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Domestic Policy Options: International Trends in Liability and Redress

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Abstract: The current paper analysis liability regime under Article 27 of Biosafety protocol and compare it with emerging alternatives like Africa model law and safety in biotechnology and Swiss Gene Biotechnology Law apart from other initiatives from EU and few others countries.
The paper recommends that liability regime is require at both domestic and internation level within the exsiting environmental and redress treaties with specific focus on modern biotechnology. Several developing countries including India would have to make major legislative efforts to workout the nuances for such a regime.

Keywords: Liability; Cartagena Biosafety Protocol; Developing Countries, International Trade.

Background

Presently, there is no established international liability regime for Genetically Modified (GM) crops and hence there exists the major challenge of linking GMOs to liability and redress issues. The release of GMOs into the environment raises questions of liability and redress in both public and private law realms arising from the uncertainties. Traditionally, the discussion of legal responsibility, duty and obligation has focused on the potential environmental damage associated with GMO release.

The entry into force of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol) has signalled the start of a process that should lead to the development of international rules on liability and redress. The mandate for this is found in Article 27 of the Protocol which provides that:

> ...the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a

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> process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.[1]

The first Conference of the Parties serving as the Meeting of the Parties (COP/MOP) that took place in 2004 adopted a specific decision on liability, formally acknowledging that the elaboration of a liability and redress regime is 'crucial for the effective implementation of the Protocol'.[2] As a result, the first COP/MOP formally started the process leading to the adoption of a liability and redress regime by setting up an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress.

The development of a liability and redress regime under Article 27 of the Biosafety Protocol follows a series of other sectoral environmental liability regimes that have been adopted over the past two decades. This implies that the development of a legal regime concerning genetically modified organisms (GMOs) is not conceived in a vacuum but benefits from the experience accumulated with existing legal frameworks. In fact, a number of basic legal concepts have been previously discussed in other fora and the liability and redress regime under the Biosafety Protocol should be able to largely draw from the existing legal regimes.

Similarities notwithstanding, the development of a liability and redress regime for GMOs raises a number of questions that need to be addressed separately. This is linked to the fact that the introduction of GMOs into the environment raises novel issues which have not necessarily been examined in the context of previous negotiations over environmental liability regimes. Thus, one of the main operative principles of the Biosafety Protocol is the precautionary principle and this principle influences the whole legal regime to put in place something which needs to be reflected in the liability and redress regime. Further, what constitutes damage arising as a result of the introduction of GMOs into the environment cannot be limited to definitions usually adopted till now. Some of the novel elements that need to be incorporated include the question of socio-economic damage and patent liability.

At the domestic level, the development of a liability regime is

influenced by several factors. First, the existing legal regime exhibits the same limitations as the international law regime insofar as it does not include any biotechnology-specific liability regime. Second, the adoption of a liability and redress regime at the international level necessitates the adoption of a related liability and redress regime at the national level since the rules adopted under the Biosafety Protocol will not address all relevant domestic situations. Third, the existing compensation and liability regime is insufficient to deal with some of the specificities of genetically modified organisms.

Existing Liability Regimes

There is at present no international liability framework directly applicable to biotechnology. Nevertheless, the types of issues surfacing in the context of biotechnology are not completely new and states have previously developed a number of responses at the national and international levels to address the consequences of harm arising as a result of legal or illegal activities.

