INTELLECTUAL PROPERTY AND SHARING REGIMES IN AGRICULTURAL GENOMICS: FINDING THE RIGHT BALANCE FOR INNOVATION

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I. INTRODUCTION

Investors in agricultural genomics share the goal of fostering further innovation and improving the health of consumers.[1] This goal is particularly im-

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portant when the products of research may help address food security concerns associated with the effects of climate change.[2] In addition to research, innovation in plant breeding and genomics has always been highly dependent on access to high quality, diverse breeding materials.[3] At present there is a robust discussion surrounding innovation and access to resources while funders and industry alike find sources of research and development funding to be less than ideal.[4] One recurrent aspect of this discussion is whether present intellectual property (IP) practices and governance encourage or, alternatively, stand in the way of innova-

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1. *See* Wilf Keller, *Agriculture-Plants: Crop Genomics for a Healthy Canada*, GENOME CANADA, 2, 4 (July 3, 2007), http://www.genomecanada.ca/medias/PDF/en/Agriculture-Plants.pdf (describing how Canada's investment in plant-based genomics research and prioritizing of agricultural innovation has the potential to have a positive impact on human health in the country).

2. *See* Charles Siebert, *Food Ark*, NAT'L GEOGRAPHIC MAG., July 2011, http://ngm.nationalgeographic.com/2011/07/food-ark/siebert-text (discussing the challenges posed by climate change and an increasing global population, which demands solutions such as the use of seed banks to preserve and store different crop varieties that may provide the needed diversity to adapt to climate change); *see also* Matthew Rimmer, *The Doomsday Vault: Seed Banks, Food Security and Climate Change*, *in* INTELLECTUAL PROPERTY AND EMERGING TECHNOLOGIES: THE NEW BIOLOGY (Matthew Rimmer & Alison McLennan ed., 2012); Laura K. Snook et al., *Crop Germplasm Diversity: The Role of Gene Bank Collections in Facilitating Adaptation to Climate Change*, *in* CROP ADAPTATION TO CLIMATE CHANGE 495–506 (Shyam S. Yadav et al. eds., 2011) (describing the role of gene bank collections in providing access to information and reproductive material for researchers, breeders, and farmers studying and adapting to climate change).

3. *See* Graham Dutfield, *Turning Plant Varieties into Intellectual Property: The UPOV Convention*, *in* THE FUTURE CONTROL OF FOOD 27, 43 (Geoff Tansey & Tasmin Rajotte eds., 2008) (suggesting "innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as possible."). "Germplasm" is a term commonly used when discussing plant genetics stock, and includes all living tissue from which new plants can be grown, including seeds, stems, leaves, pollen, or even just a few cells that can be cultured into an entire plant. It is used by geneticists and plant breeders to "describe the genetic stocks within a species of plants collectively." Charles R. McManis & Eul Soo Seo, *The Interface of Open Source and Proprietary Agricultural Innovation: Facilitated Access and Benefit-Sharing Under the New FAO Treaty*, 30 WASH. U. J.L. & POL'Y 405, 413–14 (2009) (citing JOHN MILTON POEHLMAN, BREEDING FIELD CROPS 4–5 (3d ed. 1987)).

4. *See, e.g.*, Kevin Lynch & Munir Sheikh, *Wanted: Culture of Innovation*, GLOBE & MAIL, Sept. 16, 2011, http://www.theglobeandmail.com/commentary/wanted-culture-of-innovation/article594471/ (analyzing Canada's struggle with productivity and innovation and discussing four areas where successful innovation happens); Konrad Yakabuski, *Canada's Innovation Gap*, GLOBE & MAIL, July 27, 2010, http://www.theglobeandmail.com/report-on-business/commentary/canadas-innovation-gap/article1203108/ (discussing Canada's poor record of innovation and explaining that "innovation is the only sure way for Canada to [create wealth and] be more productive").

tion in agricultural genomics.[5] Some claim that exclusive IP rights ensure incentives for innovation and are key drivers of the recent surge of innovative research in biotechnology.[6] Others claim proprietary policy models hinder innovation (particularly in the context of development programs), and recommend open sharing models as an attractive alternative.[7]

The Intellectual Property and Policy Research Group (IPPRG) has examined a range of approaches to intellectual property and sharing in genomics.[8] Based on the IPPRG's studies of human, animal, and agricultural genomics, we believe that a balance of IP and sharing possibilities are fundamental to support ongoing innovative research. In agricultural genomics, frameworks for IP protection and sharing have been largely established through the development of international agreements implemented in diverse ways by national governments.[9]

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5. *See generally Patents and Innovation: Trends and Policy Challenges*, ORGANISATION FOR ECON. CO-OPERATIONS AND DEV., 9–10 (Jan. 16, 2004), http://www.oecd.org/dataoecd/48/12/24508541.pdf (summarizing views on both sides of the debate and highlighting various factors and features that can promote or discourage further innovation).

6. *See* John Manley, *Intellectual Property: A New Kind of Arms Race, with Patents as Ammo*, GLOBE & MAIL, Oct. 5, 2011, http://www.theglobeandmail.com/news/opinions/opinion/intellectual-property-a-new-kind-of-arms-race-with-patents-as-ammo/article2190761/ (examining Canada's intellectual property regimes and arguing that "Canada needs an intellectual property framework that fairly balances the rights of creators, consumers and society as a whole."); Barrie McKenna & Richard Blackwell, *Canada Picks Up Pace in Patents*, GLOBE & MAIL, Aug. 24, 2011, http://www.theglobeandmail.com/report-on-business/small-business/sb-growth/going-global/canada-picks-up-pace-in-patents/article1873617/ (describing the recent patent surge in Canada and Canada's "culture of innovation"). *But see Patents and Innovation: Trends and Policy Challenges*, *supra* note 5, at 9 (explaining that patents can encourage or hinder innovation depending on specific conditions, such as where they "limit[] access to essential knowledge").

7. *See* Claude Henry & Joseph E. Stiglitz, *Intellectual Property, Dissemination of Innovation and Sustainable Development*, 1 GLOBAL POL'Y 237 (2010) (arguing the "dysfunctional approach" of the current global regime has been designed disproportionately by special interests in the United States, and that consideration of alternative models, such as open-source and publically-financed innovation, would be more beneficial on an international level).

8. See *About*, INTELL. PROP. & POL'Y RES. GROUP, http://ipprg.wordpress.com/about-2/ (last visited Sept. 19, 2012) for more information on this organization. For more details on the IPPRG's current project, the GE^{3}LS component of the Genome Canada funded "Genomics of Sunflower" Project, see *Genomics of Sunflower*, SUNFLOWER GENOME, http://www.sunflowergenome.org/ (last visited Sept. 19, 2012). While the primary focus of the project is on genomics sequence and mapping data, other potential outputs of the project (and the more relevant products for our purposes) include products such as a drought tolerant woody sunflower, suitable for creating an available dual use (food-fuel) biomass in developing countries. *Id.*

9. *See, e.g.*, International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, S. TREATY DOC. NO. 110-19 (signed by the United States Nov. 1, 2002) [hereinafter ITPGRFA]; Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS]; International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89 (as revised at Ge-

The existing regimes initially grew out of efforts to guarantee proprietary protections, which historically had not been available, for innovations related to plants and agriculture.[10] With those regimes came growing concerns about (and a set of agreements aimed at) preserving key agricultural resources for food and agriculture,[11] and preserving domestic biodiversity.[12]

In this Article, we review the major legal and policy regimes that govern IP and sharing in the agricultural genomics arena. While we take the view that there must be a balance between options for proprietary protection and sharing of genetic resources, the current set of agreements is piecemeal and immensely complex. It is not clear, in any case, that an effective balance has yet been reached. An array of international and national IP and sharing regimes impose very different—and sometimes conflicting—requirements on potential innovations in the agricultural genomics space. This state of complexity has the potential to undermine the practice of (and investment in) innovative research, though further study is needed in this area.[13] We discuss herein the appearance of small-scale, multi-stakeholder initiatives aimed at resolving case-specific conflicts between sharing and IP interests, as well as broad-scale initiatives to examine existing regimes and identify norms in international IP rights management.[14] We conclude that there is a need for further efforts directed towards finding an encom-

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neva on Nov. 10, 1972, Oct. 23, 1978, & Mar. 19, 1991) (entered into force Aug. 10, 1968) [hereinafter UPOV] (translated into English as the International Union for the Protection of New Varieties of Plants).

