

A COMPARATIVE LAW METHODOLOGY USING THREE DIFFERENT LEGAL REGIMES; THE UNITED STATES, THE EUROPEAN UNION, AND THE WORLD TRADE ORGANIZATION IN ANALYZING THE DEBATE OF GENETICALLY MODIFIED ORGANISMS USED IN FOOD WITH COMPLICATIONS FOR HUMAN HEALTH, THE ENVIRONMENT AND GLOBAL TRADE,

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**THE GENETIC OR TRANSGENIC¹ MODIFIED FOOD DEBATE WITH
COMPLICATIONS FOR HUMAN HEALTH, THE ENVIRONMENT AND GLOBAL
TRADE.**

**THE LEGAL DECISIONS OF THE WORLD TRADE ORGANIZATION, THE
UNITD STATES AND THE EUROPEAN UNION ARE ANALYZED.**

LATEST INFORMATION :

May 21, 2010-

**The Food and Drug Administration (FDA) issued a Nationwide
Alfalfa Sprout Recall due to a Salmonella Outbreak in 10
States.²**

APRIL 27, 2010-

**The Supreme Court of the United States heard oral arguments
for first time in its history on a case involving a
genetically modified crop made by Monsanto. The crop uses a
genetically engineered resistant herbicidal in alfalfa,
known as "ROUNDUP READY".³**

APRIL 7, 2010-

**The Court of Justice of the European Communities "ECJ" was
referred by way of a Preliminary Ruling from the Conseil
d'état (France) lodged on the 3 of February 2010, cases
involving Monsanto SAS, Monsanto International, Monsanto
Technology LLC, Monsanto International SARL, Monsanto
Agriculture France SAS, Monsanto Europe, SA et al. There
were four Questions of Law for the highest European Union
Court to decide on by way of a Preliminary Ruling.⁴**

INTRODUCTION

The debate⁵ includes the following:

OUTLINE

- 1. Scientific and Factual Issues.**
- 2. Ethical and Value Issues.**

3. Legal Issues.
4. Institutional Issues.
5. Risk Assessment Issues.
6. Societal Issues.
7. Safety Issues.
8. LACK (Emphasis added) of Forum to Debate.
9. GMO Benefits. What are they? What do they Promise?
10. Barriers to GMO. Are the Real or Based on Hysteria?

This Paper will analyze the legal issues and leave the rest to all of us to discuss.

WORLD TRADE ORGANIZATION (WTO)

Global trade is accomplished mainly through the World Trade Organization.

To understand the complexity of the legal issues, I will use an example of global trade involving organic and non organic products, cotton shirts.

First, let us assume that County A has recently legislated an environmental protection measure permitting organic agriculture production and banning the use of intensive non-organic production practices on all types of products , i.e., clothing, food, beverages , medicines, alcoholic beverages , etc.

Second, let us assume that Country B uses the same standards of production methods.

Third, let us assume that Country C does not agree to an organic products' standardization and that it produces the same products using whatever method it can.

All of these Countries, A,B and C and wish to export their products to each Country. Countries A and B would allow exports into each Country; however, both A and B would deny C the exports that C produces.

According to the principle of like products, A, B's and C's exports would be determined to be similar because their different product production methods (PPM) do not create different end-use features; they are both cotton shirts.

Hence, the trade position to allow C's exports into countries A and B would negate the countries PPM-based environmental objectives. Trade dispute resolution through the WTO legal process in the DSB would render a judgment in favor of Country C.

If we use two environmental cases, Tuna-Dolphin⁶ and the Shrimp-Turtle⁷ the actual decisions confirm that Country C prevails over Countries A and B on export policies.

According to the World Trade Organization, the position of each Country would be equivalent. Due to the Principle of Like Products and Product Production Methods, (PPM) Countries A, B and C do not create different end uses for their products.

The Tuna-Dolphin⁸ and the Shrimp-Turtle⁹ cases were heard by the Dispute Settlement Body (DSB) of the WTO.

This internal structure is typical of an international body based on treaties and conventions from the post World War II.

Since the decision is binding and the countries in this example have not gained anything from spending money, time and research on preserving the dolphin and turtle from their nets. The only action a country can take would be to put a label on the product that is dolphin safe, i.e., in the United States one would see in a grocery store, cans of tuna fish with labels on it showing that they are dolphin safe.

Then it would be left to the consumer as they check out and pay before they can take home the can of tuna as to whether or not it matters to them that by buying a dolphin

safe can of tuna they are stopping the needless slaughter of dolphins.

The same scenario can be used when buying a can of shrimp. The can can be labeled turtle safe and the consumer would make the ultimate decision. Thereby showing in this simplistic example of global trade and whether or not environmental issues matter and that the consumer really cares about dolphins and/or turtles being caught in nets and needlessly being slaughtered. The conclusion one could reach would be that the power of the consumer really matters and that people can take action, at least in western democracies to change the way netting was done in the past by fishermen thereby eliminating the need for any further governmental interference in their lives.

