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The Legal and International Trade Implications of Regulatory Lags in GM Crop Approvals

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The myriad of litigation and class action suits surrounding Syngenta's Viptera corn covers many issues that have been well addressed in previous litigation and literature. However, the case of Syngenta v Bunge raised the fascinating issue of 'regulatory lag', i.e., a situation where there are significant delays in approval of a GM product in an emerging export market, or differences in the regulatory approval timetable between significant export markets. In this case, Syngenta argued that Bunge's blanket refusal to accept Viptera corn into its facilities because China had not yet approved the variety, even though the variety was approved in the United States and in many other larger export markets, amounted to illegal activity that would cause significant harm to Syngenta. Although the litigation was ultimately settled in December 2014 by a confidential agreement between the parties, the case raises significant issues for the technology developers, producers, handlers, processers and shippers in instances where 'regulatory lag' is occurring or is possible. This article examines the legal implications of these lags for these parties, including an examination of their potential legal obligations and liabilities.

Keywords: adventitious presence, asynchronous approvals, commercialization, liability, low-level presence, regulation, trade barriers

1. Introduction

Time is money. This time-worn axiom of business school courses and the corporate world is also particularly applicable to the regulatory world. The time required for technology development firms to receive regulatory approval for a genetically modified (GM) crop, and thus the ability to commercialize the technology, has consistently increased over the past two decades. Jaffe (2005) reported that in spite of no new traits being regulated, the United States Department of Agriculture (USDA) consultation process had more than doubled over the first decade of GM crop regulation. The average number of months to get regulatory approval in the United States between 1994 and 1999 was 5.9 months, and between 2000 and 2004 it took 13.6 months. A 2011 report released by EuropaBio that examined regulatory approval times in Brazil, Canada, the European Union and the United States documented that the average time to approve a GM crop in the United States had risen to 25 months (EuropaBio, 2011). An industry report prepared by Phillips McDougall (2011) identified that the average number of months required for a GM event to receive regulatory approval in 2011 was 65 months, up from 49 months in the 2008 to 2012 period.1 The total cost of receiving variety approval in key markets in 2011 was estimated to be US$136M. Figure 1 illustrates the regulatory time in months for the four leading GM crop producing nations over the period 2006 to 2012.

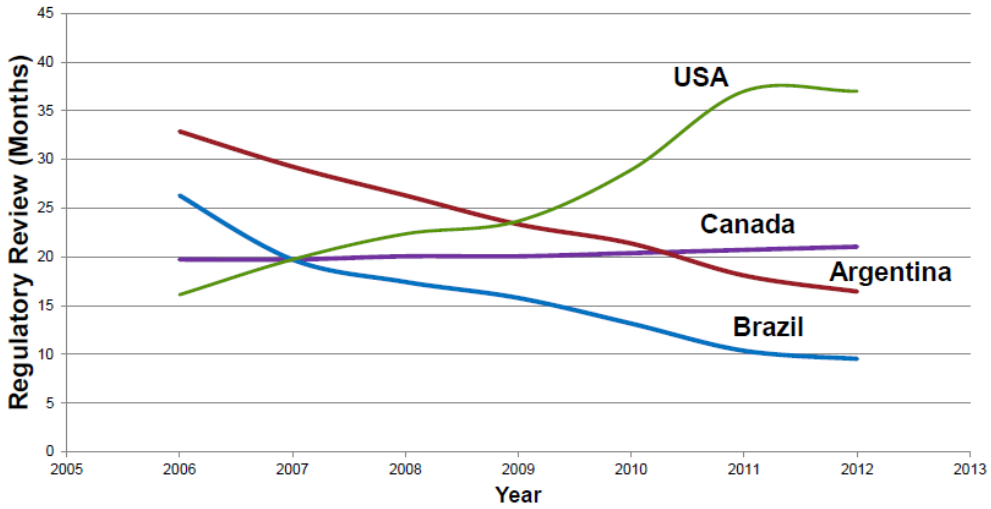

Figure 1 Regulatory cultivation approval times, 2006 to 2012

Source: Dewar, 2014.