10. *See* Graham Dutfield, *Turning Plant Varieties into Intellectual Property: The UPOV Convention*, *in* THE FUTURE CONTROL OF FOOD (Geoff Tansey & Tasmin Rajotte eds., 2008).

11. *See, e.g.*, Elisabetta Gotor et al., *The Perceived Impact of the In-Trust Agreements on CGIAR Germplasm Availability: An Assessment of Bioversity International's Institutional Activities*, 38 WORLD DEV. 1486 (2010) (discussing the mission and objectives of the Consultative Group on International Agricultural Research (CGIAR) to conserve genetic material of major staple crops to make it freely available for breeding and research in food security and productivity).

12. *See* The Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79, 31 I.L.M. 818 [hereinafter CBD] (entered into force Dec. 29, 1993). The CBD has three main objectives: "(1) The conservation of biological diversity[,] (2) The sustainable use of the components of biological diversity[, and] (3) The fair and equitable sharing of the benefits arising out of the utilization of genetic resources." *Introduction*, CONVENTION ON BIOLOGICAL DIVERSITY, http://www.cbd.int/intro/ (last visited Sept. 19, 2012).

13. There are numerous anecdotes, including within our own work, which suggest that conflicting commitments to proprietary or shared outputs amongst stakeholders can slow or otherwise hinder funding for potentially innovative research. We discuss some of these anecdotes in detail below.

14. *See* GRAEME B. DINWOODIE & ROCHELLE C. DREYFUSS, A NEOFEDERALIST VISION OF TRIPS: THE RESILIENCE OF THE INTERNATIONAL INTELLECTUAL PROPERTY REGIME (Oxford Univ. Press 2012).

passing solution for enabling IP protection while balancing proprietary approaches with the means of accessing plant genetic resources (PGRs).[15] We believe a better balance between IP protection and sharing of genetic resources and knowledge will ultimately foster investment and stakeholder confidence in innovation.

II. THE INTERNATIONAL SPECTRUM: FROM SHARING TO PROPRIETARY PROTECTIONS

A. *Background on Proprietary Rights and Sharing*

The existence of proprietary rights relating to agricultural genomics and seeds represents a relatively recent development in the history of plant breeding. Historically, plant and seed material were regarded as communal resources to be freely shared.[16] Indeed, normal agricultural practices permitted—and even expected—farmers to save, replant, and resell seeds to other farmers.[17] Trait development gradually became dependent on academic and farmer sharing, and the

15. Plant genetic resources, or PGRs, are defined in the International Treaty on Plant Genetic Resources for Food and Agriculture as "any genetic material of plant origin of actual or potential value for food and agriculture." ITPGRFA, *supra* note 9, at art. 2. This definition is consistent with the terminology used in the U.N.'s Convention on Biological Diversity. *See* CBD, *supra* note 12, at art. 2.

16. *See* Margaret Llewelyn, *The Legal Protection of Biotechnological Inventions: An Alternative Approach*, 19 EUR. INTELL. PROP. REV. 115, 117 (1997) (explaining that originally the patent system was viewed as an inappropriate restriction on plant life); *Integrating Intellectual Property Rights and Development Policy*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 58 (Sept. 2002), http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (indicating that the historical role of IP in agriculture was its application to mechanical inventions, and that protection of plant varieties developed only recently, and was shaped by prevailing economic conditions of developed countries); *see generally* Carl E. Pray & Anwar Naseem, *The Economics of Agricultural Biotechnology Research, ESA Working Paper No. 03-07*, AGRIC. & ECON. DEV. ANALYSIS DIV., FOOD & AGRIC. ORG. OF THE U.N. (2003), *available at* ftp://ftp.fao.org/docrep/fao/007/ae040e/ae040e00.pdf (describing the shift from public investment (for the public good) in agricultural research to private (for profit) investment, which has had a direct impact on how developing countries access agricultural technology, especially seeds, which they have traditionally accessed by sharing or saving methods).

17. *See* Laurent Belsie, *Plants Without Seeds Challenge Historic Farming Practices*, CHRISTIAN SCI. MONITOR, July 30, 1998, http://www.csmonitor.com/1998/0730/073098.feat.feat.6.html (describing the practice of seed-saving historically as a fundamental tenet of agriculture with far-reaching cultural significance); Rick Weiss, *Seeds of Discord; Monsanto's Gene Police Raise Alarm on Farmers' Rights, Rural Tradition*, WASH. POST, Feb. 3, 1999, http://www.artsci.wustl.edu/~anthro/articles/monsanto1.html (describing the role of the USDA, land grant colleges, and extension services in development of new seed varieties—this research was publically financed, and patents were seldom sought or enforced).

genetic composition of these seeds was seen as an important element of a common heritage.[18] It was not until the development and widespread use of hybridization[19] techniques in the early 20th century, and the growth of a more robust seed industry, that proprietary protections began to become established for developers of agricultural seeds.[20] As these proprietary rights came into being, a stakeholder reaction also took place, with a focus on preserving agricultural resources and institutionalizing new approaches to sharing.[21]

International policy governing agricultural innovation currently reflects the dual goals of proprietary interests and sharing, and the two approaches continue to develop and coexist dynamically.[22] In making this differentiation, it is important not to overstate the case. These policy objectives are not entirely inconsistent. Indeed, patents and PVP enactments are not solely intended to protect inventors: Patent statutes require that innovative processes and products be fully disclosed in the interest of fostering further innovation, and exemptions from infringement often exist for breeding or experimental uses. Further, the CBD and International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) expressly recognize the importance of proprietary rights in fostering innovation, and particularly national proprietary interests in domestic genetic resources.[23] Indeed, in the international arena, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and International Union for the Protection of New Varieties of Plants (UPOV) mandate the existence of proprietary rights protection as a necessary component of agricultural innovation, with certain countries (including the United States and to some extent Canada) making

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18. International Undertaking on Plant Genetic Resources for Food and Agriculture, Res. 8/83, U.N. Doc. A/RES/8/83, Annex I, art. 1.1 (Nov. 23, 1983) [hereinafter Undertaking]; *see also* JACK RALPH KLOPPENBURG JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY, 1492–2000, at 152–90 (Cambridge Univ. Press 1988) (analyzing PGR's shift in status from a "free good" to an international commodity whose ownership is linked to conflict and competition).

19. "Hybridization, or scientifically combining and breeding seeds, was the first method by which companies were able to control replanting of seeds. For the first time, farmers were able to purchase improved seeds for a better crop. The drawback was that the second generation of crops did not fare as well as the first generation." Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, 164 (2005).

20. KLOPPENBURG, *supra* note 18, at 11; *see also* Stein, *supra* note 19, at 164–68 (tracing the private industry and judicial influences in the development of modern proprietary protections).

21. KLOPPENBURG, *supra* note 18, at 11; *see also* Stein, *supra* note 19, at 176–77 (discussing the role of private-public partnerships in helping to "alleviate the difficulties experienced by the public sector in securing access to technologies").

22. McManis & Soo Seo, *supra* note 3, at 407–08.

23. *See* CBD, *supra* note 12, at art. 16(2); ITPGRFA, *supra* note 9, at art. 13.2(b)(iii).

