# The Regime Complex for Plant Genetic Resources

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#### Abstract

The study of regimes has focused on the negotiation of rules that, in practice, have been codified into single agreements. Scholars have generally assumed that individual regimes are decomposable from others. Given the rising density of international institutions, we suggest that an increasingly common phenomenon is the "regime complex"—a collective of partially-overlapping regimes. We suggest that regime complexes evolve in special ways. They are laden with legal inconsistencies because the rules in one regime are rarely negotiated in the same fora and with the same interest groups as rules in other regimes. These inconsistencies, which occur at the joints between regimes, focus a process of problem-solving as actors attempt to resolve inconsistencies through the process of implementation; in turn, viable solutions focus later rounds of formal rule-making and legalization. We illustrate the concept of regime complexes using the rarely studied issue of property rights in plant genetic resources (PGR). Over the last century governments have created property rights in these resources in a Demsetzian process: as new technologies and ideas have made PGR more valuable, property rights have allowed firms and governments to appropriate that value. We explore our conjectures about the development of rules in a regime complex through the PGR case.

## The Regime Complex for Plant Genetic Resources

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#### I. Introduction

International institutions have proliferated rapidly in the postwar period.<sup>2</sup> New treaties and organizations have been created as new problems have risen on the international agenda. As the number of international institutions grows, international norms are also becoming more demanding and intrusive. International institutions increasingly address topics, such as rules on intellectual property and food safety, that affect national policies far "behind the border." The growing density of international institutions, coupled to their new-found intrusiveness, has also been accompanied by a shift in political processes. Governance systems dominated by elites have given way to more participatory and democratic modes; the policy process has become more complex as a growing array of government agencies, transnational organizations and experts become engaged in decision-making and implementation.<sup>4</sup>

These trends—in particular the rising density of international institutions—make it increasingly difficult to isolate and "decompose" individual international institutions for study.<sup>5</sup> Yet the vast majority of effort to build and test theories about the origins, operation and influence of international regimes has been conducted as though such decomposition was feasible. Most empirical studies focus on the development of a single regime, usually centered on a core international agreement and administered by a discrete organization.<sup>6</sup> Such studies occasionally note the often complicated links between and among international institutions, but the scholarly literature on cooperation has generally not

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<sup>&</sup>lt;sup>2</sup> Shanks et al. 1996. In-depth studies of particular areas of international cooperation—such as trade, arms control, or human rights—all point to the same general pattern of rising numbers of institutions.

<sup>&</sup>lt;sup>3</sup> Lawrence et al. 1996.

<sup>&</sup>lt;sup>4</sup> Howse 2002; Keohane and Nye 2000; Slaughter 1997; Skolnikoff 1993.

<sup>&</sup>lt;sup>5</sup> Keohane and Nye 2000.

<sup>&</sup>lt;sup>6</sup> For example, in the field of international environmental politics the archetype is the Montreal Protocol on ozonedepletion, which has been the subject of analysis from multiple perspectives such as the role of state power (Benedick 1998), scientific expertise (Parson 2002), side-payments (DeSombre and Kaufman 1996) and ideas (Litfin 1994).

focused on explaining institutional "interplay." Those studies that have focused on institutional interactions have tended to examine hierarchical or "nested" regimes—such as regional trade agreements that are embedded within the larger global trade regime—in which some international rules and norms have explicit precedence over others. The bulk of scholarship on international regimes has also taken a functional approach to analyzing cooperation and not given close attention to how the framing of issues affects the boundaries of regimes. Lack of systematic attention to setting boundaries and to the interactions between international institutions across defined boundaries leaves a large hole in the existing body of theory about international institutions. Yet the rising density of the international system makes it likely that interactions among regimes will be increasingly common.

In this article we address this gap in theory by advancing several arguments about regime interactions under conditions of institutional density. We develop and explore these arguments through the lens of an understudied issue in international relations: the control of plant genetic resources (PGR). The PGR case is important because it lies at the nexus of critical areas of world politics—intellectual property, environmental protection, agriculture, and trade. Rather than a single, discrete regime governing the control of PGRs, the relevant rules are found in at least five clusters of international legal agreements—what we call *elemental regimes*—as well as in national rules within key states, especially in the United States and members of the European Union. These elements overlap in scope, subject, and time; events in one affect those in others. We term the collective of these elements a regime complex: an array of partially overlapping institutions governing a particular issue-area, among which there is no agreed upon hierarchy. While the PGR regime complex is unusual in its intricacy, we do not think it is unique. Rather, we suggest that the PGR regime complex is an exemplar of an important contemporary phenomenon—a proliferation of regime complexes caused by the increasing depth and scope of international rules is making individual agreements less decomposable from others. The PGR case, we argue, is a harbinger of things to come.

