Liabilities and economics of transgenic crops

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Two growing patterns threaten current crop production practices in intensive agriculture: the cross-pollination of genetically modified (GM) crop varieties with conventional varieties, and the germination of volunteer GM seeds (seeds dropped, blown, or inadvertently planted). Cross-pollination of GM crops with crop varieties destined for non-GM, GM-free, or "organic" niche markets is of great concern to the corresponding producers. The growth of volunteer GM seeds can be controlled chemically, but at an added cost for producers. Both of these problems must be rapidly addressed to ensure that the adoption rate of GM crops remains high and that the commercialization of future varieties is not jeopardized.

Looming challenges

The first generation of GM crop products is poised to begin its eighth year of production in Canada, the United States, and several other nations. The large majority of these food products are derived from three leading crops in North America: canola (rapeseed), corn, and soybeans. For the most part, GM products entered the marketplace with minimal new regulation. The atmosphere surrounding the anticipated introduction of next-generation GM crops with novel uses is likely to be vastly different[1]. Next-generation crops will face restructured regulatory systems, radically altered marketplaces, and new technology options[2].

Currently, the agrochemical industry faces two major challenges if it is to realize the potential of GM crops in the food, health, industrial, and environmental markets[1]. On the one hand, to pay for large development and commercialization costs, investors and firms that have funded GM-related technologies must capture a share of the return on that investment. On the other hand, corporations and regulators must also ensure that the new traits and varieties created do not impose risks or liabilities that offset (or swamp) the value generated. At the farm level, in particular, there is significant risk of profit reduction and for co-mingling of plants with new traits with other crops, creating potential new liabilities.

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In general, first-generation, "input-trait" GM crops (those traits with purely agronomic benefits) have been judged by regulators as substantially equivalent to existing varieties and have been allowed to be introduced into many of the existing commodity food systems without any segregation. Many of these GM crops have the potential to cross-pollinate with other compatible crops of the same species or with weedy relatives, or to become volunteers in other crops, creating potential new environmental or crop–weed management risks that may offset the crops' benefits or create quality problems and new liabilities in other crops or the food system. Second-generation crops, which involve output modifications (traits with health and nutritional benefits), will likely only be viable if their purity or quality can be assured, which is problematic given the difficulty of attaining gene containment. Third-generation crops with new industrial, nutraceutical, or pharmaceutical properties will likely require effective gene control systems or simply will not be permitted to be released.

The problem with current intellectual property (IP) protection is that it does not fully control the use of transgenes once they are expressed in seed. Most GM crops can be propagated in subsequent years with seed from previous years. Although regulations and private contracts attempt to manage that activity, many in the industry note that these contracts are far from being enforceable. Industry sources estimate that in 2000 in the Saskatchewan region of Canada alone, more than 300,000 acres of wheat were planted with unregistered or obsolete plant varieties. Exports by volume are composed of some varieties that have not been, or are no longer, approved for release in Canada. Regionally across western Canada, wheat exports contain 0.6–2.4% of these unregistered or obsolete varieties[3]. Furthermore, Monsanto (St. Louis, MO) officials have estimated that without technology use agreements, they would lose as much as 25% of the royalty payments for "Roundup Ready" crops without hybrids; even with technology use agreements, they estimate that 10% of the acreage planted with Roundup Ready crops are not covered by agreements and do not involve royalty payments.

Fundamentally, the allocation of the benefits and management of these risks will need to be brought about by a combination of institutional and biological controls. The public sector will continue to have a say on when, where, and how GM crops are introduced and propagated, as well as in adjudicating property rights. Meanwhile, private firms will likely have a major role in managing and enforcing contracts and systems to capture their benefits and to manage the risks and liabilities of these new crops. Although regulation and market pressure may prevent some gene transfers, many genes are likely to continue to undergo dispersal and survival beyond a season[4]. Regardless of how effective regulations or contracts are, some producers (either deliberately or inadvertently) will misappropriate these new technologies, diluting the benefits and creating potential new risks and liabilities. Furthermore, even if all "cheating" (producers' illegal use of technology protected in a patent) could be controlled, many plant species are promiscuous sexually, creating natural gene flow to related species.

The liability cost of genes from GM crops "escaping and going rogue," or co-mingling and adversely affecting quality of other plant-based products, is significant.

