis under the CBD. The Multilateral System does not apply to aquatic animal genetic resources. However, arguably the definition of ‘plant genetic resources for food and agriculture’ (PGRFA) is broad enough to include aquatic plants. Annex 1 (listing the plants to which the Multilateral System applies) does not currently list aquatic plants but there appears to be no impediment to include other materials and Contracting

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194 *New Instrument Resolution*, above n 7 [2].
195 *Protocol* art 4(4).
196 *Plant Treaty* art 3.
197 *Plant Treaty* art 10.
198 Greiber, above n 25, 34.
199 *Plant Treaty* art 12(3)(a).
200 Humphries, above n 61, 86.
201 *Plant Treaty* art 11(2).
Parties may decide to provide facilitated access to these resources. Recipients cannot claim intellectual property that limits facilitated access ‘in the form’ received from the Multilateral System. If a recipient prevents others from using any product they develop using materials from the System they must share a percentage of their commercial benefits with an international fund. Under this cooperative arrangement and through a SMTA, Contracting Parties provide access to each other’s PGRFA for research, breeding and training subject to benefit sharing arrangements in the areas of technology transfer, information exchange, capacity building and the benefits of commercialisation. The Governing Body has the power to sanction violators of the SMTA by excluding them from obtaining other resources within the Multilateral System.

Under the Plant Treaty, the benefits ‘should flow primarily, directly or indirectly, to farmers in all countries, especially in developing countries and countries with economies in transition, who conserve and sustainably utilize [PGRFA]’. The Multilateral System includes the physical samples as well as certain digital resources, although it does not extend to sharing commercially sensitive knowledge such as that controlled by intellectual property claims. The Multilateral System’s Global Information System on Plant Genetic Resources for Food and Agriculture ‘integrates and augments existing systems to create the global entry point to information and knowledge for strengthening the capacity for PGRFA conservation, management and utilization’.

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202 Plant Treaty art 15(3) and (4).
203 Plant Treaty art 12(3)(d).
204 Plant Treaty art 13(2)(d).
205 Plant Treaty arts 12(3)(a) and 13(2).
206 Plant Treaty art 11(4).
207 Plant Treaty art 13(3).
208 Plant Treaty art 12(3)(c).
other words, it is a ‘conglomeration of existing (and future) systems’, rather than a single database\textsuperscript{211} and is built on cooperation between Contracting Parties to the Plant Treaty.\textsuperscript{212} In summary, the Plant Treaty provides a model where \textit{ex situ} resources and their digital components are held in trust and can only be freely accessed for a defined purpose. The benefits from their subsequent use do not flow to the provider \textit{per se} but towards fulfilling a common purpose of the collective members to the Plant Treaty.

Apart from the Plant Treaty which could only potentially apply to Antarctica’s \textit{ex situ} plant genetic resources, the CBD’s territorial bilateral approach is the norm for ABS rules globally.\textsuperscript{213} This bilateral approach has limitations when dealing with Antarctica’s \textit{ex situ} genetic resources because it depends on resolving temporal and spatial complexities outlined above for each accession. The collective multilateral approach under the Plant Treaty also has challenges. For example, a similar closed list approach to aquatic genetic resources is limited by the fact that these resources could include thousands of species with many yet to be discovered\textsuperscript{214} and the Antarctic Treaty System structure has no governing body capable of holding sanctioning powers for contraventions of ABS rules. However, unlike the territorial bilateral approach where the provider is responsible for access as well as being the recipient of benefits that flow from their subsequent use, this purpose driven collective multilateral approach breaks the ABS territorial nexus so that the provider country grants \textit{access} but the \textit{benefits} flow to the collective to achieve a particular goal.

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{211} Lawson, above n 209, 36.
  \item \textsuperscript{212} \textit{Plant Treaty} art 17.
  \item \textsuperscript{213} There are other specialised multilateral mechanisms that do not yet apply to Antarctica’s \textit{ex situ} genetic resources such as the \textit{Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits} World Health Assembly Resolution 64.5 of 24 May 2011 (Sixty-fourth World Health Assembly, WHA64/5, 2011) Agenda item 13.1 <apps.who.int/gb/ebwha/pdf_files/WHA64/A64_R5-en.pdf>. The PIP framework only applies to the sharing of H5N1 and other influenza viruses with human pandemic potential; at art 3.\textsuperscript{214}
  \item \textsuperscript{214} \textit{IWG Intersessional Workshops}, above n 68 [49].
\end{itemize}
\end{footnotesize}
Whether the ABS model to be adopted by the New Instrument will resolve the complex jurisdictional issues surrounding Antarctica’ *ex situ* genetic resources remains to be seen. What is clear is that leaving ABS to the current patchwork of ABS regimes runs the risk that the benefits from the use of Antarctica’s *ex situ* genetic resources will not flow back to the conservation of the Antarctic Treaty Area or to achieve freedom of scientific investigation as envisaged by the Antarctic Treaty. More creative options under the existing frameworks should be explored in the meantime. The following section gives insights into an often overlooked ‘multilateral’ approach to accessing and sharing the physical and digital genetic resource – the framework of defences for patent infringements under the TRIPS Agreement of the WTO.

V. A Patent Solution for Regulating Antarctica’s Ex Situ Resources

While there is much debate about the impacts of patents on the scientific objectives of the Antarctic Treaty, there has been less attention on how the framework of defences under TRIPS might offer an existing multilateral approach to sharing knowledge and technology concerning Antarctica’s *ex situ* resources in a way that is consistent with the Antarctic Treaty’s objectives.\(^{215}\) TRIPS provides an international framework for national patent laws of WTO Members. Its objective is to promote ‘technological innovation and for the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare and to a balance of rights and obligations’.\(^{216}\) To this end, TRIPS sets out a minimum level of patent protection\(^{217}\) but leaves it up to each Member to determine the means by which this level of protection is secured in their legal system.\(^{218}\) Generally,

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\(^{216}\) *TRIPS* art 7.

\(^{217}\) *TRIPS* art 27.

patent holders have exclusive rights over their inventions that are either products or processes, subject to disclosure of their invention.\textsuperscript{219}

The ATCM has raised questions about whether patents’ exclusive rights interfere with freedom of scientific investigation in accordance with the \textit{Antarctic Treaty} and whether the confidentiality required prior to lodgement of a patent claim is compatible with obligations for the free exchange of scientific observations and results.\textsuperscript{221} A concern is that broad patent claims relating to Antarctica’s genetic resources could restrict access to the physical and digital resource for further research or use by others and direct the benefits towards the patent holder, rather than the provider of the genetic resource on behalf of the Antarctic Treaty System.\textsuperscript{222} WTO Members, however, have the option to include exceptions and defences in their national laws that regulate the circumstances in which patented genetic resources and their derivatives can be shared without the authorisation of the patent holder. This defence framework has a multilateral effect because the circumstances for sharing do not depend on bilateral agreements between parties to a given transaction. Patent law defences may explicitly provide that contractual agreements attempting to limit a particular defence are void.\textsuperscript{223} While patent laws are national in operation, TRIPS and its defence framework have evolved to manage the globalised use of patented products and processes across multiple national jurisdictions.

Exceptions against infringement must be in accordance with the ‘three step test’ under Article 30 of TRIPS. They must: (a) be limited in their impact on rights; (b) ‘not unreasonably conflict with a normal exploitation of the patent’; and (c) ‘not unreasonably prejudice the legitimate interests of the patent owner, taking account of

\textsuperscript{219} TRIPS art 28.
\textsuperscript{220} TRIPS art 29.
\textsuperscript{221} A Gap Analysis, above n 2626, 16.
\textsuperscript{222} See Jabour-Green and Nicol, above n 215, 94.
\textsuperscript{223} See eg Bundesgesetz über die Erfindungspatente 1954 [Federal Act on Patents for Inventions 1954] (Switzerland) art 35a(Abis)(4).
the legitimate interests of third parties’. Examples under national laws include experimental use exceptions, non-commercial use exceptions, breeding exceptions, regulatory review exceptions and innocent bystander exceptions. TRIPS also allows other circumstances where the permission of the patent holder is not required for the use of a patented invention. Examples include the principle of exhaustion, compulsory licensing and temporary presence defences. The purpose of the following discussion is not to enter the debate about whether TRIPS achieves technology transfer. Rather, the aim is to give insight into how TRIPS-compliant defences approach the sharing of patented Antarctic genetic resource inventions with respect to two of the legal temporal and spatial complexities identified above for the ABS of Antarctica’s ex situ resources under the CBD and the Nagoya Protocol. These complexities are: first, how to fairly approach changes of intent between commercial and non-commercial uses of the resources; and second, how to overcome the shortcomings of the CBD’s geographical origin approach to ABS including the territorial restrictions of national laws, and the extent to which they capture the ABS of digital resources separate to the ABS of physical resources.

A. Change of Intent for Purpose of Use

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224 TRIPS art 30 as interpreted in Canada- Pharmaceutical Products Case, above n 218 [7.20]-[7.21], [7.31] and [7.54].
225 See eg Australia’s Patents Act 1990 (Cth) s119C.
226 See, eg, Patents Act 1977 (UK) c 37, s 60(5)(a).
228 See eg Australia’s Patents Act 1990 (Cth) s119A.
230 The following examples are not restricted by the three step test in above n 224 and accompanying text.
231 See TRIPS art 6.
232 See TRIPS art 31.
The ATCM has identified that ‘there is a time lag of approximately 8-10 years between developing sufficient knowledge base about an [Antarctic] organism, and a commercial product based on that organism entering the market.’ The time lag raises questions about how to deal with situations where the recipient has originally accessed the genetic resource with the intent of non-commercial research but subsequently the recipient or third parties use the genetic resource for a commercial purpose. The distinction between commercial and non-commercial uses is important for the effective operation of several aspects of the CBD and the Nagoya Protocol’s ABS regime. The distinction helps to distinguish between the different modalities of ensuring compliance (user measures or contractual enforcement), between the sharing of monetary and non-monetary benefits, and between simplified and normal access conditions as outlined below.

Significantly, countries are obliged to ‘create 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, taking into account the need to address a change of intent for such research’. This provision links facilitated access with the objective that knowledge should be generated to conserve and sustainably use the resources and some commentators have argued this requires publicly available knowledge. The requirement for simplified access becomes complicated when Antarctica’s ex situ genetic resources are in water-based as opposed to land-based facilities. Where the resources are held in territorial waters, UNCLOS provides that ‘marine scientific research ... shall be conducted only with the express consent of and under the...

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234 Biological Prospecting – a Way Forward, above n 7777, 12.
235 See Humphries, above n 161, 257.
237 Protocol art 8(a). See also CBD art 15(2).
238 See Kries and Winter, above n 236236, 67.
conditions set forth by the coastal State’. Given that the CBD defers to UNCLOS in the case of conflict, this may create an anomalous situation where countries are obliged to create simplified access for non-commercial uses of Antarctic ex situ aquatic resources located in land repositories but not for the same resources in facilities located in territorial waters. Given the difficulties with distinguishing between non-commercial or ‘pure’ research and research whose purpose it is to produce a commercial outcome, particularly in the area of biotechnology, this complex array of ABS laws concerning the purpose of use may impede the access and exchange of scientific information about Antarctica’s resources contrary to the objectives of the Antarctic Treaty.

Patent law can offer insights into how to treat commercial and non-commercial uses of Antarctic ex-situ genetic resources to fulfil the objectives of the Antarctic Treaty. Many countries have non-commercial use exceptions that only facilitate pure rather than commercial or applied research. However, experimental use exceptions which allow use of a patented genetic resource invention that would otherwise infringe a patent holder’s rights differ under national laws in whether they allow uses with ultimately non-commercial as well as commercial uses. For example, the Belgian exception excludes experiments with purely commercial purposes but it applies in cases of mixed

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239 UNCLOS art 245.
240 CBD art 22.
245 Ibid 41.
commercial and scientific purposes. Emerging norms for experimental use exceptions seek to strike a balance between the two phases of research. For example, the German exception does not distinguish between commercial and non-commercial uses, as long as the ultimate goal is to promote technical or scientific progress.

ABS laws concerning Antarctica’s genetic resources could take a similar pragmatic approach to commercial and non-commercial phases of research that may concern the physical or digital Antarctic ex situ genetic resource. This is not inconsistent with the way in which the Antarctic Treaty System regulates Antarctica’s in situ resources. None of the Antarctic Treaty System treaties explicitly regulate bioprospecting for in situ genetic resources of potential value. Bioprospecting, however, is a scientific activity, even if it is ultimately for a commercial purpose, and indirectly falls within the access provisions of the Antarctic Treaty System as well as the benefit sharing provisions of Article III of the Antarctic Treaty. The requirement to record the purpose of use at the time of taking the resource does not appear to affect whether access will proceed. The focus of access restrictions under the Antarctic Treaty’s prior notification and the Madrid Protocol’s and the CCAMLR’s permit systems is arguably concerned with the

249 David Leary, ‘Bi-polar Disorder? Is Bioprospecting an Emerging Issue for the Arctic as well as Antarctica?’ (2008) 17(1) Reciel 41, 44.
250 See above n 29 and accompanying text.
252 See above n 61 and accompanying text.
253 See above n 36 and following text.
accumulation of scientific information for the protection of Antarctica’s environment and for the benefit of humankind, rather than with questions of whether the access will result in commercial or non-commercial uses. Unlike under the CBD where the conditions of access may be dependent upon the purpose of use of the genetic resource, a specialised instrument concerning Antarctic genetic resources (such as the New Instrument) could follow the German experimental use exception approach because the Antarctic Treaty does not distinguish between the two forms of uses for the purposes of ABS, as long as the ultimate goal is to promote technical or scientific progress.

B. Geographical Origin of the Genetic Resource

At the heart of the sovereignty territorial approach to ABS under the CBD is the need to determine the geographical origin of the genetic resources to ascertain from whom permission is required for the resources’ access and towards whom the benefits of their use should flow. The proceeding sections have argued that because the Antarctic Treaty does not apply to ex situ genetic resources but the CBD may apply on a case-by-case basis, the ‘origin’ becomes the repository in which the physical resource is held, which means that the benefits from the physical or digital resource do not automatically flow back to the Antarctic Treaty Area. This is especially problematic for the use of Antarctica’s digital resources. If a bilateral contract, similar to the Micro B3 Agreement, incorporates benefits from the use of the digital resource derived from an ex situ genetic resource, the biological origin is traced through the viral licence clause back to the accession of the geographical location of the physical ex situ resource in a national jurisdiction to which the CBD applies and not necessarily the original in situ location in Antarctic waters. Derivatives including digital resources that are accessed independently of genetic resources fall outside the scope of the ABS obligations. A key question therefore is how to ensure that subsequent uses of ex situ Antarctic digital resources, such as those that are part of the DNA barcode project, and that do not

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254 See above n 174 and accompanying text.
255 See above n 165 and accompanying text.
256 See above n 107 and accompanying text.
depend on access to the physical samples, are held accountable to information sharing obligations under the *Antarctic Treaty*.