However, when we discuss labeling regarding genetically modified food, in the US the companies that control this market were able to keep labeling off the product. Therefore the consumer is left ignorant of the biotechnology of genetic modification at the genetic level of the food that consumers eat. If we take this one step further any type of illness from eating GMO food would not be available to be traced so that it could be stopped and that liability would be placed on the proper legal person or legal entity.

In the US, there has been a "GMO Right to Know Act that has proposed by several members of the House and Senate but it has been pending for years but it has never reached the floor of Congress or the Senate of the US for a vote.

However, there was a poll taken of people who live in the EU Member States. The poll indicated that 75% of the people polled did not want to buy genetically modified food and they wanted labels if they were going to make sure that they did not buy this type of product. At the present time there is labeling required in the EU but not in the US.

In the US, Dan Quayle's Council on Competitiveness¹⁰ in 1992 required that GMO food products be allowed into the

consumers' marketplace. The FDA at that time strongly objected. The Executive Office then replaced the head of the FDA with a person who was the senior attorney for Monsanto at that time. Subsequently, the FDA did not develop any type of surveillance of GMO food products. Thereby leaving the consumer totally ignorant in the US as to what type of food are we eating. Is it affecting our health? Is it affecting the environment?

Without the proper type of regulation the consumers of the US will never know.

THE EUROPEAN UNION

At this point, lets turn our attention to the EU legal regime and how there legal regime negotiates with the makers of GMO food products and whether or not the EU consumer has more protection or knowledge as to the effects of GMO food products.

In the EU, there has not been a ruling on the issues raised in their legal regime which are totally different than the legal regime of the US.

There are very similar cases in the US and the EU which have reached the highest court in the EU and the US. The coincidental timing is unheard of from this author. At the present time, the largest manufacturer of GMO food products, Monsanto, Is presently the main party in a case that oral arguments were just heard in front of the US Supreme Court.

At the same time, the EU Court of Justice(ECJ) had to rule on similar issues in which Monsanto is the main party. Since neither the US or the EU court has ruled on this issues, any outcome is possible. However, I will attempt to illustrate what will probably happen in these legal regimes which affects almost 900 million people. The EU has approximately 550 million people. The US has approximately 350 million people.

The history of the EU and the US are intentionally left out of this paper and how each legal system operates in contrast to the other. The reason is that the present moment is the most important and the most fascinating regarding the GMO food debate.

In both the EU and the US Monsanto has reached the highest court and each side has presented its case and in neither the EU or the US has there been a ruling. The present brings the issue to the forefront of each regime simultaneously. This paper will present the legal issues involving food, health, environment and trade from each viewpoint including the World Trade Organization (WTO) which relies on its Member countries to rule on unless the issue is outside the competency of the WTO Charter.

In addition, the Cartagena ¹¹Protocol to the Biological Convention on Biological Diversity is at odds with the WTO. Both regimes are not aligned with the following:

THE CARTAGENA PROTOCOL ON BIOSAFETY AND THE CARTAGENA PROTOCOL TO THE RIO BIOLOGICAL CONVENTION ON BIOLOGICAL DIVERSITY

The IWC is the only international body empowered by participating nation-states to draft whale conservation regulations. According to Article 65 of the UN Convention on the Law of the Sea, states shall cooperate with a view to the conservation of marine mammals, and in the case of cetaceans, shall in particular work through the appropriate international organization for their conservation, management, and study.

The UN Conference on the Environment and Development in Rio De Janiero in 1992 further reinforced this ruling by recognizing the IWC as the legitimate body overseeing whale conservation regulations.

The Rio document called Agenda 21 also gave reinforcement to the World Charter for Nature by stating: "Governments and legislators should establish judicial and

administrative procedures for legal redress and remedy of actions affecting environment and development that may be unlawful or infringe on rights under the law, and should provide access to individuals, groups, and organizations

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity has a precautionary approach, contained in paragraph fifteen of the Rio Declaration On Environment and Development.¹²

The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of safe handling and the use of living modified organisms resulting from biotechnology that may have an adverse effect on the conservation of biological diversity, taking into account risks to human health and the sustainability use and especially focusing on international movements.¹³

In focusing on the EU, I will also focus on how the EU interacts with the WTO thereby bringing in the third legal regime on human health, environmental and global trade.

In using an analogous case, the highest court in the Netherlands is the Rechtbank 's-Gravenhage which is located in the Hague. It asked the ECJ for a ruling on 4 preliminary questions of European Community Law that has not yet been decided by the ECJ¹⁴

The following Questions¹⁵ were referred to the ECJ for a preliminary ruling:

Questions:

(1) Must Article 9 of Directive 98/44 ... be interpreted as meaning that the protection provided under that provision can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been

isolated from that material and inserted into the cell of an organism?