As a first cut at understanding the implications of rising institutional density, we advance four broad and related conjectures about the dynamics of regime complexes.

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<sup>&</sup>lt;sup>7</sup> The few exceptions include Young 2002: Stokke 2001.

<sup>&</sup>lt;sup>8</sup> Young 2002; Wendt, 1999.

<sup>&</sup>lt;sup>9</sup> There is a growing literature on PGR, but little of it seeks to explain change in international rules. See e.g Kloppenberg 1988; Pardey 2001; Evenson 2002; and Helfer 2002. The comprehensive *Cambridge World History of Food* gives hardly any attention to international rules; its index does not even offer entries for the WTO, TRIPs or UPOV; see Kiple and Ornelas 2000. Scholarship on environmental protection has touched on PGR as it relates to biodiversity; scholarship on trade has also touched on this subject because PGR is part of TRIPs. There is an extensive literature on most of the individual agreements that we discuss but few studies examine the interactions between treaties—as we do. An exception is Helfer 2002. Those that do examine such interactions focus mainly on conflicts between the CBD and TRIPs because that was the political hotbed in the 1990s, but as we show the conflicts and synergies extend over many other agreements and began long before the 1990s.

These conjectures flow from the core attribute of a regime complex: multiple regimes which functionally overlap yet are not hierarchically-organized. Our first conjecture is that within a regime complex, interactions among the elemental regimes significantly shape the development of substantive rules. In the existing literature on regime formation the standard, if implicit, presumption is that regimes are negotiated on a largely clean institutional slate. Organized interests arrive at the proverbial bargaining table and vie for control over the outcomes, which in turn are implemented often through creation of institutions that are tailored to the task. In cases where parties negotiate in the context of an existing institution, such negotiations are usually focused on amending or adjusting the rules to which the institution is already tailored—an extension of existing arrangements rather than any fundamental change. In regime complexes, by contrast, international negotiations occur not on a clean slate but rather against an array of existing rules. Consequently, we expect to observe that it will be difficult for governments to orchestrate negotiating strategies that achieve particular aims because it is difficult—even for powerful states—to exert leverage in many diverse for a simultaneously and consistently. The move to cooperation on "behind the border" issues only exacerbates this problem because it is no longer foreign ministries that dominate international diplomacy: instead, a raft of domestic agencies, often with quite distinct agendas, are increasingly playing active roles in international relations. 10

Second, the existence of distinct negotiating fora creates opportunities for forum-shopping by both states and non-state actors. The availability of multiple fora should lead both states and non-state actors to seek out the forum most favorable to their interests. In this study we explore not only the degree to which forum-shopping occurs but also the impact forum-shopping has on the evolution of rules within regime complexes. We expect that factors such as barriers to entry, voting rules, and linkages among issues help to explain forum selection.

Third, we expect that the existence of a dense array of international institutions will make it likely that negotiators will agree on rules in one forum that are inconsistent with those in another. We hypothesize that the evolution of rules and norms in a regime complex is driven in large part by efforts to resolve legal inconsistencies between substantively overlapping rules developed in different fora. Scholars have noted the move to law in world politics. An implication of that shift should be not only attempts to cause changes in behavior through the use of law—for example, negotiation of legally-binding treaty commitments—but also pressure to assure legal consistency among regimes affecting world politics. Consistency—treating like situations alike -- is a core element of the legal paradigm, and we examine how efforts to attain legal consistency affect substantive outcomes. Efforts at ensuring consistency, we expect, are an important driver of rule change. Whereas in standard theories of international regimes the evolution of the

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<sup>&</sup>lt;sup>10</sup> Slaughter 1997

<sup>&</sup>lt;sup>11</sup> Goldstein et al. 2000.

regime is driven by political contests over the core rules of the regime, we argue that the evolution of regime complexes often occurs through a process that is focused on inconsistences at the "joints" between elemental regimes. Within each elemental regime an enormous organizational and legal machinery exists to ensure consistency down to the placement of commas. However, it is inconceivable that governments could negotiate detailed and demanding rules in each elemental regime that are consistent with all other elemental regimes. There is no single, omnibus international negotiation—rather, multiple negotiations on different timetables and dominated by different organizations and interests.