The result of regulatory assessment times increasing in the United States, holding steady in Canada and decreasing in Argentina and Brazil is an international regulatory lag. Strong GM-adopting nations are able to approve GM crops more expeditiously than other nations. For example, the European Union is essentially in regulatory gridlock, having only approved one GM crop for cultivation in the past decade. As of 2016, the EU has 74 pending variety submission packages (Dewar, 2014). Another example is offered by the Chinese regulatory system, which will not even accept submission of a package for regulatory review until the new variety has been approved in another jurisdiction. Regulatory inefficiencies create substantial regulatory delays in securing international approvals for new GM crop varieties (figure 2), thus triggering substantial concerns for the commodity handling and trading industries. The nature of these concerns lies predominantly with the low-level presence of approved GM varieties in shipments of non-GM commodities to international markets expressing a preference to avoid GM products. These challenges are further exacerbated when some nations' regulatory approval systems lag those of other nations. This creates the situation of adventitious presence, where a GM crop is approved in the exporting country but not in the importing country, meaning that it is not allowed to be imported into that country; this discrepancy acts as a barrier to international trade.

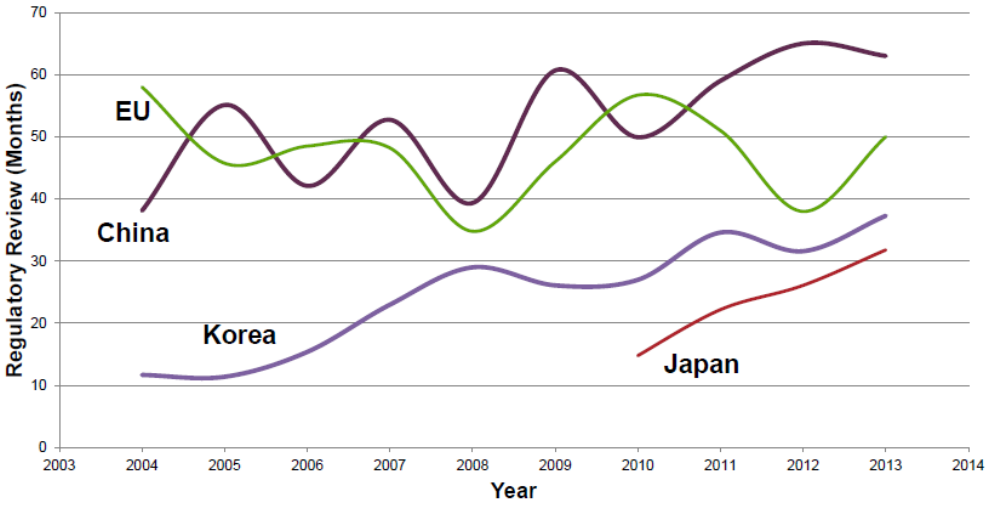

Figure 2 Regulatory import approval times, 2004 to 2013.

Source: Dewar, 2014

Is there a solution to this conundrum of asynchronous approval of GM events? While this concept has been much discussed, it has yet to become commercial reality. This article offers a unique perspective on asynchronous approvals, discussing the Patent Cooperation Treaty as a potential model for measures to reduce the challenges of regulatory lag in relation to GM crops.

The following section provides background on the issue of regulatory lag and highlights the legal implications of prolonged lag. Section 3 examines the Patent Cooperation Treaty, highlighting the need for its creation and the objectives of its implementation. The article concludes with a discussion of the major challenges the GM crop industry would face in structuring a similar agreement to resolve the regulatory lag problem.

2. Background

International trade functions at purity levels that are specific to each delivery contract. That is, one contract may have a commodity impurity level or threshold of 5 percent for other commodity types, weed seeds, insect fragments, dirt, etc., while another contract may specify an impurity threshold of 2 percent. Impurity thresholds vary according to how much the importer is willing to pay, as increasingly higher purity levels raise the cost of each tonne of commodity that is imported. The key message is that commodity trade does not function internationally at levels of 100 percent purity.