(2) Proceeding on the basis that the DNA sequence described in claim of [the] patent ... is present in the soy meal imported into the Community by Cefetra and that the DNA is incorporated in the soy meal for the purposes of Article 9 of Directive 98/44 and that it does not perform its function therein: does the protection of a patent on biological material as provided for under Directive 98/44, in particular under Article 9 thereof, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether that DNA performs its function, and must the protection as provided under Article 9 of Directive 98/44 therefore be deemed to be exhaustive in the situation referred to in that provision, in which the product consists in genetic information or contains such information, and the product is incorporated in material which contains the genetic information?

(3) Does it make any difference, for the purposes of answering the previous question, that [the] patent was applied for and granted (on 19 June 1996) prior to the adoption of Directive 98/44 and that such absolute product protection was granted under national patent legislation prior to the adoption of that directive? ¹⁶

(4) Is it possible, in answering the previous questions, to take into consideration the TRIPS¹⁷ Agreement, in particular Articles 27 and 30 thereof?'

The facts are that In 2005 and 2006, certain companies in imported a number of soy meal consignments from Argentina. At the request of Monsanto, it took samples of the Soy Food Product and then Monsanto analyzed the Soy Food Product. After receiving the results, Monsanto then claimed that the samples contained trace amounts of the DNA that

were characteristic of their herbicide "Ready Roundup" for soy beans that were made into soy meal. ¹⁸

Monsanto claimed that the imported soy meal was in violation of a patent in obtained in June 1996 from the European Patent Office for a DNA sequence when introduced into the soya made the plant resistant to certain herbicides. ¹⁹The importance of this issue cannot be understated. In the EU regime there is a legal distinction between the words, "DISCOVERY" and "INVENTION".(emphasis added by author) The discovery of genetic engineering of foods through the use of gene material or DNA is not patentable.²⁰

An invention would be in this context a DNA sequence through the indication of how it functions is patentable and that the EU allows that this would include protection extending to all the possible functions of the sequence itself²¹. A patent in light of competition within the EU would allow the holder of the patent the right to make it public and all the general public to benefit from the use of the invention. The holder of this invention would be compensated through the use of licensing to third parties the right to use the patent for a limited time.

Under the WTO, the TRIPS Agreement²² allows the Patent, in this case, GMO-DNA sequence, to normal exploitation so that it does not impede the invention. Article 30 of the TRIPS agreement does not allow the patent holder protection for future and unforeseeable uses.

Articles 27 and 30 of the TRIPS Agreement states the following:

"Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of

Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.²³"

In s the present case, Monsanto argued that the Patent enjoys

purpose bound protection. This would lead to the following question which was raised by the national court as to whether traditional patent protection exists for the type of genetic sequence. Is the patent holder protected as a chemical compound. In this case, Monsanto samples of the product that was imported from Argentina contained trace elements of the biological product in which the sequence was performed. Monsanto further argued that the patent confers upon its holder protection as a self standing product.

However if the EU Court would accept this approach it would violate the scope of protection as provided for in Directive 98/44.²⁴

Monsanto argued that it want protection as a chemical product that was in trace amounts of the imported product even though it obtained a biotechnological Patent. This line of reasoning is not logical and leads to an absurd conclusion in this case. Monsanto could be entitled to monetary damages if they sued the owners of the cattle that eat the plants that contained the DNA sequence that was the basis of the Patent. It may also lead to Monsanto claiming damages and suing all the people who ate or drank any product from the cattle that ate the plant which contained the DNA sequence that was awarded to Monsanto as the Patent holder.

At this point, one might wonder why Monsanto did not sue in Argentina. As the record indicates, Argentina does not provide for protection of Monsanto's invention. Therefore, Monsanto is using one legal system, the EU, to obtain monetary damages from another legal system, Argentina's patent laws. It is trying to remedy in the EU the problems it encountered in Argentina. ²⁵

In this case, which is different from other cases brought by Monsanto the residual nature of the DNA contained in the soy meal imported into the EU from Argentina served no function. It was just present in trace amounts of the product. Therefore, the conclusion of this case should be

that the patent is limited to the extent that the DNA sequences to the purpose stated therein.

In the EU there is the legal principle of exhaustion of remedies as laid down in Articles 34 TFEU and 35 TFEU on quantitative restrictions and measures having equivalent effect. This would mean that a patent holder who has agreed to license its patent to third parties who place the product on the market and the patent holder receives monetary compensation cannot then result to litigation against others by challenging subsequent legal transactions over and over again. According to the case law of the EU the substance of a patent right lies in an exclusive right when first placing the product in the marketplace.²⁶ This principle in this context has been confirmed by the ECJ.²⁷

In England, the High Court of England and Wales refused Monsanto the right of an injunction to block importation of soy meal from Argentina.²⁸

Now, let us turn our attention back to the WTO. First we should consider the view of the IATP²⁹

THE ISSUES

1. Will the EC and other WTO members be able to develop and maintain a regulatory system for GMO's that allows for the use of precautionary measures (see "The precautionary principle," below) to protect consumer, animal and/or plant health when there is insufficient scientific evidence to assess the risks of a biotech product presented to governments for commercialization approval?