States have in recent times adopted a number of civil liability regimes which seek to harmonise rules concerning liability and redress. A number of treaties introducing specific liability regimes have been adopted in the case of hazardous activities such as hazardous waste disposal, nuclear energy and oil pollution damage.[3] Despite the variety of fora in which these treaties have been negotiated, they tend to provide broadly similar schemes. First, they usually adopt the principle of strict liability in recognition of the need to channel liability to the promoter or operator of the dangerous activity. This is accompanied by certain exclusions such as war or acts of god. In certain cases, the strict liability framework is supplemented by a fault-based liability for individuals that cause the damage through negligence or premeditation. Some treaties provide a possibility for the entity to which the liability is channelled to have recourse against other actors, while some deny this option to the operator such as in the case of nuclear energy. Liability is also nearly always limited in time even though this limit can extend to several decades. The amount that can be obtained is also nearly always finite. In some cases, such as in the case of nuclear energy treaties, the civil liability regime includes compulsory insurance for nuclear operators as well as a subsidiary liability of the state. In other cases such as the case of oil pollution, a scheme of strict liability can be strengthened

with the introduction of an additional fund financed by a levy on oil importers. With regard to the damages taken into account, damage to the environment has usually been estimated account through the consideration of damages to persons and property as well as economic interests. There has, however, been a move towards the inclusion of other elements, such as the costs of preventive measures and the costs of restoration of a degraded environment. However, even newer treaties do not usually take into account compensation for non-economic components of the environment where measures to restore the environment cannot be taken.

Besides existing international civil liability regimes, the Council of Europe has made a significant contribution by adopting a convention devoted to liability and environmental damage in general (Lugano Convention).[4] While the Lugano Convention is only a regional instrument, it has some noteworthy features that could be taken into account in the development of a liability regime for modern biotechnology. Its overall objective is to ensure adequate compensation for damage resulting from activities dangerous to the environment. Among its interesting features, the Lugano Convention recognises among dangerous activities the production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with GMOs 'which as a result of the properties of the organism, the genetic modification and the conditions under which the operation is exercised, pose a significant risk for man, the environment or property'.[5] The Lugano Convention is also noteworthy with regard to the definition of damage it proposes which includes not only impairment of the environment – limited to the costs of measures of reinstatement actually to be undertaken – but also the costs of preventive measures and any loss or damage caused by preventive measures.

Existing Biotechnology-related Liability Regimes

The liability and redress regime under the Biosafety Protocol is likely to borrow from existing international environmental liability regimes. Nevertheless, since there is little in existing international frameworks which is directly relevant in the case of modern biotechnology, further insights on the possible shape of an international and a domestic liability and redress regime can be gained by examining some of the existing biotechnology-specific liability regimes.

At present there exist some regional instruments which can provide appropriate pointers for the development of an international regime in the context of the Biosafety Protocol and some national laws that can be referred to in the context of the development of a regime at the national level. This section considers the Organisation of African Unity's Model Law on Safety in Biotechnology which contains a section on liability as well as Switzerland's Gene Technology Act liability regime which constitutes one of the most evolved regimes in this area so far.

The liability and redress regimes to be adopted under the Biosafety Protocol and in India are likely to be different from either the African Model Law or the Swiss Act. Nevertheless, both are relevant because they address issues that must also be considered and because the development of liability regimes at the national and international levels must be considered together.

The African Model Law on Safety in Biotechnology

African countries have been in favour of the development of a stringent liability and redress regime dating from the period of negotiations for the adoption of the Biosafety Protocol. As part of the process leading to the operationalisation of the Protocol, African states adopted in 2001 a Model Law on Safety in Biotechnology which includes an Article 14 specifically addressing issues of liability and redress.

The Model Law imposes strict liability for any harm caused by GMOs or GMO products that are imported, made, in contained use, released or placed on the market. Such harm must be fully compensated. Under Article 14, liability is attached to the person responsible for the activity which results in the damage as well as to the provider, supplier or developer of the GMO. In situations where there is more than one person responsible for the damage, injury or loss, liability is joint and several.

With regard to environmental damage, Article 14 largely follows the model proposed by the Lugano Convention and provides that compensation must include the costs of reinstatement of the environment, rehabilitation or clean-up measures which are actually being incurred and, where applicable, the costs of preventive measures.

One of the important contributions of the Model Law is with regard to socio-economic aspects. It specifically provides that liability extends to harm or damage caused directly or indirectly to the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community. Such harm includes the

following: disruption or damage to agricultural systems, reduction in yields and damage to the economy of an area or community.