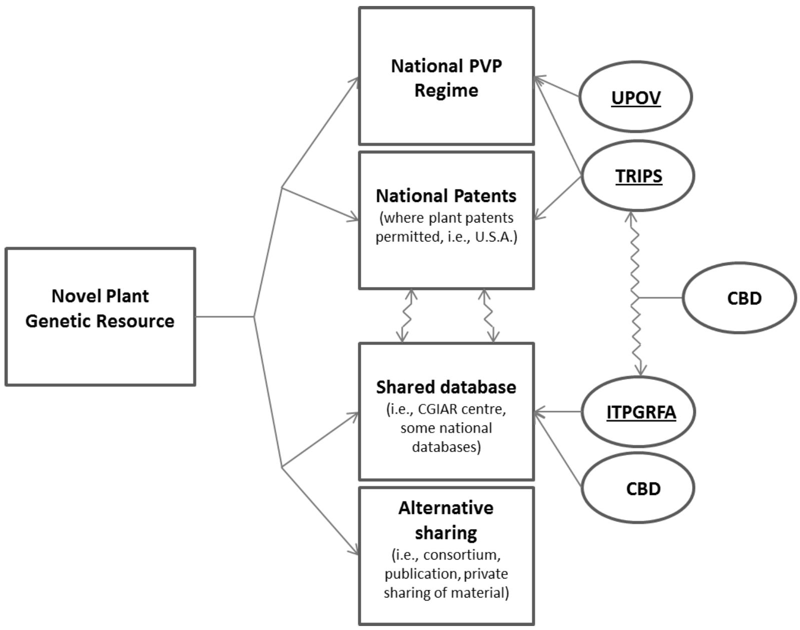
such rights available in the form of patents.[24] As these regimes have been implemented, there has been a corresponding effort to ensure that shared resources remain available to breeders. To this end, the ITPGRFA and actors such as the Consultative Group on International Agricultural Research (CGIAR) reify sharing as a fundamental mode of exchange in the agricultural community, and establish their own rules to govern the availability and sharing of agricultural resources.[25] The Convention on Biological Diversity (CBD) was developed to bring national and international biodiversity interests to the fore, and mandates measures on benefit sharing and facilitated access to genetic resources.[26] Though our discussion focuses mainly on the developing balance amongst international instruments governing proprietary interests and sharing, we note that similar developments are reproduced—to varying degrees—in certain domestic regimes, including the United States and Canada.

24. *See* TRIPS, *supra* note 9, at art. 27(3)(b) (indicating that although plants and animals may generally be excluded from patentability, some form of proprietary protections *must* be available for plant varieties); UPOV, *supra* note 9 (outlining breeder's proprietary rights with regards to new varieties of plants).

25. *See* ITPGRFA, *supra* note 9, at pmbl., art. 1.1. ITPGRFA recognizes that "fair and equitable sharing of the benefits" of PGR is fundamental, and has sharing, conservation, and sustainable use of these resources as its primary objectives.

26. CBD, *supra* note 12, at pmbl. The CBD is supplemented by the Cartagena Protocol, which addresses Living Modified Organisms (LMOs)—defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." The Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 3(g), Jan. 29, 2000, 2226 U.N.T.S. 208, 39 I.L.M. 1027 [hereinafter Cartagena Protocol]. "Biotechnology" is defined as the application of techniques that "overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection." *Id.* at art. 3(i)(b).

Figure 1: Array and Relationship of Regimes for Novel Plant Genetic Resources



B. *Institutionalizing Proprietary Interests in Agriculture: UPOV, TRIPS, and Patent Regimes*

As noted above, prior to the mid-20th century, proprietary protections had generally not been available for plants and agriculture. A general consensus existed that it was more important to retain the free exchange of information with respect to new plant materials amongst farmers, breeders, and breeding institutions in order to ensure dissemination of the best possible plant varieties.[27] In addition, it was generally deemed unlikely that innovators in the plant arena could meet the novelty, inventive step, and disclosure requirements necessary for patent protection.[28]

This growing desire for intellectual property protection for plants, articulated and lobbied for by the burgeoning seed industry, was formally instituted in

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27. *See* Llewelyn, *supra* note 16, at 117.

28. *See* Aniruddha Sen, *Clear and Complete Disclosure in Biotechnology Patent Applications – A Comparison of the Laws in the USA, Europe and India*, 2 HANSE L. REV. 91, 91 (2006) (discussing the difficulty in adapting the traditional patent requirements to biotechnology innovation).

the UPOV agreement, signed in 1961 and adopted to date by over sixty-five countries, including most large agriculture- and seed-producing nations.[29] Under UPOV, member nations are required to adopt legislation that institutes proprietary protection for all plant "varieties"[30] that are new, distinct, uniform, and stable.[31] Developers of plant varieties meeting these requirements are then granted the exclusive right to market or offer for sale, produce, reproduce, import, or export the "variety" or any material developed or harvested therefrom.[32]

UPOV has been modified several times since its adoption and more recent modifications allow countries to include, at their discretion, so called "breeders' rights exceptions" or "farmers' privileges."[33] Exceptions are available for non-commercial (private) uses, experimental purposes, and for breeding other new varieties.[34] Farmers' rights under UPOV are optional, and where available, allow farmers limited rights to save and replant seeds derived from protected varieties.[35] Importantly, farmers' rights are also subject to the rights of plant

29. UPOV, *supra* note 9. See *Members of the International Union for the Protection of New Varieties of Plants*, INT'L UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS (Apr. 27, 2012), http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf, for status and participation information of UPOV member nations.

30. "Variety" is defined as "a plant grouping within a single botanical taxon of the lowest known rank, which grouping . . . can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping . . . and considered as a unit with regard to its suitability for being propagated unchanged . . . ." UPOV, *supra* note 9, at art. 1(vi). It is worth noting that rights under UPOV extend to all novel varieties that meet the criteria, regardless of how they are derived and are thus relevant for varieties characterized by or developed through genomics techniques and/or biotechnology. *See id.* at art. 5.

31. *Id.* at art. 5(1). To be "new," a plant variety cannot have been offered for sale or marketed earlier than one year before the application for protection is filed in the source country, or for a period longer than four years in any other country. *Id.* at art. 6(1). To be "distinct," the variety must be "distinguishable from any other variety whose existence is a matter of common knowledge" anywhere in the world. *Id.* at art. 7. Varieties that are "common knowledge" are defined rather simply as any plants that meet the definition of "variety" in Article 1(vi), and includes varieties that have not obtained protection according to the Convention. Int'l Union for the Protection of New Varieties of Plants, *The Notion of Breeder and Common Knowledge*, C(Extr.)/19/2 Rev., Annex, ¶¶ 22–24 (Aug. 9, 2002). To be "uniform" and "stable," the variety's relevant characteristics must remain true and sufficiently uniform upon repeated propagation, subject to the variation that may be expected due to the particular features of its propagation. UPOV, *supra* note 9, at arts. 8, 9. *See also* Dutfield, *supra* note 3, at 35 (explaining "[t]he uniformity requirement also shows the specific nature of the UPOV system, since this requirement cannot practically be the same for species with different ways of reproduction . . . .").

32. UPOV, *supra* note 9, at art. 14(1)(a). These protections also extend to varieties "essentially derived" through the use of the protected variety, significantly broadening the scope of the UPOV protections. *Id.* at art. 14(5).

33. *Id.* at art. 15.

34. *Id.* at art. 15(1).

35. *Id.* at art. 15(2).

breeders delineated in UPOV.[36] Public disclosure requirements are omitted from UPOV (unlike most patent regimes); instead, sufficient evidence must be submitted to demonstrate the variety meets the criteria or alternatively a sample must be submitted to the national authority for their own inspection.[37]

The reach and impact of proprietary interests articulated in UPOV were broadened with the passage of the TRIPS agreement.[38] Adopted in 1995 and mandatory for the over 150 members of the World Trade Organization (WTO), the TRIPS agreement institutes mandatory minimum levels of IP protection enforceable by WTO dispute resolution procedures.[39] The TRIPS agreement provides that patents shall be available for all new industrial products and processes that "involve an inventive step and are capable of industrial application."[40] Plants and animals (other than microorganisms) may optionally be exempted from patentability under TRIPS, but specifically for plants, "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[41] Importantly, the TRIPS provisions *mandate* the presence of national plant variety or patent protection (or both) for all new varieties, effectively removing the agricultural community further away from historical practices of open sharing and knowledge dissemination.[42]

The impact of the UPOV and TRIPS regimes depends in large part on their implementation and the content of national regimes.[43] Broadly, they may open the door to strong enclosures of PGRs as property in an area where they

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36. *Id.*

37. *See* Dutfield, *supra* note 3, at 35.

38. LAURENCE R. HELFER, FOOD & AGRIC. ORG. OF THE U.N., INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES: INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS 33 (2004) [hereinafter HELFER, REGIMES AND POLICY OPTIONS].

39. TRIPS, *supra* note 9, at pmbl., art. 64(1); *Members and Observers*, WORLD TRADE ORG., (Aug. 24, 2012), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (listing the 157 current members of the WTO).

40. TRIPS, *supra* note 9, at art. 27(1).

41. *Id.* at art. 27(3)(b). Some authorities view the Article 27(3) exemption as a key concession to developing countries in the negotiation process, but others find it of limited practical significance in agri-biotech and related fields. *See* Brian D. Wright & Philip G. Pardey, *The Evolving Rights to Intellectual Property Protection in the Agricultural Biosciences*, 2 INT'L J. TECH. & GLOBALISATION 12, 19 (2006).