Fourth, we explore how governments contend with inconsistencies in international rules through the processes of putting those rules into force. The vast literature on policy implementation demonstrates that in domestic contexts the anticipation of such conflicts occurring during implementation often gives rise to broad, aspirational rules and then attempts to work out differences between actual performance and formal norms through the process of implementation. <sup>12</sup> In the international context we similarly hypothesize a greater reliance on broad ex ante rules as well as ex post implementation and interpretation of those rules.

Our study shows that the participants in the PGR regime complex contend with rule inconsistencies in two ways. When feasible, they adjust the norms through interpretation and build in flexibility that allows diverse interpretation strategies because it is exceedingly cumbersome to make formal changes in international rules—transaction costs are high, reopening one area of negotiation often entrains other issues that have been set aside, and states find it difficult to anticipate outcomes and follow a clear strategy ex ante as the issues become complex and link across multiple issue-areas. In other cases, where the inconsistencies are fundamental, attempts to implement conflicting rules are treated as laboratories for experimentation and learning. Solutions worked out "on the ground," in turn, focus subsequent efforts to make formal changes in the rules.

In examining these linked hypotheses, we also make several claims about the specific evolution of rules in the PGR regime complex—a largely ignored topic in international relations, but one that is increasingly significant. For most of history, PGRs-such as genetic codes, seed varieties, and plant extracts--were treated as the "common heritage of all mankind." They were understood to be freely available to all and owned by none. By the end of the 1990s, however, the normative framework that governed PGRs was radically transformed—though as we show, this transformation occurred unevenly. Genetic resources were no longer considered to be common heritage; rather, new international and domestic rules declared them to be sovereign property, subject to private ownership through intellectual property rights such as patents. We draw on Demsetzian theories of the creation of property rights to argue that the rise of property rights in PGR

<sup>&</sup>lt;sup>12</sup> Ingram 1977; Bardach and Kagan 1982; Stewart 1975.

<sup>&</sup>lt;sup>13</sup> Kloppenburg 1988

was the result of the rising value of PGR, which in turn was largely the product of exogenous technological changes. We examine the rules that govern PGRs in their natural state—"raw" resources—as well as the "worked" resources that consist of the intellectual property built up through improvements to the plant genomes. Raw PGRs are those found in the wild, such as a flower in the rainforest that contains a yet undiscovered gene that cures cancer. Worked genetic resources, by contrast, are the products derived from that flower—such as the cancer-fighting drug.

Over the course of the 20th century both worked and raw genetic resources became much more important. Technological change permitted new and far-reaching techniques of genetic manipulation, creating greater value-added in novel worked products. Raw resources also rose in perceived value—both as an input to innovation and as a valuable environmental good in their own right. New technologies made it easier to identify potentially valuable genetic resources in a haystack of samples, and new ideas emphasized the intrinsic value of nature—leading firms, governments and NGOs to believe that genetic resources were significantly rising in value, and that in turn induced them to create new rules that allowed them to claim property rights on these resources. We show how the combination of new technologies and ideas contributed, along with exogenous shocks and other factors, to a dramatic change in governing norms. Subsequent events have demonstrated that the rise in value of raw PGR has been much lower than many anticipated; nonetheless, the PGR case illustrates that *perceived* value change can be as significant as real value change for a Demstezian transition in property rights.

In this article we do not and cannot attempt a full derivation or rigorous test of our conjectures about the dynamics of a regime complex, nor do we present an exhaustive case study of the evolution of the PGR regime complex. Rather, our aim is to show, through our discussion of the PGR case, that there is utility in analyzing regime interactions systematically and guided by the concept of regime complexes. We first summarize the PGR case and theorize about the factors that have caused changes in property right norms over the last century. We introduce each element of the regime complex and show how the interactions between elemental regimes have become more numerous as the international rules have become more intrusive and demanding. Second, we explore the significance of the concept of a regime complex for the theories of international institutions, focusing on the four conjectures introduced above.

