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European decisions about the "Whack-a-mole" game

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Introduction

This article reports on several court decisions in Europe that illustrate the seemingly unending delays and barriers, within the EU structure, for genetically-engineered crops. Like the fun-park children's game—wherein each time the player whacks a mole, another mole instantly pops to the surface so that the player must whack again—each time a producer of a GE crop appears to have approval for planting, another delay and barrier arises. Specifically, this article canvasses the decisions of the European Court of Justice (ECJ) in *Pioneer Hi-Bred Italia Sri against the Minister of Agriculture, Food, and Forest Policy* (Italy) (6 Sept 2012),[1] the French Council of State in *Company Monsanto SAS against the Minister of Agriculture, Food, and Fisheries* (France) (1 August 2013),[2] the General Court of the ECJ in *Pioneer Hi-Bred International, Inc against the European Commission* (26 Sept 2013),[3] and the General Court of the ECJ in *Hungary against the European Commission* (13 Dec 2013).[4]

Member State Bans

On April 22, 1998, the European Commission (Commission) authorized the placing on the market of genetically engineered maize (MON810). Monsanto has maintained continuous authorization for this maize since 1998 and is presently seeking renewal of authorization for an additional ten years.

Despite this Commission authorization, nine member states of the European Union have banned MON810 from being grown by farmers within their territories.[a] Of these nine bans, legal cases have been brought against the bans in two countries: Italy and France.[b]

Italy

In October 2006, Pioneer Hi-Bred applied to the Minister of Agriculture, Food and Forest Policy to sell MON810 to Italian farmers. In May 2008, the Minister of Agriculture, Food and Forest Policies informed Pioneer Hi-Bred that the Italian government would not entertain Pioneer's application until after the Italian government and its regional governments had adopted rules for coexistence between conventional, organic, and genetically-engineered crops.

Pioneer Hi-Bred responded with a lawsuit seeking to annul the Minister's suspension. Pioneer emphasized that MON810 is a permissible seed within the EU approved seed catalog and that the EU had authorized the release into the environment of MON810. Pioneer argued that Italy could not supersede an EU authorization and that Italy had no legal basis for suspending the EU authorization pending coexistence rules. The Italian Council of State, the highest Italian court, referred the legal dispute to the European Court of Justice (ECJ) for interpretation of EU law.

On September 6, 2012, the ECJ ruled favorably to Pioneer Hi-Bred.[1] First, the ECJ ruled that Italy was not legally entitled to annul the EU authorization of MON810 because EU law gave that authority to the EU central authority. Once the EU central authority authorized MON810 for release and placed MON810 on the common catalog of permissible seeds, Pioneer had the full legal authorization needed to market MON810. Second, the ECJ ruled that nothing in the authorizing legislation, most specifically considering Dir 2001/18/EC Article 26, allowed Italy to prohibit the planting of MON810 while Italy developed a coexistence policy for the nation and its regions. The ECJ further reasoned that if Italy could ban and delay MON810, Italy would undermine the EU common policy on genetically modified crops, food, and feed.

The response to the ECJ ruling favorable to Pioneer Hi-Bred was twofold. Italy ignored the ruling by giving notice to the European Commission that Italy was invoking emergency measures to safeguard human, animal, and environmental health in Italy.[c] In other words, Italy did not honor the ECJ ruling but rather invoked different, but already tried, reasons for continuing the Italian ban. Simultaneously, the European Commission reasserted its desire to move forward with legislation that would amend EU law expressly to allow member states to ban authorized genetically engineered crops from their territories, regardless of science and risk analyses establishing safety.[5]

The EU proposal to allow the member states to ban authorized genetically engineered crops has two implications. One implication is the Commission's attempt to find a practical way to resolve the interminable approval process. If member states can ban, the EU apparently hopes that the logjam at the approval stage can be broken and the process can move forward expeditiously regarding future applications. To this author, the EU proposal does not appear likely to achieve this practical way forward, but rather simply to create an additional, even higher barrier. The second implication is an implied renegotiation of the EU Treaty as to what power is allocated to the EU as a central

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governing institution and what power resides within the sovereign prerogative of individual member states. If the prerogative resides with the member states to ban genetically-engineered crops from being grown, would this also apply to the prerogative to ban foods consisting of, containing, or produced from genetically engineered crops? If the latter is true, then not only is the EU called into question as a common agricultural market, but also the likelihood of violations to international treaty commitments, such as the World Trade treaties, would probably rise.