42. HELFER, REGIMES AND POLICY OPTIONS, *supra* note 38, at 21.

43. "[R]eview of national plant variety legislation shows that countries are exploiting [the freedom to implement the treaties in different contexts], presumably tailoring plant IP legislation to local circumstances." Bonwoo Koo et al., *Plants and Intellectual Property: An International Appraisal*, 306 SCIENCE 1295, 1297 (2004). These national regimes may vary significantly in light of the breadth and imprecise nature of many UPOV and TRIPS provisions. For a detailed analysis of the content of these frameworks, the interplay of their provisions, and implementation by national governments, see HELFER, *supra* note 38.

were traditionally unavailable, notwithstanding the exemptions potentially available for breeders and farmers.[44] In a few jurisdictions, intellectual property interests in plants and agriculture have been further strengthened through the expansion of patent rights that apply to plants (or aspects thereof, as the case may be).[45] Other WTO signatories have adopted a form of UPOV plant variety protection to satisfy this TRIPS requirement in the absence of patent regimes applicable to plants and agriculture,[46] and still other nations have instituted unique forms of plant IP protection that depart significantly from UPOV.[47]

C. *Shared Resources: The Consultative Group on International Agricultural Research and the International Treaty on Plant Genetic Resources for Food and Agriculture*

As proprietary protections available for plants and agriculture expanded internationally, there was a corresponding effort to preserve historically productive practices of sharing and free exchange of agricultural material. To this end, the CGIAR was established in 1971 by the World Bank, the Food and Agriculture Organization of the U.N. (FAO), and the United Nations Development Program.[48] CGIAR was intended, *inter alia,* as a research hub for improving crop productivity and as a means of institutionalizing the long-practiced exchange and

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44. *See* McManis & Soo Seo, *supra* note 3, at 417–18 (citing Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT'L L. 641, 645–46 (2004)) (suggesting that "as intellectual property protection was extended to an ever-widening array of genetic materials, the traditional paradigm that PGRs formed part of the public domain gave way to an enclosure of such resources as property.").

45. Expansions in Canadian and U.S. intellectual property law will be discussed in detail *infra* Part II.E. It is important to note that due to the existence of bilateral "TRIPS+" treaties (such as trade agreements negotiated between developing nations and proponents of stronger IP rights, including the United States) guaranteeing stronger IP protections than those agreed upon in TRIPS, many developing nations have not implemented rights under TRIPS Article 27(3). *See* Wright & Pardey, *supra* note 41, at 19.

46. TRIPS, *supra* note 9, at art. 27(3)(b).

47. *See* Koo et al., *supra* note 43, at 1296 (discussing India's approach to their TRIPS obligations, specifically focusing on farmer's rights and other departures from UPOV). The variability of national plant IP regimes in the wake of TRIPS serves to create some level of uncertainty for innovators seeking proprietary protections in multiple nations. *See* Eran Binenbaum et al., *South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops*, 51 ECON. DEV. & CULTURAL CHANGE 309, 311 (2003).

48. *Consultative Group on International Agricultural Research (CGIAR)*, WORLD BANK, http://go.worldbank.org/QUMSIOM5P0 (last visited Sept. 19, 2012).

preservation of seeds to help address development challenges.[49] Originally comprising four research centers that focused on key cereal food crops, CGIAR has been widely supported and has since expanded to include dozens of governmental and non-governmental partners, and now numbers fifteen agricultural research centers in total.[50]

As CGIAR has grown, its focus has also shifted. The role of CGIAR as an institution has always been a combination of leveraging resources into productivity improvement projects on one hand, and sustainability (promoting biodiversity and the preservation of plant resources) on the other.[51] In recent years, many CGIAR centers have shifted funding away from capital-intensive productivity research[52] and moved towards projects that emphasize sharing and the preservation of local knowledge and resources.[53] CGIAR centers now house more than 600,000 unique accessions of plant germplasm (of the estimated six million stored globally[54])—many of them derived from locally important food staples.

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49. *See* Derek Byerlee & Harvey Jesse Dubin, *Crop Improvement in the CGIAR as a Global Success Story of Open Access and International Collaboration*, 4 INT'L J. COMMONS 452, 453, 456–57, 462 (201) (discussing the origins of the CGIAR and its emphasis on open research and its free exchange of materials, which helps less-developed countries gain access to valuable plant information and material).

50. *History of CGIAR*, CGIAR, http://www.cgiar.org/who-we-are/history-of-cgiar/# (last visited Sept. 19, 2012).

51. The goals of preserving biodiversity and increasing yields are not, in CGIAR's view, antithetical to each other. Many authors have noted the importance of preserved plant genetic resources as elements of successful yield-enhancing breeding programs. *See, e.g.*, David Hoisington et al., *Plant Genetic Resources: What Can They Contribute Toward Increased Crop Productivity?*, 96 PROC. NAT'L ACAD. SCI. 5937, 5937–38 (1999) (describing the work of CGIAR centers in "collecting, preserving, and utilizing global agricultural resources" and the impact this has on breeding programs).

52. In fact, the percent of total CGIAR funding allocated to crop genetic improvement between 1992 and 2005 fell from twenty-four percent to sixteen percent: *See* Prabhu Pingali & Tim Kelley, *The Role of International Agricultural Research in Contributing to Global Food Security and Poverty Alleviation: The Case of the CGIAR*, *in* 3 HANDBOOK OF AGRICULTURAL ECONOMICS 2381, 2388–89 (Robert E. Evenson & Prabhu Pingali eds., 2007).

53. *See* Christopher B. Barrett, Operations Evaluation Dept., World Bank, *The CGIAR at 31: An Independent Meta-Evaluation of the Consultative Group on International Agricultural Research, Natural Resources Management Research in CGIAR: A Meta-Evaluation*, WB Doc. 16185, Annex 3, at 103–04 (2003) (discussing ways in which to bridge scientific and local knowledge). Some traditionally productivity-focused centers have also, in recent years, focused more extensively on national policymaking and resource management research. Mitch Renkow & Derek Byerlee, *The Impacts of CGIAR Research: A Review of Recent Evidence*, 35 FOOD POL'Y 391, 401 (2010).

54. *See* Hoisington et al., *supra* note 51, at 5938.

CGIAR policies on data and seed sharing have traditionally been very open, with PGRs commonly being supplied on request to scientists, breeders, and others.[55]

The CGIAR system has come to represent one of the most important international germplasm collections, in terms of the quantity and diversity of accessions, as well as their free availability. However, the system is not flawless; there are diverse interests pursued by the fifteen CGIAR centers operating independently and without a legal charter.[56]

With the rise of proprietary interests in plant genetic resources, as discussed above, there was growing concern that the accessibility of collections such as CGIAR's would be hampered or limited by the institution of intellectual property rights.[57] There were also concerns that the CBD (discussed in Part II.D) could open the door to measures encouraging *retention* of national resources rather than renewing a focus on sharing.[58] These issues led to attempts within the international community to formally institutionalize shared resources such as those held by CGIAR, while ensuring that sharing takes place in an equitable manner.[59]

The 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture (the Undertaking)[60] began this process by declaring plant genetic resources a common heritage of humanity that should be available to anyone, consistent with CGIAR policy and practice.[61] Subsequent "In-Trust Agree-

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55. Gotor et al., *supra* note 11. The accession records indicate that the vast majority of CGIAR germplasm samples are provided to other CGIAR centers, national depositories, and university researchers, with developing countries benefiting in particular. *See* CARY FOWLER ET AL., GLOBAL FORUM ON AGRIC. RESEARCH, GERMPLASM FLOWS BETWEEN DEVELOPING COUNTRIES AND THE CGIAR: AN INITIAL ASSESSMENT 4 (2000), *available at* http://www.fao.org/docs/eims/upload/206939/gfar0065.PDF.

56. *See, e.g.*, Barrett, *supra* note 53, ¶ 2.4 (discussing CGIAR's approach to natural resource management in the context of CGIAR's structural functioning).

57. *See* CONSULTATIVE GROUP ON INT'L AGRIC. RESEARCH, CGIAR CENTER STATEMENTS ON GENETIC RESOURCES, INTELLECTUAL PROPERTY RIGHTS, AND BIOTECHNOLOGY 2–4 (1999), *available at* http://library.cgiar.org/bitstream/handle/10947/253/mtm9805e.pdf?sequence=1. The CGIAR found it necessary to release a statement emphasizing its ethical role as trustee of genetic resources and of the sharing of this knowledge. *Id.*

58. *See* Cary Fowler, *Accessing Genetic Resources: International Law Establishes Multilateral System*, 51 GENETIC RESOURCES & CROP EVOLUTION 609, 612 (2004).

