Chapter 6

WHO SHALL OWN THE GENES OF FARMED FISH?

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Abstract

Breeding companies need some form of legal or biological protection measures to assure revenues from genetic improvement and investment in genetic material. Fish farmers and fish breeders need access to genetic resources for food production and further development and sustainable use of fish genetic material. The objective of this chapter is to discuss the international and domestic legal processes and the needs of fish breeders in the aquaculture sector. For this we will review:

1. The rationale for ensuring access to and for using legal measures for protection of breeding materials in aquaculture

2. A Norwegian case on Norwegian salmon breeding and farming, where three dimensions that may affect choices of protection and the scope for access to fish genetic resources are considered: Awareness among fish breeders of international regulations of genetic resources; evolving structures within the aquaculture sector; technological developments and biological features presenting options and barriers

3. The options available for protection of aquaculture genetic resources in both developed and developing countries.

Introduction

Fish breeding companies need legal protection of their genetically improved broodstock to ensure revenues from their investments in breeding and genetic improvement activities. The same players may also want access to genetic resources for further improvements and innovation. The question of how these conflicting concerns can be balanced in the aquaculture industry has recently got increasing attention and interest (Greer and Harvey,
2004; Rosendal et al., 2006; Olesen et al., 2007). In this paper, we will review and discuss the present situation and alternative regulations of protection of and access to breeding material and genetic resources in the aquaculture industry.

**Background**

Until about three decades ago, genetic resources including collections of wild and improved material in publicly owned gene banks, was subject to free and open access. From a legal perspective, genetic resources were largely regarded as a Common Heritage of Mankind. This status was first challenged by the evolving Plant Breeders’ Rights regime and altered practices in the patent system. New biotechnologies have increasingly allowed innovations in breeding and genetics to fulfill the criteria for patent protection (Bent et al. 1987; Crespi 1988). As a consequence, there has been a shift away from the view that genetic resources are common goods and towards a situation where it is regarded as a commodity that can be privatized. At the same time it has raised concerns about misappropriation, where the intellectual property system (IP) using patenting facilitates appropriation of resources and knowledge of rural communities and developing countries. Such “bio-piracy” has been described as today’s form of colonialism (Merson, 2000; Martin and Vermeylen, 2005).

In response to this development, the Convention on Biological Diversity (CBD, 1992) introduced national sovereign rights to genetic resources as an attempt to compromise between primary owners and users of these resources (Rosendal, 2000). A parallel process produced the Trade-Related aspects of Intellectual Property Rights1 (TRIPS) agreement under the World Trade Organization (WTO), with the main objectives to harmonize, strengthen and expand the scope of intellectual property rights (IPR) protection in all technological fields. This includes biotechnology and new or improved breeding and selection methods as well as genetic engineering. TRIPS is said to promote innovation by establishing exclusive private rights to **inter alia** genetic resources through intellectual property rights, while the CBD aims at balancing the skewed distribution of biological resources and biotechnology between the North and the South (Rosendal, 2001; 2006). Besides the existing international legislation on patent law under the World Intellectual Property Organization2 (WIPO), there are also ongoing negotiations in the Standing Committee in the WIPO for an even higher degree of international harmonization in this field (Tvedt, 2005a, pp. 311-344). In response, access regulations have been proliferating, especially among biodiversity rich, but less industrialized countries of the South.

Norway played a leadership role in the international negotiations that led to evolving norms and regulations for access and benefit sharing of genetic resources within the framework of the UN Convention of Biodiversity (CBD). Furthermore, Norway is among the first developed countries to embark on a legislative process for regulating access to these resources. According to the CBD, Norway is also responsible for the management of half of

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1 For details, see http://www.wto.org/english/tratop_e/trips_e/trips_e.htm
2 The World Intellectual Property Organization is a specialized agency of the United Nations. It is dedicated to developing a balanced and accessible international intellectual property system, which rewards creativity, stimulates innovation and contributes to economic development while safeguarding the public interest. See http://www.wipo.int/about-wipo/en/what_is_wipo.html.
the world population of Atlantic salmon. Here we will therefore present a Norwegian case while also discussing it in wider global perspective where appropriate.

