INSIDE

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IN FUTURE ISSUES

"Hot seed" and the "law of the cotton belt": federal circuit rules on passive third-party transfer or liability under the Plant Variety Protection Act

The Plant Variety Protection Act (PVPA), 7 U.S.C. §§ 2321-2581, "protects owners of novel [sexually reproduced] seed varieties against unauthorized sales of their seed for replanting purposes." *Asgrow Seed Co. v. Winterboer,* 513 U.S. 179, 181 (1995). It does so by giving the holders of a PVP certificate broad exclusive rights. Among other protections given to certificate holders, the PVPA prohibits the unauthorized sale, offer for sale, "or any other transfer of title or possession" of PVPA-protected seed. 7 U.S.C. § 2541(1). It also prohibits the dispensing of protected seed to another "in a form which can be propagated, without notice as to being a protected variety under which it was received...." *Id*. § 2541(6). Finally, the PVPA probibits anyone from instigating or actively inducing the performance of any of the acts it proscribes. *Id*. § 2541(8).

Prior to 1994, the PVPA expressly limited the exclusive rights of PVP certificate holders by granting two exemptions from infringement liability to farmers. First, farmers were permitted to save protected seed for use on their own farms. Second, certain "farmer-to-farmer" sales of excess "saved seed" were also exempted. *Id*.§ 2543 (amended 1994). In 1995, the Supreme Court construed the farmer-to-farmer exemption to apply to sales, for reproductive purposes, of only so much seed as the farmer had saved for replanting his or her own acreage. *Asgrow Seed Co. v. Winterboer*, 513 U.S. at 192. Sales for reproductive purposes above that amount were not exempted.

In 1994, Congress narrowed these exemptions, including eliminating the right of farmers to resell seed for reproductive purposes. *See* 7 U.S.C. § 2543. The 1994 amendments, however, apply only to PVP certificates issued after April 4, 1995, or to certificate applications which were pending on that date. All other certificates remain subject to the 1970 PVPA. *See generally* Ernest D. Buff & Leslie G. Restaino,

C*ontinued on page 2*

Deferral program for FSA shared appreciation agreements

On April 23, 1999, Farm Service Agency (FSA) amended it regulations regarding shared appreciation agreement (SAA) requirements to allow certain Farm Loan Program borrowers subject to an SAA that ends prior to December 31, 2000, to have the obligation to pay all or part of the recapture amount due under the agreement suspended for up to three years. 64 Fed. Reg. 19,863 (1999) (interim rule) (affecting 7 C.F.R. pt. 1951). This rule is effective April 23, 1999 and comments can be submitted until June 22, 1999.

In response to the now infamous farm crisis of the 1980s, Congress passed the Agricultural Credit Act of 1987. Pub. L. No. 100-233 101 Stat. 568 (1988). This landmark legislation established the basic framework for the debt-restructuring provisions that still apply to Farm Service Agency (FSA), formerly the Farmers Home Administration (FmHA), loan programs. Under this framework, in some situations, a delinquent farm loan borrower may be eligible for a write-down of debt owed to FSA. The first of these "write-downs" occurred in 1988, and a significant number of farmers have received this assistance since then.

Continued on page 3

The Best Way To Protect Plant-Related Inventions, 5 Intell. Prop. Strategist 7 (1999). The scope of the unamended version of § 2543 thus remains relevant.

Until May 19, 1999, an arguably unresolved issue under the unamended PVPA was whether a passive third-party to a sales transaction involving protected seed could be held liable for infringement as a participant in the transfer if the transfer was unauthorized by the certificate holder and outside of the farmer-to-farmer exemption. In this context, a "passive" third party might be a ginner or delinter of cottonseed who merely conditioned the seed for replanting and transferred it at a customer's request without brokering the transfer. Whether this issue had been resolved is debatable because in 1983 in *Delta and Pine Land Co. v. Peoples Gin Co.*, 694 F.2d 1012 (5th Cir. 1983), the Fifth Circuit had held that a farmer cooperative that had brokered the exchange of protected seed of its members was not exempted from infringement liability. In reaching its holding, however, the court expressed the view that had the cooperative not been acting as a broker the result would have been different:

> A sale is exempt if the seller instructs his cooperative to forward his seed to a particular named buyer. In that situation, the cooperative has not arranged the sale. Nor has it played an active role in the transaction. It merely has served as the vehicle for the transfer of possession.

Peoples Gin Co., 694 F.2d at 1017. The decision in *Peoples Gin Co.*, therefore, appeared to support the proposition that a third-party who participated in an unauthorized transfer of protected seed but who did not arrange for the transfer was not liable for infringement.

