NOTE

CURRENT AND EMERGING ISSUES ON GENETICALLY MODIFIED ORGANISMS

Justice Leonardo A. Quisumbing*

Biotechnology[1] is one field where the law appears to lag behind the science. Yet modern biotechnology is now a booming multi-billion dollar global industry, particularly in food biotechnology. The latter, however, is mired in controversy. Much of it concerns genetically modified organisms and the dangers they pose, when released to the environment or ingested as part of food products for people or feeds for livestock.

Bishop Jesus Varela, an adviser of Biotechnology Foundation, recently underscored the essence of the debate about GMO and food products:

> Society has a moral responsibility to feed the world's burgeoning population. The solution is not population control, but rather, food production. Food biotechnology promises us this is possible though there are risks... Whether GMO can and will deliver its promise to alleviate world hunger remains to be seen. It has enormous potentials. But the risks have to be addressed.[2]

The controversy has reached the streets, most vehemently from the religious sector defending local producers as well as allegedly victimized consumers. Boycotts of GMO food products have been initiated by various religious leaders throughout the country.[3]

The response of the government to the boycott demanding a moratorium on biotech crops such as Bt (bacillus thuringiensis) corn partakes of a forensic challenge to anti-biotech forces. Government authorities claim that the moratorium would mean "reversing more than five years of scientific studies by the government and the private sector", and that such a moratorium would be considered only after a showing by 'overwhelming' scientific evidence that the crop

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[1] "Recombinant DNA and associated techniques [hereinafter recombinant technologies] include the array of techniques used to isolate, cultivate, purify, replicate and convert DNA sequences and other biological products such as lower and higher life forms, cell lines and plasmids." Cannon, Brian C. *Toward A Clear Standard of Obviousness for Biotechnology Patents*, 79 CORNELL L. REV. 735, 737-40 (1994).

[2] "Ex-Bishop Urges Caution on GMOs", Philippine Daily Inquirer, August 12, 2003, p. 14, c. 6.

[3] "Boycott of GMO Food Launched", TODAY, July 22, 2003, p.3 c.2.

poses health and environmental dangers.[4] This position has been directly assailed by some prominent members of the scientific community, arguing[5] that such genetically altered crops were not yet 'scientifically proven to be safe for consumption'.

Despite the deadlocks in trade disputes between organic food producers and GMO technology users[6], other countries in the developing world have built up biotechnology capacities independent of foreign aid. China and India have both been reported as having utilized GMO biotechnology more than most developing countries, on justifications that GMO biotechnology would "overcome widespread poverty, malnutrition, hunger and disease."[7] Given this alleged justification, will GMO biotechnology, (which encompasses recombinant DNA technology or bio-engineering, gene splicing, and genetic modification) truly come to the rescue? If so, at what risks, and ultimately, at what price to consumers, organic producers, government regulators, and other parties who will inevitably bring controversies on these matters to the judicial forum? The following sections discuss some of the landmark cases that have emerged in jurisprudence across the world, addressing unique issues arising concomitantly with the proliferation of use of GMO biotechnology.

Patent on a Life Form: Microbes Win in America

During a round-table conference with judges of the Court of Appeals for the Federal Circuit and patent attorneys in Washington, D.C. early this year, we had a chance to discuss whether a living creature or life form could be the subject of a valid patent.[8] Attention was called to the case of *Diamond v. Chakrabarty*[9].

In 1972, Dr. Ananda Chakrabarty, a GE microbiologist, applied for a U.S. patent on 'human-made, genetically engineered bacterium', which, unlike ordinary bacteria, was capable of breaking down multiple components of crude oil. The patent examiner denied his application on the ground that 'micro-organisms are products of nature' and that 'living things were not patentable'. The Patent Board

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[4] *Ibid.*

[5] *Ibid.*

[6] Bhala, Raj and David A. Gantz, *WTO Case Review 2002*, ARIZ. J. INT'L. L. (Summer, 2003), at 143, 152; *see also* Echols, Marsh. *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998).

[7] "From Indian Taboo, Biotech Is Born", International Herald Tribune, August 19, 2003, p. 11, c.2.

[8] *See* Marden, Emily. *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, Boston Coll. L. Rev. (May, 2003), < http://www.bc.edu/schools/law/lawreviews/meta-elements/journals/bclawr/44_3/02_FMS.htm > [733, 737-84]

[9] 447 U.S. 303 (1980).

of Appeals upheld the examiner's decision. The Court of Customs and Patent Appeals reversed the Board. Commissioner Diamond (Patent Board of Appeals) went on certiorari before the U.S. Supreme Court.

