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The Aquadvantage Salmon: Who Owns Escaped Genetically Modified Animals?

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THE AQUADVANTAGE SALMON: WHO OWNS ESCAPED GENETICALLY MODIFIED ANIMALS?

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I. INTRODUCTION

It is likely that the last Atlantic salmon you ate was not caught from the depths of the Atlantic Ocean. In fact, it is highly probable that the salmon was never caught at all. The vast majority of Atlantic salmon sold in the United States is "farm raised" salmon, which are salmon that never swim freely in any body of water other than a fish pen.[1] This system of fish farming is known as aquaculture. The global production of salmon, which exceeded one million tons in 2008, is the top aquaculture money maker.[2] Moreover, aquaculture accounts for seventy-three percent of global salmon production.[3] Aquaculture allows for greater control of production and also helps deter the overfishing of already fragile wild Atlantic salmon populations.[4] Increasingly, however, the aquaculture process has been subject to criticisms relating to the prevalence of disease and sea lice in its products, the frequency of

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1. U.N. FOOD & AGRIC. ORG., FISHERIES AND AQUACULTURE STATISTICS: AQUACULTURE PRODUCTION 48 (2008), http://www.fao.org/docrep/013/i1890t/i1890t.pdf [hereinafter FISHERIES AND AQUACULTURE STATISTICS].

2. *Id.* at 28; CABI INT'L, ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS: VOLUME 3, METHODOLOGIES FOR TRANSGENIC FISH 70 (Anne R. Kapuscinski et al. eds., 2007).

3. FISHERIES AND AQUACULTURE STATISTICS, *supra* note 1, at 48 (data as of 2008).

4. Dams, in particular, have devastated salmon populations throughout the United States to such an extent that the International Union for Conservation of Nature (IUCN) has placed Atlantic salmon on its "Red List" for threatened animals; the species is extinct from most New England rivers, and the species was added to the federal Endangered Species list in 2000 for the few remaining rivers in Maine in which a salmon population still exists. *See* INT'L UNION FOR CONSERVATION OF NATURE, SPECIES SURVIVAL COMM., SALMON AND CLIMATE CHANGE: FISH IN HOT WATER, IUCN RED LIST OF THREATENED SPECIES (2009), http://cmsdata.iucn.org/downloads/fact_sheet_red_list_salmon.pdf.

species escape, and the creation of "dead zones" from highly concentrated waste.[5] Additionally, there is a growing awareness that the antibiotics used on farmed salmon may not be healthy for human consumption.[6] More significantly, the depleted state of wild fisheries places increased demand on the production capacities of aquaculture.[7] In order to make salmon aquaculture a more viable and productive business, scientists have begun creating genetically modified (GM) Atlantic salmon with various traits.[8] With the production of the AquAdvantage Salmon (AAS), which grows up to four times larger than traditional Atlantic salmon because of the introduction of growth hormone genes from other fish, AquaBounty Technologies (AquaBounty) has been at the forefront of genetic modification in Atlantic salmon.[9] AquaBounty markets the AAS as a panacea for fish farming issues and global protein shortages.[10] The patenting and production of GM salmon, however, presents a number of potential risks, including food safety, market dominance over a very important food source, and various property issues resulting from AAS escaping and cross-breeding with wild salmon. This last consideration is the focus of this comment.

If AAS escapes and either out-competes the native salmon populations or mates with them and forever alters their genetic makeup, then this will result in a showdown of competing legal interests. Conventional Atlantic salmon fishermen (hereinafter non-GM fishermen) and public stakeholders in wild Atlantic salmon have certain property

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5. *See generally* Bill Trotter, *Pesticide Use, Lobster Deaths Probed in Down East Waters*, BANGOR DAILY NEWS, Jan. 7, 2011, http://new.bangordailynews.com/2011/01/07/business/pesticide-use-lobster-deaths-probed-in-down-east-waters/?ref=relatedBox (covering not only harm to lobster populations, but also the wider Atlantic Ocean environment).

6. *Id.*

7. *See* U.N. FOOD & AGRIC. ORG., FISHERIES AND AQUACULTURE: FISH FOR FOOD, LIVELIHOOD AND TRADE (2009), ftp://ftp.fao.org/docrep/fao/011/i0765e/i0765e09.pdf ("If overall production is to keep pace with an expanding world population, and given the strong likelihood that capture fisheries will remain stagnant, future growth will have to come from aquaculture.").

8. CABI INT'L, *supra* note 2, at 77-79 (mentioning the following possible GM traits: growth enhancement, disease resistance, cold tolerance, metabolism (i.e., creating fish capable of consuming plants), sterility, saltwater tolerance, and environmental monitoring (e.g., fish that change color when levels of certain chemicals are present in the water)).

9. Transgenic Salmonid Fish Expressing Exogenous Salmonid Growth Hormone, U.S. Patent No. 5,545,808 col.5 ls.12-15 (filed Aug. 13, 1996).

10. AQUABOUNTY TECHNOLOGIES, INC., ENVIRONMENTAL ASSESSMENT FOR *AQUADVANTAGE*® SALMON 12 (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf.

interests based on the public trust doctrine. Biotechnology companies, such as AquaBounty, arguably have a more discrete and enforceable property interest based on their patent of AAS. Few parties dispute AquaBounty's right to protect and produce its patented fish so long as the fish remain in AquaBounty's production sites. But what will happen if AquaBounty's fish escape into the wild? No case law definitively resolves this question. This paper, therefore, relies on an analogy to case law addressing the capture of wildlife and patent infringement of GM plants. Because the factual details in these two areas of GM plant law may differ from those in the GM animals context, the following hypothetical escape scenario is offered as the factual foundation of a potential lawsuit against non-GM fishermen for infringement of an AAS patent:

> The AAS has been mass produced at a number of New England aquaculture sites with great success. One night, however, the combination of a power outage and a huge storm compromises a low containment system at an aquaculture site. A number of AAS escape and populate the surrounding area. Resulting generations, which may be wild-AAS hybrids or simply second generation AAS, express the same genes for increased growth and cold resistance that AquaBounty patented in AAS. After a couple of years, the AAS fish farm discovers that its revenues have been decreasing by a small margin and traces this decrease to greater competition at a local fish market. After sending an experienced AAS representative to the market, the fish farm realizes—based on anecdotal evidence from the fishermen and increased growth characteristics of the fish—that these fish are likely wild-AAS hybrids. The representative buys some of the fish and discovers that they contain the patented genes of AAS. AquaBounty, which has a license with the fish farm to maintain its intellectual property rights in AAS, sues the fishermen for infringement. At trial, the fishermen discover that there is no such thing as an "innocent infringer" and find themselves responsible for damages to AquaBounty for lost profits.[11]

Two major issues must be addressed: How can non-GM fishermen protect their property interests in native salmon given the threat of escape in a pre-escape market? How should property rights be determined in a post-escape market?

11. *See* 35 U.S.C. § 284 (2006).

This Comment explores these two questions through the lenses of wildlife law and patent law. Part II looks to the AAS itself and answers many of the questions about how it is produced, how it is contained, and how the current production and containment systems will change significantly when the focus moves from research and development to large-scale production for consumption. Part III looks to traditional legal concepts of property ownership in wild animals and shows how the traditional concept of capture, when applied to the unique circumstances of GM animals, leaves more questions than answers about how to determine possession of AAS. It then explores the public trust doctrine as an alternative means of protection for non-GM fishermen. Part IV shows how the existing state of GM patent law favors biotechnology companies over non-GM farmers and fisherman, whether or not they intend to infringe the GM organism patent. Finally, Part V concludes that this uncomfortable relationship between these two traditional approaches to property law and GM animals requires judicial and legislative adjustment to provide for equitable treatment of non-GM fishermen subject to unintentional infringement suits. It also offers three existing pre-escape remedies to act as preemptive measures against possible infringement suits and one post-escape response to infringement suits.

II. An Overview of AAS and Issues of Escape

A. The AquAdvantage Salmon

The AAS is a genetically modified Atlantic salmon with growth characteristics not found in wild or traditional farm-raised Atlantic salmon.[12] A chimeric gene is created by combining an Ocean Pout antifreeze protein (AFP) promoter with Chinook salmon growth hormone (GH).[13] This chimeric gene is then "microinjected into fertilized,

12. '808 Patent, col.5 ls.11-12.

13. *Id.* cols.4-5 ls.67, 1-3. The Chinook GH increases the growth rate of the AAS. Use of the Ocean Pout AFP promoter allows the AAS to continue growing in cold temperatures that would hamper or completely stop growth in traditional wild salmon. *See* Pew Charitable Trusts, Future Fish? Issues in Science and Regulation of Transgenic Fish 8 (2003) ("The ocean pout's promoter tells the genes linked to it to stay 'on' in cold temperatures—a factor critical to the ocean pout's ability to survive in its arctic habitat. Unmodified Atlantic salmon normally produce very little growth hormone in colder temperatures. Placing the salmon's growth hormone gene under the control of the ocean pout's cold tolerance promoter, however, causes the salmon to make growth hormone year-round and to reach market size in half the normal time." (citations

nonactivated Atlantic salmon eggs."[14] The result is a transgenic fish that allows AquaBounty to manipulate both the phenotypic and genotypic characteristics of the salmon and pass these traits on to later generations.[15] The changes in growth are astounding. The AquaBounty patent application claims that "[a]t eight months old, the average increase of the transgenic fish was 4-fold and the largest transgenic fish was eight times bigger than the non-transgenic controls."[16] According to AquaBounty, this is the largest increase in size ever reported for a transgenic fish and the gene transfer technique described would be applicable in "many different species of fish."[17] The final hurdle for AquaBounty and the focus of this paper for purposes of determining the legal consequences of escape is FDA environmental approval.[18]

AquaBounty is currently applying for approval of AAS under the New Animal Drug Application (NADA) of the Federal Food, Drug, and

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omitted)). In a recent presentation to the United States Food and Drug Administration (FDA), AquaBounty claimed that the chimeric gene has passed through ten generations of AAS in a stable and predictable manner. *See* U.S. FOOD & DRUG ADMIN., VETERINARY MEDICINE ADVISORY MEETING COMMITTEE: AQUADVANTAGE SALMON 105 (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230471.pdf.

