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Evolving legal regimes, market structures and biology affecting access to and protection of aquaculture genetic resources

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Abstract: The maturing aquaculture sector currently faces a number of challenges relating to the objectives of sustainability, conservation, equity and access to and legal protection of genetic resources. The study investigates, through interviews, how actors in the aquaculture sector perceive their options with a view to accessing aquatic genetic material and to protecting innovations in breeding. Moreover, the study analyses how corporate strategies, technological developments, and international regulatory regimes are perceived to affect these options, building also on scientific literature and other legal and policy documents. A methodology of descriptive and explorative case study within the qualitative domain is applied for this. Included are comparisons of findings from Norwegian case studies on Atlantic salmon and Atlantic cod with similar studies on marine shrimp in India and tilapia in South East Asia and Africa.

Aquaculture is increasingly characterized by pressure toward higher production efficiency and short-term profits. Hence, actors in the aquaculture sector face emerging difficulties pertaining to affordable access to improved breeding material and technology, while also securing adequate funding for sustainable breeding programmes. Public ownership or support seems to be important measures to balance these objectives that may otherwise be hard to combine. This is particularly the case during the early phases of implementation and operation of applied aquaculture breeding programs. An alternative model with cooperative/farmers' ownership is also worth considering in many situations, particularly after the first establishment phase.

Key words: salmon, cod, access, breeding, innovation, intellectual property rights

Highlights: ► Through interviews and literature examine how actors in the aquaculture sector perceive their options in balancing access to and legal protection of aquatic genetic material ► Biology of breeding suggests that value creation results from continuous upgrading and improvement, and patenting is not useful for this as it freezes innovation ► Consolidations and privatization are drivers for increased patenting ► ► How to avoid monopolization in a globalised market; how to avoid illegal reproduction; and how to maintain affordable access to aquatic breeding material.

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1 Introduction

This study aims to examine how evolving legal regimes at international and domestic levels as well as structural and biological factors affect choices and strategies pertaining to access to and legal protection of aquatic genetic resources. Innovation, breeding and aquaculture happen under the jurisdiction of the home country where the activities are going on. Globalisation in the sense of adaptation to global markets is taking place regarding law, policy and biotechnology relevant for aquaculture. The overall topic, to which this manuscript contributes, is how biotechnology, policy and law together affect innovation in aquaculture.

A central socio-economic challenge in fish breeding is how affordable access to genetic diversity and techniques and manners of protecting innovative efforts by exclusive rights to genetic resources can be balanced in a more optimal manner to spur innovation. Fish breeders and breeding companies at all levels in the aquaculture sector need some type of legal or biological protection of their innovations and improvement of genetic material in order to ensure economic returns on their investments in genetic improvements and stimulate innovation. At the same time, breeders and farmers need affordable access to genetic material in order to produce food and to continue upgrading, innovation and breeding. How may a balance be achieved between legal protection and affordable access? The aim here is to identify actors' perceptions of needs for regulating access to aquatic genetic resources and legal protection of the results:

1. How do actors in the aquaculture sector perceive their options with a view to accessing aquatic genetic material and protecting innovations in breeding, and what are the main factors affecting these options?
2. How may a balance be achieved between access to and protection of improved breeding material? More specifically, how to encourage investments in costly breeding programmes while keeping access to breeding material affordable?

These two research questions are explored on the background of several changes happening internationally. The industry's vulnerability to fish disease and epidemics is a central biological factor that will also be discussed in this connection.

Aquaculture is one of the fastest-growing sectors of food production, and there are great expectations that the aquatic Blue Revolution may constitute the next wave for enhanced food security in the world (Greer and Harvey, 2004:25). It is hoped that a Blue Revolution may circumvent some of the flaws of its predecessor, the Green Revolution, for instance by basing productivity on a less narrow genetic base, and contributing to equitable benefit sharing. However, less than 10 per cent of total aquaculture production is based on genetically improved material (Gjedrem *et al.*, 2011). This suggests a potential for increased use of improved genetic material and improved efficiency in aquaculture production.

Existing international legal frameworks regarding both affordable access and exclusive rights have been developed for protection of innovation in other areas, notably for plant varieties and for technical non-biological inventions in the patent system. The most important property rights to results of breeding, which establishes exclusive rights to improved plant varieties, are based upon the plant breeders' rights as set out in the various editions of the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV-based national systems for protection of *plant varieties* are based on an assessment of the plant variety being considered as *new*, *distinct*, *uniform*, and *stable*, to be subject to a partly exclusive right to commercial uses.

Beside the system for protection of plant varieties in UPOV-based systems, granting patents to biological inventions has been an important step in making exclusive rights more available. Patent systems are traditionally national in scope and application. However, when negotiating the treaties leading to the establishment of the World Trade Organization (WTO), global standards for harmonisation of various aspects of intellectual property rights were taken to a global level, with increased geographical scope as a result. In addition to the WTO, the World Intellectual Property Organization (WIPO) has a mandate to strive towards cooperation and harmonisation of IPR in all member countries. Harmonized IPR regulations target all technological fields similarly, including biotechnology.

Increased applications for exclusive rights to biological material acquired from the territory of other countries became an important background for the negotiation of the Convention on Biological Diversity (CBD). The CBD has three interrelated objectives: conservation, sustainable use of biodiversity, and access and equitable sharing of benefits from use of genetic resources. The scope of the CBD covers conservation and sustainable use of wild species and improved breeding stocks, as well as equitable sharing of benefits derived from the use of the world's genetic resources.[2] This issue has been the subject of controversial negotiations over the years since the establishment of the CBD. Negotiations resulted in a Protocol on Access and Benefit Sharing (ABS) at the 10th Conference of the Parties to the CBD in Nagoya, in October 2010.[3] The tension between the overlapping and often conflicting objectives of the various international treaties is a controversial North-South issue.

Unlike plants, access to or exchange of fish genetic resources and legal protection of investments and research in aquaculture have not been addressed extensively (Greer and Harvey, 2004:5) until recent years by Rosendal *et al*. (2006), Olesen *et al*. (2007), Bartley *et al.* (2009), and Ramanna Pathak (2012).