As part of the effort to ensure that GM crop varieties that have not been approved for import in a particular market do not affect exports to that market, the grain handling industry has established identity-preservation systems. These systems are purposefully designed to ensure that every effort is made to prevent an unapproved variety from entering the system. However, in spite of the best intentions of those participating in identity-preservation systems, comingling of unapproved varieties still occurs. The problem that results from detection of unapproved comingling is that international trade comes to a complete stop when a country with a zero tolerance policy detects the unapproved variety.

While there is significant analysis in the literature of the potential trade and economic impacts of asynchronous approvals of GM crops (Henseler et al., 2013; Stein and Rodriguez-Cerejo, 2010), this article will examine the *legal* implications of situations where a lag exists between key jurisdictions in the approval of a specific GM crop. In particular, this case will focus on the legal ramifications of a delay in Chinese approval of Syngenta's Agrisure product line containing the MIR162 insecticidal trait. This trait provides protection against the 'multi-pest complex' which

Syngenta asserts costs U.S. farmers over $1 billion per annum in lost yield and grain quality.

U.S. regulators approved Agrisure Viptera for sale in 2010 and the product was commercially launched in August 2010 in advance of the 2011 planting season. In addition to domestic approval, Syngenta also received import approval from Canada, Japan, Australia, Brazil, Mexico, New Zealand, South Korea, Russia and Taiwan. Significantly, import approval was also sought from China but had not been achieved by product launch.

We describe this temporal delay in approvals as a 'regulatory lag' that could have significant legal consequences for developers and marketers of new GM crops. In this regard, Syngenta's experience is illustrative, as Syngenta has faced a series of legal actions as a direct consequence of this lag. In addition to defending themselves, they have commenced complementary legal action against key actors in the U.S. corn distribution chain in an attempt to preserve market access for products containing its MIR162 trait.

Court documents filed by Syngenta asserted that it hoped to have import approval from China by March 2012 (Syngenta, 2011) but it was not received until December 2014. During this delay China began rejecting shipments of U.S. corn due to the presence of the MIR 162 trait. Although other factors may be at work (including a significant price correction for U.S. corn), U.S. corn exports to China have subsequently dropped by 85 percent, and many assert that the rejection of unapproved GM corn is a significant causal factor (Tidgren, 2014). Given these circumstances, the lawsuits have inevitably followed.

2.1 LAWSUITS SURROUNDING VIPTERA CORN

A. Syngenta v Bunge

Bunge North America is a U.S. corporation that operates 71 grain and milling facilities and 66 elevators in the United States. A major part of its business involves the purchase and storage of grains and oilseeds prior to selling on to domestic and international customers. It is a long-standing policy of Bunge not to accept grains or oilseeds containing transgenic material for those markets where export approval has not been obtained:

> All Bunge facilities are integrated into the export market, which is why the terms of Bunge's purchase contract states that Bunge will not accept grains or oilseeds containing transgenic events not approved for U.S. export markets (Syngenta, 2011).

In 2010, Bunge advised that it would not accept deliveries of Viptera corn varieties absent import approvals from Korea and Japan. This stipulation was removed once the approvals were received. In 2011, Chinese imports of U.S. corn grew by 500 percent over the previous year and imports had been increasing significantly since 2009 (Tidgren, 2014). This increased demand led Bunge to enter into several large contracts to export U.S. corn to China in the spring of 2011. As Bunge was aware of China's 'zero-tolerance' policy towards the presence of unapproved GM traits, they began (in line with the previous example) refusing any Viptera corn at any of its facilities in July 2011. The policy was to remain in place until import approval from China was received. In response to this policy change, Syngenta commenced legal action against Bunge in August 2011 seeking damages for lost profits and irreparable harm to its reputation (Syngenta, 2011).