France

In December 2007, the Minister for Agriculture and Fisheries suspended the authorization for growing MON810 in France. Monsanto quickly brought a legal action for annulment of this suspension. In swift response in February 2008, the French Minister reiterated the 2007 suspension and announced that France would not permit MON810 on French farms until Monsanto had obtained renewed authorization for MON810.[d] Monsanto brought a new action for annulment in late February 2008. Ultimately, the French Council of State, France's highest court, referred the Monsanto action to the ECJ.

On September 8, 2011, the ECJ ruled[6] that on the particular facts of this legal dispute, that EU law did allow France a mechanism by which to challenge the EU authorization by the invocation of emergency measures. But the ECJ also ruled that France must abide by procedural obligations set forth in the relevant law (Reg. [EC] No 1829/2003) and that France must "establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment." The ECJ sent the legal matter back to the French Council of State for a determination as to whether the actions of the French Minister satisfied the procedural and substantive rules for the invocation of emergency measures.[7]

The French Council of State decided Monsanto SAS against the Minister of Agriculture and Fisheries (the February 2008 legal action) on August 1, 2013.[2] In brief, the Council of State canceled the Minister's suspension and ordered the French State to pay a civil fine to Monsanto SAS and every other participant joining Monsanto SAS to challenge the ministerial suspension. As for the reasons given by the Council of State for ruling favorably to Monsanto SAS, the court decided:

(1) Under EU law, an authorized product continues to be authorized until the renewal application is either granted or denied. Consequently at present, MON810 continues to be an authorized crop under EU law and MON810 is on the list of seeds, contained within the EU authorized seed catalog, permissible for purchase by European farmers.

(2) While EU law does allow a Member State to take emergency actions, the Minister of Agriculture and Fisheries committed an error of law when the Minister invoked these emergency measures. The Minister committed an error because the Minister had not presented evidence of "a clear and serious risk to human health, animal health, or the environment." Rather, the Council of State concluded that the Minister had only raised issues about which the Minister desired further discussion concerning MON810.

(3) The Council of State also ruled that French domestic laws, such as the French Environmental Code or the French Rural Code, could not supersede the governing EU law of Reg. (EC) 1829/2003 by which the European Commission had authorized MON810 after a risk assessment determining MON810 as safe for human and animal health and safe for the environment.

The French response to the ECJ ruling favorable to Monsanto SAS was predictable. France simply re-imposed the ban claiming new and different legal justifications. Just as France had reasserted the ban time and again since December 2007, France maintains its ban against the growing of authorized MON810 to the present day. In response to the French government's consistent refusal to abide by EU risk assessments, French scientists Marcel Kuntz, Agnes Ricroch, and John Davison protested in print:

"We feel it is time to stop this farce, where politicians feel free to ignore scientific advice and to make decisions based solely on political motives and personal prejudices…That certain non-governmental organizations that pretend to be defenders of the environment are unable to rationally examine the scientific facts is regrettable but not unexpected. However when the governments of EU member states openly undermine the credibility of EFSA (European Food Safety Agency) and other national risk evaluation committees by creating false pseudoscientific documents, it raises the question of access to objective scientific information for European citizens."[8]

The French scientists' concerns gained prominence again on November 12, 2013, when the EFSA responded to Austria's November 2012 notification of alleged new scientific evidence about the safety of MON810. EFSA concluded that the Austrian presentation did not constitute sufficient new evidence to lead EFSA to reconsider its earlier conclusions that MON810 maize is safe for humans, animals, and the environment.[9]

