Owning Omega-3: Monsanto and the Invention of Meat

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In August of 2010, Anna Salleh of the Science Unit of the Australian Broadcasting Corporation broke a story about Monsanto seeking to patent the enhancement of meat, including omega-3 fatty acids:

Enhanced pork is sparking debate over the ethics of placing patents on food. Patent applications covering the enhancement of meat, including pork with omega-3 fatty acids, are stimulating debate over the ethics and legalities of claiming intellectual property over food. Monsanto has filed patents that cover the feeding of animals soybeans, which have been genetically modified by the company to contain stearidonic acid (SDA), a plant-derived omega-3 fatty acid... Omega-3s have been linked to improved cardiovascular health and there are many companies engineering them into foodstuffs. But the new patent applications have touched a raw nerve among those who see them as an attempt by the company to exert control over the food chain. (Salleh 2010)

This article provides a critical evaluation of the controversy of Monsanto’s patent applications, and the larger issues over patenting food. It first considers the patent portfolio of Monsanto; the nature of the patent claims; and the examination of the claims by patent examiners. Second, it examines the withdrawal and revision of the patent claims by Monsanto in the wake of criticism by patent authorities and the public disquiet over the controversial application. Third, this article considers the larger policy issues raised by Monsanto’s patent applications – including the patenting of plants, animals and foodstuffs. There is also a consideration of the impact of patents upon the administration of healthcare, competition and research.

Monsanto and Its Patent Portfolio

Monsanto is an agricultural biotechnology company based in the United States. Originally, the company was focused on the production and marketing of agricultural chemicals and herbicides. As the result of the expiry of patents on key chemicals, the company has shifted its focus to the field of biotechnology. In his remarks to the 2010 Annual Report, Hugh Grant (2010), the chief executive officer, President, and Chairman of Monsanto, envisaged this future role for the company:

Creating value for farmers around the world by developing and delivering best-in-class seeds and traits is at the heart of our business. Our customers are clear in what they want from Monsanto. They want us to continue to invest in research and development (R&D) to help bring innovative approaches to the farm. They want more top-performing germplasm and trait choices across geographies. They want a broad array of product choices across all crops. And they want us to price our products in a way that encourages trial and adoption.

Monsanto has been a significant player in patent law and agriculture. As well as developing extensive patent portfolios in a range of sectors, the company has been involved in a number of key test cases such as the matter of In re Fisher on patent utility (Rimmer 2007); the case of Schmeiser v Monsanto on patent infringement; a battle in the European Court of Justice over a

soybean patent, and disputes over technology user agreements. In this most recent patent application, Monsanto has once again tested the limits of patent laws, with its pioneering patents in respect of SDA omega-3 soybeans.

Of late, Monsanto has been engaged in extensive research and development (R&D) in respect of stearidonic acid (SDA) omega-3 soybeans:

Monsanto researchers are developing SDA (stearidonic acid) omega-3 soybeans that result in an improved soybean oil containing enhanced levels of omega-3s. Working with food companies, Monsanto is looking to incorporate these oils in many foods, including beverages and snack bars. Researchers discovered there may also be benefits to livestock consuming the omega-3 soybean oil as well. Monsanto employees studied the effect on chickens, pigs, fish and cows (all raised for their meat) consuming SDA omega-3 through their soy meal feed (these animals are regularly fed soy meal/soy protein today). Early studies show after eating feed with the omega-3 soybean oil, the animals have more omega-3s in their system, improving animal health similarly to humans. And, as a result of increased omega-3 levels in these animals, the omega-3s can be passed on to consumers who eat the cow, chicken or pig meat. (Monsanto 2010)

Monsanto has been assiduously building a portfolio of patents relating to SDA omega-3 soybeans. As of 2010, there were 22 patent families – with filings in a range of countries. Six of these patent families related to animals and animal by-products. Six patent families cover animal feed. Five of these patent families related to the use of SDA oil in food elements. Five patent families focused on the genetic elements, which allow the production of SDA in soybeans. One patent family concerned the transformation event. Five patent families related to industrial uses of the oil and oil applications.

In 2009, Monsanto Technology LLC filed a patent application under the Patent Co-operation Treaty for ‘methods of feeding pigs and products comprising beneficial fatty acids’ (Hartnell et al. 2008). The patent application describes the field of the invention thus: ‘The invention relates to the enhancement of desirable characteristics in pigs and/or pork products through the incorporation of beneficial fatty acids in animal feed or in animal feed supplements’. The application elaborates: ‘More specifically, it relates to methods of production and processing of pork products compromising polyunsaturated fatty acids including stearidonic acid’.