The litigation centred around three main issues. First, Syngenta sought an injunction to suspend Bunge's policy. Second, Syngenta alleged that as Bunge was a federally licensed warehouse operator under the terms of the United States Warehouse Act (USWA) it was under an obligation to treat all agricultural producers fairly and accept the corn. Given that all other major grain companies were continuing to accept Viptera, and that Bunge had previously accepted corn containing traits not approved for export to China, its refusal to do so therefore constituted both a breach of s. 245 (a) of the Act and its contractual obligations towards Syngenta. Finally, Syngenta also alleged that Bunge had breached the terms of the Lanham Act by claiming it was 'unable' to accept Viptera corn. Under the terms of s. 43 (a) of the Lanham Act, businesses that believe they have been damaged may bring an action against those that make 'false and misleading' claims that misrepresent their business or products (Lanham Act, 1946).

The United States District Court rejected Syngenta's request for an injunction and also rejected Syngenta's claims under the USWA. The court also rejected Syngenta's claim under the Lanham Act (Syngenta, 2011). On appeal to the 8th Circuit, the court affirmed the findings on the injunction and the USWA and sent back the Lanham Act claim to the District Court for final disposition (Syngenta, 2014). Prior to any further hearing, the dispute was settled out of court in December 2014 shortly after China agreed to allow imports of Viptera corn.

While Syngenta was the plaintiff in the aforementioned suit, it has subsequently been named as defendant in two other disputes following China's rejection of U.S. corn shipments containing traces of MIR 162 in November 2013. Neither dispute has yet gone to court, but the litigation is likely to be lengthy and expensive in both instances.

B. Cargill v Syngenta

On September 12, 2014 Cargill commenced legal action against Syngenta alleging that it has lost over US$90 million because Syngenta began selling Viptera corn prior to obtaining Chinese export approval. Cargill alleges that Syngenta's decision led to widespread infiltration of MIR 162 into the U.S. corn supply and that any shipment of corn to China would be likely to contain traces of Viptera:

> Cargill is a supporter of innovation and the development of new GMO seed products. But we take exception to Syngenta's actions in launching the sale of new products like MIR 162 before obtaining import approval in key export markets for U.S. crops. Syngenta's actions are inconsistent with industry standards and the conduct of other biotechnology seed companies (Pearson, 2014).

A fascinating aspect of this litigation is that some suggest that the extent of the damage suffered is not solely attributable to regulatory lag, but may actually be exacerbated by Syngenta's marketing strategy:

> Syngenta made a conscious decision to market MIR 162 despite knowing that such action had the potential to cause large losses to others involved in the supply chain. Does that constitute a legitimate basis for this legal action? It's unclear, but the disgruntlement of Cargill and other grain handlers is not difficult to understand. It's reasonable to ask whether Syngenta can maintain a successful long-term biotech seed business if it insists on acting primarily to maximize its short-term earnings. Yes, the company no doubt spent several years and millions of dollars in developing MIR 162, so its interest in commercializing the technology is obvious. But the potential benefit to Syngenta from marketing MIR 162 in the current year likely would be measured in millions of dollars. The loss in value to the rest of the agriculture/food supply chain – including farmers – is being measured in billions. The potential costs could multiply quickly due to Syngenta's decision to allow limited planting in 2014 of a newer trait – Agrisure Duracade – that is not approved for importation by either China or the European Union. Syngenta seems to be rolling the dice (Pearson, 2014).

Public questioning of Syngenta's strategy has also emerged from within the U.S. grain industry itself. In January 2014, the National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) issued the following statement:

> U.S. farmers, as well as the commercial grain handling and export industry, depend heavily upon the exercise of due corporate responsibility by biotechnology providers with respect to the timing of product launch

> and commercialization. We therefore seek assurances from Syngenta that it will follow suit by publicly announcing that it will suspend immediately its commercialization of Viptera and Duracade products in the United States until such time as China and other U.S. export markets have granted required regulatory approvals and authorizations.

As if to emphasize the importance of this request, an April 2014 NGFA-commissioned study estimated that Agrisure Viptera–related trade disruptions had already cost U.S. corn and soy farmers between US$1 billion and US$2.9 billion in losses (Fisher, 2014a). A companion study also estimated that Syngenta's impending release of a second generation product, Viptera Duracade, prior to Chinese import approval could increase these losses by between US$1.2 and US$3.4 billion (Fisher, 2014b).