14. '808 Patent, col.5 ls.8-9.

15. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 20-21. The genotypic differences refer to the fact that these new salmon now carry the chimeric gene, while the phenotypic changes refer to the actual physical expression of genes in the AAS (e.g., increased size and earlier changes in coloration). Both of these changes may be important in resolving legal disputes over ownership, given that they can distinguish AAS from a group of wild or traditional farm raised salmon. *Id.* at 9.

16. '808 Patent, col.5 ls.13-16.

17. *Id.* col.5 ls.16-17.

18. The labeling of GM foods and health consequences from consumption of GM foods are issues beyond the scope of this paper. For further information, see, e.g., Jennifer Corbett Dooren, *To Label or Not Label Lab-Spawned Salmon*, WALL ST. J., Sept. 22, 2010, *available at* http://online.wsj.com/article/SB10001424052748703399404575506340629229692.html, which outlines criticisms of non-labeled genetically modified salmon. *See also* U.S. FOOD & DRUG ADMIN., BACKGROUND DOCUMENT: PUBLIC HEARING ON THE LABELING OF FOOD MADE FROM THE AQUADVANTAGE SALMON (2010), *available at* http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm (providing the most up-to-date discussions being organized by the FDA to address labeling concerns); Consumer Right to Know Food Labeling Act of 2010, H.R. Res. 6325, 111th Cong. (2010) (a failed House bill, proposed for the purpose of requiring GM foods to be specially labeled); PEW CHARITABLE TRUSTS, *supra* note 13, at 29-34 (covering consumption issues ranging from allergens, potential toxic compounds, and elevated levels of hormones in GM salmon).

Cosmetic Act (FFDCA).[19] Any NADA approval by the FDA, however, will be conditioned on National Environmental Policy Act (NEPA) approval.[20] Regulations promulgated under NEPA focus on the overall environmental impact of allowing the production of AAS and require either a categorical exclusion or an environmental assessment (EA) as a condition for approval.[21] AquaBounty's AAS did not qualify for a categorical exclusion and AquaBounty was therefore required to submit an EA to the FDA.[22] AquaBounty suggested that the FDA make a finding of no significant impact (FONSI) on the environment because, under the specific circumstances presented in their application, the AAS is "highly unlikely to cause any significant effects on the environment, inclusive of the global commons, foreign nations not a party to this action, and stocks of wild Atlantic salmon."[23] The EA and requested FONSI are both based on strong evidence that AAS escape is unlikely. However, continued investigation of escape is necessary for two reasons. First, the model used by AquaBounty in its EA underestimates the potential harm from escape. Second, the specific circumstances used in the EA to justify the FONSI are unrealistic when applied to anticipated wide-scale production in more escape-prone fish farms. This Comment therefore explores in greater detail the specific findings and reasoning underlying the EA in order to understand why AAS production and escape poses a significant danger to non-GM fishermen.

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19. 21 U.S.C.A. § 360b(a)(1) (2008) (requiring that any new animal drug must comply with various portions of the Federal Food, Drug, and Cosmetic Act based on the purposes of the new drug (human consumption in the case of the AAS)); U.S. FOOD & DRUG ADMIN., CTR. FOR VETERINARY MEDICINE, BRIEFING PACKET: AQUADVANTAGE SALMON ii (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf [hereinafter FDA BRIEFING PACKET].

20. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4347 (2006).

21. *See* 21 C.F.R. § 514.1(b)(14) (2010). A categorical exclusion is something that the FDA has found to "not individually or cumulatively have a significant effect on the human environment." *See* 40 C.F.R. § 1508.4 (2010). An EA, however, is a public document that requires the FDA to determine whether AquaBounty must prove the safety of the AAS through a more thorough and rigorous Environmental Impact Statement (EIS) or whether there is a "finding of no significant impact" (FONSI), which allows AquaBounty to continue with production under NEPA. *See id.* § 1508.9.

22. *See generally* AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10.

23. *Id.* at 11.

B. Escape, Survival, and Impact

The scientific model used in the EA and other investigations of potential environmental impacts from the escape of GM organisms into the wild is known as a predictive risk assessment model.[24] This model focuses on three factors: the likelihood of escape, the likelihood of survival and reproduction after escape, and the impact or "harm" caused by this surviving GM population on the "receiving" wild population.[25]

1. Escape

Determining the likelihood of escape is a central feature of the EA and also of independent studies such as the CABI Report.[26] The reason for this focus is simple: if no fish escape, then there is no need for concern about gene-flow or harm to native populations. The very specific nature of AquaBounty's production site is essential to the FONSI requested in their EA. Therefore, an important question for the future is whether companies purchasing AAS for production will follow the same specific parameters of the current site in spite of their cost and difficulty to maintain.[27] The specific AquaBounty system presented in the EA is a redundant containment system that takes advantage of three methods of containment: physical, geographic, and biological.[28]

Physical containment refers to the actual structures used at the AquaBounty sites. Conventional aquaculture sites often rely on what are

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24. *See generally id.* at 54; CABI INT'L, *supra* note 2, at 6.

25. NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 75 (2002). The EA produced for the FDA also explores these same questions. *See* AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 54 ("The potential hazards in this EA center on the likelihood and consequences of *AquAdvantage* Salmon escaping, becoming established in the environment, and spreading to other areas.").

26. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 54; CABI INT'L, *supra* note 2, at 6.

27. AquaBounty has spent years developing AAS so that it can sell it to farmers who will then harvest the fish. AquaBounty's current primary goal, therefore, is merely approval and sale of the fish. *See infra* note 60. The goals of fish farmers purchasing AAS, however, will include more efficient and cost-effective production, which will almost certainly lead to different production site designs.

28. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 59-69; CABI INT'L, *supra* note 2, at 209.

known as "open systems."[29] Open systems, however, are exceptionally prone to escapes and hence unsuitable for GM salmon.[30] AquaBounty's proposal, therefore, relies on a closed system with redundant containment features, such as metal screens, jump fences, and lethal chemicals in drain areas.[31] Closed systems, despite their increased containment features, are still prone to escape. Containment failures in closed systems can result from natural disasters (e.g., floods, earthquakes, or excessive snow), human actions (e.g., either negligence or intentional release/theft of the valuable AAS), and mechanical errors (e.g., fish eggs can escape through filtration systems).[32] Finally, closed systems are also far more expensive to operate.[33]

Geographic containment measures refer to the location of sites in areas in which the fish should not be able to survive if they manage to escape from the closed system.[34] In the case of AquaBounty's proposed site, the eggs are grown on Prince Edward Island, while the actual fish are raised approximately 2,500 miles away in the Panamanian highlands.[35] AquaBounty's EA determined that if the eggs were to escape from the production site on Prince Edward Island, they would be able to survive during the warmer winter months, but only if they escaped in later life stages.[36] The EA claims that, at the grow-out facility in Panama, fish would be able to survive in the immediate vicinity of the facility, but that a combination of warmer water temperatures (higher than twenty-five degrees Celsius) and hydroelectric plants along the route to the ocean would stop any seaward migration.[37] Geographic containment mechanisms, like physical containment mechanisms, are effective, but also very costly. The CABI report notes that the cost of maintaining sufficiently cold water temperatures in tropical areas would be "very difficult and costly" for raising salmon and that this cost would be in addition to the increased "cost of transport to processing facilities and markets."[38]

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29. CABI INT'L, *supra* note 2, at 218 (noting that open systems are cheap because they are contiguous with natural waterways and require few or none of the filtration systems necessary in closed systems).
30. *Id.* at 219-20.
31. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 54-55, 63.
32. CABI INT'L, *supra* note 2, at 214-17.
33. PEW CHARITABLE TRUSTS, *supra* note 13, at 16.
34. CABI INT'L, *supra* note 2, at 220-21.
35. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 13.
36. *Id.* at 69.
37. *Id.*
38. CABI INT'L, *supra* note 2, at 220-21.

Biological containment of AAS stands as the final layer of redundancy in the AquaBounty containment system. Biological containment, like physical containment, refers to a host of potential mechanisms.[39] AquaBounty's current system has two layers: it attempts to create an all-female population and to make this all-female population sterile.[40] The all-female egg production system claims a one hundred percent success rate.[41] The system is based on a process that utilizes gynogenesis.[42] This system, however, is only successful if it can be assured that all escaped fish are stopped from having any contact with fish of the opposite sex.[43] AquaBounty accounts for this shortcoming with the second process of inducing triploidy in the fish used for production.[44] The triploidy inducement process results in AAS having three sets of chromosomes in its somatic cells, which reduces the development of gonads to the point that AAS is effectively sterile.[45] However, even AquaBounty acknowledges that the triploidy inducement process does not have a one hundred percent success rate.[46] In addition to being an imperfect system, triploidy inducement is also an exceptionally costly system. The CABI report claims that the monitoring mechanisms needed would be too expensive for all "but the best funded hatcheries" and that estimated monitoring costs could add between $0.02

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39. *Id.* at 222-23, 231 (mentioning three overarching categories: single sex populations by various means, induced sterility by various means, and genetic use restriction technologies (GURTs)).

40. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 59.