In a split decision, 5 to 4, the U.S. Supreme Court in 1980 held that Chakrabarty's bacterium is patentable. The majority reasoned that Congress meant the patent law to be of wide scope, so as to cover anything under the sun made by man's ingenuity. The fact that the applicant's microorganism is alive is without legal significance for purposes of the patent law, according to the majority, citing another case, *In re Bergy*[10]. What is decisive is the fact that the applicant's microbe bore markedly different characteristics from any found in nature, with the potential for significant utility. The relevant distinction is not between living and inanimate things but between man-made inventions and products of nature. Chakrabarty's claims were upheld. His bacterium passed the triple tests of utility, novelty, and non-obviousness upon which patentability of an invention depends.

This development, according to the minority view, went against the 1970 law known as the Plant Variety Protection Act, which specifically excluded bacteria. The dissenters argued that only the U.S. Congress, not the Supreme Court, could broaden the reach of patent laws. It may be recalled that in 1930, the Plant Patent Act covered only species (whether fruits, nuts or flowers) that are asexually propagated. Breeders' monopoly control over staple crops was rejected, particularly over potatoes. On the other hand, the 1970 Statute on Plant Variety Protection gave only patent-like protection to food crops sexually reproduced (such as corn, wheat, and rice). Prescinding from this analysis, Chakrabarty decision, from the minority point of view, looked novel indeed. This radical development was further bolstered soon by actions taken by the Patent Office itself. It granted a series of patents to another microbiologist (Kenneth Hibberd) on a new line of corn, covering the process of creating the new variety as well as the product --- namely the deoxyribonucleic acid sequence, genes, cells, tissue culture, seed, specific parts of the plant, and the entire plant itself.

Thereafter, it is said the patent office started granting patents on "products of nature", or functional equivalents. Products of skill rather than invention received patents. Even university researchers, under the Bayh-Dole Act of 1980, could take patents on federally funded projects. This led to colleges and individual academic researchers entered into contracts with private corporations engaged in biotechnology and related sciences for commercial production of GMO products. Companies were created just to buy other companies possessing patent rights.

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[10] 563 F.2d. 1031.

The inevitable result: well-grounded fear of US monopolies or oligopolies in the biotech industry, agribusiness and research. Anxious Europeans responded with regulations that apparently built a grand trade barrier against American ingenuity.[11]

Labelling and Traceability: 'Frankenfood' in Europe

GMO may be defined as organisms in which the genetic material (deoxyribonucleic acid) has been altered in a way that does not occur naturally by mating or natural recombination.[12] The technology of alteration is known as genetic engineering, recombinant DNA technology, or modern biotechnology. This technology allows selected individual genes to be transferred from one organism into another, as well as between non-related species.

Anti-biotechnology forces can be classified into three groups: rejectionists, reformists, and moderates. Rejectionists believe that plant biotechnology is wrong and dangerous for environmental safety as well as ethical-ideological reasons. Reformists dislike new alien foods for humans and manufactured feeds for livestock, claiming that the science, business, and government sectors gravely mishandled the issues surrounding GMO products. Moderates, on the other hand, clamor for immediate labeling of GMO products, the isolation of GMO crops to reduce cross-pollination, and the use of tracers to prevent genetic pollution.

In 1996, the first GMO product (tomato paste with a fish gene) appeared in the United Kingdom. There was an initial overwhelming demand for the product due to its low market prices. But by Christmas of 1998, sales dropped to nearly zero. European market chains had joined forces to eliminate GMO ingredients from their own product brands, largely due to the success of lobbying from influential non-governmental organizations such as Greenpeace. 'Frankenfood' became a by-word to denigrate GMO products.[13]

In 1998, the European Union closed its doors entirely to GMO crops, for reasons not entirely apolitical. The controversy had devastated theUS farm-

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[11] Huizenga, David E. *Protein Variants: A Study on the Differing Standards for Biotechnology Patents in the United States and Europe*, 13 EMORY INT'L L. REV. 629 (1999); *see also* Tomans, Stephens. *Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms.* 9 IND. J. GLOBAL LEGAL STUD. 187, 203 (2001).

[12] Watson, J.D. and F.H.C. Crick. *A Structure for Deoxyribonucleic Acid.* 171 NATURE 737 (1953).

[13] Franken, Mathew. *Fear of Frankenfoods: A Better Labelling Standard for Genetically Modified Foods.* 1 MINN. INTELL. PROP. REV. 153, 158-59 (2000).

products market in Europe. Soya product sales, for instance, were slashed in half against competition brought in by soya products from engineered herbicide-resistant soybeans. The spread of the 'mad cow disease' (BSE, or bovine spongiform encephalopathy) also shook public confidence in GMO food products.