The Fifth Circuit in *Peoples Gin Co.* was not required to reach the issue of whether a purely passive third-party was liable for infringement by participating in the transfer of "hot seed" because the defendant in that case had acted as a broker. However, the issue of whether a passive third party was liable for the transfer of protected seed without the certificate holder's authorization or the protection of a PVPA § 2543 exemption was squarely presented and decided by the Federal Circuit in *Delta and Pine Land Co. v. The Sinkers Corp.*, No. 98-1296, 1999 WL 305019 (Fed. Cir. May 19, 1999). Characterizing the issue as one of first impression, the Federal Circuit rejected the approach taken in *Peoples Gin Co.* and held that a passive third party who knows or should have known that a transfer of protected seed was neither authorized nor exempt under the unamended PVPA § 2543 exemptions is liable for infringement.

The principal claim at issue in *Delta and Pine Land* was the claim by the Delta and Pine Land Company and the Mississippi Agricultural and Forestry Experiment Station that The Sinkers Corporation had transferred possession of PVPA-protected cottonseed in violation of PVPA § 2541(1). Both plaintiffs held PVP certificates for cottonseed. Sinkers was primarily engaged in the delinting and conditioning of cottonseed for use as planting seed. The plaintiffs alleged that Sinkers was transferring, without their authority, large quantities of protected seed outside of the farmer-to-farmer exemption. Sinkers, on the other hand, claimed that it was merely a passive third party to transfers within the farmer-to-farmer exemption.

The district court found that Sinkers did not broker any seed transfers or transfer title to any seed. Instead, seed was delivered to it by its farmer and farmer cooperative customers. Sinkers then delinted and conditioned the seed and transferred possession of the seed to whomever its customers requested. While the seed was in its possession, Sinkers had only the control necessary to process it and to deliver it in accordance with its customers' requests.

Based on these facts, the district court relied on *Peoples Gin Co.* to hold that Sinkers was not liable for infringement in the absence of "active intervention" by Sinkers in the sale of seed. The Federal Circuit, however, rejected that approach and its focus on the defendant's involvement of the sale of seed. In the view of the Federal Circuit, neither the plain meaning of PVPA § 2451(1), which proscribes unauthorized transfer of possession of protected seed as well as its sale, nor the intent of the PVPA as a whole supports that approach.

The Federal Circuit began its analysis by noting that the term "active" does not appear in PVPA § 2541(1). It reasoned, therefore, that the transfer of possession need not be an "active" one, as would be the case if the defendant acted as a broker. At the same time, the Federal Circuit acknowledged that some limit had to be placed on the liability of those who participated in the unauthorized transfer of protected seed. Otherwise, a completely innocent party who transferred possession at the request of another could face liability. The solution to this dilemma, reasoned the Federal Circuit, is to read into the PVPA a "limitation of scienter, even though one is not expressly set forth therein." *Delta and Pine Land Corp.*, 1999 WL 305019 at *7.

On this basis, the Federal Circuit held that PVPA § 2541(1) "requires that a delinter, ginner, or other third-party transferor facilitating a farmer-to-farmer sale knew (knowledge is presumed in a scenario where the third party brokers the transaction) or should reasonably know that its unauthorized transfer of possession is an infringing transaction, i.e., that the sale is not exempt under section 2543." *Id.* at *8. In other words, "[l]iability for infringement under section (1) ... turns on knowledge." *Id.*

For the Federal Circuit, imposing a scienter requirement is superior to the approach taken by *Peoples Gin Co.* because it reaches those third-parties who passively participate in a transfer of possession while knowing that the transfer violates the PVPA. Under the *Peoples Gin Co.* approach, third-parties who did not "actively" participate in such transfers would escape liability notwithstanding their knowledge of the PVPA violation. *Id.* at 7.

As to what might constitute scienter, particularly under the "should have known standard," the Federal Circuit opined that "'red flags'" may put a delinter such as Sinkers on notice. "If a farmer

Cont. on p.3

VOL. 16, NO. 6, WHOLE NO. 187 May 1999

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Agricultural Law Update is published by the American Agricultural Law Association, Publication office: Maynard Printing, Inc., 219 New York Ave., Des Moines, IA 50313. First class postage paid at Des Moines, IA 50313.

Letters and editorial contributions are welcome and should be directed to Linda Grim McCormick, Editor, Rt. 2, Box 292A, 2816 C.R. 163, Alvin, TX 77511.

SAA/Continued from page 1

Under the statute and regulations that govern the FSA debt restructuring process, when a farm borrower receives a write down of his or her debt, the farmer must sign a Shared Appreciation Agreement (SAA) and a mortgage or other security document securing the SAA. Under this agreement, under certain circumstances, the farm borrower promises to pay back a portion of the debt that has been "written off" if the property securing the agreement increases in value.

