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What Role for Humanitarian Intellectual Property? The Globalization of Intellectual Property Rights

Susan K. Sell*

I. INTRODUCTION

Globalization of intellectual property rights poses new challenges in fields ranging from medicine to agriculture. The dramatic expansion of intellectual property rights threatens reduced access to life-saving medicines and essential crops. Even though promising advances in biotechnology may enhance the nutritional content of basic crops, access to those critical developments is endangered by current regulatory trends.

The 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO), is the most important international law governing intellectual property rights.¹ TRIPS extends patent rights to a wide variety of agricultural biotechnology innovations, including pharmaceutical products, pesticides, and plant varieties.² It establishes a twenty-year patent term for these innovations.³ TRIPS requires states to

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1. See Peter Drahos & John Braithwaite, *Intellectual Property, Corporate Strategy, Globalisation: Trips in Context*, 20 WIS. INT'L L.J. 451, 451 (2002).

2. See United Nations Council on Trade and Development- International Center for Trade and Sustainable Development Project on Intellectual Property Rights and Sustainable Development, *Intellectual Property Rights: Implications for Development 77* (2003) [hereinafter UNCTAD-ICTSD Project on Intellectual Property Rights] (summarizing biotechnology patent protection under TRIPS Article 27.3(b)), available at http://www.ictsd.org/pubs/ictsd_series/iprs/PP/PP_3CH_07.pdf; SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 8 (2003).

3. Agreement on Trade Related Aspects of Intellectual Property Rights,

provide adequate and effective enforcement mechanisms both internally and at their borders.⁴ The price of information and technology is increased under TRIPS because monopoly privileges are extended to patent-holders and TRIPS makes WTO dispute settlement procedures available to patent holders claiming violation of intellectually property rights.⁵ If a complaining government is successful in its claim, the WTO can authorize trade sanctions against the violating state.⁶ These settlement procedures and powers to punish make TRIPS a real force in the world.

Intellectual property rights reflect an inherent tension between the strong desire to promote and reward creative energy and the desire to make the fruits of that creativity available to the public.⁷ The granting of exclusive rights must be balanced against the economic effects of higher product and transaction costs⁸ and the potential “exclusion from the market of competitors who may be able to imitate or adapt the invention in such a way that social value is increased.”⁹ Thus, the question is whether intellectual property rights should be treated as “a public goods problem for which the remedy is commodification, or a monopoly of information problem for which the remedy is unfettered competition[?]”¹⁰

Strong intellectual property protection is justified by a market approach, because such protection provides incentives to “increase the number of commercially available products and thereby serve the public interest.”¹¹ However, it is important to question which public interests these rights serve. In the context of agricultural biotechnology, stakeholders include

April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C; LEGAL INSTRUMENTS- RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited Nov. 15, 2004).

4. *See SELL, supra* note 2, at 9.

5. *See id.*

6. *See id.*

7. *See id.* at 15.

8. *See id.*

9. *See id.* at 15 (citing MICHAEL TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL TRADE* 250 (1995)).

10. James Boyle, *A Theory of Law and Information: Copyright, Spleens, Blackmail, and Insider Trading*, 80 CAL. L. REV. 1413, 1450 (1992).

11. Risa L. Lieberwitz, *The Marketing of Higher Education: The Price of the University's Soul*, 89 CORNELL L. REV. 763, 782 (2004) (reviewing DEREK BOK, *UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION* (2003)).

private sector seed companies, public corporations, research institutions, and resource-poor farmers.¹² Intellectual property rights holders benefit from exclusive control of their innovations, as do those who have the resources to gain access to these innovations via the commercial market. Yet market-based solutions have failed to serve marginalized populations, such as the millions of people afflicted with HIV/AIDS and smallholder subsistence farmers in developing countries. The fact that smallholder farmers account for seventy-five percent of the world's undernourished population is evidence of this failure.¹³ In contemporary life science industries, market mechanisms fail to deliver innovation into the public domain.¹⁴ Indeed, "[i]nternational markets for technologies are inherently subject to failure due to distortions attributable to concerns about appropriability, problems of valuing information by buyers and sellers, and market power, all strong justifications for public intervention at both the domestic and global levels."¹⁵ There is a great need to strike a balance between a patent-holder's exclusive rights and the provision of agricultural technology to marginalized populations throughout the world. Solutions that will maximize the benefit of protecting innovation and yet minimize the risk of harm created by the potential overextension of this protection must be explored. It is therefore essential that policymakers consider "humanitarian" policies that promote social goals, such as protecting public health and alleviating malnutrition.

This paper addresses the appropriateness of patent protection for agricultural innovations which could provide extensive benefits to marginalized populations if placed in the public domain. First, it places global intellectual property rights into a broader structural context and discusses a number of issues present in the expansion of agricultural intellectual

12. Cf. UNCTAD-ICTSD Project on Intellectual Property Rights, *supra* note 2, at 107-08 (discussing the rights of plant breeders and the interests of farmers).

13. See Robert Lettington, *Small-scale Agriculture and the Nutritional Safeguard under Article 8(1) of the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights: Case Studies from Kenya and Peru*, UNCTAD-ICTSD, Capacity Building Project on Intellectual Property Rights and Sustainable Development 7 (Draft November 2003), available at <http://www.iprsonline.org/unctadictsd/docs/lettingtonfinaldraft.pdf>.