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<sup>&</sup>lt;sup>14</sup> Demsetz 1967; Libecap, 1989; Merrill, 2002

<sup>&</sup>lt;sup>15</sup> As such, this study contributes to the literature on the political influence of ideas; see Goldstein and Keohane 1993. Whereas much of this research has focused on grand notions that diffuse broadly—such as trade liberalism or the protection of human rights—our study shows the importance of a more narrowly focused set of ideas.

<sup>&</sup>lt;sup>16</sup> Peters et al. 1993 and Godoy et al. 1993.

## II. Explaining Norm Change: The Rise of Property Rights in Plant Genetic Resources

PGRs have been a central part of human civilization since its inception, though genes per se were not well understood until recently. The improvement of wild genetic resources is a hallmark of organized agriculture, and the surplus of productive agriculture is what has allowed civilizations to develop by moving people off the land and into cities. Whether in the wild or in seed banks, for centuries PGRs were viewed as a resource that was shared in common and accessible to all—a system that did not assign private ownership of these resources and later became labeled the "common heritage of mankind." We call this basic structure of property rights the "common heritage-open access" system. Common heritage was the rule of ownership: PGRs could not be owned by individuals or states. Open access meant that state did not generally restrict others from obtaining small samples of PGR, such as seeds or small clippings from plants. <sup>18</sup>

In the 20th century this structure of property rights changed. By the 1990s, governments increasingly viewed raw PGRs as sovereign resources rather than common heritage; increasingly, governments also afforded individuals a wider range of varied intellectual property rights for worked PGR, including full utility patents, and they negotiated international trade agreements and treaties that required other governments to do the same. Other international agreements did not embrace this approach, and for some time there was considerable conflict among the various regime rules (as we show, this conflict still persists in some areas). Ultimately, however, a consensus emerged, most fully in the late 1990s. We call this new system of propertization the "sovereign resources—intellectual property rights" approach.

To describe and explain this fundamental normative shift toward enclosure we look to the theory of property rights famously developed by Demsetz and elaborated by Libecap and others. Demsetz suggested that the development of property rights is a function of changes in value: "property rights arise," he argued, "when it becomes economic for those affected by externalities to internalize benefits and costs." In other words, when the private value of a good rises, potential owners will agitate to change property rules so that it becomes easier for them to seize the added value. To be sure, collective action problems may prevent efficiency-enhancing transitions, but often, as the broad literature on property

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<sup>&</sup>lt;sup>17</sup> Common heritage as a legal principle can be found in other arenas; for example, it had been applied to ownership of seabed resources in the UN Law of the Sea Convention.

<sup>&</sup>lt;sup>18</sup> Exceptions do exist, such as the (unsuccessful) efforts to keep the rubber tree a monopoly of Brazil in the 19<sup>th</sup> century.

<sup>&</sup>lt;sup>19</sup> Demsetz 1967; Libecap 1989;

<sup>&</sup>lt;sup>20</sup> Demsetz 1967.

rights illustrates, property rights are created when underlying costs and benefits shift.<sup>21</sup> Nonetheless, Demsetzian arguments are frequently criticized for failing to specify the mechanisms by which property rights develop.<sup>22</sup> While our primary goal in this article is not to provide a gloss on the theory of property rights, we do illustrate in some detail the particular process by which property rights in PGR arose globally.

That process took decades. The rise of for-profit seed companies in the 1920s, based on expensive R&D to breed and test new crops, began to eclipse publicly funded agricultural research as a source of new value in crops and also created the first pressures to provide intellectual property protections for worked PGR. But it was technological changes in the 1970s and 1980s—in particular, the rise of biotechnology and genetic engineering—that created a strong push for intellectual property protection because investors believed these changes would transform agricultural breeding just as they were transforming the pharmaceutical industry. In pharmaceuticals the new business model focused on "blockbuster" products that required strong intellectual property rights to yield windfall profits.<sup>23</sup> At the same time, tropical nations began to view raw PGR as a new source of wealth—the cure for cancer, for example, might be found in a tropical plant extract. New assay machines made it possible to screen the properties of a much larger quantity of raw PGRs at lower cost, raising the value of raw PGRs. The biotechnology revolution created the impression that if valuable PGRs were discovered they could be transformed readily into "blockbuster" drugs that would generate huge revenues. Southern, biodiverse states sought to ensure that they would be well compensated for harboring these important resources. The result of all these changes was significant pressure to replace the "common heritage-open access" system with the current "sovereign rights-intellectual property rights" system. Rather than treating these resources as held in common and shared, this shift in legal rules meant that raw PGRs would be treated as sovereign resources just like oil or timber. And rather than unprotected innovations, worked PGRs would be protected by a wide range of intellectual property rights.