Patent law largely deals with the knowledge component of the genetic resource and can give insights into how to conceptualise and regulate the sharing of the digital resource independently from the physical resource. Instead of using the geographical origin as the link between the physical and the digital resource, emerging norms in Europe incorporate a functional temporal approach for clarifying the point at which a derivative is sufficiently removed from the genetic resource invention on which it is based to no longer be protected under patent law.\(^\text{257}\) For example, under patent law, protection generally extends to every plant or animal containing the inventive element or resulting from a patented process.\(^\text{258}\) This means that a broad patent claim concerning a fish’s gene promoter such as an antifreeze protein may have the same outcome as patenting the fish and a patent holder may be able to prevent others from using it for breeding purposes. The question will come down to the extent to which a new strain may contain the patented inventive element before a user is liable for infringement.\(^\text{259}\) For example, would a user be liable for infringement if an antifreeze gene promoter from an initial patented transgenic fish is present, but not expressed or ‘switched on’ in subsequent fish strains that are the result of a cross between the transgenic fish and another strain incorporating different genetic combinations?\(^\text{260}\) An emerging European approach suggests that a patented trait may be *present* in material derived from the invention without attracting infringement, but that a patent may only be protected when the patented trait is *performing its function at the time of* the alleged infringement (not


\(^{260}\) Ibid.
merely present but also expressed). This clarifies when functionality is relevant for proprietary interests – at the time of the use that constitutes infringement, rather than at the time of the original accession or some other indefinite time.

Applying patent law’s functional temporal approach to an Antarctic ex situ digital resource means that the functionality of the in situ genetic resource could be a more relevant benchmark than geographical location when determining the biological origin for the purposes of benefit sharing. Under this approach, the subsequent use of an Antarctic digital resource may trigger benefit sharing under Article III of the Antarctic Treaty if the characteristics of the original in situ resource are merely present in the resulting product or process. However, these benefit sharing obligations could only be limited by legitimate proprietary interests over the resulting patented product that expresses the functional characteristics of the original resource at the time of its use. In this way, subsequent uses of ex situ Antarctic digital resources that are acquired independently of the physical sample could fulfil information sharing obligations under the Antarctic Treaty while not offending TRIPS obligations.

Several commentators suggest how territorial limitations of the CBD’s ABS concept could be overcome using multilateral models such as the Plant Treaty. The present chapter highlights how patent laws are similarly evolving to overcome the limitations of the territorial approach for sharing patented genetic resource inventions that span multiple jurisdictions in the globalised market. The way in which the principle of exhaustion and temporary vessel defences can achieve multilateral objectives within national regimes have been argued elsewhere. Another example of a cooperative multilateral approach is the framework for compulsory licensing as amended by the 2001 Doha Ministerial Declaration on TRIPS (Doha Declaration) that may prove

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262 See above n 196 and accompanying text.

263 See Humphries, above n 161, 266.

insightful in the way it promotes technology transfer and benefit sharing to fulfil a global objective.

Compulsory licensing is a type of non-voluntary authorisation to use a patent holder’s intellectual property without their permission but in return for a reasonable set fee.\textsuperscript{265} It may also operate as a defence, for example, for a breeder using a patented aquatic genetic resource to create new strains\textsuperscript{266} or a researcher using the resource to create a new drug subject to reasonable remuneration to the patent holder. The requirements for compulsory licences are generally standard in all patent laws\textsuperscript{267} in accordance with the minimum requirements under Article 31 of TRIPS.\textsuperscript{268} One of the minimum requirements is that the licence must be primarily for the supply of the domestic market.\textsuperscript{269} This effectively limited the ability of countries that could not make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.\textsuperscript{270} In response to paragraph 6 of the Doha Declaration,\textsuperscript{271} the WTO’s General Council decided to waive Article 31(f). This waiver effectively allows generic copies made under compulsory licences to be exported to countries that lack


\textsuperscript{266} Humphries, above n 259, 217.

\textsuperscript{267} Visser, above n 265, 10.

\textsuperscript{268} For example, each case must be considered on its merits; the applicant must generally have attempted to obtain a licence from the patentee; a licence must be limited in scope and duration to the purpose for which it is granted, may not be exclusive, may not be assigned, must be primarily for the supply of the domestic market, may be terminated if circumstances leading to it cease to exist, subject to the licensee’s legitimate interests; and the patent holder must receive adequate remuneration; \textit{TRIPS} art 31.

\textsuperscript{269} \textit{TRIPS} art 31(f).


\textsuperscript{271} ‘WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement’; \textit{Doha Declaration} para 6.
production capacity if certain procedures and conditions are followed. Eligible importing and exporting WTO Members ‘are encouraged to use the system set out in [the] Decision in a way which would promote’ the ‘transfer of technology and capacity building in the pharmaceutical sector’.273

A similar cooperative approach to technology transfer that achieves a particular purpose could be applied to the ABS of Antarctica’s _ex situ_ genetic resources. If an _in situ_ Antarctic genetic resource was originally acquired in accordance with the CBD so that a jurisdiction’s national ABS laws apply to a given Antarctic genetic resource located within its national repository, that country has the sovereign right to restrict other countries or people from using it for research, breeding or other purposes. The Nagoya Protocol’s innovative ‘user measures’ require Contracting Parties to take measures to comply with the provider country’s access requirements, to address non-compliance with those requirements and to cooperate with other Parties in cases of alleged non-compliance.274 However, using the compulsory licensing approach, by collective agreement either through the Conference of the Parties to the CBD or by membership in the Antarctic Treaty System, countries could recognise the sovereign right to regulate genetic resources within their jurisdictions but waive access obligations, including compliance with user measures, in relation to those genetic resources within their repositories that originated from Antarctic waters. As mentioned above, there is precedent under the Nagoya Protocol for allowing more simplified or relaxed ABS procedures for using genetic resources but only in relation to non-commercial purposes.275 The compulsory licensing approach above, however, recognises that even requirements that protect commercial interests can be relaxed to fulfil a global purpose, in that case, to ensure poorer countries have access to affordable medicine which indirectly benefits all of humankind.

273 Ibid [7].
274 Protocol arts 15 and 16.
275 Protocol art 8(a).
Under this approach, while the provider would not be able to limit the exchange or use of an Antarctic *ex situ* genetic resource that it provides, it would receive a reasonable set fee from the recipient at the time of its provision. The unlimited exchange or use of an Antarctic *ex situ* genetic resource in the form received from the recipient would mean that the benefits of using the genetic resource are not directed back to the nation granting access but are instead fulfilling the *Antarctic Treaty*’s primary benefit sharing requirement of freedom of scientific investigation, including the exchange and free availability of scientific observations and results of Antarctica’s resources for the benefit of all of humankind. This approach is also consistent with the technology transfer obligations under the CBD (as distinct from its ABS provisions) for the transfer of information and technologies that make use of genetic resources, not only towards the provider of the resource but towards all CBD Parties, particularly least-developed ones.

VI. Conclusion

There is a mounting argument that leaving regulation of Antarctic *ex situ* genetic resources to the complex matrix of ABS systems outside the Antarctic Treaty Area undermines the *Antarctic Treaty*’s principles including international cooperation and freedom of scientific investigation that ‘accords with the interests of science and the progress of all [hu]mankind.’ The complexity of ABS rules is not surprising when considering the unique governance arrangements in Antarctica where sovereign rights are on hold and the regulation of *ex situ* resources is beyond the reach of the Antarctic Treaty System. What is surprising is the extent of uncertainty relating to the status of Antarctica’s *ex situ* physical and digital resources under the CBD’s and the Nagoya Protocol’s bilateral territorial ABS system. The status needs to be determined on a case-by-case basis depending on the timing and circumstances of the original extraction from Antarctic waters as well as a temporal link between the physical and digital resource. This determination is almost impossible without effective coordination between *ex situ*
facilities. Unfortunately however, information repositories often contain data in forms that are not easily shared with each other’s systems, and coordination of aquatic gene banks is lagging behind similar repositories holding terrestrial germplasm. The result is a complicated *ad hoc* global exchange system based on the territorial origin of the genetic resource where the benefits flow to the provider country and not the Antarctic Treaty Area to meet the *Antarctic Treaty*’s objectives and principles.

Trying to find a fair and equitable solution that supports the *Antarctic Treaty*’s principles of cooperation and freedom of scientific investigation requires a search for a common ground between the CBD’s bilateral territorial approach and the *Antarctic Treaty*’s cooperative commons approach to ABS. One option is a multilateral approach similar to the Plant Treaty that breaks the ABS territorial nexus so that the provider country grants access but the benefits flow to the collective to achieve a particular goal. Whether the New Instrument under UNCLOS will incorporate an approach similar to the Plant Treaty framework for aquatic genetic resources remains to be seen. A multilateral model that already applies to Antarctica’s *ex situ* patented genetic resource inventions is the framework of TRIPS-compliant patent law defences, which offers existing practical solutions to the territorial regulation of increasingly global genetic resource inventions. This chapter has offered insights into how the defence framework approaches two of the challenges of ABS systems: effectively overcoming the blurred practical distinction between commercial and non-commercial uses that differentiates ABS rules; and overcoming the shortcomings of the geographical origin approach to ABS including the territorial restrictions of national laws and the extent to which they capture the ABS of digital resources separate to the ABS of physical resources.

At the time of writing it is too early to tell whether the scope of the New Instrument under UNCLOS will include Antarctica’s *ex situ* genetic resources. Despite the flaws of leaving the increasing use of Antarctica’s genetic resources up to national bilateral ABS laws based on the CBD, ATCM Consultative Parties appear to be taking a wait-and-see approach in the hope of riding out the regulatory storm that is brewing. In the meantime, there is ample scope for investigating creative TRIPS-compliant solutions for sharing *ex situ* resources that support the *Antarctic Treaty*’s objective of free exchange
of information and resources in the ‘interests of science and the progress of all [hu]mankind.’
CHAPTER 8 CONCLUDING CHAPTER

This is the pre-peer reviewed version of the following article that is based on text from chapters 1 and 8 - Fran Humphries, ‘A Patent Defence Approach to Sharing Aquaculture Genetic Resources across Jurisdictional Areas’ (2017) The Journal of World Intellectual Property, 1-18 (advanced online version).

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8.1 Introduction

In recent years there has been a tidal wave of legal analysis on laws regulating access to genetic resources and sharing the benefits from their use (ABS laws)\(^1\) as humans begin to unlock their potential for conservation, global food and health security. There has been a similar increasing interest in the restrictive effects of patents on accessing genetic resources used for agriculture and pharmaceutical sectors.\(^2\) Yet, it has only been recently that aquatic genetic resources and aquaculture have entered into the regulation debate.\(^3\) As a consequence, targeted analysis is still lacking on identifying a clear and consistent approach to technology and knowledge transfer of aquatic genetic resources under patent laws and ABS laws across jurisdictions. This thesis conducted this analysis across three jurisdictional areas – within national jurisdiction, beyond national jurisdiction and in the Antarctic Treaty Area.

The analysis is urgent for several reasons. Capped and declining wild capture fisheries and the rapid rate at which aquaculture must increase to meet global protein

\(^1\) See, eg, a comprehensive ABS bibliography at <http://www.bioversityinternational.org/fileadmin/user_upload/online_library/publications/pdfs/897.pdf>
\(^2\) See, eg, Johanna Gibson, Community Resources: Intellectual property, International Trade and Protection of Traditional Knowledge (Ashgate, 2005).
\(^3\) See Chapter 1 n 161.
requirements means that farmers and researchers require increasing access to aquatic genetic resources as the building blocks for developing new strains of aquatic animals and plants. Developing countries rely heavily on growing a sustainable aquaculture sector for their food supply, sustainable livelihoods and trade. Currently, technological change in developing countries is mainly a process of dissemination rather than of invention of technology. Given that developing countries supply approximately 80 per cent of global aquaculture production, global food and health security is dependent not only on transferring to these countries the physical samples needed for breeding but also the know-how for generating new strains and technologies based on the resources. There is also growing interest in the aquaculture research sector about biotechnology techniques (such as transgenic species and DNA vaccines) for finding solutions to the looming global food and health security crisis as the world’s hungry population expands exponentially.

At a time, however, when the sector has its greatest need for access to the physical as well as the digital genetic resources during its early stages of domestication, these resources are becoming subject to increasing patent protection and a complex array of ABS regimes across the three jurisdictional areas. Most current legal scholarship focuses on the restrictive effects of patent regimes on technology transfer and conflicts between patent and ABS regimes. This thesis has looked instead at the similarities between the regimes to isolate common legal problems that they face in implementing technology transfer obligations. The way in which these regimes resolve these common legal problems was the starting point for

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4 See Chapter 1 n 3.
5 See Chapter 1 n 169 -171.
7 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) 6.
8 See, eg, Chapter 1 n 5-7.
9 Industrial aquaculture was virtually unknown thirty years ago: Rex A Dunham, *Aquaculture and Fisheries Biotechnology: Genetic Approaches* (CABI, 2nd ed, 2011) 2.
11 See Chapter 1 n 174.
answering the research question – can a TRIPS-compliant patent law defence framework for technology and knowledge transfer offer certainty and structure for fairly sharing physical and digital genetic resources for use in aquaculture under ABS regimes? Some of the current scholarship focuses on how ABS law can influence the development of patent law. The benefit of doing the converse is that while ABS regimes are relatively new, patent law already has a body of normative rules targeted towards the common legal challenges for regulating the sharing of knowledge and genetic resource products that span multiple jurisdictions within the globalised market. The three legal challenges analysed in this thesis related to questions of derivatives, commercial use and extra-territoriality but more challenges are arising as genetic resource technologies advance.

The central problem for this thesis was that the lack of integration of approaches to sharing aquatic genetic resources under patent law and ABS regimes causes a complex system of laws that may apply to a given resource. Such confusion about the circumstances in which the use and exchange of a genetic resource or derivative are affected by patent and ABS rules can deter research, inhibit local inventions and undermine the conservation of genetic diversity in aquaculture. The purpose of this thesis was to find practical solutions to the implementation of the complex web of technology transfer obligations (both stand alone obligations and those embedded in ABS frameworks) across the three jurisdictional areas using the approach, principles and emerging normative content of a TRIPS-compliant patent law defence framework. It did this by identifying the extent to which ABS regimes accommodate aquaculture’s special characteristics and challenges for the exchange and use of aquatic genetic resources (aim 1). The approach taken to resolve the intersecting three legal challenges (Figure 3: Intersecting Legal Challenges, p 33) were analysed in relation to the TRIPS-compliant patent law defence framework (aim 2). The evolving normative rules under this framework was then analysed as a guide for creating certainty and structure to technology transfer obligations under instruments regulating aquatic genetic resources

Chapter 8

sourced from: waters within national jurisdictions (aim 3); waters beyond national jurisdiction (aim 4); and from the Antarctic Treaty Area (aim 5). The Chapters sequentially addressed these aims.

The thesis is structured in accordance with Griffith University policy on ‘PhD Thesis as Published and Unpublished Papers’ (Appendix 1) and this final chapter synthesises all of the papers in relation to the research question, arguments and conclusions.
8.2 Challenges for ABS in aquaculture

The instruments examined in this thesis that influence ABS and technology transfer in aquaculture relate to aquatic genetic resources of the following jurisdictional areas:

- Areas within national jurisdiction:
  - Convention on Biological Diversity (‘Convention’);¹³
  - 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 (‘Nagoya Protocol’);¹⁴ and
  - Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’);¹⁵

- Areas beyond national jurisdiction (called the ‘deep sea’ in this thesis):
  - United Nations Convention on the Law of the Sea (‘UNCLOS’);¹⁶ and
  - International Covenant on Economic, Social and Cultural Rights (International Covenant);¹⁷

- Antarctic Treaty Area:
  - Antarctic Treaty;¹⁸
  - Protocol on Environmental Protection to the Antarctic Treaty (‘Madrid Protocol’);¹⁹ and
  - Convention on the Conservation of Antarctic Marine Living Resources (‘CCAMLR’).²⁰

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¹⁸ Antarctic Treaty, opened for signature 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961) (‘Antarctic Treaty’).
Other instruments examined with potential relevance to aquaculture include the *International Treaty on Plant Genetic Resources for Food and Agriculture* (‘Plant Treaty’)\(^{21}\) and the proposed New Instrument under *UNCLOS* on the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction (the New Instrument)\(^{22}\).