2. Will the panel agree with the EC that some of its regulatory objectives for GMO's fall outside of the competence of WTO agreements and are covered by other international agreements (e.g. the objective to preserve biodiversity against plant species invasion by GM varieties)? The EC argues that measures to

preserve biodiversity are the competence of the Cartagena Protocol on Biosafety, to which the U.S. is not a party.

The WTO does not recognize the protocol as containing presumptively authoritative standards.

Indeed, WTO members have not allowed the secretariat of the Convention on Biological Diversity, to which the protocol is appended, to be an observer at the WTO Committee on Trade and Environment.

3. How will the panel document its use of expert opinion in determining the factual matters that pertain to the main legal issues of the dispute? Determining whether the EC has violated the provision against "undue delay" in its regulatory review procedures will depend on how the panel interprets the "vast amount of materials" about GMO's submitted by the experts.

Determination of violation will also depend on how the panel interprets the answers from experts to questions put to them and to the disputing parties by the panel. Panelists are not required to use expert opinion to make their ruling and the U.S. argued unsuccessfully that no expert opinion was needed to decide the dispute.

4. How will the panel use previous WTO dispute panel and appellate body rulings on "scientific uncertainty" to justify its ruling? The disputants interpret past WTO rulings differently to support their arguments. Particularly important is how the panelists rule on the relation of "insufficient scientific information" to "scientific uncertainty" as that relation was ruled in the case of a dispute over SPS measures that Japan took to prevent blight in apples.

Next, consider the issue of the Burden of Proof based on the following two (2) cases: In Japan Agricultural Products II³⁰, with respect to the issue of the burden of proof, the

Appellate Body reversed the Panel's findings with respect to Article 5.6, holding that the Panel could not have made the finding at issue, because the United States as the complaining party had not made a relevant claim and, a fortiori, had not established a prima facie case.

Since the United States did not even claim before the Panel that the 'determination of absorption levels' is an alternative measure which meets the three elements under Article 5.6, the opinion that the United States did not establish a prima facie case that the 'determination of absorption levels' is an alternative measure within the meaning of Article 5.6. ... Article 13 of the DSB and Article 11.2 of the SPS Agreement suggest that panels have a significant investigative authority.

In EC - Hormones³¹, the EU submitted that "the 'substantive' provisions of the SPS Agreement can only be addressed if recourse is made to GATT Article XX(b), if, and only if, a violation of another provision of GATT is first established.

The Panel, in a finding not addressed by the Appellate Body, rejected this argument, indicating that according to Article 1.1 of the SPS Agreement, two requirements need to be fulfilled for the SPS Agreement to apply: (i) the measure in dispute is a sanitary or phytosanitary measure; and (ii) the measure in dispute may, directly or indirectly, affect international trade. There are no additional requirements. The SPS Agreement contains, in particular, no explicit requirement of a prior violation of a provision of GATT, which would govern the applicability of the SPS Agreement, as, asserted by the European Communities.

The Panel then added, with respect to the relationship between the SPS Agreement and Article XX(b) of GATT 1994, that any provisions of the SPS Agreement impose 'substantive' obligations which go significantly beyond and are additional to the requirements of Article XX(b).

The panel finds the EU claim that the SPS Agreement does not impose 'substantive' obligations additional to those already contained in Article XX(b) of GATT not to be persuasive. It is clear that some provisions of the SPS Agreement elaborate on provisions already contained in GATT, in particular Article XX(b). The final preamble paragraph of the SPS Agreement provides, indeed, that the Members desired 'to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b) '.

Examples of such rules are, arguably, some of the obligations contained in Article 2 of the SPS Agreement.

Next, consider the following information to be used in the GMO DISPUTE:

According the position of the US, the EU offers no basis for its request for a preliminary ruling on GMO's.

The EU will not lift the moratorium until decisions are based on scientific principles and evidence, not politics, and until each biotech product application is processed without undue delay.

The rulings in both the Tuna-Dolphin and the Shrimp-Turtle³² cases confirm that Members are in compliance with the SPS Agreement if they adopt international standards. Necessary health protection must be based on scientific evidence and not on the opinion of politicians. The Standard setting organizations referred to in the SPS Agreement are the FAO Codex authority for international food safety, evaluation and harmonization.

This authority includes, but are not limited to the following, determining and eradicating food-borne hazards, food additives, microbiological contaminants, veterinary drugs and pesticide residue that are harmful to human, animal and plant life of our food chain.

However, the SPS Agreement also recognizes that there are varied ways of assuring food safety and animal and plant health protection by adopting an approach based on mutual recognition (Equivalence) negotiated on a bilateral or regional basis which requires negotiations, co-operation, confidence. Burden of proof is on the exporting country to demonstrate an equivalent level of health protection. Exporting country must give access to its authorities, facilities, equipment and procedures. If protection is the identical, the exporting country's procedures should be accepted.