59. *See* Chidi Oguamanam, *Intellectual Property Rights in Plant Genetic Resources: Farmers' Rights and Food Security of Indigenous and Local Communities*, 11 DRAKE J. AGRIC. L. 273, 281–82 (2006) [hereinafter Oguamanam, *Farmers' Rights*] (noting the developing nations' interest in preventing biotech companies from acquiring PGRs from CGIAR institutions without providing compensation to indigenous farmers).

60. Undertaking, *supra* note 18.

61. *Id.* at Annex I, art. 1.1; Gotor et al., *supra* note 11, at 1487–91 (emphasizing CGIAR's sharing policy). Commentators note that this agreement was "forc[ed] through" by developing country members of the FAO, and that eleven developed countries (the United States and

ments"—concluded in 1994 between the FAO and the individual CGIAR centers—further set the legal foundation for a multilateral system of germplasm exchange and confirmed that the CGIAR collections are held in trust for the benefit of society.[62]

Proponents of a formal access and benefit sharing regime (and/or an international instrument guaranteeing farmers' rights) were not satisfied with the International Undertaking due to its non-binding nature and limited impact relative to IP rights, and remained concerned that the availability of shared resources would be subsumed by proprietary interests.[63] Access and benefit sharing concerns were addressed in a more systematic fashion with the negotiation and ultimate agreement of a stronger instrument in ITPGRFA.[64] ITPGRFA is currently ratified by over 120 nations and deals with PGRs for food and agriculture (as opposed to the "raw" genetic resources that are the focus of the CBD) and issues related to their access and benefit sharing.[65] Under the terms of ITPGRFA, signatories commit to the conservation and sustainable use of PGRs for food and agriculture and to minimize or eliminate threats to their preservation and shared availability.[66] Generally, these obligations are met through donation of a shared national database of plant germplasm by signatory nations.

Canada included) were unwilling to support the agreement until its scope was limited. *See* Susan Bragdon, et al., *Safeguarding Biodiversity: The Convention on Biological Diversity (CBD)*, *in* THE FUTURE CONTROL OF FOOD, (Geoff Tansey & Tasmin Rajotte eds., 2008). An Agreed Interpretation of the International Undertaking was signed in 1989. Agreed Interpretation of the International Undertaking on Plant Genetic Resources, FAO Conference Res. 4/89, CGRFA/Res/C4-89E (Nov. 29, 1989). This interpretation noted that the common heritage principle was "not incompatible" with proprietary interests including breeder's rights, and provided such a limitation on the scope of the Undertaking. *Id.* at ¶¶ 1–2.

62. *See, e.g.*, AGREEMENT BETWEEN [NAME OF CENTER] AND THE FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO) PLACING COLLECTIONS OF PLANT GERMPLASM UNDER THE AUSPICES OF FOA, art. 3 (1994), *reprinted in* BOOKLET OF CIGAR CENTRE POLICY INSTRUMENTS, GUIDELINES AND STATEMENTS ON GENETIC RESOURCES, BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS 2, 3 (Version II July 2003).

63. *See* Oguamanam, *Farmers' Rights*, *supra* note 59, at 283–84.

64. ITPGRFA, *supra* note 9; *see* Oguamanam, *Farmers' Rights*, *supra* note 59, at 285 (discussing farmers' rights in ITPGRFA and the Undertaking). ITPGRFA was also intended to help align the Undertaking with the access and benefit sharing provisions of the CBD, discussed in Part II.D. *See also* Kelly Day-Rubenstein & Paul Heisey, Econ. Research Serv., USDA, *Plant Genetic Resources: New Rules for International Exchange*, AMBER WAVES, June 2003, http://webarchives.cdlib.org/sw1vh5dg3r/http://ers.usda.gov/AmberWaves/June03/pdf/awjune2003plantgeneticfeature.pdf.

65. *See* Bragdon et al., *supra* note 61, at 90 (noting "the Treaty, rather than the CBD, now sets the rules for access to [genetic resources] and benefit sharing . . . .").

66. ITPGRFA, *supra* note 9, at arts. 1.1, 5.2. The ITPGRFA indicates that the listed obligations be implemented into national agricultural and environmental strategies, and that coop-

The key provisions of ITPGRFA obligate contracting parties to provide "facilitated access"[67] to PGRs under their management and control and in the public domain.[68] "Facilitated access" is not explicitly defined therein, but ITPGRFA provides that access must be provided "expeditiously" and should not involve more than a minimal cost.[69] Further, access need only be granted where resources are used "solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture" while industrial non-food and pharmaceutical uses are generally prohibited.[70] ITPGRFA's provisions permit access to all signatories as well as "legal and natural persons" under their jurisdiction, including private commercial entities.[71] These PGRs are considered part of the "Multilateral System" of access and benefit sharing under the auspices of the Governing Body of ITPGRFA.[72] Facilitated access obligations are limited to PGRs derived from sixty-four key food and feed crops,[73] and accessions used for breeding, research, and training purposes. There is no bar to private parties pursuing proprietary rights (such as may be available) on new varieties or other developments arising from the use of shared PGRs, as long as such proprietary rights do not interfere with access to (and use of) the resource by others.[74]

In an effort to balance the potential availability of proprietary rights in PGRs to commercial producers, ITPGRFA specifies that private parties claiming proprietary rights on varieties derived from accessed resources must pay a percentage of the profits that arise therefrom into a communal fund administered by

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eration with other Contracting Parties directly and through the FAO is essential to effective implementation of ITPGRFA's provisions. *Id.* at art. 7.1.

67. *Id.* at art. 12.1.

68. *Id.* at art. 11.2. While private collections are not subject to the provisions, ITPGRFA requires that Contracting Parties take measures to "encourage" private parties to contribute to communal seed pools. *Id.* at arts. 11.3, 16.2.

69. *Id.* at art. 12.3(b).

70. *Id.* at art. 12.3(a).

71. *Id.* at art. 12.2.

72. *Id.* at art. 11.4.

73. *Id.* at Annex I. For a discussion of the negotiations leading to the list of materials included in Annex I, see Lim Engsiang & Michael Halewood, *A Short History of the Annex I List*, *in* THE FUTURE CONTROL OF FOOD 249–50 (Geoff Tansey & Tasmin Rajotte eds., 2008).

74. *See* ITPGRFA, *supra* note 9, at art. 12.3(d). Article 12 of ITPGRFA prohibits any assertion of IP rights that would limit facilitated access to any PGR governed by the Multilateral System. *Id.* at art. 12. This language has not been tested or commented upon by international lawmakers, but logically it prohibits the granting of national patent or PVP rights on MTS crops or portions thereof (isolated germplasm, for instance). Less clear, however, is the impact of the language on national protection of improved varieties or uses of germplasm falling within "experimental use" guidelines. McManis & Soo Seo, *supra* note 3, at 452–53.

the Governing Body.[75] Access is facilitated through the use of a Standard Materials Transfer Agreement (SMTA) in which the contracting parties agree to be bound by these terms.[76] Benefit sharing under ITPGRFA remains a work in progress, however, as there is no clear guidance on how to identify profits that arise from use of resources obtained through the Multilateral System. Breeders may employ dozens of accessions in developing a new strain, complicating questions of whether and from what accessions a new variety was developed and who deserves what level of remuneration.[77]

While ITPGRFA is a new mechanism and its ultimate impact on access and benefit sharing remains untested, it has already been accepted by some nations as an important resource for access and benefit sharing policymaking, with potential implications for innovators and breeders worldwide. ITPGRFA has largely been hailed as an important tool in supplying innovative researchers with key genetic inputs,[78] and SMTAs agreed upon under the auspices of ITPGRFA are rapidly becoming the standard instruments for international exchange of PGRs for food and agriculture.[79] It is unclear, however, to what extent these access and benefit sharing provisions provide the necessary balance to proprietary rights in providing and preserving resources for innovation.[80]

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75. ITPGRFA, *supra* note 9, at art. 13.2(d); HELFER, REGIMES AND POLICY OPTIONS, *supra* note 38, at 87. It is important to note that, prior to the passage of ITPGRFA, these resources were commonly free to access for public and private researchers alike, with no associated accounting of profits. *See* Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 40 (2004) [hereinafter Helfer, *Regime Shifting*].

