A CASE STUDY OF MANAGEMENT OF IPRS IN SOYBEAN BIOTECHNOLOGY: EVIDENCE FROM BRAZIL AND A SUCCESSFUL COEXISTENCE IN CANADA AND USA

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ABSTRACT

Intellectual property rights (IPRs) influence the use and application of crop biotechnology. It is often argued that without IPRs, the life-science industries would have no incentive to spend the resources necessary to develop new crops. The aim of this paper is to identify and assess issues of IPRs and their influence on soybean biotechnology research and development (R&D). This identification and assessment will be accomplished by performing a comparative analysis on Monsanto's Roundup Ready (RR®) soybean in Brazil (one of the major soybean producing nations of the world), Canada, and the United States. Drawing from data obtained through document review and in-depth informant interviews, the research discusses the challenges of protection and enforcement of IPRs. These challenges influence the uptake and R&D of soybeans in plant breeding and in farmers' fields. The research shows the role of key institutions, such as Brazilian Agricultural Research Corporation (EMBRAPA), and the impacts of changing technology due to patent expiration. Findings show the RR® first generation soybean is profoundly important, despite the marketing to encourage farmers to quickly switch-over to the RR® second-generation soybean. The research also indicates the availability of generic traits post-patent expiration, which are only confined to the public research institutions. This, however, can be influenced by the performance advantages with new traits and demand for enhanced seed biotechnology. Findings indicate that technology fees are a major issue for life science industries and farmers involved in the case study. This paper concludes with recommendations for further research, action on the management of IPRs, and how to reconcile IPRs with farmers' rights and other local interests in seed biotechnology.

Keywords: collaboration; generic trait; herbicide tolerant soybean; incentives; intellectual property rights; patent expiration; protection and enforcement; royalty system; soybean biotechnology; technology fee.

I. INTRODUCTION

Intellectual property (IP) plays an important role in the business strategy of the life sciences industry, and, more specifically, crop biotechnology. Intellectual property facilitates innovation and promotes a strong, dynamic economy. The legal, policy, and technical framework underlying IPRs changes frequently, and this is certainly true for crop biotechnology. The specific case study examined in this paper is the soybean breeding industry, which is a success story of advances in crop technology enabling countries such as Brazil, Canada, and the United States, to make soybeans a major global crop and commodity. From an IP perspective, soybeans provide a unique and important case study, as evidenced by this paper. This research also reinforces the importance of soybeans as a major crop biotechnology in the world today. On one hand, this case study brings together a variety of stakeholders in the development of crop biotechnology, including plant breeders and researchers, members of the life sciences industries, and farmers and their associations. On the other hand, it offers an important research opportunity regarding the challenges involved in balancing IPRs and the benefits of access to knowledge inside the RR® soybean.

This paper addresses the implications of current issues and changes in IP management and how to best understand them. The purpose is to identify and assess IPR issues and how they influence soybean biotechnology R&D by adopting an empirical and technical case study of the management of IPRs in soybean biotechnology in Brazil, Canada, and the United States. Through in-depth interviews with stakeholders, this paper sheds light on the challenges and opportunities—along with the benefits and risks—presented when the patent rights on RR® soybean expire. Patent expiration means potential competition with generic traits and related issues. There are several implications derived from the expiration of the patent, including farmers continuing to harvest RR® first generation soybean, but no longer having to pay technology fees, and no longer having to abide by contractual restrictions on saving and re-using the first-generation seeds. In addition, there are particular performance advantages with new traits, and the demand for enhanced seed biotechnology to take into consideration. This paper examines the specific case study of herbicide tolerant soybean biotechnology, soybean production, and the effects of the first-generation RR® soybean when put into the public domain. Important context is included in this case study, including the history and development of soybeans and its importance in global agriculture and trade. The findings of this research are presented in four major sections of this paper: 1) the role of key institutions such as EMBRAPA in Brazil in responding to the issues and changing technology associated with patent expiration, 2) the most compelling impacts of IPRs and patent expiration associated with the herbicide tolerant soybean, 3) the soybean technology and royalty system; and 4) complementary findings from Canada and the United States.

This paper conceptualizes and presents a framework for the three key dimensions of managing intellectual property: collaboration, incentives, and protection/enforcement. As this paper will argue, the complexity of protecting IPRs is a dynamic situation and it proves challenging for a variety of institutions, including the nation-state of Brazil, the private multinational company Monsanto, major national seed firms, individual farmers that engage in production, and companies that control the soybean market both within and outside of Brazil (e.g.

Argentina). Often, management of IP requires dealing with different legal jurisdictions. To ensure its return on investment, Monsanto protects its RR® soybeans with patents registered in Brazil (as well as in other countries such as the United States and Canada).[1] Monsanto licenses the RR® soybeans to seed companies in Brazil, which then act on behalf of Monsanto according to a signed contract.[2] They then establish an agreement with farmers to buy the seeds with Monsanto's technology, thereby requiring they pay Monsanto a fee called "rate of use of technology."[3] Similarly, Monsanto has agreements with other seed companies to incorporate RR® soybeans into their seeds through breeding.[4] Both the resistance gene (the transgene construct) that is inserted into a special variety and the variety of RR® soybean (with the transgene insert) were patented by Monsanto in the United States.[5] When soybean breeders crossed patented soybean varieties with existing Brazilian varieties, Monsanto commercialized the resulting varieties in Brazil.[6] However, the absence of enforcement mechanisms in Brazil encouraged farmers to save RR® soybean seeds for planting or resale.[7] This is also the case in Argentina, where there is not a strong control system or seed law, which allowed Argentine farmers to save the technology fee on soybean seeds.[8]

Notwithstanding, Monsanto is concerned that the second generation of genetically modified (GM) soybean, referred to as Intacta® Roundup Ready® 2 Pro—which has already been patented in Brazil and elsewhere—is likely to be sold on the black market and smuggled in Brazil if Monsanto licenses Intacta® RR® 2 Pro to local seed dealers.[9] Under license stipulation, Monsanto collects a

1. *See* Karine Peschard, *Monsanto wins $7.7b lawsuit in Brazil – but farmers' fight to stop its 'amoral' royalty system will continue*, THE CONVERSATION (Oct. 31, 2019, 8:54 AM) https://theconversation.com/monsanto-wins-7-7b-lawsuit-in-brazil-but-farmers-fight-to-stop-its-amoral-royalty-system-will-continue-125471 [https://perma.cc/8DQA-2B6V].

2. CONG. RSCH. SERV., GENETICALLY ENGINEERED SOYBEANS: ACCEPTANCE AND INTELLECTUAL PROPERTY RIGHTS ISSUES IN SOUTH AMERICA 2 (2003), https://www.everycrsreport.com/files/20031017_RS21558_3e8eb146548c2919e03b21e247aecff89ddcbc58.pdf [https://perma.cc/5SPJ-BFCH].

3. *See id.*; *see also* Marcelo Dias Varella, *Intellectual Property and Agriculture: The Case on Soybeans and Monsanto*, 18 J. TECH. L. & POL'Y 59, 76-77 (2013).

4. CONG. RSCH. SERV., *supra* note 2, at 2.

5. *E.g.*, U.S. Patent No. 7,141,722 (filed Aug. 18, 2004); U.S. Patent No. 9,944,945 (filed Nov. 12, 2014).

6. Varella, *supra* note 3, at 67.

7. *See* CONG. RSCH. SERV., *supra* note 2, at 4.

8. CONG. RSCH. SERV., *supra* note 2, at 3.

9. Hugh Bronstein, *Monsanto Signs Royalty Deals with Argentine Farmers*, REUTERS (June 7, 2011, 11:34 AM), http://www.reuters.com/article/argentina-monsanto-soy-idUSN0717504320110607 [https://perma.cc/427G-YZHY].

technology fee and then gives 12.5 percent of the total collected fee to the licensed firm.[10] The signed agreements between Monsanto and other licensed seed companies ensure that these companies do not insert other genes with different characteristics into varieties that contain Monsanto's technology.[11] Furthermore, these licensed seed companies cannot use the Monsanto gene for sale or set up new contracts with other firms for commercialization.[12] However, DNA-tracing technology and the investigation of agreement violations or unauthorized re-use of seed has been costly.[13]

The commercial status of RR® soybean in Brazil was disputed in the Brazilian courts in 2014. "An important aspect in the disputed case involved a group of growers from the State of Mato Grosso who requested to stop the fee collection on the GM soybean. Another important aspect in this Brazilian case was that the soybean seeds were not bought directly from Monsanto."[14] The GM soybean planted in Brazil was a cross between Monsanto RR® soybeans, which had been imported illegally from Argentina, with conventional Brazilian soybeans.[15] Monsanto was also unable to sell RR® soybeans in Brazil for some time because the Brazilian authorities temporarily banned GM crops.[16] "Regardless of the ban, the main production centers rapidly adopted GM soybeans. The Brazilian authorities could not avoid the RR® soybean variety due to the wide spread of this variety among farmers. Eventually, Brazilian authorities legalized planting the RR® soybean."[17] As a result, Monsanto sought IPRs on the soybean variety, which in turn lead to Brazil becoming the second largest soybean producer in the world.[18]

10. Nael Thaher, Leveraging Intellectual Property Management for Crop Biotechnology Innovation 101-02 (June 2017) (Ph.D. thesis, University of Guelph), https://atrium.lib.uoguelph.ca/xmlui/bitstream/handle/10214/11382/Thaher_Nael_201707_PhD.pdf?sequence=1&isAllowed=y [https://perma.cc/CQY7-TWHQ].

11. *Id.* at 102.

12. *Id.*

13. *See* W. Lesser, *Chapter 3: Intellectual Property Rights under the Convention on Biological Diversity*, *in* AGRICULTURE AND INTELLECTUAL PROPERTY RIGHTS: ECONOMIC, INSTITUTIONAL AND IMPLEMENTATION ISSUES IN BIOTECHNOLOGY 35, 44 (V. Santaniello et al. eds., 2000); *see also* CTR. FOR FOOD SAFETY, *MONSANTO VS. U.S. FARMERS* 23 (2005).

14. Thaher, *supra* note 10, at 102.

15. Varella, *supra* note 3, at 75.

16. Thaher, *supra* note 10, at 102.

17. *Id.*

18. Daniel E. Meyer & Christel Cederberg, *Pesticide Use and Glyphosate-Resistant Weeds – a Case Study of Brazilian Soybean Production*, SIK (2010), https://www.diva-portal.org/smash/get/diva2:943716/FULLTEXT01.pdf [https://perma.cc/7TKX-7LHX].

Nowadays, Monsanto's policy shifts in the Brazilian context and the expiration of patents, which could also pave the way for generic version of the seeds without going through the costly R&D process, are discussed. Potential competition with generic traits and related issues are expected to cause profound changes in the coming years.[19]

The next section proceeds with an overview of the methods involved in the present research, including data-gathering and analysis techniques. Section three then provides context for the case study of RR® soybean, which includes IP laws and the diffusion and commercialization of GM soybean in Brazil. This section is, in turn, divided into three subsections: (i) the history and development of soybean biotechnology; (ii) the herbicide tolerant soybean (RR® soybean); and (iii) soybean production and trade. This will be followed by findings from Brazil, which include EMBRAPA and private industry collaboration, implications from patent expiration on herbicide tolerant soybean, soybean technology, and the royalty system. This is then followed by complementary findings from Canada and the United States. Finally, a discussion and conclusion section summarizing the research findings and their implications.

II. METHODS

The research in this paper serves to identify and address IPRs issues, and their influence on soybean biotechnology research and development. It is based primarily on key informant interviews, and to some extent on reviews of pertinent literature. The paper contextualizes the study in the relevant and systemic literature and thereby adopts a case study approach. The creative interaction between a literature review, the procedure of data collection, and the contemplation of the researcher's own thoughts and desires, were provided by the implementation of a literature review before and during data collection.[20] This paper represents qualitative research with all data drawn from stakeholders' interviews throughout these countries. The findings from this paper highlight how intellectual property law was implicated in Brazilian soybean biotechnology and the subsequent rapid transfer of GM soybean technology in Brazil after 2001. The findings further illustrate the challenges and opportunities, along with benefits and risks, waiting when the patent rights on RR® soybeans expire.

19. Thaher, *supra* note 10, at 103.

20. *See generally* MICHAEL QUINN PATTON, QUALITATIVE RESEARCH AND EVALUATION METHODS (3d ed. 2001).

A. Data-Gathering and Analysis Techniques

This research was framed through a case study approach, and was based on logically linking the data to be collected and analyzed to the original research questions. The qualitative approach is important due to the exploratory nature of the research questions.[21] According to Yin, Eisenhardt, and Graebner, a case study is the preferred strategy when focusing on a current phenomenon in a real-life context, and is suitable for answering 'how' and 'why' questions.[22] The case study approach enables one to understand the dynamics present within a single setting.[23] The research study has a main phase of research activity that involves human participants for data collection purposes. Participants were contacted in regard to the qualitative research on soybean biotechnology and management of IP from Brazil, which complement the findings from within the Canadian and American context and interviews.

In-depth, key informant interviews were conducted with 17 individuals (*n*=17) involved in the soybean industry (R&D) and IPR-related issues in soybean biotechnology from Brazil at the research sites of EMBRAPA and Monsanto, as shown below in Figure 1. Participants were from the following different backgrounds and positions: global policies coordination, business development office, plant IP protection, regulatory director, head of technology transfer, research scientists, and plant breeders. In-depth key informant interviews were also conducted with 11 individuals (*n*=11) from Canada and the United States from the following organizations: Monsanto Canada, Agriculture and Agri-Food Canada, Canadian Food Inspection Agency, University of Ottawa, Canadian Seed Growers Association, Crop Life Canada, Ontario Agri-Food Technologies and University of Arkansas, United States.

21. DAVID SILVERMAN, INTERPRETING QUALITATIVE DATA 33 (5th ed., 2015).

22. Robert K. Yin, *Case Study Research: Design and Methods, in* 5 APPLIED SOCIAL RESEARCH METHODS SERIES 7 (3d ed., 2003).

23. Kathleen M. Eisenhardt, *Building Theories from Case Study Research*, 14 ACAD. MGMT. REV. 532, 534 (1989); Yin, *supra* note 22, at 15; *see also* Kathleen M. Eisenhardt & Melissa E. Graebner, *Theory Building from Cases: Opportunities and Challenges*, 50 ACAD. MGMT. REV. 25, 25 (2007).