In spite of the aforementioned joint request, and ongoing and future losses predicted to be in the billions of dollars, Syngenta placed Agrisure Duracade onto the U.S. market for the 2015 growing season in the absence of Chinese (and EU) import approval (Pearson, 2014).

Given the sums involved, and the clear displeasure with Syngenta's commercial decision making, lawsuits of this nature are likely to be pursued vigorously by Cargill and other actors in the U.S. grain system. Indeed, Tidgren (2014) notes that,

> The same day that Cargill filed its case, Trans Coastal Supply Company, another U.S. corn exporter, filed a putative class action against Syngenta alleging that Syngenta's "premature release" of Viptera has caused Trans Coastal to lose around $41 million.

While Cargill and Trans Coastal are significant corporate litigants bringing suit against Syngenta, they were not the only actors in the U.S. grain supply system to commence litigation surrounding Viptera corn in late 2014.

C. Viptera-related class action lawsuits

In October 2014, four specialist class action law firms began an action against Syngenta for damage caused to U.S. corn farmers by China's rejection of shipments containing traces of Viptera corn. The suit seeks damages approaching US$1 billion and has so far enlisted over 300 farmers (Syngenta Corn Litigation, 2014). Potentially affected corn farmers are encouraged to join the litigation at a website established by the law firms that clearly outlines the arguments that will be pursued:

> If you've arrived here, you are probably a corn farmer feeling the financial impact of Syngenta's bioengineered corn. A recently filed class action lawsuit alleges that Switzerland-based Syngenta knowingly marketed two genetically modified strains of corn – Agrisure Viptera and Agrisure

> Duracade – that are illegal in China. When China detected a genetic trait found in Viptera (MIR162), they stopped accepting shipments. That caused the price of corn to plummet. That affects you, your farm and your family (Syngenta Corn Litigation, 2014).

Syngenta has stated that it will vigorously defend its actions:

> We developed a superior product that helps farmers; we applied for and received government approvals from the U.S. and major export markets at the time; and we submitted an import application to the Chinese government that was timely, accurate and complete. Syngenta believes the lawsuits are without merit and strongly upholds the right of growers to have access to approved new technologies that can increase both their productivity and crop yields. The issues involved in these cases are extremely important and affect every American farmer's right to benefit from new technologies that help grow better crops. When a US-approved product like Agrisure Viptera (event MIR162) is kept out of a market for political and economic reasons, farmers – and consumers – lose (Bennett, 2015).

Given the sums of money involved, and the impact of a loss on Syngenta's business model, this litigation is likely to continue for some time.

3. The Patent Cooperation Treaty as a Model for Reducing Regulatory Lag?

The litigation highlighted above dramatically illustrates the legal consequences of regulatory lag. The marketing of a product caught in a regulatory lag has resulted in years of expensive and time-consuming litigation that will ultimately resolve little. It may indeed rectify problems associated with regulatory lag by placing a chill on the market and making developers less likely to put products to market in a timely fashion.

One previous effort in this realm was the establishment of the Biosafety Clearing House under the Cartagena Protocol on Biosafety. This initiative was designed to ensure that the trade of GM products could be managed through the Biosafety Clearing House. This initiative failed for two reasons. First, the Biosafety Clearing House does not include many of the largest GM crop producing nations, namely Argentina, Australia, Canada and the United States. Given that these four countries have no reason to comply with the Biosafety Clearing House, the vast majority of trade in GM products occurs outside of its scope of governance. The second reason for the Biosafety Clearing House failing to live up to its potential is that the Cartagena Protocol on Biosafety has been co-opted by the environmental movement as simply a pawn to ensure that every possible barrier against GM crops is erected by member states. Rather than serving as a mechanism to facilitate trade in GM crops, the

Biosafety Clearing House became a mechanism for ensuring there is zero trade in GM crops or food products.

While the goal of achieving a truly harmonized and completely synchronous global approvals system is very unlikely, are there methods, means or precedents that can be employed so GM regulatory lag (and its attendant legal consequences) can be reduced or minimized?

