Beyond Equal

From Same but Different to the Doctrine of Substantial Equivalence

John Paull[1]

A same-but-different dichotomy has recently been encapsulated within the ill-defined concept of "substantial equivalence". By invoking this concept the genetically modified organism (GMO) industry has escaped the rigors of safety testing that might otherwise apply.

The curious concept of "substantial equivalence" grants a presumption of safety to GMO food. This presumption has yet to be earned, and has been used to constrain labelling of both GMO and non-GMO food. It is an idea that well serves corporatism. It enables the claim of difference to secure patent protection, while upholding the contrary claim of sameness to avoid labelling and safety scrutiny. It offers the best of both worlds for corporate food entrepreneurs, and delivers the worst of both worlds to consumers.

The term "substantial equivalence" has established its currency within the GMO discourse. As the opportunities for patenting food technologies expand, the GMO recruitment of this concept will likely be a dress rehearsal for the developing debates on the labelling and testing of other techno-foods - including nano-foods and clone-foods.

"Substantial equivalence"

"Are the Seven Commandments the same as they used to be, Benjamin?" asks Clover in George Orwell's "Animal Farm". By way of response, Benjamin "read out to her what was written on the wall. There was nothing there now except a single Commandment. It ran: ALL ANIMALS ARE EQUAL BUT SOME ANIMALS ARE MORE EQUAL THAN OTHERS". After this reductionist revelation, further novel and curious events at Manor Farm, "did not seem strange" (Orwell, 1945, ch. X).

Equality is a concept at the very core of mathematics; but beyond the domain of logic, equality becomes a hotly contested notion - and the domain of food is no exception. A novel food has a regulatory advantage if it can claim to be the same as an established food - a food that has proven its worth over centuries, perhaps even millennia - and thus does not trigger new, perhaps costly and onerous, testing, compliance, and even new and burdensome regulations. On the other hand, such a novel food has an intellectual property (IP) advantage only in terms of its difference. And thus there is an entrenched dissonance for newly technologised foods, between claiming sameness, and claiming difference.

The same/different dilemma is erased, so some would have it, by appeal to the curious new dualist doctrine of "substantial equivalence" whereby sameness and difference are claimed simultaneously, thereby creating a win/win for corporatism, and a loss/loss for consumerism.

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[1] The Fenner School of Environment and Society, Australian National University, Canberra, ACT 0200, Australia <john.paull[a]anu.edu.au>

This ground has been pioneered, and to some extent conquered, by the GMO industry. The conquest has ramifications for other cryptic food technologies, that is technologies that are invisible to the consumer and that are not evident to the consumer other than *via* labelling. Cryptic technologies pertaining to food include GMOs, pesticides, hormone treatments, irradiation and, most recently, manufactured nano-particles introduced into the food production and delivery stream.

Genetic modification of plants was reported as early as 1984 by Horsch *et al*. The case of Diamond v. Chakrabarty resulted in a US Supreme Court decision that upheld the prior decision of the US Court of Customs and Patent Appeal that "the fact that micro-organisms are alive is without legal significance for purposes of the patent law", and ruled that the "respondent's micro-organism plainly qualifies as patentable subject matter". This was a majority decision of nine judges, with four judges dissenting (Burger, 1980). It was this Chakrabarty judgement that has seriously opened the Pandora's box of GMOs because patenting rights makes GMOs an attractive corporate proposition by offering potentially unique monopoly rights over food.

The rear guard action against GMOs has most often focussed on health repercussions (Smith, 2007), food security issues, and also the potential for corporate malfeasance to hide behind a cloak of secrecy citing commercial confidentiality (Smith, 2004). Others have tilted at the foundational plank on which the economics of the GMO industry sits: "I suggest that the main concern is that we do not want a single molecule of anything we eat to contribute to, or be patented and owned by, a reckless, ruthless chemical organisation" (Grist, 2008, 22).

The GMO industry exhibits bipolar behaviour, invoking the concept of "substantial difference" to claim patent rights by way of "novelty", and then claiming "substantial equivalence" when dealing with other regulatory authorities including food, drug and pesticide agencies; a case of "having their cake and eating it too" (Engdahl, 2007, 8). This is a clever slight-of-rhetoric, laying claim to the best of both worlds for corporations, and the worst of both worlds for consumers. Corporations achieve patent protection and no concomitant specific regulatory oversight; while consumers pay the cost of patent monopolization, and are not necessarily apprised, by way of labelling or otherwise, that they are purchasing and eating GMOs, and thereby financing the GMO industry.