14. See Keith E. Maskus and Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279 (2004).

15. *Id.* at 288.

property protection. Second, it focuses on conflicts between commercial breeders and smallholder subsistence farmers. The article then examines the current framework of the international intellectual property rights regime, including a discussion of TRIPS and The International Convention for the Protection of New Varieties of Plants (UPOV), bilateral and regional free trade agreements, and the Bayh-Dole Act of 1980. The discussion next reflects upon the changing role of land grant universities in transferring the benefits of agricultural technology. Finally, this paper concludes with policy options for the future.

II. STRUCTURAL DIMENSIONS

The contemporary global intellectual property regime is embedded in a broad structural context characterized by asymmetrical power relationships.¹⁶ Over the past thirty years, the globalization of financial markets and the shift towards an unfettered faith in laissez faire markets ideology pursued by the Reagan and Thatcher administrations has resulted in an increase in corporate transnational power *vis-à-vis* the state.¹⁷ States, seeking to be globally competitive, have liberalized markets, engaged in deregulation and privatization, and implemented new regulatory structures designed to promote efficiency and enforce market-friendly behavior.¹⁸ According to Philip Cerny, “[t]he institutions and practices of the state itself are increasingly marketized or ‘commodified,’ and the state becomes the spearhead of structural transformation to international market norms both at home and abroad.”¹⁹ States have increasingly privatized once-public services, such as prisons, hospitals, military support services and even “mission-critical” functions, such as providing protection for the head of the 2003 Coalition Provisional Authority in Iraq, L. Paul Bremer III. The expansion of intellectual property rights and the privatization of federally funded research under the Bayh-Dole Act must be seen as an instance of this larger trend.²⁰

16. See SELL, *supra* note 2, at 17.

17. *Id.* at 19.

18. *Cf. id.* at 19-20.

19. Philip Cerny, *Political Globalization and the Competition State*, in *POLITICAL ECONOMY AND THE CHANGING GLOBAL ORDER* 300, 304 (Richard Stubbs & Geoffrey Underhill eds., 2nd. ed. 2000).

20. 35 U.S.C. §§ 200-212 (2001). The Bayh-Dole Act of 1980 permits universities to patent inventions resulting from federally funded research.

These broad economic changes have profoundly affected developing countries. Earlier models of economic development such as import-substituting industrialization, popular in Latin America and India, were discredited by economic stagnation and the debt crises of the 1970s-1980s.²¹ Meanwhile, the success of the East Asian “Tigers” vindicated export-led development and integration into global markets.²² Many developing countries subsequently reversed decades-old policies of economic nationalism in favor of market liberalization and privatization and consequently slashed public budgets.²³ Governments in developing countries began to compete to attract foreign investment and eased former restrictions of foreign investors’ activities.²⁴ The new push toward export-led growth meant that developing countries needed access to industrialized country markets.²⁵ The dependence of developing nations on trade gave the United States considerable economic leverage.²⁶ Those developing countries sought access to the expansive United States market.²⁷ Using the U.S. Trade Act of 1974,²⁸ the Office of the United States Trade Representative, at the behest of high-technology firms, threatened trade sanctions against developing countries unless they adopted and enforced highly protective intellectual property policies.²⁹ Such economic coercion was an important factor behind developing countries’ ultimate acceptance of TRIPS.³⁰

This liberalizing agenda favors “finance capital and other mobile factors of production.”³¹ Transnational firms in knowledge-intensive sectors such as pharmaceuticals,

21. See Thomas Biersteker, *The “Triumph” of Neo-classical Economics in the Developing World: Policy Convergence and Bases of Governance in the International Economic Order*, in GOVERNANCE WITHOUT GOVERNMENT: ORDER AND CHANGE IN WORLD POLITICS 102, 121-22 (James Rosenau & Otto Czempel eds., 1992).

22. *Id.*

23. See generally *id.* at 105-07, 121-26.

24. See generally *id.*

25. See generally *id.*

26. See generally *id.*

27. See Biersteker, *supra* note 21 at 105-07, 121-26.

28. See 19 U.S.C. § 2411 (1999).

29. See SELL, *supra* note 2, at 87-94.

30. See *id.* at 9, 87-94, 109-11.

31. Andrew Baker, *Globalization and the British ‘Residual State’*, in POLITICAL ECONOMY AND THE CHANGING GLOBAL ORDER 362, 363-64 (Richard Stubbs & Geoffrey R.D. Underhill eds., 2nd ed. 2000).

chemicals, software, and entertainment “have the resources, motivations and capabilities to roam the world searching for the kind of opportunities that promise lucrative rewards.”³² These privileged sectors participate in “globalized” markets insofar as “there are a small number of participants who know one another and operate across countries with a common conception of control.”³³ TRIPS reflects the wishes of these privileged sectors and globalizes their preferred conception of control by establishing a high level of protection.