41. *Id.* at 40. The EA's claim of one hundred percent success, however, fails to note an important caveat about the lack of validation outside AquaBounty's own self-interested studies: the briefing packet initially produced by AquaBounty prior to the EA noted that "[t]he effectiveness of the methods used by AquaBounty to insure that an all-female population of AquAdvantage Salmon is produced has not specifically been evaluated quantitatively in any studies to date." FDA BRIEFING PACKET, *supra* note 19, at 127.

42. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 59; CABI INT'L, *supra* note 2, at 222 (gynogenesis is achieved by disrupting the process of mitosis through temperature or pressure shocks, resulting in an activation of the ova without a contribution from any male genes).

43. CABI INT'L, *supra* note 2, at 222.

44. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 59.

45. *Id. See also* CABI INT'L, *supra* note 2, at 225-29 (providing a more detailed explanation of the process).

46. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 60 (claiming a success rate of 98.9%-100%); *see also* CABI INT'L, *supra* note 2, at 229 ("The possibility of fertile triploids is one of the major shortfalls of triploidy as a biological confinement method for transgenic fish.").

to $0.04 per kilogram of salmon to the market cost.[47] Although the statistical possibility of escape seems small, it is important to keep in mind the magnitude of potential harm as well as the likelihood that these statistically small possibilities of escape will increase with the need for greater production capacity at financially competitive fish farms.

2. Survival

Survival refers to AAS's ability to coexist with native species after escape.[48] This does not require reproduction, but merely survival alongside the native population.[49] The likelihood of survival is measured through the concept of fitness.[50] AAS's fitness is determined by considering the interaction between its unique genotypic and phenotypic makeup and the wild environment into which it escapes.[51] Despite the slightly different approaches used in the CABI Report and the FDA EA, one point is emphasized by both reports: it is exceptionally difficult to predict the consequences of releasing a genetically modified living organism, which has only ever been examined in controlled settings, into a wild environment with any number of variables occurring on both meta- and micro-levels.[52]

3. Impact

Two potential impacts must be considered: the possibility that AAS will survive and mate with wild Atlantic salmon[53] and/or that AAS will

47. CABI INT'L, *supra* note 2, at 227.
48. *Id.* at 120-121.
49. *See, e.g.*, *infra* notes 53-54.
50. CABI INT'L, *supra* note 2, at 126.
51. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 55 (referring to the likelihood of "establishment" in terms of "the effect of the transgene on the fitness of the animal for the ecosystem into which it is released").
52. *Id.* at 33 ("The complexity of the interactions between these effects and, in turn, their interactions with the environment, makes it difficult to predict the overall fitness of GH-transgenic salmon in the environment relative to their wild counterparts."); *see also* CABI INT'L, *supra* note 2, at 178-79 ("Because such complex studies [those that account for the various micro and macro issues in a wild environment] are difficult using only confined experimental units, G x E effects will be an important source of incertitude in ecological risk assessment for transgenic fish.").
53. The CABI report identifies a number of different gene-flow scenarios, including a purge scenario (although the least dangerous post-escape scenario, it is still dangerous because the process of purging the GM genes from the wild stock can take generations), a spread scenario (a high-risk scenario in which the GM fish can spread and compete with

survive, compete with wild Atlantic salmon, and establish itself in the same area as wild populations even in the absence of gene flow.[54] These two potential impacts, although technically different, both result in the same dilemma: Atlantic salmon (whether second-generation AAS or wild-AAS hybrids) containing AquaBounty's patented genetic material will find their way into non-GM fishermen's nets.

C. Why We Cannot Rely on the AquaBounty Containment System

The AquaBounty system, despite its various flaws, relies on a strong principle of redundancy. In this sense, it is likely one of the best containment systems that could be developed and follows many of the recommendations of the CABI report.[55] A successful risk assessment, however, balances the potential for escape against the potential for harm. AquaBounty's EA fails to make this balance by underestimating the harm posed to non-GM fishermen from an AAS escape. First, the EA underestimates the magnitude of the uncertainty in its escape and survival models. An irreversible harm, the loss of native Atlantic salmon, should not be balanced against the "certainties" of a narrowly defined containment system when we cannot even predict the effects of escape. Second, the EA fails to account for various stakeholders involved in the harm being considered.[56] Under the current regulatory system utilized for GM animals, the FDA need only consider the interests of AquaBounty, the object of the transgenic process (i.e., the AAS), and the consumers of the AAS.[57] Such an evaluation of harm fails to consider the property interests of non-GM fishermen.[58] Finally, the

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the wild stocks for resources and space), and the Trojan gene scenario (a high risk scenario in which the GM fish outcompetes the wild fish for reproductive opportunities, only to have far weaker post-reproduction survival skills—leading to a collapse of entire wild stocks). CABI INT'L, *supra* note 2, at 127-28, 132.

54. The CABI Report cites a number of potential consequences of an escape that do not result in gene flow, including reproductive competition, food competition, migration pattern disruption, changes in the number of predators, changes in predation rates on other species, and changes in water flow. CABI INT'L, *supra* note 2, at 157-158.

55. *See generally id.* at Chapter 8.

56. NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, *supra* note 25, at 111 (noting that the FDA has informally agreed to consider effects on wild populations, but no specific regulations or guidance exists to ensure quality or thoroughness of this consideration and that the process is closed to public participation).

57. *Id.*

58. *See* Press Release, Senator Olympia Snowe, Senator Snowe Urges Halt of Review Process for Genetically Engineered Salmon (Nov. 1, 2010), *available at* http://www.asf.ca/news.php?id=595 ("Transgenic [GM] fish have the potential to

weaknesses of this exceptionally narrow containment system are only further compounded when we look to the future of AAS fish farming. The current site produces a few hundred tons of fish and utilizes every possible method of containment, despite the various costs mentioned above.[59] This current approach makes sense because the public relations and development benefits of becoming certified by the FDA outweigh the costs of such a system.[60] But what happens when AquaBounty, a self-described "technology company," sells its technology to fish farmers looking to produce on a scale more fit for mass consumption? AquaBounty officials have already indicated their intention to sell AAS to fish farmers who wish to operate in the United States (given reduced travel costs) at predicted amounts of 2,000 tons—several times greater than AquaBounty's current production.[61] Once profits are more dependent on operating costs and factors of supply and demand, the likelihood of decreased containment measures and resulting escapes will increase.

The possibility of an AAS escape, therefore, is real but immeasurable. Furthermore, the consequences of escape are quite real but even more difficult to predict—AquaBounty admits this uncertainty in its Briefing Packet to the FDA.[62] The uncertainty surrounding the quantification of risk and the magnitude of harm, however, should not work as a paralytic for the planning of a legal response to various claims and counterclaims that could result from an escape. Unfortunately, the current state of our legal framework for approaching property interests in GM animals is almost as uncertain as the risks of an AAS escape. Two major areas of law—wildlife law and patent law—reveal the sources of this uncertainty.

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negatively affect our current wild capture fisheries, aquaculture operations, and other sectors of the economy that depend on healthy marine and freshwater ecosystems. Thus it is of paramount importance that this precedent-setting application be subject to a suitable, rigorous environmental review process.").

59. FISHERIES AND AQUACULTURE STATISTICS, *supra* note 1, at 114.

60. An AquaBounty executive has already indicated that the company's main objective is the sale of this technology to other fish farming companies, stating that "[w]e do not wish to be the next Marine Harvest. We do not want to be the world's largest salmon producer. We want to supply technology and solutions to that industry." *Id*. at 113.

61. *See id*. at 114.

62. AQUABOUNTY TECHNOLOGIES, INC., *supra* note 10, at 33.

III. WILDLIFE LAW: THE FIRST CAPTURE AND PUBLIC TRUST DOCTRINES

A. The First Capture Doctrine

For fishermen and hunters alike, it is well accepted law that "pursuit alone vests no property or right in the huntsman."[63] Therefore, when hunting foxes today or over two hundred years ago, it is best practice to "mortally wound" or "greatly maim" your prey to ensure possession.[64] This is the basic law of first capture and one of the bedrock principles of American property law applied by courts and memorized by first-year law students.[65] The rule offers courts a bright line rule for determining property ownership of a wild animal based on the act of killing or significantly restricting the animal's movement.[66] The rule has also led, in part, to the "tragedy of the commons," encouraging the fastest and most efficient capture of resources, despite potential waste.[67] This mentality has contributed to the depleted state of many fisheries, including salmon.[68]

The minority in *Pierson* rejected the popular first capture doctrine and instead emphasized the culture of the sport as well as the effort advanced by the pursuing hunters.[69] The dissenting justice posed the following rhetorical question:

> But who would keep a pack of hounds; or what gentleman, at the sound of the horn, and at peep of day, would mount his steed, and for hours together, *"sub jove frigido,"* or a vertical sun, pursue the windings of this wily quadruped, if, just as night came on, and his stratagems and strength were nearly exhausted, a

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63. Pierson v. Post, 3 Cai. R. 175, 177 (1805).

64. *See id.*

65. JESSE DUKEMINIER ET AL., PROPERTY 17 (Vicki Been et al. eds., 6th ed. 2006).

66. *Id.*

67. DALE D. GOBLE & ERIC T. FREYFOGLE, WILDLIFE LAW: CASES AND MATERIALS 124 (Robert C. Clark et al. eds., 1st ed. 2002).

68. Alliance Against IFQs v. Brown, 84 F.3d 343, 344 (9th Cir. 1996). In discussing the tragedy of the commons, the Ninth Circuit noted that:

> [c]ommercial ocean fishing combines difficult and risky labor with large capital investments to make money from a resource owned by no one, the fish. Unlimited access tends to cause declining fisheries. The reason is that to get title to a fish, a fisherman has to catch it before someone else does. This gives each fisherman an incentive to invest in a fast, large boat and to fish as fast as possible.