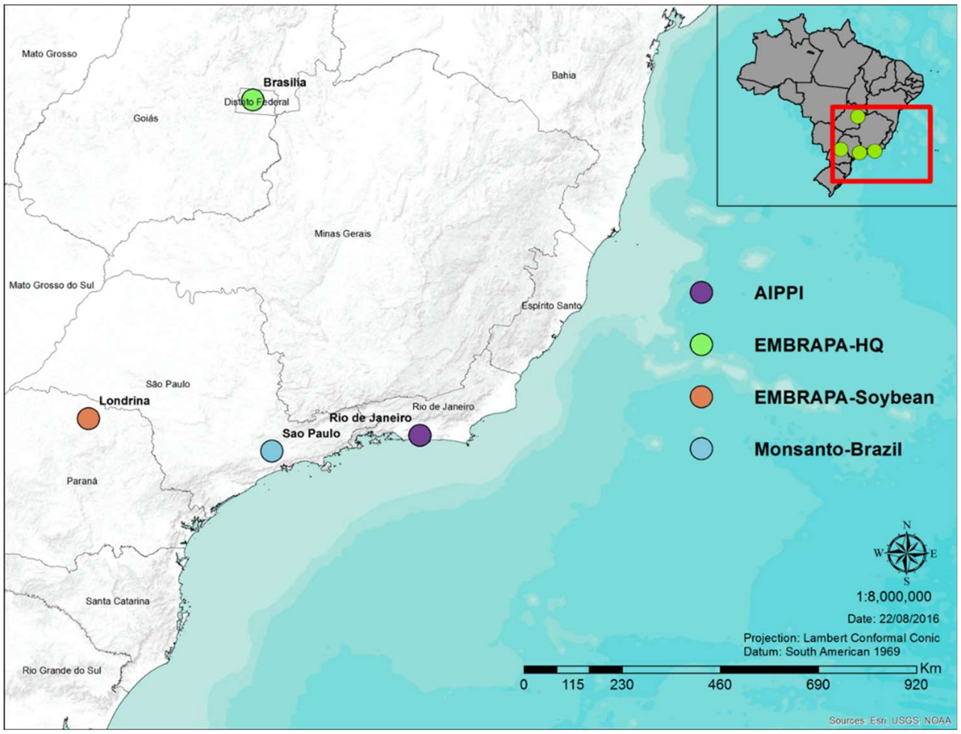

Figure 1. A map highlighting the research sites of EMBRAPA-HQ, EMBRAPA-Soybean, and Monsanto-Brazil.

The research questions were divided into two main groups. The first included general questions asked of every interviewee, and the other group consisted of specific questions related to the case study of soybeans. The content of the interviews was contextualized and shaped by relevant themes found in the relevant literature. The systemic literature review informed the data collection and analysis by providing sensitizing concepts that guided the development of research design and data collection.[24] These sensitizing concepts provided a deep perception into the interpretation of data and the development of interview protocol decisions related to participant selection. Description of the data provides background and context, while also helping gather important data.[25] It is worth mentioning that, in

24. *See* KATHY CHARMAZ, CONSTRUCTING GROUNDED THEORY 30-31 (Jai Seaman ed., 2d ed. 2014).

25. *See* Yan Zhang & Barbara M. Wildemuth, *Qualitative Analysis of Content*, *in* APPLICATIONS OF SOCIAL RESEARCH METHODS TO QUESTIONS IN INFORMATION AND LIBRARY SCIENCE 318, 323 (Barbara M. Wildemuth ed., 2d ed. 2017).

order to engage interviewees in natural and spontaneous conversation, and to encourage discussion of information relating to management of IPRs in crop biotechnology, all of the interviews followed a conversational structure to allow personal views and a variance of voices to emerge.[26] Equally important, this approach created the space for conversations to evolve around certain themes, and for the interviews to expand well beyond the initial questions.[27] The interview responses provided insight on issues for IP management and effective technology transfer in crop biotechnology.

All interviews were digitally audio-recorded and hand-written notes were taken with consent of the interviewees. The recording and notes were later transcribed by the researcher and checked to verify accuracy before analyzing for emergent themes. After each interview, a detailed description of reflected thoughts was recorded as a reflective journal, which was used to align with the original views of the interviewees. These hand-written notes permitted deeper reflection regarding the data and themes emerging from the interviews. All of the research activities were approved by the Research Ethics Board (REB) at the University of Guelph (REB Number 15AP007).

The interviews were analyzed descriptively through rigorous qualitative analysis by the researcher by utilizing a constant comparative method of data collection, analysis, and inductive open coding to allow for emergent themes within the management of IPRs in soybean biotechnology.[28] This qualitative research tends to use inductive analyses, which identify the critical themes that emerge.[29] A systemic approach to understanding the data informed the data collection process, categories of coding, and the theoretical approaches and contribution of this research. A final list of codes was created by identifying and categorizing themes in the text, and the transcripts were re-coded as necessary to ensure inter-coder reliability. The final list of codes was checked to further ensure accuracy, authenticity, and relevancy. At this level, previous coding was studied to further develop themes, and the focused codes were categorized together based on the related emergent themes. The final stage involved interpreting the data and

26. *See* STEINAR KVALE, INTERVIEWS: AN INTRODUCTION TO QUALITATIVE RESEARCH INTERVIEWING 5–6 (Astrid Virding ed., 1996).

27. *See id.* at 6.

28. *See* Nicholas Mays & Catherine Pope, *Qualitative Research: Rigour and Qualitative Research*, 311 BMJ 109, 110 (1995); Elizabeth H. Bradley et al., *Qualitative Data Analysis for Health Services Research: Developing Taxonomy, Themes, and Theory*, 42 HEALTH SERVS. RSCH. 1758, 1758 (2007); *see also generally* PATTON, *supra* note 20.

29. *See generally* PATTON, *supra* note 20.

writing notes regarding the relation of the coding to the objectives of the research study. Data analysis was complemented by use of the qualitative data analysis software NVivo 11.

B. Research Context

Plant innovations must have a means by which they can be protected by patents or a *sui generis* system according to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.[30] The pattern of IP protection in crop biotechnology in Brazil is reminiscent of legislation in India and China due to strict protection and enforcement of IPRs.[31] In Brazil, the IP laws are harmonized with the international TRIPS Agreement, (reconciliation of TRIPS and the national IP laws that set the minimum standards of IP protection among members' countries).[32] Therefore, in Brazil, the Industry Property Law (Law 9.279/96) and Plant Variety Protection Law (Law 9.456/97) came into force to protect transgenic microorganisms by patents and to protect plant varieties by the *sui generis* system, respectively.[33]

The diffusion of GM soybeans, and Brazil's involvement in crop biotechnology associated with GM organisms, is relatively recent. After the approval of cultivation and commercialization of Monsanto's GM soybean in 1998, Monsanto signed an agreement with Brazil's most important entity of agricultural research, EMBRAPA, regarding research and development of new varieties of GM soybean.[34] A year afterward—and in response to campaigns against the commercialization of GM soybean in the country—a federal court issued a decision prohibiting the commercialization of GM soybean.[35] Brazil, however, had gone from a country where GM crops were illegal before 2001 to being classified as the second largest area of crop biotechnology in the world in

30. Roberta L. Rodrigues et al., *Intellectual Property Rights Related to the Genetically Modified Glyphosate Tolerant Soybeans in Brazil*, 83 ANNALS BRAZILIAN ACAD. SCI. 719, 720 (June 2011), https://www.scielo.br/j/aabc/a/fmfBS65GYRHPTFZDgTN3NPk/?lang=en [https://perma.cc/2QAH-NGW7].

31. *Id.* at 727.

32. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 300.

33. Rodrigues et al., *supra* note 31, at 720.

34. Sybil D. Rhodes, *South American Adopters: Argentina and Brazil*, *in* HANDBOOK ON AGRICULTURE, BIOTECHNOLOGY AND DEVELOPMENT 86, 91-92 (Stuart J. Smyth et al. eds., 2015).

35. *Id.*

2014.[36] Parente et al. stated, in the early 2000s, most GM soybeans in Brazil were being imported and smuggled from neighboring Argentina where RR® soybean varieties were commercially grown.[37] Yet, the state Rio Grande do Sul supported GM soybean and farmers were allowed to grow RR® soybeans temporarily in 2003.[38] Afterward, the Biosafety Law was passed by the Brazilian Congress.[39] The Biosafety Law (Law 11.105) came into force in 2005. RR® soybeans were allowed four years later in 2003. By 2007, the total number of soybean varieties registered for sale in Brazil was 61, of which 75% were RR® soybean and 25% were conventional soybean.[40]

Brazil is the second largest producer and exporter of soybeans in the world, and the country has become a global flagpole in soybean production.[41] The soybean area harvested in Brazil in 2012 is shown below in Figure 2.[42] Five states are responsible for 80% of Brazil's soybean production: Rio Grande do Sul and Parana in the South, Mato Grosso, Goias, and Mato Grosso Sul in the Mid-West.[43] Mato Grosso has the highest adopted rate of soybean biotechnology with 7.78 million hectares, followed by Parana with 4.77 million hectares.[44] As mentioned previously, soybeans continue to be the most adopted crop biotechnology with herbicide tolerance traits and stacked traits technology (herbicide tolerance and

36. *Top Ten Facts,* INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APPLICATIONS (April 9, 2021, 6:21 PM), https://www.isaaa.org/resources/publications/briefs/49/toptenfacts/default.asp [https://perma.cc/3MKV-6YY3].

37. Ronaldo Parente et al., *Public Sector Organizations and Agricultural Catch-up Dilemma in Emerging Markets: The Orchestrating role of Embrapa in Brazil*, 52 J. INT'L BUS. STUD. 646, 659 (2020).

38. Meyer & Cederberg, *supra* note 18.

39. Rhodes, *supra* note 35, at 93.

40. *See* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2011,* INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APPLICATIONS 26-27 (2011), https://www.isaaa.org/resources/publications/briefs/43/download/isaaa-brief-43-2011.pdf [https://perma.cc/UW7R-VJE5].

41. *See id.*

42. Meyer & Cederberg, *supra* note 18; Diego Arias et al., *Agriculture Productivity Growth in Brazil: Recent trends and future prospects*, WORLD BANK GRP. (Sep. 24, 2017), http://documents1.worldbank.org/curated/en/268351520343354377/pdf/123948-WP-6-3-2018-8-39-22-AriasetalAgriculturalgrowthinBrazil.pdf [https://perma.cc/32LY-FHS2].

43. Meyer & Cederberg, *supra* note 18.

44. Anderson Galvão et al., *Biotechnology Reporting*, CELERES (Dec. 14, 2012), http://celeres.com.br/wordpress/wp-content/uploads/2012/12/RelBiotecBrasil_1202_ingl.pdf [https://perma.cc/FQX5-8YDD].

insect resistance) in Brazil.[45] However, the production growth of stacked traits was slowed by the delay of regulatory approval in China, as China is the largest importer for Brazilian soybean grains.[46]

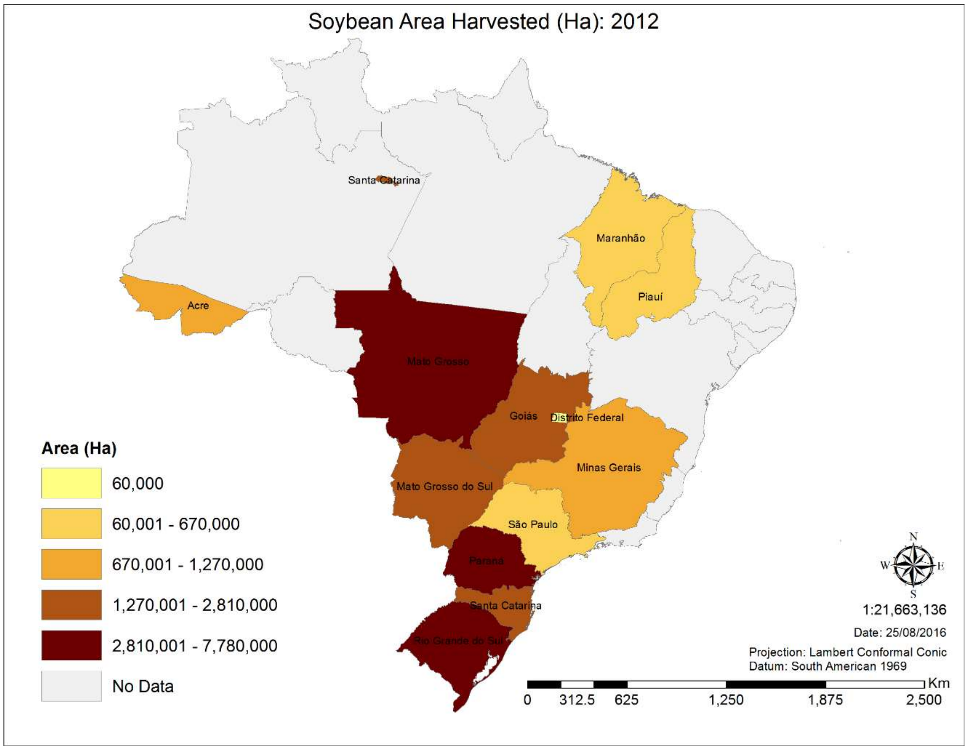

Figure 2. The soybean production in Brazil by area harvested (Ha) in 2012.

There was a rapid and widespread adoption of RR® soybeans resulting in excessive reliance on only a single herbicide (glyphosate).[47] Crossings between the herbicide-tolerant trait (RR® soybean) and the Brazilian soybean varieties are now the most widely commercialized strain by Monsanto in Brazil.[48] The expanded global demand for soybeans over the past several decades was a key factor in

45. *Id.* at 1-2.
46. *See id.* at 3.
47. Meyer & Cederberg, *supra* note 18.
48. Varella, *supra* note 3, at 67.

shaping the early adoption of crop biotechnology in South America (Brazil and Argentina) and the diffusion of GM soybean throughout Brazil.[49]

C. History and Development: The Crop Biotechnology, Soybean

Soybean, *Glycine max* L., is a legume with over 3000 years of history in East Asia and more recently expanded production across the world, from Canada to Brazil and then to Ghana.[50] Soybean is an important crop across the world and is increasingly consumed among the world's poorest people and those preferring plant proteins.[51] More than three-quarters of production is, however, used in animal feed.[52] Soybean oil is widely used for human consumption, as well as in soaps, biofuels, and fatty acids in a range of industrial products.[53] Interestingly, soybean is not among the 64 major crops and forages in the multilateral International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[54] The treaty recognizes the contribution of farmers and indigenous people for their use and commercialization of agricultural biodiversity.[55] This treaty also provides other strategies such as information-exchange, access to technology, and capacity building.[56] The exchange of seeds for breeding, research, and training is facilitated by the ITPGRFA.[57] However, China opposed adding soybeans to the list of major crops and forages in the treaty.[58]

Soybeans are a self-pollinating crop, so soybean breeder flowers emasculate by removing the anthers or the male part of the flower by hand and then pollinating

49. Rhodes, *supra* note 35, at 86.

50. *Glycine Soja*, SCIENCE DIRECT (Apr. 19, 2021, 11:59 AM), https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/glycine-soja [https://perma.cc/HK2J-ZNPN].