While states have ABS and technology transfer obligations under the various instruments, they have struggled with their implementation,\(^{23}\) largely because of the practical difficulties of balancing private interests (such as patents) with the public interest in accessing genetic resource technologies to create new technologies.\(^{24}\) This thesis has argued that to be able to effectively balance these interests, policy and lawmakers must first understand the special characteristics and challenges for the exchange and use of genetic resources for use in aquaculture.

Chapter 2 highlighted that as a relatively new food production sector\(^ {25}\) that carries the heavy burden of meeting increasing global demands for protein,\(^ {26}\) the need for accessing and exchanging physical and digital genetic resources is particularly acute in aquaculture. This need is essential for achieving domestication, which requires genetic variation to prevent inbreeding depression,\(^ {27}\) as well as for improving the sector’s cost effectiveness and optimal resource use through continued improvements in genetics and disease management among other things.\(^ {28}\) As 90 per cent of aquaculture is based


\(^{23}\) See for example the implementation gap in relation to *UNCLOS* technology transfer obligations: *Letter Dated 30 June 2011 from the Co-Chairs of the Ad Hoc Open-ended Informal Working Group to the President of the General Assembly*, Ad Hoc Open-ended Informal Working Group, 66th sess, Agenda Item 77(a), UN Doc A/66/119 (30 June 2011) [36].


\(^{25}\) See Chapter 2 n 10.

\(^{26}\) See Chapter 2 n 9.


on wild stocks, the majority of its genetic resources are potentially captured by ABS or technology transfer obligations examined in this thesis. Yet, the highly fecund nature of aquatic animals and the practice of hatchery production and stocking of fish fry in natural and man-made bodies of water produces a genetic co-mingling ‘at least as pervasive as that in agriculture’ making it hard to ‘identify a genetic chain of custody’. This raises the first legal challenge for the exchange and use of genetic resources for use in aquaculture – the extent to which ABS regimes regulate derivatives of self-replicating genetic resource technologies (derivatives challenge, Figure 3: Intersecting Legal Challenges, p 33). This thesis has examined how regimes within national jurisdiction specifically regulate ‘derivatives’ without defining their scope, and deep sea and Antarctic regimes are silent on whether they regulate derivatives. However, it concludes that the question of derivatives is crucially important for farmers who need to know if subsequent generations (whose breeding lines originally incorporated the relevant genetic resources) fall within the obligations. Similarly, researchers need to know the extent to which natural and synthetic compounds and digital resources of relevance to aquaculture are captured by the obligations.

Unlike terrestrial agriculture sciences, which have a firm grounding of basic knowledge built on thousands of years of agricultural practices, the status and trends of the conservation and use of aquatic genetic material is poorly understood. What is lacking in aquatic science is the accumulation of basic knowledge on, for example, the genetic make-up at the subspecies (population or strain) level, where gains from selective breeding are likely to arise. As a generalisation, the ABS regimes categorise basic science as ‘non-commercial’ research (for example benefiting the scientific commons)

30 ABS regimes may also relate to domesticated resources in some circumstances: see Convention definition of ‘Country providing genetic resources’ which ‘means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country’: at art 2.
31 Greer and Harvey, above n 10, 33-35.
32 See Chapter 5.
33 See Chapters 6 and 7.
34 FAO (Commission on Genetic Resources for Food and Agriculture) Status of Preparation of the State of the World’s Aquatic Genetic Resources for Food and Agriculture, 14th Sess, Agenda Item 5.1, CGRFA 14/13/16 (15-19 April 2013) [7].
35 Greer and Hervey, above n 10, 8; Bartley et al, above n 7, 2.
and applied science as ‘commercial’ research (for example benefiting the investors in the research). While much of the basic research on terrestrial genetic material was done before ABS requirements became an international issue,36 aquaculture is not similarly benefiting from the free flow of aquatic samples and knowledge in its current early stages of development. This raises the second legal challenge for the exchange and use of genetic resources for use in aquaculture – the difficulty of distinguishing between commercial and non-commercial uses for which different ABS rules apply (commercial use challenge, Figure 3: Intersecting Legal Challenges, p 33). Chapter 2 argued that this difficulty is likely to hinder the research that is necessary to sufficiently expand the sector to meet its expected world production targets.

The third legal challenge for the exchange and use of genetic resources for use in aquaculture identified in the research is how to address the transfer of technologies based on migratory aquatic genetic resources located in multiple jurisdictions from multiple providers (extraterritoriality challenge, Figure 3: Intersecting Legal Challenges, p 33). Chapter 2 argued that this challenge largely arose from conflict over terrestrial genetic resource exchange, which produced the predominant territorial and transactional approach to ABS regimes. It concluded that these assumptions underlying ABS have less relevance for sharing genetic resources in aquaculture.37 Terrestrial resource conflict was generally between ‘South’ poorer nations where the majority of genetic resources for global crops originated and ‘North’ richer nations who profited from technologies arising from their use.38 Access and benefit sharing was an attempt to create fairness and economic incentives for conserving and sustainably using biological resources and their genetic diversity by requiring users of genetic resources to compensate those who bear the cost of conserving and providing genetic resources.39 Conversely, resource exchange for commercially important aquaculture species generally flows from South to South or North to South.40 Structural developments of the

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36 Greer and Hervey, above n 10, 8.
37 See Chapter 2 n 23.
40 Bartley et al, above n 7, 32.
aquaculture sector are leading to fewer and larger companies so conflicts are likely to evolve between small and large-scale private actors rather than between countries, which causes complexities for the territorial basis of ABS. Chapter 6 argued that the free flow of migratory aquatic genetic resources between jurisdictional areas makes it difficult to pinpoint their origin for the territorial assumptions of ABS. The challenges for the transactional basis of ABS are evident in Antarctica where there is no territorial sovereignty or an entity with legal authority as the ‘provider’ of the genetic resource. As a consequence, there is no clear legal mandate for users of genetic resources to compensate those who bear the cost of conserving and providing genetic resources, causing complexities for the transactional basis of ABS. As the next sections outline, this thesis concluded that ABS of aquatic genetic resources is being shoe-horned into a proprietary ABS concept designed for terrestrial genetic resource exchange, which does not have the same extent of extra-territorial complexities as their aquatic counterparts.

8.2.1 A TRIPS-compliant patent law defence framework for aquaculture

As aquaculture moves from an art to a science, becoming an intensive, knowledge-based enterprise serviced by scientific institutions that diffuse new technologies and innovations for corporate clients, there is increasing interest in protecting investment in genetic resource inventions by way of patents. Chapter 3 introduced the role of patents for the exchange and use of genetic resources, technologies and knowledge in aquaculture, which was elaborated through various case studies in the subsequent chapters. Patent holders have exclusive rights over the making, use, sale, offering for sale and importing of the products of an invention as well as rights to prevent a person from unauthorised use of a patented process. Examples in this thesis of genetic resource products included those relating to actual genetic materials such as lysosome constructs and DNA vaccines as well as products that are produced by the use of

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42 World Bank, above n 6, 4.
43 TRIPS art 28(1)(a).
44 TRIPS art 28(1)(b).
45 See Chapter 2 n 92.
46 See Chapter 2 n 84.
genetic materials, such as synthetic sponge chemical compounds,\textsuperscript{47} antifreeze protein vectors\textsuperscript{48} and recombinant luciferase from the deep sea shrimp.\textsuperscript{49} Examples of genetic resource processes in this thesis included tuna germ cell transplantation surrogate technology,\textsuperscript{50} developing transgenic fish,\textsuperscript{51} and breeding methods such as polyploidy and hybridisation.\textsuperscript{52} Some countries may allow the patenting of conventional breeding techniques,\textsuperscript{53} but even some of those that do not allow it have found that the \textit{products} produced from these processes are patentable in principle.\textsuperscript{54} Under patent law, protection generally extends to every plant or animal containing the inventive element or resulting from a patented process.\textsuperscript{55} This means that a broad patent claim over a gene or gene carrier (vector) of a plant or animal may have the same outcome as patenting the whole plant or animal and a breeder would need permission from the patent holder to use it.\textsuperscript{56} Problems for technology transfer in the sector arise where permission is denied or not affordable. If a country has a strong and clear patent law defence framework, breeders can use genetic resources under certain circumstances with confidence that they will not be liable for patent infringement.

While much has been written about defences against infringement under \textit{TRIPS},\textsuperscript{57} legal scholarship lacks critical analysis of the full range of defences that may be available to users of patented aquatic genetic resource inventions to create further innovations in aquaculture. Chapter 4 addressed the thesis’ second aim – to examine the role of a \textit{TRIPS}-compliant patent law defence framework for the exchange and use of physical and digital genetic resources in aquaculture. It mapped the defence seascape, navigated

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\textsuperscript{47} See Chapter 5 n 83 and following text.
\textsuperscript{48} See Chapter 7 n 84.
\textsuperscript{49} See Chapter 6 n 25 and following text. Not all of these examples were patented at the time of writing the thesis but they are indicators of the sorts of products that are capable of being claimed.
\textsuperscript{50} See Chapter 6 n 30 and following text.
\textsuperscript{51} See Chapter 2 n 74, Chapter 7 n 83.
\textsuperscript{52} See Chapter 2 n 75-76.
\textsuperscript{53} See Chapter 1 n 37.
\textsuperscript{54} \textit{Plant Bioscience Limited v Syngenta Participants AG and Groupe Limagrain Holding} (European Patent Office Enlarged Board of Appeal, G0002/13, 25 March 2015) 66.
\textsuperscript{56} Nuffield Council on Bioethics, \textit{The Use of Genetically Modified Crops in Developing Countries: A Follow-Up Discussion Paper} (Discussion Paper, 2004) 88 [6.10].
the tensions between public and private interests in the physical and digital genetic resource on which a patented invention is based and gave insight into how defences can resolve difficulties posed by aquatic genetic materials’ self-replicating and multi-jurisdictional nature. World Trade Organisation Members’ defences applying to aquaculture must be compliant with their TRIPS obligations under article 6 (exhaustion), article 27(1) (non-discrimination), article 30 (‘three step test’ for exceptions) and article 31 (requirements for compulsory licences) interpreted in accordance with the Declaration on the TRIPS Agreement and Public Health.\textsuperscript{58} Chapter 4 examined the defences of experimental use, breeding, regulatory approval, compulsory licensing, non-commercial use, farmers privilege, exhaustion, innocent bystander, temporary presence and some alternative defences based on compensation. While defences may not discriminate between fields of technology,\textsuperscript{59} such as defences that only apply to aquaculture, there may be bona fide defences to deal with problems that may exist only in certain product areas.\textsuperscript{60} These must be based on factors other than a technical field, such as requiring regulatory approval before marketing.\textsuperscript{61} Chapter 4 asked whether defences can be adapted, or more specific bona fide defences crafted, to deal with problems that may only exist for developing new aquaculture products and strains.

One problem that exists for product area was called the ‘functionality question’ – the extent to which the patented characteristics in a subsequent strain must be sufficiently different from the patented original that was used to create the new strain before a defence will apply under patent law (derivative challenge, Figure 3: Intersecting Legal Challenges, p 33). For example, emerging breeding defences exempt the use of biological material for breeding, discovery and development of a new variety.\textsuperscript{62} A question for breeders is whether they would be excused from infringement if the biological materials (for example a patented trait) were merely present in the new strain

\textsuperscript{58} Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001, adopted 14 November 2001) (‘Doha Declaration’).

\textsuperscript{59} TRIPS art 27(1).


\textsuperscript{62} See Chapter 4 n 83 and following text.
Chapter 8

and what happens if the trait is expressed in current and future generational strains? The thesis argued that there is guidance emerging in Europe where 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 (or expressed)\(^63\) at the time of the alleged infringement.\(^64\) While the functionality question has not yet been clarified for breeding defences, this approach would mean that they would be available if the relevant patented characteristics are present but not expressed in the final strain. The Chapter argued that the key to answering the functionality question is clarifying when functionality is relevant.\(^65\) According to the European approach, a defence may only apply if the patented characteristic is not functional at the time of the alleged infringement, which means that breeders can experiment with subsequent generations until such time as a new strain expresses the original patented trait.\(^66\)

A second problem identified for the product area was the requirement for regulatory approvals of genetic resource inventions for human consumption. This effectively gives a patentee a longer monopoly over the genetic resource within the patent claim. Regulatory approval defences allow the performing of experiments on a patented invention for the purpose of preparing regulatory approval for a limited term before the end of the patent term.\(^67\) Whether such a defence applies to aquaculture or research tools of relevance to aquaculture differs markedly around the world. Without such a defence, however, genetic resources could be tied up from other uses for lengthy periods (at least 21 years outside of the 20 year patent protection period in the case of one genetically engineered salmon)\(^68\) while the genetic resource invention awaits environmental, health and safety approvals. The long time period between research of a genetic resource and its eventual use highlights a broader challenge relating to commercial use of genetic resource inventions (commercial use challenge, Figure 3:

\(^65\) See Chapter 4 n 96.
\(^66\) See Chapter 4 n 97.
\(^67\) See Chapter 4 n 100 and following text.
\(^68\) See Chapter 4 n 105.
Intersecting Legal Challenges, p 33). Many exceptions under national patent laws make a distinction between non-commercial uses (generally allowed) and commercial uses (generally not allowed) of a patented invention. In cases where an activity has both commercial and non-commercial benefits, some laws require the subjective intention of the users to be ascertained. 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. In light of the difficulties for distinguishing between the two types of uses, particularly in the area of biotechnology, some jurisdictions are now seeking to strike a balance between the non-commercial and commercial phases of research and do not distinguish between the two as long as the ultimate goal is to promote technical or scientific progress. In this case, the patent holder’s interests would be adequately protected by the functional origin approach above, regardless of whether the subsequent use was for commercial or non-commercial purposes.

A third problem identified for the product area concerned the infringement of aquatic genetic resource inventions that may spontaneously self-replicate in multiple jurisdictions (extra-territoriality challenge, Figure 3: Intersecting Legal Challenges, p 33). The act of breeding or self-replicating genetic resource inventions (for example a transgenic fish) without the authorisation of a patent holder can amount to infringement unless an emerging innocent bystander defence applies. Increasing commercial interest in roaming open ocean cage technologies raises the problem of infringement if the caged fish that expresses a patented genetic resource invention breed in waters where a patent is claimed. Chapter 4 suggested a novel approach to

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69 See Chapter 4 n 59-63 and 126-135.
72 Advisory Council on Intellectual Property, Patents and Experimental Use (Report, October 2005) 19 (’Patents and Experimental Use’).
75 See Chapter 4 n 152 and following text.
76 See Chapter 4 n 168 and following text.
facilitating technology transfer under a modified form of the temporary presence defence. Every WTO Member must have a defence preventing a Member country from enforcing a patent against a visiting vessel when that vessel temporarily or accidentally enters its domestic waters. The purpose of the defence is to facilitate uninterrupted travel but it might also be indirectly used to facilitate experimental use for breeding purposes in aquaculture infrastructure under certain circumstances.