Four key liability issues can be identified and at least partially quantified: first, the potential for volunteer GM seed (seed inadvertently left in a field after harvest) to germinate the following year(s); second, the potential for pollen flow from GM crops to non-GM crops; third, the potential for co-mingling of GM and non-GM crops (this could jeopardize the value both of the crop in some markets and of downstream foods, products, or product lines if transgenes remain undetected before processing); and fourth, the potential for environmental risks associated with uncontrolled gene flow from GM varieties into related plants to impede export of GM varieties to nations that do or do not want to adopt the new technologies.

Gene flow and containment

Gene flow from GM plants creates liabilities in two ways. First, through conventional agricultural harvest practices, some seeds are left behind that germinate in the spring and, depending on the crop planted, may create a tolerance-level liability. The second is that pollen of a GM plant could fertilize a non-transgenic or "conventional" plant and the resulting hybrid seed might possess the trait for that transgene.

There is no harvesting system in place in the world that is capable of containing all the seeds produced on a plot of land. Many factors can combine to result in a large number of seeds ($>10^3$/acre) remaining in fields. These seed germinate during planting in the following season, and, in the case of GM strains, the resulting volunteer plants must be controlled. In canola, for example, spraying with 2,4-dichlorophenoxyacetic acid (2,4-D) controls this problem. This chemical application means an additional cost to the producer of 1.50–2.00 Canadian dollars (C$) per acre, however, and is not an acceptable option for organic producers. The introduction of herbicide-tolerant wheat (wheat that would survive being sprayed with a specific chemical that would normally kill its herbicide-sensitive ancestor) is expected to make controlling volunteers even more difficult, as 2,4-D does not control volunteer wheat, and thus producers will have to use a more expensive chemical to control herbicide-tolerant wheat volunteers. Officials at Monsanto have suggested that the most cost-effective method to control volunteer GM wheat will be to tank-mix and apply the herbicides Roundup and Assure at an estimated cost of C$6.19 per acre. This method of controlling volunteer GM wheat is more than triple the cost of volunteer GM canola control. Officials with Aventis (Research Triangle Park, NC) suggest that all corn chemicals, with the exception of Liberty, can be used to control volunteer StarLink GM corn. The application rates of these chemicals differ and therefore the costs vary.

A recent study prepared for the Canola Council of Canada (Winnipeg, MB) surveyed 650 western Canadian canola growers on numerous issues, one of which was management of volunteer canola[5]. Half of the producers surveyed grew transgenic herbicide-tolerant canola and half grew non-GM canola. Of the producers planting transgenic herbicide-tolerant canola in 2000, 61% said that the difficulty of managing volunteer transgenic herbicide-tolerant canola was about the same as that of volunteer conventional canola. Interestingly, 16% said that managing volunteer transgenic herbicide-tolerant canola was easier than managing conventional canola varieties. The remaining 23% said that it was more difficult to manage volunteer transgenic herbicide-tolerant canola.

There is already significant evidence that some weeds are developing resistance to one or more of the herbicides involved in the control of weeds in canola-growing areas.

Cross-pollination is an issue of great importance to commercial agriculture, yet for some crops only minimal literature is available on this subject. For example, the most recent research conducted on outcrossing rates with wheat was carried out in Saskatchewan in the 1930s[6]. This has resulted in a research gap of over 60 years, and studies presently underway[7,8] are challenging the standards currently in place to prevent wheat cross-pollination. Following the publication of Losey's[9] controversial study in *Nature*, which claimed that GM corn pollen was toxic to monarch butterflies, numerous other studies[10–15] were initiated, many of which concluded that 90% of corn pollen is deposited within five meters of the edge of cornfields. Canola pollen, however, is dispersed over a more varying range[16], and in one instance has been traced to a distance of 25 km (B. Kennedy, personal communication). For additional information on gene flow in other GM crop varieties, see Eastham and Sweet's[17] recent European study on gene flow through pollen transfer.