The liability provisions are linked to a system of criminal sanctions in a range of situations outlined in Article 15. This includes cases where GMOs are imported, released or placed on the market without the written approval of the competent authority, where conditions attached to the grant of approval are violated, where false, misleading or deceptive information is provided in order to secure an approval, where GMOs are not labelled or identified or where identification is misleading or deceptive. The consequences applied under Article 15 include the usual sanction of imprisonment and fine as well as the prohibition of engaging in any activity related to GMOs for any natural or legal person that is convicted of infringement.

Overall, the African Model Law clearly reflects African states' negotiating positions during the Biosafety Protocol negotiations and their stated desire to introduce stringent liability and redress regimes as an integral part of the operationalisation of the Protocol.[6]

The Swiss Gene Technology Law

Switzerland is one of relatively few countries to have gone through a comprehensive legislative debate over genetic engineering and has adopted a biosafety legislation with a liability regime. The regime adopted offers a number of interesting lessons for the development of national and international liability regimes. This is due to the fact that while Switzerland has often adopted progressive environmental policies over the past few decades, its policies in the field of biotechnology are also strongly influenced by the important biotechnology industry lobby. Consequently, given the prevailing culture of consensus, the resulting legislation is a compromise which is generally acceptable to all actors, including the biotechnology industry and NGOs opposed to modern biotechnology.

The Gene Technology Law is a general biosafety law that has as its main aim the protection of humans, animals and the environment from abuses of gene technology and to serve the welfare of humans, animals and the environment in the application of gene technology.[7] Particularly important is that the law is based on the precautionary and the polluter-pays principles.

The liability regime adopted as part of the law is a central component of the overall biosafety regime adopted. This is related to

the fact that the legislation is in part the result of a compromise whereby Switzerland would not enforce a moratorium on GMOs but would provide a legal framework providing strict conditions for the release of GMOs and a strong liability regime.

The central characteristic of the liability regime is the adoption of a strict liability framework where the injured party is a consumer or farmer. Thus, the Law provides that

> ...the person subject to authorisation is solely liable for damage that occurs to agricultural or forestry enterprises or to consumers of products of these enterprises through the permitted marketing of genetically modified organisms, that is a result of the modification of the genetic material.[8]

In other cases, there is a product liability regime whereby the person who has been given the authorisation to introduce GMOs into the environment is liable for defects which, according to the state of knowledge and technology at the time when the organism was marketed, could not have been recognised. One exception is that the person subject to authorisation can take action against persons who have handled organisms inappropriately or have otherwise contributed to the occurrence or exacerbation of the damage.

The legislation also specifically provides a duty to compensate environmental harm. It provides that the person who is liable for the use of the GMOs must also reimburse the costs of necessary and appropriate measures that are taken to repair destroyed or damaged components of the environment, or to replace them with components of equal value.

Another noteworthy feature concerns the time limit for bringing up claims against the person subject to authorisation. It recognises that it is currently impossible to determine with precision the point at which damages will occur. As a result, the law provides that the right to claim damages expires thirty years after the event causing the damage or thirty years after the date on which the GMO was marketed.

The law also addresses the question of damages to areas which are not the object of real property rights, such as common lands. It provides that where the person liable to restore or repair the environment does not take appropriate measures, the relevant community is statutorily given the right to seek reparation. This constitutes one question, which must be addressed at the international level concerning areas that do

not fall under national sovereignty. The direct or indirect introduction of GMOs in the high seas is, for instance, an issue which needs to be addressed on the basis of the precautionary principle even if existing GMOs are not deemed to constitute significant threats to the high seas at present.

With regard to procedural aspects, the law specifically addresses the question of burden of proof. While it emphatically puts the onus on the party claiming damages to prove causation, it also provides that the judge can be satisfied with an 'overwhelming probability' where the proof cannot be provided with certainty.