Beyond extending property rights, competitiveness concerns moved the United States to relax its antitrust policies.³⁴ The Reagan administration codified this approach in the Antitrust Division’s Merger Control Guidelines of 1982.³⁵ Reflecting the influence of the Chicago School of Economics, the new guidelines abandoned the populist focus on market structure in favor of the Chicago school’s focus on price theory.³⁶ “In this view, only business practices that reduce output and increase prices are anti-competitive; business practices that expand output are pro-competitive.”³⁷ In contrast to earlier approaches, according to the Chicago school, “[h]igh levels of market concentration and the exercise of market power may be indicative of efficiencies.”³⁸ The 1982 guidelines presented an expanded definition of relevant markets. The guidelines allowed the introduction of non-structural factors, such as foreign competition or the possession of new technology that was important to long-term competitiveness.³⁹ The Justice Department argued that “anti-trust laws should not be applied in a way that hinders the renewed emphasis on . . . competitiveness.”⁴⁰

This new thinking removed most intellectual property licensing from antitrust scrutiny. As Thomas Hayslett points

32. Randall Germain, *Globalization in Historical Perspective*, in *GLOBALIZATION AND ITS CRITICS* 67, 81 (Randall D. Germain ed., 2000).

33. Neil Fligstein, *Markets as Politics: A Political-Cultural Approach to Market Institutions*, 61 *AM. SOC. REV.* 656, 663 (1996).

34. See SELL, *supra* note 2, at 72-74.

35. See SUSAN K. SELL, *POWER AND IDEAS* 159 (1998).

36. See *id.* at 158.

37. *Id.*

38. MARC EISNER, *ANTITRUST AND THE TRIUMPH OF ECONOMICS* 105 (1991).

39. See *id.* at 198.

40. PAUL S. HOFF, *INVENTIONS IN THE MARKETPLACE: PATENT LICENSING AND THE U.S. ANTITRUST LAWS* 19 (1986).

out, under Reagan's administration, "executive agencies viewed the economic incentives provided by intellectual property rights as legitimate means of extracting the full economic benefit from innovation."⁴¹ In effect then, "[i]ntellectual property rights acted as a 'magic trump card' allowing many previously suspect arrangements to proceed without challenge from the [Federal Trade Commission] or [Department of Justice]."⁴² Keith Maskus and Jerome Reichman suggest that today:

There are virtually no products sold on the general products market that do not come freighted with a bewildering and overlapping array of exclusive property rights that discourage follow-on applications of routine technical know-how. Weak enforcement of antitrust laws then further reinforces the barriers to entry erected upon this thicket of rights, while the need to stimulate and coordinate investment in complex innovation projects justifies patent pools, concentrations of research efforts, and predatory practices formerly thought to constitute misuses of the patent monopoly.⁴³

So-called patent "thickets" have proliferated, in which overlapping patent rights require those seeking to commercialize new technology to obtain licenses from multiple patent holders.⁴⁴ "A growing thicket of rights surrounds gene fragments, research tools, and other upstream inputs of scientific research, and the resulting transaction costs impede and delay research and development undertaken in both the public and private sectors."⁴⁵

III. ISSUES IN AGRICULTURE

What are the implications of the foregoing for agriculture? "Increasingly . . . [intellectual property] rights have invaded the research commons itself and made it both costly and difficult to obtain cutting-edge technologies needed for public health, agricultural production, environmental protection, and the provision of other public goods."⁴⁶ Critics of the increasing commodification of what was once treated as the public domain

41. Thomas L. Hayslett III, *1995 Antitrust Guidelines for the Licensing of Intellectual Property: Harmonizing the Commercial Use of Legal Monopolies with the Prohibitions of Antitrust Law*, 3 J. INTELL. PROP. L. 375, 382 (1996).

42. *Id.*

43. Maskus and Reichman, *supra* note 14, at 297.

44. Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1090-91 (2003).

45. Maskus and Reichman, *supra* note 14, at 298. See also Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

46. Maskus and Reichman, *supra* note 14, at 303-04.

have raised at least six issues of concern: (1) threats to traditional agriculture and food security; (2) abuses of monopoly power; (3) increased dependence on costly commercial agriculture; (4) threats to biodiversity; (5) “biopiracy;” and (6) questions of benefit sharing.⁴⁷ The discussion in this article focuses on the first three issues of concern.

Technological, judicial, and legislative changes together have produced a radical shift from public to private provision of seeds. As Professor Keith Aoki points out, “[t]he private seed market for grains was almost nonexistent at the beginning of the twentieth century, due to free government seed distribution and the widespread practice of farmer seed saving.”⁴⁸ According to Professor Aoki, “the intersection of biotechnical knowledge and methods and expanded legal protections for plant breeders transforms seed germplasm into a paradigm commodity.”⁴⁹ Legislative changes, including the United States Plant Variety Protection Act of 1970,⁵⁰ “increased expectations of seed industry profits and thereby helped to stimulate an upsurge in mergers and acquisitions”⁵¹ Life sciences corporations “emerged out of a wave of mergers, acquisitions, joint ventures and strategic partnerships involving companies in a wide range of fields such as chemicals, seeds, processed foods, dietary supplements and pharmaceuticals.”⁵² Advances in biotechnology spurred the consolidation process throughout the 1970s and particularly in the 1980s.⁵³ The 1973 development of the recombinant DNA technique, “which enabled foreign genes to be inserted into microorganisms,” helped launch the era of commercial biotechnology.⁵⁴ Notably, although “the Cohen-Boyer method for combining DNA from different organisms” was patented, “the patents were licensed nonexclusively and cheaply to encourage firms to take licenses rather than to challenge the patents.”⁵⁵ This technology had

47. See, e.g., Lettington, *supra* note 13, at 33-37.

48. Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 268-69 (2003).

49. *Id.* at 261.

50. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970).

51. GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCES INDUSTRIES* 149 (2003).

52. *Id.* at 147-48.

53. *Id.* at 148.

54. *Id.*

55. Rai and Eisenberg, *supra* note 45, at 300.

been federally funded, and “[m]any observers attribute the rapid progress of the biotechnology industry to the fact that this technology was made widely available rather than licensed exclusively to a single firm.”⁵⁶ In 1980, the U.S. Supreme Court ruled in *Diamond v. Chakrabarty*⁵⁷ that a man-made, oil-eating bacterium could be patented. This case led to the expansion of rights to own living organisms and injected greater certainty into the development of commercial biotechnology. The ability to acquire patents on altered life forms helped biotechnology startup companies to raise venture capital.

The combination of expanded intellectual property rights and relaxed antitrust enforcement has led to marked economic concentration in the life sciences industries. The “vertical integration” of plant breeding, agrochemical, and food processing corporations has led to a situation in which the top ten seed companies control thirty percent of the world’s \$23 billion commercial seed market.⁵⁸ Corporate plant breeders are obtaining broad patents that will have “far reaching” consequences.⁵⁹ “Breeders are patenting entire species (cotton), economic characteristics (oil quality), plant reproductive behaviour (apomixes), and basic techniques in biotechnology (gene transfer tools).”⁶⁰ Six major industrial groups now control most of the technology “which gives freedom to undertake commercial research and development in the area of [genetically modified] crops.’ These are (i) Agravo and Plant Genetic Systems (PGS); (ii) Du Pont and Pioneer; (iii) ELM, DNAP, Asgrow and Seminis; (iv) Monsanto, Calgene, DeKalb, Agracetus, PBI, Hybritech and Delta and Pine Land Co.; (v) Novartis; and (vi) Zeneca, Mogen and Avanta.”⁶¹ Furthermore, six agricultural biotechnology companies alone hold seventy-five percent of all U.S. patents granted to the top thirty patent-holding firms: Monsanto, Du Pont, Syngenta, Dow, Aventis, and Grupo Pulsar.⁶² This combination of economic

56. *Id.*

57. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-18 (1980).

58. GAIA/GRAIN (Genetic Resources Action Council), *Intellectual Property Rights and Biodiversity: The Economic Myths*, § 4.2 (1998) [hereinafter GAIA/GRAIN, *Intellectual Property Rights and Biodiversity*], at <http://www.grain.org/briefings/> (last visited Nov. 15, 2004).

59. *Id.*

60. *Id.*

61. DUTFIELD, *supra* note 51, at 170.

62. *Id.* at 154.

concentration with extensive and broad patenting means that a handful of global corporations are making huge inroads toward control of the world's food supply and are entangling farmers and indigenous peoples in an increasingly complex web of licensing and royalty obligations. As Keith Maskus and Jerome Reichman suggest:

[T]he natural competitive disadvantages of follower countries may become reinforced by a proliferation of legal monopolies and related entry barriers that result from global minimum [intellectual property] standards. Such external restraints on competition could consign the poorest countries to a quasi-permanent status at the bottom of the technology and growth ladder.⁶³

The current system skews research towards rich and middle-income countries' markets and sectors.⁶⁴ Most notably, there is a tendency in the public health sector to neglect tropical diseases in favor of focusing on cancer and so-called lifestyle afflictions, requiring drugs to combat obesity, balding, and erectile dysfunction. Consequently, only thirteen of 1,233 new drugs marketed between 1975 and 1997 were approved for tropical diseases in particular.⁶⁵ As Professor Hammer suggests, "the rhetoric of strong intellectual property rights leading to innovation that meets social needs rings particularly hollow" for poorer countries most afflicted by tropical diseases.⁶⁶ Similarly, there is a focus on the interests of higher-income markets in the agriculture sector, resulting in the development of crops unsuitable for subsistence and smallholder farming and a dearth of research beneficial for less lucrative micro-climates.⁶⁷ The disproportionate emphasis on wealthier countries' market needs can be corrected through changes in private-public collaboration and through the allocation of more funding towards "the goal of helping subsistence farmers."⁶⁸ Historically, seed companies preferred to develop hybrids because farmers must purchase new hybrid seed every planting season.⁶⁹ Since the offspring of hybrid plants do not breed true-to-type, hybrid seeds offer a "form of

63. Maskus and Reichman, *supra* note 14, at 282.

64. See Lettington, *supra* note 13, at 51.

65. Peter F. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics, and Public Health*, 5 J. INT'L ECON. L. 883, 888 (2002).

66. *Id.*

67. See Lettington, *supra* note 13, at 50-51.

68. John H. Barton, *Nutrition and Technology Transfer Policies*, UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development 14-15 (2003), at <http://www.iprsonline>.

69. UNCTAD-ICTSD, *supra* note 2, at 107.

biological protection.”⁷⁰ However, for plant varieties that lack this built-in biological protection, plant breeders can appeal to plant breeders’ rights. Plant breeders’ rights “generally do not encourage breeding related to minor crops with small markets.”⁷¹ As a result, the private sector under invests in crops and technologies suitable for smallholder farmers, and these public goods are underprovided.