It is important to emphasize that the range and timing of pollen dispersal is specific for crop type. For example, canola is frequently an open-pollinating crop that is pollinated by wind or vector insects (such as bees). Herbicide-tolerant varieties can cross-pollinate with each other, with non-transgenic or herbicide-sensitive varieties (such as Westar), and with weedy relatives (such as various mustard plants)[18–20]. This has resulted in cross-pollinated hybrids that are resistant to more than one chemical. Other permutations of crossbreeding of GM and non-GM crops under winter survival rates can be seen in modified sugar beets[4]. In 1999, the first triple-resistant canola was discovered in Alberta[21]. On testing, these plants were found to be resistant to the herbicides Roundup, Liberty, and Pursuit by trait tests and genetic analysis for the recombinant genes. Although many in the canola industry had predicted that this would occur eventually, this triple-resistant hybrid was created by variety cross-pollination in just two years. Though resistant to herbicides, the hybrid variety is still susceptible to 2,4-D and can be controlled. The concern among many producers is that other crops, such as wheat, may already have developed resistance to some herbicides, making it more difficult to control cross-pollinated weeds or volunteers, so that efforts to do this may be extremely expensive or all but impossible (see "Answers blowing in the wind").

Because canola, particularly the *Brassica rapa* variety, is an open-pollinating crop, there is considerable concern about canola genes escaping into related wild species. Technically, *Brassica napus* (also canola) can self-pollinate, but frequently up to as much as 50% of its pollen is dispersed. Mayer and Furtan[22] estimate that any infestation of herbicide-resistant wild mustard above four plants per square meter would reduce the benefits of transgenic herbicide-tolerant canola to below zero. There is already significant evidence that some weeds are developing resistance to one or more of the herbicides involved in the control of weeds in canola-growing areas.

Recent research in France has examined the potential for genes from canola to flow into wild mustard, hoary mustard, and wild radish[23]. This study found the average rates of out-crossing to be 0.18% for wild mustard, 1.9% for hoary mustard, and 23.8% for wild radish. Collaborative research between groups in Canada and France[24] has also shown that cross-pollination between canola and wild mustard is virtually nonexistent. The study examined 2.9 million wild mustard seeds and concluded that “no hybrid was found …. [A]ctual cross-fertilization appeared very low, below one per million”[24]. A study on potential hybridization between canola and hoary mustard[25] found that although it was technically possible, the hoary mustard seed had to be imported from France in order for the study to be carried out in Canada, as hoary mustard cannot survive the winter season on the Canadian prairies. Although wild radish is a weed in the Maritimes region of Canada (with only one sighting in Alberta), given the limited canola production there, the potential for gene escape into wild radish was judged to be remote at best.

The inability to manage gene flow has had disastrous consequences in at least two instances in Europe. In May 1999, the Swiss Department of Agriculture (Bern, Switzerland) and the district president of Baden–Wurttemberg (Tubingen, Germany) announced that Pioneer Hi-Bred’s (Des Moines, IA) non-GM corn seed varieties, Ulla and Benicia, had been found, on the basis of PCR tests, to be “contaminated” with foreign genes[26]. As a result, many cornfields were burnt or destroyed and Swiss seed importer Eric Schweizer Samen AG (Winterthur, Switzerland) had to offer payments of 700 Swiss Francs per hectare to compensate affected farmers.

Later, in the spring of 2000, it was announced that the European Union (EU) had found a breeder’s lot of canola seed imported by Advanta (Winnipeg, MB) that contained 0.4% unapproved GM traits. Advanta quickly determined that the unexpected presence of GM canola was caused by gene flow from GM foundation seeds that had been planted in a neighboring field. Canadian seed growers had followed isolation rules, but the genes still moved into the conventional foundation seed. Although the total acreage of the seed planted in most countries was insignificant (Sweden and Germany had 300 hectares and France had 600 hectares), the outrage expressed by environmental groups, the media, and some government officials surprised many in the Canadian canola industry. Although many termed the EU response an “over-reaction” and felt that the Europeans were reacting “hysterically,” this incident highlights the need for both technological and regulatory solutions to prevent recurrence of similar incidents. The European countries faced a cost in dealing with this problem: France ordered all 600 hectares to be plowed down and Sweden allowed the canola to be harvested but prohibited it from entering the domestic or European market.