51. *See Food Aid*, AM. SOYBEAN ASS'N (Apr. 19, 2021, 11:40 AM), https://soygrowers.com/key-issues-initiatives/key-issues/other/food-aid/ [https://perma.cc/XEC8-X5P2].

52. *Soy*, WWF (Apr. 19, 2021, 11:25 AM), https://wwf.panda.org/discover/our_focus/food_practice/sustainable_production/soy/? [https://perma.cc/J2PF-5KUL].

53. *Id.*

54. *See* International Treaty on Plant Genetic Resources for Food and Agriculture, Annex 1, Nov. 2, 2001, 2400 U.N.T.S. 303.

55. *See id.* art. 1.

56. *See id.* art. 5-6.

57. *Id.* art. 7 § 7.2(b).

58. REGINE ANDERSON, GOVERNING AGROBIODIVERSITY: PLANT GENETICS AND DEVELOPING COUNTRIES 99 (2008).

with pollen from another plant.[59] Plant breeders usually select for desired agronomic traits (drought tolerant, herbicide tolerant, abiotic stresses tolerant, yield, etc.) that are likely to be in the the female parent.[60] The male parent is usually the donor of the new trait.[61] The soybean has been the subject of biotechnology and genetic modification for over three decades to complement the conventional plant breeding tools and enhance the quality of new varieties of soybean. The process by which a single gene trait can be transferred from one crop to another to create a new technology of crops, such as herbicide tolerant and insect resistant, is called transgenic technology.[62] Most transgenic technologies could be examined for patenting, and nearly all industrialized countries allowed patents on genes and DNA sequences, but that is no longer the case.[63] For example, the marker assisted selection (MAS) is a tool to select crop traits where the gene and the markers for a specific trait are known.[64] This method typically takes plant breeders 7 to 10 years to develop new crop varieties.[65] The seed technology categorizes the results of plant breeding into: 1) open-pollinated crop such as corn; 2) inbred varieity, such as rice; and 3) hybrid seed or F1 (referring to the first filial generation).[66] The first two categories can maintain the same features in case of multiplication and seed savings. Hybrid seeds result from crossing two distinct, inbred parent lines (pure lines) of several cycles of repeated self-pollination, thereby producing sexual offspring that is similar to the parents.[67] Therefore, hybrid seeds must be produced each season and cannot be saved for future plantings.[68] This is due to the natural loss of heterosis in subsequent generations, which consider a natural incentive or biological protection, for private plant breeding.[69] Nowadays, breeders are able to edit genes without any foreign gene transfer, allowing permanent modification of

59. *See* INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APPLICATIONS, AGRICULTURAL BIOTECH (A LOT MORE THAN JUST GM CROPS) 4-5 (2014), https://www.isaaa.org/resources/publications/agricultural_biotechnology/download/Agricultural_Biotechnology.pdf [https://perma.cc/A5KR-AWJ5].

60. *Id.* at 5, 23.

61. *Id.* at 5.

62. *Id.* at 22.

63. *See generally* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 595-596 (2013).

64. AGRICULTURAL BIOTECH (A LOT MORE THAN JUST GM CROPS), *supra* note 60 at 2.

65. *See id.* at 12.

66. *See id.* at 4.

67. *See id.* at 6.

68. *See generally* R.W. ALLARD, ENCYCLOPEDIA BRITANNICA, PLANT BREEDING, (Apr. 19, 2021, 11:29 AM), https://www.britannica.com/science/plant-breeding/Hybrid-varieties [https://perma.cc/T66T-L634].

69. *See generally id*.

genes within organisms.[70] This new technique called CRISPR-Cas technology has potential to reduce the number of breeding selection cycles.[71]

D. Herbicide Tolerant Soybean (Roundup Ready® Soybean)

The herbicide tolerant plants (e.g. RR®), are sometimes called glyphosate resistant soybeans. Glyphosate is a non-selective herbicide originally developed and released by Monsanto.[72] Roundup® is Monsanto's trademark for their glyphosate product.[73] Monsanto patented the use of glyphosate as a herbicide in 1974.[74] This patent expired in 2000.[75] Monsanto has since continued the rights to the Roundup® trademark.[76] Glyphosate can be applied on GM soybeans during the post-emergence period, which kills the weeds and non-GM plants.[77] Glyphosate was a spectacular success for Monsanto, both as a herbicide and a business phenomenon. The herbicide is used by farmers as part of "no-till" cultivation methods, which minimize erosion and conserve topsoil.[78] These practices contributed to adoption of the research and glyphosate herbicide tolerant soybean.[79] Farmers and producers gained benefits from the GM soybean after

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70. Gavin J. Knott & Jennifer A. Doudna, *CRISPR-Cas Guides the Future of Genetic Engineering*, 361 SCIENCE 866, 867 (Aug. 31, 2018).

71. *Id.* at 866.

72. *See, e.g., Genetically Modified Soybean*, WIKIPEDIA (June 14, 2021, 11:40 PM), https://en.wikipedia.org/wiki/Genetically_modified_soybean [https://perma.cc/GVJ8-ZYAV].

73. *See Roundup-Trademark Details*, JUSTIA (Apr. 12, 2021, 7:47AM), https://trademarks.justia.com/722/75/roundup-72275068.html [https://perma.cc/Z5QK-8GPM].

74. *Glyphosate*, U.S. ENV'T PROT. AGENCY (Apr. 12, 2021, 8:30 AM), https://www.epa.gov/ingredients-used-pesticide-products/glyphosate [https://perma.cc/DW6W-Y8NV]; B. Tickes, *Maximizing the Use of Glyphosate*, (Apr. 12, 2021, 8:45 AM), https://cals.arizona.edu/crops/pdfs/062512%20Maximizing%20the%20Use%20of%20Glyphosate.pdf [https://perma.cc/BYA4-7T2W].

75. *See* Patricia Van Arnum, *US Patent Expiry of Roundup Creates Uncertainty in Glyphosates*, INDEP. COMMODITY INTEL. SERVS. (Dec. 11, 2000), https://www.icis.com/explore/resources/news/2000/12/11/128125/us-patent-expiry-of-roundup-creates-uncertainty-in-glyphosates/ [https://perma.cc/LC23-MKVE]; *see also* Tickes, *supra* note 75.

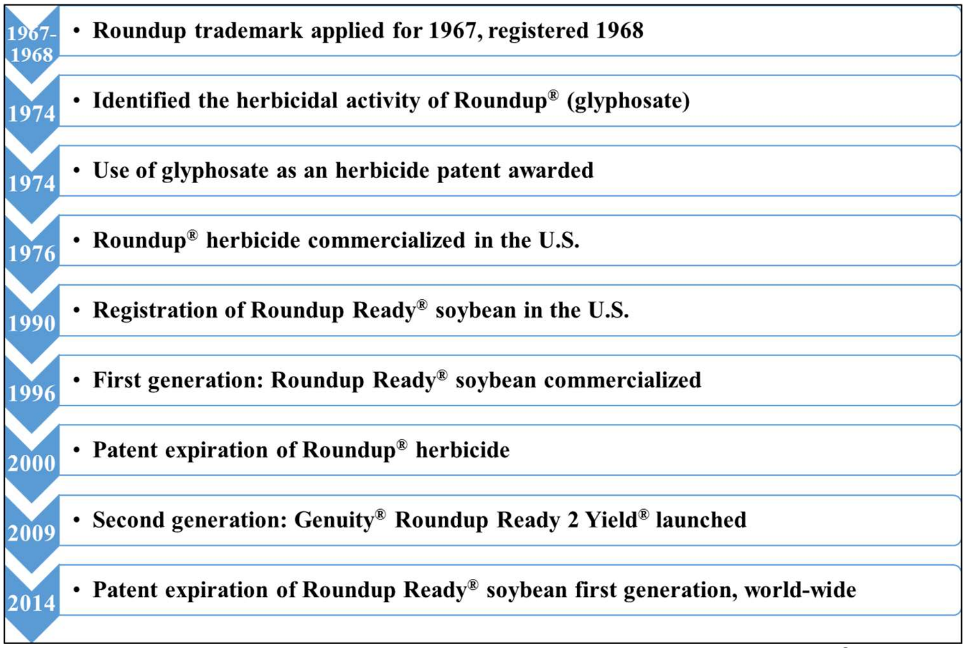
76. *Roundup-Trademark Details*, *supra* note 74.

77. *See* Tickes, *supra* note 75.

78. *See Glyphosate*, *supra* note 75.

79. *See* Jorge Fernandez-Cornejo & William D. McBride, U.S. DEP'T AGRIC., REPORT NO. 786, GENETICALLY ENGINEERED CROPS FOR PEST MANAGEMENT IN U.S. AGRICULTURE: FARM-LEVEL EFFECTS 14 (Apr. 2000),

Monsanto introduced it in the mid-1990s.[80] These benefits included reduction in production costs (savings due to the elimination of farming practices such as field scouting by farmers to identify weeds), flexibility in land management and timing,



better yields and quality, and less application of herbicides (because RR® soybeans are not harmed by the herbicide).[81] The technology timeline for the Roundup® trademark and first-generation glyphosate tolerant soybean are illustrated below in Figure 3.

Figure 3. Technology timelines for the Roundup® trademark and first-generation glyphosate tolerant soybean.

The full commercial name of Monsanto's herbicide tolerant soybean is Roundup Ready® soybean. RR® soybean is a platform technology and the most

https://www.ers.usda.gov/webdocs/publications/41121/15699_aer786_1_.pdf?v=1023.1 [https://perma.cc/X5D7-WGE4].

80. *See id.*

81. David S. Bullock & Elisavet I. Nitsi, *Roundup Ready Soybean Technology and Farm Production Costs: Measuring the Incentive to Adopt Genetically Modified Seeds*. 44 AM. BEHAV. SCI. 1283, 1284 (2001).

widely adopted crop biotechnology in the world.[82] The Roundup Ready Soybean® trademark was applied for in 1995, registered in 1997, and cancelled in 2004.[83] The Roundup Ready® trademark was applied for in 1993, registered in 1995, and is still active and owned by Monsanto.[84] Farmers in the United States, Canada, and other parts of the world rapidly began using the technology on their farms because of the improved weed control benefits. Additionally, Monsanto licenses the GM trait and also acquires rights from other seed companies (Bayer Crop Science, Dow AgroSciences, and Dupont (Pioneer Hi-Bred)) through collaboration because the GM trait may be incorporated with other proprietary traits of soybean seed.[85] This approach of cross-licensing between two companies was a key factor that influenced the availability of RR® soybean in the market.[86]

Presently, over 90 percent of the soybeans grown in the United States are GM soybeans, and 60 percent of the soybeans in the United States are exported abroad, mainly to China, Japan, and Mexico.[87] This is, however, the first

82. David S. Bullock & Elisavet I. Nitsi, *Roundup Ready Soybean Technology and Farm Production Costs: Measuring the Incentive to Adopt Genetically Modified Seeds*. 44 AM. BEHAV. SCI. 1283, 1284 (2001).

83. ROUNDUP READY SOYBEANS, Registration No. 2,103,950.

84. ROUNDUP READY, Registration No. 1,889,104.

85. *See* Jennifer M. Latzke, *Roundup Ready Soybean Trait Patent Nears Expiration in 2014*, HIGH PLAINS J. (Mar. 26, 2015), https://www.hpj.com/archives/roundup-ready-soybean-trait-patent-nears-expiration-in-2014/article_8c7a83b7-2a37-5291-9204-2633eb3e4c0d.html [https://perma.cc/SYU5-QXV9]; GianCarlo Moschini, *Competition Issues in the Seed Industry and the Role of Intellectual Property*, CHOICES MAGAZINE (2010), https://www.choicesmagazine.org/UserFiles/file/article_120.pdf [https://perma.cc/P58Q-89RN]. In September 2016, Bayer AG acquired Monsanto to form one of the world's largest agricultural companies. *Bayer and Monsanto to Create a Global Leader in Agriculture*, BAYER CROP SCI. (Sept. 16, 2016), https://www.cropscience.bayer.us/news/press-releases/2016/09142016-bayer-and-monsanto-to-create-a-global-leader-in-agriculture [https://perma.cc/9R94-SQ4N]. Other mergers that happened in the life sciences industries: ChemChina and Syngenta, Dow and Dupont. James M. MacDonald, *Mergers in Seeds and Agricultural Chemicals: What Happened?,* U.S. DEPT. AGRIC. (Feb. 15, 2019), https://www.ers.usda.gov/amber-waves/2019/february/mergers-in-seeds-and-agricultural-chemicals-what-happened/ [https://perma.cc/6C8D-XQPC]. Dow and Dupont merged in 2015, but in April 2019 Dow successfully split from Dupont. *Dow Completes Separation from DowDuPont*, DOW (Apr. 1, 2019), https://corporate.dow.com/en-us/news/press-releases/dow-completes-separation-from-dowdupont—-.html [https://perma.cc/SL9Q-6QT2].

86. *See* Moschini, *supra* note 85, at 12-13.

87. Daniel Grushkin, *Threat to Global GM Soybean Access as Patent Nears Expiry*, 31 NAT. BIOTECHNOLOGY 10, 10-11 (2013), https://www.naveenbioinformatics.co.in/2013/06/threat-to-global-gm-soybean-access-as.html [https://perma.cc/RZB9-AJ9K].

widespread crop transgenic trait to go off patent.[88] The RR® soybean patent was registered in the United States in 1990, issued as a patent in 1994, and showed up in the field in 1996. As a result, the original Monsanto patent (U.S. patent # 5,352,605) was due to expire in 2011[89] (after the designated duration of 17 years' protection under the old regime).[90] Monsanto, however, managed to keep the patent active through to 2014 using the USPTO re-examination system (five years from a re-examination process in 2009, RE 39,247),[91] and maintained that this extension also applied in other countries such as Brazil.[92] In Canada, the RR® soybean patent expired in late 2011.[93] The process to request a patent re-examination is contained in 35 U.S.C. § 302, and it is a frequently used post-grant procedure in the United States Patent and Trademark Office.[94] This process can be requested by any person to challenge the validity of a patent based on prior art, and the patent office will re-examine the issued patent as a new patent application.[95] The patent owner can submit new claims, provided they are not more broad than the claims in the original patent.[96] The re-examination certificate will incorporate new claims determined to be patentable.[97] Table 1 below shows some of Monsanto's patents related to the RR® soybean trait as protected under United States patent law.