With the advent of genetic engineering, plant breeders sought to safeguard their investments through strong patent protections. Depending on national law, patents may be available for “the use of the new gene to transform a plant, on the transformation process, and most significantly on the transformed plant itself.”⁷² The protection of transgenic plants enables genetic engineering firms to have “more confidence in their ability to reap the fruits of their research.”⁷³ That is because transfer or insertion of the patented gene into other plants constitutes patent infringement.⁷⁴ Before the adoption of the 1991 Union for the Protection of New Varieties of Plants (UPOV91), plant breeders were forced to choose to protect their plant varieties with *either* a plant breeders’ right *or* a patent. However, UPOV91 “removed the 1978 [UPOV’s] ban on dual protection and now permits member states to protect the same plant variety with both a breeders’ right *and* a patent.”⁷⁵ Professor Robert Lettington argues that this expansion of intellectual property rights into the agricultural sector has threatened the public sector’s traditional focus on the needs of smallholder farmers.⁷⁶ First of all, “private sector intellectual property rights may limit public sector access to innovations and germplasm that may be adaptable to smallholder needs and conditions while also limiting public sector research options due to concerns over the unhindered distribution of the products of its research.”⁷⁷ Second, the “failure of intellectual property systems to preserve the integrity of the public domain,

70. Barton, *supra* note 68, at 10.

71. UNCTAD-ICTSD, *supra* note 2, at 106.

72. Barton, *supra* note 68, at 11.

73. *Id.*

74. *Id.*

75. Laurence R. Helfer, *Intellectual Property Rights in Plant Varieties: An Overview With Options for National Governments* 15, (FAO Legal Papers Online No. 31, 2002), at <http://www.fao.org/Legal/prs-ol/lpo31-2.pdf> (emphasis added).

76. Lettington, *supra* note 13, at 8.

77. *Id.*

and the consequent development of intellectual property rights strategies in public institutions, risks distorting research priorities to the detriment of smallholder farmers.”⁷⁸

In developing countries, a large number of farmers are smallholders who do not participate in the transgenic seed market in any substantial way.⁷⁹ Instead, these farmers engage in seed-saving, replanting, and “across-the-fence” exchange.⁸⁰ This is particularly the case in many African countries where the public and private sectors play a minimal role in seed production and distribution.⁸¹ The smallholder farming sector plays an important role in contributing to national food needs. For example, such farmers produce “fifty-one percent of Latin America’s maize, seventy-seven percent of its beans and sixty-one percent of its potatoes.”⁸² In Africa, smallholder farmers produce the “majority of grains and legumes and almost all root, tuber and plantain crops.”⁸³ Furthermore, fifty to sixty percent of Peruvians and seventy to eighty percent of Kenyans depend on smallholder agriculture for their livelihood.⁸⁴

According to Professor Lettington, subsistence farmers traditionally save seeds for reuse, trade, and experimentation with new hybrids.⁸⁵ Such experimentation contributes to the planet’s biodiversity, as evidenced by the farmers in Professor Lettington’s study who produced “as many as [thirty or forty] distinct varieties of potato, and [five or ten varieties] of maize, on farms of little more than a hectare.”⁸⁶ In the past, American laws covering plant varieties incorporated the notion of farmers’ rights in which farmers retained their freedom to engage in these important and traditional activities.⁸⁷ However, in August 1994 the U.S. Congress amended the Plant Variety Protection Act and removed the farmer’s exemption.⁸⁸ As a result, “it is now expressly illegal for farmers to sell or

78. *Id.*

79. UNCTAD-ICTSD, *supra* note 2, at 107; Barton, *supra* note 68, at 6.

80. UNCTAD-ICTSD, *supra* note 2, at 107.

81. *Id.*

82. Lettington, *supra* note 13, at 13.

83. *Id.*

84. *Id.*

85. *Id.* at 24.

86. *Id.*

87. UNCTAD-ICTSD, *supra* note 2, at 107.

88. Pub. L. No. 103-349, § 10, 108 Stat. 3136, 3142 (1994) (amending 7 U.S.C. § 2543).

save seeds from proprietary crop varieties without receiving permission from breeders and paying royalties.”⁸⁹ Ironically, according to Professor Aoki, while the U.S. Patent Office in the “early 19th century began to collect and catalogue and make” seed freely available, by the early twenty-first century, the commodification of germplasm had transformed the U.S. patent office, into a “primary means” of attacking the longstanding “practice of farmer seed-saving.”⁹⁰ Grassroots activists are convinced that American industries are seeking these same results through TRIPS by pushing a particular interpretation of *sui generis* protection under Article 27.3(b).⁹¹

Ultimately, TRIPS restricted the patenting of life forms, but Article 27.3(b) requires that members provide intellectual property protection for plant varieties or an “effective *sui generis*” system.⁹² However, there really is no consensus on what a *sui generis* system needs to include. Additionally, the negotiations leading to the adoption of Article 27 provide little guidance because they provide no record on the meaning of *sui generis*.⁹³ American plant breeders have been pushing the UPOV as the model *sui generis* system. American support of UPOV may be due in part to how generous UPOV is to the corporate plant breeder.⁹⁴ Fifty-one countries, many of which are industrialized, have joined the UPOV, which was last amended in 1991.⁹⁵ The 1978 version of UPOV provided two limitations on the monopoly rights of plant breeders.⁹⁶ First, other breeders could freely use UPOV-protected varieties for research purposes.⁹⁷ Second, farmers could reuse the seed for

89. SETH SHULMAN, *OWNING THE FUTURE* 90 (1999).

90. Aoki, *supra* note 48, at 331.

91. See GAIA/GRAIN, *Signposts to Sui Generis Rights: The International Context of the Sui Generis Debate*, § 1.1.1 (1998), at <http://www.grain.org/briefings/?=173.id/gtbc/issue3.html>.