**Norwegian Case**

An interdisciplinary research team combining legal analysis, biology and political science studied the possibilities for regulating the access to genetic resources used in aquaculture (Rosendal et al., 2006). The same research team also studied the strategies of the aquaculture industry and the national and international regulations in the field (Olesen et al., 2007). This was carried out by interviewing central players within Norwegian salmon breeding and farming to study their needs and considerations with respect to such regulations. Three dimensions affecting options for access and protection of fish genetic resources were considered:

- Evolving regulations and results from interviews
- Changing structures in the aquaculture sector
- State of the art of biological and technological developments

**Relevance**

The topic is particularly relevant in Norway these times, because access legislation is now in the process of being developed. Today the question of property rights to genetic resources, other than intellectual property rights, is not solved in Norwegian legislation. A government appointed Expert Committee on Biodiversity proposed a new Act for Nature Diversity stating that **genetic material** is a **common resource** open for everyone to use (NOU, 2004). This entails that there are no exclusive property rights to genetic material, save when the terms for intellectual property rights are fulfilled. If these principles become part of the forthcoming Nature Diversity Act, then genetic resources in Norway can be said to be in a **public domain**.

However, the more recent Wild Marine Resources Act (of 6th June 2008) (NOU, 2005) demands that any utilization of marine genetic resources must go through a procedure involving the Ministry of Fisheries. However, neither the proposition nor the Wild Marine Resources Act discusses the balance between exclusive rights and access to genetic resources. Still in 2008, the question of property rights to genetic resources, other than intellectual property rights, is not solved in Norwegian legislation.

Furthermore, the issue is of current interest in Norway due to the rapidly growing aquaculture industry with particularly valuable genetic material of salmon and rainbow trout. Also, farming of Atlantic cod is now growing rapidly in Norway, and other new species (halibut, scallop etc.) are underway.

Biodiversity represents one of our most valuable resources, although this value is still hard to quantify in economic terms. Greer and Harvey (2004, p. 28) argue that “variations among wild salmon stocks will become increasingly important to the relatively new aquaculture industry as fish farmers continue to look for desirable characteristics to introduce into cultured species”. In addition, the already improved Atlantic salmon genetic material represents a valuable resource for Norway, and has been one of the most important

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1 Norges offentlige utredninger (Norwegian Governmental Reports) NOU 2004:28, pp. 526, 634
contributions to the strong competitiveness of Norwegian salmon on the world market. The Norwegian salmon stocks, including the wild stocks, constitute valuable genetic resources that can be further developed and utilized. From this it follows that access to both wild and improved genetic resources are valuable.

Norway implemented the EU Patent Directive (Directive 98/44/EC) in 2003. Exactly what a patent under this legislation grants an exclusive right to remains to be seen, as this has not been legally tried in Norway. It also remains to be seen how patent practice will develop.

Concerns have been expressed that the Norwegian aquaculture industry may become dependent on external companies and must pay royalties for using interesting salmon genetic material originating from Norway (Gjerstad, 2000; Fish Farming International, 2000). For instance, commercial breeders may find a useful gene in a wild salmon stock, patent an isolated or modified expression of this material, and go on to demand monopoly prices from other companies that use that gene or knowledge about the gene. Patenting of genes by Norwegian players was presented as the solution to this problem. In such a scenario, commercial actors may obtain wild genetic material free of charge, due to the legal status of genetic resources being common resources according to the draft Nature Diversity Act or due to the lack of access regulation.