Id.

69. *See Pierson*, 3 Cai. R. at 180-81 (Livingston, J., dissenting).

> saucy intruder, who had not shared in the honors or labors of the chase, were permitted to come in at the death, and bear away in triumph the object of pursuit?[70]

Justice Livingston's question suggests that property rights, and also our sympathies, should lie with the party that actually expends effort in pursuit of the fox, as opposed to the "saucy intruder."[71] The majority's approach continues to be the common law rule. Justice Livingston's dissent, however, resonates in later interpretations of the first capture doctrine.

In *Shepard v. Leverson*, for example, the New Jersey Supreme Court held that ownership can be established through means other than basic capture if the owner of the animals sufficiently identifies the animals as his or her property.[72] There, the plaintiff, Shepard, failed to properly identify a number of oysters when he transferred them from a populated area of the river to an area previously never populated by oysters.[73] The court held that when Shepard placed the oysters into the new portion of the river without attaching some kind of "earmark" to each oyster, he was abandoning his property back into "the common stock, from which it cannot be distinguished" and relinquishing all his rights to the oysters.[74] Despite its ultimate holding against Shepard, the majority had sympathies similar to Livingston in his *Pierson* dissent because of the effort expended by Shepard and the social benefits accruing from harvested oyster beds.[75] Some courts, therefore, have limited the first capture doctrine in ways to empower the claims of the worthy hunter over those of the "saucy intruder."[76] In addition to balancing the interests of certainty in *Pierson* and fairness in *Shepard*, courts often find themselves considering a third interest: the right of states to protect land and wildlife under the public trust doctrine.

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70. *Id.*

71. *See id.* at 182 (arguing that capture of wild animals should only require that the pursuer be "within reach or have a reasonable prospect . . . of taking what he has thus discovered").

72. 2 N.J.L. 391 (N.J. 1808).

73. *Id.* at 372.

74. *Id.* (Shepard was transferring the oysters because the new area of the river was apparently a fertile but unpopulated place for an oyster bed).

75. *Id.* at 373.

76. *See, e.g.,* Brown v. Eckes, 160 N.Y.S. 489, 490-491 (N.Y. 1916) (holding that escaped bees cannot be claimed property of their prior owner unless he maintains an ability to identify them by keeping them in sight as they escape).

B. Public Trust Doctrine: Foundation

The public trust doctrine is an exceptionally old common law doctrine concerning state rights and duties to protect public lands.[77] These common law roots, relying on the typical references to Roman law as well as to Blackstone,[78] lend an air of authority—but also uncertainty—to the application of the public trust doctrine.[79] Therefore, it is important to understand the existing precedent before considering possible extensions of the doctrine.

Three Supreme Court cases help to identify the foundation of the public trust doctrine in terms of wildlife. *Illinois Central Railroad v. Illinois*,[80] seen by some as the "heart" of the public trust doctrine, serves as a strong pronouncement of states' rights of enforcement.[81] *Illinois Central* concerned a title dispute between Illinois and the Illinois Central Railroad.[82] The railroad claimed ownership of certain portions of land around and under Lake Michigan through title given by the state.[83] The Court, however, held that this land could not have been validly transferred to the railroad by the state legislature because it was owned by Illinois in trust for the public.[84] The Court described the title to the lands as being "held in trust for the people of the State that they may enjoy the navigation of the waters, carry on commerce over them, and have liberty of fishing therein freed from the obstruction or interference

77. *See, e.g.,* Ill. Cent. R.R. v. Illinois, 146 U.S. 387 (1892).

78. *See, e.g.*, Geer v. Connecticut, 161 U.S. 519, 523, 526 (1896); *see also* Oliver A. Houck, *Why Do We Protect Endangered Species, and What Does That Say About Whether Restrictions on Private Property to Protect Them Constitute 'Takings?',* 80 IOWA L. REV. 297, 311 n.77 (1995) ("The majority in Hughes overruled the "ownership" rationale announced in Geer, stating, '[W]e now conclude that challenges under the Commerce Clause to state regulation of wild animals should be considered according to the same general rule applied to state regulation of other natural resources.' However, the majority did not, and could not, overrule principles dating back to Roman law that wild animals are the common property of the citizens of a state.").

79. *See* Susan Horner, *Embryo, not Fossil: Breathing Life into the Public Trust in Wildlife,* 35 LAND & WATER L. REV. 23, 24 (2000) ("While the public trust doctrine has been universally accepted as a viable part of our legal heritage in the late Twentieth Century, it is anything but a working tool in the practices of public interest and conservation advocates across the nation.").

80. 146 U.S. 387 (1892).

81. *See* Patrick Redmond, *The Public Trust in Wildlife: Two Steps Forward, Two Steps Back*, 49 NAT. RESOURCES J. 249, 251 (2009) (referring to *Illinois Central* as "the source of the modern American public trust doctrine").

82. *Ill. Cent. R.R.*, 146 U.S. at 443-44.

83. *Id.*

84. *Id.* at 452.

of private parties."[85] *Illinois Central*, therefore, stands for the claim that navigable waterways and the lands under these waterways are the most traditionally protected public lands under even minimal public trust considerations.[86]

Geer v. Connecticut is the next foundational case.[87] *Geer* extends the waterway rights defined in *Illinois Central* to wildlife, including Atlantic salmon.[88] The *Geer* Court upheld a Connecticut statute fining a man for shooting birds in Connecticut during the proper hunting season because he intended to transport them for sale outside of Connecticut state boundaries.[89] The Court found this rather restrictive statute valid based on the state's public trust power, holding that the power to control wildlife "is to be exercised, like all other powers of government, as a trust for the benefit of the people, and not as a prerogative for the advantage of the government, as distinct from the people, or for the benefit of private individuals as distinguished from the public good."[90] *Geer*, therefore, is a clear extension of public trust powers to wildlife contained within a state's borders.

Hughes v. Oklahoma,[91] however, overruled certain aspects of *Geer* by refusing to allow a state to use the doctrine to interfere with interstate commerce (i.e., the limitation placed on sale of game birds in another state).[92] The Court emphasized that states do not have any actual title or ownership in wildlife for the same reasons that the hunter in *Pierson* could not show ownership until the fox was killed.[93] The Court, however, also emphasized that they were not overruling the general applicability of the public trust doctrine to states' wildlife, but were simply rejecting any concept of actual legal ownership that would upset the supremacy of the Commerce Clause.[94] The public trust doctrine,

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85. *Id.*

86. Redmond, *supra* note 81, at 251.

87. 161 U.S. 519 (1896).

88. *See* Horner, *supra* note 79, at 39 (noting how a series of cases extending the waterway rights of the traditional public trust doctrine to animals found within those waterways "set the stage" for *Geer* and the ultimate recognition of states' rights to regulate all forms of wildlife).

89. *Geer,* 161 U.S. at 519-22.

90. *Id.* at 529.

91. 441 U.S. 322 (1979).

92. *Id.* at 335.

93. *Id.* at 334-35.

94. *Id.* at 335-36 ("The general rule we adopt in this case makes ample allowance for preserving, in ways not inconsistent with the Commerce Clause, the legitimate state concerns for conservation and protection of wild animals underlying the 19th-century legal fiction of state ownership.").

therefore, remains a strong source of states' rights to control waterways and wildlife within their own borders, provided that proper deference is given to the Commerce Clause.

The Court has focused on the doctrine's coverage of certain areas and interests. Patrick Redmond defines these first two issues in terms of the doctrine's geographic scope and protected uses.[95] A third issue, however, has been left relatively underdeveloped by the Court: the application of the doctrine to establish states' obligations.

C. Public Trust Doctrine: States' Obligations

Application of the public trust doctrine occurs in two possible ways: rights and obligations. The foundational cases explored above concern the application of rights. *Illinois Central* established Illinois's right to regain its land, while *Geer* extended this right to the control of wildlife. *Hughes*, meanwhile, limited this right by highlighting that state ownership was a legal fiction that could not overcome the limits of the Commerce Clause. The Court, therefore, has chosen to emphasize the rights of states to protect lands and property held in trust.

In contrast, some commentators suggest that the states' obligation to enforce the interests of the trust is the doctrine's most important function. Professor Joseph Sax was one of the first and most famous of these proponents.[96] In *Liberating the Public Trust Doctrine from its Historical Shackles*, he advances the thesis that "[o]ur task is to identify the trustee's obligation with an eye toward insulating those expectations that support social, economic and ecological systems from avoidable destabilization and disruption."[97]

Sax's vision of the public trust doctrine as obligating state action on behalf of and in response to the claims of its beneficiaries, although absent from Supreme Court precedent, has seen some successes at the state level.[98] Courts in Louisiana and California have indicated a strong commitment to exploring the obligations imposed by the public trust doctrine, so long as suits are brought in their proper form against state

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95. Redmond, *supra* note 81, at 258.

96. *See, e.g.,* Joseph L. Sax, *Liberating the Public Trust Doctrine from Its Historical Shackles*, 14 U.C. DAVIS L. REV. 185, 193 (1980).