Overall, Chapter 4 concluded that a *TRIPS*-compliant patent law defence framework is an underutilised tool for encouraging technology transfer. The flexibilities that WTO Members have about the means by which the minimum level of patent protection is secured in each Member’s legal system can be manipulated to suit the technological capabilities of a state. For example, some states have narrow experimental use exceptions allowing for example the investigation of a patented genetic resource invention for the purposes of testing and further developing the invention (experimenting ‘on’ the invention) while others have broader exceptions allowing the investigation not only of the invention itself but also using it as a tool to investigate a gene and its expression (experimenting ‘with’ the invention). The chapter argued that for those states with good biotechnological infrastructure, a narrow defence is advantageous for protecting investment in research tools, while for those seeking to build their technological capabilities, a broader defence can give breeders and researchers greater access to research tools without a licence.

The remaining Chapters built the argument that a *TRIPS*-compliant patent law defence framework offers normative content for effectively balancing private and public interests to facilitate fair technology transfer of genetic resources that is consistent with

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77 See Chapter 4 n 175 and following text.
78 See Chapter 4 n 174.
79 See Chapter 4 n 177.
80 *Canada – Pharmaceutical Products Case*, above n 60 [4.30].
82 *Gene Patenting and Human Health*, above n 81, 339 [13.87].
83 See Chapter 4 n 70 and following text concerning debate about whether the broader exemption is *TRIPS*-compliant.
84 See Chapter 4 n 79 and following text.
the proprietary approach to technology transfer within national jurisdiction, as well as
the stewardship approach in the deep sea and cooperative approach in the Antarctic
Treaty Area. The following sections discuss the complexities of ABS regimes in the three
jurisdictional areas. By tackling the three common legal problems (derivatives,
commercial use and extra-territoriality), they demonstrate how a TRIPS-compliant
patent law defence framework for technology and knowledge transfer can offer
certainty and structure for fairly sharing physical and digital genetic resources for use in
aquaculture under ABS regimes.

8.2.2 Proprietary approach to technology transfer of aquatic genetic resources
within national jurisdiction

The aim of Chapter 5 was to analyse the relationship between the TRIPS-compliant
patent law defence framework and the proprietary approach to technology (including
knowledge) transfer of aquatic genetic resources sourced within national jurisdiction for
use in aquaculture. Specifically, it looked at the proprietary approach under the
Convention and Nagoya Protocol. While much of the literature focuses on the conflicts
between the Convention and TRIPS, Chapter 5 examined the similarities between the
regimes. It found that both regimes have a common approach to technology transfer as
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 set up frameworks
for technology transfer along the whole technology change spectrum – from
dissemination to building capacity to further develop technologies to suit local
conditions. Both recognise that access, use and transfer cannot simply be open or closed
but instead depend on a balancing of rights and obligations according to the
circumstances of each case. Finding similarities between the regimes to achieve
consistency seems obvious given that many Convention-related technologies are of a
proprietary nature. Some of its obligations explicitly require the transfer of patented

85 See Chapter 1 n 174.
86 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
technologies to be provided on terms consistent with intellectual property protection.\textsuperscript{87} The \textit{Convention}'s Conference of the Parties has flagged that ‘options for technology transfer [under the \textit{Convention}] may be influenced by the approach taken in national patent laws on such issues as research exemptions’.\textsuperscript{88} Chapter 5 asked therefore, whether a \textit{TRIPS}-compliant patent law defence framework can be used to interpret and clarify technology transfer obligations under the \textit{Convention} and \textit{Nagoya Protocol}.

Chapter 5 outlined the transactional and territorial nature of the \textit{Convention}'s and \textit{Nagoya Protocol}'s proprietary approach to technology transfer under its ABS framework. Under this regime, provider states have sovereign rights to control access to genetic resources sourced from their jurisdiction.\textsuperscript{89} In return for access, users must share with the provider state, on mutually agreed terms, the results of research and development and the benefits they derive from the commercial and other uses of the genetic resources, which can include technology transfer.\textsuperscript{90} The \textit{Nagoya Protocol} sets up the procedures and enforcement of this transactional framework. If ratified, domestic access permits that are linked to contractual benefit sharing agreements between private parties are supported by an enabling framework of access and benefit sharing national laws in provider and user countries.\textsuperscript{91} The Chapter argued that while the \textit{Nagoya Protocol} has a general obligation for collaboration and cooperation for technology transfer that benefits developing countries, regardless of whether they are the provider,\textsuperscript{92} its framework essentially treats technology transfer as an optional form of benefit sharing within its transactional framework.\textsuperscript{93} The standard of fairness under this proprietary approach to technology changes depending on the beneficiary to whom the technology or benefits flow,\textsuperscript{94} but it ultimately depends on having a provider legally or jurisdictionally entitled to obtain the benefits.

\textsuperscript{87} \textit{Convention} art 16(2).
\textsuperscript{88} \textit{The Role of Intellectual Property Rights}, above n 86, 14 [41].
\textsuperscript{89} \textit{Convention} arts 3 and 15(1). \textit{Nagoya Protocol} preamble and art 6.
\textsuperscript{90} \textit{Convention} arts 15, 16 and 19. \textit{Nagoya Protocol} arts 1 and 5.
\textsuperscript{92} \textit{Nagoya Protocol} arts 22 and 23.
\textsuperscript{93} \textit{Nagoya Protocol} art 1.
\textsuperscript{94} See Chapter 5 table 1.
The *Convention* does, however, have a strong framework of stand-alone technology transfer obligations\(^95\) that seems to have been eclipsed by the transactional ABS framework that became the focus of the *Nagoya Protocol*. Chapter 5 argued that in general the implementation of the stand-alone technology transfer obligations are not similarly constrained by the transactional and territorial nature of proprietary ABS regimes.\(^96\) It argued that these obligations have more in common with the *TRIPS*-compliant patent law framework’s concept of non-discriminatory fairness that is aimed at achieving the global economy’s long term efficiency and not only for the advancement of the provider’s interests.\(^97\) The Chapter analysed some of the complexities and differences between the ABS framework and stand-alone technology transfer obligations for addressing the three common legal problems (derivatives, commercial use and extra-territoriality) and how normative developments in patent law defences can offer a consistent approach towards their resolution.

The scope of the ABS and stand alone technology transfer obligations hinges on the use of ‘genetic resources’\(^98\) but determining what types of derivatives they encompass is complex (derivative challenge, Figure 3: Intersecting Legal Challenges, p 33). Genetic resources means ‘genetic material of actual or potential value’,\(^99\) which is sufficiently flexible to cope with rapid technological developments.\(^100\) The chapter argued that while derivatives for the purposes of ‘utilisation of genetic resources’ are confined to ‘naturally occurring biochemical compounds’,\(^101\) derivatives falling under stand-alone technology transfer obligations are not similarly confined.\(^102\) Arguably contractual benefit sharing can be obtained from a broader range of derivatives.\(^103\) While there is

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\(^95\) See Chapter 5 table 1.
\(^96\) See Chapters 5, 6 and 7.
\(^97\) See Chapter 5 n 67 and following text.
\(^98\) *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’.
\(^99\) *Convention* art 2.
\(^101\) *Nagoya Protocol* art 2(e).
\(^102\) See Chapter 5 n 94.
\(^103\) Which can include not only benefits arising from the ‘utilisation of genetic resources’ (the R&D phase) but also those arising from ‘subsequent application and commercialisation’: *Nagoya Protocol* art 5(1).
no common understanding of the concept of derivatives, it could include physical natural compounds, physical synthetic compounds and intangible digitalised information concerning the resource or compounds.\textsuperscript{104} Tvedt and Schei argued that the decisive criterion for whether a derivative falls within the scope of obligations seems to be the biological origin rather than the biological form.\textsuperscript{105} Transfer of genetic information into digital form does not change its character\textsuperscript{106} and natural and synthetic derivatives that can be linked back to the original resource are likely to fall within the scope. The question is what is the requisite link between the original resource and the derivative for the latter to fall within ABS obligations? In practice the demarcation is often made through private law ABS agreements.\textsuperscript{107}

Using sea sponges as an example, Chapter 5 argued that the approach to the ‘functionality question’ taken by the TRIPS-compliant patent law framework can give insight into how a legal, rather than an ad hoc contractual demarcation can be made, giving certainty to users and providers of the derivatives. It argued that a derivative must have its biological origin in the original genetic resource before ABS or technology transfer obligations apply, which could mean that the relevant genetic characteristic or trait is either present or expressed in the derivative (a broad link). However, where it is a derivative of a patented genetic resource invention, then technology transfer could be triggered under both the TRIPS-compliant patent law defence framework and the Convention/Nagoya Protocol obligations if a derivative contains but does not express the original genetic resource invention at the time of its use (a stronger link). In other words, the Chapter concluded that the biological origin (either present or expressed) of the derivative is the determining factor for whether technology transfer obligations apply and these obligations can only be restricted by patented genetic resource


\textsuperscript{105} Tvedt and Schei, above n 100, 21.

\textsuperscript{106} 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.

\textsuperscript{107} Tvedt and Schei, above n 100, 24.
inventions that are based on the functional origin (expressed, not merely present) of the relevant genetic resource invention.

Chapter 5 examined the uncertainty about when ABS and technology transfer obligations are triggered across the research to commercialisation continuum and how obligations address changes of intent from non-commercial to commercial uses (commercial use challenge, Figure 3: Intersecting Legal Challenges, p 33). It concluded that under the Nagoya 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 Nagoya Protocol’s ABS framework. The Convention on the other hand imposes a legal obligation on its parties to set up a stand-alone technology transfer framework for genetic resources, which may arguably include subsequent commercial products. To provide certainty about whether technology transfer applies to commercial applications, the Chapter suggested using a similar approach to the Swiss farmers’ privilege defence and provide that any contractual agreements that attempt to limit the technology transfer laws are void. While none of the ABS and stand-alone technology transfer obligations limit their scope to non-commercial uses (a different question to commercial products above), the Nagoya Protocol permits simplified measures on access for non-commercial research purposes. This provision links facilitated access with the objective that knowledge should be generated which helps to conserve and sustainably use the resources, which arguably requires publicly available knowledge. The Chapter concluded that clarification is necessary about how ABS obligations address changes of intent of use so that a country’s simplified measures for non-commercial use are not abused. It argued that the solution may lie in emerging norms of the TRIPS-compliant patent law

108 See Chapter 5 n 24.
109 See Chapter 5 n 165.
110 Convention art 15(7) expressly includes commercial use in its scope.
111 Nagoya Protocol art 8(a).
113 See Chapter 5 n 167.
framework that do not distinguish between commercial and non-commercial uses as long as the ultimate goal is to promote technical or scientific progress.114

While the Convention applies to genetic resources within a state’s national jurisdiction and to processes and activities carried out by a state’s nationals within its control within or beyond the limits of its national jurisdiction,115 the Nagoya Protocol only applies to genetic resources within national jurisdiction.116 Chapter 5 found that 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,117 pose key challenges for certainty and enforcement of technology transfer across national boundaries. Given that the majority of aquaculture programs require regular inputs from migratory wild stocks,118 it is crucial for the future of the industry to address the challenges of meeting patent law defence criteria and technology transfer obligations in trans-boundary situations. The transactional and territorial nature of the proprietary approach under these instruments means that 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.119 This raises questions of equity and competition between different provider parties that are sharing genetic resources and may lead to a ‘race to the bottom’ regarding ABS and technology transfer requirements.120 It also creates complexities for the user-provider relationship over resources sourced outside of national jurisdictions (see next sections). To this end, the Nagoya 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’.121

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114 See Chapter 5 n 174.
115 Convention art 4.
118 This is to prevent inbreeding depression: Gjedrem, above n 29, 20.
120 Ibid 17–18.
121 Nagoya Protocol art 10.
Chapter 5 argued that the Nagoya Protocol offers innovative solutions to tackle cross jurisdictional compliance with access user measures but these do not extend to technology transfer as a form of benefit sharing. The Chapter concluded, however, that exhaustion and temporary presence defences under patent law can be used as a model for achieving multilateral objectives within national regimes. The temporary presence defence has been explained above. 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. If a country prescribes national exhaustion, both domestic sale and importations are infringements. If a country prescribes international exhaustion, a third party can for example purchase a patented aquatic genetic material product from the patent holder on the market in one country and then import it into another country for resale there, but the third party cannot make and sell the product themselves. This promotes technology transfer by having less costly patented aquatic genetic resources available for experimental and breeding uses than those in other jurisdictions. The Chapter proposed modifying ABS laws to incorporate this multilateral approach to technology transfer and concluded that if a state wants to attract technology transfer of genetic resources, it could choose a system of international exhaustion rather than national exhaustion for the sale and use of genetic resources.

In summary, as patents are proprietary in nature, the TRIPS-compliant patent law defence framework offers normative solutions to the challenges for implementing technology transfer under the Convention and Nagoya Protocol’s proprietary approach to ABS. These solutions to the problem of derivatives, commercial use and extraterritoriality of aquatic genetic resources are consistent with the Nagoya Protocol but are not limited by the transactional and territorial basis for the laws. These solutions are also consistent with the stand-alone technology transfer obligations under the

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122 See above n 78.
124 Ibid 16.
125 See Chapter 4 n 141.
126 See Chapter 5 n 213.
**Convention** that are not similarly constrained by the transactional and territorial nature of the proprietary approach to ABS.

### 8.2.3 Stewardship approach to technology transfer of aquatic genetic resources beyond national jurisdiction

The aim of Chapter 6 was to analyse the relationship between the *TRIPS*-compliant patent law defence framework and the stewardship approach to technology (including knowledge) transfer of aquatic genetic resources sourced from areas beyond national jurisdiction (the ‘deep sea’) for use in aquaculture. Specifically, it looked at the approach under *UNCLOS* and the human rights *International Covenant* that facilitates the use of deep sea genetic resources for the benefit of the scientific and technological progress all humankind.

The gap under *UNCLOS* for ABS governance over deep sea genetic resources has been extensively debated. The New Instrument under *UNCLOS* on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction is under negotiation to address this gap. This Chapter investigated the less explored regulatory vacuums relating to technology transfer of genetic resources for use in domestic aquaculture, as well as high seas aquaculture of the future. It is unclear whether the New Instrument will directly address these areas. The Chapter looked specifically at how *UNCLOS*, the *International Covenant* and *TRIPS* balance the ‘legitimate’ interests of creators of genetic resource technologies with the public interest in accessing and sharing the knowledge and materials to create other technologies and strains in aquaculture. The reason for the analysis is that while there are existing technology transfer obligations under *UNCLOS*, commentators have argued that their implementation is hampered by the obligation to have ‘due regard for all legitimate interests including...the rights and duties of holders, suppliers and recipients.

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128 *New Instrument Resolution*, above n 22.
of marine technology’. Their reasoning is that patents may be a legitimate interest preventing the transfer to developing states because these exclusive rights trump the obligation to ‘endeavour to foster’ technology transfer in a case of conflict. Similarly, the knowledge sharing obligations under the marine research provisions are limited by ‘legitimate uses of the sea compatible’ with UNCLOS. The problem for implementing technology transfer is that there is no guide for determining ‘legitimacy’ under UNCLOS.