This section tells the story of the shift to propertization and examines the role of international regimes in that process. The transformation did not occur smoothly according to a single plan or initiative; nor did the transformation occur through a single, omnibus negotiation aimed at the creation of a new international regime. Rather, as we describe, there were six distinct strands of activity, each of which addressed some important, but partial, aspect of the PGR issue. Each of the five strands constitutes what we call an elemental regime—an institution, based on a treaty or agreement, that reflects agreed principles and norms and codifies specific rules and decision-making procedures. Three of these elemental regimes are explicitly focused on agriculture, and two extend far beyond agriculture to broader issues:

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<sup>&</sup>lt;sup>21</sup> Levmore, 2002.

<sup>&</sup>lt;sup>22</sup> Id.; Libecap, 1989.

<sup>&</sup>lt;sup>23</sup> Pisano 2002.

- The 1961 International Convention for the Protection of New Varieties of Plants (UPOV), as amended in 1978 and again in 1991, governs the property rights that plant breeders can claim over new plant varieties that they breed intentionally. These treaties require members to recognize "plant breeders' rights", a form of intellectual property protection for plant varieties widely implemented in industrialized countries.
- The FAO, which has been the locus for negotiation of two key international agreements: the 1983 *International Undertaking on Plant Genetic Resources* and the 2001 *International Treaty on Plant Genetic Resources*. FAO for are also the main sites for international negotiations on agricultural matters.
- The Consultative Group on International Agriculture Research (CGIAR), an international network of crop research centers. Efforts to breed improved crops have been aided enormously by the tremendous wealth of samples in CGIAR's "gene banks".
- The World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which sets minimum international standards for the protection of intellectual property rights;
- The 1992 UN *Convention on Biological Diversity* (CBD), which is aimed at the protection of global biodiversity, but simultaneously promotes the sharing of the economic benefits that arise from the utilization of genetic resources—an issue that continues to arise on the international agenda.

In addition to these five international institutions, the PGR regime complex has been influenced by activities at the domestic level, notably the rules about protection of intellectual property in the United States, the main center of agricultural and pharmaceutical innovation and to a lesser degree the rules in the European Union. The US has been a key driver of change in the intellectual property field; innovations that began in the US, such as the patenting of life-forms, have subsequently been enshrined, partly as a result of US insistence, in agreements such as TRIPs.

Each of these strands is complicated, in part because many of these institutions were established not only to regulate activities related to PGR. We aim to present only the most fundamental points of each. As shown in figure 1, the debates over international PGR rules occurred broadly in two dimensions. One dimension concerned the *rules for ownership* of PGR—from "common heritage-open access" to some form of exclusive property right held either by individuals (e.g., a firm) or collectively (e.g., a community of traditional farmers). The other dimension was the *mechanism for allocating benefits* from

raw and worked PGRs—whether a market-based system, or a system in which public institutions intervened. Even as the norms of ownership over PGR converged there remained strong disagreements over the allocation of benefits. Developing countries desired rules that would regulate the flow of benefits by forcing PGR innovators to share the benefit stream with those states that provided the raw PGR; industrialized states preferred a more free-market approach.