76. ITPGRFA, *supra* note 9, at art. 12.4.

77. *See* Helfer, *Regime Shifting*, *supra* note 75, at 37.

78. *See* Christine Frison et al., *Intellectual Property and Facilitated Access to Genetic Resources Under the International Treaty on Plant Genetic Resources for Food and Agriculture*, 32 EUR. INTELL. PROP. REV. 1, 2 (2010) (indicating that while further action in implementation is needed, ITPGRFA "represents invaluable support for public, private, and hybrid public/private innovation").

79. *Second Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture*, FOOD AND AGRICULTURE ORGANIZATION, GB-2/07/Report, ¶¶ 66–68, *available at* ftp://ftp.fao.org/ag/agp/planttreaty/gb2/gb2repe.pdf (noting "the Governing Body endorsed the option that an interpretative footnote or series of footnotes would be included to relevant provisions of the SMTA indicating that these provisions should not be interpreted as precluding the use of the SMTA for transfers of non-*Annex I* material . . . .").

80. In particular, critics question whether ITPGRFA's provisions apply to parts and components of PGRs for food and agriculture, such as isolated genes. *See* Frison et al., *supra* note 78, at 3 (stating "[i]t is still not clear . . . if a recipient can seek IPRs over isolated parts and components of those seeds or cuttings from materials within the MLS, such as genes.").

D. *Emphasizing National Priorities on the Sharing-Proprietary Spectrum: The Convention on Biological Diversity*

Efforts to govern the protection of and access to PGRs are complicated by the overlay of the CBD, which is aimed primarily towards the preservation and sustainable use of agricultural resources.[81] Its provisions also emphasize access to genetic resources and equitably sharing benefits arising from their use.[82] The CBD was drafted in part to address concerns surrounding access to and use of indigenous biological resources in developing nations by large corporate entities (so-called "biopiracy"), and contains strong provisions reinforcing national retention of PGRs.[83] In a sense then, the CBD sets up a parallel spectrum of proprietary possibilities and sharing mandates with respect to a country's national resources, with an ultimate focus on protecting biodiversity.

The CBD recognizes national regimes' ownership interests in PGRs, even while supporting the seemingly incompatible theme of facilitated access. Article 15(1) of the CBD reinforces the principles of national sovereignty and protection of domestic genetic resources.[84] The second part of Article 15 illustrates the importance of guaranteeing availability of protected materials, noting that parties "shall endeavor to create conditions to facilitate access to genetic resources . . . by other Contracting Parties."[85] The language used in this provision (i.e. *shall endeavor*) is noticeably weak: its effect is further mitigated by the fact that access to PGRs between interested parties must in all cases be on "mutually agreed terms."[86]

Article 16 focuses on access to and transfer of technologies that are relevant to the sustainable use of biological diversity, and the interaction between intellectual property and environmental protection.[87] It reiterates the importance

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81. CBD, *supra* note 12, at pmbl. Stated otherwise, the CBD "seeks to preserve the natural world and maintain society's traditional, essentially agrarian, relationship to it." Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 255 (1998).

82. CBD, *supra* note 12, at art. 1.

83. *See* Zinatul A. Zainol et al., *Biopiracy and States' Sovereignty over Their Biological Resources*, 10 AFR. J. BIOTECH. 12,395, 12,395 (2011).

84. CBD, *supra* note 12, at art. 15(1). States have "the sovereign right to exploit their own resources pursuant to their own environmental policies." *Id.* at art. 3. *See* Bragdon et al., *supra* note 61, at 86 (noting that Article 15 of the CBD explicitly extends sovereign rights over property and vests determining access to genetic resources with national governments).

85. CBD, *supra* note 12, at art. 15(2). Critics note, however, that the "commodity-based" approach of the CBD was "forced to yield to the desire of the majority for the creation of a multilateral system of exchange and benefit sharing." Fowler, *supra* note 58, at 612.

86. CBD, *supra* note 12, at art. 15(4).

87. *Id.* at art. 16; *see also* McManis, *supra* note 81, at 261.

of providing access to genetic resources for the purposes of conservation or sustainable use,[88] but further notes that such access must be "consistent with the adequate and effective protection of intellectual property rights."[89] Article 16 was instituted as a compromise between negotiating groups at opposing ends of the sharing-proprietary continuum and represents an effort to balance proprietary interests and access to agricultural materials.[90]

The net effect of these provisions on IP and open sharing can vary significantly due to divergent national views on key provisions and what constitutes implementation of the CBD.[91] Thus, while some authorities may view their PGRs as sovereign resources not to be shared without significant remuneration, others may take the view that national interests are best served by open sharing and participation in institutions such as CGIAR and the ITPGRFA.

Thus far, there has been no concerted effort in the international arena to integrate the CBD with other international regimes discussed herein, though it would arguably be beneficial to do so. Even though the CBD recognizes "[t]he objective of giving legal certainty to the user of genetic resources must be balanced against the need to ensure that the source country's rights are appropriately protected and exercisable,"[92] it offers no concrete strategy for implementing these twin priorities. Ultimately, with respect to intellectual property and sharing and access to PGRs, the CBD adds a layer of complexity that remains problematic for developers and other stakeholders.[93]

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88. CBD, *supra* note 12, at art. 16(1).

89. *Id.* at art. 16(2), 16(5).

90. *See* McManis, *supra* note 81, at 264 (noting that these interests were not conclusively resolved in the final document).

91. Bernard Le Buanec, *Plant Genetic Resources and Freedom to Operate*, 146 EUPHYTICA 1, 3 (2005) (observing that "developed countries tended to focus on conservation, using policy measures, whereas developing countries gave priority to the access and benefit-sharing issue and advocated for legislative measures."); *see also* Bernd Siebenhüner & Jessica Suplie, *Implementing the Access and Benefit-Sharing Provisions of the CBD: A Case for Institutional Learning*, 53 ECOLOGICAL ECON. 507, 512–19 (2005) (discussing the role of highly diverse interests among the parties and how these are magnified in the context of CBD implementation).

92. Tomme Rosanne Young, *4 Challenges Ahead: Legal and Practical Prerequisites for the Development of a Certificate of Source, Origin or Legal Provenance for the CBD*, *in* A MOVING TARGET: GENETIC RESOURCES AND OPTIONS FOR TRACKING AND MONITORING THEIR INTERNATIONAL FLOWS § 4.3.6 (Manuel Ruiz Miller & Isabel Lapeña eds., 2007) (citing 3d Ad-hoc Working Group on ABS, *Summary Analysis: Legal Certainty for Users of Genetic Resources Under Existing Access and Benefit-Sharing (ABS) Legislation and Policy*, UNEP/CBD/ABS/3/INF/10 (2005)).

93. *See* KATHRYN GARFORTH & CHRISTINE FRISON, QUAKER INTERNATIONAL AFFAIRS PROGRAMME, KEY ISSUES FOR THE RELATIONSHIP BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (2007), *available at* http://uclouvain.academia.edu/ChristineFrison/Papers (follow

E. *The Sharing-Proprietary Spectrum at the National Level: The United States*

While this discussion has focused on the impacts of international regimes on proprietary interests and sharing, it is worth recognizing that domestic regimes can reflect similar efforts to create a balanced set of possibilities. The United States is particularly noteworthy in this regard, having very potent frameworks for both proprietary protection of plants and agriculture, as well as a robust system for sharing plant germplasm.[94]

The United States initially established limited patent rights for asexually reproduced varieties of plants covered under the Plant Patent Act of 1930.[95] This very narrow right was broadened in 1970 with the introduction of plant variety protection—per the Plant Variety Protection Act of 1970[96]—largely consistent with the types of protections contained in the UPOV. The scope of U.S. proprietary rights available for plants was expanded significantly in the landmark *Diamond v. Chakrabarty* case, where the Supreme Court declared that patent protection could potentially extend to "*anything* under the sun that is made by man."[97] Indeed, based on *Chakrabarty*, in 1985 the U.S. Patent and Trademark Office (U.S. PTO) determined in *Ex parte Hibberd* that sexually reproducing plants are patentable.[98] "Following that decision, the U.S. PTO began accepting patent applications for such plants, despite the fact that Congress had never given the U.S. PTO authority to grant utility patents for sexually reproducing plants."[99]

"Key Issues for the Relationship . . . and Agriculture" hyperlink) (analyzing specific issues raised in implementing the CBD and the ITPGRFA). The CBD has further complicated the agricultural genomics arena with its explicit embrace of the "precautionary principle" in regulating biotechnology products (LMOs) through the Cartagena Protocol. *See* Cartagena Protocol, *supra* note 26, at art. 12.