The Preamble to the SPS includes harmonization, international standardization, Members' autonomy (in allowing each to set their own standards higher than the international standards based on scientific evidence), improving the health of humans, animals and the environment, etc.

In EU/Hormones³³ the Appellate Body declined to take a position on the status of the precautionary principle in international law. The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges.

The precautionary principle is regarded by some as having crystallized into a general principle of customary International law. Whether it has been widely accepted by Members as a principle of customary international law appears less than clear.

Consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. Since the EC has taken a number of steps to revise its regulatory system to commercialize GMOs, the U.S. objectives in bringing the dispute are not entirely clear.

One underlying objective is to get a dispute panel and/or appellate body ruling that there is no basis in the WTO agreements to support EC's argument "that states have the right to adopt a precautionary approach when dealing with GMOs. In support of this argument, the EC cites articles 10(6) and 11(8) of the Cartagena Protocol on Biosafety , an international public law agreement to which none of the plaintiffs are parties.

The "precautionary approach" derives from German air pollution legislation in 1968 as a result of suggestive but not conclusive evidence that industrial air pollution was damaging the environment. In addition to justifying the government's authority to take preventative action against environmental damage, the legislation required that the regulatory actions be "proportional" to the potential for harm and that there be an assessment of the costs and benefits of action and inaction. Subsequent formulations of the precautionary principle, including those applied to the risk analysis of GMOs, have specified the relation between scientific evidence and a typology of scientific uncertainty, and the need to shift the burden of proof to the technology developer to demonstrate the safety of a new technology ("harmful until proven safe").

An EU Communication describes precaution as a risk management tool, which is part of a risk analysis framework rather than the overall guide to its (i.e., the framework's) implementation.

According to this argument, precautionary action should only be taken after experts prepare an "objective" quantitative risk assessment. Precaution is seen as a temporary measure pending further risk assessment.

The United States and the European Union have totally different view points over the social, ethical and environmental effects over the use of genetically modified organisms (hereinafter called GMO'S). The first litigation

arose in the WTO over the use by the United States of hormones in beef. Even though the dispute is still ongoing, the WTO Appellate Body issued a decision in the Beef Hormones³⁴ dispute, which are key principles of WTO law.

First, the standard of review by the fact finding panel is in Article 11 of the DSU which is neither a "de novo" review nor a "total deference" but, in fact, an "objective assessment of the facts". The Appellate body then holds that the relevance of the Precautionary Principle in the interpretation of the SPS Agreement cannot override the explicit wording of Articles 5.1 and 5.2 on the assessment of risks since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement.

However, the Appellate body continues by stating that this principle is also in the 6th paragraph of the preamble and in Article 3.3. In this context, the SPS explicitly recognizes Members' rights to establish their own appropriate level of sanitary protection that may be higher than the existing international standards, guidelines or recommendations.

The Precautionary Principle by itself does not relieve the panel of applying customary law in interpreting treaties in relation to the SPS Agreement. In a complaint that a member violated the SPS Agreement Article 5.5, is that the Member imposing the three distinct elements must be present. First, the Member imposing the measure complained of has adopted its own level of protection against risks to human life or health in different situations.

Second, that the levels of protection are arbitrary or exhibit unjustifiable differences in the treatment.

The final element to establish a breach of 5.5 would be to find that the unjustifiable or arbitrary difference results is in reality a disguised restriction of international

trade. In the decision, the Appellate body suggested that the European Union could justify its ban if it provided convincing scientific evidence that there was a danger to human health. As a consequence of the failure of the EU to bring forth scientific evidence or bring its policies in alignment with the decision, the WTO allowed the US and Canada to suspend existing concessions on EU items, i.e., cheese, Perrier water and foie gras which resulted in penalties of 117 million to the US and 8 million to Canada³⁵.

The European Communities has adopted approval procedures for agricultural products produced with the benefit of modern biotechnology. Up to October 1998, the European Communities implemented those procedures, and approved more than ten biotech products.

Consumers in the European Communities have been enjoying the benefits of these products, without any adverse health or environmental effects.

Starting in October 1998, however, the European Communities suspended its own approval procedures. In particular, the European Communities suspended consideration of Applications for, or granting of, approval of biotech products under the EU approval system. The approvals moratorium has restricted imports of agricultural and food products from the United States. Moreover, the member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans are restricted imports of agricultural and food products from the United by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States. "The measures affecting biotech products in the EU include: the suspension by the EU of consideration of applications for, or granting of, approval of biotech products³⁶.