88. *See id.*; Latzke, *supra* note 85.

89. U.S. Patent No. 5,352,605 (filed Oct. 4, 1994).

90. *Duration of Patent Protection*, JUSTIA (Apr. 15, 2021, 7:54 AM), https://www.justia.com/intellectual-property/patents/duration-of-patent-protection/ [https://perma.cc/B2XK-YC7C]; *see also 2701 Patent Term [R-10.2019]*, U.S. PAT. & TRADEMARK OFF. (June 25, 2020) https://www.uspto.gov/web/offices/pac/mpep/s2701.html [https://perma.cc/7K66-LNCB].

91. U.S. Patent No. RE39,247 (filed Aug. 22, 2006); *see also 2209 Ex Parte Reexamination [R-10.2019]*, U.S. PAT. & TRADEMARK OFF. (June 25, 2020), https://www.uspto.gov/web/offices/pac/mpep/s2209.html [https://perma.cc/TBG8-EMX5].

92. *See* Patricia Covarrubia, *Brazil: Monsanto Defeated*, IPTANGO (June 4, 2013), https://iptango.blogspot.com/2013/06/brazil-monsanto-defeated.html [https://perma.cc/HG28-MX2C].

93. *See* GFM Network News, *Don't jump gun on RR patent expiry: Monsanto*, CAN. CATTLEMEN (Jan. 6, 2011), https://www.canadiancattlemen.ca/daily/dont-jump-gun-on-rr-patent-expiry-monsanto/ [https://perma.cc/84SR-ZZS7].

94. *See* 35 U.S.C. § 302.

95. 35 U.S.C. §§ 302-303.

96. N. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1349 (Fed. Cir. 2005).

97. *Id.*

Table 1. Monsanto's patents related to the RR® soybean trait.[98]

U.S. Patent	Publication / Grant Date	Patent Title / Trait
4,535,060	1985	Inhibition resistant 5-enolpyruvyl-3-phosphoshikimate synthetase, production and use
4,940,835	1990	Glyphosate-resistant plants
5,352,605	1994	Chimeric genes for transforming plant cells using viral promoters
5,530,196	1996	Chimeric genes for transforming plant cells using viral promoters
5,633,435	1997	Glyphosate-tolerant-5-enolpyruvylshikimate-3-phosphate synthases

Monsanto already introduced the second generation of RR® soybeans in the United States and Canada in 2009, called Roundup Ready® 2 Yield®.[99] Monsanto developed this trait to provide farmers more yield and profit potential.[100] Table 2 details the regulatory approval database of the GM soybean events with glyphosate herbicide tolerance. Mon 87701 x Mon 89788 was introduced in South America and was promoted as being tolerant to herbicide and resistant to insects.[101] Mon 87701 has gene cry1Ac and originated in Bacillus thuringiensis (Bt), and Mon 89788 has gene cp4 epsps, which is produced by transformation mediated by Agrobacterium sp.[102] The latest gene decreases binding affinity for glyphosate, thereby conferring an increased tolerance to glyphosate herbicide.[103]

98. *See generally U.S. Patent Full-Text and Image Database*, U.S. PAT. & TRADEMARK OFF. (Apr. 10, 2021, 2:33 PM), patft.uspto.gov/netahtml/PTO/srchnum.htm [https://perma.cc/P4WZ-XCBM].

99. *Roundup Ready Soybean Patent Expiration*, *supra* note 83.

100. *Id.*

101. *See Event Name: MON87701 x MON89788*, INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APPLICATIONS (April 12, 2021, 12:53 PM), https://www.isaaa.org/gmapprovaldatabase/event/default.asp?EventID=159&Event={recEvents.EventName} [https://perma.cc/MG6F-JGVQ].

102. *Id.*

103. *See id.*; Wagner Justiniano et al., *Intacta RR2 PRO® (MON87701 x MON89788) for Management of the Main Target and Non-Target Insects in Soybeans*, 3 GLOB. J. OF BIOLOGY, AGRIC. & HEALTH SCIS. 11, 12 (2014).

Table 2. The Regulatory approval database of the GM soybean events with glyphosate herbicide tolerance.[104]

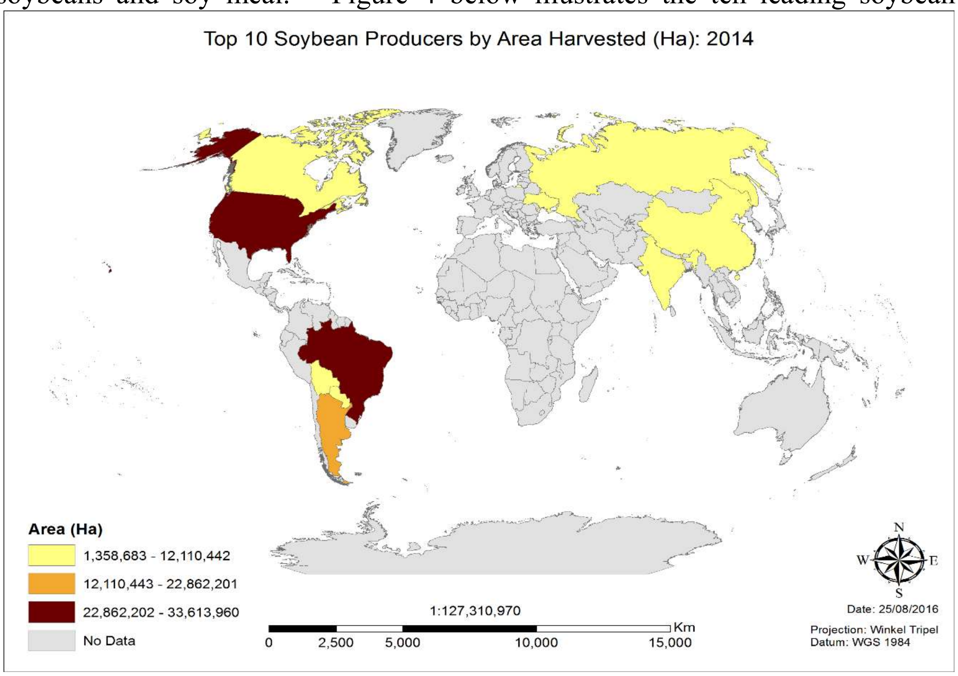
Soybean Event	**Trade Name**	**Trait (s)**	**Country**	**Year of Regulatory Approval**
GTS 40-3-2 Monsanto	Roundup Ready® soybean	Glyphosate tolerance	Argentina	1996
			Brazil	1998
			Canada	1996
			USA	1995
Mon89788 Monsanto	Genuity® Roundup Ready 2 Yield®	Glyphosate tolerance	Canada	2007
			USA	2007
Mon87701 x Mon89788 Monsanto	Intacta® Roundup Ready® 2 Pro	Stacked (Glyphosate tolerance & insect resistance)	Argentina	2012
			Brazil	2010
Mon87705 Monsanto	Vistive Gold®	Stacked (Glyphosate tolerance & modified product quality)	Canada	2011
			USA	2011
Mon87708	Genuity	Stacked	Canada	2012

104. *GM Events with Glphosate herbicide tolerance*, INT'L SERV. FOR ACQUISITION AGRI-BIOTECH APPLICATIONS (April 9, 2021, 8:30 PM), http://www.isaaa.org/gmapprovaldatabase/gmtrait/default.asp?TraitID=2&GMTrait=Glyphosate%20herbicide%20tolerance [https://perma.cc/TC5N-4XQU].

Monsanto	Roundup Ready 2 Xtend	(Glyphosate & Dicamba tolerance)		
			USA	2011
DP356043 Dupont	Optimum GAT®	Stacked (Glyphosate & Sulfonylurea tolerance)	Canada	2009
			USA	2007

E. Soybean Production and Trade

The United States, Brazil, and Argentina are currently responsible for about 80 percent of the global soybean production and dominate world exports of soybeans and soy meal.[105] Figure 4 below illustrates the ten leading soybean



105. Meyer & Cederberg, *supra* note 18.

producing countries in the world by area harvested in 2014. The United States was the leading soybean producing country with an area harvested of 33 million hectares.[106] Brazil was the second leading country with an area harvested of 30 million hectares, and Canada was the seventh leading country with an area harvested of two million hectares.[107]

Figure 4. The top 10 soybean producers by area harvested (Ha) in 2014.

The most important export markets for American soybean are China, the European Union, Japan, Mexico, and Taiwan.[108] While Brazil is the second largest producer and exporter of soybeans in the world, China is the most important market for the export of Brazilian soybean grains, and Europe is the most important market for the export of Brazilian soybean meals and oils.[109] China consumes nearly one-third of global soybean production and imports over 60 percent of global soybean exports of which over 90 percent is soybean biotechnology.[110] The global markets for oilseeds and the increasing demand for soybeans in China are key factors in producing increasingly more soybeans.[111] The top five countries in the world for growing the largest hectares of crop biotechnology are illustrated below in Table 3. RR® soybean, as a crop biotechnology, had one of the highest adoption rates, and has widespread use among farmers around the world.[112]

106. *See generally Global Soybean Production*, FOOD & AGRIC. ORG. UNITED NATIONS (June 16, 2021, 10:41 PM), http://www.fao.org/faostat/en/#search/Global%20Soybean%20Production [https://perma.cc/7PN3-D5MC].

107. *See generally id.*

108. *See generally* U.S. DEPT. OF AGRIC. (June 16, 2021, 10:48 PM), https://www.ers.usda.gov/topics/crops/soybeans-oil-crops/ [https://perma.cc/583C-8WLU].

109. MERRILL MATTHEWS, THE SEEDS OF IP POLICY: A GROWING AGRICULTURAL SUCCESS STORY 5-6 (2012), https://www.ipi.org/docLib/20120425_Seeds_of_IP_Policy.pdf [https://perma.cc/EXE3-47MW].

110. FRED GALE, CONSTANZA VALDES & MARK ASH, USDA, INDEPENDENCE OF CHINA, UNITED STATES, AND BRAZIL IN SOYBEAN TRADE 1 (2019), https://www.ers.usda.gov/webdocs/outlooks/93390/ocs-19f-01.pdf?v=822.1 [https://perma.cc/HEJ3-WVD2]; See also generally John Newton & Megan Nelson, China Uses One-Third of World's Soybeans, 2018, https://www.fb.org/market-intel/china-uses-one-third-of-worlds-soybeans [https://perma.cc/L6LY-3M5S].

111. *See* Meyer & Cederberg, *supra* note 18, at 9.

112. *See* CLIVE JAMES, ISAAA, BRIEF NO. 37, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2007 3-4, https://www.isaaa.org/resources/publications/briefs/37/executivesummary/pdf/Brief%2037%20-%20Executive%20Summary%20-%20English.pdf [https://perma.cc/GYQ3-QATJ].

Table 3. The top five countries for growing the largest areas of crop biotechnology in 2014.[113]

Rank	**Country**	**Area (million hectares)**	**Adoption of Crops Biotechnology**
1	United States	73.1	Over 90% of principal crops (maize, soybean and cotton). Other crops canola, sugar beet, alfalfa, Papaya, squash.
2	Brazil	42.2	Over 93% of principal crop (soybean). Other crops maize, cotton.
3	Argentina	24.3	100% of principal crop (soybean) and 80% of principal crop (maize). Other crops cotton.
4	India	11.6	95% of principal crop (cotton).
5	Canada	11.6	95% of principal crop (canola). Other crops maize, soybean, sugar beet.

The global area for herbicide tolerant soybean was around 81 million hectares in 2012, which occupied 47 percent of all crop biotechnology planted globally.[114] The top three countries in the world in terms of growing the most hectares of herbicide tolerant soybean are illustrated below in Table 4. The United States, Brazil, and Argentina are also the principal producers of GM soybeans in 2011.[115]

Table 4. The top countries for growing the largest hectares of biotech soybean in 2017.[116]

113. *Top Ten Facts*, *supra* note 37.

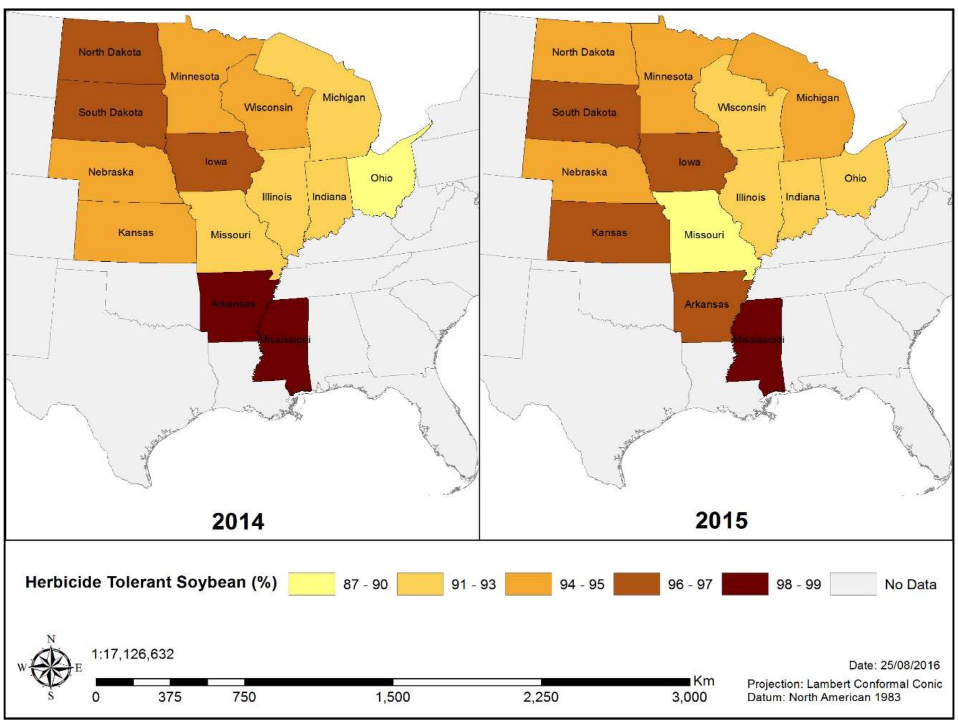
114. *See Global Status of Commercialized Biotech/GM Crops,* ISAAA (2012), https://www.isaaa.org/resources/publications/briefs/44/executivesummary/ [https://perma.cc/84NN-J84Z].