Besides the liability regime itself, the law provides that the central government can also provide that parties wishing to commercialise GMOs may have to provide financial guarantees to cover their potential liability.

Other National Agreements

The Nigerian Guidelines impose strict liability for any harm, injury or loss caused directly or indirectly by GMOs and it is specified that the harm encompass personal injury, damage to property and financial loss. The German Act (amended in June 19, 2004) covers broad areas of private damage and liability. It includes damage to health and property and the recent amendment includes detailed heads of financial damage. Three scenarios were outlined for possible compensation: one, contamination leading to a crop being prevented from entering the market; two, contamination inducing a genetically modified labeling requirement and three, contamination destroying an *organic* distinction. Other nations like China and New Zealand have provided for private liability regimes through GMO application/registration regulations. The reach of these regimes is limited because the country's application or registration procedures need to be violated to hold a person liable.

However, Chinese regulations are distinct from others and include economic loss as one of the items for claiming compensation. The Chinese regulation is unique because it contains a damage threshold and provides redress only for those damages that cause *great economic loss*. Unfortunately the threshold quantifier of *great* is not defined (Chinese Agricultural Regulation Chapter 6 Principle 32(4), Chinese Genetic Regulation).

In the US, regulation of biotechnology products is primarily shared between three federal agencies: the Food and Drug Administration, the US Department of Agriculture and the Environmental Protection Agency. Relying on the existing laws, the agencies establish requirements pertaining to the production and use of such products, and allocate liability for the failure to comply with these requirements specified by the agencies. The US has not established any federal measures or agreements specifically tailored to address whether compensation would be available for environmental damage resulting from transboundary movements of GMOs. The damage is addressed under the existing federal legal regimes and/or the state legal system.

Specificity of Liability for Genetically Modified Organisms

The introduction of GMOs into the environment triggers a number of difficult legal questions. This is due to the fact that GMOs are substantially different from many other products insofar as they have the potential to actively interact with wild organisms once they are introduced into the environment. This explains in part the relatively strict conditions that a number of countries have put in place to regulate the introduction of GMOs into the environment so as to prevent the occurrence of harm. Nevertheless, given that the technology remains relatively recent and that its full impacts have not been ascertained, it is impossible to exclude that significant harm will not ensue following the release of GMOs into the environment. Given that human control over the technology largely ceases after the release into the environment, there is a need to provide legal mechanisms that assign liability for harm arising as a result of the release of GMOs into the environment. This has, for instance, been demonstrated in the case of the StarLink corn recall in the United States.[9]

In this context, liability and redress constitute one legal response to harm arising from legal or illegal activities. The primary function of liability regimes is usually to provide reparation to affected parties. This often takes the form of compensation. In the case of environmental harm, this may also include the restoration of the environment. Liability and redress regimes can also fulfil other functions. They can, for instance, have a preventive function to induce operators to adopt measures to minimise the risks of damage so as to reduce their exposure to financial liabilities. In this sense, liability regimes contribute to the

implementation of the polluter-pays principle by imposing the integration of environmental and social costs. Liability rules can also act as an incentive to promote implementation of the existing environmental rules. Liability regimes thus provide a mechanism which can be used not only for compensation of damage having already occurred but can also contribute to damage prevention.

Three main elements need to be taken into account in the context of the development of a liability and redress regime for GMOs. The first element is environmental damage which is central in the Biosafety Protocol given that it is an environmental law treaty. In this context, significant assistance can be derived from existing liability and redress regimes but a number of issues nevertheless need to be considered in the specific context of biotechnology.

Second, as recognised in Article 26 of the Protocol, socio-economic aspects also constitute an important concern of Member states and in fact some of the main impacts of the introduction of GMOs in agriculture may turn out to be the socio-economic aspects related to livelihood concerns. These impacts need to be addressed in the context of a comprehensive liability and redress regime which contributes to strengthening of the regulatory framework for biotechnology generally. Similarly, risks to human health which also fall within the scope of the Biosafety Protocol need to be taken into account since a number of GMOs end up directly or indirectly in the food chain.