The lemma of "substantial equivalence" does not bear close scrutiny. It is a fuzzy concept that lacks a tight testable definition. It is exactly this fuzziness that allows lots of wriggle room to keep GMOs out of rigorous testing regimes. Millstone *et al*. (1999, 526) argue that "Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgement masquerading as if it is scientific. It is moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit informative scientific research". "Substantial equivalence" grants GMOs the benefit of the doubt regarding safety, and thereby leaves unexamined the ramifications for human consumer health, for farm labourer and food-processor health, for the welfare of farm animals fed a diet of GMO grain, and for the well-being of the ecosystem, both in general and in its particularities.

"Substantial equivalence" was introduced into the food discourse by an Organisation for Economic Co-operation and Development (OECD, 1993) report: "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles". It is from this document that the ongoing mantra of assumed safety of GMOs derives: "Modern biotechnology … does not inherently lead to foods that are less safe … Therefore evaluation of foods and food components obtained from organisms developed by the

application of the newer techniques does not necessitate a fundamental change in established principles, nor does it require a different standard of safety" (OECD, 1993, 10). This was at the time, and remains, an act of faith, a pro-corporatist and a postcautionary approach. The OECD motto reveals where their priorities lay: "For a better world economy" (OECD, 2008). The term "substantial equivalence" was preceded by the 1992 USFDA concept of "substantial similarity" (Levidow, Murphy and Carr, 2007) and was "borrowed" from a prior usage by the US Food and Drug Agency (USFDA) where it was used pertaining to medical devices (Miller, 1999, 1042).

Even GMO proponents accept that "Substantial equivalence is not intended to be a scientific formulation; it is a conceptual tool for food producers and government regulators" (Miller, 1999, 1043). And there's the rub - there is no scientific definition of "substantial equivalence", no scientific test of proof of concept, and nor is there likely to be, since this is a 'spinmeister' term. And yet this is the cornerstone on which rests the presumption of safety of GMOs. Absence of evidence is taken to be evidence of absence. History suggests that this is a fraught presumption. By way of contrast, the patenting of GMOs depends on the antithesis of assumed 'sameness'. Patenting rests on proven, scrutinised, challengeable and robust tests of difference and novelty. Lightfoot *et al*. (2000, 1) report that transgenic plants exhibit "unexpected changes [that] challenge the usual assumptions of GMO equivalence and suggest genomic, proteomic and metanomic characterization of transgenics is advisable".

GMO Milk and Contested Labelling

Pesticide company Monsanto markets the genetically engineered hormone rBST (recombinant Bovine Somatotropin; also known as: rbST; rBGH, recombinant Bovine Growth Hormone; and the brand name Prosilac) to dairy farmers who inject it into their cows to increase milk production. This product is not approved for use in many jurisdictions, including Europe, Australia, New Zealand, Canada and Japan. Even Monsanto accepts that rBST leads to mastitis (inflammation and pus in the udder) and other "cow health problems", however, it maintains that "these problems did not occur at rates that would prohibit the use of Prosilac" (Monsanto, 2007). A European Union study identified an extensive list of health concerns of rBST use (European Commission, 1999). The US Dairy Export Council however entertain no doubt. In their background document they ask "is milk from cows treated with rBST safe?" and answer "Absolutely" (USDEC, 2006). Meanwhile, Monsanto's website raises, and answers, the question: "Is the milk from cows treated with rbST any different from milk from untreated cows? No" (Monsanto, 2007). Injecting cows with genetically modified hormones to boost their milk production remains a contested practice, banned in many countries.

It is the claimed equivalence that has kept consumers of US dairy products in the dark, shielded rBST dairy farmers from having to declare that their milk production is GMO-enhanced, and has inhibited non-GMO producers from declaring their milk as non-GMO, non rBST, or not hormone enhanced. This is a battle that has simmered, and sometimes raged, for a decade in the US. Finally there is a modest victory for consumers: the Pennsylvania Department of Agriculture (PDA) requires all labels used on milk products to be approved in advance by the department. The standard issued in October 2007 (PDA, 2007) signalled to producers that any milk labels claiming rBST-free status would be rejected. This advice was rescinded in January 2008 with new, specific, department-approved textual constructions allowed, and ensuring that any "no rBST" style claim was paired with a PDA-prescribed disclaimer (PDA, 2008).