The amount that can be recaptured under an SAA depends on how much the mortgaged real estate has appreciated from the time the SAA was signed to the time when payment is due. If there is no appreciation in value, no payment is due under the SAA. If payment under the SAA is triggered within four years after the SAA is signed, the recapture is set at seventy-five percent of the increase in the value of the mortgaged real estate. If payment is triggered more than four years after the SAA is signed, or if the SAA expires, the recapture is set at fifty percent of the increase in value of the security property. Under no circumstances, however, can the borrower ever be asked to pay back more than he or she had written down.

The regulations governing SAAs list the events that will "trigger" the SAA obligation. These regulations provide that the obligation under the SAA will become due at the end of its term (usually ten years) or sooner, if one of the following "trigger" events occurs: the sale or transfer of the mortgaged property (other than to spouse upon the death of the borrower); the farm borrower's cessation of farming; the payment in full of the underlying remaining debt to FSA; or the acceleration of the note.

Because the first SAAs were signed in the late 1980s, many are now at or approaching the end of their ten year term. Although some have questioned FSA's interpretation of the contract requirements, the current regulations provide that the expiration of this term triggers the recapture provisions contained in the SAA. Farmers who may have not understood the terms of the original agreement or forgotten about the potential obligation, have received, or may soon receive, notice that FSA intends to recapture a portion of the debt that was written down. These notices, in combination with near-record low farm prices, have resulted in protests from some in the farming community. In response, FSA recently announced the new deferral program to ease the burden of repayment of the SAA obligation.

Under this deferral program, FSA has the authority to suspend a farmer's obligation to pay the SAA recapture amount for one to three years. In order to qualify for the first year of this deferral, the farmer must certify in writing that he or she cannot afford to make the recapture payment. The suspension can be renewed for up to two additional years, although at the end of the first and second years of suspension, there will be a review of the farmer's financial circumstances. The renewal of the suspension will be limited to the amount the farmer is unable to pay based on his or her Farm and Home Plan.

In order to be eligible for the deferral program, a farmer must request the suspension of the recapture payment by thirty days after the notification of the recapture amount due or May 24, 1999, whichever is later. A farmer who has already entered into an agreement to pay the recapture amount, including an agreement to refinance the recapture payment, is not eligible for the suspension. The deferral program only applies to SAAs that end prior to December 31, 2000.

There are a number of questions that remain regarding the interpretation and implementation of the SAA deferral program. These questions concern the certification that a farmer has to sign in order to establish eligibility, the appropriate exercise of appeal rights, and controversies regarding the borrower's right to appeal the appraised value of the real estate. In order to obtain the deferral, a borrower must sign an agreement acknowledging that a set recapture amount is owed. Thus, there are also important issues regarding legal strategies for dealing with the SAA obligation and the deferral program. Farmers Legal Action Group, Inc. has helpful information on these issues available on its Internet web site at http://www.flaginc.org

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PVPA/*Cont. from p. 2*

returns year after year with more seed than he or she could possibly use, based on either Sinkers's knowledge of the actual size of the farmer's knowledge of the actual size of the farmer's acreage or ... [with] simply an absurdly large amount of seed, then clearly this seed is not being saved for reproductive purposes just for the farmer's own acreage, and Sinkers would have scienter." *Id*. at 9. The court also cautioned that a delinter's obtaining written assurance of compliance with the PVPA § 2543 exemptions from its customers would not "impart immunity" if the "certificate holder can prove actual knowledge, or show that the delinter or ginner should have known it was handling hot seed...." *Id*.

The Federal Circuit's decision was not unanimous, however. The single dissenter argued that the scienter requirement would lead to ginners and delinters becoming "paper-keeping traffic cops" because they would have to insist on their customers providing them with representations or other written assurances that the transfers were within the PVPA § 2543 exemptions, including the farmer-to-farmer exemption. *Id*. at *13. Inevitably, according to the dissent, there will be "glitches here and there in the paper trail" as well as "mountains of paper piling up throughout the Cotton Belt." *Id*. at 13. In the dissent's view, the *Peoples Gin Co.* approach not only was preferable, but represented the well-settled "law of the Cotton Belt" which should be left intact. *Id.* at 13-14.

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Federal regulation of concentrated animal feeding operations

The Clean Water Act classifies pollutants as discharges from either point sources or nonpoint sources. Point-source pollution is defined to include pollution flowing from pipes, ditches, and other identifiable sources (33 U.S. Code § 1362(14)). One of the other sources listed as a point source is a concentrated animal feedlot operation (CAFO).