		Principal for Assigning Ownership of PGR			
		Common	Property Rights		
		Heritage	Sovereign	Private and	
			(state-owned)	Community	
Mechanism for allocating benefits from PGR	Market-based	Traditional 19 <sup>th</sup> century system		Late 20 <sup>th</sup> century national patents: -U.S. -E.U. TRIPs	
	Regulated	FAO 1983 Undertaking FAO 2001 Treaty (R35, W35) CGIAR gene banks	FAO 1989 and 1991 revisions to Undertaking  CBD (1992)  FAO 2001 Treaty (other raw)  CGIAR gene banks (immediately post 1992, before FAO 2001 Treaty)	FAO 2001 Treaty (other worked)	

**FIGURE 1: Two Dimensions of Debate.** Note that the FAO Treaty distinguishes the rules that apply to both raw ("R") and worked ("W") PGRs for a core group of 35 staple food crops, denoted "R35" and "W35". The CGIAR gene banks (and other international gene banks) traditionally operated on the principle of open access (with regulated benefits—in the sense that the system was organized and maintained for public purposes not private, market-based innovations), but the creation of the CBD in 1992 posed a challenge to that system by claiming sovereign ownership of raw PGR. The FAO 2001 Treaty eliminated that challenge for the most important food crops. (The same rules apply to 29 crops used for animal feed.)

Mindful of these two broad dimensions to the debate—rules of ownership and mechanisms for allocating benefits—we now briefly describe the major elemental regimes and how they changed during the 20<sup>th</sup> century. We focus on sometimes arcane conflicts

between rules in each of these regimes that, we show, set the agenda for where governments, firms and NGOs focused their efforts at altering domestic and international rules. Through this process focused on conflicts at the joints between elemental regimes the rules in the larger regime complex evolve.

#### The Common Heritage-Open Access System

PGRs were governed by the common heritage-open access system for most of human history. Though genes themselves were not fully understood until recently, the economic importance of genetic resources had been long recognized. Nonetheless, under the original "system" there were no property rights in genetic resources, nor did states bar access to genetic resources <u>per se</u>. As a result there was much international diffusion of PGR, particularly as long-distance trade expanded and as imperial nations established central collections, such as Kew gardens outside London, stocked with plants sampled from around the globe. Antions tried but often failed to maintain control over genetic resources; for example, China went to great lengths to preserve the silkworm monopoly, but ultimately lost it to two enterprising Nestorian monks. Silkworms, rubber trees and a few other special resources of obvious high value were the exception—otherwise, genetic resources were free for anyone who bothered to take them.

Under the common heritage-open access system there was little difference in treatment between what we term "raw" and "worked" PGR. In the agricultural context, the dividing line between raw and worked was and often remains indistinct because worked materials, alongside with raw materials collected in the field, are the source of new worked materials. <sup>26</sup> The first moves toward intellectual property protection in PGRs addressed worked resources. Through the early 20<sup>th</sup> century, most agricultural innovation was funded by governments and performed in research centers and universities and there was little pressure to employ intellectual property as an incentive for innovation. <sup>27</sup> By the 1920s a limited, industrial business of breeding had emerged, and with it pressure for protection arose. The most prominent innovative activity was on hybrid plants, which had their own built-in mechanism for protecting intellectual property—hybrids lose their vigor after one generation, and thus farmers need to purchase new seed every season. <sup>28</sup> But many other innovations would require new legal mechanisms for protection; for example, plants that propagate asexually (e.g., cuttings from fruit trees or flowering plants). In response, in 1930 the US passed the Plant Patent Act for plants that are reproduced by

<sup>&</sup>lt;sup>24</sup> Kloppenburg 1988.

<sup>&</sup>lt;sup>25</sup> Stone 1994; Raeburn 1995.

<sup>&</sup>lt;sup>26</sup> Indeed, one of the major continuing areas of contestation has been the treatment of traditional crop varieties that have been improved incrementally and informally by generations of farmers. This is the so-called "farmers' rights" issue; we discuss it briefly below.

<sup>&</sup>lt;sup>27</sup> Evenson 2002

<sup>&</sup>lt;sup>28</sup> Griliches 1957.

asexual means.<sup>29</sup> Other countries also offered limited forms of intellectual property protection for breeders. Such rights allowed breeders to bar competitors from copying their innovations but did not prevent breeders from using a competitor's improved variety as an input to their own new variety. This was an important step toward property rights in PGR. Nonetheless, the primary focus of agricultural policy was on subsidization rather than intellectual property rules as mechanisms for fostering innovation—farmers in the US, for instance, were given free seed until the 1920s.<sup>30</sup>

Internationally, property rights for worked PGR were first introduced through the 1961 UPOV Agreement, which revolved around the concept of "plant breeders rights." Plant breeders' rights are a weak form of intellectual property protection in comparison to patents, but the eligibility requirements are more easily met. Plant breeders were concentrated in the industrialized states, and as a result UPOV largely reflected their interests. As of January 2003, 50 states were parties to at least one of the UPOV agreements. While UPOV introduced some form of property right for worked PGR—the plant breeder right—raw PGR was still treated as common heritage. Plant breeders and seed companies, as well as the major botanical institutions, continued to gather PGR from around the world in the belief that genetic information was scientific knowledge and could not be owned.