94. *See generally* P.K. Bretting, *The U.S. National Plant Germplasm System in an Era of Shifting International Norms for Germplasm Exchange*, 760 ACTA HORTICULTURAE 55 (2007) (discussing both national and international programs the United States has implemented to regulate the sharing of and proprietary interests in germplasm).

95. Plant Patent Act of 1930, Pub. L. No. 71-245, 46 Stat. 376 (codified as amended at 35 U.S.C. §§ 161–164 (2006)).

96. Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1542 (codified at 7 U.S.C. §§ 2321–2582 (2006)).

97. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)) (emphasis added).

98. Ex parte Hibberd, 1985 WL 71986, at *443 (B.P.A.I. Sept. 24, 1985). *Ex Parte Hibberd* established the right of plant breeders to patent their plant materials under Section 101 of the Patent Act. This provided new opportunities and possibilities for plant breeders and seed companies to protect their products. *Id.* at 444–45.

99. CTR. FOR FOOD SAFETY, MONSANTO VS. U.S. FARMERS (2005), *available at* http://www.centerforfoodsafety.org/pubs/CFSMOnsantovsFarmerReport1.13.05.pdf.

This point of law was settled by *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, in which the U.S. Supreme Court affirmatively held that plants could be the subject of utility patents.[100] The Court found the existence of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 did not indicate a Congressional intent to withhold patent protection from plants per se.[101] In the United States, therefore, patent rights are fully available to plants meeting relevant criteria of patentability.

Less directly, *Chakrabarty* and related decisions have served as unofficial precedent for the expansion of patent rights in other jurisdictions, including Canada.[102] The net implication of these decisions has been to dramatically expand the scope of proprietary interests available in plants, in the United States, Canada, and other jurisdictions.[103] In the United States, it is now standard practice for plant innovations developed through the use of biotechnology to be the subject of utility patent applications (commonly paired with applications for variety protection).[104]

At the same time this dramatic expansion of proprietary rights in PGRs occurred in U.S. courts, a similar expansion in mechanisms to ensure the availability of shared plant resources has developed. An organized plant germplasm system has existed in some form in the United States since 1898 and the current National Plant Germplasm System (NPGS) has been administered by the USDA and its Agricultural Research Service (ARS) since the early 1970s.[105] The explicit aim of the NPGS is to facilitate the conservation and exchange of plant genetic resources and also to enable access to these resources for farmers across the world.[106] The NPGS maintains a large and diversified network of over twenty

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100. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001).

101. *Id.* at 149–54.

102. *See, e.g.*, Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (Can.); Monsanto v. Schmeiser, [2004] 1 S.C.R. 902 (Can.) (holding a Monsanto patent on Roundup Ready Canola to be valid).

103. *See generally* MATTHEW RIMMER, INTELLECTUAL PROPERTY AND BIOTECHNOLOGY: BIOLOGICAL INVENTIONS (2008) (describing the expansion of intellectual property law to cover biotechnology).

104. *See* Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 991 tbl.1 (2003) (comparing the use of IP between the private and public sector); *see generally* Mark D. Janis & Jay P. Kesan, U.S. Plant Variety Protection: Sound and Fury . . . ?, 39 Hous. L. Rev. 727 (2002) (discussing the growth and use of utility patents and plant variety patents in the U.S.).

105. *See USDA's History Comes Alive at the National Agricultural Library*, USDA AGRIC. RESEARCH SERV. (Aug. 1, 2012), http://www.ars.usda.gov/is/AR/archive/aug12/nal0812.htm.

106. Bretting, *supra* note 94, at 56. To a large degree, these centers have become increasingly important, serving to balance the simultaneous proliferation of property rights in plant resources. *See id.* at 56–58.

seed banks—including, in total, more than 500,000 accessions of over 14,000 species[107]—that accepts donations and actively pursues the collection of new materials. It has also become the leading international distributor of plant germplasm and commands a significant percentage of the ARS' yearly expenditures.[108] Researcher P.K. Bretting notes that NPGS operations have expanded significantly in the last twenty years, and foresees further expansion of NPGS acquisition and distribution efforts in response to the growth of plant IP rights and phytosanitary regulatory restrictions.[109]

Thus, even as the United States stands at the forefront of broad proprietary interests in plant and agriculture innovation, it also maintains one of the world's most important sources of germplasm information and seed sharing. The coexistence of these divergent regimes mirrors the dynamic efforts of balancing growing proprietary interests with sharing and preservation interests in PGRs.

III. IMPACTS ON POTENTIAL INNOVATORS

Taken together, efforts to balance regimes promoting proprietary protection in the agricultural genomics arena with those encouraging preservation of shared resources have given rise to a highly complex set of possibilities for researchers and innovators, as depicted above.[110] Proprietary protections in the form of plant variety protection (in some cases modeled after UPOV) and plant patents exist concurrently with regimes and actors (for example, CGIAR) concentrating on the preservation and open sharing of agricultural resources, particularly those crops identified by ITPGRFA as being critical to sustainable food security.[111] Interplay between the regimes is modulated to some extent by the overlay of the CBD, with concerns about sustaining indigenous biodiversity thrown into the mix.[112] It is important to note that national and international proprietary and sharing interests are not intended to be mutually exclusive. Indeed, framers of both ITPGRFA and the CBD explicitly provide for the possibility of

107. *National Plant Germplasm System*, USDA AGRIC. RESEARCH SERV. (Aug. 26, 2012), http://www.ars-grin.gov/npgs/stats/summary.stats.

108. *See* BD. ON AGRIC., NAT'L RESEARCH COUNSEL, MANAGING GLOBAL GENETIC RESOURCES: THE U.S. NATIONAL PLANT GERMPLASM SYSTEM (1991). For illustrative purposes, between 1986 and 1989 expenditures on NPGS-related activities increased from $13 million to $28 million. *Id. at* 92 tbl.3-1.

109. Bretting, *supra* note 94, at 57–59.

110. *See supra* Figure 1.

111. *See* ITPGRFA, *supra* note 9, at pmbl. ("Recognizing that this Treaty and other international agreements relevant to this Treaty should be mutually supportive with a view to sustainable agriculture and food security . . . .").

112. *See* CBD, *supra* note 12, at pmbl. (discussing the overall goals for the CBD including the incorporation of indigenous biodiversity).

resources being the subject of IP protection.[113] In return for this recognition, both ITPGRFA and CBD attempt to preserve value in agricultural resources (and the resources themselves) in the different methods discussed above.[114]

Much has been published about the potential impacts of growing proprietary possibilities on innovative research in biotechnology.[115] Based on our own research across human, animal, and agricultural genomics, we believe that different conformations of IP and sharing are appropriate (at different stages of innovative genomics research), and that these mechanisms are best applied in a case-specific manner. Thus, while public domain sharing may produce high levels of innovation in a small research community,[116] the same may not be true for the development of commercial health care or some agricultural products.[117] Similar-

113. *See* ITPGRFA, *supra* note 9, at art. 13.2(b)(iii) (discussing that access and transfer of plant material "shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights"); CBD, *supra* note 12, at art. 16 (discussing the role of intellectual property rights within the context of the CBD).

114. *See supra* Part II.C.