Third, another element which needs to be examined by state parties is the question of patent liability, a novel element in the context of what is primarily conceived as an environment-related liability regime. Patent liability is relevant in the context of the debate for two broad reasons. First, while there is no recognised legal connection between the granting of a patent on a GMO and the biosafety procedures leading to its commercialisation, the link exists in practice and needs to be recognised. Second, while the liability of persons illegally using a patented invention has generally been separate from biosafety considerations, this is, for instance, not the case in the context of genetically modified seeds where there is a potential clash of liabilities between the liability of the entity commercialising the seed and the liability of the farmers found in possession of genetically modified seeds without having purchased it from a licensed dealer.

Towards Liability Regimes for Genetically Modified Organisms

Modern biotechnology is a technology that has the potential for undesirable impacts even if it is implemented according to the biosafety standards that a number of countries, including India, have adopted. The simple fact that some or all of these risks may be realised is sufficient to warrant the development of a liability and redress regime. This is true at the national level for all countries which do not have liability regimes which can cover the specificities of modern biotechnology. This is also true of international law which does not include a liability regime that could cover the kinds of risks arising in the context of the release of GMOs into the environment.

Liability and Redress: An Integral Part of the Biosafety Regulatory Framework

The development of liability rules is a necessary complement to the development of biosafety frameworks. This is already implied in Article 27 of the Protocol which acknowledges that the task was left unfinished during the negotiations for the Protocol. The special characteristics of modern biotechnology reinforce the need for a separate statutory liability scheme. Relying on existing mechanisms such as torts in common law countries or existing principles of international law is an inadequate legal strategy because it creates significant uncertainty of outcomes in view of biotechnology's specificities. This will therefore neither allow the orderly development of the biotechnology industry nor provide an adequate level of protection to the environment and human health.

The Biosafety Protocol which provides the main regulatory framework for modern biotechnology seeks to balance the recognition of the potentially dangerous nature of GMOs, by providing the possibility to base decisions on the precautionary principle, and the promotion of transboundary movements of GMOs. This approach requires the adoption of a liability regime to complement a system which does not ban the transboundary movement of GMOs but recognises the potential for harm. This liability regime should be related to the primary instrument and reflect the main objective of the Biosafety Protocol which is to ensure an adequate level of protection concerning the transfer, handling and use of GMOs. This provides a way to ensure

that the precautionary principle is implemented throughout the regulatory regime put in place, from the risk assessment to the liability regime and the sanctions imposed.

At this juncture, it is not possible to do more than outline a few elements that would be required to ensure the adoption of a liability regime that contributes to realising the operative principles of the Biosafety Protocol and of the existing biosafety regulatory instruments at the domestic level. First, the liability and redress regime adopted needs to have clearly defined aims related to underlying instruments. These include the need to foster environmental conservation together with the need to protect human health. More specifically, liability rules need to contribute to conserving biodiversity, soil fertility and the integrity of living organisms.

Second, liability rules need to have socio-economic objectives, including the realisation of the right to food and generally of fostering access to food as a basic need. As recognised by the African Model Law, the introduction of GMOs can have disruptive impacts on the local economy of a community which may have direct repercussions on food security where agriculture is mainly a livelihood activity.[10] Beyond the issue of basic needs, liability rules should also contribute to ensuring consumer choice between organic – and generally non-GM products – and GM products. In environmental protection terms, the development of liability rules has direct connections with the issue of co-existence of GM and non-GM crops. Without taking measures to ensure the complete separation of GM and non-GM crops, consumer choice will simply be denied in practice. Consumer choice is in fact an issue which has been given increasing recognition. Thus, in the context of the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (Århus Convention), the Convention's core issues have been further debated concerning GMOs following its entry into force.[11] This resulted in the adoption of a set of Guidelines on GMOs by the first Meeting of the Parties to the Århus Convention. These Guidelines provide relatively general, yet GMO specific, guidance to states concerning public participation in decision-making regarding certain GMO-related activities, access to information, its collection and dissemination as well as access to justice.[12] These Guidelines constitute an important first step in strengthening the tools available to consumers, farmers and citizens to ensure transparency in GMO-related decisions.