3.1 THE PATENT COOPERATION TREATY

There are several similarities between seeking international regulatory approvals for GM crops and the process for seeking intellectual property protection for inventions in multiple jurisdictions. As with GM crops, inventors must seek patent protection from national patent offices, just as import approval for a GM crop must be received from individual national authorities in the putative importing state. Just as there are no 'international' approvals for GM crops there is no such thing as an 'international' patent. However, efforts to harmonize and streamline the international patent system have been ongoing since the drafting of the Paris Convention in 1883; these efforts culminated with the development of the Patent Cooperation Treaty. As Nepelski and De Prato state,

> The Patent Cooperation Treaty is one of the major undertakings in the process of patent harmonization. It is an international treaty for rationalization and cooperation with regard to … patent applications and the dissemination of the technical information contained therein. The PCT does not give the right to "international" patents … the task of granting patents remain[s] exclusively in the hands of national patent offices (Nepelski and De Prato, 2013).

Negotiations for the Patent Cooperation Treaty were concluded in 1970, and it entered into force in 1978. Its membership now extends to 148 countries. As stated above, the PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an 'international' patent ***application***. The PCT is administered by the World Intellectual Property Organisation (WIPO).

While WIPO does not grant patents, or provide any legal protection for inventions, they argue that the PCT provides advantages for the applicant, national patent offices and the general public:

> (i) the applicant has up to 18 months more than he has in a procedure outside the PCT to reflect on the desirability of seeking protection in foreign countries, to appoint local patent agents in each foreign country, to prepare the necessary translations and to pay the national fees; he is

> assured that, if his international application is in the form prescribed by the PCT, it cannot be rejected on formal grounds by any designated Office during the national phase of the processing of the application; on the basis of the international search report or the written opinion, he can evaluate with reasonable probability the chances of his invention being patented; and the applicant has the possibility during the international preliminary examination to amend the international application to put it in order before processing by the designated Offices;
>
> (ii) the search and examination work of patent offices can be considerably reduced or virtually eliminated thanks to the international search report, the written opinion and, where applicable, the international preliminary examination report that accompany the international application;
>
> (iii) since each international application is published together with an international search report, third parties are in a better position to formulate a well-founded opinion about the patentability of the claimed invention.

To put this more simply, the international patent application process under the PCT provides a more streamlined and cost-effective application for multiple jurisdictions. Furthermore, by subjecting the application to an 'international' search at one of the member national patent offices, all patent authorities in the 148 nations will be able to assess the initial patentability of the invention via a common source of information. However, the PCT does not interfere with the sovereignty of these national offices in that they still make the ultimate decision re patentability and are free to seek additional information and analysis beyond that produced by the initial international search.

In 2013 over 200,000 PCT applications were made worldwide, a 5 percent increase on the previous year. Fifty-seven percent of the growth came via U.S. applicants, with a further 29 percent of the growth attributable to Chinese applicants. Over 57,000 applications came from U.S. applicants. However, Panasonic Corporation of Japan was the single largest applicant, filing over 2,700 applications (PCT Yearly Review, 2014).

To be clear, the PCT does not replace national patent offices and does not provide international patent protection. However, it is argued that a PC-type model for GM crop approvals could assist in reducing regulatory lag considerably. In essence, the PCT system is intended to reduce unnecessary duplication among patent offices and supports work sharing between those offices. If countries with an interest in importing GM crops could create a regime whereby a common application containing all necessary scientific and other information could be used then the possibility of a limited form of synchronous approval becomes possible. If national sovereignty concerns necessitated a PCT-like model where the final approval decision still rests

with a national body, a common application and accompanying data set could nevertheless streamline and harmonize the application process across multiple jurisdictions, thus significantly reducing the potential for damaging regulatory lags such as those encountered by Syngenta's Viptera corn.