These international rules, policies and obligations need to be transferred to the national level for them to become applicable in a direct manner among private and public parties under national jurisdiction. Therefore, when discussing law and aquaculture the main focus needs to be at the national legal level, while keeping an eye at developments in international law and policy. Since law is only one of many, and a relatively new factor driving innovation in aquaculture, it is interesting to follow up with a more detailed understanding of how the actors reflect on the needs for new legislation.

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[2] The CBD defines *genetic resources* as genetic material of actual or potential value.

[3] The Nagoya Protocol recognizes the interdependence between countries with regard to 'genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide … and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture' UNEP/CBD/COP/10/L.43/Rev.1: p. 6.

2 Methods

This study uses an interdisciplinary approach and research strategy. It includes components of biology/biotechnology, law and policy – and these three areas of research draw from their respective methodological backgrounds. Interdisciplinary research involves an additional challenge in combining different methodologies and contributing to the development of an interdisciplinary method for communicating and discussing the respective findings. We applied the same approach as described and applied by Olesen *et al*. (2007), and the outline of this paper given below also reflects our approach to this complex and interdisciplinary issue.

Section 3 explores the three main elements or drivers that are suggested to be the most crucial ones for the changes in the perceptions of the actors in relation to affordable access and protection of rights (Rosendal *et al*., 2006). We apply a methodology of descriptive and explorative case study within the qualitative domain, as this allows more in-depth understanding of factors and mechanisms through multiple observations (King *et al*., 1994). This implies drawing on written material such as reports from the aquaculture sector and legal and policy documents of relevance to the sector. The authors have monitored developments in the Norwegian aquaculture sector over several years. An important focus is the development of breeding programmes, and for this purpose relevant documentation from key actor interviews is added, both interviews carried out by Olesen *et al*. (2007) and more recent interviews of external users of Norwegian salmon as well as Norwegian actors in cod breeding. This has provided a thorough description of the various phases of the process, necessary for the detailed case study method (King *et al*., 1994).

Section 3.1 describes the use of Norwegian salmon genetic resources by foreign breeders and farmers, basically limiting the examination to salmon breeding in Chile and to the sale of the majority of the Norwegian salmon breeding programme to a multinational corporation. The other part of the structural section pertains to the use of Norwegian cod genetic resources by the Norwegian aquaculture sector. This investigation of structural factors includes considerations of various forms of ownership of the genetic resources and breeding programs (governmental, private, cooperative and multinational) and trends regarding merging and privatization. Diverging interests in access, benefit sharing and legal protection tend to be based on differences in technological and economical capacity to utilize genetic resources and on differences in holding biological diversity (Rosendal, 2000, 2006a; Raustiala and Victor, 2004).

Section 3.2 explores the biology of fish, as the importance of fish diversity may imply different perceptions of needs and interests in aquaculture compared to the plant and pharmaceutical sectors. This is relevant for the discussion about whether there is a need for a differentiated approach to ABS for various types of genetic resources (Bartley *et al.*, 2009).

In section 3.3 we rely mostly on the methodology of law. Legal analyses in these fields raise a challenge due to the fact that rules are found at two levels: the international and domestic legislation. In this field, the topic is to explore how these two legal systems interrelate. National law is binding and directly applicable for private parties. The national legal system is heavily influenced by norms at the international level. When exploring this legal area, the challenges of these two levels need to be taken into account.

For the discussion in section 4, we supplement the empirical data with non-structured and open key-actor interviews. The aim here is not to provide statistical surveys, but to explore the various arguments applied as well as perceived needs and interests among stakeholders in the sector. Applying a similar methodology as used in a previous study of the domestic salmon sector in Norway, we made a selection from individuals that are involved in fish breeding (Olesen *et al.*, 2007). The respondents represent the two cod-breeding companies that provide practically all of the roe for cod farming in Norway, one private and one public breeding programme. In addition, we interviewed three representatives from the Norwegian Ministry of Fisheries and Coastal Affairs about their perspectives on property rights and access issues concerning public involvement in breeding programmes. We conducted interviews with five foreign breeding actors, including representatives for multinational corporations and international organisations central in fish breeding, in order to attain views from the user side regarding access to improved breeding material in aquaculture. Finally, we included viewpoints from discussions spurred by our paper presentations at international conventions.

3 Developments in the structural situation in aquaculture, the biology of aquaculture species and changes in law

3.1 The Norwegian aquaculture sector in brief – structural developments

3.1.1 Foreign acquisition of farmed salmon

There is a firm emphasis on rural concerns in the Norwegian policies and history of development of industry and society in general, including in aquaculture (White Paper, 2004–2005). Public investments and ownership have been widely used to strengthen innovation in breeding and other aquaculture technologies (Liabø *et al*., 2007). The strong public engagement in breeding from the early 1970s made Norway a pioneer in technological developments (Liabø *et al.*, 2007).

Salmon farming in Chile dates back to the early 1970s when Japan and Chile started cooperating on breeding of Coho salmon and a decade later the first Norwegian company – Chisal – was established in Chile with Atlantic salmon from Norway. Most salmon breeding companies in Norway sign contracts with cooperating multipliers that propagate their genetic material for further sale to the industry, whereby the multipliers agree that the material cannot be utilised for further breeding or sold for breeding purposes. These private law agreements have not prevented the material from being acquired (without authorization) for example by breeders in Chile and other competing countries. Prior to the heavy outbreak and epidemics of infectious salmon anaemia (ISA), which resulted in closing down of the majority of the salmon industry in Chile a few years ago, the Norwegian companies Marine Harvest, Fjord Seafood and Cermaq constituted some of the most dominant owners in the Chilean salmon sector; controlling about one fourth of the Chilean salmon industry (Liabø *et al.*, 2007). Norwegian breeders still have the largest market share of stem fish, roe production and production of farmed salmon globally.