Definitions in the Code of Federal Regulations (40 C.F.R. Parts 122–124) enumerate the animal feeding operations (AFOs) that will be considered to constitute a point source. Whenever an AFO meets the definition of a CAFO and is a point source of pollutants, it needs a National Pollutant Discharge Elimination System (NPDES) permit (C.F.R. §§ 122.23, 124.52).

AFOs are categorized according to size, measured in the number of "animal units," to determine whether they constitute a point source under federal regulations. An animal unit is basically one feeder cow, and is defined to mean:

> a unit of measurement for any animal feeding operation calculated by adding the following numbers: the number of slaughter and feeder cattle multiplied by 1.0, plus the number of mature dairy cattle multiplied by 1.4, plus the number of swine weighing over 25 kilograms (approximately 55 pounds) multiplied by 0.4, plus the number of sheep

Continued on page 7

*The Biosafety Protocol and the Cartagena Negotiations**

By Drew L. Kershen

Chronology of events

At the second meeting of the Conference of the Parties (COP-2) to the Convention on Biological Diversity (Jakarta, November 1995), COP-2 conferees decided to establish an Open-ended *Ad Hoc* Working Group on Biosafety (commonly called the Biosafety Working Group or BSWG). COP-2 gave the BSWG the task of negotiating a Biosafety Protocol relating to the safe transfer, handling, and use of living modified organisms (LMOs).[1]

Since November 1995, the BSWG has met six times to develop a Biosafety Protocol. In accordance with a COP-4 decision (Bratislava, 1998), the COP instructed the BSWG to complete its negotiating task at the Sixth Session of the BSWG in Cartagena, Colombia between Sunday February 14 and Monday February 21. Upon completion of the negotiations, COP further instructed the BSWG to forward its negotiated Biosafety Protocol to an extraordinary session of the Conference of the Parties (Ex-COP) that would be held on February 21-22 in Cartagena immediately following BSWG-6. At the Ex-COP, the Parties would formally adopt the BSWG-negotiated Biosafety Protocol as the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity." It did not happen.

When the BSWG gathered in Cartagena, almost the entire text of the draft Biosafety Protocol under consideration remained in brackets–i.e., almost the entire text remained in dispute. The entire text remained in brackets because the Biosafety Protocol has become the battleground between those who desire a moratorium on biotechnology as an industry and those who view biotechnology as the technological breakthrough of the 21st century. These two positions on biotechnology–opponents of biotechnology (primarily from environmental, anti-corporate, and anti-technology organizations) and the proponents of biotechnology (primarily from agricultural, industrial, and scientific organizations)–are unalterably and implacably opposed. Consequently, the BSWG-6 delegates faced the unenviable task of bridging the unbridgeable.

On Monday, February 21, the BSWG held its final plenary session as an active subunit of the Conference of the Parties. The Chair of the BSWG presented to the final plenary session an unbracketed text of the Biosafety Protocol containing thirty-nine articles, two textual annexes, and one empty annex to be filled by decisions of later COPs. After brief discussion, the Chair gaveled the text (UNEP/CBD/BSWG/6/L.2./Rev.1 – 21 February 1999) as the adopted text of the BSWG.[2] Once gaveled as adopted, the Chair opened the floor for comments on the text. Delegates from more than fifty nations spoke. Not a single delegate spoke favorably about the Biosafety Protocol that had just been adopted.

At the Ex-COP plenary on Monday, February 21, the Chair of the BSWG presented the BSWG-6 report and attached the BSWG Biosafety Protocol (UNEP/CBD/BSWG/6/L.2/Rev.1–21 February 1999) for consideration by the COP extraordinary session. Delegates to the Ex-COP refused to adopt the BSWG-6 report because they feared that adopting the BSWG-6 report would impliedly also adopt the BSWG Biosafety Protocol. At this impasse, the Ex-COP Chair proposed that the delegates to Ex-COP reopen the negotiations on the Biosafety Protocol using the BSWG text for reference purposes only. After two additional days of negotiations, the Ex-COP plenary session of Wednesday February 23 (from 2:30 a.m. to 5:30 a.m.) agreed to suspend the negotiations on the Biosafety Protocol. Ex-COP further agreed that the COP of the Convention on Biological Diversity would resume its negotiations on the Biosafety Protocol no later than the fifth meeting of the COP, presently scheduled for May 2000.