However, parsimonious labelling is prohibited:

> *No labeling may contain references such as 'No Hormones', 'Hormone Free', 'Free of Hormones', 'No BST', 'Free of BST', 'BST Free','No added BST', or any statement which indicates, implies or could be construed to mean that no natural bovine somatotropin (BST) or synthetic bovine somatotropin (rBST) are contained in or added to the product* (PDA, 2008, 3).

Difference claims are prohibited:

> *In no instance shall any label state or imply that milk from cows not treated with recombinant bovine somatotropin (rBST, rbST, RBST or rbst) differs in composition from milk or products made with milk from treated cows, or that rBST is not contained in or added to the product. If a product is represented as, or intended to be represented to consumers as, containing or produced from milk from cows not treated with rBST any labeling information must convey only a difference in farming practices or dairy herd management methods* (PDA, 2008, 3).

The PDA-approved labelling text for non-GMO dairy farmers is specified as follows:

> *'From cows not treated with rBST. No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows' or a substantial equivalent. Hereinafter, the first sentence shall be referred to as the 'Claim', and the second sentence shall be referred to as the 'Disclaimer'* (PDA, 2008, 4).

It is onto the non-GMO dairy farmer alone, that the costs of compliance fall. These costs include label preparation and approval, proving non-usage of GMOs, and of creating and maintaining an audit trail.

In nearby Ohio a similar consumer *versus* corporatist pantomime is playing out. This time with the Ohio Department of Agriculture (ODA) calling the shots, and again serving the GMO industry. The ODA prescribed text allowed to non-GMO dairy farmers is "from cows not supplemented with rbST" and this is to be conjoined with the mandatory disclaimer "no significant difference has been shown between milk derived from rbST-supplemented and non-rbST supplemented cows" (Curet, 2008). These are "emergency rules": they apply for 90 days, and are proposed as permanent. Once again, the onus is on the non-GMO dairy farmers to document and prove their claims. GMO dairy farmers face no such governmental requirements, including no disclosure requirement, and thus an asymmetric regulatory impost is placed on the non-GMO farmer which opens up new opportunities for administrative demands and technocratic harassment.

Levidow *et al*. (2007) argue, somewhat Eurocentrically, that from its 1990s adoption "as the basis for a harmonized science-based approach to risk assessment" (26) the concept of "substantial equivalence" has "been recast in at least three ways" (58). It is true that the GMO debate has evolved differently in the US and Europe, and with other jurisdictions usually adopting intermediate positions, yet the concept persists. Levidow *et al*. nominate their three recastings as: firstly an "implicit redefinition" by the appending of "extra phrases in official documents"; secondly, "it has been reinterpreted, as risk assessment processes have … required more evidence of safety than before, especially in Europe"; and thirdly, "it has been demoted in the European Union regulatory procedures so that it can no longer be used to justify the claim that a risk assessment is unnecessary" (58).

Romeis *et al*. (2008) have proposed a decision tree approach to GMO risks based on cascading tiers of risk assessment. However what remains is that the defects of the concept of "substantial equivalence" persist. Schauzu identified that: such decisions are a matter of "opinion"; that there is "no clear definition of the term 'substantial'"; that because genetic modification "is aimed at introducing new traits into organisms, the result will always be a different combination of genes and proteins"; and that "there is no general checklist that

could be followed by those who are responsible for allowing a product to be placed on the market" (2).

Benchmark for Further Food Novelties?

The discourse, contestation, and debate about "substantial equivalence" have largely focussed on the introduction of GMOs into food production processes. GM can best be regarded as the test case, and proof of concept, for establishing "substantial equivalence" as a benchmark for evaluating new and forthcoming food technologies. This is of concern, because the concept of "substantial equivalence" is scientific hokum, and yet its persistence, even entrenchment, within regulatory agencies may be a harbinger of forthcoming same-but-different debates for nanotechnology and other future bioengineering.

The appeal of "substantial equivalence" has been a brake on the creation of GMO-specific regulations and on rigorous GMO testing. The food nanotechnology industry can be expected to look to the precedent of the GMO debate to head off specific nano-regulations and nano-testing. As cloning becomes economically viable, then this may be another wave of food innovation that muddies the regulatory waters with the confused - and ultimately self-contradictory - concept of "substantial equivalence".