In Norway, salmon breeding programs were started with public financing in 1971 by the non-profit research institute AKVAFORSK[4] (Gjøen and Bentsen, 1997). The base populations of these programs were collected from Norwegian rivers (Atlantic salmon) and from Scandinavian farmed populations (rainbow trout). The breeding populations for Atlantic salmon and rainbow trout were transferred in 1985–1989 to 'The Norwegian Salmon Breeding Association' under the cooperative ownership of the salmon farmers' organizations.

However, as a result of an economic crisis in the late 1980s, ending with the bankruptcy of the cooperative Fish Farmers Sale Organisation, this activity was transferred to a shareholder company in 1992 (at present Aqua Gen AS).[5] At that time it was decided that the value of the breeding material should be secured in a way that took care of the public interest. The structure of ownership was therefore divided between private and public shareholders, but this structure was only bound for a five year period. At the end of that period, a different government was in charge and the largest public shareholder was turned into a private venture company[6] that in 2007 decided to sell its shares in Aqua Gen AS. The other shareholders decided to waiver their pre-emptive rights. The German EW Group, which is also the holding company of the world's leading poultry genetic companies (Aviagen), concluded an agreement to take over majority ownership of the shares in Aqua Gen AS (Fish Farmer 2007). Thus the Ministry of Fisheries and Coastal Affairs (MFCA) gradually lost control over the material from the originally public breeding programme for salmon.

Currently, the Norwegian legal system is unclear about regulating genetic material originating in the wild or coming from public breeding programmes, and hence a comprehensive management system for aquatic genetic resources is not in place. The sale of Aqua Gen AS to the German EW Group is illustrative of the dilemma. Aqua Gen had become the leading supplier of genetic material to the global salmon farming industry, with just over 35 per cent of the world market. Single genes or other inventions based on this material can now be patented; the likely consequence is that others' use of the same genes can be restricted. Through the sale to a private foreign company, Norwegian salmon farmers may end up in a situation with limited access to breeding material from Norwegian rivers. This breeding material can now in theory be patented and removed from the public domain. The development has moved from a situation of public control and ownership, via a cooperative situation, to the current situation of increasingly dominating market actors. Market dominance is often sought through internal vertical integration, controlling several parts of the chain from breeding and hatcheries to sale of finished products, with a monopoly as a possible future situation at the other end of the continuum. This raises a question about possible effects of recent Norwegian access regulations in the Nature Diversity Act and the Marine Wild Species Act.

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[4] Institute of Aquaculture Research AS.

[5] The largest owner was Verdane Capital. There is also cooperation between Aqua Gen and Norsvin and the two have established Geninova. By 2007, AquaGen had about 50 per cent of Norwegian roe production; Salmo Breed had 40 per cent, while Mowi- and Raumastammen provided the last 10 per cent (Liabø *et al*., 2007).

[6] The Four Seasons Venture, later renamed Verdane Private Equity AS.

3.1.2 Domestic cod breeding

Until the financial crisis and the extensive recession starting in Europe and USA in 2008, cod farming was increasing rapidly and the prospects looked very promising. Cod production was also growing in Canada, USA, Iceland and the Faroe Islands, but Norway has been far ahead in terms of production, breeding and technological development (FHL, 2008).[7] Farmed cod has been a rapidly growing industry in Norway; over three years the production increased from 946 tonnes in 2003 to more than 10,000 tonnes in 2006. The downside of cod farming is that, unlike salmon, cod is caught wild throughout most of the year, giving steady competition to farmed fish. Another problem is that, similar to early phases of salmon farming, the cod farming sector is plagued with disease. During the financial crisis and its aftermath in 2009–2010, the cod sector was hit especially hard. At the same time cod quotas for wild fish were increasing, causing prices to plummet (Dreyer and Bendiksen, 2010). On the positive side, before the recession there was at least a stable market that was already familiar with this product and the quotas for wild cod fish were relatively small.[8]

Capital investments in cod farming from 2000–2007 were about NOK 2 billion and the maintenance of breeding programmes is very capital intensive (FHL, 2008). The national project on cod breeding was initiated in 2001, with Nofima-Tromsø[9] as the main research actor in collaboration with the Ministry of Fisheries and Coastal Affairs (MFCA). There was also a private actor engaged in breeding, MarineBreed, with production and breeding based on genetic improvement through selection of families and also based on wild fish catches from various localities along the coast (Liabø *et al.*, 2007:77). The low demand for cod roe resulted in bankruptcy for MarineBreed (*fish.no*, 2011). The commercial prospects have gone from strenuous to almost total collapse in the cod farming sector. There is an increasingly high discrepancy between capacity and actual production in the cod farming sector (IntraFish, 2007). This situation points to the need for increased security in order for the sector to survive, with regard to secure innovation, secure access to healthy breeding material, and improved development of vaccines and medicines.

The current official goal is to retain the national cod breeding material and associated competence and knowledge bases that are being built up as a Norwegian public good asset. The end goal is not, however, to keep the breeding programme for cod within the public sphere. The official view is rather that cod, like salmon, is intended to become profitable and commercialised at some point down the line, but the legal process of how to deal with this has only just started.[10]

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[7] Intervju med NN, Research Institute, Norway 9 Juni 2009.

[8] R&D leader at Norsk Sjømatsenter, Jørgen Borthen (to *Nordlys,* 12 February 2007).

[9] Nofima-Tromsø (Fiskeriforskning) is a national research institute owned by the private Norut Gruppen AS (51 per cent) and the Ministry for Fisheries and Coastal Affairs (49 per cent).

[10] Interview with NN1, Ministry of Fisheries and Coastal Affairs, 26 August 2009.

3.2 Technological developments and the biology of cod and salmon

Deliberate or unintended inbreeding has been practised in fish breeding – often with severe inbreeding depression as a result (Bentsen and Olesen, 2002; Eknath and Doyle 1990; Kincaid et al., 1977). Fish are more complex organisms than plants and will, like other animal species, usually suffer from inbreeding depression and reduced viability if inbreeding occurs. Furthermore, genetic-improvement programs for farmed fish (referred to as breeds or stocks rather than varieties) are usually based on selection of the best-performing individuals within the population as parents to the next generation, rather than selection between populations or strains. The larger the genetic variation within the population, the better is the prospect of rapid response to selection. Consequently, genetic improvement programs for fish will aim at minimizing inbreeding and maintaining as much genetic variation as possible within the population.