## The Demise of the Common Heritage-Open Access System

While change was already afoot by the early 1960s, the major shock to the common heritage-open access system was the invention of recombinant DNA technology in the 1970s. By allowing innovators to work directly at the genetic level, the scope for innovation in plant resources increased dramatically. This technological change markedly raised the perceived value of PGR. It first stimulated interest in more fully protecting worked PGR through intellectual property rights, and ultimately stimulated interest in extending protection to raw PGR as well. In Demsetzian fashion, actors agitated to create property rights in response to the possibility for increasing the value of plant genetic resources and the desire to appropriate that value for themselves. Much of the key activity at this point occurred in the US domestic context, but this domestic-level activity created pressure for later changes in international rules—rules that the US, wielding its market power, successfully extended globally.

The biotechnology revolution that began in the 1970s led to many new firms engaged in genetic engineering, and to the creation of broad "life sciences" companies

<sup>30</sup> JEM Ag Supply v. Pioneer Hi-Bred 2001.

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<sup>&</sup>lt;sup>29</sup> Rories 2001.

<sup>&</sup>lt;sup>31</sup> Barton 1982.

<sup>&</sup>lt;sup>32</sup> All but two of which were parties to the 1978 UPOV (29 states) or the 1991 (19 states), see Helfer 2002.

<sup>&</sup>lt;sup>33</sup> Evenson 2002.

focused on biological innovation. At the same time, a more general change in the role of intellectual property in the economic system was underway. Patents began to be perceived as strategic business assets, and intellectual property law became a major field, particularly in the US. A critical breakpoint in the US was the Supreme Court's 1980 decision, in the landmark case of *Diamond v. Chakrabartv*, that patent protection extended to living modified organisms—in that particular case, genetically-engineered bacteria.<sup>34</sup> Before Diamond the patentability of genetically-modified living things, outside the narrow confines of the 1930 Plant Patent Act, was unclear. After Diamond, and some subsequent cases, US firms could safely employ the full panoply of genomic techniques and receive complete utility patent protection.<sup>35</sup> That same year (1980), Congress passed the Bayh-Dole Act, intended to encourage innovation by allowing universities and private firms to claim property rights on government-funded research. (In practice, most university attempts at technology licensing were not profitable; even as the reality proved quite different, the perception of a "gold rush" created pressure to change the rules. <sup>36</sup>) In short. these two changes--one judicial and one legislative--transformed the US domestic playing field with regard to property rights in genetic resources. Since 1980, the conventional wisdom in the U.S. has been that strong patent rights are essential to the modern biotechnology-based innovation system—that view has been driven especially by pharmaceutical firms, but agriculture has been carried in the coattails.<sup>3</sup>

The increasing protection of worked PGR under industrialized country domestic laws as well as the UPOV Agreement led developing countries to organize a counteroffensive: the 1983 FAO Undertaking on Plant Genetic Resources. The FAO Undertaking, which is not legally-binding, was put on the FAO's agenda with pressure from developing countries, mainly from Latin America, and a small number of industrialized countries, in particular Spain, that were sympathetic to the developing country arguments. Often rich in biodiversity, developing countries have been the source of many commercially valuable genetic samples, yet received little compensation. The concern within developing countries that their genetic resources were being exploited resonated with the then-recent effort to establish a New International Economic Order aimed at a redistributing global wealth through new international institutions and reigning in the powers of multinational corporations.

The FAO Undertaking was driven by the fact that developing countries resented the lack of open access to improved varieties bred by seed companies, some of which were the products of raw germplasm samples that developing countries themselves had provided under the common heritage rule. This was, of course, exactly the result that the UPOV

<sup>34</sup> Diamond v. Chakrabarty, 447 US 303 (1980)

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<sup>&</sup>lt;sup>35</sup> Some doctrinal uncertainties remained that are not germane to our argument; see JEM Ag Supply v. Pioneer Hi-Bred 2001; Barton 1998.