European Commission Delays

On July 6, 2001, Pioneer Hi-Bred International, Inc notified the competent Spanish authority of an application seeking authorization for placing on the market a genetically engineered insect-resistant maize 1507. After favorable consideration, the Spanish authorities passed the application to the European Commission for appropriate action under Directive 2001/18/EC. The application languished at the European Commission until November 6, 2013, a period of twelve and one-half years, before the Commission passed a decision favorable toward approval to the European Council of Ministers.[10] While forward movement at the Commission level has now occurred, the EU approval process has many steps yet to traverse. Pioneer Hi-Bred has not yet received approval for placing on the market its genetically engineered maize 1507. Moreover, the Commission acted only after being forced to do so by the ECJ through a decision of September 26, 2013.[3]

In its September 2013 decision, the ECJ set forth the chronicle of delays that Pioneer Hi-Bred encountered at the Commission. These delays included six different requests—2005, 2006, 2007, 2011, and 2012 (twice)—to the European Food Safety Agency

(EFSA) to evaluate the safety of Maize 1507. Each time the EFSA responded confirming that Maize 1507 was safe for humans, animals, and the environment.

In its decision, the ECJ ruled that the Commission could not avoid a decision by arguing that the Commission delayed in order to gain assurance that its recommendation would gain approval at the Council level. The ECJ rejected this argument because "it would be possible for the Commission to block the adoption of the final decision indefinitely. That would adversely affect the applicant which would be unable to bring any form of action in that regard."[3]

More specifically on the substance, the ECJ ruled that the Commission had a duty to act within the time-frames specified in the governing laws and regulations that, if strictly followed, required a decision within a period of 210 days. While the ECJ did not rule that the Commission had to act within 210 days, the ECJ made it clear that twelve and one-half years (4560 days) was not in compliance with the laws and regulations. In addition, the ECJ made it clear that the Commission could not avoid its duty to act by asking, time and time again, for EFSA and other committee opinions whenever Pioneer requested the Commission to act.

The ECJ decision thus ruled:

"The European Commission has failed to fulfill its obligations under Article 18 of Directive 1011/18/EC…on the deliberate release into the environment of genetically modified organisms… by failing to submit to the Council a proposal relating to the measure to be taken pursuant to Article 5(4) of Council Decision of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission."[3]

The ECJ also showed its displeasure with the Commission's failure to fulfill its obligations by ordering the Commission to pay the costs of the litigation.[3]

However, the General Court of the ECJ seems to have undermined its ruling in *Pioneer Hi-Bred International against the European Commission*[3] by its decision, rendered just three months later, in *Hungary against the European Commission*.[4]

In this legal dispute, Hungary, supported by Austria, France, Luxemburg, and Poland, challenged the Commission's approval of the genetically modified potato (Amflora) that BASF had pursued patiently and insistently since 1996. Hungary argued that the Commission had violated legislative procedural rules for approval.

The Commission had gone through the entire legislative process thereby giving the Commission the legal authority to grant approval. But before the Commission acted, it sought reassurance again from EFSA on the potato's safety. When the EFSA responded anew that the potato was safe, the Commission granted approval (2 Mar 2010) for release into the environment.

The Commission did not resubmit its March 2010 approval to EU Committees and the EU Council for their actions and votes, taking into account this new EFSA opinion on safety.

The General Court ruled in favor of Hungary, deciding that the Commission had to send its draft approval, based on the new EFSA opinion, back through EU Committees and the EU Council. The General Court decided that these institutions may have acted differently in light of this new EFSA opinion and, therefore, the Commission had violated the required legislative procedure. Consequently, the General Court annulled the approval.

Fourteen years of work by BASF seeking approval came to naught. Even after BASF had apparently gained approval, BASF learned from the General Court four years later that it faced yet another hurdle within the EU structures governing genetically-modified crops.

Brief Comments

The saga of the European decisions evidencing the "Whack-a-mole" game in Europe has consequences beyond just reading and understanding the four cases canvassed in this article. Several consequences are worth highlighting.