Containment regulations can also make adoption of new crops prohibitive. Many producers only adopt new crop varieties after watching a neighbor’s success. A common practice for producers in western Canada is to seed 80 acres of a new variety as a test before fully adopting it. This field size represents roughly 10% of the average farm’s 870 total cultivated acres[27]. When Monsanto and AgrEvo (now Aventis) introduced their GM herbicide-tolerant canola varieties, they did so with 80-acre production contracts, as they believed this was the most economical method for producers to evaluate the new technology. The increased use of buffer zones at current or, in future, expanded dimensions to control cross-pollination could drastically reduce the adoption rate of new-technology crops. If the buffer zone of 660 feet for Aventis’ Starlink corn is used as a base, this entirely removes the option of 80-acre production contracts, as the buffer zone would consume the entire 80 acres. Moving to 160-acre production contracts is still very restrictive, as 76% of the land would be consumed in the buffer zone. Producers would be required to plant 40 acres in the center of a quarter section, a sub-optimal evaluation size. The remaining 120 acres in a quarter section would yield a sub-optimal return. Based on this, producers may not want to devote nearly 20% of total cultivated acres to testing new varieties.

Labeling and discrimination

Given these uncertainties, it seems inevitable that volunteer plants and cross-pollinated varieties will be co-mingled in the commodity food system. Consumer acceptance of GM plant materials in commercial products is continually changing. Regardless of the market, surveys continue to show substantial and rising consumer preferences for organic and non-GM crops or plant products. Consumers want to know what they are eating and they want to discriminate (despite the lack of a scientific basis for such discrimination) between organic, GM-free, and GM foods and ingredients. In response, some regulatory authorities have adopted process-based (rather than product-based) labeling rules to enforce segregation of GM and GM-free produce on the market[28]. As several recent analyses of organic and non-GM products[29,30] have revealed the presence of GM material, control of GM cross-pollination and volunteer GM seed will be essential to foster consumer trust in products labeled non-GM and organic.

Co-mingling of GM and non-GM seeds has already imposed significant costs on the food industry. Perhaps the best-known case relates to Aventis’s StarLink corn. This variety was approved for use in the United States as an animal feed and was required to be produced in segregated areas, surrounded by a buffer crop, which also was supposed to be marketed as feed. To make a long story short, the GM trait in the feed corn was found to have entered the human food chain, contaminating an estimated 10% of all foods containing corn meal. The costs of containing and removing the StarLink variety have been huge. Aventis has budgeted more than $1 billion to compensate producers and pay for the logistics of withdrawing StarLink, and many food manufacturers, such as Taco Bell (Irvine, CA), have had to recall whole product lines that have been contaminated.

Although the StarLink contamination was an extreme case, it does not seem to have destroyed public confidence in the processed corn products. There are, however, examples where contaminations have jeopardized entire product lines. The introduction of transgenic herbicide-tolerant canola in western Canada destroyed the growing, albeit limited, market for organic canola. Because of the likelihood of outcrossing and pollen flow, buyers have shown increased reluctance to buy organically produced western Canadian canola because it might contain transgenes, which would violate the voluntary organic growers association standards in Canada. There is little authoritative data on the volumes or prices of western Canadian organic canola, but some ballpark estimates are possible using industry sources (D. Grier, personal communication). A conservative estimate would put the size of the market at less than 2% of the total canola market, equal to about 20,000 tons of organic canola traded annually, at a 100% price premium to conventional oil. This lost market amounts to between C$100,000 and C$200,000 annually, but the calculation probably underestimates the opportunity cost of a market that many thought had significant potential for growth over this period.

In a related case, in 1999 the EU detected the presence of a protein in a shipment of honey from Canada that originated from pollen with an unapproved GM traits and rejected the shipment. After honey is filtered, it contains 0.1% pollen, which falls well under the EU ban on GM products that contain more than 1% GM content, but in this case the traits found were not yet approved for consumption in the EU. Honey production in western Canada relies in part on honeybees collecting nectar from canola. As a result, honey shipments to the EU dropped $4.8 million between 1998 and 2000 (or by 55%), to the lowest level in more than ten years. Meanwhile, total ship-

Answers that blow in the wind

Very scant information is available concerning dispersion of pollen in the field. Some attempts have been made to model the process: for example, Giddings[38] has used Gaussian plume modeling, which considers such factors as the distance pollen can travel and the wind direction to assess pollen dispersal over distances up to 1,000 m. She has demonstrated how pollen dispersion occurs in ryegrass and noted that pollen can disperse and accumulate in non-downwind directions. In certain crops, pollen dispersal mediated by insects and other vectors is also important in determining gene and/or pollen movement.