The failure by the EU to consider for approval applications for the biotech products mentioned in Annexes IA and IB to this request; and national marketing and import bans maintained by member States, as described in Annex II to this request. The consultation request then noted that these measures appeared to be inconsistent with the EC's obligations under specified provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"), the Agreement on Agriculture ("Agriculture Agreement"), the Agreement on Technical Barriers to Trade ("TBT Agreement") and the General Agreement on Tariffs and Trade 1994 (GATT 1994)"³⁷

Consequently, on August 7, 2003, the United States requested the establishment of a panel. The Dispute Settlement Body ("DSB") considered the U.S. panel request along with similar requests from Canada and Argentina, at its meetings held on August 18 and August 29, 2003. This panel was established at the August 29, 2003 meeting of the DSB, with the following terms of reference: To examine, in the light of the relevant provisions of the covered agreements cited by the United States³⁸ and Argentina³⁹, the matter referred to the DSB by the United States, Canada and Argentina in those documents, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements.

After 1998, the EC adopted an across-the-board moratorium under which no product application was able to reach the final stage of approval. This moratorium effectively prohibits exports of many U.S. agricultural products to Europe, including most corn and corn products.

The United States, based on the belief that the moratorium appeared to breach World Trade Organization (WTO) rules, brought a challenge under the WTO dispute settlement mechanism.

Under the WTO Agreement, members are free to establish approval procedures for new agricultural products in order to examine risks to health, safety, and the environment.

Decisions are to be based on scientific principles and evidence, and must be made without undue delay. But the EU moratorium on new biotech products and the member State product bans were not based on scientific evidence.

To the contrary, the products covered by the EU measures are safe, as recognized for many products by the EU's own scientific committees.

By not allowing its approval system to operate, the EU is imposing undue delays on biotech approvals, resulting in extensive delays and preventing the marketing of many crops grown in the United States.

The United States argued in the WTO case that the EU has adopted a general moratorium on 10 all new biotech products, and separate product-specific moratoria on each new biotech product.

Under this moratorium, the EU has not implemented its own regulations to allow for review of biotech applications to take place - it could have taken decisions on the product applications currently being reviewed, but did not do so.

The WTO Agreement requires that approval decisions be made without "undue delay." The United States argued that the moratorium violated this obligation by imposing undue delay on the more than 25 products in the EU's regulatory review pipeline, some having languished with little movement since 1998.

Findings of the WTO Panel:

The WTO Panel upheld the central U.S. claims. The Panel found that the EU adopted a moratorium on the final approval of biotech products, starting in 1999 up through

the time the panel was established in August 2003. The Panel found that the EU had presented no scientific or regulatory justification for the moratorium, and thus that the moratorium resulted in "undue delays" in violation of WTO rules. The Panel also identified specific, WTO-inconsistent "undue delays" with regard to 24 of the 27 pending product applications that were listed in the U.S. complaint.

With respect to each of the EU member state bans on biotech crops approved by the EU prior to the adoption of the moratorium, the Panel upheld the United States' claims that, in light of positive safety assessments issued by the EU's own scientists, the member state bans were not supported by scientific evidence and were thus inconsistent with WTO rules. Recent EU approvals of a few biotech products -made after, and perhaps in response to, the United States' filing of its WTO case -does not mean that the EU has lifted the moratorium. Many safe, proven biotech products remain stalled in the EU's complex approval procedures.

In addition, even the few products that were approved had to go through an extraordinary process involving needless delays, and approval by the EU Commission over the objections of many EU Member States⁴⁰.

THE UNITED STATES

In Mississippi, agriculture is a 5.5 billion dollar industry and the number 1 industry of the state. This industry employs 30% of the workforce and covers approximately 11 million acres of the state.⁴¹ The cotton and soybean markets are the two largest sectors of their agriculture market. Cotton contributes approximately \$600 million dollars and soybeans approximately 350 million dollars to Mississippi's economy.⁴²

In 1996, 1997 and 1998 Monsanto had licensing agreements due to its patented product the contained a Roundup Ready Trait

herbicide. This agreement is required to be executed by all farmers who use their biotechnological product, Roundup Ready seed for cotton and soybeans. Monsanto bundles these two products together through an incentive program.

This incentive program provides farmers with a valuable technology fee refund on the second technology fee if the farmer has to replant as long as the farmer certifies that he will use a Monsanto product as his sole source for all crops replanted on his farm. This type of transaction makes the buyer purchase a Monsanto product not due to the fact that it is a better economical choice, but to obtain a refund on the patent seed which has a glyphosate trait which the farmer planted first and now has to buy the glyphosate herbicide called Roundup Ready Herbicide which is solely offered by Monsanto.⁴³

The market share of Monsanto in the soybean and cotton markets are impressive. In 1998, Monsanto with Dupont spent 8 billion dollars buying up the seed market.⁴⁴

The soybean market share of Monsanto went from 69% in the year 2001 to 76% in the year 2003.⁴⁵

In the herbicide tolerant cotton market, Monsanto has a 92% market share.⁴⁶

In pursuing a claim for antitrust the claimant must be able to prove that there are two distinct markets and that there is a tie in product by a selling arrangement from a seller who has sufficient market power to require the buyers to accept the tying and the burdensome terms that they would not accept in a completely competitive market.⁴⁷

In *Scruggs*⁴⁸ the Court had found that he had failed to meet his burden of producing significant probative evidence that Monsanto forced farmers who wanted to buy their seed was also forced to purchase the Roundup Ready herbicide.