92. *Id.* at 7.

93. Johanna Sutherland, *TRIPS, Cultural Politics and Law Reform*, in 16 *PROMETHEUS* 291, 295 (1998).

94. See GAIA/GRAIN, *UPOV on the War Path* (June 1998) [hereinafter GAIA/GRAIN, *UPOV on the War Path*], at <http://www.grain.org/briefings/>.

95. See International Convention for the Protection of New Varieties of Plants, Dec. 2 1961, as amended on Mar. 19, 1991 (listing the states party to the convention as of Oct. 24, 2002), available at http://www.upov.int/en/publications/gazette/pdf/pub422_24-10-02.pdf (last visited Nov. 15, 2004).

96. GAIA/GRAIN, *UPOV on the War Path*, *supra* note 94.

97. See *id.*

the following year's harvest under certain conditions.⁹⁸ The 1991 revision narrowed down the exemption for competing breeders, deleted the so-called farmers' privilege, and extended the breeders' monopoly right to the products of the farmer's harvest.⁹⁹ "Although the UPOV system allows on-farm replanting, its rules restrict farmers' freedom to buy seed from sources other than the original breeders."¹⁰⁰ UPOV91 "does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes."¹⁰¹ To join UPOV today, nations must sign the 1991 treaty.¹⁰² Countries eschewing the UPOV system can adopt *sui generis* systems of protection that allow "farmers to acquire . . . protected seed from any source and/or requiring protected varieties to display qualities that are genuinely superior to existing varieties."¹⁰³

In a comparative study of smallholder farming in Peru and Kenya, Robert J. L. Lettington did not find evidence that plant variety protection (PVP) legislation harmed smallholder agriculture.¹⁰⁴ However, he argued that "the current system of PVP [legislation] is failing to create solutions to existing problems."¹⁰⁵ In particular, PVP legislation has created incentives that direct resources away from subsistence farmers' needs in favor of those of large commercial agricultural enterprises.¹⁰⁶ It also promotes the use of commercial seed as opposed to landraces or "wild" cultivars.¹⁰⁷ "The end result has been a hastening of the deterioration of food security in these areas . . ."¹⁰⁸ Professor Lettington suggests that governments that seek to limit the cost of seed in economically and climatically marginal areas may "need to place limits on the nature of intellectual property rights."¹⁰⁹

98. *See id.*

99. *See id.*

100. UNCTAD-ICTSD, *supra* note 2, at 107.

101. Helfer, *supra* note 75, at 17 (citing J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*, KLUWER L. INT'L. 141 (2000)).

102. GAIA/GRAIN, *UPOV on the War Path*, *supra* note 94.

103. *See* UNCTAD-ICTSD, *supra* note 2, at 107.

104. *See* Lettington, *supra* note 13, at 32.

105. *See id.*

106. *See generally* GAIA/GRAIN, *UPOV on the War Path*, *supra* note 94.

107. *See generally id.*; Lettington, *supra* note 13, at 34.

108. Lettington, *supra* note 13, at 34.

109. *Id.*

IV. THE REGULATORY ENVIRONMENT

In examining the regulatory environment in this context, the central question is what degree of discretion states have in limiting intellectual property rights to support smallholder agriculture. There are at least two dimensions to the answer: one addresses the letter of the law, the other addresses the broader context of asymmetrical power. Focusing on the formal features of intellectual property law, texts, and institutions, one sees plenty of room for state discretion and flexibility in adapting the global minimum standards to local concerns.¹¹⁰ However, this formal universe is embedded in a system of asymmetrical power relationships and global capitalism that constrain weaker states' abilities to exploit the flexibilities crafted into the law.¹¹¹

TRIPS provides substantial flexibility for developing countries.¹¹² Article 27.3(b) specifies that countries may adopt an "effective *sui generis* system" to protect plant varieties.¹¹³ Under TRIPS, countries may adopt patent protection for plant varieties, UPOV91, an alternative *sui generis* system, or some combination of these forms of protection.¹¹⁴ While corporate plant breeders would prefer that developing countries adopt UPOV91 as their domestic legislative standard, these countries are by no means required to do so.¹¹⁵ The UPOV treaties are one type of *sui generis* protection designed to serve the interests of plant breeders. In a searching and thorough analysis of developing countries' options, Professor Laurence Helfer has arrayed the options on a spectrum ranging from maximum discretion to minimal discretion for developing countries to tailor their systems to meet their particular needs.¹¹⁶ States that adopt TRIPS and ratify or accede to UPOV91 have the least discretion.¹¹⁷ According to Professor

110. *See id.* at 32.

111. *See generally id.* at 32-34; SOUTH CENTRE/CIEL IP, QUARTERLY UPDATE: FIRST QUARTER 2004, FIRST QUARTER 2004: INTELLECTUAL PROPERTY AND DEVELOPMENT: OVERVIEW OF DEVELOPMENTS IN MULTILATERAL, REGIONAL, AND BILATERAL FORA, *available at* <http://www.southcentre.org/info/sccielipquarterly/ipdev2004q1.pdf> (last visited Oct. 1, 2004) [hereinafter South Centre].