Nanotechnology engineers particles in the size range 1 to 100 nanometres - a nanometre is one billionth of a metre. This is interesting for manufacturers because at this size chemicals behave differently, or as the Australian Office of Nanotechnology expresses it, "new functionalities are obtained" (AON, 2007). Globally, government expenditure on nanotechnology research reached US$4.6 billion in 2006 (Roco, 2007, 3.12). While there are now many patents (ETC Group, 2004; Roco, 2007), regulation specific to nanoparticles is lacking (Bowman and Hodge, 2007; Miller and Senjen, 2008). The USFDA (2008) advises that nano-manufacturers "must show a reasonable assurance of safety … or substantial equivalence".

A recent inventory of nano-products already on the market identified 580 products. Of these 11.4% were categorised as "Food and Beverage" (WWICS, 2007). This is at a time when public confidence in regulatory bodies is declining (HRA, 2007). In an Australian consumer survey on nanotechnology, 65% of respondents indicated they were concerned about "unknown and long term side effects", and 71% agreed that it is important "to know if products are made with nanotechnology" (MARS, 2007, 22).

Cloned animals are currently more expensive to produce than traditional animal progeny. In the course of 678 pages, the USFDA (2006) "Animal Cloning: A Draft Risk Assessment" has not a single mention of "substantial equivalence". However the Federation of Animal Science Societies (FASS) in its single page "Statement in support of USFDA's risk assessment conclusion that food from cloned animals is safe for human consumption" states that "FASS endorses the use of this comparative evaluation process as the foundation of establishing substantial equivalence of any food being evaluated. It must be emphasized that it is the food product itself that should be the focus of the evaluation rather than the technology used to generate cloned animals" (FASS, 2008, 1).

Contrary to the FASS derogation of the importance of process in food production, for consumers both the process and provenance of production is an important and integral aspect of a food product's value and identity. Some consumers will legitimately insist that their Kalamata olives are from Greece, or their balsamic vinegar is from Modena. It was the British public's growing awareness that their sugar was being produced by slave labour that enabled the boycotting of the product, and ultimately the outlawing of slavery (Hochschild,

2006). When consumers boycott Nestle, because of past or present marketing practices, or boycott produce of USA because of, for example, US foreign policy or animal welfare concerns, they are distinguishing the food based on the narrative of the food, the production process and/or production context which are a part of the identity of the food. Consumers attribute value to food based on production process and provenance information (Paull, 2006). Products produced by slave labour, by child labour, by political prisoners, by means of torture, theft, immoral, unethical or unsustainable practices are different from their alternatives. The process of production is a part of the identity of a product and consumers are increasingly interested in food narrative. It requires vigilance to ensure that these narratives are delivered with the product to the consumer, and are neither lost nor suppressed.

Throughout the GM debate, the organic sector has successfully skirted the "substantial equivalence" debate by excluding GMOs from the certified organic food production process. This GMO-exclusion from the organic food stream is the one reprieve available to consumers worldwide who are keen to avoid GMOs in their diet. The organic industry carries the expectation of providing food produced without artificial pesticides and fertilizers, and by extension, without GMOs. Most recently, the Soil Association, the leading organic certifier in the UK, claims to be the first organisation in the world to exclude manufactured nonoparticles from their products (Soil Association, 2008). There has been the call that engineered nanoparticles be excluded from organic standards worldwide, given that there is no mandatory safety testing and no compulsory labelling in place (Paull & Lyons, in press).

The twisted rhetoric of oxymorons does not make the ideal foundation for policy. Setting food policy on the shifting sands of "substantial equivalence" seems foolhardy when we consider the potentially profound ramifications of globally mass marketing a dysfunctional food. There is a 2x2 matrix of terms - "substantial equivalence", substantial difference, insubstantial equivalence, insubstantial difference - and while only one corner of this matrix is engaged for food policy, and while the elements remain matters of opinion rather than being testable by science, or by some other regime, then the public is the dupe, and potentially the victim. "Substantial equivalence" has served the GMO corporates well and the public poorly, and this asymmetry is slated to escalate if nano-food and clone-food are also folded into the "substantial equivalence" paradigm. Only in Orwellian Newspeak is war peace, or is same different. It is time to jettison the pseudo-scientific doctrine of "substantial equivalence", as a convenient oxymoron, and embrace full disclosure of provenance, process and difference, so that consumers are not collateral in a continuing asymmetric knowledge war.

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