Comparing salmon and cod breeding, there are a few important differences. One important difference has to do with technological and structural developments over time, as salmon is much further down the road in terms of breeding, market consolidations in the sector, and marketing compared to cod. The salmon-farming sector in Norway as a whole has a long history of being characterised by rapid market fluctuations, with accompanying rapid bonanzas and great losses. The same is true for cod and shrimp which we also examine and compare, but salmon is ahead on these parameters and we will return to this dimension as we comment upon future developments in the various sectors.

Another central difference is biological, as cod tends to mature and spawn in the sea cages, with the added risk – and added cost – this represents to the local environment. Unlike salmon, cod spawns in the sea rather than in the rivers. It is argued that escaped salmon may affect wild populations through problems related to competition, gene flow and disease transmission (Ferguson *et al*., 2007). Escaped cod may represent a more immediate problem for wild fish relatives as it may spawn in the sea cages, both in terms of possible competition and gene flow and as a source of pests and diseases (Svåsand *et al.*, 2007). Carp and some types of shrimp farming (monodon) represent similar challenges to local wild species, as they are also native to India (Ramanna Pathak, 2012). Although exotic species may also represent a threat to ecosystems, farmed tilapia seems to be regarded as less problematic in South-East Asia. GIFT tilapia originates from three African locations and has been subject to very successful breeding in Asia through the GIFT programme (Eknath and Hulata, 2009; Greer and Harvey, 2004; Ponzoni *et al*., 2010). Currently, however, the GIFT breeding material is inaccessible to African breeders, as African countries have been excluded from benefitting from the GIFT programme out of fear of genetic contamination (Ponzoni *et al*., 2010).[11] Significantly, it is only in the case of the African tilapia that this type of concern has had implications for access issues in aquaculture.

An important common biological aspect is the relatively long time interval (two to three years) between acquisition of roe and marketing of farmed fish. This makes

[11] WorldFish and the FAO are now engaged in a project in Ghana, which aims to test possible consequences of reintroduction in an organised manner. The rationale is that if WorldFish fails to do this, it is very likely that African countries will soon experience irresponsible introduction of farmed tilapia through other channels (interview, Raul Ponzoni, WorldFish, November 2009).

salmon in particular more vulnerable to market fluctuations compared to most agriculture crop production, where seeds will yield a harvest the same or following year.

Modern biotechnology is expected to increase genetic improvement of aquaculture species, and the fields expected to have most significant impact are DNA markers and transgenics (Hayes and Andersen, 2005). Furthermore, application of new tools of molecular genetics for gaining understanding about genetic regulation of complex traits such as disease resistance may be important. The recent decade's research funds have prioritized genomic research and applications in animal production, including aquaculture. However, in order to apply genomic information and molecular genetics efficiently, a sustainable selective breeding program is a prerequisite (Myhr *et al.*, 2011; Olesen *et al.*, 2011).

During the last decade, genomic research about salmon in Norway has been given great priority, through for example the FUGE research program of the Research Council of Norway. This is expected to be a strong driving force for patenting of innovations in this field. Interestingly, two salmon breeding companies in Norway (AquaGen) and Scotland (Landcatch Natural selection) did not choose to patent the QTL gene for the important and costly viral disease infectious pancreas necrosis (IPN) before they published the results (Houston *et al.*, 2008; Moen *et al.*, 2009). This may reflect that the companies at that time found it too cumbersome and demanding to enforce patent rights of such a gene. However, as this happened before AquaGen was taken over by the strong MNC EW group, patenting might still become the chosen protection strategy for a new and important QTL for disease resistance in farmed salmon in the near future. Both of the largest salmon breeding companies in Norway continue to search for different DNA markers and QTLs for disease resistance, and a representative from one of them finds it much easier to market the seeds when they can market a special feature such as genetic resistance (Olesen *et al.*, 2007).

The genomic and disease research and cod genome mapping programme have had a much shorter history compared to salmon, but QTLs are also expected to be discovered in cod, as e.g. exceptionally high heritability (0.68) has been recently reported for vibriosis (Bangera *et al.*, 2011), and research for possible QTLs is on-going. However, for most diseases many genes with small effects are likely, and for these traditional selection or genome wide selection (GS) (Meuwissen *et al.*, 2001) will be needed to improve genetic resistance, with less scope for patenting.

3.3 International obligations and domestic legislation: access, equitable sharing, conservation, and innovation

From a practical legal point of view, domestic legislation is the most directly applicable one. This does not exclude that changes at the international level can influence the behaviour of the actors in a specific area. Also the theory of law can have a motivating effect on the behaviour, in a more indirect manner.

Two main clusters of laws and norms are, as introduced above, particularly relevant: intellectual property rights and fairness-based rules of rights to genetic material, including affordable access. Since this is an area of law where national legislation affects international activities (trade, access to and transactions with resources), and national law is influenced by international harmonisation, these sets of law are at very different stages when it comes to institutional capacity and to the level of legal functionality, i.e. implementation at domestic level.

Patent law has a longstanding history of international harmonisation. When international harmonisation treaties were concluded, such as the TRIPS-agreement in 1994, these harmonisations were easily implemented as the institutional structure was already established. The already existing institutional structure makes harmonisation a relatively easy task, as the implementation of the harmonising rules happens by changes in the wording of the relevant acts.