97. *Id.*

98. *See, e.g.*, Nat'l Audubon Soc'y v. Superior Court of Alpine Cnty., 658 P.2d 709, 732 (Cal. 1983); Save Ourselves, Inc. v. La. Envtl. Control Comm'n, 452 So.2d 1152 (La. 1984).

agencies.[99] Louisiana is seen as a leader in its "commitment to the public trust doctrine."[100] The leading case in Louisiana, *Save Ourselves, Inc.*, uses Louisiana's constitution to establish the state's obligations to protect trust resources.[101] In that case, the Louisiana Supreme Court reversed the approval of certain permits for hazardous waste discharge because the state agency did not sufficiently investigate the potential for harm.[102] In doing so, it noted that the Louisiana Constitution codified principles of the public trust doctrine and, as a result, the public agency in charge of issuing these permits was bound as the trustee to consider issues affecting the interests of the public.[103] The court stated that "the commission's role as the representative of the public interest does not permit it to act as an umpire passively calling balls and strikes for adversaries appearing before it; the rights of the public must receive *active* and *affirmative* protection at the hands of the commission" (emphasis added).[104] This affirmative obligation is precisely what Sax and other commentators envision as the role of the public trust doctrine.[105]

California's highest court, following a similar model in *National Audubon Society v. Superior Court of Alpine County*, held that the California water rights system, which favored using a highly unique watershed for water production purposes, must be considered in conjunction with countervailing public trust concerns, which favored protection of the unique area for environmental and recreational

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99. Trust obligations are limited to the states as trustees. Thus, any suit must be brought against the state for failure to enforce its trust obligation even if a private party is causing the harm. This is because the state, not the public beneficiary seeking suit, must enforce the trust. *See, e.g.*, Ctr. for Biological Diversity, Inc., v. FPL Grp., Inc., 166 Cal. App. 4th 1349, 1367-68 (Cal. Ct. App. 2008) (dismissing a suit brought against private operators of wind farms in California that were killing birds because the proper defendant would have been the state agency that had approved the wind farms).

100. Horner, *supra* note 79, at 58.

101. *Save Ourselves*, 452 So.2d at 1157.

102. *Id.* at 1160 ("We cannot determine from this record that the agency fully understood its function or properly exercised the discretion it has been given. The commission did not assign reasons for its decision, and its factual findings do not sufficiently illumine its decision-making process.").

103. *Id.* at 1154 ("The public trust doctrine was continued by the 1974 Louisiana Constitution, which specifically lists air and water as natural resources, commands protection, conservation and replenishment of them insofar as possible and consistent with health, safety and welfare of the people, and mandates the legislature to enact laws to implement this policy.").

104. *Id.* at 1157.

105. Sax, *supra* note 96, at 188-89.

purposes.[106] After explaining the history of the public trust, as well as evolving public opinion on the importance of conservation and environmentalism, the court stated that the public trust doctrine is "more than an affirmation of state power to use public property for public purposes. It is an affirmation of the duty of the state to protect the people's common heritage of streams, lakes, marshlands and tidelands."[107] In addition to recognizing the sometimes obligatory nature of the public trust doctrine, the court also expanded the purpose of the trust, which was typically thought to encompass waterways and wildlife management after *Illinois Central* and *Geer*.[108] It noted that the public uses protected as trust resources are "sufficiently flexible to encompass changing public needs" including the "preservation of those lands [tidelands] in their natural state, so that they may serve as ecological units."[109] California, therefore, has expanded not only the application of the doctrine to include obligations, but has also expanded the doctrine to recognize a new purpose beyond access and use of waterways: preservation of waterways for environmental and recreational purposes.[110]

Louisiana and California, however, do not represent the majority state-level approach to the public trust doctrine. Surveys of state approaches highlight Louisiana and California as the exceptions for their expansion and use of the trust.[111] Nevertheless, the presence of these cases, work by commentators, and the growing awareness of environmental concerns in the United States suggest that despite its contentious and ambiguous application by the states, the public trust doctrine will continue to see expanded use.

D. Applying Wildlife Law to the Hypothetical Escape

An application of wildlife law to the hypothetical situation presented in Part I reveals an internal contradiction for determining possession of GM animals. The AAS that escaped in our hypothetical situation were

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106. *Nat'l Audubon Soc'y*, 658 P.2d at 712.
107. *Id.* at 724.
108. *Id.* at 719.
109. *Id.*
110. *Id.* ("There is a growing public recognition that one of the most important public uses of the tidelands—a use encompassed within the tidelands trust—is the preservation of those lands in their natural state, so that they may serve as ecological units for scientific study, as open space, and as environments which provide food and habitat for birds and marine life, and which favorably affect the scenery and climate of the area.").
111. *See*, *e.g.*, Horner, *supra* note 79, at 58.

created from animals that were once wild, not unlike the oysters in *Shepard*.[112] The escaped AAS, therefore, could be considered wild animals returned to the "common stock."[113] If this was the case, then the fishermen, by virtue of the capture doctrine, would have lawful possession of the AAS they catch in the wild. The genetically modified AAS, however, are very different from the wild oysters in *Shepard*. Shepard, as the court noted, did not attach an earmark to each of his oysters.[114] AquaBounty, however, followed the *Shepard* holding without even intending to apply an "earmark." Each AAS has a unique genetic makeup, which serves as an "earmark" distinguishing it from wild Atlantic salmon. This genetic makeup results in explicit physical differences (i.e., phenotypic changes) and invisible internal differences (i.e., genotypic changes) from wild salmon. AquaBounty, therefore, would have little difficulty identifying AAS after an examination and genetic testing by a scientist, such as the one who visited the fish market. The "earmark" in *Shepard*, however, was more likely intended as notice to other parties (e.g., the fishermen in the hypothetical situation) as opposed to a reminder for Shepard. Wildlife law, therefore, leaves an unsatisfying contradiction for determining ownership of escaped AAS: are GM animals, initially wild animals before being genetically altered, wild animals when they escape or do they somehow remain the property of the individual responsible for altering their genetic makeup?

The public trust doctrine raises a second set of concerns. What, if any, public property rights have been injured by the hybridization and possible extinction of wild salmon resulting from an AAS escape? An injury will certainly have occurred, given the loss of "biodiversity" (i.e., genetic variety).[115] The "ecological unit" concept in *National Audubon Society* would consider such an injury, but, as noted earlier, the California approach is the exception to the rule. In addition, access to state fisheries, one of the most traditionally protected public trust resources,[116] will also be lost if wild populations are replaced by AAS. However, some states may recognize AAS farms as beneficiaries of the

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112. *Shepard*, 2 N.J.L. at 373.

113. *Id.* at 372.

114. *Id.*

115. CABI INT'L, *supra* note 2, at 131 (noting that sufficient biodiversity within a species is a necessary element for survival).

116. *See* Redmond, *supra* note 81, at 251 ("The source of the modern American public trust doctrine was the U.S. Supreme Court's recognition . . . of a public trust held by states over navigable waterways, for the purposes of navigation, commerce, and fishing.").

public trust and treat AAS escapes as no more harmful than current problems surrounding overfishing by non-GM fishermen.[117]

Our hypothetical fishermen, therefore, have very uncertain protection from the impacts of an AAS escape under current wildlife law. Moreover, wildlife law only guides our analysis of the hypothetical escape prior to the most significant event: the sale of AAS. For the legal implications after our hypothetical fishermen sell AAS, we must turn to patent law.

IV. PATENT LAW AND THE TREND FOR GREATER PROTECTION OF GM ORGANISMS

Intellectual property law addresses many of the concerns raised in Livingston's dissent in *Pierson*. Justice Livingston, however, might have had difficulty understanding the connection in 1805. John Locke's labor theory allows an individual to possess, for example, a fence he made because he mixed his labor with the creation of that fence.[118] So how can an individual mix his labor in the capture of a fox the same way he can in the creation of a fence? In Justice Livingston's time, the answer was that a man cannot create a fox, no matter how many hours he spends hunting "*sub jove frigido*."[119] His only means for establishing lawful possession, therefore, was through capture.[120]

In a modern context, however, specific types of livings organisms can be "created" in a technical sense through processes of genetic modification. The foundation of patent rights in genetically modified organisms has two interrelated bases: the traditionally broad approach to allowing utility patents[121] and the continued expansion of this protection to new GM organisms, particularly GM plants owned by Monsanto.[122] The GM plant patent cases, although not directly discussing GM animals, are a necessary analogy to AAS because no case law currently exists for the escape of patented GM animals.

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117. Robin Kundis Craig, *A Comparative Guide to the Eastern Public Trust Doctrines: Classifications of States, Property Rights, and State Summaries*, 16 PENN ST. ENVTL. L. REV. 1, 63, 67 (2007) (noting that states like Maine are conflicted about whether to define currently existing, non-GM aquaculture sites as "fishing" under traditional trust definitions).

118. *See generally* JOHN LOCKE, TWO TREATISES OF GOVERNMENT (Peter Laslett ed., Cambridge Univ. Press 1988).

119. *Pierson*, 3 Cai. R. at 180-81. The phrase translates to "under cold skies."

120. *Id.*

121. *See* Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

122. *See infra* Part IV.B.