Table 1. Pollen dispersal from three selected GM crops

Property	Canola	Wheat	Corn
Potential to outcross	Yes	Yes (limited)	Yes (limited)
Detected distance of pollen drift	2.5–25,000 m[a]	48–400 m[b]	50 m[c]
Chemical control of volunteers	Yes (C$1.50–2.00/acre)	Yes (C$6.19/acre)	Yes (varying rates)
Required isolation distance between plots for seed	100 m (like varieties), 800 m (other canola crops)	3 m (same crop kind), 10 m (other crops)	15–200 m (depending on plot size)

[a] Controversy exists about the distance canola pollen can travel. Canola pollen has been detected at distances as great as 25,000 m (B. Kennedy, personal communication).
[b] Published research cites maximum detected wheat pollen travel at 48 m[39]. As cited by Kahn *et al.*[39], wheat pollen has been detected at distances as great as 400 m
[c] Research on corn pollen[40] shows that 99% of corn pollen was measured at 50 m and 100% at 100 m.
[d] All isolation distances have been established by the Canadian Seed Growers Association[41]. The 3–10 m range for wheat depends on the pedigree level of the seed.

ments to all markets rose by 5% over the same period[31]. Recently, the EU banned Canadian honey because of the inability of Canadian honey producers to guarantee the absence of pollen from GM plants not yet approved in the EU[32]. This action by the EU has driven down domestic honey prices in Canada and cost the industry a market that has on average earned more than C$5.3 million over the past decade.

It is not clear yet who will bear the ultimate liability for cross-contaminations or co-mingling. The StarLink incident spawned numerous lawsuits by producers, producer organizations, and various states (such as Missouri) against Aventis in an attempt to seek compensation for depressed corn prices that they claim resulted from lost foreign sales. Similarly, the pending counter-suit in Canada by Percy Schmeiser against Monsanto and the Saskatchewan Organic Directorate lawsuit[33] argue that because Monsanto owns the IP, it also should be liable for any lost sales due to contamination.

IP and export issues

Finally, many countries have ineffective IP protection mechanisms, reducing their attractiveness as markets for new technologies and causing them to lag in the adoption of new traits and varieties. In the canola sector, few companies export new cultivars to major growing regions in China or India because of their lack of effective IP protections. As a result, about half of canola producers worldwide are unable to access the latest technologies, which is one of the contributing factors to lower yields in those areas. For instance, despite significant subsidies for irrigation and fertilizer, India and China post average canola crop yields almost 40% and 3% lower than Canada's, respectively.

Finding a more effective IP protection mechanism that is not dependent on institutions that in many of these countries are very weak might improve the diffusion of new cultivars and technologies. If developing-world yields were to rise even 5% as a result of the introduction of new varieties, total canola production there would rise by about one million tons, worth approximately $225 million to those producers and their markets. In brief, plants and people cannot be trusted to do what markets require. As a result, genes move, creating co-mingled traits in the food system and liabilities in the transfer of technologies between markets.

Control of liabilities

Institutional control, biological control, or a combination of both is required to manage the risks of GM crops. The public sector evaluates new GM crops for safety considerations, examining the new products against known products to determine whether they bring any new risks related to human consumption, the environment, and livestock (if used as feed). If a new GM variety is determined to be substantially equivalent, it will usually be approved for release. Most regulators also have some ability to examine risks once products enter the market and can intervene if an unexpected risk is detected. Although some of these products might be released only conditionally (for example, for production in a specified area or under conditions of isolation or segregation from food crops), most will be released without condition. In both cases, the private sector is generally responsible for managing the risks of new GM products once they enter the market. They use a combination of contracts, testing, and auditing to ensure compliance.

Although these instruments are very important, they cannot keep all the risks in check—in the field, genes are likely to be transferred and/or transported. Regardless of how effective regulations or contracts are, some actors will either deliberately or inadvertently misuse new technologies, creating potential new risks and liabilities. More importantly, however, many plant species are promiscuous sexually, creating natural gene flows (transfers and transports). In short, new biological control mechanisms are needed to manage many of the risks and liabilities of GM crops[1,34] (see p. 581).