Rights and rules on ABS were first introduced as new norms at the international level in the CBD in 1992. At the time of signing the CBD, there were no existing national or international institutions in which these rules could be integrated and made functional. This structural difference between these two regimes has only to a limited extent been recognised as an explanatory factor for understanding the lack of success of ABS in providing concrete benefits (Rosendal, 2006a, 2006b). The obligations set out in the CBD were not followed up until 2009, when the Norwegian Nature Diversity Act passed Parliament. At the time of writing (2012), the Ministry of the Environment has still not presented the administrative regulations for making the act operational between citizens. The lacking legislative, policy and institutional structures are likely to hamper implementation of the ABS norms and objectives of the CBD.

Access to genetic resources, conservation, equitable sharing of benefits, and IPR systems to boost innovation are all internationally agreed objectives – but they are not necessarily mutually compatible (Rosendal, 2006a). However, they are interlinked in that conservation is basically a prerequisite for access, innovation and benefit sharing. The essence of the CBD is to tie the utilization of genetic resources to ABS as a commercial mechanism for sharing a fair and equitable part of the benefits created by the utilization of genetic resources (GR) to purposes of conservation and sustainable use. Access to the genetic resources is a prerequisite for use and thus benefits are to be created in a short term perspective. Little innovation will take place without affordable access. Long term use and benefit creation from genetic resources presupposes conservation and maintenance of the resource base. The CBD attempts to establish a system for innovation based on biodiversity contributing in a fair manner to the long-term conservation of diversity.

IPR legislation is based on a completely different set of normative justifications. It seeks justification in spurring the incentives for innovation. (Innovation based on biological and genetic resources is important for mankind, as otherwise useful products and processes could be left undeveloped or undiscovered if innovation is stifled.) There are, however, indications that recent developments in bio-patents might have a chilling effect on innovation. This includes the potentially stifling effect from broad patent claims as access to technology will come under exclusive rights of the patent owner and increase transaction costs with respect to litigation, patent mapping and other non-innovative adverse effects (EU, 2008).

Changes in patent law to become relevant for the bio-innovative branch have mainly come from case law and not from legislators or a political desire to alter the legal system. The most comprehensive change dates back to the 1980s and a case before the US Supreme Court, Diamond v. Chakrabarty.[12] Here the United States Supreme Court concluded that 'everything under the sun' is eligible for patent protection in the USA. The case here was a genetically modified bacterium. Since the time of the Chakrabarty case in 1980, patents have been granted to innovations based on and

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[12] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

covering living organisms. Patents in biotechnology have been found to become increasingly broad and the patent criterion of inventive step has been lowered (Safrin, 2004). It has also been pointed out that patent filings are increasingly replacing journal articles as places for public disclosure, hence reducing the body of knowledge in the literature (U.S. Department of Energy Genome Project, 2010). These tendencies raise more general questions about whether patents contribute to innovation or not.

The parliament of Norway, the Storting, has on several occasions, as when accepting the EU Directive on biotechnological inventions and later when Norway joined the European Patent Organisation (EPO), expressed that these amendments were politically acceptable only if other measures were taken to counter an expansive patent system. This assumption from the Storting was given limited weight in the recent judgment on a patent to a virus and to the vaccine developed from this virus. Here a virus from Ireland and similar viruses were patented by a foreign actor. A Norwegian company developed a new and supposedly more effective vaccine based on a virus strain found under Norwegian jurisdiction. The court of appeal accepted the patent and applied a quite expansive interpretation of the protected objective despite concerns raised about whether this patent was in line with the political signals which only a few years ago were emphasized as essential in order to accept the latest changes in patent law and when giving competence to EPO on behalf of Norway. There are also other signs showing that these political signals are not given any practical weight in the execution of patent rules. The board of ethics for the patent office has received only one case and in that case the patent was granted despite their recommendation to reject it. Each small step in making the patent system stronger seems insignificant, but in sum the system is becoming increasingly strong for large actors.

The patent systems do not recognise norms outside their own logical and internal justification. Thus, the patent system as a commercial system has not been coupled with ABS as a redistributive and commercial system. The link between exclusive rights and access rules is problematic, as very limited amounts of benefits arising from utilization of genetic resources have been shared with providers. The ABS in the CBD seeks to balance expanding patent regimes by establishing a compromise between access to technology and access to the input factors in biotechnology – genetic resources (Koester, 1997; Rosendal, 2000). This interaction between different international objectives has caused North-South conflicts over access to seeds and medicinal plants versus patented technology in the agriculture and medicinal sectors (Gehl Sampath, 2005; Sheldon and Balick, 1995). This differs from aquaculture and animal husbandry, where breeding material has usually not moved from south to north. Without benefit sharing from utilisation of genetic resources, there may be less will and ability to conserve biodiversity in developing countries – although this particular dimension has less immediate relevance in aquaculture compared to the agricultural and pharmaceutical sectors (Bartley *et al.*, 2009).

Turning to domestic norms and regulations in Norway, the overall goals for aquaculture are linked to safeguarding coastal settlements and increasing value, sustainable management and innovation (White Paper, 2004–2005:9, 136). Norway acknowledges responsibility for about one third of the world’s remaining populations of wild Atlantic salmon, as well as environmental responsibilities through Norwegian-owned salmon farming and production domestically and in other countries (White Paper, 2008–2009:142). This raises interesting questions about the relationship between Norwegian utilisation of this resource and Norway’s responsibility for managing the wild material according to the CBD. At the domestic level, Norway has recently developed two relevant legal acts: The Nature Diversity Act of 2009[13] and the Act on Management of Wild Marine Resources of 6 June 2008.[14] The two acts establish similar but not identical approaches to the balance between access to and legal protection of genetic resources. The Wild Marine Resources Act grants discretion for the government to establish a procedure of governmental permission before bioprospecting of *wild* marine genetic resources, and is hence of less immediate relevance to export from breeding programmes, where the material may no longer be regarded as wild. The Nature Diversity Act establishes genetic material as a common resource that should remain a common property resource in Norway, and it also gives the Ministry the discretion to require permits for accessing genetic resources. Both Acts require the respective ministries to supplement the legislation with detailed administrative regulations for access to genetic resources, which have not yet been developed.