The abstract of the invention gives a sense of the breadth of the patent:

The present invention provides for improved pork products for human consumption and methods of producing such pork products by incorporating healthy lipids containing stearidonic acid into swine feed products. Furthermore, the present invention provides methods for producing said products. In one embodiment of the invention, an animal may be fed feed comprising a transgenic plant product. In other embodiments of the invention, pork meat products for human consumption, such meat products comprising SDA, EPA, and DHA are disclosed. In further embodiments of the invention, pork products comprising novel fatty acid profiles are disclosed. (Hartnell et al. 2008)

The patent application describes the field of the invention thus: ‘The invention relates to the enhancement of desirable characteristics in pigs and/or pork products through the incorporation of beneficial fatty acids in animal feed or in animal feed supplements’. The application elaborates:

3 Monsanto Technology LLC v. Cefetra BV and Others (2010), C-428/08, European Court of Justice.
‘More specifically, it relates to methods of production and processing of pork products compromising polyunsaturated fatty acids including stearidonic acid.’

The scope and breadth of protection afforded by a patent is determined by its claims. The scholars, Lionel Bently and Brad Sherman, emphasise that ‘the primary function of the claims is to set out the scope of the legal protection conferred by the patent’ (2009, pp. 263–364). The pair comment:

A number of different rules and procedures regulate the form that claims ought to take. At a general level, the contents of the claims must comply with the substantive requirements for patentability: namely, subject matter, novelty, and non-obviousness. The claims must also define the matter for which protection is sought in terms of the technical features of the invention, be clear and concise, be supported by the description, and relate to one invention, or a group of inventions that are so linked as to form a single inventive concept. (Bently & Sherman 2009, p. 368)

Bently and Sherman reflect that patent claims are a highly specialised legal discourse designed to be read by patent attorneys, examiners, judges, and scientists:

As well as being written for specialists, the drafting and reading of claims builds upon well-established and sophisticated techniques and procedures that make them difficult for the uninitiated to understand. (Bently & Sherman 2009, p. 365)

In my opinion, the major claims in Monsanto’s initial patent application were breathtaking. Claim 1 is for a:

[P]ork product for human consumption comprising stearidonic acid and wherein the concentration of said SDA is at least 0.05 g per 100 g of fat in the pork product and wherein a portion of said SDA is incorporated in the tissues of said pig after said pig is provided a feed composition containing SD.

Claims 2 to 17 provide variations on the first claim. Claim 18 relates to

[T]he pork product of claim 1 wherein said pork product is selected from the group consisting of bacon, ham, pork loin, pork steaks, lard, pork rinds, or other pork products.

Claims 19 to 33 offer further variations on claim 18. Claim 34 is for a ‘method of producing pigs comprising providing a nutritious composition comprising stearidonic acid (SDA) as a feed source for said pigs’. Claim 35 provides that such a ‘nutritious composition comprises seeds selected from the group consisting of soybeans, safflower, sunflower, canola, and corn’. Claim 46 concerns a ‘pork meat product for human consumption comprising stearidonic acid and eicosapentaenoic acid’. Claim 70 concerns a:

[S]wine feed comprising (a) stearidonic acid; (b) gamma linolenic acid (GLA); (c) additional feed components wherein said swine feed comprises at least about 0.10% stearidonic acid and about 0.07% GLA, wherein the ratio of SDA/GLA is at least about 1.3.

The patent application has 89 claims in total.

For a patent to be valid, an applicant must establish that the invention can be classified as patentable subject matter. Furthermore, the applicant must demonstrate that the invention is novel and displays an inventive step according to a person skilled in the art, at the time of filing. Moreover, an applicant must show that the invention has utility or industrial applicability.
The international preliminary patentability report by the patent examiner, Kevin Rooney, of the European Patent Office was quite critical of the patent application put forward by Monsanto (Patentscope 2010). On the criteria of novelty, the examiner was of the view that only patent claims 51–69 displayed novelty. He was of the view that claims 1–57 and 70–89 lacked novelty because they had been anticipated by a range of documents and patents (Daza et al. 2007; Kang & Park 2007; Guil-Guerrero 2007; Kriese, et al. 2004; Wilson, et al. 2002; Arhanet et al. 2006; CSIRO and the University of Tasmania 2007). On the criteria of an inventive step, Rooney was of the view that none of the claims were valid. However, on the criteria of utility or industrial applicability, Rooney was satisfied that the patents satisfied such criteria.