The lower District Court said there was not a genuine dispute of material fact as to the existence of a tying arrangement, or evidence of sufficient market power by Monsanto in the biotechnological market to demand a tying product with burdensome demands. The lower District Court also found no evidence of two markets.

In this case Monsanto argued successfully that framers could choose any type of herbicide they wanted, however Monsanto also argued that there was a Federal Mandate of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was only included in the 1996, 1997 and 1998 Agreements. However, this type of logic make not be acceptable to those who understand econometrics. The question put into different terms would be as follows: Why would a farmer pay for a premium for a product with an enhanced seed trait (genetically modified to withstand glyphosate herbicide) and then choose not to use the enhancing characteristic spray thus tying together 2 products, the Monsanto seed and herbicide spray, Ready Roundup.

Another method of analyzing this issue is whether or not Monsanto had the market share and the power in the herbicide tolerant trait and seed markets to force farmers to buy the herbicide Roundup with the seed containing the Roundup Ready trait.

Legal precedent lies within the United States Supreme Court decisions on a product which has a patent. Their decisions have held that patent tying to be illegal per se due to the arrangement of creating a monopoly.⁴⁹

In Mississippi, federal antitrust law does not pre-empt state antitrust law. But serves to supplement it.⁵⁰ Mississippi antitrust law prohibits tying.⁵¹ This Statute prohibits the following:

A contract, understanding or agreement, expressed or implied, between two or more persons, corporations or firms

- (a) To restrain trade;
- (b) To hinder competition in the sale or purchase of a commodity; or
- (c) To engross or forestall a commodity.⁵²

Mississippi Law prohibits tying arrangements and imposes broad rights, greater than federal law and that under the state law there does not need to be a showing of intent if Monsanto can accomplish results to a degree that is against the public welfare of its citizens.⁵³ Under state law, the core concern is that tying prevents goods from competing directly for consumer choice on their own merits. This type of competition is foreclosed out of the marketplace when tying occurs by bundling 2 products from 2 different markets by a legal entity which has at least 50% market share in each market.

Under state law, the trait in the patent seed is tied to the purchase of the herbicide, Roundup.⁵⁴

Monsanto licenses its Roundup Ready trait through an interrelated licensing scheme that imposes a no replantPolicy on the farmer.

The practical effect of this policy is to require every American farmer using Roundup Ready trait to repurchase seed every year.

The no-replant policy started a new trend placing unprecedented restrictions on the freedom of farmers to use the new technology.⁵⁵ Based on evidence in the record, this no-replant policy is having significant adverse economic impacts on the industry, weeding out competitors and farmers who simply cannot continue on the technology treadmill.⁵⁶

This is apparent when you look at the company's practices in the United Kingdom, Argentina and Brazil. Thus the no replant policy places Mississippi farmers at a competitive disadvantage on the global market with farmers in Brazil

who do not have to purchase new seed each year. Furthermore, the additional costs to Mississippi farmers, is not for the patented product; it is for the new seed.

In this case, is the anticompetitive restriction of this tying in of Ready Roundup seed to Roundup Herbicide a subsidy to Monsanto for its Patent free from antitrust scrutiny.

In the present case in front of the United States Supreme Court, Monsanto⁵⁷ on Writ of Certiorari from the United States District Court of Appeals for the Ninth Circuit has the Respondents, Geertson Seed Farms, et al., supporting the position of Monsanto. Interestingly, (on a side issue) the attorney for Geerston, was nominated by President Obama to fill Justice Stevens position as he leaving the bench this summer. Geerston is represented by Elena Kagan, Solicitor General of the United States.

In their Reply Brief, the position is that the lower court erred in the permanent injunction it rendered against Monsanto. The rationale that is given follows: The Animal and Plant Health Inspection Services (APHIS) identified protective measures and was preparing an environmental impact statement. (EIS) The lower court enjoined all new planting of Roundup Ready Alfalfa without taking into consideration whether such relief was necessary under the National Environmental Policy Act of 1969. (NEPA)

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It is respondent's position that Monsanto's violation of this act results in an injunction only to the extent that Geerston would otherwise suffer irreparable harm. The lower court erred in refusing to wait until APHIS's scientific expertise was concluded through the EIS and allow their opinion to be presented as to less harsher measures which may have been justified and their protective measures would have sufficed to protect the respondent, Geerston.

Instead, the lower court and the court of appeals erred in upholding an overly broad injunction against the Petitioner, Monsanto.⁵⁹

On page 22⁶⁰, the following is stated on behalf of Geerston by Elena Kagan, "For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed and the case should be remanded with instructions to vacate the permanent injunction entered by the district court."

CONCLUSION

The results of this comparative law analysis of 3 different legal regimes in analyzing the debate of genetic modified foods concludes that at the end of this debate all positions will or already have solidified without any type of legal synergy. Unless there synergistic energy by each legal regime we will have to wait until there is a catastrophic event with complications of a global nature for all legal regimes to understand that we are all connected no matter where we live to cooperate understand and consider the other legal regimes for the good of all of us.