The prospects for the COP being able to reach consensus on a Biosafety Protocol upon resumption of the negotiations are not good. The Opponents reject the adopted BSWG Biosafety Protocol. The Opponents will not accept any Biosafety Protocol unless it becomes a binding, international biotechnology assessment that as a practical matter creates a moratorium on biotechnology as an industry. The Proponents will forcefully oppose the revisions supported by the Opponents. Moreover, the Proponents are willing to live without an international Biosafety Protocol. The Proponents would rather not have an international Biosafety Protocol than a Biosafety Protocol that excessively impedes biotechnological research and development.[3]

Substantive disputes

Because the thirty-nine articles and two annexes have been reopened for negotiation, the entire text is subject to substantive disputes. Therefore, the author has decided to select several substantive disputes that he believes dominated the negotiations in Cartagena. The author will briefly describe each substantive dispute. The author will then give the BSWG Biosafety Protocol resolution of each dispute *in italic font* to remind the reader that the BSWG Biosafety Protocol is not an official document of the Conference of the Parties to the Convention on Biological Diversity. If a Biosafety Protocol ever emerges from COP negotiations, the renegotiated Biosafety Protocol [will] [may] [might] [will not] [may not] [might not] present resolutions of the substantive disputes that are different from the resolutions found in the BSWG Biosafety Protocol (UNEP/CBD/BSWG/6/L.2/Rev.1–21 February 1999).

Definition of modern biotechnology

The Opponents want the definition of modern biotechnology to be as expansive as possible. The Opponents want an expansive definition because they want all methods by which LMOs may be produced to come within the legal regulation of the Biosafety Protocol. The Opponents realize that modern biotechnology is an evolving, changing technology. The Opponents do not want a Biosafety Protocol that might become outdated because the biotechnology industry changes to a new technology not covered by the Protocol.

The Proponents want a definition that specifically describes the covered technology(ies). More specifically, the Proponents want the definition to cover only in vitro nucleic acid techniques.

The BSWG Biosafety Protocol defines modern biotechnology to include in vitro nucleic acid techniques and fusion of cells beyond the taxonomic family.

Contained use

The Proponents want LMOs intended for contained use to be excluded from the Biosafety Protocol. The Proponents argue that contained use LMOs present minimal risk to biological diversity. Moreover, the Proponents argue for the unimpeded flow of biotechnological techniques from developed to developing nations and

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of international research exchanges between scientists. If LMOs intended for contained use are subject to the advance informed agreement procedures of the Biosafety Protocol, the Proponents argue that research institutes and their scientists will be at the mercy of international bureaucratic procedures.

The Opponents argue that contained use of LMOs should be fully within the Biosafety Protocol because risks exist that LMOs may escape from contained facilities and because LMOs themselves present health risks to the scientists and the other employees at contained use facilities.

The BSWG Biosafety Protocol includes LMOs intended for contained use within the Protocol but only for the general principles of Article 2; for unintended transboundary movements and emergency procedures of Article 14; for handling, transport, packaging and identification of Article 15; and the information sharing of Article 17. The BSWG Biosafety Protocol does not subject LMOs intended for contained use to the advance informed agreement procedures, the risk assessment procedures, and the risk management procedures set forth in the Protocol.

Products of LMOs

The Opponents argue that the Biosafety Protocol should apply fully to all LMOs and their products. The Opponents argue that the products of LMOs present environmental and health risks either directly (by contact) or indirectly (as waste products). Therefore, the Opponents argue that before medicines (such as over-the-counter pregnancy tests created through cell fusion techniques), clothes (denim from genetically modified cotton), foods such as cheese, beer, wine (fermented with genetically modified yeasts or ingredients), or industrial products (refined from genetically modified plants or animals) can cross international boundaries, the Biosafety Protocol should subject these products of LMOs to advance informed agreement, risk assessment, and risk management procedures specifically set forth in the Protocol.

The Proponents argue that products of LMOs, as non-living matter, present no risks to the environment or human health different from equivalent products produced by non-biotechnology techniques. The Proponents argue that these products of LMOs and equivalent non-LMO products should undergo identical environmental and health evaluations solely under domestic regulatory regimes. The Proponents argue that products of LMOs should not be subjected to an additional international environmental and health regime created by the Biosafety Protocol.

The BSWG Biosafety Protocol excludes products of LMOs from the scope of the Protocol and its regulatory procedures. The BSWG Biosafety Protocol refers to products of LMOs only for purposes of information in Article 17 on information-sharing and in Annexes I and II relating to risk assessment and risk management.

Agricultural commodities

The Proponents argue that the Biosafety Protocol should focus on the intentional release of LMOs into the environment. The Proponents argue that it is the intentional release of LMOs into the environment that raises substantial risks to biological diversity which is the subject matter of the Convention on Biological Diversity. The Proponents argue that agricultural commodities that are destined for processing or for direct consumption as feed or food should be excluded from the Protocol. If agricultural commodities destined for further processing or direct consumption are brought within the Protocol, the Proponents argue that nations will use the Protocol to distort free trade in agricultural commodities.