A number of issues also arise with regard to the choice of elements from existing civil liability regimes. Concerning the level of protection necessary in the context of modern biotechnology, the central role of the precautionary principle in the regulation of biotechnology necessitates the adoption of a strict liability approach. This is linked both to current uncertainties concerning the magnitude of possible damages and the extent to which they may occur over a long period of time. This is, for instance, the position adopted by Brazil and Switzerland.[13]

With regard to damages, the liability and redress regime needs to build upon existing principles in the field of civil liability and take into account the specificities of modern biotechnology. This implies providing a definition of damages which includes damages to the environment, to human health, to property and to economic interests. Further, the definition of damages needs to determine whether plaintiffs must wait for actual damage to become visible or whether an evidence of gene introgression is sufficient. Another difficulty which needs to be addressed concerns the different levels of risk involved with damages in different regions. Because of the nature of GMOs, the introduction of a genetically modified variety in an area which is a centre for diversity for the crop in question is of much higher significance in terms of biodiversity conservation than its introduction in another region. The liability and redress regime, therefore, needs to include special rules concerning the contamination of centres of origin given their importance in meeting today's and tomorrow's food needs for the whole of humankind. This may imply adopting an even stricter regime for zones that are either known to be ecologically sensitive or known to be of great importance for biodiversity conservation.

Another issue which needs to be determined in the liability regime is an identification of the natural/legal person responsible for the damages that may occur. Given the ability for GMOs to actively interact with wild organisms once introduced into the environment, the liability regime needs to address this issue in clear terms. The liability regime needs to ensure that a lack of specificity in liability rules does not indirectly lead to final users such as farmers being held responsible. This is an inappropriate solution given that farmers are generally unable to distinguish GM crops from non-GM crops. As a result, the solution adopted in the Swiss Law which targets the person/entity receiving the authorisation from the state to introduce a specific GMO into the

environment provides an appropriate starting point. This has the advantage of making the identification of the person/entity liable relatively easier since, in an increasing number of cases, commercialised GMOs are protected by patent rights. Further, the absence of a rule focusing the liability on the patent-holder may render GMOs unattractive to farmers who might see themselves as liable to being sued by their neighbours for contamination of their fields.[14]

Patent Liability and Environmental Liability

Patent liability does not directly fall within the scope of Article 27 of the Biosafety Protocol, largely because the Protocol does not deal with intellectual property rights issues. Similarly, patent laws and treaties do not address biosafety concerns because the patent regime is in general conceived as fulfilling a different function. Nevertheless, there are increasing links between the two fields which need to be taken into account at different points in the regulatory framework. In terms of liability, the central issue is that there are different 'liabilities' for different actors that may be triggered in the context of a single event. These liabilities may be complementary or may be opposed. This is why a comprehensive liability regime for modern biotechnology needs to consider all dimensions of the issue.

The question of the respective liabilities of the company commercialising GMOs for environmental contamination and the liability of farmers who are found in possession of GM seeds without having purchased them from a licensed dealer is best illustrated in a judgment of the Canadian Supreme Court in *Monsanto Canada Inc. v Schmeiser* which provides an appropriate basis for discussing these issues at the national and international levels.[15]

This judgment raises a number of questions which are not explored here from the point of view of patent law. Besides patent issues, the judgment raises broader questions since it fails to address other important issues related to the introduction of genetically modified seeds into the environment. Thus, it does not consider questions related to biosafety, or questions related to the environmental liability of the company commercialising the genetically modified seeds, or questions related to farmers' rights or privileges.