112. *See Helfer, supra* note 75, at 23.

113. *Id.* at 22.

114. *See id.* at 23.

115. *See generally id.* at 22.

116. *See id.* at 34-47.

117. *See id.* at 37.

Helfer, states wishing to retain maximum flexibility and discretion to serve the needs of smallholder agriculture would be well-advised to adopt TRIPS *only*.¹¹⁸

The advantages of TRIPS are that its provisions on plant varieties “do not refer to or incorporate any preexisting intellectual property agreements, including the 1978 and 1991 UPOV Acts.”¹¹⁹ TRIPS members are neither required “to become members of UPOV nor to enact national laws consistent with either UPOV Act in order to comply with their obligations under TRIP[S].”¹²⁰ Article 27.3(b) preserves “significant leeway for national governments to work out the precise manner in which they will balance protection of IPRs against other international obligations and national objectives.”¹²¹ “The chances are, that for a poor nation, neither a UPOV nor a regular patent approach will actually encourage private-sector research. Hence, such a nation is probably best-off adopting minimum compliance with TRIPS”¹²² TRIPS, unlike UPOV91, preserves the right of subsistence farmers to exchange seed.¹²³ For a nation in which the exchange is an issue, it would be wise to incorporate both subsistence farmer exemptions and research exemptions in national plant breeders’ rights legislation.¹²⁴ Countries wishing to adopt the stronger UPOV91 system should consider incorporating waivers or exemptions for subsistence and smallholder farmers.¹²⁵ In countries lacking significant private sector competition, as is often the case in poor countries, public sector seed provision will be important to promote competition to stimulate both variety and lower prices.¹²⁶

Public-private partnerships in agriculture might stimulate the transfer of technology so that public sector seed providers could adapt technology to subsistence farmers’ needs.¹²⁷ In order for such arrangements to work, private firms would need to retain opportunities to capture economic benefits in the market sector, while keeping the technology affordable for the

118. See Helfer, *supra* note 13, at 39-46.

119. *Id.* at 22.

120. *Id.*

121. *Id.* at 31.

122. Barton, *supra* note 68, at 11.

123. See *id.* at 15, 19-20.

124. See *id.* at 19.

125. See *id.* at 23-24.

126. See *id.* at 12, 14.

127. See *id.* at 15.

subsistence sector.¹²⁸ This two-tiered arrangement has some parallels in the control of access to medicines and would require safeguards against diverting subsistence-priced technology into the market sector.¹²⁹

Focusing on TRIPS and the letter of the law, one can conclude, as does Professor Helfer, that:

States that implement the four core TRIP[S] requirements in good faith – that is, states that grant breeders intellectual property rights and enforcement measures applicable to varieties in all species and botanical genera and that provide those same rights and measures to breeders from other TRIP[S] member states – are unlikely to have their laws challenged successfully.¹³⁰

However, public international law such as TRIPS is embedded in a broader context of asymmetrical power relationships between developed and developing countries, and between producers and consumers of the fruits of biotechnology. This context reduces the amount of leeway that poor states have in devising regulatory approaches most suitable for their individual needs and stages of development.¹³¹ In particular, developing countries increasingly have been subject to bilateral and regional pressure to surrender the flexibilities afforded by TRIPS.¹³² Bilateral investment treaties, bilateral intellectual property agreements, and regional free trade agreements concluded between the United States and developing countries and between the European Union and developing countries invariably have been considered to be “TRIPS-Plus.”¹³³ For example, in the intellectual property provisions covering agriculture in the Central American Free Trade Agreement framework, developing countries are most often required to ratify or accede to UPOV91 as their *sui generis* system of protection and “to undertake ‘all reasonable efforts’ to make patent protection available for plants.”¹³⁴

Furthermore, developing countries have failed to take full advantage of TRIPS flexibilities not only in the agricultural marketplace, but the pharmaceutical market as well. This is

128. See Barton, *supra* note 68, at 15.

129. See *id.*

130. Helfer, *supra* note 75, at 34.

131. See generally Lettington, *supra* note 13, at 32-34; South Centre, *supra* note 111, at 1.

132. See generally South Centre, *supra* note 111, at 12.

133. See *id.*

134. See *id.*

largely because such nations are eager to attract foreign investment and are concerned about alienating potential investors.¹³⁵ They also are eager to have access to technologies that may aid in their development, provide reliable nutrition, and which have the potential to address a myriad of pressing social and economic problems.¹³⁶ Most of these countries lack significant bargaining leverage and the capacity to resist the high-pressure tactics of the United States Trade Representative and the industries that it represents.¹³⁷

In these circumstances it is imperative that public institutions take the lead in assisting developing countries in the implementation of suitable legislation that conforms to their international legal obligations. Public institutions, such as land grant universities, must also continue to make the fruits of their research available to those who need it most on terms that the recipients accept. The 1980 Bayh-Dole Act allowed "grantees to seek patent rights in government-sponsored research results."¹³⁸ The idea behind this was that many inventions with commercial potential lay fallow in university laboratories, and that patenting opportunities would give universities incentives to search research labs for significant and marketable inventions.¹³⁹ The Bayh-Dole Act has resulted in at least a ten-fold increase of university patenting activity since 1979.¹⁴⁰ This flurry of patenting activity has had the beneficial effect of generating revenue for cash-strapped public universities. For instance, the patent infringement award that the University of Minnesota won for the development of the drug Ziagen has provided much-needed funding for research and graduate student support.¹⁴¹ University patent portfolios also help to attract private sector funding, especially in biotechnology.¹⁴²

However, the Bayh-Dole Act also has created new divisions

135. See generally GAIA/GRAIN, *Intellectual Property Rights and Biodiversity*, *supra* note 58

136. See generally GAIA/GRAIN, *Signposts to Sui Generis Rights: The International Context of the Sui Generis Debate*, (1998), at <http://www.grain.org/briefings/?=173.id/gtbc/issue3.html>.