Recently, the majority of the shares (50.2%) of Norway’s Aqua Gen, which is the world’s largest salmon breeding company, were purchased by Germany’s EW group. The EW group is the largest player in poultry genetics. The purchase was approved by the Norwegian authorities, but was heavily debated (see www.intrafish.no on i.a. January 18. 2008). The opponents held the Norwegian Seafood Federation responsible for selling a strategic important company out of the country. They were concerned that the German company will patent the genetic material developed by Norwegians and that Norwegian fish farmers have to pay high royalties to use the fish material in the future. Irrespective of patenting, Norwegian salmon multipliers and farmers may have to pay higher royalties for roe and seed from the externally controlled Aqua Gen in the future.

**Survey of Norwegian Players in Fish Breeding and Farming**

Olesen et al. (2007) reported that the Norwegian players in aquaculture were not very familiar with the evolving national and international norms and regulations on intellectual property rights to genetic materials or with the evolving access regulation regimes. Those who did recognize the emerging regimes, clearly stated that there must be a balance between intellectual property rights (IPR) and access regulations to prevent that vast genetic resources currently shared are being controlled commercially by a few companies. Their experiences were that these regulations were highly complex and currently of low relevance for most players in fish breeding. Furthermore, strict regulations were considered to severely limit the developments in this field, because few players has the size and economic strength to pursue key patents and thus limit and possibly exclude activity by the many small and economically vulnerable players in the sector today.

Market consolidations and privatization are among the factors that the companies themselves recognized as most important in changing the ground rules within the sector. Even though the similar history of the plant and agricultural sector does not seem to have a high visibility among the relevant players, most are becoming more concerned with the questions
of access to and protection of the wild and improved breeding material that is central to their trade. This realization is predominantly linked to external use of Norwegian salmon genetic resources, as most breeders are still confident in the superiority of their own breeding lines. Nevertheless, the breeders also acknowledged their vulnerability, should access to new and improved materials or traits become severely restricted.

**Alternative Biological and Legal Protection Mechanisms and How to Balance Access Regimes**

The legal protection of the use of genetically improved plant varieties has been regulated through Plant Breeders Rights within the International Union for the Protection of New Varieties of Plants (UPOV). Plant breeders’ rights are based on characterization of new, distinct, uniform and stable varieties, i.e. phenotypic and/or genetically uniform populations. Access or exchange of fish genetic resources and forms of legal protection of investments or research on these resources in aquaculture have, however, not been addressed extensively (Greer and Harvey, 2004), although there are important differences between plant and fish populations in terms of phenotypic and genetic characterization. Plant populations, and in particular commercial plant varieties, are often formed as a result of homogenizing processes like inbreeding and vegetative propagation. Accumulation of inbreeding does not seem to impair the viability and performance of plant populations as it normally does in animal populations. Breeding programs for fish normally aim at minimizing inbreeding and maintaining genetic variation within the population. Hence, the populations will not be uniform and stable, but variable and evolving from generation to generation.

Legal and biological aspects relating to various options of biological and legal protection of aquaculture genetic resources are discussed by Rosendal et al. (2006) and Olesen et al (2007). Until now, most animal breeding programs have relied on various biologically based strategies to encourage the users of their genetic material to deal directly with the program.

**Biological Protection Strategies**

The most common strategy in aquaculture breeding programs is continuous upgrading of the genetic quality of its material to maintain competitive power and hence make the customers come back regularly for new purchases. Still, the buyer may, of course, reproduce the material without the knowledge of the supplier, and it will have to be considered as de facto free-access material. Hence, it will be difficult for a superior program to gain a large competitive advantage, since other programs may hitchhike (though with some delay) on its genetic progress. This may increase the focus by the breeding programs on marketing and service/support rather than on increasing the genetic progress.

Crossbreeding and hybrids are widely applied in many plant species, because it is relatively easy to produce a large number of inbred lines and to identify crossbreds that express significant heterosis effects. The heterosis effects will be gradually lost in progeny generations, and denying access to the parent lines will protect them from piracy. In aquaculture breeding, applied crossbreeding programs are however scarce due to problems
with inbreeding depression and high costs of developing/keeping parent lines and combining crossing and selection.