With regard to biosafety, an important dimension of the case not addressed so far by judges is the relationship between patent liability and environmental liability. While patent protection is one of the main

legal incentives for the development of modern biotechnology in the private sector, biosafety regulations are the main instrument through which environmental and health impacts of GMOs are examined. One of the main reasons why biosafety should be considered in such a case like this is that it brings up different but complementary aspects to the dispute. The patent dispute looked exclusively at the question of whether Mr Schmeiser had infringed a patent. A biosafety dispute would also have looked at the issue of whether Monsanto should be deemed responsible for introducing into the environment a genetically modified construct which has the potential to self-replicate. Seen from this broader perspective, the dispute between Mr Schmeiser and Monsanto becomes a question of the respective liability of Mr Schmeiser concerning the patent infringement versus Monsanto's liability for the contamination of his property. This raises problems which were not addressed by the court.

First, there is a need for clarity concerning the responsibility of different entities and individuals involved in the introduction of genetically modified seeds into the environment. As noted above, an appropriate solution is to provide that the entity which has been given the authorisation to introduce a GMO into the environment is solely liable for damage that is a result of the modification of genetic material. Should a different solution prevail, the legal framework should at least clearly demarcate the responsibility of the entity marketing the genetically modified organism and the responsibility of other users. In *Monsanto v Schmeiser* where the farmer is deemed to have infringed the patent even if his fields were in fact contaminated, this would seem to absolve the entity marketing the seeds from any liability and shift the burden to users. On the basis of the Schmeiser decision, the principle established would appear to be that the only legal relationship that farmers have with Monsanto is with regard to patent protection. In a situation where their fields are contaminated, they would only be able to sue their neighbours for the contamination.

Second, the issue of a balance of liabilities raises the question of the control that farmers have or can have over the land they own or use. Different farmers may take different decisions concerning the kind of agriculture they want to undertake and some decide to pursue organic agriculture. Since the definition of organic agriculture implies that there should be no genetically modified plants, contamination by genetically modified seeds would immediately disqualify organic farmers from

selling their crops as organic and would lead to a loss of earnings since organic products in general fetch a higher price than non-organic ones. Unless there is a clear decision to forego organic or conventional agriculture, contamination of crops should be compensated by the entity causing the contamination. The entity which benefits from the commercialisation of the genetically modified seed should be the one shouldering the costs related to the contamination of the environment.

Third, this also raises the issue of farmers' rights. The situation can be divided between the rights of farmers who purchase genetically modified seeds and other farmers. In the case of farmers who purchase, for instance, Roundup Ready Canola from Monsanto, they have to sign a technology-use agreement which contractually restricts the rights they have over the seeds they purchase. These agreements have, for instance, been challenged in some cases in the United States but the courts have found that even if they deprive farmers of some statutory rights this does not invalidate the contract which they voluntarily sign as part of the purchase agreement with the company.[16] While the situation of farmers who are bound by a technology-use agreement seems clear at least in North America, these contractual provisions should not, in principle, affect the rights of other farmers. Farmers who do not purchase these seeds should have the rights they customarily enjoy as part of the 'farmer privilege' enjoyed under the plant breeders' rights system. These farmers should theoretically have the right to save and use seeds that they have grown even if they have been pollinated by genetically modified pollen. *Monsanto v Schmeiser*, however, seems to indicate that unless a farmer had no inkling of the potential presence of genetically modified seeds, s/he would be liable. In practice, this means that the onus of the proof is on farmers. This also implies that if farmers grow non-genetically modified crops in an area where genetically modified crops are grown, there could be a presumption that they 'ought to know' of the possible presence of protected genetically modified seeds on their fields.