115. *See* James, *supra* note 113, at 4.

116. *See* INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APP., GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS IN 2017 9, 16, 20, 34, 24, 50, 52 (2017), https://edisciplinas.usp.br/pluginfile.php/4402024/mod_resource/content/1/isaaa-brief-53-2017.pdf [https://perma.cc/2UKU-K73G].

Rank	**Country**	**Area (million hectares)**
1	United States	34.05
2	Brazil	33.70
3	Argentina	18.10
4	Paraguay	2.68
5	Canada	2.50
6	Bolivia	1.28
7	Uruguay	1.09

The United States continues to be the lead country for planting GM soybeans with over 94 percent adoption for soybean biotechnology.[117] A percentage



117. *Top Ten Facts*, *supra* note 37.

breakdown of all herbicide tolerant soybeans planted in the United States in 2014 and 2015 is illustrated below in Figure 5.[118]

Figure 5. Soybean biotechnology as a percentage of all soybeans planted in the United States in 2014 and 2015.

Soybean is an important crop in Canadian agriculture. Canada's soybean production expanded widely, from southern Ontario into other growing regions across Canada (Quebec and Manitoba), after the mid-1970s.[119] The total production area for soybeans in Canada was approximately "5.3 million acres in 2016, down 1.9% from 2015."[120] Iran, China, Japan, Italy, and Bangladesh were the top five export markets for the Canadian soybean in 2019.[121] In 2012, The herbicide tolerant soybean represented approximately 80 percent of the total area

118. *See Recent Trends in GE Adoption*, U.S. DEP'T OF ARGIC. (July 17, 2020), https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption/ [https://perma.cc/P3BQ-VF28].

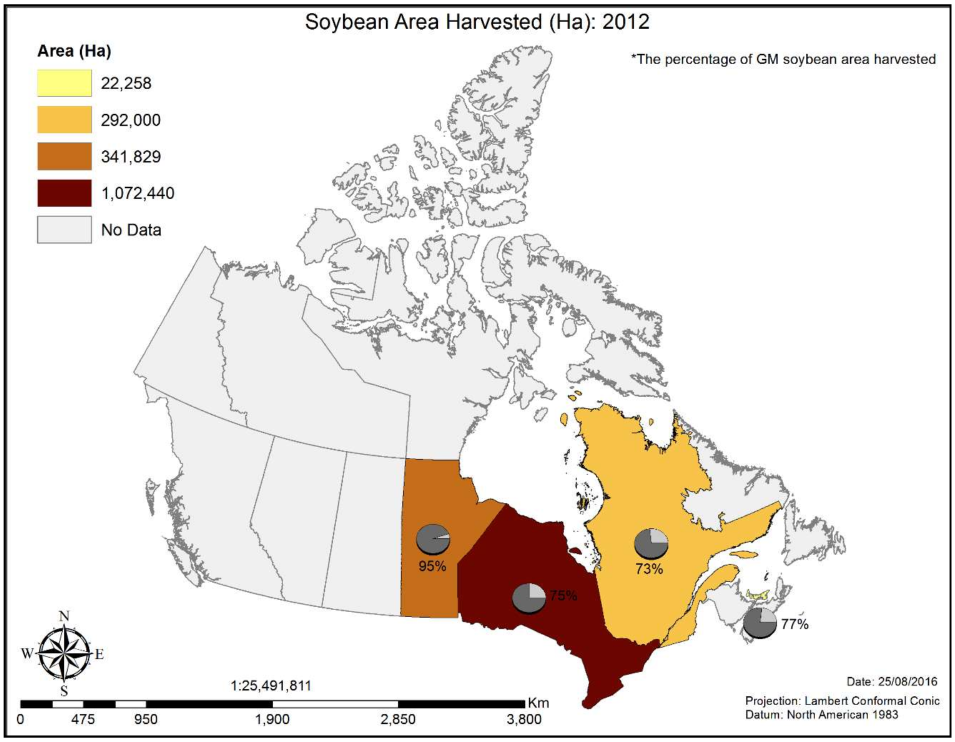
119. *See* Erik Dorff, *The soybean, agriculture's jack-of-all-trades, is gaining ground across Canada*, STATISTICS CAN. (Apr. 10, 2021, 2:31 PM), http://www.statcan.gc.ca/pub/96-325-x/2007000/article/10369-eng.htm [https://perma.cc/9EL6-ZUNZ].

120. *Principal field crop areas, March 2016*, STATISTICS CAN. (Apr. 10, 2021, 2:30 PM), http://www.statcan.gc.ca/daily-quotidien/160421/dq160421b-eng.htm [https://perma.cc/E8Z3-DJFV].

121. *Top 20 Export Markets*, SOY CAN. (Feb. 2021), http://soycanada.ca/statistics/top-20-export-markets/ [https://perma.cc/5RDK-CED3].

of soybean production in Canada, as illustrated below in Figure 6.[122] Certainly, the GM soybean is an important crop in the Canadian agricultural innovation system.

Figure 6. The soybean area planted by major growing regions in Canada with the percentage of GM soybean area harvested in 2012.



III. RESULTS

All participants have noticed that genetically modified glyphosate treatment soybeans have brought great value to Brazil's farmers and the country's economy. Public research institutions in Brazil, such as EMBRAPA, are increasingly limited in their ability to develop new crops using RR® soybean technologies.[123] Other

122. *See* CAN. GRAIN COMM., QUALITY OF CANADIAN SOYBEAN, OILSEED-TYPE 2017 7 (2017), https://www.grainscanada.gc.ca/en/grain-research/export-quality/oilseeds/soybean-oil/2017/oil-soybeans-quality-report-17.pdf [https://perma.cc/RY29-3BDC].

123. T*op 20 Export Markets*, *supra* note 121.

private companies, such as Monsanto, that hold IPRs on their inventions, are compensated through the technology fees and the payment of royalties.[124]

According to Brazilian interviewees, this business model has played an important role in fostering new investments in Brazilian agricultural production. As IPRs proliferate, soybean biotechnology and soybean productivity are facing new challenges relevant to the future of the Brazilian people and at the center of global agriculture developmental policy. Protection and enforcement of IPRs for this crop influences the uptake and development of crop biotechnology elsewhere for other crops. Therefore, the potential to foster new investment and international partnerships in Brazilian agricultural production holds a benefit for the global food supply, and, overall, soybean R&D benefits other areas of the world and provides new innovations related to soybean products.

A. EMBRAPA and Private Industries Collaboration

EMBRAPA collaborates and has partnerships with many private companies for crop biotechnology.[125] The first contract between EMBRAPA and Monsanto was signed in 1996.[126] EMBRAPA developed the first cultivar using RR® soybean in its breeding program in 2005. As reported by participants, Monsanto licensed the first-generation RR® gene to EMBRAPA, and then EMBRAPA inserted the RR® gene into an EMBRAPA cultivar to develop a new cultivar of soybean such as Conquista/ValiosaRR (replaced by EMBRAPA58/BRS242RR), BRS133/BRS245RR, and EMBRAPA59/BRS244RR.[127] Based on the signed agreement, EMBRAPA owns this new cultivar and Monsanto owns the gene (trait).[128]

Other private companies such as BASF and Bayer Crop Science have followed the same business strategy of Monsanto. To get a sense of the issues relating to management of IPRs in soybean biotechnology, respondents were asked to identify the relevant IP management strategies, such as collaborations with the private sector as well as incentives to improve crop biotechnology related to the soybean biotechnology. One interviewee emphasized that EMBRAPA has three

124. *See* André Shigueyoshi Nakatani et al., *Effects of the glyphosate-resistance gene and of herbicides applied to the soybean crop on soil microbial biomass and enzymes*. 162 FIELD CROPS RES. 20, 20-29 (2014).

125. Parente et al., *supra* note 38, at 646.

126. Karine Peschard & Shalini Randeria, *Taking Monsanto to Court: Legal Activism Around Intellectual Property in Brazil and India*, 47 J. PEASANT STUDIES 792, 806 (2020).

127. *See generally* Nakatani, *supra* note 124, at 20-29.

128. *See generally id.*

soybean research programs: 1) conventional breeding that involves genetic variability; 2) RR® soybean where 50 cultivars have been developed in the past, and 3) Intacta® RR® 2 Pro where 11 cultivars have been developed. As another interviewee reported, EMBRAPA started field tests to develop new varieties of GM soybean through a partnership with the German BASF to produce herbicide (imidazoline) tolerant soybeans because glyphosate is not efficient in controlling weeds. Another interviewee stated that EMBRAPA collects royalties on the new cultivar through this collaboration; however, the technology fee is divided between EMBRAPA and BASF. In this case, EMBRAPA is taking part of the technology fee which is different from the case of Intacta RR® 2 Pro with Monsanto. Another interviewee, in regard to incentives, stated that Monsanto returned some funding for EMBRAPA to invest in soybean biotechnology research and capacity development. As was pointed out by another interviewee, EMBRAPA has negotiated the continued development of new varieties of RR® soybean first generation after the end of IP protection. But, as this participant further elaborated, RR® soybeans will be in a very small area in the next few years due to patent expiration. Based on this, it seems farmers will be growing less first-generation RR® soybeans in the future.

As one participant explained during an in-depth interview, EMBRAPA has a corporate social responsibility policy oriented towards farmers in order to maintain conventional varieties of soybeans. Another participant confirmed that EMBRAPA continues to act for the benefit of farmers, thus demonstrating the corporation's adoption of this responsibility. This might explain why EMBRAPA has not actively sought to reclaim farmers' saved seeds to replant in the next season. For example, a participant described how EMBRAPA effectively gave away a new crop technology—a virus-resistant, dry bean variety that was developed by EMBRAPA's breeders—because they decided to not collect royalties for the first three years of marketing the new variety. After this, they sought commercialization of the new cultivar.

One participant elaborated on this, stating, "[t]here is the challenge of enforcement of IP in Brazil, and most of cases have been litigated under the Plant Variety Protection Act." As one participant observed, farmers are affected by the cost of IPs (mainly the price of soybean biotechnology), but are eager for a new crop technology. Another stated that the pressure of market forces could influence IP protection in the country. Therefore, the decision not to reclaim saved seeds, primarily soybeans, was made jointly between EMBRAPA-Headquarters and EMBRAPA-Soybean. The collaboration between EMBRAPA and private industries, as well as other IP management strategies (such as incentives, protection, and enforcement), is illustrated in Figure 7.

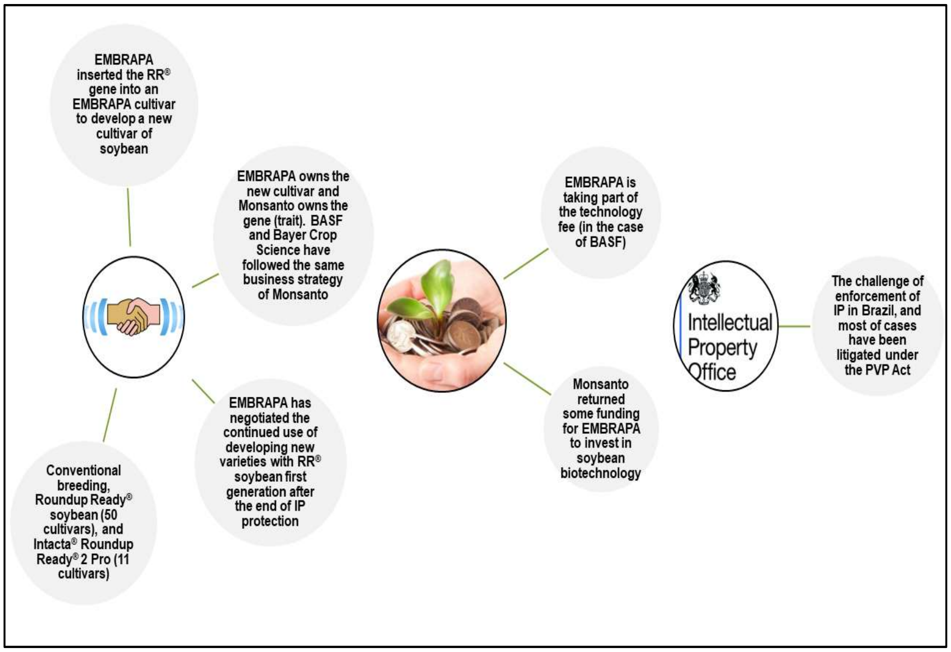


Figure 7. A schema of EMBRAPA and private industries' collaboration, and other IP management strategies (such as incentives, protection, and enforcement).

B. Implications from Patent Expiration on Herbicide Tolerant Soybean

The expiration of the RR® soybean patent provides an excellent opportunity to explore the role of the IP system in relation to contemporary agriculture, food security, and IP issues. To get a sense of the impact of the expiration of the first-generation RR® patent, respondents were asked whether farmers prefer to keep using RR® first generation of soybeans in its generic form, or even whether generic seeds of RR® soybeans would be available in the market.[129] The RR® soybean and

129. *See Generic*, MARRIAM-WEBSTER (Apr. 15, 2021, 9:30 AM), https://www.merriam-webster.com/dictionary/generic [https://perma.cc/G4SM-WUAK] (A "generic" product (such as a drug) is one that does not have "a particular brand name"); Grant Gerlock, *Generic seeds could have a short lifespan*, HARVEST PLAINS PUB. RADIO (Mar. 6, 2013), https://www.hppr.org/hppr-economy-and-enterprise/2013-03-06/generic-seeds-could-have-a-short-lifespan [https://perma.cc/QPZ5-EN87] (explaining that a generic product, such as seeds, may be produced without patent infringement when the patent has expired. Typically, generic producers do not have to bear the cost of research and development. As a result, generic products are usually sold for lower prices than its branded equivalent because of the increase in competition among producers).

the RR® second generation soybean was profoundly important for all of the respondents. As one participant stated, Monsanto already switched the RR® soybean to the RR® 2 stacked with Bt. in Brazil. Another soybean breeder from EMBRAPA shared the same thought, asserting Intacta® RR® 2 Pro provides higher yield potential in specific regions in Brazil. In addition, this new technology gave farmers more freedom in the field regarding the spray time of herbicides. As mentioned previously, Monsanto introduced Intacta® RR® 2 Pro (herbicide tolerant and insecticide resistant) in South America in 2013, and Genuity® RR® 2 Yield (herbicide tolerant) in North America in 2009.[130]

This new technology of soybean has been approved for import in most countries, to include the United States, Japan, and several countries within the European Union.[131] One interviewee shared his perception on the new soybean technology regarding weed control, stating the change from conventional soybeans to RR® soybeans after 1995 was important, but the change from RR® soybeans to RR® 2 Pro made no difference as it relates to weed control. Despite this sentiment, most of the participants reported the production of RR® soybeans will stop soon as farmers want RR® 2 Pro soybeans because of the additional benefits.