The PCT is not without flaws or critics. While WIPO and others may cite impressive growth in PCT applications and laud its accomplishments (Erstling and Boutillon, 2006), other research suggests that the PCT process is only suited to certain types of particularly sophisticated technologies. Koury states,

> Wadhwa et al. have shown that only sophisticated patents are filed through the PCT track. They blame this on the "costly and time-insensitive application process for PCT patents." In essence, the PCT as it stands today has become a hamlet for rich innovators and for applications that have "market potential in multiple countries, global visibility, or diverse applications" (Khoury, 2012).

While such a position will be of little concern to major global life-science corporations, it may be of concern that some research (Nepelski and DePrato, 2013) suggests that the PCT has not necessarily improved the process of international patent protection and that PCT membership does not necessarily result in technology transfer to developing countries after they have joined the PCT. Nepelski and DePrato also indicate that some businesses still prefer to seek national patent protection directly in target markets, rather than using the PCT as their 'default' patenting process when seeking to enter foreign jurisdictions.

Ultimately, one's opinion of the success of the PCT will depend on whether it is viewed as a tool for streamlining application processes and reducing delay and duplication, or whether it is viewed as a vehicle for the ultimate harmonization of the international patent system. If its goal is viewed as the former, then there is clear potential for a PCT-like regime to be applied to approvals for GM crops in like-minded jurisdictions. At a minimum, the PCT warrants further study as a model for a regime that could reduce or eliminate damaging regulatory lags in the GM crop approval process.

4. Application Challenges

As with any international governance issue, challenges exist regarding agreement on protocol, precedents and implementation. We summarize three of the most pertinent issues facing the development of a PCT-type structure for synchronous approval.

First, identifying a champion (or champions as the case may well be) is problematic. With the present trans-Atlantic gap regarding regulatory approval of GM crops, it would be a logical assumption that this issue is not going to be easily, or

readily, addressed through such a mechanism. Establishing a new international protocol would take several years of discussion before parties reach a consensus on the scope, objectives and structure of such an agreement, to be followed by a further period of several years during which enough nations would have to not only sign, but also ratify the agreement prior to it coming into effect. For example, when the Cartagena Protocol on Biosafety was agreed upon in 2000, it required ratification by 50 nations prior to coming into effect as an international agreement. This process took three years.

What incentives exist that could encourage non–GM crop producing nations to participate in such an agreement? While international trade is disrupted by the detection of the low-level presence of unapproved GM events, the disruption imposes a higher cost on the exporting nation than on the importing nation, as the importing nation simply rejects the shipment and is not required to deal with it after this point. It is up to the exporter to find an alternative market for a rejected shipment. Even nations that produce GM crops, such as China, are taking significant amounts of time to approve GM events for import, indicating that there is little incentive for these countries to increase their regulatory efficiency. It is doubtful that non–GM crop producing nations would recognize efficiencies to improve their regulatory import approval process.

Finally, monitoring and/or enforcement of any new agreement will be a daunting challenge. Assuming that if nations were provided with a period whereby approved GM events could not be used to disrupt international trade as regulatory approvals were pending, establishing a mechanism that would be capable of enforcing some type of punitive means on those nations that took longer than was agreed to in the approval of GM events is highly unlikely. Domestic sovereignty would seem to be increasing in importance, and national governments that propose ceding sovereignty to an international agreement or protocol within this present time period would be viewed most unpopular. Separating the political realities and, indeed, the politics from this issue might well be the challenge that proves insurmountable.

In spite of these challenges, which in general terms are applicable to the negotiation of any international agreement, we strongly assert that efforts to streamline GM crop approval processes are a worthwhile endeavor. The legal consequences of GM regulatory lag are significant and ongoing. Unless action is taken to address these consequences, a rapidly decelerating approvals process could grind to a complete halt. Negotiations may be difficult, and a modest goal of streamlining approvals may be a long way from the end goal of synchronous approvals, but the

status quo is not a viable option. The development and operation of the PCT provide a model worth pursuing with some vigour.

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Endnotes

[1] Firms were surveyed about the actual and expected costs for the 2008-2012 period in 2011. The 49-month figure represents the time in the 2008-2010 period, as firms also provided data for their experiences in 2011.