The Chapter argued that insights into how TRIPS balances legitimate interests and legitimate uses through its patent law defence framework can guide normative development of a similar benchmark for determining when a private or proprietary interest may constitute a ‘legitimate’ interest or use sufficient to override UNCLOS’ technology and knowledge obligations. Human rights obligations concerning creator’s rights, cultural rights, the right to adequate food and the right to enjoy the benefits of scientific progress and its applications were introduced into the analysis. The reason for their analysis was because of their similarities to the TRIPS-compliant patent law defence framework, their trans-jurisdictional approach to technology transfer and their relevance for protecting the rights of people in developing countries that provide most of the world’s aquaculture products.

UNCLOS refers to ‘natural resources’ but does not define ‘genetic resources’ nor indicate the extent to which these include derivatives. UNCLOS is also silent about the kinds of marine technologies that fall within its technology transfer obligations. For consistency with national regimes and in light of the connection between deep sea bioprospecting and biotechnology, it is likely that the New Instrument will include derivatives in their proposed ABS regime. However, the link with the resource sufficient to trigger ABS obligations would need clarification (derivative challenge, Figure 3: Intersecting Legal Challenges, p 33). The Chapter argued that the implied
trigger of whether a resource or derivative falls within current technology transfer obligations is its geographical origin. However, research suggests that it is often impossible to establish whether derivatives originate from genetic resources within or beyond national jurisdiction.\textsuperscript{137} To achieve consistency with national ABS regimes, it argued that biological origin may be a more appropriate or supplementary benchmark.\textsuperscript{138} This broader benchmark would include derivatives of a deep sea genetic resource whose characteristics or technologies are either present or performing the genetic resource’s original function, as long as those characteristics can be traced back to the original biological resource.\textsuperscript{139}

The *International Covenant* treats ‘legitimacy’ in more narrow terms when striking an effective balance between creator’s rights and the public interest in enjoying the benefits of deep sea technologies. Here the creator’s protected interests must be ‘resulting’ in the sense of being ‘directly generated’ from the production (not passively present in it) before their interest is sufficiently legitimate to limit others’ rights to benefit from scientific progress and its applications.\textsuperscript{140} The Chapter argued this approach is consistent with the *TRIPS*-compliant patent law defence functional origin approach for determining when a patent interest is sufficient to preclude technology transfer. In this case, *UNCLOS* technology transfer obligations (and/or ABS obligations under the New Instrument) would only be limited by legitimate proprietary interests in patented deep sea genetic resources that are based on the narrower *functional* origin and not the broader biological origin of the relevant genetic resource invention.

*UNCLOS* does not define ‘marine scientific research’ and there is scholarly debate about whether its knowledge sharing obligations include non-commercial as well as commercial research.\textsuperscript{141} Marine scientific research must not ‘unjustifiably interfere with other legitimate uses’ of the deep sea.\textsuperscript{142} It is important therefore to ask whether a

\textsuperscript{138} See Chapter 6 text following note 228.
\textsuperscript{139} Ibid.
\textsuperscript{140} See Chapter 6 n 202 and following text.
\textsuperscript{141} See Chapter 6 n 241.
\textsuperscript{142} *UNCLOS* art 240(c).
commercial use would be sufficiently legitimate to ‘justifiably interfere’ with obligations for transferring knowledge and building developing states’ capacities to develop their own technologies (commercial use challenge, Figure 3: Intersecting Legal Challenges, p 33). Chapter 6 argued that bodies under TRIPS and the International Covenant have clarified the term ‘legitimate’ when it comes to the sharing of knowledge and technologies. The WTO Panel observed in relation to the three step test for defences under article 30 TRIPS that both society and the scientist have a ‘legitimate interest’ in using the patent disclosure to support the advance of science and technology143 and are justifiable where supported by social norms.144 The International Covenant’s Committee has found that any limitation (such as patent law) on interests must be proportionate, must pursue a legitimate aim and must be strictly necessary for the promotion of the general welfare of a democratic society.145 These stewardship approaches are consistent with the objective of the marine scientific research provisions under UNCLOS which is to increase scientific knowledge of the marine environment for the benefit of humankind as a whole.146 The Chapter concluded that emerging norms in the TRIPS-compliant patent law defence framework – which do not distinguish between commercial and non-commercial phases of research as long as the ultimate goal is to promote technical or scientific progress147 – offer consistency and clarity to UNCLOS’ marine scientific research knowledge sharing obligations. The legitimate interests of a patent holder can be protected by balancing their ‘legitimate interests’ when their inventions are subsequently used in accordance with the functional origin approach above.

In summary, the TRIPS-compliant patent law defence framework is a mechanism for technology transfer that can already be applied to patented deep sea genetic resource technologies for use in aquaculture. Its consistency with the stewardship approach to technology transfer under UNCLOS and the International Covenant means that its

143 Canada – Pharmaceutical Products Case, above n 60 [7.69].
144 Ibid.
145 Committee on Economic, Social and Cultural Rights, General Comment No. 17 (2005): The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which he or she is the Author (Article 15, Paragraph 1 (c), of the Covenant), 35th Sess. UN Doc E/C.12/GC/17 (12 January 2006) [22-23].
146 UNCLOS preamble and arts 143, 243 and 246[3].
147 See Chapter 6 n 240.
normative content can offer a model that provides certainty and structure for balancing public and private interests in resources beyond national jurisdiction. This is a positive first step in effectively implementing technology transfer obligations under UNCLOS and the New Instrument.

8.2.4 Cooperative approach to technology transfer of *ex situ* genetic resources from the Antarctic Treaty Area

The aim of Chapter 7 was to analyse the relationship between the *TRIPS*-compliant patent law defence framework and the cooperative approach to technology (including knowledge) transfer of aquatic genetic resources sourced from the third jurisdictional area – the Antarctic Treaty Area – for use in aquaculture. This third jurisdictional area is neither fully within nor beyond national jurisdiction but has its own unique cooperative governance arrangements. Specifically the Chapter examines the cooperative approach underlying the Antarctic Treaty System (including the *Antarctic Treaty*, *Madrid Protocol* and *CCAMLR*) and the *Plant Treaty* that may have future relevance to Antarctica’s plant genetic resources. Under this approach, private and public interests in the genetic resources are balanced with the objective of furthering a collective purpose for technology transfer. In the case of the *Antarctic Treaty*, the technology transfer purpose is primarily to promote international co-operation in, and freedom of, scientific investigation in Antarctica for the benefit of the interests of science and the progress of all humankind. In the case of the *Plant Treaty*, the technology transfer purpose is to flow the benefits of using plant genetic resources primarily to farmers in all countries, especially those that are developing and in transition, who conserve and sustainable use plant genetic resources for food and agriculture.

148 Including all ice shelves and land below 60 degrees south latitude: *Antarctic Treaty* art VI.
149 *Antarctic Treaty*, art II.
150 *Antarctic Treaty*, preamble para [4].
151 *Plant Treaty* art 13(3).
While there is abundant literature about the lack of regulation for ABS of Antarctica’s genetic resources, few have analysed the legal confusion and complexity arising from the application of multiple national ABS laws to the use of Antarctica’s *ex situ* genetic resources. In particular, there is little debate about the extent to which relying on systems based on the transactional and territorial nature of proprietary approach to ABS can undermine the *Antarctic Treaty*’s technology transfer objectives. Chapter 7 analysed access and technology transfer obligations under the *Antarctic Treaty* that are applicable to Antarctica’s *in situ* genetic resources and the lack of authority to regulate its *ex situ* genetic resources. It then analysed bilateral ABS regimes (*Convention* and *Nagoya Protocol*) and regimes with multilateral mechanisms for technology transfer (*Plant Treaty* and *TRIPS*-compliant patent law defence framework) of relevance to Antarctica’s *ex situ* genetic resources. The Chapter argued that legal authority for regulation of *ex situ* genetic resources under the *Convention* is tenuous and complicated and becomes more complex when dealing with the abstract information and knowledge (the digital resource) separate from the physical resource sample.

The Chapter concluded that it is necessary to determine on a case-by-case basis whether the *Convention’s* and *Nagoya Protocol’s* access and technology transfer obligations apply to Antarctica’s *ex situ* genetic resources. This depends on factors including the timing and circumstances of the original extraction from Antarctic waters, the national legislative requirements applicable to the nationals performing the extraction, and the circumstances under which the material passed into the possession of the *ex situ* holder, including any contractual agreements. The Chapter argued that gaining accurate information to make this determination is almost impossible because unlike the plant networks, there is no coordination between aquatic gene banks for effective information sharing. However, if these factors can be determined, then the *Convention’s* framework may regulate Antarctica’s *ex situ* genetic resources physically located in government (and in some countries, private) facilities.

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152 See Chapter 1 n 173.
153 See Chapter 7 n 148 and following text.
154 See Chapter 7 n 161 and following text.
155 See Chapter 7 n 163.
156 See Chapter 7 n 97.
within national jurisdictions, but not genetic resources and derivatives that were deposited in an ex situ facility before the *Convention* entered into force,¹⁵⁷ not in repositories within the jurisdiction of nations that are not party to the *Convention*, and only where the samples were acquired ‘in accordance with the *Convention*’.

A major limiting factor for the *Convention’s* ABS and stand-alone technology transfer framework is that derivatives accessed independently from genetic resources fall outside the scope of the obligations.¹⁵⁸ Many global initiatives store only the genetic data and information relating to Antarctic genetic resources that can be subsequently used for research and development purposes.¹⁵⁹ The flow of this data through uncoordinated aquatic depositories means that the link with the original resource may be severed. The question is how to ensure that subsequent uses of ex situ Antarctic derivatives including digital genetic resources that do not depend on access to the physical sample are held accountable to information sharing obligations under the *Antarctic Treaty* (derivative challenge, Figure 3: Intersecting Legal Challenges, p 33).

Initiatives like the *Micro B3 Agreement* based on the *Convention’s* bilateral proprietary approach arguably only trace biological origin through a viral licence clause back to the accession of the geographical location of the physical ex situ resource in a national jurisdiction to which the *Convention* applies and not necessarily the original Antarctic in situ waters. As patent law largely deals with the knowledge component of the genetic resource, its ‘functional origin’ approach can give insight into how to regulate the sharing of the digital resource independently from the physical resource. If applied to ABS of Antarctica’s ex situ resources, the subsequent use of an Antarctic digital resource may trigger the *Antarctic Treaty’s* knowledge sharing obligations if the characteristics of the original in situ resource are present in the resulting product or process. However, these obligations could only be limited by legitimate proprietary interests over resulting patented product that expresses the functional characteristics of the original resource.

¹⁵⁸ Greiber et al, above n 119, 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.
¹⁵⁹ See Chapter 7 n 105 and following text.
at the time of its subsequent use.\textsuperscript{160} The Chapter concluded that subsequent uses of patented \textit{ex situ} Antarctic digital resources that are acquired independently of the physical sample could therefore fulfil information sharing obligations under the \textit{Antarctic Treaty} while not offending \textit{TRIPS} obligations.\textsuperscript{161}

There is often a lengthy time lag between research and commercial development of technologies based on Antarctic genetic resources.\textsuperscript{162} This raises questions about how to deal with situations where the recipient has originally accessed the genetic resource with the intent of non-commercial research but subsequent recipients use it for a commercial purpose (commercial use challenge, Figure 3: Intersecting Legal Challenges, p 33). The distinction is important for its \textit{ex situ} genetic resources that may be subject to both \textit{Convention} and \textit{UNCLOS} obligations. The Chapter argued that this may create an anomalous situation where states are obliged to create simplified access for non-commercial uses of Antarctic \textit{ex situ} genetic resources located in land repositories\textsuperscript{163} but not for the same resources held in territorial water facilities.\textsuperscript{164} It argued that this complex array of ABS laws concerning the purposes of use may impede the access to, and exchange of, scientific information about Antarctica’s resources contrary to the \textit{Antarctic Treaty}. The Chapter argued that emerging norms for \textit{TRIPS}-compliant patent law defences that do not distinguish between commercial and non-commercial uses, as long as the ultimate goal is to promote technical or scientific progress can provide a consistent approach to resolving this complexity. It concluded that this approach is consistent with the Antarctic Treaty System because access restrictions under the \textit{Antarctic Treaty}’s prior notification requirements and the \textit{Madrid Protocol} and \textit{CCAMLR} permit systems are arguably concerned with the accumulation of scientific information for the protection of Antarctica’s environment and for the benefit of humankind, rather than with questions of whether the access will result in commercial or non-commercial uses.\textsuperscript{165}

\textsuperscript{160} See Chapter 7 n 265.
\textsuperscript{161} See Chapter 7 conclusion.
\textsuperscript{162} \textit{Biological Prospecting in Antarctica: Review, Update and Proposed Tool to Support a Way Forward}, Antarctic Treaty Consultative Meeting, 30th mtg, Agenda Item 17, IP 67 (May 2007) 12.
\textsuperscript{163} \textit{Nagoya Protocol} art 8(a).
\textsuperscript{164} \textit{UNCLOS} art 245.
\textsuperscript{165} See Chapter 7 n 257 and following text.
Finally, the Chapter highlighted the problem that the Convention’s transactional and territorial proprietary approach means that benefits (including technology transfer) from using Antarctica’s *ex situ* genetic resources flow to the provider country and not to the Antarctic Treaty Area and its scientific objectives, unless mutually agreed in a contract over a specific genetic resource (extra-territoriality challenge, Figure 3: Intersecting Legal Challenges, p 33). It argued, however that the purpose driven cooperative approaches under the *Plant Treaty* and *TRIPS*-compliant patent law defence framework break the ABS territorial nexus so that the provider state grants access but the benefits flow to the collective to achieve a particular goal. It raised the example of compulsory licensing as amended by the *Declaration on the TRIPS Agreement and Public Health 2001 (Doha Declaration)*\(^\text{166}\) as an approach for promoting technology transfer and benefit sharing to fulfil a global objective. This is a type of non-voluntary authorisation to use a patent holder’s intellectual property without their permission in return for a reasonable set fee. To promote the transfer of technology and capacity building in the pharmaceutical sector, the *Doha Declaration* resulted in a decision allowing generic copies of patented inventions made under compulsory licences to be exported to countries that lack production capacity if certain conditions are followed.\(^\text{167}\) It argued that by using this cooperative approach as an example, nations could recognise sovereign rights to regulate genetic resources but agree to waive access restrictions for Antarctica’s *ex situ* genetic resources for uses that are carried out for peaceful purposes, scientific investigation in the interests of all humankind and the preservation of the Antarctic environment.\(^\text{168}\)

In summary, the overwhelming complexity for whether a specific Antarctic *ex situ* physical or digital resource falls within ABS or technology transfer obligations causes uncertainty for the equitable sharing of emerging genetic resource technologies from Antarctica for use in aquaculture. The Chapter concluded that the *TRIPS*-compliant patent law framework is consistent with the cooperative approach to technology

\(^{166}\) *Doha Declaration*, above n 58.