Demand for RR® 2 Pro soybeans is increasing. As another participant noted, Brazilian farmers are acquainted and aware of the differences between RR® 1 and RR® 2. Compared to the RR® first-generation soybean, the RR® 2 Pro has many advantages for farmers in Brazil, especially given that the weather in most regions of Brazil is otherwise favorable for soybean pests. Many participants acknowledged the benefits of RR® 2 Pro soybeans to Brazilian farmers, with one stating the "RR® 2 Pro is tolerant to glyphosate, resistant to insects, higher yield potential," and therefore results in more beans per pod, more bushels per acre, and, finally, more potential for profits.

Interview participants reportedly observed changes in the availability of RR® soybean in the market. As one explained, Monsanto is trying to use any mechanism to reduce the availability of RR® first-generation soybean in the market. Another

130. *See* Fox Business News, *Monsanto Eyes 2013 Intacta RR2 Soybean Launch In Argentina*, SEED TODAY (Aug. 24, 2012), https://www.seedtoday.com/article/105497/monsanto-eyes-2013-intacta-rr2-soybean-launch-in-argentina [https://perma.cc/4ZTQ-YSCA]; Matt Hopkins, *Monsanto To Launch 2nd Generation Of RR Soybeans*, CROP LIFE (June 16, 2009), https://www.croplife.com/crop-inputs/seed-biotech/monsanto-to-launch-2nd-generation-of-rr-soybeans/ [https://perma.cc/7J9P-LTCN].

131. *See Monsanto's Intacta Rr2 Pro™ Poised To Deliver A New Wave Of Benefits For South American Countries*, AGRONEWS (March 26, 2013), http://news.agropages.com/News/NewsDetail—-9268.htm [https://perma.cc/SVM2-GJNQ].

claimed the RR® first-generation soybean will be a forgotten technology in the future. However, as mentioned previously, EMBRAPA has negotiated with Monsanto for the continued use and marketing of RR® first-generation soybeans for developing new varieties.[132]

EMBRAPA, farmers' associations, and other stakeholders are aware there will be no technology fees post patent expiration in 2014-2015 in Brazil.[133] Farmers, therefore, will pay less money for new cultivars developed by EMBRAPA containing the genes of the RR® first-generation.[134] Monsanto also confirmed that it will maintain the regulatory approval on RR® soybean until 2021, but as one participant confirmed, Monsanto will not do anything after this date.[135] One participant stated EMBRAPA may maintain regulatory approval beyond 2021 for specific markets—such as in China and the European Union—if it is inexpensive and simple to do so. Another reported that 65 percent of certified seeds and 35 percent of saved seeds in the market in the last season came from GM soybeans. The price of soybean seeds depends on demand and the Chicago Mercantile Exchange (American Financial and Commodity Derivative), as one participant stated, with additional considerations in export markets following the patent expiration. The relatively low prices of soybean seeds are an additional consideration. A summary of implications from patent expiration on herbicide tolerant soybean is illustrated in Figure 8.

132. *Monsanto Eyes 2103 Intacta RR2 Soybean Launch In Argentina*, *supra* note 131; Hopkins, *supra* note 131.

133. *See* Roger A. McEowen, EXPIRATION OF BIOTECH CROP PATENTS-ISSUES FOR GROWERS 2 (Apr. 8, 2011), https://www.calt.iastate.edu/system/files/CALT%20Legal%20Brief%20-%20Expiration%20of%20Biotech%20Crop%20Patents%20-%20Issues%20for%20Growers.pdf [https://perma.cc/LPA8-44AP].

134. *See id.* at 2.

135. *See generally id.* at 3.

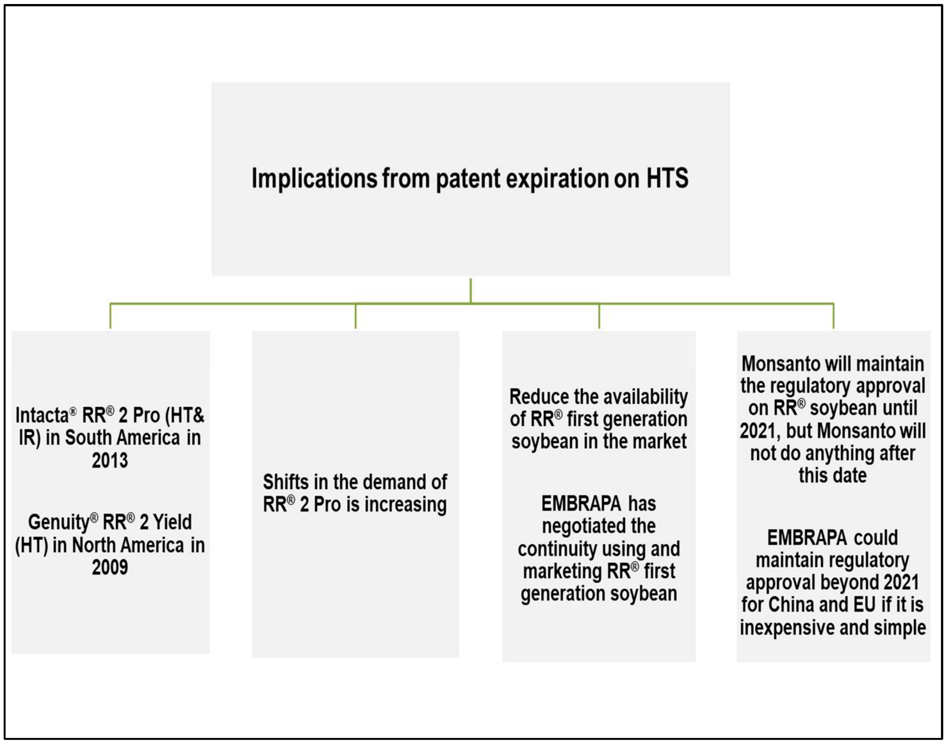


Figure 8. A summary of implications from patent expiration on herbicide tolerant soybean.

C. The Soybean Technology and Royalty System

EMBRAPA was the country's leading soybean plant breeder until the approval of the Cultivar, or the Plant Variety Protection Law, in 1997.[136] This Act has assured plant breeders and cultivar owners the legal IPRs over their cultivars, which could then generate royalties.[137] The Seed Law is managed by the Ministry of Agriculture, which regulates the production of certified and inspected seeds.[138]

136. Decreto No. 9.945, establishing the Plant Variety Protection Law and enacting other measures, Diário Oficial da Uniao [D.O.U.] de 4.28.1997 (Braz.); *Cultivar market*, EMBRAPA (Apr. 14, 2021, 4:38 PM), https://www.embrapa.br/en/tema-mercado-de-cultivares/perguntas-e-respostas [https://perma.cc/QCG6-CDXG].

137. Decreto No. 9.945, establishing the Plant Variety Protection Law and enacting other measures, Diário Oficial da Uniao [D.O.U.] de 4.28.1997 (Braz.).

138. *See Law No. 6.507 providing for the inspection and control on the production and trade of propagative materials*, ECOLEX (Apr. 15, 2021, 10:05 AM), https://www.ecolex.org/details/legislation/law-no-6507-providing-for-the-inspection-and-

This law regulates the national cultivar registry and approval of the bylaws of the national cultivar protection service.[139] Plant breeders' rights in Brazil are based on legislation passed in 1978 by the International Union for the Protection of New Varieties of Plants (UPOV), which allows farmers to save seeds to replant in the next season depending upon the bill and size of seeds, but prohibits their sale.[140] Plant Breeders' Rights are up for debate in the Brazilian Congress in order to update and to conform to the UPOV 1991.[141] Farmers oppose this update because it will change the equation in Brazil regarding saving seeds and commercialization of crop biotechnology.[142]

Private seed industries invested heavily in Brazilian markets after the implementation of IP laws in 2005. As one participant stated, farmers are affected by IP and they do not have the freedom to operate. Legislation and policy are sometimes difficult to understand. The technology fee is a major issue in the fight and debate between farmers and Monsanto. For instance, the Monsanto-soybean battle with farmers ended in 2014.[143] Monsanto offered to reduce the price on its new Intacta® RR® 2 Pro soybeans in exchange for dropping the case against Monsanto over royalties paid in previous years (from 2010-2014) on the RR® first generation.[144] This lawsuit involved a group of farmers who claimed Monsanto collected royalties on its expired patent in 2010 under Brazilian laws, while Monsanto defended this claim asserting that the international patent did not expire until 2014.[145]

There are two types of fees on the RR® soybean: royalty and technology fees. EMBRAPA protects a newly developed cultivar through PBR and collects

control-on-the-production-and-trade-of-propagative-materials-lex-faoc026398/ [https://perma.cc/BEW6-9RQ7].

139. *Id.*

140. International Convention for the Protection of New Varieties of Plants, Oct. 23, 1978, UPOV Pub. No. 295(E).

141. *See* Newton Silveiera & Alison Francisco, *The UPOV 1991 and a New Regulatory Framework for New Varieties of Plants in Brazil*, INSTITUTO BRASILEIRO DE PROPRIEDADE INTELECTUAL (Nov. 24, 2020), https://ibpi.org.br/the-upov-1991-and-a-new-regulatory-framework-for-new-varieties-of-plants-in-brazil/ [https://perma.cc/2Q5Z-7E9X].

142. *See* Behrokh M. Maghari & Ali M. Ardekani, *Genetically Modified Foods and Social Concerns*, 3 AVICENNA J. MED. BIOTECHNOL 109 (2011).

143. *See generally* Alastair Stewart, *South America Calling: Monsanto's Brazil Royalty Talks*, PROGRESSIVE FARMER (Jan. 11, 2013), https://www.dtnpf.com/agriculture/web/ag/blogs/south-america-calling/blog-post/2013/01/11/monsantos-brazil-royalty-talks [https://perma.cc/KH7F-2B2E].

144. *See id.*

145. *See id.*

royalties from farmers based on the UPOV system, whereas Monsanto collects technology fees from farmers on the patented gene at elevators or trade gates. One interviewee shared his thoughts, asserting that the grain elevator operators would test the soybeans to check whether they were RR® soybeans, and, if they were, the operator could collect a technology fee from farmers representing 7.5 percent of the soybean grain.[146] In accordance with this procedure, a farmer must show a receipt of purchase for RR® soybeans from Monsanto or other licenses. This documentation would provide evidence that farmers had paid the price of the seeds and technology fee. The test is called the strip test, for which Monsanto arranges and supports the cost.[147] The seed law in Brazil allowed farmers to save seeds in case of farmers' payback royalties and technology fees on the harvested seeds.[148] This approach is different from what is happening in the United States and Canada because of respective differences in IP protection and enforcement. Another interviewee indicated the patent on RR® first-generation of soybean is in the public domain and can be used freely as long as the trait and the seed containing it were acquired legally. It would be difficult without mandatory testing to differentiate between seeds that contain RR® first generation trait and seeds that contain RR® second-generation trait, which is still under patent.

Nowadays, Monsanto is concerned in testing Bt for the trait in the RR® 2 Pro by strip test. As one interviewee explained, Monsanto changed its policy regarding the price: they implemented one price that is the soybean price and technology fee combined into one set. This interviewee commented on the policy of Monsanto toward the price of soybean seeds, saying, "this change is happening because of intellectual property and farmers' attitudes towards IP in Brazil." A summary of the soybean technology and royalty system is shown in Figure 9.

146. *See generally Brazilian farmers battle Monsanto*, GMWATCH (July 25, 2012), https://www.gmwatch.org/en/latest-listing/51-2012/14091-brazilian-farmers-battle-monsanto-royalties [https://perma.cc/U3TU-36RF].

147. *See generally Rapid GMO Testing Kits for Leaf, Single Seed, and Bulk Grain Samples*, ENVIROLOGIX (Apr. 15, 2021, 8:57 AM), https://www.envirologix.com/gmo-testing/gmo-testing-kits-protein/ [https://perma.cc/MZ2V-LZJJ].

148. *Brazilian farmers battle Monsanto*, *supra* note 149.

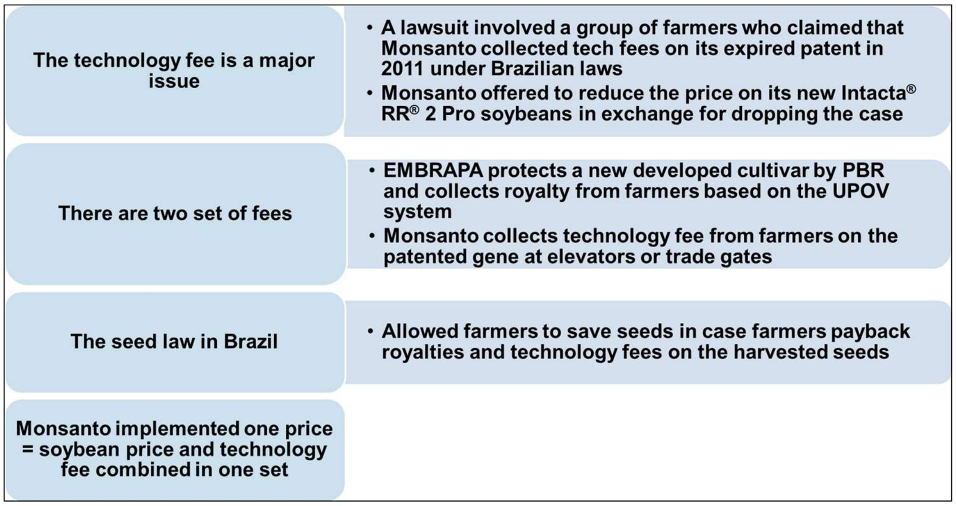


Figure 9. A summary of the soybean technology and royalty system.