Use of sterile fish in aquaculture will prevent unauthorized propagation efficiently. In several aquaculture species, applicable methods based on polyploidy are available for commercial-scale propagation of sterile production animals (Pepper, 1991; Sutterlin and Collier, 1991, Felip et al., 2001, Nell, 2002). These are routinely used in some production systems today (Bonnet et al., 1999; Nell, 2002) to avoid problems with sexual maturation and spawning. The methods have not been widely applied in salmon farming due to consumer skepticism to chromosome manipulated organisms and undesirable side effects of triploidy on productivity (lower growth and yields as reported by O’Flynn et al., 1997).

Legal Protection Strategies

Legal protection measures include branding, material transfer agreements (MTA), patenting, and a *sui generis* system for aquaculture. Traditionally, the approach for seeking legal property rights for genetically improved populations of fish has been to register product names and trademarks. Strictly, this will not protect the genetic material from being propagated and used by outsiders, but only prevent unauthorized use of the registered name. Branding can be combined with additional measures such as biological protection strategies like continuous upgrading or crossbreeding of the material, or with high quality management of the seed production process, good customer support and services, and high profile information and marketing strategies. Then the customers may find safety and production benefits from returning to the branded sources. The Norwegian players referred to by Olesen et al. (2007) seemed to conceive this strategy as the most relevant for the current situation although it does not hamper access to genetic material for further research and development unless it is combined with MTAs.

Private legal contracts (Material transfer agreements; MTA) between seller and buyer have traditionally been the most common means for regulating trade and transfer of livestock. Here, the breeding program supplies the user with genetically improved broodstock or seeds, often via a multiplier, on conditions involving e.g. financial returns to the breeding program and limitations on the use of the material. Possible financial benefits arising from a successful and competitive strategy in the breeding nucleus may be partly channeled back from multipliers through a contracted royalty fee on each egg or juvenile sold. However, the experience with this type of MTAs among some of our respondents was mixed. There have been problems with control, enforcement and monitoring of the terms of the agreements with the multipliers, and instances of contract violations have occurred. One problem seems to be the difficulties in tracing and verifying the number and origin of marketed seed. Another challenge is that it is only legally binding for the two parties signing the agreement and not for any third parties. To secure investments in breeding, this approach must be combined with strong rules on restricting further distribution of the material and improved tracing opportunities.

Patenting is one of the strongest protection measures. To be granted a patent, the invention must fulfill the patent criteria; it must be regarded *novel*, involve a sufficient level of *inventive step* and have a use (*industrially applicable*). The invention to be patented may entail either a product or a process related to biological material. If the process combines a biological process
only with a very low level of technological, non-biological knowledge, it can also be patented. This will probably be the most common case for patents in the fish breeding sector, as the pure biological processes, such as selection and crossbreeding, will be known to everyone and thus form a part of the prior art. One reason why patents have not been applied extensively to the aquaculture sector might be that it is difficult to fulfill the patent criteria. This might be due to lack of knowledge about which gene variants or genotypes are present in superior animals. Genes may directly or indirectly be patented through e.g. patents on a gene sequence, major gene affecting an important trait, a genetic marker, a method for identifying a genetic marker or a transgenic animal. A scan of Norwegian fish patents in 2007 only revealed three such patents, one involved a genetic marker for disease resistance (Patent NO 317342) and two on transgenic fish (patent NO 321650 and application NO 20064420) (Olesen et al., 2007). Thus, increased knowledge about the genome of each fish species will increase the applicability of the patent system for protecting the commercial use of such knowledge. Gene technology may reduce the barriers to patenting inventions, but has so far not been much applied in animal breeding in spite of high expectations for a long period. Another problem with patenting genes in breeding populations may be the long time from application to granting a patent, while there is a continuous genetic improvement from selection programs. For species with short generation intervals, a moderate non-recurrent genetic improvement by a gene exchange or transfer may be passed over by a couple of generations of selection in a modern breeding program. Hence, patents affecting the fish breeding options severely may either be related to genes with large effects on important traits, as e.g. patents on the gene itself or on technical processes on selecting for such genes, (via e.g. marker genes linked to it, so called marker assisted selection, MAS). For instance, high rates of royalties for getting access to a gene variant (allele) or for using a technology for selecting for (increasing frequency of) the allele may prohibit other smaller breeding companies from choosing specific efficient breeding strategies (e.g. MAS). The MAS technology may also be of temporary value if it concerns only one specific gene, because it will be irrelevant when the favorable gene variant eventually reaches fixation in the target population. Patented transgenic fish must also show long-term competitive benefits with respect to consumer price (production cost) and product quality in order to affect breeders’ options for access and protection significantly. If so, transgenic technology will facilitate protection through patenting in the same way as other gene technology mentioned above.