The use of sterile seeds is well established—ancient Egyptians and Greeks produced seedless grapes circa 3000 BC. However, the potential of "terminator" technology to produce sterile seeds is highly controversial. Developing-world development agencies, governments, and environmental non-governmental organizations (NGOs) all have expressed concern that terminator technology could threaten landrace varieties, increase corporate concentration, reduce biological diversity, and ultimately destabilize agroeconomies of less-developed countries[35]. In October 1999, mounting pressure from these and other opponents forced Robert Shapiro, then Monsanto's CEO, to announce: "We are making a public commitment not to commercialize sterile seed technologies, such as the one dubbed 'terminator'"[36].

As Monsanto's initial interest in sterility technology was prompted not by environmental concerns, but by the need to protect its intellectual property and prevent "brown bagging," convincing opponents that terminator technology is a potential solution to gene flow is likely to be an uphill struggle. It is interesting to note, however, that Monsanto's decision to halt development has not discouraged other companies from investigating sterile-seed technology: on May 8, 2001, for example, Syngenta received a patent for controlling plant fertility[37].

From a scientific perspective, such genetic use-restriction technologies (GURTs) as terminator need to be reassessed, as they clearly provide advantages. First, they can act as built-in safety mechanisms to prevent the escape or spread of potentially harmful traits (such as herbicide tolerance) from new GM crops. And second, they can reduce product liabilities assigned to the seed growers by preventing contamination through co-mingling with non-GM crops.

Conclusions

Irrespective of scientific rationale, current political and societal pressures are likely to lead to more stringent regulation of future GM varieties. In effect, regulators will be faced with the choice of either outright rejection or imposition of regulations for detailed production and market segregation. Outright rejection of new GM crops would be excessive given the level of risk and potential benefits. What's more, if more stringent risk-management measures are introduced, they could jeopardize future R&D investments in GM products. Capital is one of the most liquid commodities in today's marketplace and, by banning GM products, countries (and the global industry) risk losing not only investment capital, but R&D-intensive firms as well.

The introduction of the first wave of GM products went largely unnoticed by consumers and much of the food industry. This pattern cannot (and will not) be repeated for second- or third-generation products. As noted above, the costs of denying the risks are potentially very high, ranging from a net present value of C$1–2 million lost sales in the organic canola market to the $1 billion cost of the StarLink failure.

Similarly, control mechanisms are not cheap. Often, regulatory responses, whether national or international, can cost in the millions for technologies that are widely dispersed, with both high fixed and variable costs. One potential advantage of GURTs such as terminator is that although they are expensive to develop, the overall cost may be as low as $250,000 per new variety released[35]. As this would add only about 10% to the price of developing a new commercial variety (and many firms report at least a 10% loss on their return due to incomplete enforcement of intellectual property), this option may be substantially more effective than other approaches.

Many of the risks and potential liabilities of GM crops are only partially manageable by public and private institutions. Although institutional costs to manage risks are high, the cost of failure is even higher. Ultimately, an inability to manage the risks and control the liabilities may reduce net returns on investments so much that GM technology may become infeasible.

To realize the benefits of GM crops while minimizing risks, changed attitudes are required in both government and industry. On the institutional side, governments can and should improve the regulatory oversight of GM crops, aggressively pursuing the use of refugia, contract registration, regional regulation, and mandatory crop rotations and audits. The agbiotech industry must also take its responsibilities more seriously. The introduction of first-generation GM products was directed at getting producers to adopt the technology, and many of these producers do not seem to have had a strong appreciation of the importance of managing and containing the technology. This must be addressed by educating producers and increased benefit sharing by private firms.

Although the initial cost of introducing a control mechanism may be high, the long-term benefits of such a technology may be sufficient to justify commercialization.

GM crops are currently affecting producers and exporters of not only edible crops and oilseeds, but other products as well. Therefore some form of control mechanism is needed. To maintain the current situation will only result in higher costs for seed development companies and producers in the long run. With the socio-economic distortions created by subsidies on the decline, there will be some affects on trade and hence on producers[34]. Regulators and industry officials must examine the effects on the market of commercial release of a control mechanism for GM crops, compared with the results of leaving the situation as it is, with an expected rise in litigation costs. Although the initial cost of introducing a control mechanism may be high, the long-term benefits of such a technology may be sufficient to justify commercialization.

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