A. The Foundation of Patent Rights in Living GM Organisms

The initial formation of patent law predates any consideration of genetically modified organisms.[123] The power to grant patents is provided explicitly in the Constitution, which gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[124] From this Constitutional grant of power, Congress enacted 35 U.S.C. § 101, which defines the range of possible subject matter for patents.[125] This range is based on the Patent Act of 1793, which very broadly defined the possible subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter."[126] Congress has kept this same exact language in 35 U.S.C. § 101, aside from changing "art" to "process," so that there remains a very broad range of patentable subject matter.[127]

In 1980, the Supreme Court interpreted § 101 in a manner consistent with this earlier Act and Thomas Jefferson's belief that "ingenuity should receive liberal encouragement."[128] The majority in *Chakrabarty*, relying on 1952 Committee Reports for § 101, found patentable subject matter to "include anything under the sun that is made by man," with the only limits being "[t]he laws of nature, physical phenomena, and abstract ideas."[129] *Chakrabarty* is a landmark case not because it reinforces the "philosophy" of Jefferson or the intent of the drafters of the 1952 amendments, but rather because it applies this intent to the creation of living organisms, an issue not foreseeable by Jefferson or the 1952 drafters. Charkrabarty, a scientist for the General Electric Corporation, created a living organism in the form of a bacterium that was capable of breaking down crude oil.[130] The United States Patent and Trademark Office (USPTO) and Court of Customs and Patent Appeals both rejected Chakrabarty's patent application because living organisms were not then

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123. *See* Act of Feb. 21, 1793, ch. 11, §1, 1 Stat. 318.
124. U.S. CONST. art. I, § 8, cl. 8.
125. 35 U.S.C. § 101 (2006); *see also id.* § 102 (requiring novelty); *id. at* § 102 (requiring an invention be non-obvious); *id. at* § 112 (requiring an enabling written description).
126. Act of Feb. 21, 1793, ch. 11, §1, 1 Stat. 318, 319.
127. *See* 35 U.S.C. §101 (2006).
128. *Chakrabarty*, 447 U.S. at 308.
129. *Id.* at 309.
130. *Id.* at 305 (the bacterium was intended for use in cleaning up oil spills).

considered patentable under § 101.[131] The Supreme Court reversed these decisions based on the broad interpretation outlined above and a labor theory argument which focused on the fact that Chakrabarty himself had created a bacterium with "markedly different characteristics from any found in nature and one having the potential for significant utility."[132]

The patenting of living organisms, as a result of *Chakrabarty* and the trend towards greater protection, has gone far beyond oil-eating bacteria. In 1984, Harvard University filed a patent application for what has become know as the "Harvard Mouse."[133] In essence, it was a mouse engineered to be more susceptible to cancer than common mice, and therefore an aid in cancer research efforts.[134] Unlike earlier applications for similar subjects, however, Harvard took the unique step of claiming not only the procedural and manufacturing elements of creating the mouse, but also the mouse itself.[135] This was possible given the broad ruling only a few years earlier in *Chakrabarty*.

The move from patenting an oil-eating microorganism to an animal is not a small one. Canada's highest court rejected the very same Harvard application accepted by the U.S. Patent Office based on a distinction between lower and higher life forms.[136] Plant patent acts similar to those in the U.S. and the "common sense differences" between lower forms of life and plants/animals led the Canadian Court to accept the patent application in terms of process, but reject any actual claims for

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131. *Id.* at 306.

132. *Id.* at 310. A four member minority tried unsuccessfully to undermine this trend towards broader patent protection. The minority claimed that later plant patent acts in 1930 and 1970 would be made redundant by the majority's overly broad interpretation of § 101. *Id.* at 320. Legal scholars reinforce the minority's argument, pointing to historical records and more contemporary records that explicitly exclude plants from utility patents under § 101. Malla Pollack, *Originalism, J.E.M., and the Food Supply, or Will the Real Decision Maker Please Stand Up?*, 19 J. ENVTL. L. & LITIG. 495, 505-07 (2004) (noting a complete absence of plant utility patents pre-1836, and citing to Committee Reports from legislation creating the plant patent, which state that "[a] new variety [of seed] once it has left the hands of the breeder may be reproduced in unlimited quantity by all").

133. U.S. Patent No. 4,736,866 (filed Apr. 12, 1988). At this time, the patented mouse was titled "Transgenic non-human mammals," which would later describe any number of comparable experiments following the Harvard mouse, including the AAS.

134. 866 Patent at col.1 l.39, col.3 ls.16-19.

135. *Id.* at col.9 ls.35-38, col.10 ls.1-2. ("A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.").

136. Comm'r of Patents v. President & Fellows of Harvard Coll., [2002] 4 S.C.R. 45 (Can.).

ownership of the mouse itself.[137] The United States and Canada, however, would later find common ground in allowing utility patents to be applied to GM plants owned by Monsanto. These U.S. and Canadian Monsanto cases make up the second, more modern basis for the patent protection of GM organisms.

B. The Modern Basis for GM Organism Patents

1. Expansion of § 101 Protection to GM Plants

The broad subject matter and superior protection of a utility patent has been essential to the success of biotech companies such as Monsanto and AquaBounty. The plant patent acts that were the foundation of the minority's argument in *Chakrabarty*, a weaker source of protection, do not offer the same exclusivity and power of control of a utility patent.[138] In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International*, therefore, the Court granted agricultural businesses the power to patent seeds under § 101.[139] J.E.M. had a licensing agreement for the sale of its corn seeds.[140] Pioneer, a seed seller, had purchased J.E.M seeds without a license and then resold those seeds.[141] J.E.M. brought a patent infringement suit and Pioneer responded by challenging the validity of J.E.M.'s patent.[142] In essence, Pioneer claimed that the patent was invalid for the corn seeds because Congress had provided the Plant Protection Act (PPA) and Plant Variety Protection Act (PVPA) as the exclusive means for patenting plants.[143] The majority, however, found that § 101 and the PPA/PVPA could coexist, rejecting Pioneer's repeal by implication argument.[144] Justices Breyer and Stevens, in dissent, essentially adopted Pioneer's repeal by implication argument (i.e., that the presence of more specific

137. *Id.* at 46.
138. Pollack, *supra* note 132, at 504-06 (noting that these plant patent acts allow farmers to save seeds and conduct research on patented plants, two major issues for agricultural corporations such as Monsanto, who do not want farmers saving their GM seeds for next year's harvest).
139. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).
140. *Id.* at 127.
141. *Id.* at 128.
142. *Id.* at 128-29.
143. *Id.* at 129.
144. *Id.* at 145-46 (Breyer, J., dissenting).

statutes for the patenting of plants would make invalid any attempt to patent a plant under § 101).[145]

Putting aside the conflicting opinions in *J.E.M. Ag Supply*, the ultimate concern is the effect of extended utility patent protection on the property rights of non-GM farmers and fishermen. Under PVPA, farmers could conduct research on seeds and save seeds for future harvest instead of purchasing new seeds every year.[146] Such patent protection did little for biotechnology companies hoping to enforce broad licensing agreements against farmers saving their seeds for subsequent generations. The holding in *J.E.M. Ag Supply*, however, gave these companies the exact protection they were seeking in the form of utility patents for GM plants, GM animals, and "anything under the sun."

2. The Consequences of Patenting "Anything Under the Sun"

The traditionally broad approach to granting patent rights, as noted earlier, began long before the creation of GM organisms. A continued application of this trend to protect "anything under the sun" to GM organisms, therefore, has had and will continue to have a number of unforeseeable consequences. Living organisms, such as plants and animals, are self-replicating, in the sense that they reproduce themselves. This means that living organisms do not conform well to the "exhaustion doctrine," which eliminates many of the patent holder's rights after the sale of patented seeds.[147] As a result, the protections granted to

145. *Id.* at 152 ("Even a prescient court would have had to say, as of 1931, that the 1930 Plant Patent Act had, in amending the Utility Patent Statute, placed the subject matter of the PPA—namely plants—outside the scope of the words 'manufacture, or composition of matter.'").

146. 7 U.S.C. § 2543 (1994) ("[I]t shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section."). The process of seed saving is very old and in many ways is the precursor to genetic modification because by saving the best seeds farmers were able to ensure better harvest each year. *See, e.g.*, Tempe Smith, *Going to Seed?: Using Monsanto as a Case Study to Examine the Patent and Antitrust Implications of the Sale and Use of Genetically Modified Seeds*, 61 ALA. L. REV. 629, 634 (2010) ("Saving seed is a long-established practice in agrarian societies; seed saving has been practiced in the United States since before the Pilgrims came in 1620 and throughout the world for over 10,000 years.") (citations omitted).

147. Rita S. Heimes, *Post-Sale Restrictions on Patented Seeds: Which Law Governs?,* 10 WAKE FOREST I.P. L. REV. 98, 98 (2010) ("Generally, when someone purchases a patented good she is free to use it, take it apart and rebuild it, and even re-sell it to another without infringing the patent through the 'first sale' or 'exhaustion doctrine.'");

companies like Monsanto are so broad that they can implicate unintentional infringers who harvest GM crops that have blown onto their lands and reproduced themselves without the farmer's knowledge.[148] The unique self-replicating nature of seeds and the common practice of seed saving have resulted in a series of cases that unfortunately sustain the trend of greater patent protection for living organisms that started with *Chakrabarty*.

In *Monsanto Co. v. Scruggs*, the U.S. Court of Appeals for the Federal Circuit settled the conflict between self-replication and the exhaustion doctrine.[149] Scruggs, a cotton and soybean farmer, had purchased GM seeds from Monsanto, but never signed the licensing agreement to refrain from reusing subsequent generations of saved seeds.[150] These particular seeds, like most Monsanto seeds, are designed so that farmers can spray Monsanto's RoundUp pesticide directly onto the crops without any harm to the GM plants, while killing any surrounding non-GM plants.[151] Scruggs relied on a number of arguments, including the exhaustion doctrine, to claim that once the seeds had been sold to him he was free to save them to use for a second generation.[152] The court responded sharply, stating that "[t]he fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology."[153] The court went so far as to claim that applying the exhaustion doctrine to subsequent generations of seeds "would eviscerate the rights of the patent holder" despite Monsanto's continued ability to sell the RoundUp necessary for treatment of GM plants harvested from saved seeds.[154] Scruggs lost his exhaustion argument and was subject to an injunction based on Monsanto's patent enforcement rights under 35 U.S.C. § 154(a)(1).[155]

In addition to the unique issue of self-replication, the trend toward greater patent protection for living organisms has upset a way of life for

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see also Monsanto Co. v. Scruggs, 459 F.3d 1328, 1335-36 (Fed. Cir. 2006) ("The first sale/patent exhaustion doctrine establishes that the unrestricted first sale by a patentee of his patented article exhausts his patent rights in the article.").