Transgenic modified organisms are patentable in Brazil, according to the Industrial Property Law of 1996 as shown below in Table 5.[149] Yet, private seed industries are facing a problem of protection and enforcement of their intellectual property. From 1998 to 2005, RR® soybeans were not approved in Brazil and farmers were using soybean technology without paying a technology fee.[150] After 2005, Monsanto was able to launch and commercialize the technology RR® soybeans and receive royalty and technology fees. Monsanto previously charged a technology fee on the RR® first-generation U.S.$ 15/ha, which is cheaper than the technology fees on the RR® 2 Pro U.S.$ 30/ha.[151] One interviewee noted the price of RR® soybean is U.S.$ 115 per seed bag, which includes the soybean price and technology fees.[152]

Table 5. Intellectual property laws related to crop biotechnology enacted by the legislature in Brazil.[153]

149. Rodrigues et al., *supra* note 31, at 719.

150. F.M. Franke, et al., *The institutional and legal environment for GM soy in Brazil*, PLANT RSCH. INT'L (2009), https://edepot.wur.nl/15247 [https://perma.cc/XUF4-RTG9].

151. *See Brazilian farmers battle Monsanto*, *supra* note 149.

152. *Id.*

153. *Laws/Regulations*, WIPO LEX (Apr. 10, 2021, 2:43 PM), https://wipolex.wipo.int/en/legislation/members/profile/BR [https://perma.cc/A7NR-FFRU].

Intellectual Property Laws	**Law Number**	**Protection**
Industrial Property Law 1996	Law No. 9.279	Patents, trademarks, trade secrets
Plant Variety Act 1997	Law No. 9.456	Plant variety protection
Biosafety Law 2005	Law No. 11.105	Genetic resources, plant variety protection
Access and Benefits Sharing of Genetic Resources 2015	Law No. 13.123	Genetic resources, traditional knowledge

D. Canada and the United States

In light of their respective management of IPRs, the situation is drastically different in Canada's and the United States' soybean sectors as compared to the Brazil's.[154] The relevant IP management policies and strategies related to GM soybeans are the Patent Act, which covers soybean traits, and the Plant Breeders' Rights, both of which are found in Canada and the United States.[155] The trait patents on GM soybean are the most tested protection for soybeans, especially as compared to PBRs and plant cell patents.[156] Furthermore, the patent holder's internal IP policies, business and marketing strategies, and technology use agreements between the soybean developer and the purchasers (farmers), are relevant IP management policies and strategies related to GM soybeans. Licensing of patents is obviously essential for private industries in crop biotechnology.

To get a sense of policy issues and IP-related issues in crop biotechnology and the key IP related factors influencing the availability of soybean biotechnology in Canada and the United States' markets, respondents were asked to identify useful incentives to strengthen IPRs and improve crop biotechnology in soybeans. Further clarity is needed on patentable subject matter (e.g., higher life forms) through an updated Patent Act or guidance from the Canadian IP Office. As one

154. *See generally* Matthew S. Clancy & GianCarlo Moschini, *Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture* 3 (Iowa State Univ. Ctr. For Agric. & Rural Dev., Working Paper No. 17-WP 575, 2017), https://www.card.iastate.edu/products/publications/pdf/17wp572.pdf [https://perma.cc/HK3F-MZCM].

155. *See id.* at 4-5.

156. *See id.*

participant indicated, in a modern agricultural context the patenting of higher life forms remains controversial and has been the subject of two high-profile Supreme Court of Canada (SCC) decisions in the last 10 years.[157] The two cases are *Harvard v. Canada (Commissioner of Patents)* in 2002, and *Monsanto Canada Incorporated v. Schmeiser* in 2004, respectively.[158] The outcomes of the Harvard Mouse case culminated with a SCC decision that entire higher life forms—including plants and animals—were un-patentable.[159] Subsequent to the SCC decision, Harvard obtained a Canadian patent on the method of producing the mouse and its specific use in testing carcinogens.[160] One participant shared the same thought, asserting that this illustrated an important distinction between Canada's practice at that time, and practices of other countries—such as the United States—where the Harvard Mouse patent was granted on the entire life form.

In another case, Monsanto sued Schmeiser for patent infringement of RR® canola seeds without having paid for the technology.[161] The SCC held that unauthorized possession of canola plants incorporating Monsanto's patented genes and cells, for commercial purposes, constituted an infringement of the patent.[162] As was pointed out by one participant, the court drew a distinction between the patenting of a gene or cell, which it affirmed as being valid, and the patenting of the plant itself.[163] This participant elaborated by indicating that the decision was controversial and led to concerns amongst anti-GM, such as some civil society and consumer groups about the ability to patent "the genes of life" and quasi-related unease about corporate concentration in the agriculture and food sectors. However, stakeholders in the agricultural biotechnology sector received the decision positively, as the participant recognized "as it affirmed the validity of their gene and cell patents and demonstrated that they could successfully seek recourse in cases of infringement."

The participants asserted, the resultant changes in law and technologies created enforceable property rights, which in turn have conferred monopolistic rights to the inventor, leading to increased private investment in agricultural

157. *See* Harvard v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (Can.); Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.).

158. *See* Harvard, [2002] 4 S.C.R. 45 (Can.); *see also* Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.).

159. Harvard v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (Can.).

160. Erika Check, *Canada stops Harvard's oncomouse in Its tracks*, NATURE (Dec. 12, 2002), https://www.nature.com/articles/420593b [https://perma.cc/SVH6-2ZCL].

161. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.).

162. *Id.*

163. *Id.*

research. As participants continued commenting on the most useful incentives, strong and enforceable IPRs have provided the private sector in many industries with the incentive to invest significant amounts of time and money to undertake R&D. The expressed desire of crop sector representatives for improved value capture mechanisms for crops including what could be taken as an indication that the same is, or could be, true of agriculture. Another participant shared his thought regarding the most useful incentives, asserting that the creation of improved products creates value for farmers and end use customers. Whether it is herbicide tolerance or insecticide resistance, the farmers need to see increased yield or decreased cost to create an environment where investment in biotechnology is shared equally between farms, seed retailers, and Monsanto as the technology developer. As one participant elaborated, long term value is sometimes sacrificed for short term gain by a few individuals who infringe on patents; however, this is the minority and most farmers appreciate the benefits of the technology brought forward by biotechnology companies.

To get a sense of prevalent issues in the soybean sector and management of IP, the respondents were asked to identify the important issues concerning management of IPRs in soybean biotechnology and how IP can be leveraged for soybean biotechnology innovation. As one participant reported, the subject of IP as it relates to innovation does not end with the legislation. Many issues and disparate viewpoints also surround the organizational or "hands on" management of IP, both in the private sector and public research institutions. Issues related to IP management are distinct from the legislative issues. Participants asserted these issues primarily related to: 1) the management policy of the initial assignment of ownership (whether it be to the institution, the researcher, or the funder); 2) the transfer of ownership and management policies that are usually applied in practice by an office of technology transfer or other intermediary; 3) the length of time negotiating with public institutions; 4) the inconsistencies in management policies across public and academic institutions; 5) the lack of management of idle IP assets; and 6) cross-licensing thickets. As was pointed out by one participant, the issues from a business perspective largely deal with "the inconsistent approach and lack of best practices among research institutions, universities and government labs, and business-unfriendly IP management." Participants shared the same thought, asserting the existence of "misinformation and urban legends about current practices in the market." They continued their thoughts on leveraging IP for soybean biotechnology innovation so long as the legal system, regulators, and the science community continue creating reasonable certainty that a technology creator will be rewarded for innovation (creation of IP), then innovation can flourish and investment by companies, both large and small, will be sustained and lead to further innovation building on the base of existing technologies and crop types.

The pattern in the soybean industry is completely different from other biotechnology crops. To get a sense of patent expiration of RR® first-generation soybean, the respondents were asked to identify the implications of patent expiration for farmers. As one participant indicated, farmers will have to decide if they want to continue growing varieties incorporating this trait for which they no longer have to abide by contractual restrictions or take advantage of the benefits of newer varieties that may include contractual restrictions such as on saving and re-using seed. Another participant indicated that farmers now have the ability to save and plant RR® first-generation soybeans as long as the variety does not have another form of IP. Even though the patent on RR® first-generation soybeans has expired, in many cases there are other forms of IP on some varieties including plant cell patents, plant breeders' rights, and single-use contracts.

A soybean seed's herbicide tolerance trait only comprises a part of its value.[164] Much of the investment goes to creating genes that have value by creating yield, disease resistance, and suitability to specific geographies.[165] One participant asserted farmers will be the beneficiary of patent expiration as companies invest to create new traits including RR® 2 Yield and RR® 2 Xtend that provide improved features and benefits to their soybeans. Even though farmers could access the RR® first-generation soybean technology and save and re-use that seed on their farm, most participants reported not doing so because there are new and enhanced options available in the marketplace with benefits they are willing to pay for.

Another participant asserted farmers do not want to pay the royalty and technology fees. One participant shared the same thought, indicating greater availablity and use of off-patent soybean varities, such as lower costs for seed that provides greater incentive to save seed of off-patent varieties for future replanting, plus potential market access challenges for farmers if developers no longer support "discontinued" RR® first-generation soybean varieties. Monsanto has made information available to farmers on the use and management of RR® first-

164. *See generally* Craig Adeyanju, *The Top Factors that Move the Price of Soybeans*, FUTURES KNOWLEDGE (Oct. 28, 2014), http://www.futuresknowledge.com/news-and-analysis/grains/the-top-factors-that-move-the-price-of-soybeans/ [https://perma.cc/4UUG-JH76].

165. *Return on investment in genebanks,* CROP TRUST (June 17, 2021, 2:28 AM), https://www.croptrust.org/our-mission/crop-diversity-endowment-fund/return-investment-genebanks/ [https://perma.cc/QT9N-EB9C].

generation soybean varieties whose patent has expired.[166] Monsanto is investing in new traits that create value for farmers who grow soybean such as RR® 2 Yield and RR® 2 Xtend.[167] As one participant indicated, farmers will always benefit from increased competition and investment. The choice of what kind of technology to use remains with the farmer. Another participant asserted, "Farmers enjoy the freedom using RR® first-generation without paying the royalty; Monsanto is allowing the free use."

The Canadian IP regime is often criticized for not keeping pace with improvements and system modernizations of its closest competitors, notably the United States and the European Union. As one participant indicated, as research and development costs continue to rise and the rate of turnover of new inventions increases, there is an even greater need to collaborate with other sectors and other countries in order to share costs and benefits. In this environment, the abiltiy to negotiate and protect IPRs is critical, and a clearly defined operating environment becomes increasingly important. These trends are fueling a worldwide drive to strengthen IPRs. For instance, the United States has become one of the most attractive countries for biotechnology investment, in part due to its patenting environment, which is considered to be one of the world's strongest.[168] As was pointed out by one participant on strengthening Canada's IP regime, by amending the Patent Act to allow for explicit patenting of higher life forms, proponents argue that this is necessary to bring Canada in line with its international competitors and create incentives for foreign investment. Intellectual property and technology transfers would enable Canadian producers to have access to cutting-edge innovations.

Others argue that overly protective IP regimes could inhibit competition, innovation, and the diffusion of knowledge and technology. As one participant pointed out, patent thickets and the complexity of cross-licensing are evidence of this. This participant continued to elaborate, saying that an uncompetitive IP regime is thought to discourage both domestic and foreign investment and commercialization, and, in turn, disadvantage the import and export potential of a nation. Perhaps this is a rational reason behind the deals and mergers of the largest

166. *See generally* CTR. FOR FOOD SAFETY, *supra* note 13, at 19.

167. *See Roundup Ready 2 Yield® Soybeans*, BAYER (Aug. 30, 2021), https://traits.bayer.com/soybeans/Pages/Roundup-Ready-2-Yield.aspx [https://perma.cc/BL6V-DL25]; *Roundup Ready 2 Xtend® Soybeans*, Bayer (Aug. 30, 2021), https://traits.bayer.com/soybeans/Pages/Roundup-Ready-2-Xtend.aspx [https://perma.cc/EVH6-4MWD].

168. Naomi Davies, *US top destination for biotech investment*, FDI INTELLIGENCE (Aug. 25, 2020), https://www.fdiintelligence.com/article/78316 [https://perma.cc/SNH8-TLR8].

multinational companies, such as Bayer AG and Monsanto, Syngenta and ChemChina, and Dow Chemical and Dupont in recent times.[169]

To get a sense of the key IP-related factors influencing the availability of RR® soybeans in the market, one participant reported that single-use contracts, plant breeders' rights, and plant cell patents contribute to the availability of RR® soybeans on the market. But the biggest factor influencing the availability of RR® soybeans is the performance advantage with new traits and breeders' choice that provide the best chances of success for their genetics. Participants indicated that "ownership and patent" are influencing the availability of RR® soybeans. There is demand for enhanced seed technology that includes better quality and yield. This demand might drive the availability of soybean biotechnology or lack thereof. As one participant indicated, Monsanto believes in providing access to "knowledge inside seeds" by broadly licensing traits so that other breeders and companies can leverage the value of the trait in their own genetics and provide the benefits of the trait to more farmers.

One challenge with seed technology is that it only provides a benefit once inserted into a seed. As was pointed out by one participant on balancing IPRs and the benefits of access to knowledge inside seeds was how to both share and protect simultaneously. The GM-tolerant herbicide has contributed to the diffusion of GM soybeans in Canada and elsewhere. As one participant indicated, the development of shorter season varieties adapted to the Canadian climate has had a greater impact on diffusion of GM soybeans than the GM trait itself. Farmers are looking for ways to decrease their input costs and labor in managing their crops during the growing season. As one participant indicated, GM varieties have allowed farmers to do this, but there is still a significant demand for non-GM food grade soybeans for overseas markets, such as Japan. In considering whether the absence of IP or the presence of IP has led to the diffusion of GM soybean, one participant reported that the diffusion of this trait happened rapidly in countries where there are systems to protect IP and also in countries that did not protect IP effectively. Another participant commented that an individual GM trait prevalence in the market is more related to the value it creates than the presence of IP; however, IP will enable an environment where traits with value are created and commercialized. A summary of complimentary findings from the United States and Canada is shown in Figure 10.

169. *See* MacDonald, *supra* note 86.

The biggest factor influencing the availability of RR® soybeans	**The AgAccord (in the U.S.)**	**The PVP in Canada and USA prevents farmers from saving seeds**
• **The performance advantage with new traits and breeder's choice to breed with the newest traits that provide the best chance of success for their genetics**	• **To address IP issues post patent expiration in seed biotechnology and support a transition to the marketplace.** • **The Generic Event Marketability and Access Agreement (GEMMA) & the Data Use and Compensation Agreement (DUCA)**	• **Public research institutions would continue to offer soybean varieties containing RR® first generation trait post patent expiration**

Figure 10. A summary of complimentary findings from the United States and Canada.