The Opponents argue that agricultural commodities are living seeds that can reproduce in the environment. Consequently, the Opponents argue that the likelihood of seeds being diverted from their intended destination for processing or for direct consumption as feed or food is too great a risk to take without subjecting transboundary movements of agricultural commodities to the advance informed agreement, risk assessment, and risk management procedures of the Biosafety Protocol.

The BSWG Biosafety Protocol includes agricultural commodities within the scope of the Protocol. However, the BSWG Biosafety Protocol in Article 5 specifically excludes agricultural commodities intended for processing or direct consumption as feed or food from the advance informed agreement provisions of the Protocol. Exporters of agricultural commodities produced from genetically modified plants must comply with the handling, transport, packaging, identification, and information-sharing requirements of the Protocol.

Application of advance informed agreement procedures

The Opponents argue that every transboundary movement of every LMO, on a shipment-by- shipment basis, should be subject to the advance informed agreement, risk assessment, and risk management procedures set forth in the Biosafety Protocol. Moreover, the Opponents argue that these procedures should be mandatory for every transboundary movement of every LMO. The Opponents argue that an individual country could only adequately assess and control the impact of LMOs on its environment and human health if each country makes its own decisions on a shipment-by-shipment basis.

The Proponents argue that advance informed agreement, risk assessment, and risk management procedures should apply only to the first transboundary movement of LMOs. The Proponents argue that once a country has given consent, performed a risk assessment, and specified the conditions for risk management that there is no need for additional environmental and health evaluations unless new scientific evidence emerges that makes the first transboundary movement evaluation invalid. The Proponents argue that an LMO approved once is sufficient protection for the environment and human health.

The BSWG Biosafety Protocol specifies in Article 5 that the advance informed agreement procedures apply only to the first intentional transboundary movement of LMOs into an importing country. The Protocol allows the importing country to state whether the decision to allow entry applies to subsequent imports of the same LMOs.

Social and economic considerations

The Proponents argue that the purpose of the Biosafety Protocol is reducing risks of LMOs to the environment and human health. The Proponents argue that the Protocol should focus its environmental and health evaluations upon the LMOs created by biotechnology and their risk and benefits to the environment and human health. The Proponents argue that the Biosafety Protocol should focus narrowly upon environmental and human health risk and benefits of biotechnological products.

The Opponents argue that the Biosafety Protocol should authorize a technological assessment of biotechnology. The Opponents argue that a focus on environmental and human health risks is too narrow a focus for nations to be able fully to assess and control the impacts of biotechnology. The Opponents argue that the Biosafety Protocol should mandate that nations perform a technology assessment that takes into account social, economic, cultural, religious, and ethical considerations in the advance informed agree-

Continued on page 6

Cartagena/*Cont. from page 5*
ment, risk assessment, and risk management procedures of the Protocol.

The BSWG Biosafety Protocol in Article 24 states that Parties may take into account socio-economic considerations in reaching a decision on import. However, Article 24 requires that these socio-economic considerations be consistent with a Party's other international obligations and be related to the impact of LMOs on the conservation and sustainable use of biological diversity.

Liability

The Opponents argue that the Biosafety Protocol should create an international liability regime for harms caused by LMOs. Moreover, the Opponents argue that the liability regime should be a strict liability regime backed by performance bonds and corporate/governmental guarantees to insure that those held liable do in fact pay for the harms caused. In addition, the Opponents argue for a broad definition of the covered harms that would include social, economic, cultural, religious, and ethical damages.

The Proponents argue that liability is an issue that should be left exclusively to the domestic laws of the various Parties to the Protocol. The Proponents argue that the creation of an international liability regime in the Biosafety Protocol is an unwarranted and unnecessary interference with the sovereignty of individual nations. Moreover, the Proponents argue that the liability regime proposed by the Opponents is excessively punitive.

The BSWG Biosafety Protocol purposefully does not present a resolution to the liability debate. Rather, the Biosafety Protocol in Article 25 provides that the COP of the Convention shall adopt a process to elaborate international rules and procedures for liability with the goal that this COP process should be completed within four years of its initiation.

Relationship to other international agreements

The Proponents argue that the Biosafety Protocol should not diminish or otherwise affect the obligations that the Parties to the Protocol have under other international treaties and international conventions. The Proponents argue that the Biosafety Protocol should recognize the existence, the jurisdictional competence, and the expertise of other international agreements and organizations. The Proponents argue that the Biosafety Protocol should be coordinated with and complementary to other international agreements.