148. *See, e.g.*, Monsanto Canada Inc. v. Schmeiser [2004] 1 S.C.R. 902 (Can.).

149. *See generally Scruggs*, 459 F.3d at 1328.

150. *Id.* at 1333.

151. *Id.*

152. *Id.* at 1335.

153. *Id.* at 1336.

154. *Id.*

155. *Id.* at 1338 (quoting 35 U.S.C. § 154(a)(1) (2006) ("[T]he right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.")).

many conventional and organic farmers. The inability to reuse saved seeds, a technique as old as U.S. farming itself, has resulted in a strong emotional response from farmers and activists.[156] Recent reports, furthermore, suggest that Monsanto controls around 95% of all soybeans in the United States and 85% of all corn.[157] The obvious result is a lack of choice in U.S. seed markets.[158] Another less obvious result is that innocent farmers are being held liable for infringement because self-replicating plants cover such a vast area of U.S. farmlands that they can easily cross-contaminate non-GM crops. There are so many GM farms at this point that their crops can establish themselves through gene-flow to non-GM fields by simply blowing in the wind or being transferred by bees.[159] Monsanto denies that they would ever bring suit against farmers who did not knowingly infringe their patents in a substantial way.[160] But popular anecdotes about settlements suggest otherwise.[161] Admittedly, there is no Monsanto case directly on point in the United States. It is, however, well accepted precedent that intent is not required for patent infringement.[162] In *Monsanto Canada v. Schmeiser*, for example,

156. *See, e.g.*, FOOD, INC. (Magnolia Pictures 2008) (covering the struggle of Moe Parr, a seed cleaner, who for years had helped farmers save seeds for next year's harvest); *see also* Monsanto Co. v. Parr, 545 F. Supp. 2d 836 (N.D. Ind. 2008).

157. Christopher Leonard, *Monsanto Uses Patent Law to Control Most of U.S. Corn, Soy Seed Market*, ASSOCIATED PRESS, Dec. 16, 2009, http://www.cleveland.com/nation/index.ssf/2009/12/monsanto_uses_patent_law_to_co.html.

158. *Id.* (reporting that Monsanto is under investigation by the Federal government and a few states for potential antitrust violations).

159. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2755 n.3 (2010).

160. *Monsanto Answers Your Questions About the Movie Food, Inc.*, MONSANTO, http://www.monsanto.com/food-inc/Pages/default.aspx (last visited Jan. 19, 2011) ("It has never been, nor will it be, Monsanto policy to exercise its patent rights where trace amounts of our patented traits are present in farmers' fields as a result of inadvertent means. We have no motivation to conduct business in this manner, nor have we ever attempted to conduct business in this manner—and we surely would not prevail in the courts if we did.").

161. Armen Keteyian, *Agricultural Giant Battles Small Farmers*, CBS NEWS, Apr. 26, 2008, http://www.cbsnews.com/stories/2008/04/26/eveningnews/main4048288.shtml--Popular. Keteyian discusses the Runyons, farmers in Indiana, who assert that Monsanto illegally trespassed on their land to gain samples of seeds and then threatened a patent infringement suit. Monsanto eventually dropped the claims, but not until after the Runyons claim they almost lost their farm. *Id*.

162. Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627, 645 (1999) ("Actions predicated on direct patent infringement, however, do not require any showing of intent to infringe; instead, knowledge and intent are considered only with respect to damages." (citations omitted)).

Monsanto was allowed to bring suit against a potentially unintentional infringer in Canada.[163]

In *Schmeiser*, the Canadian Supreme Court found Schmeiser, a canola farmer, guilty of infringement despite the fact that he never signed a purchase agreement with Monsanto or used the RoundUp pesticides necessary for benefiting from use of Monsanto's GM canola.[164] The *Schmeiser* opinion makes two major conclusions extending the trend of patent protection: a rejection of a "gene-flow" defense and the court's broad definition of "use" for purposes of infringement.

From the very beginning of the case, the court makes it abundantly clear that it was not willing to accept a defense based on gene-flow.[165] It only wished to deal with the issue of applying "established principles of patent law."[166] As a result, the factual dispute between Monsanto (who claimed that 95-98% of Schmeiser's crops were GM canola) and Schmeiser (who claimed it was only one of his various fields that contained GM canola) was never considered by the Canadian Supreme Court.[167] Deference to the lower court's fact finding is not surprising. The fact, however, that both courts acknowledged the likely effects of gene-flow but were nevertheless unconcerned with determining the degree of its impact or the possibility of such a defense in future cases indicates a clear preference for avoiding such factually complicated but important considerations.[168] The very real impact of gene-flow was seen only a few years later, when Schmeiser forced Monsanto to settle in a separate suit where he had definitive proof of gene-flow.[169] Ignoring

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163. Robert Stack, *How Do I Use This Thing? What's It Good for Anyway? A Study of the Meaning of Use and the Test for Patent Infringement in the Monsanto Canada Inc. v. Schmeiser Decisions*, 18 I.P.J. 277, 286 (2005) ("There was no general finding that Schmeiser was aiming to grow a pure Round-up resistant crop on which to spray or that he had other long term plans for exploiting the Transgene. Nor did the FCTD find that Schmeiser was preparing to spray in 1998. Schmeiser testified that he would have needed far more Roundup than he had purchased in 1998 in order to spray in that year, and neither Justice MacKay nor Monsanto challenged the accuracy or significance of this testimony.").

164. *Id.*

165. *Schmeiser*, 1 S.C.R. 902, at para. 2.

166. *Id.* at para. 3.

167. *Id.* at paras. 64-65.

168. *Id.* at paras. 66-68.

169. Matt Hartley, *Grain Farmer Claims Moral Victory in Seed Battle Against Monsanto*, GLOBE & MAIL (CANADA) (March 20, 2008), *available at* http://www.theglobeandmail.com/news/national/article26378.ece (describing Percy Schmeiser's successful settlement with Monsanto after the second time his crops were cross contaminated by GM crops and his refusal to sign what he referred to as a "gag order" as a term of the settlement).

gene-flow allowed the court to go directly to the issue of defining use, which had even worse consequences for Schmeiser.

Monsanto's GM plants, as described earlier, are useful because they allow farmers to spray RoundUp pesticides directly onto crops without harming the growth of those crops. Planting GM canola without subsequent use of RoundUp, therefore, would make no sense.[170] Percy Schmeiser, however, never used RoundUp on his GM crops.[171] How then did he infringe Monsanto's patent without ever using the GM canola's one uniquely engineered feature? The court was able to find infringement, despite this lack of functional use, because it defined "use" exceptionally broadly. The court rejected the contention that the patent existed only for the sake of the specific RoundUp resistant genes and instead contended that the patent granted Monsanto full rights to the canola plant itself.[172] Therefore, the mere presence of Monsanto's specific genes in the entire genetic make-up of the canola plant was sufficient to find infringement because Schmeiser sowed and cultivated the seeds.[173]

There is some irony in the majority's holding. The majority, unlike the dissent, did indeed claim it was possible to own an entire plant merely by virtue of adding a small amount of genetic variation. It compared this variation to a "lego block" in a larger overall "lego structure," which is the wild plant prior to genetic modification.[174] The damages remedy based on this analogy reveals the contradiction and irony in the majority's reasoning. After taking Schmeiser all the way to the Canadian Supreme Court in defense of their patented GM canola, Monsanto was awarded nothing in damages.[175] The accounting method for determining damages required that Schmeiser pay Monsanto for the difference between the "profit attributable to the invention and his profit

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170. This is different from the factual situation in *Scruggs*, where the defendant also claimed that he was not using RoundUp, but only the cotton seeds containing the resistance. Scruggs wanted to use the GM cotton not for its RoundUp resistance, but for its Bollgard trait, which imparted the plant with a genetic resistance to certain insects that did not require the use of pesticides. *See Scruggs*, 459 F.3d at 1339.

171. *Schmeiser*, 1 S.C.R. 902 at para. 81.

172. *Id.* at para. 80.

173. *Id.* at para. 92.

174. *Id.* at para. 42. *But see id.* at para. 156 (Arbour, J., dissenting) ("There is no genuinely useful analogy between growing a plant in which every cell and every cell of all its progeny are remotely traceable to the genetically modified cell and contain the chimeric gene and putting a zipper in a garment, or tires on a car or constructing with Lego blocks. The analogies are particularly weak when it is considered that the plant can subsequently grow, reproduce, and spread with no further human intervention.").

175. *Id.* at para. 105.

had he used the best non-infringing option."[176] The court found that the Schmeisers' profits "arose solely from qualities of their crop that cannot be attributed to the invention."[177] These attributes of the "best non-infringing option" (i.e., everything but the genetic variation), which would be found in the "parent" canola plants Monsanto used to develop its GM canola or in the seeds saved by non-GM farmers for centuries, nevertheless are patentable by Monsanto based on the lego analogy. Furthermore, while this reasoning protected Schmeiser from losing his farm, it also gave Monsanto and similar biotech companies the greatest possible protection for their GM crops. The parallel victories between greater patent protection and expansion of GM crops are hard to ignore. A recent case, however, offers some hope for non-GM farmers, and perhaps non-GM fishermen.

In June 2010, Monsanto was back in court protecting their property interests in a different RoundUp Ready crop: RoundUp Ready Alfalfa.[178] In *Monsanto v. Geertson Seed Farms*, Monsanto responded to an injunction that barred further planting of their GM Alfalfa based on gene-flow concerns until completion of a full Environmental Impact Statement pursuant to NEPA.[179] The plaintiffs in the case, alfalfa farmers and food safety groups, had successfully challenged a Finding of No Significant Impact under the more lenient and abbreviated Environmental Assessment used to approve the GM Alfalfa.[180] The Court reversed the injunction because it was not possible to prove the required showing of irreparable injury under the four-factor test for approving a permanent injunction.[181] The holding, however, was narrow because the failure to prove irreparable injury stemmed from the broad nature of the injunction, which barred all planting of GM Alfalfa during the pending EIS.[182] Nevertheless, the Court's opinion actually offered non-GM farmers two powerful tools for proving the injurious effects of gene-flow from GM plants.