115. For examples from the life sciences sector, see Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (discussing the role of proprietary protections in creating "anticommons"—the underutilization of resources where too many owners possess the right to exclude—and cautioning that this may have an adverse effect on innovation); Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091 (2006) (analyzing the gene patenting debate and dominant policy concerns); Zhen Lei et al., *Patents Versus Patenting: Implications of Intellectual Property Protection for Biological Research*, 27 NATURE BIOTECH. 36 (2009) (surveying academic agricultural biologists, and reporting their belief that "proliferation of IP protection has a strongly negative effect on research in their disciplines"); Kevin E. Noonan, Letter to the Editor, *Conflating MTAs and Patents,* 27 NATURE BIOTECH. 504 (2009) (responding to the survey reported by Zhen Lei et al., and qualifying the findings of that study); Rebecca Goulding et al., *Expansion of the Canadian Research Exemption for Biotechnology Research Tools*, 30 BIOTECH. L. REP. 59 (2011). For examples from the agricultural sector, see Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCIENCE 174, (2003), http://www.sciencemag.org/content/301/5630/174.full.pdf (discussing the role of public institutions in research and development of agricultural products and the limitations they have faced with the advent of IPR); Joel I. Cohen et al., *Proprietary Biotechnology Inputs and International Agricultural Research*, *in* REPORT OF THE CGIAR EXPERT PANEL ON PROPRIETARY SCIENCE AND TECHNOLOGY, app. C-1 (1998) (presenting data that shows considerable confusion amongst CGIAR developers regarding the existence of relevant intellectual property and their freedom to operate); Frison et al., *supra* note 78 (examining ITPGRFA's scope, the interplay of IP rights and the Multilateral System of Access, and concerns about conservation and sustainable use).

116. *See* Matthew R. Voell et al., *A Response to Rome: Lessons from Pre- and Post-Publication Data-Sharing in the* C. Elegans *Research Community*, 11 BMC GENOMICS 708 (2010) (concluding that sharing in other research communities may prove useful as it did with *C. elegans* researchers).

117. *See* Emily Marden, *Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 MINN. J.L. SCI. & TECH. 217 (2010). In the latter case, strong IP pro-

ly, we have taken the position that a strong research exemption from proprietary protection may be appropriate where innovations have the potential to stimulate or generate additional improvements.[118]

Our position on the agricultural sharing-proprietary balance is that strong proprietary protection serves a useful purpose for innovation under certain circumstances, but that strong IP protections should be counterbalanced by protection and preservation of shared resources. We believe that neither option is fundamentally sufficient in and of itself.[119]

Toward this end, we believe that both regimes that grant IP *and* those that mandate the sharing of such resources are necessary for continued innovation in the agricultural genomics space. At the same time, our view is that the current array of possibilities has developed in an *ad hoc* manner, and—in light of the resulting overlay of international regimes and diverse national systems based on distinctive policy goals—has resulted in an unduly complicated system. The collective impact on innovators by these fragmented and complex regimes has not been conclusively documented and remains difficult to unravel for developers and academic commentators alike.[120]

Nonetheless, there have been some recent, notable efforts by stakeholders to respond to perceived negative impacts from the current state of complexity. For example, the Public Intellectual Property Resource for Agriculture (PIPRA) was formed to facilitate ongoing research and innovation in plant biotechnology for public researchers (and researchers of development and food security issues in particular) by providing an easily accessible clearinghouse.[121] To this end, PIPRA began gathering and cataloging patent and licensing information from major public sector organizations (mostly U.S. universities) in an online database.[122] The consolidation "increase[d] transparency and lower[ed] transaction costs—supporting better commercialization of agricultural biotechnology innovations from the public sector."[123] PIPRA also promotes better IP management

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tection may provide for a level of investment that engages innovators in a long, expensive regulatory process. *Id.* at 221–22.

118. *See* Goulding et al., *supra* note 115.

119. This position is consistent with recent findings reported by Angus Livingstone, Managing Dir., Univ.-Indus. Liaison Office, Univ. B.C., Technology Transfer Overview: Biotechnology and the Law (Feb. 8, 2012) (on file with author).

120. For examples of developer confusion existing as a result of this complex regime, see Cohen et al., *supra* note 115.

121. *About Us*, PIPRA, http://www.pipra.org/about/ (last visited Sept. 19, 2012). Although "[t]he early model of PIPRA was a clearinghouse . . . [PIPRA] moved away from identifying [its] core function as a patent clearinghouse, and toward a model that provides services and products that [it] found are most demanded by [its] stakeholders." *Id.*

122. *Id.*

123. *Id.*

"among public sector organizations, including education and outreach on humanitarian use licensing and a range of other topics."[124] Over time, PIPRA has added to its range of services, including publishing the influential Intellectual Property Handbook, which guides stakeholders through the various sharing and IP choices available in national and international regimes, including TRIPS, UPOV, ITPGRFA, and the CBD.[125]

There have been other cases where groups of stakeholders have set up consortia in direct response to issues related to the potential for innovation.[126] In one well documented example, Cereon Genomics (a genomics research group established by Monsanto in 1997) invested significant resources in identifying polymorphisms within published *Arabidopsis* sequence data.[127] When genomics researchers affiliated with the company initially suggested pursuing an open sharing model to encourage both public and private innovation, management expressed concern that uncontrolled release of the information could undermine proprietary potential and hesitated at sharing without a strict delimiting MTA accompanying all disclosures.[128] After much discussion, Cereon ultimately released the data in parcels to a community database—the Arabidopsis Information Resource—and made the data accessible to academic researchers without the rigidity of standard MTAs or licenses.[129] Cereon went on to valuable commercial developments stemming from its *Arabidopsis* research, as did public researchers.[130] The net result has been presented as a model of how novel approaches to public-private collaboration and genomics data sharing can benefit public researchers without damaging proprietary possibilities for industry.[131]

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124. *Id.*

125. *Id.* The Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices is designated as one of PIPRA's core activities and is published in conjunction with the Centre for the Management of Intellectual Property in Health Research and Development (MIHR). *See id*; *About the ipHandbook*, IPHANDBOOK OF BEST PRAC., http://www. iphandbook. org /handbook/about/ (last visited Sept. 19, 2012).

126. In addition to the *Arabidopsis* community example below, the *C. elegans* community demonstrates how openness and sharing of research results and insights can underpin a culture of innovation. *See* Voell et al., *supra* note 116.

127. *Arabidopsis* is considered an important model system for plant biology and was the first plant genus to have its genome sequenced. *See* Steven Rounsley, *Sharing the Wealth. The Mechanics of a Data Release from Industry*, 133 PLANT PHYSIOLOGY 438, 438 (2003) (detailing the release of the *Arabidopsis* polymorphism collection in 2000 by Monsanto's Cereon Genomics unit).

128. *Id.* at 439.

129. *Id.* at 439–40.

130. *Id.* at 438, 440.

131. *Id.* at 440.

These efforts have proven helpful in addressing the case-specific issues of particular groups of stakeholders. We believe, however, that continued efforts to clarify and balance proprietary and shared interests in agricultural genomics are necessary. In a recent presentation on the subject of fostering agricultural innovation, Rochelle Dreyfuss noted that there has been a race toward guaranteeing strong proprietary protections globally, without, perhaps, the necessary reflection on fostering benefits vis-à-vis various stakeholder groups.[132] In their more thorough work on the subject, Professors Dreyfuss and Graham Dinwoodie go on to suggest that in interpreting and implementing the TRIPS agreement, the WTO has lacked a sufficient framework to also take into account the necessary balance between producers and users of knowledge goods and values inherent in proprietary protection models.[133] In light of their findings, Dinwoodie and Dreyfuss identify a need to reassess the current status of IP regimes at an international level.[134] As such, they call for an International *Acquis*—or convocation of the relevant parties to identify norms in the management and provision of IP rights—to undertake this task.[135]

We conclude with our own hope that such a meeting of global stakeholders actually takes place and goes some way toward recognizing the complexities, tensions, and commonalities that exist within the current international and national regimes. We suggest that such a meeting could help streamline the existing regimes, whether via thorough exploration of the relationships amongst existing agreements or through the establishment of a new international instrument that integrates the various possibilities. The aim is to help clarify the impacts of different avenues for protecting and sharing innovations, and to help foster approaches that promote innovation while remaining responsive to the needs of all relevant stakeholders.

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132. Rochelle Dreyfuss, Presentation at the Intellectual Property & Policy Research Group Conference on Changing Goals of Governance for Agricultural Genomics: An Examination of Current Regulatory and Intellectual Property Regimes, Constructing and International Intellectual Property Acquis (November 18, 2011).

133. *See* DINWOODIE & DREYFUSS, *supra* note 14, at 9–12; *see also* Chidi Oguamanam, *Canada: Time to Take Access and Benefit Sharing Over Genetic Resources Seriously*, 60 U. NEW BRUNSWICK L.J. 139, 140 (2010) (indicating a framework addressing these concerns is currently under development).

134. *See generally* DINWOODIE & DREYFUSS, *supra* note 14, at 175–203 (describing how to create a legal framework around which to structure future international IP lawmaking).

135. *See id.* at 20, 177.