The risks of the patent law in the traditional breeding with competition between patent holders and traditional breeders have also been focused (Noiville, 1999, Rye, 2000). For example, a company may sell genetically modified animals without the breeders’ permission to use their genetic material (breed, strain or stock). Other problems arise from very broad patents (further discussed below). Rye (2000) also stressed the problem of the lack of legal mechanisms for sharing the benefits between a patent holder and the breeder or owner developing the fish population from which the patented gene or animal originated. From an ideal perspective, the scope of the protection should encompass all that the inventor has added to the state of the art, but nothing more. If it covers more than the addition to the state of the art, the patent protection is too broad. It is assumed that broad patents may severely hamper access to breeding stocks, as this will make its use too costly for smaller companies. Similarly, if there are many patents in one field of technology, it may become difficult and costly for new inventors to obtain licenses from all patent holders. Such practical and monetary obstacles may hinder the development of new inventions in a technical field. The
problems of misappropriation resulting from patenting, bio-piracy and practice of patenting of spurious “inventions” with lack of novelty and inventive step has also been addressed by Hoare and Tarasofsky (2007). These authors concluded that it will be difficult to design patent rules that are effective in preventing misappropriation of genetic resources until fundamental debates on the role and scope of the IP system are concluded. Should an IP system be a tool to ensure equitable practice, or is this outside the scope of such system? They also raise fundamental questions to the recent trends with broadening in scope of patents, lowering novelty requirements and advances in technology and what kind of products should be patentable. It is suggested that other policy instruments than disclosure of origin of the genetic resources may be more effective in ensuring equitable benefits while not hindering access and research. Other options such as use of existing legal principles within the patent law (doctrine of “unclean hands”, rules on inventions that are contrary to ordre public and morality, raising the bar with respect to the degree of innovation required by an inventor) and other mechanisms (e.g. use of competition law, international legal cooperation and some kind of a liability regime).

Patenting has also been recommended as a preventive strategy to prevent others from patenting the same invention (Fish Farming International, 2000; Gjerstad, 2000). This is, however, a costly and by no means secure strategy. To publish the new invention or new knowledge may be a better strategy, as it brings the knowledge into the public domain and thus prevents others from patenting it. The use of patents in a breeding program is a very costly process, both in terms of achieving and enforcing the patent. This strategy may be best suited for larger companies within a technological sector.

Even if the patent system is applicable for the fish breeding sector and facilitates the strongest protection, there are essential legal and biological barriers linked to patenting as a strategy for securing investments in fish genetic improvement programs. Gene transfer and other gene modifications could provide a strong protection mechanism to aid enforcement, but this strategy is hardly compatible with restrictive Norwegian and some EU-countries’ views on genetically modified animals.

Romstad and Stokstad (2005) discussed market power and patenting of genetic resources. When the degree of monopoly increases as a result from patenting, the possibility to provide the products for a price larger than the production cost increases. Furthermore, the use of market power and cost of exclusion can make private provision less efficient than an ideal public provision.