First, the opinion from the lower court, which was not disputed by the parties on appeal, indicated that the failure to address major issues in an EA can result in a violation of NEPA and the need for a more thorough EIS.[183] Second, although no irreparable injury was proven,

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176. *Id.* at para. 102.
177. *Id.* at para. 104.
178. *See* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).
179. *Id.* at 2749-52.
180. *Id.* at 2750-51.
181. *Id.* at 2759-61.
182. *Id.*
183. *Id.* at 2751-53.

given the broad remedy granted, the Court was clear that gene-flow or the mere threat of gene-flow grants standing to seek an injunction.[184]

While the "victory" in *Geertson* was minimal, the case demonstrated a recognition by the Court that the property interests of biotech companies, which seem to stretch back in time to Jefferson's Patent Act of 1793, are finally being balanced against competing interests of conventional farmers. In *Geertson*, the Court recognized both an environmental and economic injury to the non-GM farmers in this balancing of interests.[185] This recognition, however, has taken years since the initial GM plants of Monsanto were first grown in the United States in 1996.[186] Is it too late? And what help will it be for non-GM fishermen, who will soon be entering the even newer world of property rights in GM *animals*?

C. Applying Patent Law to the Hypothetical Escape

Patent law, even more so than wildlife law, has adverse consequences for the hypothetical fishermen described in Part I.[187] Wildlife law does not resolve the issue of possession of AAS hybrids nor does it provide the protection non-GM fishermen might receive from the public trust doctrine.[188] Patent law, however, is quite clear that the trend favors protection of intellectual property owned by biotechnology companies.[189] The patent for AAS, therefore, would be considered infringed upon as soon as the fishermen sold escaped AAS or AAS hybrids. Much like Percy Schmeiser, non-GM fishermen would be liable for infringement after having sold fish containing the genetic "lego blocks" inserted into AAS by AquaBounty, whether the fish are escaped first generation AAS, later generations of AAS, or simply AAS-wild hybrids expressing the specific AAS genetic advantages.

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184. *Id.* at 2755 ("Such harms [i.e., burdens from investigating and protecting against gene-flow], which respondents will suffer even if their crops are not actually infected with the Roundup ready gene, are sufficiently concrete to satisfy the injury-in-fact prong of the constitutional standing analysis. Those harms are readily attributable to [the Animal and Plant Health Inspection Service's] deregulation decision, which, as the District Court found, gives rise to a significant risk of gene-flow to non-genetically-engineered varieties of alfalfa.").

185. *Id.* at 2756.

186. *See Food, Inc. Movie*, MONSANTO, http://www.monsanto.com/food-inc/Pages/default.aspx (last visited Mar. 19, 2011).

187. *See supra* Part I.

188. *See supra* Part III.

189. *See supra* Part III.

Thus, patent law, as it currently stands, makes it clear that the self-replicating nature of wild animals, the fishermen's innocence, and gene-flow are not valid defenses against infringement claims. The fishermen, despite never having heard of AAS, will be held liable for infringing the AAS patent.

V. CONCLUSION

The current legal framework for determining property rights in AAS lacks clarity and equity. Wildlife law is bound by an internal contradiction: capture is the dominant principle, but proper identification can trump capture. However, the mostly invisible genetic "earmarks" of AAS fail to give notice to anyone other than AquaBounty, which defeats the purpose of notice as developed in *Shepard*. Ownership from a property standpoint, furthermore, is only an important pre-sale consideration and fisherman will receive no benefit from being able to possess, but not sell their salmon catches.[190] The current state of wildlife law for determining possession of GM animals escaped into the wild, therefore, offers no legal certainty of possession for either the patent holders or captors of escaped GM animals. Courts should further develop the basic concepts of identification, as provided in *Shepard*, in a way that takes into account the unique nature of GM animals without imputing identification to parties based on largely invisible genetic earmarks.

Patent law, which will be the focus for purposes of the post-sale disputes surrounding AAS, lacks equity. Innocent fishermen, under the current case law, will be subject to liability for the unintentional sale of AAS, despite their best efforts to capture wild Atlantic salmon. Fishermen, therefore, need remedies addressing the inequities in patent law. Conceptually, it is useful to conceive of a non-GM fishermen's remedies as existing in two broad categories: pre-escape remedies, which protect their existing rights, and post-escape remedies, which respond to possible AquaBounty suits. Courts and legislatures should use these existing but *insufficient* remedies as tools for establishing a more

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190. For the purposes of AAS, therefore, wildlife law is far less important than patent law, which has post-sale consequences. Not all GM animals are only valuable when sold and consumed, however. Situations may also arise in which courts find themselves having to determine the ownership of GM pets with economic and sentimental value, such as a glowing pig. *See, e.g.*, Sheryl Lawrence, Comment, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 259-63 (2007).

equitable balance between the rights of biotechnology companies and innocent fishermen. However, the uncertainty and insufficiency of these remedies should also serve as a warning that the current state of property law as applied to GM animals is not a workable system.

A. Pre-Escape Remedies

1. Seeking an Injunction of AAS Production Based on Gene-Flow Concerns

The first possible course of action relies on the framework laid out in *Geertson*.[191] This is not the most effective option because the Geerston Court, although opening the door for standing, also made it quite clear that a full injunction against the use of GM organisms is not necessary to avoid irreparable injury. The path, however, is well documented in *Geertson* and it is an appealing option so far as it acts as a prophylactic measure to avoid injury entirely.

In terms of the actual injunction, fishermen would need to demonstrate how the unique nature of wild animals, as opposed to plants in *Geertson*, makes a permanent or exceptionally broad injunction necessary. This will be difficult. The fact that reversing an escape and establishment of AAS might be impossible because it will result in the actual destruction of existing wild populations certainly favors the fishermen's petition for injunction. AquaBounty and affiliated fish farms, however, can also fall back on the fact that the containment systems for AAS, at least as they currently exist, boast almost one hundred percent containment success. So long as AAS farms can boast reasonably high levels of containment, the courts will likely not favor a full injunction against all AAS farms. Courts would also be reluctant to enforce more nuanced injunctions, given that this would require continual monitoring to ensure enforcement (e.g., requiring all new fish farms to follow certain containment processes).

2. Using the Public Trust Doctrine to Stop or Limit AAS Sites at the State Level

The public trust doctrine offers fishermen and non-GM stakeholders a better means to block the construction of AAS sites. As discussed in Part III, some state courts view their public trust doctrine as not only granting state rights to control trust resources, but also imposing

191. *See supra* Part III.

obligations on the state to ensure the protection of trust resources.[192] If non-GM fishermen make a compelling case about the unique danger posed by AAS to state waters, the most traditionally protected of trust resources, then courts can use the public trust doctrine to force more in-depth environmental review at the state level. The insufficiency of the federal system of review for AAS also bolsters the effort to seek imposition of obligations. Fishermen will need to bring this suit against the state (e.g., the Department of Marine Resources) as the trustee, and not private fish farms.

3. State Legislation to Require Heightened Review and Insurance

A legislative remedy is a more optimal approach because it would allow non-GM fishermen and stakeholders to rally public support and also could avoid the influence of patent protection trend. In addition to public pressure, states might respond to such requests for two reasons. First, states that border fish farms, but do not have their own cash-generating fish farms, would have an incentive to protect their wild industries from bordering escapes. Second, the public trust doctrine would serve as an equally useful leveraging tool in the legislative context. The supremacy of federal patent law obviously poses a barrier to any state legislation directly affecting the legal definition of infringement. Effective legislation, therefore, would likely take the form of heightened environmental review standards as well as strict insurance liability. Insurance liability for AAS farms would not only serve as a source to remedy the damages of any escape, but would also act as a deterrent against the start-up of underfunded fish farms.

B. Post-Escape Remedies

Post-escape remedies, as mentioned above, are far less promising for non-GM fishermen. As patent law currently exists, there are no defenses for unintentional infringement or gene-flow. Non-GM fishermen, much like non-GM farmers, will be held liable for infringement. As demonstrated by *Scruggs* and *Schmeiser*, challenges to the validity and enforcement of GM organism patents will not be considered valid defenses. Therefore, challenging the damages, as was successfully done in *Schmeiser,* is the best existing strategy for non-GM fishermen charged with infringement. In essence, non-GM fishermen must demonstrate that they do not benefit from their sale of AAS anymore than they would

192. *See supra* Part III.

from the sale of wild Atlantic salmon. This is more difficult in the case of AAS than GM plants because the AAS sold by fishermen will invariably be larger and hence more valuable in net weight than the wild fish they normally catch. Fishermen, however, can claim that the AAS is worth far less than wild caught non-GM salmon because their consumer base does not want to eat GM salmon. As a result, they may actually be suffering losses from their capture and sale of AAS. This, of course, is an insufficient remedy. Innocent fishermen should not be subject to the expense of litigation for unintentional infringement caused by gene-flow in the first place.

The uncomfortable relationship between GM plants and patent law should not be extended to GM animals. The confusion created by GM animals in the wildlife law context alone should serve as notification that GM animals are not typical property. Courts and legislatures must respond to these confusions not by further entrenching this uncomfortable relationship, but by recognizing the realities of gene-flow and offering non-GM fishermen some protection from the consequences of patenting "anything under the sun" in our modern world of GM animals.