As the quotation from M Kuntz, A Ricroch, and J Davison set forth above[8] indicates, these constant and seemingly interminable delays and barriers undermine science research, agency scientific opinions, and scientific education for the people of Europe. Public policy formed, enacted, and enforced on the basis of pseudoscience is almost assuredly an undesirable approach for modern societies to adopt. The Advisory Committee on Releases to the Environment (ACRE), the UK governmental advisory body concerning genetically engineered crops, recently wrote,

"Our conclusion that the EU's regulatory approach is not fit for purpose for organisms generated by new techniques, also applies to transgenic organisms produced by 'traditional' GM technology…[T]he potential for inconsistency is inherent because they [genetically-engineered crops] may be phenotypically identical to organisms that are not regulated."[11]

Moreover, a very concrete reaction to the "Whack-a-mole" game is for companies to decide to stop playing. BASF has moved its biotechnology division to the United States, stopped cultivation of the Amflora potato, and announced that it will no longer develop genetically engineered crops for the EU market. Concurrently, Monsanto Company has announced that it will no longer seek approval for genetically engineered crops in Europe. Europe has thus deprived itself of scientific innovation and highly skilled human capacity.

In addition to the damage to science, the saga described in this article also undermines the rule of law. Blatant disregard for the laws and regulations governing genetically engineered crops by Member States and the Commission assuredly generates disrespect for laws and legal institutions. Blatant disregard also gives rise to cynicism and derision. Politicians are in charge and make these decisions, but the public in Europe and worldwide see them as naked manipulators. Hopefully these four court decisions reinforce and reestablish the rule of law for researchers, companies, farmers, and citizens who expect to be treated fairly and in a timely fashion in accordance with the rule of law regarding agricultural biotechnology.

Update

In this journal (v4[3]), the author reported on the OSGATA case.[12] On January 13, 2014, the Supreme Court of the United States declined to accept an appeal of the decision reported

earlier. Consequently, the Federal Circuit Court's opinion is the controlling decision. The OSGATA case is now over, and the Federal Circuit Court ruled favorably to Monsanto Company.

Disclosure of Potential Conflicts of Interest

No potential conflict of interest was disclosed.

Endnotes

[a]The nine Member States having a de jure or de facto ban on MON810 include Austria, Bulgaria, France, Germany, Greece, Hungary, Italy, Luxembourg, and Poland.

[b]In early 2008, the Commission challenged a Polish law adopted in 2006 banning the use of genetically-engineered crops as feed. However, the Polish government delayed implementation of the 2006 law several times with the most recent postponement until January 1, 2017. In September 2013, the ECJ decided that the case should be dismissed because the Commission challenge to the Polish law was premature. "EU loses lawsuit against Polish GM feed ban": http://www.eurofoodlaw.com/food-technology/genetic-modification/eu-loses-lawsuit-against-polish-gm-feed-ban-91967.html

Despite the delay on implementation of the 2006 law, the Polish government, by executive actions, has blocked the growing of genetically engineered crops by Polish farmers. In June 2013, the Commission initiated a lawsuit against Poland in the ECJ to require Poland to comply with EU legislation requiring Member States to create of a registry for growing GE crops and to adopt legal principles for monitoring GE crops. As of this article, this Commission action against Poland is pending in the ECJ. USDA GAIN Report, *EU Commission take Poland to the EU Court on GM issue* (No. PL1318 June 21, 2013).

[c]Italy invoked emergency measures in the identical language to the French invocation of emergency measures. M Kuntz, A Ricroch, and J Davison, "EFSA rejects Italian request for a ban on Monsanto's MON810 maize," BlogActiv Team (Oct. 9, 2013), http://guests.blogactiv.eu/2013/12/05/efsa-rejects-italian-request-for-a-ban-on-mon-810-maize/ (In case this blogpost disappears, the author also has a copy of this cited BlogActive post in his personal files.)

This article discusses the French invocation of emergency measures in the following section under the heading "France."

[d]The French Minister assuredly anticipated that the renewal application would ricochet around the EU approval structure for years and years. The French Minister anticipated correctly. Monsanto applied for renewed authorization prior to expiration of the MON810 authorization (expiration on April 18, 2007). As of November 2013, the EU has yet to complete action upon the renewal application for MON810.

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