The Opponents argue that the Biosafety Protocol should explicitly bind its signatory Parties to the international stance that the Biosafety Protocol has priority over other international agreements. Unless the Parties give the Biosafety Protocol priority, the Opponents argue that other international agreements, particularly trade agreements, will undermine the objectives and obligations of the Biosafety Protocol. The Opponents want the Biosafety Protocol to establish the international legal principle that environmental protections trump trade obligations.

The BSWG Biosafety Protocol provides a delicate balance on this issue. Article 31 reads as follows:

> *The provisions of this Protocol shall not affect the rights and obligations of any Party to this Protocol deriving from any existing international agreement to which it is also a Party, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.*

Trade with non-parties

The Opponents support an article in the Biosafety Protocol that would prohibit Parties to the Protocol from trading in LMOs with Non-Parties to the Protocol. The Opponents argue that by including such a trade ban in the Protocol, all nations would have an incentive to become signatories to the Protocol. Furthermore, the Opponents argue that without such a trade ban that a significant risk exists that nations will trade in LMOs in ways that are inconsistent with or contrary to the objectives and principles of the Protocol.

The Proponents oppose an article banning trade in LMOs between Parties and Non-Parties to the Protocol. The Proponents urge rejection of a trade ban asserting that the ban would be unrealistic as a matter of enforcement and counterproductive to obtaining widespread adoption of the Protocol by sovereign nations. Moreover, the Proponents argue that the COP Decision II/5[4] mandated that the Protocol minimize unnecessary impacts on biotechnology research and development and that this minimization requirement means that the Protocol cannot include a trade ban in LMOs with Non-Parties.

The BSWG Biosafety Protocol does not adopt a ban on trade in LMOs between Parties to the Protocol and Non-Parties. The Protocol in Article 21 deals with Non-Parties by stating that trade between Parties and Non-Parties should be "consistent with the objectives of this Protocol and shall be carried out on the basis of its principles." In addition Paragraph 2 of Article 21 states that Parties shall encourage non-Parties to adhere to this Protocol and to participate in information-sharing about LMOs as provided in the Protocol.[5]

Precaution

The Proponents argue that the Biosafety Protocol should build from a foundation of scientific standards of risk assessment and risk management. The Proponents argue that de minimis risks, hypothetical worries, subjective judgments, and technophobic fears would gain protection if the Biosafety Protocol adopted the precautionary principle as advocated by the Opponents. Scientific knowledge should be the fundamental stance of the Biosafety Protocol.

The Opponents argue that the fundamental principle that should guide the Biosafety Protocol is the precautionary principle. The Opponents argue that Parties should be allowed to refuse biotechnology or biotechnological products in a preventative, precautionary manner until biotechnology carries the burden of proof that the technology and its products are free from risks for the environment and human health. Risk aversion should be the fundamental stance of the Biosafety Protocol.

The BSWG Biosafety Protocol does not use the term "precautionary principle" in the adopted text. The Protocol does acknowledge the precautionary approach in the Preamble. Moreover, in the interrelationship between Articles 8 and 12, the Protocol implicitly allows the use of the precautionary approach in the decision-making process for advance informed agreement. However, under Articles 8 and 12, the Parties commit themselves to undertaking risk assessment and advance informed agreement in a scientifically sound manner.

The Protocol—the steps to a binding international document

The Ex-COP in Cartagena in February 1999 did not adopt the BSWG Biosafety Protocol as an official document of the Convention on Biological Diversity. The COP will continue discussions about the BSWG Biosafety Protocol sometime in the year 2000. Hence, at present there is no biosafety protocol as an international document. Even if the COP ultimately adopts a protocol, COP adoption does not make the protocol a binding international document.

COP's adoption of a biosafety protocol sets in motion the opening of the Protocol for signature at the United Nations headquarters. As presently provided in Article 36 of the BSWG Protocol, the Protocol enters into force ninety days after the fiftieth party to the CBD signs the Protocol. Moreover, once a nation signs the Protocol, nations must still return the Protocol to their competent authorities for domestic enactment as an international protocol binding on the signatory

nation.

In light of the procedures for the biosafety protocol to become a binding international document, several outcomes are possible. First, the COP may never adopt a Biosafety Protocol. Second, the COP-adopted Biosafety Protocol may never enter into force because it never gains the minimum of fifty signatory nations. Third, the entered-into-force Biosafety Protocol may be unenforceable because sovereign nations do not enact domestic law binding the sovereign nation to the Protocol. Fourth, the Biosafety Protocol may become a signed, adopted international document.

If the fourth possible outcome occurs, the BSWG Protocol presently has two articles related to enforcement. Article 32 binds each Party to monitor its compliance with the Protocol and to report on compliance in accordance with a reporting time frame to be determined by a meeting of the Parties to the Protocol. Article 33 commits the Parties to the Protocol, at their first meeting as Parties of the Protocol, to develop cooperative procedures and institutional mechanisms to promote compliance and to deal with non-compliance. Article 33 of the BSWG Protocol emphasizes cooperative compliance procedures.