\(^{168}\) *Antarctic Treaty* preamble and arts I, II and III.
transfer under the Antarctic Treaty System and can provide certainty and structure through normative development of rules to solve the common legal problems that both systems face over the same resources.
## 8.3 Conceptual model with results

### Figure 5 Chapter questions and findings

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<tr>
<th>Primary theme</th>
<th>Chapter 2</th>
<th>Chapter 3</th>
<th>Chapter 4</th>
<th>Chapter 5</th>
<th>Chapter 6</th>
<th>Chapter 7</th>
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</thead>
<tbody>
<tr>
<td><strong>Jurisdictional area</strong></td>
<td>Overview of ABS regimes in all jurisdictional areas</td>
<td>Overview of patents in aquaculture</td>
<td>National patent defence laws</td>
<td>Within national jurisdiction</td>
<td>Beyond national jurisdiction</td>
<td>Antarctic Treaty Area</td>
</tr>
<tr>
<td>Primary aim</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Question</strong></td>
<td>What are the special challenges that the aquaculture sector faces in the exchange of aquatic genetic resources across the three jurisdictional areas?</td>
<td>What are some of the implications for aquaculture breeders and researchers of using patented genetic resource inventions in their breeding and research programs?</td>
<td>Can patent law defences be adapted, or more specific bona fide defences be crafted, to deal with problems that may only exist for breeding new strains in aquaculture?</td>
<td>How can a TRIPS-compliant patent defence framework be used to interpret and clarify technology transfer obligations under the Convention and Nagoya Protocol?</td>
<td>How can the stewardship approach balance the ‘legitimate’ interests of creators of deep sea genetic resource technologies with the public interest in sharing these resources to create new technologies and aquaculture strains?</td>
<td>Can the TRIPS-compliant patent law defence framework offer an approach that clarifies the complex legal arrangements for sharing Antarctica’s ex situ resources in a way that is consistent with the Antarctic Treaty’s cooperative objectives?</td>
</tr>
<tr>
<td><strong>Main findings</strong></td>
<td>The transactional nature and territorial approach of the predominant proprietary ABS concept does not suit the history, early domestication, migratory stocks and pattern of exchange for the use of genetic resources in aquaculture.</td>
<td>Patents are starting to take hold in the sector which can have a dampening or stimulating effect on innovation. Emerging normative rules clarify whether subsequent uses of resources in breeding and biotechnology infringe patents.</td>
<td>Defences can be adapted or interpreted in a way that deals with problems that exist in certain product areas including the three legal problems of derivatives, commercial use and extra-territorial nature of aquatic genetic resources.</td>
<td>Its solutions to the three legal problems are consistent with the Convention’s proprietary approach but are not limited by the underlying transactional and territorial impediments to technology transfer.</td>
<td>UNLCOS technology transfer obligations would only be limited by ‘legitimate’ proprietary interests in patented deep sea genetic resources based on the functional, not the broader biological origin of the original resource.</td>
<td>Its solutions to the three legal problems are consistent with the cooperative approach by balancing private and public interests in the genetic resources with the objective of advancing a collective purpose for technology transfer.</td>
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8.4 Research contribution to knowledge

This thesis makes an original and innovative contribution to research on access, benefit sharing and technology transfer of aquaculture genetic resources. The fair and equitable sharing of genetic resources for use in aquaculture is largely ignored in the regulatory debate about ABS, yet the sector’s crucial role in global food security makes it an important perspective to consider. Figure 6 summarises the contribution of my research to the current state of legal analysis and knowledge, which is elaborated below.

Figure 6 Summary of research contribution to knowledge

<table>
<thead>
<tr>
<th>Analysis in current literature</th>
<th>Research contribution</th>
<th>Practical outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoe-horning ABS of aquatic genetic resources into the predominant territorial and transactional approach to ABS that has evolved to suit terrestrial genetic resources</td>
<td>(1) Questions the benefit of a geographical origin approach to technology transfer less suited to migratory physical resources and digital resources (2) Identifies the special characteristics of aquaculture genetic resource use and the legal challenges for their exchange</td>
<td>Tailoring ABS and technology transfer obligations to suit the pattern of resource exchange in aquaculture</td>
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<tr>
<td>Focus on developing a discrete ABS regime for resources of areas beyond national jurisdiction</td>
<td>Paradigm shift from ABS based on jurisdictional/geographical origin to ABS based on trans-jurisdictional (including proprietary, stewardship and cooperative) approaches to technology transfer</td>
<td>A consistent approach across jurisdictional areas for implementing technology transfer of migratory, ex situ and digital genetic resources and those whose origin is unknown</td>
</tr>
<tr>
<td>Debate about the conflict between patenting genetic resources and access to create new technologies</td>
<td>Maps patent law defences relevant for aquaculture genetic resource use and navigates a pathway towards consistency between patent law and ABS law</td>
<td>Clarifying how the defences accommodate technology transfer and how they can evolve to suit aquaculture genetic resource exchange and product development</td>
</tr>
</tbody>
</table>
My research has brought insight to the underlying transactional and territorial approach of the predominant concept of ABS which does not fully suit the use and exchange of the self-replicating, migratory nature of aquatic genetic resources, or the complex problems for sharing ex situ and digital resources to create innovation in aquaculture.

My research was the first to systematically connect the special characteristics of sharing aquaculture genetic resources (such as its predominantly wild stocks, their migratory nature, difficulties with identifying a genetic chain of custody, lack of basic research and rapid structural changes in the industry) with specific legal challenges for balancing public and private interests in physical and digital resources (regulating derivatives, commercial use and extra-territorial implementation of resource exchange).

My research offered a paradigm shift from the current approach to developing discrete ABS regimes for each jurisdictional area based on the geographical origin of a resource (within national jurisdiction, beyond national jurisdiction and the Antarctic Treaty Area), towards a trans-jurisdictional framework that can accommodate a variety of approaches to technology transfer depending on the objectives of the relevant laws. It did this by analysing proprietary, stewardship and cooperative concepts that underlie the relationship between resources and humankind under a variety of international instruments. The research contributed to the understanding of the assumptions for resource allocation and the principles of fairness underlying these three approaches. The mechanism that can draw together these approaches is a presently available, although underutilised and underestimated, framework – the TRIPS-compliant framework for patent law defences. While new ABS regimes are being developed in different international forums, adding complexity for users and providers of genetic resources, my research demonstrated how this framework can offer certainty and
structure for fairly sharing physical and digital genetic resources from the three jurisdictional areas for product development in aquaculture. It did this in two ways.

First, my research systematically mapped the patent law defences already available to farmers, researchers and other users and producers of aquatic genetic resources to protect them against patent infringement proceedings. Legal analysis of the role of patent law defences for resource and knowledge exchange has largely ignored their relevance to balancing rights and interests in the aquaculture sector. By mapping available defences, the research offered a means of promoting certainty and confidence for breeders and researchers using patented knowledge and technology to create new innovations in aquaculture. My research not only offered TRIPS-consistent modifications to the defence framework to address problems in aquatic related product areas but also gave unique insight into how defences not normally associated with genetic resources, such as the temporary vessels presence defence, can be relevant to sharing emerging technologies in aquaculture.

Secondly, my research was the first to demonstrate how the TRIPS-compliant patent law defence framework’s normative content for resolving three legal challenges – derivatives, commercial use and extraterritoriality – can be applied to the same legal challenges under evolving ABS regimes. My research has shifted the focus of the regulation debate from conflict between patent, human rights and ABS laws, towards similarities between their technology transfer frameworks. As the research unfolded, it became clear that the roadblocks for implementing technology transfer obligations are based on perceived rather than actual tensions between public and private interests in the resources, for example, the perception that patent proprietary interests will ‘trump’ the public interest in sharing knowledge for the scientific progress of humankind. This perception ignores the three underlying approaches to technology transfer that can alter the balancing of interests under different instruments that apply to the same resource. Significantly, the research revealed that the TRIPS-compliant patent law framework is consistent with all three approaches to technology transfer and is in a unique position to offer solutions to legal challenges that all regimes face when balancing interests – questions of derivatives, commercial uses and extra-territorial
aspects of sharing aquatic genetic resources. Figure 7 summarises how the TRIPS-compliant solutions relate to the three approaches to technology transfer analysed in this thesis. The practical effect of these solutions was demonstrated through case studies of emerging genetic resource technologies of relevance to aquaculture. By treating patent law as an integral part of ABS regimes and not a regime in conflict, my research demonstrated how laws with different economic, environmental and social objectives can evolve towards a consistent approach to technology and knowledge transfer.
**Figure 7 Applying TRIPS-compliant patent law defence framework to the three legal problems**

<table>
<thead>
<tr>
<th>Derivatives</th>
<th>Commercial use</th>
<th>Extra-territoriality</th>
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<tbody>
<tr>
<td>The transfer of derivative technologies based on biological origin of relevant resource is only limited by a proprietary interest based on functional origin. Eg breeding, experimental use and innocent bystander defences.</td>
<td>The transfer of technologies is facilitated as long as the ultimate goal is to promote technical or scientific progress. Proprietary interests are protected by the functional origin approach. Eg some experimental use and regulatory approval defences.</td>
<td>Breaks the territorial nexus so that the provider state regulates access but the benefits flow to the collective to achieve a particular goal. Eg temporary presence defence, compulsory licensing and exhaustion.</td>
</tr>
<tr>
<td><strong>TRIPS-compliant patent law defence approach to legal challenge</strong></td>
<td><strong>Consistency with approaches</strong></td>
<td><strong>Consistency with ABS instruments</strong></td>
</tr>
<tr>
<td>Proprietary, stewardship and cooperative</td>
<td>Proprietary, stewardship and cooperative</td>
<td>Stewardship and cooperative. Approach is also consistent with proprietary approach if benefits flow to the provider and the collective’s purpose.</td>
</tr>
</tbody>
</table>
| **Convention** (Chapter 5 & 7)  
**Nagoya Protocol** (Chapter 5)  
**UNCLOS** (Chapter 6)  
Antarctic Treaty System (Chapter 7) | **Convention** (Chapter 5 & 7)  
**Nagoya Protocol** (Chapter 5)  
**UNCLOS** (Chapter 6)  
Antarctic Treaty System (Chapter 7) | **Convention’s stand-alone obligations** (Chapter 5 & 7)  
**UNCLOS** (Chapter 6)  
Antarctic Treaty System (Chapter 7) |
8.5 Implications for patent law, ABS law and aquaculture

The thesis demonstrated through practical examples the legal complexities and risks to innovation in aquaculture if the normative content of patent law and ABS law continues to evolve in isolation. As biotechnology becomes more common in aquaculture, a single farmed product may incorporate genetic resources, derivatives and patented inventions from a range of species within a range of jurisdictional areas. Figure 1 (p 26) represents the current complex web of ABS regulation based on the predominant proprietary approach to technology transfer. A key outcome of my research is the fresh approach to resolving legal problems arising from the paradigm shift of regulation based on jurisdictional area, towards regulation based on trans-jurisdictional (including proprietary, stewardship and cooperative) approaches to technology transfer. Figure 7 demonstrates the implications of applying all three approaches to technology transfer to the instruments analysed in this thesis. A key implication of the research is that the TRIPS-compliant patent law defence framework is consistent with all three approaches and can therefore play an important role in shaping ABS rules and concepts.

International policy makers are focusing on setting up a separate ABS regime for areas beyond national jurisdiction, which will take years to negotiate. This means it will take years to resolve the uncertainty and loopholes relating to the fair and equitable sharing of deep sea and trans-jurisdictional aquatic genetic resources. My research has highlighted, however, that the TRIPS-compliant patent law defence framework is an underutilised but effective mechanism that is currently available for balancing rights and interests in genetic resources across the three jurisdictional areas. The research demonstrated practical solutions to: determining the point at which derivatives and technical knowledge are sufficiently removed from the genetic resource on which they are based for technology transfer rules to no longer apply; the difficulties for distinguishing between commercial and non-commercial uses for which different technology transfer rules apply; and how to address challenges for implementing technology transfer obligations over genetic resources located in multiple jurisdictions from multiple providers.
As *TRIPS*-compliant normative content evolves to suit new aquatic technologies and applications, it can similarly guide the patchwork of ABS regimes to provide certainty for users as well as providing an existing framework for building solutions to other common legal problems. While these regimes are evolving in different international forums, the World Trade Organisation could take the lead for increasing awareness of a *TRIPS*-compliant patent law defence framework approach to technology transfer of physical and digital genetic resource technologies. This could reframe the debate about regulating genetic resources from one of conflict between regimes, to finding common solutions to legal problems such as those proposed in this research.

At a national level, countries including Australia are currently working out how to implement their ABS obligations under the *Nagoya Protocol*. At the same time there is increasing interest in facilitating innovation in the food sector, including aquaculture, to maintain food security for growing populations. My research offers an integrated approach to tailoring ABS and technology transfer obligations to suit the unique pattern of resource exchange in the aquaculture sector that takes into account the increasing interest in patenting genetic resource technologies. It also offers practical solutions for clarifying how *ex situ* genetic resources, including digital resources, can be regulated under national law but with an approach to benefit sharing that fulfils a particular purpose as in the case of Antarctica. A key implication of my research is that moving towards domestication and product development will be turbulent unless users and providers, including farmers, researchers and *ex situ* facilities, have certainty about whether the genetic resources and derivatives they are using to make new products and processes are subject to access restrictions or benefit sharing and technology transfer obligations. Developing patent and ABS laws that are consistent with the *TRIPS*-compliant patent law defence framework outlined in this thesis can offer consistency and structure for fairly sharing physical and digital genetic resources from multiple jurisdictional areas for use in aquaculture.

### 8.6 Future research directions

This research provided a conceptual pilot study of the challenges and opportunities for an integrated approach to access, benefit sharing and technology transfer of
aquaculture genetic resources. It forms a solid basis for further empirical research about the implications of this integrated approach for the wide varieties of uses of genetic resources in aquaculture. To do this, it would be necessary to draw together more qualitative and quantitative data and information including:

- the extent, scope and nature of patents relating to genetic resources and derivatives of relevance to aquaculture;
- the extent to which stakeholders in the aquaculture sector are aware of, or rely on, patent law defences to avoid infringement;
- the extent to which stakeholders in the aquaculture sector are aware of and complying with ABS laws for the exchange of genetic resources;
- the patterns of exchange of genetic resources for use in aquaculture across the three jurisdictional areas;
- the extent to which ex situ genetic resources are used for aquaculture product development and information about their geographical and biological origin;
- the circumstances in which the digital resource is used separately from the physical genetic resource;
- whether certainty over legal problems such as those identified in this thesis would change farmers’ and researchers’ decisions for using patented genetic resource technologies in their breeding and research programs; and
- how traditional knowledge associated with using aquatic genetic resources applies to ABS in aquaculture.

The imminent release of the Food and Agriculture Organisation’s *State of the World’s Aquatic Genetic Resources* is likely to include information examined in my research including drivers impacting aquatic genetic resources for food and agriculture, *in situ* and *ex situ* conservation, institutional capacities, research and international collaboration and relevant legislation and policies. The report is also likely to fill some of the information gaps above and raise further areas for research arising from inventories of the types of aquatic genetic resources that are used by countries for food and agriculture, including aquaculture.
As negotiations for the New Instrument for genetic resources in areas beyond national jurisdiction progress there will be further opportunities to fine tune an integrated approach between patent and ABS regimes. My research questions the benefits of the fundamental jurisdictional approach to technology transfer, which can be analysed in light of new regime as it is shaped over the coming years.

At the national level, my research presents a starting point for policy development on how to implement Nagoya Protocol obligations by analysing the interconnections between ABS and patent law defences and the negative implications for technology transfer if they develop in isolation. Further research could include reviews of access and benefit sharing policies, including a review of the relevant state’s patent law defence framework in the context of its role in ABS of genetic resources.