Withdrawal of Patent Claims

In response to the international search report and the written opinion, Monsanto made amendments to the patent application on the 6 July 2010. Claims 1–89 were replaced by amended claims 1–32. Claims 34–45 were renumbered as claims 1–12. Claims 70–89 had been renumbered as claims 13–32. Such claims relate to the feed source for pigs. Monsanto had abandoned claims 1–33 and 46–69. This amounts to a significant reduction in the scope and the breadth of the patent application.

In a press release, Monsanto (2010) explained the withdrawal of some claims and the revision of other claims. It is worthwhile quoting extensively from this press release to ensure that the company’s position in the controversy is fairly presented.

The company stressed that ‘Monsanto did not invent meat’ and that ‘Monsanto does not intend to take ownership of livestock or fish or to sell company-branded milk, meat or eggs enriched with omega-3s to consumers.’ Explaining the motivations behind filing the patents, Monsanto noted: ‘The company recognises that while many see this as a positive step in finding new ways to get essential nutrients in our diets, it also raises some questions.’ The company observed:

Monsanto decided to apply for patents based on this health benefit to protect the researchers’ discovery. If the patent is granted, Monsanto does not intend to get involved in livestock or fish production or sell company-branded milk, meat or eggs enriched with omega-3s directly to consumers. (Media release, Monsanto 2010)

Monsanto noted: ‘We made this claim to ensure someone else wouldn’t file a patent claim on the derived benefit resulting from omega-3 animal feed (including Monsanto’s improved soybean’.

The company observed:

If someone else filed a patent on another step of the process (including the meat itself), it could ‘block’ the use of Monsanto’s SDA omega-3 soybeans from being used in animal feed, simply by virtue of the third party having their end-use application on file.

The company noted: ‘The Monsanto applications serve as official notice of what Monsanto scientists are working on to others in the private and public sectors.’ Monsanto stressed that the ‘disclosure of exactly what Monsanto researchers invented is necessary to protect new technological advances.’

Discussing the withdrawal of the patent claims, Monsanto emphasised that it had repudiated any claims in respect to animals and their meat:

Since the initial patent filings, Monsanto has taken steps to withdraw the specific claims in the patent
applications relating to animals and their meat. There hasn’t been any change in the derived benefits we expect from our SDA omega-3 soybeans, but because the earlier application disclosed the animal and meat benefits, no one else can now claim these as their invention. It also makes it clear **Monsanto has no plans to take ownership of or sell company-branded omega-3 enriched meat.**

The company said:

Monsanto is currently looking at ways to accomplish public disclosure of company discoveries without having to file patent applications, so in the future patent applications won’t include these derived benefit types of claims.

It noted:

The company and employees also want livestock and food producers to be free to develop products that can make the benefits of this enhanced feed available to both animals and humans.

Monsanto stressed that its key objective under patent law was to protect the soybean feed that it had developed. The company also seems to have left open the way to make patent claims about animal health.

This intriguing press release could be read in a number of different ways – depending on one’s political position and ideological persuasion.

The press release could be read at face value, and taken as a good faith account of Monsanto’s actions. The message could be alternatively read as a coded mea culpa – an admission by the company that it had overreached itself with the extensive patent claims, and had retreated to a more cautious position. Rivals and competitors could be more suspicious about the press release, seeing it as braggadocio on the part of Monsanto. Notwithstanding the withdrawal and revision of the patent claims, certain environmental groups remained unconvinced. Laura Kelly of Greenpeace was reported to be concerned that, even if they do not claim ownership of the meat, Monsanto might still claim royalties on meat product sales produced using their transgenic feed (Salleh 2010).

**Policy Themes**

This individual controversy has erupted against the background of a larger, rolling, policy debate about intellectual property and biotechnology (Rimmer 2008). Monsanto’s patent applications raise a number of larger policy themes about the ownership of plants, animals and food. The patent applications also highlight meta-questions about the impact of patent law upon patient care, healthcare and competition.

First, the patent applications raise questions about patenting plants. There have been a number of challenges to the grant of patents in relation to agriculture. In the case of **Diamond v. Chakrabarty**, the majority of the Supreme Court of the United States recognised that the **Plant Patent Act 1930** (US), the **Plant Variety Protection Act 1970** (US), and the general regime of utility patents could co-exist alongside one another.\(^5\) In the case of **JEM Ag Supply Inc v. Pioneer Hi-Bred International Inc.**, the majority of the Supreme Court of the United States held that utility patents could be granted in respect of plants – as well as plant patents and plant breeders’ rights.\(^6\) In the case of **Schmeiser v. Monsanto**, McLachlin J and Fish J of the Supreme Court of Canada emphasised: `Under the present Act, an invention


in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science’. In *Grain Pool of Western Australia v. Commonwealth*, the High Court of Australia held that the intellectual property power of the Australian Constitution supported both the patent regime and the plant breeder’s rights system. The European Patent Office has been considering the merits of patents being granted in respect of foods such as broccoli and tomatoes.