Article 33 also specifically states that its compliance procedures are without prejudice to dispute settlement procedures of Article 27 of the Convention on Biological Diversity. CBD Article 27 seeks to settle disputes by, in order of priority:

- negotiation;
- mediation;
- mutually-agreed compulsory settlement either through arbitration or decision by the International Court of Justice; or lastly
- conciliation. [6]

Conclusion

Readers can discern that the substantive debates are intertwined. Articles are related in clusters to various substantive disputes. Determining what the Biosafety Protocol decided on a particular point requires careful textual analysis and comparison of several articles at once.

Readers can also discern that, in light of the negotiation process itself, the Biosafety Protocol necessarily consists of compromises and ambiguities designed to achieve consensus. In light of these compromises and ambiguities, disputes about the correct interpretation of specific articles of the Biosafety Protocol are inevitable.

Even if the Conference of the Parties to the Convention on Biological Diversity ultimately produces a Biosafety Protocol, the Biosafety Protocol itself will remain a contentious document for many years to come.

[*] The Special Committee on Agricultural Management Newsletter, ABA-SONREEL, printed an earlier version of this article in its April 1999 edition.

[1] Living modified organism (LMO) is the legal, defined term used in the Biosafety Protocol. For purposes of ordinary discourse, many people also refer to LMOs as genetically modified organisms (GMOs). Modern biotechnology is the source of LMOs/GMOs.

[2] The full text of the BSWG Biosafety Protocol, as adopted at BSWG-6 on February 21, 1999 in Cartagena, should eventually appear on the website of the Convention on Biological Diversity < http://www.biodiv.org/ >.

[3] For excellent summaries of the Biosafety Protocol negotiations, including the Cartagena negotiations, readers should consult the *Earth Negotiations Bulletin* published by the International Institute for Sustainable Development and located on the Internet at < http://www.iisd.ca/linkages/ >. Browsers may also download BSWG documents in HTML and PDF formats from the IISD website.

[4] Decision II/5 and Annex ¶ 5(d), UNEP/CBD/COP/2/19 (Nov. 1995).

[5] Underlying the dispute about trade with Non-Parties is that fact that the United States, the producer of the greatest amount of LMOs and their products, is not a signatory to the Convention on Biological Diversity. Opponents of biotechnology who favored a trade ban in LMOs with Non-Parties viewed a trade ban provision as a way either to isolate the United States in international biotechnology trade or to force the United States to accede to the Convention on Biological Diversity.

[6] Annex II to the Convention on Biological Diversity provides greater detail about mutually-agreed arbitration and conciliation as dispute-settlement mechanisms. The Convention on Biological Diversity is at < http://www.biodiv.org/convtext/cbd0028.htm >.

CAFO/Cont. from page 3

multiplied by 0.1, plus the number of horses multiplied by 2.0" (40 C.F.R. § 122, Appendix B).

A CAFO at which more than 1,000 animal units are confined needs an NPDES permit (40 C.F.R. §§ 122.21, 122.23). A producer who has two or more type of animal should use the multiplier numbers, supplied in the definition of an animal unit, to determine if the threshold of 1,000 animal units has been reached.

CAFOs shall provide the following information:

(i) The type and number of animals in open confinement and housed under roof.

(ii) The number of acres used for confinement feeding.

(iii) The design basis for the runoff diversion and control system, if one exists, including the number of acres of contributing drainage, the storage capacity, and the design safety factor (C.F.R. §§ 122.21(i)).

Further federal regulations provide that an AFO with more than 300 animal units may be a CAFO under certain conditions (C.F.R. § 122, Appendix B). AFOs with more than 300 animal units that discharge pollutants into navigable waters through a manmade ditch, flushing system or other similar man-made device are deemed to be CAFOs under federal law. An AFO consisting of more than 300 animal units with pollutants that are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility is deemed to be a CAFO under federal law.

About 2,000 AFOs have been issued NPDES permits, either by the federal government or by U.S. states with authority to issue the permits (Unified National Strategy for Animal Feeding Operations). It is estimated that nearly 10,000 CAFOs have more than 1,000 animal units and thus should be inspected and subject to an NPDES permit.

If an AFO with less than 1,000 animal units discharges wastes only in the event of a 25 year, 24-hour storm event, it would not constitute a CAFO required to have an NPDES permit (C.F.R. § 122, Appendix B). Animal waste lagoons for AFOs with under 1,000 animal units are designed to meet these storm criteria so that they can avoid needing to be permitted under federal law.

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