At an organisational level, many aquatic ex situ repositories are also grappling with how to implement their ABS obligations under the Nagoya Protocol. More definitive research is needed about the status of ex situ genetic resources, particularly from the Antarctic Treaty Area, and ways in which users can be legally obligated to flow benefits back to benefit the conservation of an area or a purpose that transcends the contractual ABS relationship. As the network of repositories grows in the coming years, a comprehensive review of the future directions of ex situ repositories is the first step to determining which ABS and patent laws apply to particular deposits. For example, the practical effect of the laws may change depending on the types of materials to be stored (such as physical and/or digital, traditional knowledge), the purpose of the repository (commercial, non-commercial or a mix), uses of the materials (food and agriculture or pharmaceutical uses), form of access (for example open access or user pays), economic structure (such as government or joint venture) and the physical structure (for example, live fish or cryopreservation). The development of standardised best practice guidelines across the aquatic ex situ facilities taking into account these kinds of factors would create certainty for users and providers of genetic resources and promote greater exchange for aquaculture purposes.

A major future area of research involves education and extension programs to farmers and researchers, particularly in developing countries, about their rights and obligations
under the *TRIPS*-compliant patent law defence framework and ABS legislation. This could include pilot programs by the Food and Agriculture Organisation of the United Nations or the WorldFish Centre that encourage individuals, cooperatives and organisations to take advantage of patent law defences available to them so that they can confidently develop new technologies without fear of infringement. Such extension programs could have a practical outcome of positively promoting or facilitating access and technology transfer of genetic resources for developing new technologies in aquaculture.
8.7 Concluding remarks

The level of complexity for determining which ABS, technology transfer and patent law regime applies to a specific aquatic genetic resource is increasing as new aquaculture technologies are sourced from organisms and derivatives across the globe. Paradoxically, the drive for creating legal certainty by drawing artificial lines – between jurisdictional areas, between bodies of law, between commercial and non-commercial uses, between in situ and ex situ resources and between physical and digital resources – has added to the complexity and in turn created more confusion. The way forward is to take a step back and understand the way we conceptualise humankind’s relationship with other biological resources. These include controlling them by proprietary means, minding them for the benefit of the planet’s inhabitants by way of stewardship, and sharing them to achieve a collective purpose through cooperation. To simplify the way these relationships are expressed in law, this thesis assigned a predominant approach to technology transfer to each jurisdictional area but in reality, the regimes have aspects of all three approaches that can serve as the starting point for consistency.

The TRIPS-compliant patent law defence framework has evolved to overcome territorial limitations arguably because it regulates trade in knowledge that has no boundaries. In recognition that this trade is dependent upon building the collective knowledge from which new ideas are derived, it creates a flexible regime to balance proprietary interests in the processes and products of new knowledge with the public interest in sharing this knowledge to create other processes and products. In this way, its framework and normative content incorporates proprietary, stewardship and cooperative approaches to technology transfer that can be applied to clarify some of the complexities of ABS and technology transfer regimes. Finding flexible solutions to the three legal problems posed in this thesis – derivatives, commercial use and extra-territoriality – is only the start of building certainty and structure for equitably sharing genetic resources for use in aquaculture within our legal systems.
APPENDIX – GRIFFITH UNIVERSITY THESIS GUIDELINES

Inclusion of papers within the thesis

Overview

This information is not relevant to those candidates enrolled in the PhD by Prior Publication program, 602 or 8024. PhD by Prior Publication candidates should refer to the program specific thesis formatting information (https://www.griffith.edu.au/graduate-degree-research/postgraduate-research/theses/thesis-formatting).(1)

HGR candidates may include one or more papers within the body of their thesis where such papers have been produced under supervision and during the period of candidature, and where the quality of such papers is appropriate to Doctoral or Masters (Research) level/research. A thesis prepared in this way is a different thesis format, it is not a different degree.

There are several advantages to organising a thesis in this way:

• Preparing papers for publication saves time when preparing the thesis for examination as papers may make up one, or several, chapters within the thesis.
• It is to your advantage to publish work from your thesis as a means of disseminating your research, and developing your writing skills.
• It may improve the quality of your thesis as part of your thesis has already been subjected to peer review.
• Examiners may have more confidence in your thesis if they can see that you have already published your research.

In addition, you will have already met one of the criteria of examination, with the thesis submitted for publication.

As a candidature requirement, all doctoral candidates are expected to have at least one peer reviewed output accepted for publication during candidature (https://www.griffith.edu.au/graduate-degree-research/postgraduate-research-guidelines/thesis-guidelines#thesis-publication). Whilst not compulsory, candidates are encouraged to include this publication in the body of the thesis due to the advantages as outlined above.

Requirements for inclusion of papers within the thesis

Higher degree by research is a program of independent supervised study that produces significant and original research outcomes, contributing to research, engineering or equivalent (refer to Higher Degree by Research Thesis (https://www.griffith.edu.au/graduate-degree-research/postgraduate-research/theses/thesis-formatting).)

Inclusion of papers within a thesis is not a suitable thesis format for all research projects, for example collaborative projects where there may be several co-authors for each paper which may make it difficult for the examiner to establish the independence of the candidate’s contribution. Where primary data is not collected, or results obtained, until late in the candidature, or where the research will not produce a logical sequence of papers that are able to be presented as an integrated whole, candidates should also take into account whether this thesis format is an acceptable process within their discipline and likely to be received well by the thesis examiners (refer also to the examination requirements below). Candidates are required to consult with their supervisor(s) early in their candidature to determine if this thesis format is appropriate. It is expected that candidates will identify as part of the confirmation of candidature milestones (http://www.griffith.edu.au/graduate-degree-research/postgraduate-research-guidelines/#confirmation-of-candidature-requirements) if their thesis is to be prepared in this format.

Candidates should consult their Group specific guidelines in addition to the requirements detailed below.

Candidates are also encouraged to attend the workshop (https://www.griffith.edu.au/graduate-degree-research/events/workshops) “Inclusion of papers within a thesis” offered by the Griffith Graduate Research School.

Refer also to the Griffith University Code for the Responsible Conduct of Research (http://www.griffith.edu.au/visitor/our-university/our-values-and-principles/responsibility/responsible-conduct-of-research) specifically the sections pertaining to publication ethics and the dissemination of research findings, and authorship.

Status of papers

A thesis may include papers that have been submitted, accepted for publication, or published. Some disciplines may specify a variation to the status of papers requirement, refer to your Group specific guidelines.

Type of papers

For the purpose of this requirement, papers are defined as a journal article, conference publication, book or book chapter. Papers which have been rejected by a publisher must not be included unless they have been substantially rewritten to address the reviewers’ comments, or have since been accepted for publication. Some disciplines may specify a variation to the type of papers requirement, refer to your Group specific guidelines.

Number of papers

A thesis may be entirely or partly comprised of papers. A paper may also be included as a single chapter if the paper contributes to the argument of the thesis, or several papers may form the core chapters of the thesis where they present a cohesive argument. Where a thesis is entirely comprised of papers, there is no minimum requirement for the number of papers that must be included (except as noted below) and it is a matter of professional judgement for the supervisor and the candidate.

Inclusion of papers within the thesis - Griffith University

Overall, the material presented for examination needs to reflect the research thesis standard required for the award of the degree. For example, PhD candidates, on the basis of a program of independent supervised study, must produce a thesis that makes a significant and original contribution to knowledge and understanding in the relevant field of study. This remains a matter of professional judgment for the supervisor and the candidate.

Where a thesis is entirely comprised of papers, some disciplines may specify a minimum number of papers to be included, refer to your Group specific guidelines.

Authorship

The candidate should normally be principal author (that is, responsible for the intellectual content and the majority of writing of the text) of any work included in the body of the thesis. Where a paper has been co-authored, the candidate is required to have made a substantial contribution to the intellectual content and writing of the text. Co-authored work in which the candidate was a minor author can only be used and referenced in the same way as any other research publication cited in the thesis. A signature from the corresponding author is required in order to include co-authored material in the body of the thesis, refer to the declarations section below.

For co-authored papers, the attribution of authorship must be in accordance with the Griffith University Code of the Responsible Conduct of Research (https://www.griffith.edu.au/library/policies/ethical-conduct-research-personal.html), which specifies that authorship must be based on substantial contributions to one or more of:

- conception and design of the research project
- analysis and interpretation of research data
- drafting or making significant parts of the creative or scholarly work or critically revising it so as to contribute significantly to the final output.

Some disciplines may specify a variation to the authorship requirement, refer to your Group specific guidelines.

Quality of papers

Candidates should endeavor to publish their research in high quality peer reviewed publications. Papers to be included in the body of the thesis should be published (or submitted for publication) in reputable outlets that are held in higher regard in the relevant field of research. Candidates should consult their supervisors for advice on suitable publications specific to their research discipline. Some disciplines may specify quality standards that must be met for papers to be included, refer to your Group specific guidelines.

The library also provides support and advice to candidates on choosing a journal. Candidates are advised to note in particular advice in order to avoid ‘predatory’ publishers.


Copyright

As copyright in an article is normally assigned to a publisher, the publisher must give permission to reproduce the work in the thesis and put a digital copy on the institutional repository. Information on how to seek permission is available at Copyright and Articles in theses (https://library.griffith.edu.au/copyright/articles-in-theses/).

If permission cannot be obtained, students may still include the publication in the body of the thesis, however following examination the relevant chapters will be removed from the digital copy to be held by the Griffith University Library so that the copyright material is not made publicly available in the institutional repository. Students are required to advise the copyright status of each publication included in the thesis via a declaration to be inserted in the thesis, as detailed below.

Students requiring further advice regarding copyright issues can contact the Information Policy Office (https://www.griffith.edu.au/library/policies/ethical-conduct-research-personal.html) or the Library on (07) 3735 9665 or copyright@griffith.edu.au.

Group and discipline requirements

Some Groups or Elements may specify additional requirements for including papers within a thesis, refer below:

- Arts, Education and Law
- Griffith Health
- Griffith Business

Format of thesis

General

Consult the thesis preparation and formatting guidelines (https://www.griffith.edu.au/higher-degrees-research/current-research-students/thesis-preparation/inclusion-of-papers-within-the-thesis) for general information about the requirements for formatting the thesis. Some disciplines may specify a variation to the thesis format requirements below, refer to your Group specific guidelines.

Structure of Theses and linking Chapters

The structure of the thesis will vary depending on whether the thesis is partly or entirely comprised of papers. Whatever the format, the thesis must present as coherent and integrated body of work in which the research objectives, relationship to other scholarly work, methodology and strategies employed, and the results obtained are identified, analysed and evaluated.
Inclusion of papers within the thesis - Griffith University

It is general every thesis should include a general introduction and general discussion to frame the internal chapters. The introduction should outline the scope of the research covered by the thesis and include an explanation of the organisation and structure of the thesis. The general discussion should draw together the main findings of the thesis and establish the significance of the work as a whole, and should not just restate the discussion points of each paper.

It is important that candidates explicitly argue the coherence of the work and establish links between the various papers/chapters throughout the thesis. Uniting text should be added to introduce each new paper or chapter, with a concluding paragraph which introduces the research and establishes its links to previous papers/chapters.

Depending on the context of the paper(s) and nature of research, a research methods chapter may also be necessary to ensure that any work that is not included in the paper(s), but is integral to the research, is appropriately covered. Any data omitted from a paper may also be included as an addendum to the thesis.

For further information on the thesis structure, refer to the following examples of acceptable ways to format the thesis when including papers:


Format of papers

This paper may be revised for this thesis according to the general formatting guidelines; or they can be inserted in their published format, subject to copyright approval as detailed above.

Paparization

Candidates may recognize the papers to be consistent with the thesis. However, this is at the discretion of the candidate.

Declarations

All theses that include papers must include declarations (https://www.griffith.edu.au/ahigher-degrees-research/thesis-requirements) which specify the publication status of the paper(s), your contribution to the paper(s), and the copyright status of the paper(s). The declarations must be signed by the corresponding author (where applicable). If you are the sole author, this still needs to be specified. The declaration will need to be inserted at the beginning of the thesis, and for any co-authored papers, additional declarations will need to be inserted at the beginning of each relevant chapter. You may wish to consult the declaration requirements for inclusion of papers (https://www.griffith.edu.au/ahigher-degrees-research/thesis-requirements) for more information before you present the declaration.

Flow diagram to ensure that you insert the correct information in the thesis. Please note that completion of the declarations does not preclude publication.

Examination Requirements

BIBLIOGRAPHY

A  Articles/Books


Alonso, Marta and Jo-Ann C Leong, ‘Licensed DNA Vaccines Against Infectious Hematopoietic Necrosis Virus (IHNV)’ (2013) 7 Recent Patents on DNA and Gene Sequences 62


Benzie, John AH, 'Use and Exchange of Genetic Resources of Penaeid Shrimps for Food and Aquaculture' (2009) 1(3-4) *Reviews in Aquaculture* 232


Butler, TM and Garth L Fletcher ‘Promoter Analysis of a Growth Hormone Transgene in Atlantic Salmon’ (2009) 72(1) Theriogenology 62

Caelers, Antje, ‘Expression of Endogenous and Exogenous Growth Hormone (GH) Messenger (m) RNA in a GH-transgenic Tilapia (Oreochromis niloticus)’ (2005) 14 Transgenic Research 95


Dabydeen, Donnette A, James C Burnett, Ruoli Bai, Pascal Verdier-Pinard, Sarah JH Hickford, George R Pettit, John W Blunt, Murray HG Munro, Rick Gussio, and Ernest Hamel, ‘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


Dunham, Rex A, Aquaculture and Fisheries Biotechnology: Genetic Approaches (CABI, 2nd ed, 2011)

Eisbrenner, WD, N Botwright, M Cook, EA Davidson, S Dominik, NG Elliott, J Henshall, SL Jones, PD Kube, KP Lubieniecki and S Peng, ‘Evidence for Multiple Sex-Determining Loci in Tasmanian Atlantic Salmon (Salmo Salar)’ (2014) 113 Heredity 86

Eisenberg, Rebecca ‘Re-examining the Role of Patents in Appropriating the Value of DNA Sequences’ (2000) 49(3), Emory Law Journal 783

Eisenberg, Rebecca S, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) 56(3) The University of Chicago Law Review 1017

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

Fletcher, Garth L, Ming H Kao and Ron M Fourney, ‘Antifreeze Peptides Confer Freezing Resistance to Fish’ (1986) 64 Canadian Journal of Zoology 1897

Fletcher, Garth L and Matthew L Rise, Aquaculture Biotechnology (Wiley-Blackwell, 2011)

Fletcher, Garth L, Rod S Hobbs, Robert P Evans, Margaret A Shears, Amy L Hahn, and Choy L Hew, ‘Lysozyme Transgenic Atlantic Salmon (Salmo salar L.)’ (2011) 42(3) Aquaculture Research 427


Frison, Christine, Francisco Lopez and Jose T Esquinas-Alcazar (eds), Plant Genetic Resources and Food Security: Stakeholder Perspectives on the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO and Bioversity International, 2011)


Gjedrem, Trygve (ed), Selection and Breeding Programs in Aquaculture (Springer, 2005)

Gjedrem, Trygve, 'Status and Scope of Aquaculture' in Trygve Gjedrem (ed), Selection and Breeding Programs in Aquaculture (Springer, 2005) 1