It is yet unclear whether the Wild Marine Resources Act includes genetic material from public breeding programmes, as the wording uses 'living in nature' as the criterion for being a common resource (Tvedt, 2010). There are several challenges that need to be overcome in the administrative regulations. One is the relationship between access to the resource and the right to use it for a patented invention. Another challenge is the link between these rules on access and rights to genetic diversity; both the domestic dissemination as well as export of fingerlings and breeding material will invariably include the genetic material – and may hence require special protection in order to secure the interests of the breeder and/or exporter to maintain these resources as common property.

Summing up, current domestic legislation does not answer the question about rights to public breeding programs or securing the rights to the breeding material when it is sold from a breeding program as part of commercialisation. This and the fish breeders' request for balancing access and protection of genetic resources are not resolved in any of the recent acts, as the administrative regulations are not yet in place.

4 Discussion and comparison across cases

In the following three sections we look at how regulatory, biological and structural factors may affect access to improved breeding material by way of encouraging (or discouraging) intellectual property rights, such as patents. Can patents spur innovation in fish breeding? Can patents contribute to increasing the percentage of farmed fish based on genetic resources from modern family-based breeding programs above the 10 per cent reported by Gjedrem *et al*. (2011)? We first explore the interaction between access issues and structural developments in terms of increased globalisation and ownership by transnational actors – looking at the balance between access and legal protection in asymmetrical relationships (small scale/large scale actors). Next, we discuss how these structural traits compare with normative and political goals for aquaculture. The third section looks into how biological and technological developments may affect the perceived needs for applying patents in this field of innovation and hence, again affect the balance between access and legal protection.

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[13] Ot.prop. 52 2008-2009 *Lov om forvaltning av naturens mangfold*. Into force July 2009.
[14] Ot.prop. 20 2007-2008. Into force January 2009.

4.1 Affordable access issues and structural developments: foreign use of salmon breeding material and globalised aquaculture

In contrast to seeds and agriculture, there have been few cases of ABS issues arising in the aquaculture sector. A simple explanation, as stated by FAO, is that '*exchange of aquatic genetic resources has generally not been from South to North as appears to have been the case in the crop sector*' (Bartley *et al.*, 2009:33). This trend is substantiated by another conclusion in the FAO report (Bartley *et al.*, 2009:33), that '*concern for compensation for providing aquatic genetic resources used in other countries has not yet been widely expressed* (p. 33).' The exchange has taken other avenues, most importantly from South to South, as in the cases of tilapia and catfish. There is also a significant channel from North to both North and South, particularly in the case of salmon (Bartley *et al.*, 2009:38; Liabø *et al.*, 2007).

In a study of the Norwegian salmon farming sector, a frequently asked question was whether Norwegian salmon breeders might lose control over breeding material, as the salmon genetic resources were shipped out to Chile, Scotland and elsewhere (Olesen *et al*., 2007). Looking at the evolving market structure, however, we find that Norwegian actors have become very dominant in salmon farming in both Chile and Scotland. This goes a long way in answering the question of how Norwegian actors may be affected by external use of Atlantic salmon breeding material. Probably not very much, as most of the export has gone to Norwegian-owned transnational companies in other jurisdictions..

This situation nevertheless raises interesting questions in a sector with a high level of global competition. As the dominant owners in the salmon sector in Chile and Norway have been largely the same, this has raised questions about their incentives to heed the warnings about high risk of rapidly spreading diseases in Chile. As salmon is produced for international markets, it is said that Chile's loss is Norway's gain – or rather the gain of transnational corporations producing in several countries, such as Marine Harvest and Cermaq. Marine Harvest was the largest producer not only in Chile, but remains so in Norway as well as in Canada (British Colombia) and is among the largest in Scotland. The loss in market shares for the Chilean export may be picked up by other parts of e.g. Marine Harvest's salmon producers. Either way, the main losers are the local workers and communities in Chile.

While the FAO report (Bartley *et al.*, 2009) reported few signs of ABS issues arising across national borders over utilisation of aquatic genetic resources, the structural developments may give rise to future access issues between small and large scale actors in the fish farming industries. That would however, seem to be at odds with central policy goals (White Paper, 2004–2005). This brings us to the next section where we examine the interaction between structural and regulatory factors.

4.2 From public-good thinking to private ownership: norms and regulations at odds with structural developments?

The breeding sectors across species are prone to rapid structural changes in response to calls for profitability and commercialization. A recurring question is what this may imply for upgraded breeding material in public breeding programmes in terms of innovation and affordable access. Do governments intend to maintain affordable access to publicly-funded breeding material and how does this correspond with the perceived needs for any legal instruments? A general problem is how to ensure that breeding programmes receive the necessary share from improved fish to keep up the high quality of the stock. The cost of maintaining a good, disease-free product is very high, but much of the profits are reaped by other actors in the value chain (Olesen *et al.*, 2007). One question is whether the market can be expected to deliver the service of high-quality breeding programmes as long as there is little value to be reaped from this phase.

The public breeding programme on cod is seen as a public good for Norwegian breeders (Liabø *et al*., 2007), and Scottish cod farmers were also given a positive response by the Ministry of Fisheries and Coastal Affairs, when asking to access breeding material. This example from cod breeding is similar to the early days of salmon breeding in Norway, which was also characterized by publicly funded breeding programmes and a normative emphasis on sharing. It is a source of worry in the cod sector that a situation similar to that of salmon may occure; that public investments end up being privatised and the breeding material less accessible. The authorities are also concerned that the public and private cod-breeding programmes should be able to compete on a level playing field, so that the programme with public funding is not given unfair competitiveness. At this early stage, it is acknowledged that it is very hard to fund a cod-breeding programme, as the economic returns from increased growth may still be a long way off. For salmon, the real growth and economic returns from the breeding program were not apparent until about the fourth generation – and cod is still only in the second or third. There are two major reasons why public funding may be the preferred solution, at least in the early phases.