At present, the European Community continues to enforce a detailed process of approval on a case-by-case assessment of health and environmental risks before any GMO product can be released to the environment or placed in the market.[14] The continued use of GMO products for research and industrial purposes is also heavily regulated.[15] In reality, the European Community has taken a hybrid reformist-moderate stance, imposing rules for authorization and labeling of novel food containing, consisting, or produced from GMO, as well as rules for genetically modified seeds, forestry reproductive material, and medical/veterinary products.[16] Labeling of GMO presence in any final or intermediate product has been made mandatory since 1997.

There are current laudable proposals on the regulations of exchange of GMOs with countries outside of the European Union, consistent with the agreement to establish common rules for transboundary movements of GMOs in order to ensure global protection of human health and biodiversity.[17]

RANDY RAPE SEED CASE: CANADA

While subjects such as the Bt toxin in transgenic potatoes, Star Link in taco shells, RiceTec and basmati rice, Delta-Pineland and cotton, Bt pollen and monarch butterflies have predominated many of today's classic court battles on GMO issues, one significant court saga is that of a Canadian prairie farmer and the so-called Round-up Ready Canola, better known as the 'randy rape seed'.

Percy Schmeiser, a retired farmer in Canada, was one of hundreds of farmers sued by the behemoth Monsanto Company[18] (engaged in seed genomics and developing agricultural productivity through development of genetic material and biotechnology traits for seed brands and herbicides) for alleged illegal use of proprietary seeds. Schmeiser was accused of planting such seeds in his 1,400-acre

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[14] E.C. Directive 2001/18/EC.

[15] E.C. Directive 90/219/EEC.

[16] E.C. Regulation 258 on Novel Food and Novel Food Ingredients.

[17], Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027; *see also* Hagen, Paul E. and John Barlow Weiner, *The Cartagena Protocol on Biosafety: New Rules for International Trade on Living Modified Organisms.* 12 GEO. INT'L. L. REV. 697 (2000).

[18] *See* http://www.monsanto.com/monsanto/layout/about_us/default.asp

family farm without Monsanto's prior consent and without him signing a Technical Use Agreement with Monsanto. At that time, 40% of canola grown in Canada was derived from Monsanto's genetically modified seeds, popularly known as the "Round Up Ready Canola". The seeds contained an alien gene that made them resistant to a herbicide called Round-up, another product of Monsanto. Monsanto's seed police claimed that Schmeiser had used Monsanto seeds in 90% of his farm area.

In his defense, Schmeiser argued that he was a victim of Monsanto's new technology, which 'invaded his farm' after being blown by wind and carried by bees from Monsanto's contract farms to his own. Seed trucks of Monsanto trespassed into his land, which also caused Monsanto seeds to fall onto his land. When the seeds sprouted, they contaminated his organic rape seeds and eventually, all his harvests. Schmeiser filed a counter-suit, claiming $4.2 Million from Monsanto for defamation and genetic pollution due to contamination by Monsanto's seeds, making him liable to lose his certificate as an organic crop producer. Once contaminated, his produce could no longer be sold as "GMO-free". Schmeiser traveled to several countries while the case was pending, lobbying against Monsanto and GMOs in general. Ironically enough, India conferred honors on him through the 'Gandhi' award, and considered him a folk hero.

Notwithstanding the accolades, the federal court found for Monsanto. The federal judge dismissed the relevance of the source of the seeds in determining the issue of liability for illegal use of proprietary seeds. Schmeiser should have known or ought to have known that planting those seeds and growing the genetically modified canola plants without prior leave or license given by Monsanto was an infringement of the company's patent. Schmeiser was held liable for damages. The case is pending appeal with the Canada Supreme Court. The case is a salient illustration of strict liability 'treatment' applied by trial courts in patent infringement cases, focusing more on the existence of an infringement than on the justifications or personal defenses to any admitted infringement.

OF TRANSGENIC MICE AND MEN: LIFE BEYOND HARVARD'S CREATION

A final controversial case that should be brought to the attention of judges is that of the **oncomouse**, also known as the 'Harvard mouse'[19] case recently decided by the Canadian Supreme Court. The tribunal deliberated upon the

[19] Commissioner of Patents v. President and Fellows of Harvard, et al. *reported in* BIOTECHNOLOGY L. R. 148 (April, 2003); Canada Commissioner of Patents v. Harvard College, 2002-12-05, SCC at http://www.canlii.org/ca/cas/scc/2002/2002scc76.html

patentability of higher life forms such as transgenic mammals (like mice). The transgenic mammals, or the oncomouse in particular, were widely used by research laboratories throughout developed countries for the study of cancer cells and for research and testing regarding serious illnesses affecting humans.