Gold, E Richard, Yann Joly and Timothy Caulfield, 'Genetic Research Tools, the Research Defence and Open Science' (2005) 3 GenEdit 1

Greer, David and Brian Harvey, *Blue Genes: Sharing & Conserving the World’s Aquatic Biodiversity* (Earthscan, 2004)


Haugen, Hans Morten, *The Right to Food and the TRIPS Agreement: with a Particular Emphasis on Developing Countries’ Measures for Food Production and Distribution* (Brill, 2007)


Hays, Ben and Øivind Andersen, 'Modern Biotechnology and Aquaculture' in Trygve Gjedrem (ed), Selection and Breeding Programs in Aquaculture (Springer, 2005) 301


160

Hew, Choy L and Garth L Fletcher, ‘The Role of Aquatic Biotechnology in Aquaculture’ (2001) 197(1) *Aquaculture* 191

Hew, Choy, Raymond Poon, Fei Xiong, Sherry Gauthier, Margaret Shears, Madonna King, Peter Davies, and Garth Fletcher, ‘Liver-specific and Seasonal Expression of Transgenic Atlantic Salmon Harboring the Winter Flounder Antifreeze Protein Gene’ (1999) 8 *Transgenic Research* 405


Humphries, Fran, ‘Patenting Genetic Material in Aquaculture: a Red Herring or an Emerging Issue to Tackle?’ (2015) 7 *Journal of Aquaculture Research and Development*, 1


Koo, Bonwoo 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


Larsen, Janet and J Matthew Roney, ‘Farmed Fish Production overtakes Beef’, Earth Policy Institute at <http://www.earth-policy.org/plan_b_updates/2013/update114>


Lawson, Charles, Regulating Genetic Resources (Edward Elgar Publishing, 2012)


Leary, David, ‘Bi-polar Disorder? Is Bioprospecting an Emerging Issue for the Arctic as well as for Antarctica?’ (2008) 17(1) Review of European Community & International Environmental Law 41


Lee, Jong Kyu, Yeon Ju Kim, Kyoung Sun Park, Seung Chul Shin, Hak Jun Kim, Young Hwan Song, and Hyun Park, ‘Molecular and Comparative Analyses of Type IV Antifreeze Proteins (AFPIVs) from Two Antarctic Fishes, Pleuragramma antarcticum and Notothenia coriiceps’ (2011) 159(4) Comparative Biochemistry and Physiology Part B 197

Louafi, Sélim and Marie Schloen, ‘10 Practices of Exchanging and Utilizing Genetic Resources for Food and Agriculture and the Access and Benefit-sharing Regime’ in Evanson Chenge Kamu and Gerd Winter, Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity Law (Earthscan 2013) 193

Mann, Charles, ‘The Bluewater Revolution’ (May 2004) 12.05 *Wired*, 2


Mullon, Christian, Pierre Fréon and Philippe Curry, ‘The Dynamics of Collapse in World Fisheries’ (2005) 6(2) Fish and Fisheries 111

Munn, CB, ‘The Use of Recombinant DNA Technology in the Development of Fish Vaccines’ (1994) 4(6) Fish and Shellfish Immunology 459


National Research Council, Committee on Antarctic and Science, Science and Stewardship in the Antarctic, (National Academies Press, 1993)


Nguyen, Tu Thanh, Competition Law, Technology Transfer and the TRIPS Agreement (Edward Elgar, 2010)

Oberthür, Sebastian and G Kristin Rosendal (eds), *Global Governance of Genetic Resources: Access and Benefit Sharing after the Nagoya Protocol* (Routledge, 2014)


Rimmer, Matthew, Intellectual Property and Biotechnology: Biological Inventions (Edward Elgar, 2008)


Sipkema, Detmer, Maurice CR Franssen, Ronald Osinga, Johannes Tramper, and Rene H Wijffels, ‘Marine Sponges as Pharmacy’ (2005) 7 *Marine Biotechnology* 142


Tvedt, Morten Walløe, 'Patent Law and Bioprospecting in Antarctica' (2011) 47(1) Polar Record 46

Tvedt, Morten Walløe, ‘Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors’ (2013) 9(2) Law Environment and Development Journal 127


Tvedt, Morten Walløe 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


Von Kries, Caroline and Gerd Winter, ‘Harmonising ABS Conditions for Research and Development under UNCLOS and CBD/NP’ in Evanson Chege Kamau, Gerd Winter and Peter-Tobias Stoll, Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol (Routledge 2015) 75

Von Kries, Caroline and Gerd Winter, ‘Defining Commercial and Non-commercial Research and Development under the Nagoya Protocol and in other Contexts’ in Evanson Chege Kamau, Gerd Winter, and Peter-Tobias Stoll, Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol (2015 Routledge) 60

Webster, Nicole S, Rose E Cobb, Rochelle Soo, Shelley L Anthony, Christopher N Battershill, Steve Whalan, and Elizabeth Evans-Illidge, ‘Bacterial Community Dynamics in the Marine Sponge Rhopaloeides odorabile under in situ and ex situ Cultivation’ (2011) 13 Marine Biotechnology 296


World Bank, Changing the Face of the Waters: The Promise and Challenge of Sustainable Aquaculture (The International Bank for Reconstruction and Development, 2007)


Young, Heather M and Garth L Fletcher, ‘Antifreeze Protein Gene Expression in Winter Flounder Pre-hatch Embryos: Implications for Cryopreservation’ (2008) 57 Cryobiology 84

B Cases

*Association for Molecular Pathology v. Myriad Genetics, Inc.* 2013. 133 S. Ct. 2107

*Bowman v Monsanto* No. 11–796, slip op. (S.Ct May 13, 2013)


*Clinical Trials II*, Bundesgerichtshof [German Federal Court of Justice], X ZR 68/94, 17 April 1997 reported in (1997) 135 BGHZ 217

*D’Arcy v Myriad Genetics Inc* (2015) 89 ALJR 924


*Madey v Duke University*, 307 F.3d 1351 (Fed Cir 2002)


*Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902


*Plant Bioscience Limited v Syngenta Participants AG Groupe Limagrain Holding* (European Patent Office Enlarged Board of Appeal, G0002/13, 25 March 2015)

*SKF Laboratories v Evans Medical* [1989] FSR 513, 518 (Aldous J)
Stena Rederi Aktiebolga v. Irish Ferries Ltd., (2003) EWCA (Civ.) 66 (Eng.)


C Legislation

Australian Antarctic Territory Acceptance Act 1933 (Cth)

Antarctic Treaty Act 1960 (Cth)

Antarctic Treaty (Environmental Protection) Act 1980 (Cth)

Antarctic Marine Living Resources Conservation Act 1981 (Cth)

Bundesgesetz über die Erfindungspatente 1954 [Federal Act on Patents for Inventions 1954] (Switzerland)

Code de droit économique [Code of Economic Law] (Belgium)

Code de la propriété intellectuelle [Intellectual Property Code] (France)

Common Provisions on Industrial Property, Commission of the Andean Community Decision 486 (14 September 2000)

Environment Protection and Biodiversity Conservation Act 1999 (Cth)

Environment Protection and Biodiversity Conservation Regulations 2000 (Cth)

Federal Food, Drug and Cosmetic Act 1938 21 USC 321

Loi sur les Brevets d’Invention 1984 (Belgium)

National Environmental Policy Act 1969 42 USC § 4321


Patents Act 1990 (Cth)

Patents Act 1970 (India)

Patents Act 1977 (UK)


United States Code Title 35 - Patents

D Treaties/Agreements/Declarations/Directives

Agreement on Andean Subregional Integration, signed 26 May 1969, 8 ILM 910 (entered into force 16 October 1969)

Antarctic Treaty, opened for signature 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961)
Charter of the United Nations, opened for signature 26 June 1945 (entered into force 24 October 1945)

Commonwealth of Australia, Gazette: Government Notices, No 6, 14 February 2007
‘Declaration of Exempt Biological Resources under Part 8A Environment Protection and Biodiversity Conservation Regulation 2000’


Convention on the Grant of European Patents opened for signature 5 October 1973, 1065 UNTS 199 (entered into force 7 October 1978)

Declaration on the TRIPS Agreement and Public Health, WTO Doc WT/MIN(01)/DEC/2 (adopted 14 November 2001)

Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, GA Res 3384(XXX), 30th sess, Agenda Item 69, UN Doc A/RES/30/3384 (10 November 1975)


International Covenant on Civil and Political Rights, opened for signature 16 December 1066 (entered into force 23 March 1976)


Universal Declaration of Human Rights, GA Res 217A (III), UN GAOR, 3rd sess, 183rd plen mtg, UN Doc A/810 (10 December 1948)
Venice Statement on the Right to Enjoy Scientific Progress and its Applications
UNESCO, Experts’ Meeting on the Right to Enjoy the Benefits of Scientific Progress and its Application, Venice, Italy, 16-17 July 2009
<unesdoc.unesco.org/images/0018/001855/185558e.pdf>


E Patents


Hew, Choy L and Garth L Fletcher, Transgenic Salmonid Fish Expressing Exogenous Salmonid Growth Hormone (United States Patent No 5,545,808, published 13 August 1996)


Saravanane Poobalane, Kim Thompson and Alexandra Adams, ‘Vaccine’ (United States Patent No. 8,257,713, published on 4 September 2012, assigned to the University of Stirling)

Satoshi Yokohama Research Center Inouye, ‘Oplophorus luciferase’ (European Patent No 1,156,103B1, published 11 August 2010)


F Other – Reports/Resolutions/Committee Proceedings


Ad Hoc Open-ended Informal Working Group, Intersessional Workshops Aimed at Improving Understanding of the Issues and Clarifying Key Questions as an Input to the


Antarctic Treaty Consultative Meeting, A Case of Biological Prospecting, Antarctic Treaty Consultative Meeting, 34th mtg, Agenda Item 17, IP 62

Antarctic Treaty Consultative Meeting, A Gap Analysis of the Antarctic Treaty System Regarding the Management of Biological Prospecting, Antarctic Treaty Secretariat, 32nd mtg, WP 26

Antarctic Treaty Consultative Meeting, 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, WP11
Antarctic Treaty Consultative Meeting, Biological Prospecting in Antarctica: Review, Update and Proposed Tool to Support a Way Forward, Antarctic Treaty Consultative Meeting, 30th mtg, Agenda Item 17, IP 67

Antarctic Treaty Consultative Meeting, Biological Prospecting in Antarctica – the Need for Improved Information, Antarctic Treaty Consultative Meeting, 36th mtg, Agenda Item 17, WP 48


Antarctic Treaty Consultative Meeting, Electronic Information Exchange System, Antarctic Treaty Consultative Meeting Decision 10, 28th mtg, Agenda Item 17 (adopted 17 June 2005)

Antarctic Treaty Consultative Meeting, Report of the ATCM Intersessional Contact Group to Examine the Issue of Biological Prospecting in the Antarctic Treaty Area, Antarctic Treaty Consultative Meeting, 33rd mtg, Agenda Item 17, WP 13

Antarctic Treaty Consultative Meeting, Report of the ATCM Intersessional Contact Group to Examine the Issue of Biological Prospecting in the Antarctic Treaty Area, Antarctic Treaty Consultative Meeting, 33rd mtg, Agenda Item 17, WP 13


Antarctic Treaty Consultative Meeting, Resolution 6 (2013) *Biological Prospecting in Antarctica* 36th mtg (adopted on 19 May 2013)

Antarctic Treaty Consultative Meeting, *The Antarctic Biological Prospecting Database*, Antarctic Treaty Consultative Meeting, 32nd mtg, Agenda Item 17, WP1

Australian Antarctic Division, ‘Guide to Administering Environmental Approvals’ (Australian Antarctic Division, Department of the Environment, June 2014)


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)

Beardmore, John and Joanne Porter, ‘Genetically Modified Organisms and Aquaculture’ (Food and Agriculture Organization of the United Nations, Fisheries Circular No. 989, FIRI/C989(3) 2003)

Bently, Lionel, 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’)


Committee on Economic, Social and Cultural Rights, General Comment No. 17 (2005): The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of which he or she is the Author (Article 15, Paragraph 1 (c), of the Covenant), 35th Sess. UN Doc E/C.12/GC/17 (12 January 2006)


Food and Agriculture Organisation of the United Nations, Technical Guidelines for Responsible Fisheries (No. 5 Suppl. 3 Genetic Resource Management, FAO, 2008)

Food and Agriculture Organisation of the United Nations, The State of World Fisheries and Aquaculture 2014 (Food and Agriculture Organization of the United Nations, Rome, 2014)


Food and Agriculture Organisation of the United Nations, Commission on Genetic Resources for Food and Agriculture, Status and Trends in Aquatic Genetic Resources: A Basis for International Policy (Background Study Paper No 37, Commission on Genetic Resources for food and Agriculture, Food and Agriculture Organization of the United Nations, May 2007)

Food and Agriculture Organisation of the United Nations, Commission on Genetic Resources for Food and Agriculture, Status of Preparation of the State of the World’s Aquatic Genetic Resources for Food and Agriculture (14th Sess, Agenda Item 5.1, CGRFA 14/13/16 (15-19 April 2013)

Food and Agriculture Organisation of the United Nations, Commission on Genetic Resources for Food and Agriculture, Status of Preparation of the State of the World’s Aquatic Genetic Resources for Food and Agriculture (15th sess, CGRFA-15/15/17, 19-23 January 2015)


Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge, 8th sess, WIPO/GRTKF/IC/8/11 (6-10 June 2005)


Laird, Sarah A, Rachel Wynberg and Sam Johnston, Recent Trends in the Biological Prospecting (Antarctic Treaty Consultative Meeting, 29th mtg, IP 116)


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

Ponzoni, Raul W, Nguyen Hong Nguyen, Hooi Ling Khaw, Azhar Hamzah, Khairul Rizal Abu Bakar, and Hoong Yip Yee, Genetic Improvement of Farmed Aquatic Animals at The WorldFish Center (Brief 2134, WorldFish Centre, 2010)

Preliminary Finding of No Significant Impact Concerning Genetically Engineered Atlantic Salmon, 77 Fed Reg. 76,050 (4 May 2012)

Rosendal, G Kristin, Ingrid Olesen, Hans B Bentsen, Morten Walløe Tvedt and Martin Bryde, Strategies and Regulations Pertaining to Access to and Legal Protection of Aquaculture Genetic Resources (The Fridtjof Nansen Institute 2005)


<unesdoc.unesco.org/images/0018/001855/185558e.pdf>


United States Food and Drug Administration, *AquAdvantage<sup>®</sup> Salmon: Draft Environment Assessment* (4 May 2012)  


Von Kries, Caroline, Arianna Broggiato, Tom Dedeurwaerdere and Gerd Winter, *Commentary to the MICRO B3 Model Agreement on Access to Marine Microorganisms and Benefit Sharing* (MICRO B3 WP8, version 1.0, 10 June 2013) <https://www.microb3.eu/work-packages/wp8>


World Health Assembly Resolution 64.5 of 24 May 2011, *Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and other Benefits* (Sixty-fourth World Health Assembly, WHA64/5, 2011) Agenda item 13.1  
<apps.who.int/gb/ebwha/pdf_files/WHA64/A64_R5-en.pdf>

WIPO Committee on Development and Intellectual Property, ‘Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels’ (Study Paper, CDIP/5/4, 5<sup>th</sup> sess. April 26-30, 2010)