IV. DISCUSSION

Collaboration, incentives, protection, and enforcement compose an integrative model to analyze the effects of IPRs on crop biotechnology. It is clear from this research that EMBRAPA collaborates with other seed companies—in particular Monsanto—to incorporate RR® first-generation soybeans into their conventional seeds post-patent expiration. The research indicates that the RR® first-generation soybean will remain for a period of time in the commercial supply chain. Although, the research suggests that demand of RR® first-generation is limited because Brazilian farmers are already acquainted and benefitting from the RR® second-generation in most regions with increased yield, weed control, and insect control. The research also indicates that RR® first-generation may becoming a forgotten technology, particularly after 2021 as the regulatory approval of this technology expires. These findings resonate with introducing the RR® second-generation by Monsanto to reduce the availability of old seed technology.

Licensing of GM traits appears to be an essential business practice between private and public research institutions.[170] This can facilitate access to crop biotechnology, which in turn would quicken the dissemination of new technologies, all the while sharing the risk and financial resources in research and development activities.[171] Monsanto had a licensing agreement with Dow AgroSciences to use the RR® second-generation soybean and to stack it with other traits.[172] DuPont chose to not act as a licensee of the RR® second-generation soybean trait, and instead asserted its legal rights to use the RR® second-generation soybean in stacks with other soybean traits rejecting the decision to license this soybean trait.[173] Other soybean breeders from American public research institutions were able to incorporate the RR® gene into varieties after the patent expiration.[174] Public research institutions in North America were breeding with the RR® first-generation soybean for several years, and some of them continued breeding even after the patent expiration.[175] Some of these research institutions that have launched their own generic traits include the University of Arkansas, UA 5414RR, and the University of Missouri.[176] The price of generic soybean was half the price of the RR® second-generation soybean.[177] Farmers do not have to pay technology fees and can save the seeds obtained from the harvest to plant in the next season. However, the plant breeders at the University of Arkansas believe that the UA 5414RR generic trait provides 7 percent less seed yield than the second-generation RR® soybean.[178] These seeds were sold to Arkansas farmers and local seed dealers who distributed these seeds in Nebraska, Kansas, Missouri, South Carolina, Alabama, Louisiana, and Texas.[179]

170. Moschini, *supra* note 86.
171. *See id.*
172. Norman W. Hawker, *Competition Issues Arising from Generic Biotech Crops,* 18 DRAKE J. AGRIC. L. 137, 139-140 (2013).
173. McEowen, supra note 135, at 3.
174. *Id*.
175. *See id*.
176. *See generally id.*
177. *See generally id.*
178. *See generally id.*
179. *See generally id.*

An important issue concerning management of IPRs is the potential for generic soybeans in the market. For the participants interviewed in this research, RR® first-generation soybean was profoundly important, despite a quick switch over to the RR® second-generation. The findings show that Brazilian farmers are benefiting from the RR® second generation which justifies the quick switch over to this technology. The research demonstrates that the competition with generic traits is still within public research institutions, which has resulted in lower prices of soybean seeds. Other implications of post-patent expiration and availability of generic soybeans as suggested by the findings, include farmers that do not have to pay the technology fee and can save seeds to replant in the next season. However, market forces could influence the availability of generic soybeans. For example, Monsanto asserted that the regulatory approval on the RR® first generation is sustained until 2021.[180] After 2021, health and safety data is needed for regulatory approval.[181]

The findings of this research indicate that Monsanto will discontinue the regulatory responsibility after this date. In the United States, life science industries created AgAccord to address IP issues post-patent expiration in seed biotechnology and support a transition to the marketplace.[182] There are two important agreements in the AgAccord that cover issues related to patent expiration: The Generic Event Marketability and Access Agreement (GEMMA) and the Data Use and Compensation Agreement (DUCA).[183] Under the GEMMA, Monsanto decided to sustain and share regulatory responsibility until 2021 at no cost to users of the generic soybeans.[184] Under DUCA, access to health and safety data is mandatory in case Monsanto exits the market, and public or private research organizations want to use off-patent traits of soybeans as a single trait or stack off-patent traits with other traits.[185]

It seems this framework of management strategy by the biotechnology industries is similar to the Hatch-Waxman Act in pharmaceutical industries in the United States. This Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984, addresses issues related to genetics in the

180. Moschini, *supra* note.

181. *See id.*

182. *See About the AgAccord*, THE AGACCORD (April 9, 2021, 6:23 PM), http://agaccord.org/?p=about [https://perma.cc/7PPF-MXD3].

183. *See id*.

184. *See id.*

185. *See generally* Brian Wallheimer, *Living in a Post-Patent World*, SEEDWORLD (June 16, 2015), https://seedworld.com/living-in-a-post-patent-world/ [https://perma.cc/CSB6-43DV].

pharmaceutical industry.[186] For example, this law allows generic drug companies to access research and regulatory data (enablement) by the original innovator.[187] The regulatory approval of GM soybeans in the import countries needs to be renewed periodically. In China, applications must be submitted every three years, and in the European Union and Japan, every 10 years.[188] In contrast, in the United States, the GM soybeans are deregulated and approved indefinitely.[189] The findings of this research show that EMBRAPA might take steps to gain regulatory approval after 2021 to avoid trade disruption, but only if it is simple and inexpensive.

The technology fee and royalty model of plant variety contributes toward the fixed cost of the research and development that generates the intellectual property.[190] Life science industries controls patented plants by prohibiting seed crops from being produced by a farmer, for subsequent generations of planting.[191] In addition to patent rights, Monsanto adopted a successful soybean commercialization model that requires farmers to sign an agreement to limit the use of the seed to one planting season.[192] Based on this agreement, farmers cannot use or sell the seeds of the harvested crop.[193] The findings demonstrate that technology fees in seed biotechnology are a major issue for life science industries and farmers. In Brazil, for example, there was a 2014 lawsuit between Monsanto and soybean farmers in which Monsanto offered to reduce the price of its RR® second-generation soybean in exchange for dropping the case against Monsanto over royalties paid in previous years on the RR® first-generation soybean.[194] The RR® first-generation soybean trait (USP 5,352,605), as was shown previously in Table 1, was granted patent in 1994 and therefore expired in 2011.[195] This occurred under the old regime in the United States where a patent received a 17-year term

186. MATTHEWS, *supra* note 109, at 5-6.

187. *Id.*

188. Grushkin, *supra* note 88, at 10; Hawker, *supra* note 175, at 144.

189. Grushkin, *supra* note 88, at 10-11; Hawker, *supra* note 175, at 137-155.

190. OECD, INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL AND AGRO-FOOD BIOTECHNOLOGIES TO 2030 13-14 (2008), https://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/40926131.pdf [https://perma.cc/Q5RT-F3BA].

191. *See* Anthony C. Tridico & Mareesa A. Frederick, *Planting the Seeds of Infringement: The Application of the First Sale Doctrine to Self-Replicating Technology*, FINNEGAN (2013), https://www.finnegan.com/en/insights/articles/planting-the-seeds-of-infringement-the-application-of-the-first.html [https://perma.cc/Z2LW-YSMV].

192. *Id.*

193. *Id.*

194. *See, e.g.*, Peschard & Randeria, *supra* note 126, at 797.

195. U.S. Patent Full-Text and Image Database, *supra* note 99.

from its grant date.[196] Some patentees complained to the United States Congress that they would be harmed by the change in patent term provisions under the law and Congress enacted a bill to conform to the General Agreement on Tariffs and Trade (GATT) after the Uruguay Round in 1995.[197] This amendment by Congress also extended the term of patents from a 17-year to 20-year post grant.[198] Monsanto managed to extend some patent claims to 2014 (five years from the re-examination process in 2009) using a re-examination process (RE 39,247) and maintained that this extension also applied in Brazil, Canada, and elsewhere.[199] This process, which can be requested by any person other than the right holder to challenge the validity of a patent based on prior art, involves having the patent office re-examine the issued patent as a new patent application.[200] The patent owner can submit new claims, provided they are not broader than the claims in the original patent.[201] The re-examination certificate will incorporate new claims determined to be patentable.[202] This might remove any ambiguity and dispute of the date of patent expiration (i.e. 2014 instead of 2011) on the RR® first-generation soybean which applies in Brazil, Canada, and elsewhere.

It is clear from this research that patent expiration on the RR® first-generation offers opportunities for farmers to avoid paying technology fees and the ability to save seeds for replanting in the next season. This would further inform the continuity of EMBRAPA integrating the RR® first-generation soybean into varieties because EMBRAPA is a public research institution that has social responsibility toward farmers. This indicates that the IP management strategy of EMBRAPA is to make RR® first-generation soybean available to farmers post-patent expiration, without paying technology fee on the harvested seeds, while ensuring compliance with the seed law in Brazil which would allow farmers to save seeds for replanting purposes. In contrast to the seed laws in Brazil, the plant variety protection in Canada and the United States prevent farmers from saving seeds. These findings complement perspectives from the American Soybean Association that public research institutions would continue to offer soybean varieties containing RR® first-generation trait—post patent expiration. This, however, can be influenced by the performance advantages with new traits and demand for enhanced seed biotechnology.

196. *Id.*
197. Hawker, *supra* note 175, at 143.
198. *Id.*
199. *See, e.g.*, Peschard & Randeria, *supra* note 126, at 795.
200. *See* 35 U.S.C. § 303.
201. *Id.*
202. U.S. Patent Full-Text and Image Database, *supra* note 99.

V. CONCLUSIONS

The case of soybean biotechnology is a case in point of internationalized IP management practices of a dominant crop biotechnology. Monsanto is one of the largest patent holders worldwide in crop biotechnology.[203] In Brazil, Monsanto still has licensing agreements with EMBRAPA to incorporate the RR® first-generation into their conventional seeds.[204] But lack of intellectual property protection and enforcement in Brazil encouraged farmers to save RR® soybean seeds for planting and resale.[205] Therefore, Brazilian farmers could relinquish the technology fee on soybean seeds.[206] Although, the soybean biotechnology of Monsanto and other private industries are protected by patent in Brazil, when a patent expires, others will be free to copy whatever it protects without fear of infringement.[207]

This case has also shown that national legislation is not always in line with other regional or international standards. This paper identified collaboration between EMBRAPA and private industries relevant to IPRs in crop biotechnology. In particular, this paper discussed implications from patent expiration on herbicide tolerant soybean, the soybean technology and royalty system, and the essence of IP management as a successful coexistence in Canada and the United States. Enforcement of national laws that comply with the trade-related legislation, such as TRIPS, is a very important aspect in the case of soybean biotechnology.[208] The TRIPS agreement mandates strong patent protection for nearly all inventions across country boundaries and provides opportunities for countries to design their IP regimes to their own specific circumstances, to allow utilization of local resources without the intervention of IPRs.[209]

Legal approval for genetically modified crops is required prior to commercializing crop biotechnology and this is also applicable to generic version producers. Most countries, including Brazil, developed a regulatory structure for

203. CTR. FOR FOOD SAFETY, supra note 13, at 4.

204. Marcelo D. Varella & Maria E. Marinho, *Contesting Monsanto's Patents on Life: Transnational Juridical Dialogue and the Influence of the European Court of Justice on Soybean-Exporting Countries*, 16 TUL. J. TECH. & INTELL. PROP. 79, 95 (2013).

205. Guilherme Fowler de Avila Monteiro & Decio Zylbersztajn, *Economic Governance of Property Rights: Comparative analysis on the collection of royalties in genetically modified soybean seeds*, 51 REV. ECON. SOCIOL. RURAL 25, 31 (2013).

206. Varella, *supra* note 3, at 73.

207. *See id.* at 79.

208. Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 318.

209. *Id.* at 312.

GM crops based on science and provided a clear and transparent system for such approval.[210] The case of RR® soybeans in Brazil brought up debates that continued for more than six years.[211] The debate started with the commercialization approval of RR® soybeans in 1998 by the National Biosafety Technical Commission (CTNBio), which was created in 1995 within the Ministry of Science and Technology and continued until 2005.[212] This debate ended by authorizing the first harvest of the GM soybean in the country.[213] The holdups of releasing GM crops, including GM soybeans, have cost the Brazilian economy about U.S. $ 28.75 billion to date.[214]

The specific case of the RR® soybean resulted in the empirical analysis of issues arising in IP management of crop biotechnology. As discussed above, soybean is one of the most important crops in developed and developing countries. The diffusion of GM soybean technology happened rapidly in these countries due to the value this technology creates for farmers.[215] The same seems to be largely true today. The challenges facing technology transfer in GM soybean are highly relevant to the agri-food sector in Brazil and can inform global crop biotechnology IP-related policy and practices. Of particular importance are issues related to seed saving by farmers, which has proven somewhat more difficult. Life science industries invest significant resources in detecting violations and initiating lawsuits in North America related to seed saving of their transgenic varieties. Adequate protection and incentives for GM trait development depend upon seed laws, biosafety regulation, and IPR regimes.

The research unearths some of the contemporary challenges life science industries face with the IPRs associated with soybean biotechnology. The seed biotechnology industries that hold IPRs on their inventions are compensated through technology fee and royalties.[216] This approach has played an important

210. Eduardo Soares, *Restrictions on Genetically Modified Organisms: Brazil*, LIB. CONG. (Mar. 2014), https://www.loc.gov/law/help/restrictions-on-gmos/brazil.php [https://perma.cc/HTU7-9QMZ].

211. *See* Peschard, *supra* note 1.

212. Gutenberg Delfino de Souza et al., *The Brazilian GMO Regulatory Scenario and the Adoption of Agricultural Biotechnology*, WORLD OF FOOD SCI. (Apr. 20, 2021, 10:34 AM), http://worldfoodscience.com/article/brazilian-gmo-regulatory-scenario-and-adoption-agricultural-biotechnology [https://perma.cc/E7KL-Z3NP].

213. *Id.*

214. Galvão, *supra* note 45.

215. de Souza, *supra* note 215.

216. N.P. LOUWAARS ET AL., IMPACTS OF STRENGTHENED INTELLECTUAL PROPERTY RIGHTS REGIMES ON THE PLANT BREEDING INDUSTRY IN DEVELOPING COUNTRIES: A SYNTHESIS OF FIVE CASE STUDIES 4 (2005).

role in fostering new investments in Brazilian soybean production. This research aimed to create greater internal and external awareness of IP management issues in crop biotechnology innovation. Finally, from the findings in this paper, it is clear that more research is needed to further examine how to reconcile IPRs with farmers' rights and other local interest. Additional evaluation of the impact of IP related policies and initiatives would need to aim to promote the transfer and dissemination of crop biotechnology.

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VII. Declaration of Interest Statement

The authors report no conflict of interest. The funders had no role in the design of the study: in the collection; analyses; interpretation of data; in the writing of the manuscript; or in the decision to publish the results.