Notwithstanding the precedents of superior courts, a number of farmers’ collectives, environmental groups, and anti-biotechnology groups have campaigned for patents on plants to be revoked and prohibited.

Second, the patent applications highlight issues concerning patenting animals. In the case of *Martek Biosciences Corporation v. Nutrinova Inc.*, the United States Court of Appeals for the Federal Circuit considered a patent infringement action related to omega-3. All asserted claims of the patent were directed to methods for achieving high concentrations of omega-3 HUFA in an ‘animal.’ Gajarsa J of the Court of Appeals for the Federal Circuit discussed the definition of an ‘animal’ in the patent claims:

Under our precedent, because the patent does not clearly disclaim coverage of humans, it would be erroneous to limit the claims to certain types of animals that the inventor anticipated would prove useful in the invention. That is especially true in the present case because the patent expressly defines the claim term ‘animal’ broadly enough to encompass humans and discloses uses of the claimed invention applicable to humans.

Gajarsa J held: “The proper construction for the claim term “animal” is the one explicitly provided by the patentee: “any organism belonging to the kingdom Animalia,” which includes humans.” In dissent, Lourie and Rader JJ dissented:

Having examined the use of the term ‘animal’ in the claims and the specification of the ‘244 patent, I believe it is clear that one of ordinary skill in the art would conclude that, despite the purported definition in the specification, the term ‘animal’ in the claims cannot include humans.

Third, the patent applications tap into the controversy about patenting food. Anna Shih notes that ‘patenting food products and food-processing techniques is not new, or even uncommon’ (Shih 2002). She reflects:

Patenting food products and food-processing techniques is not new, or even uncommon. The US Patent and Trademark Office (USPTO) has an entire category in its patent classification system devoted to food-related patents. Class 426, entitled ‘Food or Edible Material: Products, Compositions, and Products’, includes over five hundred sub-categories covering every aspect of food and food processing, such as baked or puffed ready-to-eat breakfast cereal (subclass 621) and food-frying methods (subclass 438). Given the breadth of Class 426 and the value that many companies place on patents, nearly every food item in a supermarket or fast-food restaurant could conceivably incorporate at least one patented invention in its creation, and the patents could be directed to the food product itself, additives in the food product, the manner in which it is processed, or even the machinery used in the processing. (Shih 2002)

Nonetheless, there remains controversy over patenting food and edible material. Absurd patents – such as J.M. Smucker Company’s United States Patent Number 6,004,596 on the ‘Sealed Crustless Sandwich’ – have attracted ire (Kretchman & Geske 1997). High-minded critics are concerned about the impact of intellectual property on food security, particularly in light of climate change, urbanisation, and the growth in the world population (Patel 2007). Olivier de Schutter (2009), the special United Nations Rapporteur on the right to food, has called for flexible exceptions to patent rights and plant breeders’ rights – such as

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11 Ibid at 1382.
12 Ibid at 1382.
13 Ibid at 1385.
a broad experimental use defence; farmers’ rights compulsory licensing, crown use and acquisition; and competition regulation. He maintains that such measures are particularly important when dealing with food shortages, famines and price volatility.

The patent applications of Monsanto tapped into this larger controversy. Greenpeace Australia’s Laura Kelly observed: ‘As a community we need to decide whether we want our most basic foods to be owned by chemical companies’ (Salleh 2010).

Fourth, given the focus upon the health benefits of omega-3, the patent applications raise larger issues about the impact of patent law upon access to healthcare. In the United States, there has been much controversy over Myriad Genetics’ patents over BRCA1 and BRCA2. In response to a challenge to the validity of the patents by the American Civil Liberties Union, Sweet J expressed reservations in a United States District Court about taking a broad approach to patentable subject matter.14 The judge was particularly concerned about the impact of gene patents upon patient care, medical research, and the administration of healthcare:

The resolution of the issues presented to this Court deeply concerns breast cancer patients, medical professionals, researchers, caregivers, advocacy groups, existing gene patent holders and their investors, and those seeking to advance public health.15

The judge held:

The claims-in-suit directed to ‘isolated DNA’ containing human BRCA1/2 gene sequences reflect the USPTO’s practice of granting patents on DNA sequences so long as those sequences are claimed in the form of ‘isolated DNA.’ This practice is premised on the view that DNA should be treated no differently from any other chemical compound, and that its purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character. Many, however, including scientists in the fields of molecular biology and genomics, have considered this practice a ‘lawyer’s trick’ that circumvents the prohibitions on the direct patenting of the DNA in our bodies but which, in practice, reaches the same result. The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA’s existence in an ‘isolated’ form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to ‘isolated DNA’ containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.16

There are grave doubts as to whether the decision is consistent with the broad approach taken to patentable subject matter in previous precedents of superior courts in the United States. The matter is currently under appeal in the United States Court of Appeals for the Federal Circuit.