137. See generally *id.*

138. Rai and Eisenberg, *supra* note 45, at 290.

139. See Lieberwitz, *supra* note 11, at 771.

140. See Rai & Eisenberg, *supra* note 45, at 292.

141. See University of Minnesota Board of Regents Minutes (Oct. 8, 1999), available at <http://www1.umn.edu/regents/minutes/1999/october/board.html>.

142. See Rai & Eisenberg, *supra* note 45, at 303.

within universities. As Professors Arti Rai and Rebecca Eisenberg point out, the legislation makes no distinction between upstream and downstream research, and as a result, an increasing number of research tools have become patent-protected.¹⁴³ An unintended consequence of the Bayh-Dole Act has been the dramatic reduction of open access to research tools.¹⁴⁴ Technology transfer offices are charged with patenting and licensing technology to generate revenue for the institution. Research scientists are more interested in having access to “open science.”¹⁴⁵ The Bayh-Dole Act also has increased university collaboration with private sector biotechnology firms, raising many questions about academic freedom, research priorities, and incentives.¹⁴⁶ Some critics have gone so far as to assert that universities have lost their sense of “public mission.”¹⁴⁷

Yet the choices may not be so stark, and there may be ways to navigate the contours of the current system to better balance competing imperatives. For example, in the pharmaceutical sector, there could be clauses in agreements to allow a university to sublicense to generic manufacturers if its patent conflicts with efforts to distribute affordable drugs for HIV/AIDS victims in sub-Saharan Africa.¹⁴⁸ Professors Rai and Eisenberg offer a similarly modest and sensible suggestion for publicly-funded research. They suggest that “decisions about the dividing line between the public domain and private property should be made by institutions that are in a position to appreciate the tensions between widespread access and preservation of commercial incentives without being unduly swayed by institutional interests that diverge from the overall public interest.”¹⁴⁹ In other words, they argue that public funding agencies should decide what fruits of their investments to patent.¹⁵⁰ They also advocate addressing the upstream/downstream research tool issue by devising “a system that distinguishes cases in which proprietary claims

143. *See id.* at 290-91.

144. *See id.* at 294.

145. *See id.* at 305.

146. *See id.* at 304.

147. Lieberwitz, *supra* note 11, at 789.

148. *See, e.g.*, Michael A. Friedman, Henk den Besten & Amir Attaran, *Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 *THE LANCET* 341 (2003).

149. Rai & Eisenberg, *supra* note 45, at 303.

150. *See id.*

make sense from cases in which they do not.”¹⁵¹ Research tool exemptions would be useful to help to preserve the domain of “open science.”

V. CONCLUSION

This brief overview of some major issues involved in intellectual property protection and agricultural biotechnology underscores the fact that “the institution of property is extremely complex, and more importantly, political.”¹⁵² Yet we are no closer to resolving these controversies. “More often than not, rather than being an answer, the issue of property rights is only the beginning of a long series of vexing questions.”¹⁵³ Developing countries should do what they can to preserve their autonomy in adopting intellectual property policies that suit their levels of development. They should resist TRIPS-plus initiatives in bilateral and regional trade and investment agreements and insist upon TRIPS as their maximum standard. Developing nations should seek technical assistance that encourages them to use existing TRIPS flexibilities. They also need to participate in global standard-setting exercises concerning competition policy and address the ways in which they would prefer to regulate foreign firms’ acquisition of local firms.¹⁵⁴

Promoting genuine competition is an important policy objective. “Nations in which there is limited private sector competition in the seed industry should ensure that public sector varieties are available in competition with private sector ones.”¹⁵⁵ Professor Lettington recommends:

The activities of smallholder farmers, in particular the saving, use, exchange, and sale of farm-saved seed, should be explicitly stated as not subject to the rights of intellectual property rights holders. In accordance with the purposes and objectives of TRIPS, effort should be made to develop effective incentives for research targeted at smallholder farmers..... Limited exceptions to intellectual property rights should be permitted to promote the adaptation of protected products to the needs of smallholder farmers. These should apply to both research and development and to manufacturing and

151. *Id.*

152. Aoki, *supra* note 48, at 317.

153. *Id.* (citing Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 *IND. J. GLOBAL LEGAL STUD.* 59 (1998)).

154. See Barton, *supra* note 68, at 13.

155. *Id.*

distribution.¹⁵⁶

Universities may feel caught between the conflicting imperatives of attracting private sector funding and generating revenue through patenting activity on the one hand, and promoting public goods through “humanitarian intellectual property” policies on the other. It is clear that universities have an important role to play in preserving the balance between exclusion and access as well as paving the way to more informed, effective, and socially responsible agricultural intellectual property policies.

156. Lettington, *supra* note 13, at 8.