First, during the early phases of breeding, basic mass selection using individual phenotypic information can provide a similar and much cheaper response in growth. This is why more advanced breeding programmes are often less profitable, particularly on a short term, as they are at least equally costly to start and run as the first generations. However, phenotype or mass selection usually has much more limited prospects for selection towards a broader breeding goal with several traits, such as disease resistance. Also, it may be more vulnerable to inbreeding, with resulting genetic erosion. Hence, in the long run, the more advanced family-based breeding programmes will become more economically and biologically viable – or sustainable (Bentsen, 1990; Gjedrem, 2005; Olesen *et al*., 2011).

Second, compared to a private breeding programme that aims at short term profit, a public or cooperative programme may have a broader range of breeding goals, including animal welfare and environmental concerns (e.g. including disease and parasite resistance). It is therefore expected to obtain apparent gains in growth rate and economic returns later than a private programme – but to give healthier and more long-term, viable fish material and hence become more sustainable. This gives a competitive edge to the private cod programme in the short run, and a competitive edge to the public one in the long run. Selection for high production efficiency in terrestrial animals is known to give undesirable effects in traits like health and reproduction (Rauw *et al*., 1998). However, in the Nordic countries broader breeding goals including functional and welfare traits have been selected for. In the long term, there are examples that this strategy has paid off. The Norwegian Red (NRF) is a high-producing dairy cattle breed in which fertility and health have been included in a selection index since the 1970s.

The case of the NRF illustrates that production and functional traits can be successfully balanced in a sustainable breeding programme (FAO, 2007). This achievement has been based on an effective recording system and a willingness to place sufficient weight on the functional traits.[15]

A short-term, profit-oriented breeding programme using intensive mass selection to increase growth only, may soon need crossing and exchange with new genetic resources. Hence, that type of breeding programme may be more vulnerable to access restrictions on genetic resources, and is dependent on the existence of other compatible breeding populations. Either way, if anyone in the public or private sector wants to stay competitive, it is essential to maintain the high quality of the breeding programme. This is very costly. Just as in an evolutionary system, continuing development is needed in order to maintain fitness relative to the systems it is co-evolving with. Adapting to future changing production systems, breeding material must also be continuously upgraded to stay healthy. As new technology is continuously developed, applications of these may also be required in order to be competitive on the market.

There is seemingly little immediate value in breeding and breeding programmes. This seems paradoxical with a view to the valuable good of faster-growing and hence cheaper salmon, which results from the breeding programs. Also here we see that the willingness to pay is small but the interest in access is paradoxically high. The problem is that bringing forth fast-growing, disease-free fish is very expensive, whereas the result can be copied at very low costs. It may seem that it is neglect of this paradoxical situation that has led to pressure towards profitability and privatisation in the aquaculture sector, including the public breeding programmes. However, the cost of maintaining a good, disease-free product is very high and the question is whether the market can be expected to deliver this service, when there is such a high degree of uncertainty regarding profits. We have seen that the dominant market actors were not able to supply this service in the Chilean case. Our cases illustrate the challenge of securing the policy goals of affordable access to genetic improvements in breeding and stimulating sustainability and innovation in aquaculture. The alternative to continued funding of public breeding programmes may mean forfeiting the normative ideal of providing improved breeding material on an affordable basis. The next section explores actor interests regarding these matters in more detail.

4.3 Actor interests in light of biology and legal options

The sale of the Norwegian salmon breeding programme raises questions about access to and further improvement of breeding material in (previously) publicly-funded breeding programmes. In a situation where such material is privatised, the authorities may choose to tie legal conditions to the acquisition. These could be in the form of obligations to maintain consideration of social, animal health or environmental aspects in breeding goals and regulations aimed at maintaining affordable access to breeding material from programmes developed by public funding (e.g. restrict patenting). The issue also relates to how the obligations under the CBD have been implemented into Norwegian legislation. The authorities seems to interpret the CBD to oblige Norway to take measures to ensure that further developments of upgraded breeding material remain in

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[15] For further information see: http://www.geno.no/no/Forsiden/Om-Geno/ and http://www.genoglobal.no/no/Home/About-Geno/

the public domain and remain accessible, and they seek knowledge regarding how to formulate and enforce such regulations based on the recent Nature Diversity Act.

Most actors are becoming more concerned with questions of access and exclusive rights to the wild and improved breeding material that is central to their trade (Olesen *et al*., 2007). While most salmon breeders are still confident of the superiority of their own breeders' lines, they also acknowledge their vulnerability, should access to new and improved materials or traits become severely restricted. There may be a future need for external acquisitions of breeding material, as new diseases turn up or new characteristics are demanded (e.g. disease resistant characteristics). The genes for such traits may be found in wild materials or other improved stocks, and failing to include such characteristics due to e.g. high royalty rates would mean rapid business failure (Olesen *et al*., 2007). For transnational corporations, the solution may be to ensure access to their entire pool of breeding material across national borders.[16] For small-scale actors it is less apparent how they are supposed to deal with these challenges, and many fear that broadly permissive patent practice may limit innovation in breeding. It is largely for these reasons that the predominant strategy among aquaculture actors studied by Rosendal *et al*. (2006) was to develop some type of tracking system for control and monitoring of contracts, rather than patenting specific products.

Several interviewees argue that due to the globalised structural tendencies towards privatisation and larger and fewer firms, the aquaculture sector may be more or less forced to follow a strategy of patenting for competitive reasons. Biologically, the aquaculture sector has been less suited to the use of IPR compared to plants; mainly for reasons of genetic homogeneity often required by IPR (including patents and the UPOV plant breeders' rights). Fish populations are not patentable and animals such as fish generally need an even higher degree of genetic heterogeneity to stay healthy and avoid inbreeding, compared to plants. Nevertheless, through the application of gene technology, IPR may also be applied to genetic resources in aquaculture. Moreover, the tendency of applying for process patents to breeding techniques observed in farm animal breeding might become relevant for fish farming. Linking back to the structural developments in the fish breeding sector, the commercial need for control of breeding material may put added pressure on the search for genetic markers, also by research institutes' management, which may again ease the patent process and add pressure in this direction. Hence, there may be a drive towards more short-term quick fixes involving molecular genetics and this might be at the expense of more long-term selective breeding technology. However, as mentioned, application of molecular technologies such as genomic selection also presupposes properly managed selective breeding programmes. The level of legal regulations may increase from two directions. First there may be increased administrative regulation of access to genetic resources from both wild and improved material; and second, granting patents to foreign companies will narrow the room for breeding and innovation in Norway.