In a close split decision (5 to 4), the Canadian Supreme Court sustained the decision of the Commissioner of Patents, which had denied Harvard's application to patent the oncomouse in Canada. The majority reasoned that the words "composition of matter" in the Canadian Patent Act do not include a higher life form such as the oncomouse. Moreover, the word 'manufacture' in the context of the Act as commonly understood denotes a non-living mechanistic product or process, not a higher life form. This was clearly distinct from the Chakrabarty case which only involved a single cell microbe, a lower life form. The majority noted:

> Higher life forms cannot be conceptualized as mere "compositions of matter" within the context of the Patent Act. Just because all inventions are unanticipated and unforeseeable, it does not necessarily follow that they are all patentable. It is possible that Parliament did not intend to include higher life forms in the definition of "invention." It is also possible that Parliament did not regard cross-bred plants and animals as patentable because they are better regarded as "discoveries." Since patenting higher life forms would involve a radical departure from the traditional patent regime, and since the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues, clear and unequivocal legislation is required for higher life forms to be patentable. The current Act does not clearly indicate that higher life forms are patentable.[20]

The majority was also careful to make the distinction that:

> The patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada. The distinction between lower and higher life forms, though not explicit in the Patent Act, is nonetheless defensible on the basis of the common sense differences between the two. The non-patentability of human life is not explicit in the Patent Act. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms. It is now accepted in Canada that lower life forms are patentable but this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize **151* a lower life form as a "composition of matter" or "manufacture" than it is to conceptualize a higher life form in these terms.

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[20] *Ibid.*

On the other hand, the four dissenting justices, including Chief Justice McLachlin, held that the oncomouse was a patentable product or subject matter:

> The extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of the genetic material of which it is composed, is an inventive 'composition of matter' within the contemplated meaning of Sec. 2 of the Patent Act.

Significantly, only the claim for the product oncomouse was rejected by the Patent Exmainer, Patent Commissioner, and the Canadian Supreme Court. The claims for the process by which the oncomouse was produced won a patent Ufrom the Patent Office. Such a distinction bears substantial implications for the prospects of patent claims litigation involving GMOs.

CONCLUSION

The Philippines has yet to formulate a cohesive strategy for the treatment of GMO products. Even as the current administration may be inclined towards utilizing GMO biotechnology to improve overall agricultural productivity, legislative initiatives tend to suggest that opposite sentiments are held.[21] Executive Order No. 430 (series of 1990), created the National Biosafety Committee of the Philippines, while Department of Agriculture Administrative Order No. 8 (series of 2002), provided the guidelines for the limited importation and use of GMO crops, alleged to be in compliance with the Cartagena Protocol on Biosafety.[22]

It is not amiss to anticipate actual controversies that calling for judicial interpretation and the grant of significant reliefs. As illustrated in the previously discussed cases, issues can range from the characterization of the product for purposes of obtaining a patent (as seen in the Chakrabarty case), its distinction from the process for generating the product (as seen in the Harvard oncomouse case), the presence or absence of infringement in the face of environmental contamination or genetic pollution (as in the Randy rape seed case), or consumer health and environmental safety and the sufficiency or insufficiency of government regulation (as discussed in the Frankenfood issue in Europe). The special interests

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[21] "Bill Proposes 5-Year Ban on GMO", Philippine Daily Inquirer, August 24, 2001.

[22] D.A. A.O. No. 8, s.2002. "Rules and Regulations for the Importation and Release into the Environment of Plants, and Plant Products Derived from the use of Modern Biotechnology"; *see* Palacpac, Merle B. "Philippine Biosafety Regulations", Department of Agriculture, Philippines, *in* http://www.coa.gov.tw/coa/eng/Publications/apec/apec1/autorun/Workshop%20Report/Agri%20Biotech%20Report/Philippines/1530-1Zamboanga,%2007.22.02.ppt

of various actors in these controversies (consumers, organic food producers, GMO producers, the government, private financiers) will possibly call for a reevaluation of the treatment of previous doctrines on patent liabilities for infringements, among others. A guided familiarity with these issues as adjudicated upon in other jurisdictions, while not binding on our judiciary, may nonetheless contribute to the expeditious and accurate resolution of future cases on GMOs in the Philippines.

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