THE END

Endnotes

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4. Garcia, Deborah Koons, dir. THE FUTURE OF FOODS. 2004. DVD 2 Disks. Arts Alliance America

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6. WT/DS58/RW

7. WT/DS291/R/Add.4

8. WT/DS48/AB/R (1998)

9. WT/DS58/RW;

10. Directive 2001/18, O.J. L 106 17.4.2001, p. 1 (and its predecessor, Directive 90/220, O.J. L 117, 8.5.1990, p. 15, as amended by Directive 94/15, O.J. L 103, 22.4.1994, p. 20 and Directive 97/35, O.J. L169, 27.6.1997, p. 72); and Regulation 258/97, O.J. L 04 3, 14.2.1997, p. 1."

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12. WT/DS26/AB/R; WT/DS48/AB/R (1998) P.7
13. Convention on Biological Diversity (2000)
14. Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal, Canada. ISBN 92-807-1924-6 Article 15 of the Protocol, SCBD (2000)
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18. Case C-106/89 Marleasing[1990]; Case-212/04 Adeneler and Others [2006]; Case C-188/07 Commune de Mesquer [2008]
19. Case C-94/02 Biret & Cie v Council [2003]
20. Case C-52/100 Commission v France [2002]
21. Joined Cases C-281/03 and C-282/03 Cinu Chemicals and Others [2005]
22. Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.(OJ 1998 L 213,p13)
23. Case C-426/08., "Monsanto Technology LLG v Ceftra BV et al.
24. OJ 1994 L 336p.1

25. Michael Schroeder, "U.S.-EU Trade Fight Isn't Over, Just Sidetracked", Wall Street Journal, 3/14/03, at p.A8
26. Biotechnology Facts, Office of the United States Trade Representative , September 2006
27. Joined Cases C-267/95 and C 268/95 Merck and Beecham (1996)].
28. Monsanto v Cargill [2007] EWHC 2257 (pat)
29. WT/DS291/1
- 30 IATP, SUPPAN (2001)WT/DS291/1.
31. Julian Kinderlerer, "Regulation of Biotechnology: Needs and Burdens For Developing Countries", Sheffield Institute of Biotechnological Law & Ethics, The University of Sheffield, Sheffield, UK (2002)
32. Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, "U.S.-European Union Trade Relations: Issues and Policy Challenges", at p. CRS-10.
33. NTE Report at pp. 111-112. Before the adoption of 2001/18, the EU/European Community legislation covering the approval of genetically modified organisms, including bioengineered food, was EC Directive 90/220/EEC. This prior regime, however, was subsequently deemed inadequate by the European Commission and was repealed by 2001/18.

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35. Raymond J. Ahearn, Foreign Affairs, Defense, and Trade Division, "U.S.-European Union Trade Relations: Issues and Policy Challenges", at p.CRS-9; See, also: 2002 National Trade Estimate Report on Foreign Trade Barriers (NTE) Report at pp. 112-113; 2003 Trade Policy Agenda and 2002 Annual Report of the President of the United States on the Trade Agreements Program ('President's Trade Policy Agenda), at pp. 153-54.

36. "Question and Answers on the Regulation of GMOs in the EU", European Commission, at p. 8. "Fact Sheet: WHO Answers Questions About Biotechnology Foods", U.S. Department of State, International Information Program, at p. 4.

37. *GMOs in the WTO – The Dispute Between the U.S. and the EU: EC Regulation of GMOs and its Application*, Institute of International Economic Law, Georgetown University Law Center website

38. *USDA Agriculture Statistics (2004)*; *Mississippi State Extension Service (2004)*

39. *LePages, Inc. Vs 3M*, 324 F.3d 141 (3rd. Cir.2003)

40. *United States Steel Corp. Vs Fortner Enter., Inc.*, 249 U.S. 610 (1977)

41. *Monsanto v. Scruggs*, 342 F. Supp. 2d 584 (N.D. Miss 2004)

42. *United States v Loew's, Inc.*, 83 S. Ct. 97 (1962)

43. *California v ARC America Corp.*, 490 U.S.93 (1989)

44. Miss. Code Ann. 75-21-1 (1972)
45. Infra 51.
46. Infra 51.
47. Microsoft v U.S. 253 F.3rd 34 (D.C.Cir.2001)
49. Context Network, Biotech Traits Commercialized 2003 Global at SOY-70)
49. Dr. Robert D. Tollison adds that this "destruction of a tremendous amount of seeds each year facilitates a reduction in the supply and an increase in the price of seeds ." Tollison Supp. Rpt. p 4.
50. Infra Note 3
51. 42 U.S.C. 4321 et seq.
52. Reply Brief of Respondents supporting Petitioners, p 1-21 Monsanto v. Geerston Seed Farms
53. See note 59.