There are still no Animal Breeders’ Rights similar to plant breeders’ rights (PBR) in the UPOV system. There are however international processes looking at such possibilities. The difficult question is how such a system could be designed. The major danger in this process is that such a system would borrow or use experiences from the plant sector without taking sufficiently into account the special features of the fish breeding and farming sector. As mentioned, most fish breeding systems are dependent on heterogeneous populations and hence unsuited to fulfill the plant breeders’ rights criteria of new, distinct, uniform and stable. Perhaps this reflects a need for a specially adapted type of intellectual property system for aquaculture breeds. In legal terms this is called a sui generis system. Such a system should address such issues as what can be protected, criteria for obtaining protection and the extent of exclusive rights that can be obtained.
Other Protection Methods

Trade secrets are also used to protect inventions. Trade secrets do not guarantee an exclusive right in a similar manner as does a patent. Because the product (the commercial seed) in aquaculture may usually be copied without knowledge about the trade secrets, simply by growing and reproducing the animals, secrecy about the procedures will not alone provide exclusivity to the genetic material resulting from the activities.

Trade secrets with large effects are bound to attract attention and attempts at copying, and competitors may even patent the leaked secret. Altogether, trade secrets are a rather insecure strategy to ensure a monopoly right in the aquaculture context.

Another method to get control of external markets is heavy lobbying through high level channels in governmental agencies in the target country to introduce specific mandatory requirements to the organisms used in aquaculture. One recent example involving crustaceans is the requirements established by several Asian countries of allowing introductions of only Specific Pathogen Free (SPF) (Lightner, 2005) certified stocks of shrimps, which in consequence “monopolies” these markets to few companies offering SPF certified stocks. This happens in spite of the fact that the SPF status is strictly limited to pathogens listed in the actual SPF list used for certification, and that it does not provide information about the animals’ genetic qualities for any trait, including its ability to resist pathogens that the animals encounter in the new production environments. Hence stocks with strong innate resistance to relevant pathogens may be excluded from the new markets due to lack of SPF status.

Enforcement

A critical issue for enforcement of many protection methods is the possibility to control illegal use and document the origin of e.g. fish produced or reproduced illegally. Rosendal et al. (2006) described different methods based on gene technology and molecular biology, and concluded that DNA fingerprinting/profiling and certificates of origin were considered the most relevant for documenting the origin of fish reproduced illegally. Consumers’ demand for traceable products may give food products a competitive advantage if they can be traced back to breeding programs with a documented practice that is conceived as clean, natural and environmental friendly. In an international context, national regulations that ensure traceability all the way back to the breeding nucleus may also increase the competitiveness of the national industry. To be accepted as reliable, certificates of the fish origin need to be verifiable. For this purpose, tracing by DNA fingerprinting may be a feasible technology. It would require that tissue samples are collected, frozen and stored from all commercial broodstock in the breeding nucleus and at the hatcheries. If the certificates include information about the genetic origin of the broodstock used to produce the commercial seed, verification by DNA fingerprinting would be affordable, because a limited number of tissue samples need to be analyzed. The trace system may then be used to ensure that the breeder receives royalties according to the material transfer agreement for the use of their brood stock. It may be relatively easy to establish such a system on the national level, but an international system will be rather challenging to initiate and enforce.
Conclusion

A most significant finding is that there is a discrepancy between the knowledge of farmers and breeders with respect to access and legal rights to genetic resources and the actual possibilities and limits offered by today’s and forthcoming legislation. In order to maximize the aquaculture industries’ potential, there is an evident need for information about access and legal rights to genetic resources. A possible public domain regulation will likely increase the possibility for access to wild genetic resources.

The predominant view in the Norwegian aquaculture industry is that the sector needs to find a balance between access to breeding material and protection of own innovations in fish breeding. Coupled with this view is an emerging realization that the value of improved breeding material is invariably underestimated, leaving the farmers (during the peaks in the market) to reap most of the added value from fish breeding and farming.

Against this background, an interest in finding some way of capturing the value of the improved stocks is emerging among the fish breeders. During an evaluation of protection mechanisms, it can be concluded that all face different problems in finding a balance between verification and feasibility (strong and not too costly protection) on the one side and access for other breeders and maintaining genetic variability on the other.

References