The increased drive for patenting is not a strategy that the sector itself wishes. Actors in both the private and public sectors agree about the great value of securing free access to wild genetic resources for breeding material. Several of our interviews with actors in the private sector show that these actors realise that the real value lies in continued upgrading and improvement – and, they argue, patents are not useful for this. The protection period for a patent is twenty years. This is a long time for maintaining an

[16] Interview with NN, multinational corporation engaged in aquaculture 7 March 2011.

exclusive right in a new branch where technological development happens fast. A long-lasting exclusive right may have the effect of dampening innovation in the field. A twenty year protection period in a rapidly developing branch, hardly promotes rapid innovation in a sector where continued upgrading in a biological dynamic system is the most viable and sustainable approach. Our interviews also revealed widespread concern that evolving IPR regimes represent a constraint to future continuous upgrading and access, as this may pave the way for further monopolisation in the sector. Another interviewee held that a worst-case scenario is if a large private owner ended up controlling e.g. all Norwegian cod material. This trend is much more outspoken in other breeding sectors. In poultry, swine and dairy cattle, there has been a tremendous restructuring from many breeds and breeding programs to a few large companies dominating the global market (FAO, 2007).

On one hand, the combined biological and structural vulnerability caused by long time intervals between acquisitions and marketing, and developments in genomic technologies as well as uncertain markets, might increase the pressure for IPR in aquaculture. Moreover, common for public and private breeders is the notion that the actual enforcement of the MTAs remains uncertain and relies on trust. Hence, the private sector is now looking for ways to secure legal ownership to the improved genetic material of the breeding programme and lawyers have been contacted for this purpose. The bottom line seems to be that actors agree that there is a need to maintain balance between access and legal protection: that it is essential that breeders retain access to both wild and improved aquatic material and that the results of the public investments in breeding programmes are kept as a public good for affordable access and sustainable innovation. Nevertheless, there is a shift in thinking about the maintenance of the cod programme. As in the case of the salmon breeding programme, it is not intended to stay public forever. This illustrates the shift from public investments to private benefits from those investments; how may the public interest be secured in these situations, without depleting the incentives for private actors? The Norwegian authorities are only just starting the process of deciding on how to regulate use of this type of material, and the two relevant acts do not provide for guidance regarding non-wild material. The authorities are currently seeking solutions to future similar incidents in the aftermath of the sale of the Norwegian salmon-breeding programme to the German multinational corporation EW Group.

Whether to maintain a form of public or cooperative ownership or not is a political decision, but there seems to be a need for further discussion of whether a waiver of public control over the aquatic genetic resources in breeding programmes might go against the intentions in the most recent legislation in Norway: the Nature Diversity Act. The Nature Diversity Act establishes clear regulation of property rights or ownership to genetic material separate from that of the plants or animals where the genes are found. An immediate solution is to use the regulatory scope of the Nature Diversity Act to retain public control of genetic material in public breeding programmes, based on their character as a commons resource and as part of the public domain. While this option may no longer be applicable for salmon, it remains an option for future decisions on cod and other aquaculture species to be genetically improved in the future.

5 Summary and concluding remarks

Aquaculture is experiencing pressure towards higher production efficiency and short-term profits as well as market concentration. Hence, actors may face emerging difficulties pertaining to adequate funding for sustainable breeding programmes and affordable access to improved genetic material. Historically, aquaculture in India and Norway has mainly been based on public investments to increase production, develop and widely disseminate material to as many users as possible, rather than creating proprietary products. This illustrates the nature of breeding material as a public good.

The sale of the Norwegian salmon breeding material could have been handled differently, either by holding on to the public shares through permanent clauses beyond the five-year period, or by deciding not to sell SND Invest (former Verdane) to private actors. Several avenues can be envisaged for the public breeding programme for cod, such as keeping a permanent clause in any contract with foreign owners, which will secure Norwegian breeders affordable access to the material, which initially came from the Norwegian coast and was developed by public funding. Another policy option is to reorganise it to a farmers' cooperatively-owned or state-owned breeding program on a permanent basis.

Greater involvement of the private sector leads to stronger need for legal protection of genetic material. As this keeps knowledge out of the public domain, it is perceived to have negative implications for aquaculture. Moreover, a common concern is how to avoid the tendency towards monopolisation in a globalised market and how to maintain affordable access to aquatic breeding material. At the same time, the demand for profitability is undermining these goals.

Market consolidations and privatisation are among the structural factors that the actors themselves recognise as most important in changing the ground rules within the salmon sector (Olesen *et al*., 2007). The privatisation and commercialisation can be expected to turn the breeding goals towards only developing products for which there are economically viable markets, rather than developing new products based on social, ecological and biological criteria as well. This development has come a long way in the case of salmon, where previously public collections and publicly-funded breeding programmes and breeders' lines have now been privatised. Similar trends can be expected in the case of farmed cod. The overall structural traits of the aquaculture sector also go a long way in explaining why the aquaculture sector is much less subject to ABS conflicts between developed and developing countries compared to the plant sector. As a result of the structural developments leading to fewer and larger companies, access conflicts may be more likely to evolve between small and large-scale actors in the sector rather than between countries.

The biology of breeding suggests that the real value lies in continuous upgrading and improvement, and patents are not useful for this as they freeze innovation. The cost and time needed for obtaining a patent along with the long protection period in patent law (twenty years), hardly promote rapid innovation in sectors where continuous upgrading in a biological dynamic system is the most viable and sustainable approach. Nevertheless, similar to agriculture and pharmacy, the structural changes within the aquaculture sector seem to be much more influential than biological traits in affecting actors' perceptions of need for access and protection.

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