Overall, *Monsanto v Schmeiser* is an important decision. On the one hand, it acts as a clear warning to other farmers that they have to watch their fields for the presence of genetically modified seeds. It also indicates that patent protection seems to prevail today over the rights that landowners have and that issues concerning biosafety, co-existence and liability are of low importance. On the other hand, the finding

that the patent-holder company can in principle assert its rights on all transgenic seeds used in a commercial context whatever their origin may make the link between environmental contamination and the patent-holder easier to establish.

Policy Options

A liability regime seeks to promote the effectiveness of the underlying legal regime. The adoption of a liability and redress regime does not indicate a desire to foreclose the development of a new technology but rather to promote it while ensuring that all eventualities are taken care of. In the case of technologies whose harmful capacity has been established, preventive measures require the adoption of strong liability regimes. The same is true for modern biotechnology on the basis of the precautionary principle which provides the legal basis for addressing the uncertainties linked to this still relatively novel technology.

The development of a liability and redress regime for modern biotechnology can be linked in part to existing environmental liability and redress treaties developed over the past couple of decades since a number of basic issues are similar. Further work needs to be carried out in certain areas that have not been adequately covered earlier or that are specific to modern biotechnology. These include the question of socio-economic damage and the necessity to address the potential clash between the environmental, health and socio-economic liability of the entity introducing GMOs into the environment and the patent liability linked to the fact that most GMOs introduced on the market are protected by patents or other intellectual property rights.

A liability regime needs to be introduced at the domestic level as well as at the international level. Since it is in general not possible to 'recall' a genetically modified organism introduced into the environment, measures taken only at the national level or the international level will be insufficient to guarantee compliance with biosafety norms and principles. International law includes a number of liability regimes which can be used as a model for the development of a biotechnology-related liability regime. Domestic law is less developed in this area. Two options can be proposed to remedy this situation. Either a major legislative effort is undertaken to develop an India-specific liability regime or a regime based on existing laws such as Switzerland's gene technology act need to be introduced to ensure that existing regulatory gaps are filled.

Endnotes

1 Article 27, Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, 39 Int'l Leg. Mat. 1027 (2000) [hereafter Biosafety Protocol].

2 Preamble, Decision BS-I/8, Establishment of an Open-Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the Context of the Protocol, in *Report of the First Meeting of the Conference of the Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety*, UN Doc. UNEP/CBD/BS/COP-MOP/1/15 (2004).

3 *See for example*, Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 December 1999, UN doc. UNEP/CHW.5/29, Annex III (1999), Convention on Civil Liability for Nuclear Damage, Vienna, 21 May 1963 as amended by the Protocol of 12 September 1997 and International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, London, 27 November 1992.

4 Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, Lugano, 21 June 1993, 32 Int'l Leg. Mat. 1228 (1993).

5 Article 2(1) of the Lugano Convention, supra note 4.

6 Kameri-Mbote, P. (2004).

7 Article 1, Law relating to Non-human Gene Technology, 21 March 2003, Recueil systématique 814.91.

8 *Id*. at Article 30(2).

9 Bratspies, R. M. (2003).

10 See Article 14(5), African Model Law on Safety in Biotechnology (2001).

11 Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Århus, 25 June 1998, 38 Int'l Leg. Mat. 517 (1999).

12 Guidelines on Access to Information, Public Participation and Access to Justice with Respect to Genetically Modified Organisms, UN Doc. MP.PP/2003/3-KIEV.CONF/2003/INF/7 (2003).

13 *See*, Brazil: Article 20, Law No. 11.105 of 24 March 2005.

14 *Cf*. Section 36(a), Germany: Gesetz zum Neuordnung des Gentechnikrechts, 2004. See also Canadian Institute for Environmental Law and Policy, GMO Statutory Liability Regimes: An International Review (Toronto: CIELAP, 2004).

15 *Monsanto Canada Inc. v Schmeiser*, Supreme Court of Canada, Judgment of 21 May 2004, 2004 SCC 34.

16 *Monsanto v McFarling*, United States Court of Appeals – Federal Circuit, 23 August 2002, 302 F.3d 1291.

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