In Australia, there has been ongoing controversy over gene patents. In November 2010, the Senate Community Affairs Reference Committee released its long awaited report on gene patents. The majority of the committee recommended a number of procedural and substantive reforms to improve the quality of patents granted – particularly in the area of biotechnology. However, a minority of the committee were of the view that there should be a prohibition on gene patents altogether. A private members’ bill has been introduced into Parliament, entitled the Patent Amendment (Human Genes and Biological Materials) Bill 2010 (Cth). The sponsors include the Liberal Party mavericks, Senator Heffernan and Coonan; Greens Senator Siewert, and Independent Nick Xenophon. The rather crudely drafted bill proposes a broad prohibition:

The following are not patentable inventions: (a) human beings, and the biological processes for their generation; and (b) biological materials including their components and derivatives, whether isolated or purified or not and however made, which are identical or substantially identical to such materials as they exist in nature.


15 Ibid.

16 Ibid.
It is doubtful that such a bill will win the support of the major parties in the Australian Parliament.

Finally, the patent applications highlight questions of patent law and competition. Binney J of the Supreme Court of Canada has emphasised that patents have a strong impact upon competition in the marketplace:

The grant of a patent monopoly for [20 years]... creates, and is intended to create, serious anti-competitive effects. Once the subject matter of the patent is fenced in by the claims, others trespass (advertently or inadvertently) on the forbidden territory at their peril. The boundary is defended by a considerable arsenal of remedies conferred by the Patent Act, including an accounting of the infringer’s profits in an appropriate case. Patent litigation is usually protracted and costly... There is in the meantime a chilling effect on other researchers. They will tend to invest their talents in less litigious areas. Parliament considered this chilling effect to be a worthwhile price for the disclosure of a ‘new and useful’ invention, bringing into the public domain information that might otherwise remain a trade secret, but there is nothing in the Act to suggest that Parliament was prepared to accept the chilling effect in exchange for nothing but speculation.17

There was a concern expressed by a number of rival researchers into omega-3 – including CSIRO, the Pork Cooperative Research Centre, and Australian Pork Limited – about the impact of any patent upon research and competition in this field. Even by publishing and disclosing its research in this field, and making this material part of the prior art, Monsanto perhaps hopes to frustrate the ability of its rivals and competitors to file patents in this field.

The rivals of Monsanto remained sceptical of the validity of the patent claims, and would claim that their research anticipates that of the Missouri agricultural biotechnology company. It is certainly true that CSIRO is a significant competitor to Monsanto in the field, with patents of its own (CSIRO and the University of Tasmania 2007). As part of its Food Futures Flagship, CSIRO has been busy, developing plants that produce Docosahexaenoic acid (DHA), a healthy omega-3 oil component that is vital for human health and normally only available from fish sources. CSIRO (2010) claims that such research is an important step towards ‘improving human nutrition’; ‘reducing pressure on declining fish resources worldwide’ and ‘providing Australian grain growers with new high-value crops.’ CSIRO comments:

Although it will be some years before commercialisation, crop plants capable of producing useful levels of DHA in their own seeds would have many benefits. DHA enriched crop plants could provide consumers with cheaper and more varied sources of DHA – particularly valuable to those with fish allergies or who, because of cost, availability or choice, don’t have a high level of fish consumption in their diet. Demand on natural fish stocks as a source of DHA would be less. Fish in aquaculture could be fed DHA enriched plants, rather than continuing to use other fish as a feed, improving the sustainability of aquaculture without compromising quality. (CSIRO 2010)

CSIRO suggests that omega-3 oils are widely recognised for their ability to reduce ‘coronary heart disease risk’, ‘type-2 diabetes’, ‘Alzheimer’s disease’ and ‘asthma.’ Moreover, CSIRO has been increasingly willing to engage patent litigation,

even with large United States companies – such as in the dispute over its wireless technology.\(^\text{18}\)

So, in the future, there may well be priority disputes over patent applications between Monsanto and CSIRO.

In conclusion, the controversy over Monsanto’s patent application in relation to omega-3 has been resonant in the larger public arena because it has crystallised key issues over intellectual property and biotechnology. In particular, it raised questions about the patenting of plants, animals and food; and touched upon issues over the access to healthcare, research and competition.

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