<sup>&</sup>lt;sup>36</sup> Mowery, et al. 2001.

<sup>&</sup>lt;sup>37</sup> Pisano 2002.

Agreement aimed at. The FAO Undertaking attempted to counter the emergence of property rights in worked PGR by defining all genetic resources--raw *and* worked--as "common heritage." In its most controversial wording, the Undertaking propounded the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction;" PGRs should be available "free of charge...or on the most favorable terms." In practice, the Undertaking's common heritage approach to all PGR was only a symbolic victory. The industrialized countries relied on the principle to continue their open access to raw PGR yet refused to accept the Undertaking's principle of open access to worked PGR. The Undertaking was adopted with reservations by eight industrialized countries, all lodged because of conflict with the property rights enshrined in UPOV and domestic law. FAO soon adopted an annex to the Undertaking to provide an "agreed interpretation" that papered over the common heritage principle and allowed the industrialized countries to join. Most did, though the US, Canada, and Japan stayed out.

Institutionally, the FAO Undertaking also created the Commission on Plant Genetic Resources, which is now the central FAO forum for handling PGR issues. (Notably, the Commission helps to set policy for managing a network of all the major international collections of plant germplasm, including the CGIAR network).

## Biodiversity & Bioprospecting

The slow and uneven dissolution of the common heritage-open access system in the 1980s dovetailed with a new change afoot in an unlikely source: international environmental cooperation. Protection of special habitats such as wetlands and special animals such as whales were among the first topics for global environmental cooperation in the late 1960s and early 1970s. By the 1980s, however, conventional wisdom among international environmental experts was that the focused approach was inadequate; moreover, conservation biologists stressed the need for policies to address whole ecosystems and biological diversity worldwide, not just individual species. That conceptual shift helped to spawn negotiations, consummated as part of the 1992 UN Rio Summit, of the Convention on Biological Diversity. The destruction of tropical rain forests in particular had become a popular political issue, leading the industrialized countries to also seek controls on forest degradation. Developing countries, unhappy with this perceived intrusion, reacted by asserting sovereign control over forest resources—including genetic resources. The battle over forests and the biodiversity within them spurred attention to the value of the forests--not only the value of forests as timber, but also

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<sup>&</sup>lt;sup>38</sup> FAO Annex 1 1989

<sup>&</sup>lt;sup>39</sup> On the intellectual shift toward the "ecosystem" concept see Golley 1993; on the history of wildlife protection law, which until the late 1980s focused on specific activities, regions and types of ecosystems, see Lyster 1985.

the value of genetic resources within forests and other special ecosystems.<sup>40</sup> Protecting these resources, which the NGOs of the industrialized countries sought, became integrated with the mission of identifying and controlling access to the resources that lay undiscovered in the forest.

The touchstone for this shift to property rights in raw PGR was the notion of "bio-prospecting," which aligned the interests of environmentalists, biotechnology firms as well as the governments of developing countries that were seeking to extract greater value from their biodiversity riches. One rationale for biodiversity protection is the value embedded in genetic resources. Environmentalists eager to promote conservation suggested that genetic diversity was itself an important source of value in ecosystems like forests, one that was potentially much larger than timber or farmland value. Firms could prospect for these resources just as miners had prospected for gold in centuries past. Enclosure, rather than commons, was now attractive for raw PGR, at least in the eyes of the biodiverse-rich South.

Thus in the late 1980s developing countries began to see property rights in PGRs as a mechanism of wealth, rather than a mechanism that Northern pirates had rigged against them. The famous 1991 Merck-INbio deal, in which the US-based pharmaceutical giant contracted with a Costa Rican conservation institute for bioprospecting rights in the Costa Rican rainforest, signaled to many the dawn of a new era of bio-prospecting. 42 In the same period, the increasing sophistication of genetic manipulation meant that a raft of new plant innovations were nearing commercialization; examples included Monsanto's Round-up Ready soybeans containing a gene that conferred resistance to a powerful herbicide as well as cotton and potatoes that produced the natural insecticide Bt—allowing plants to kill some pests themselves, boosting yields and reducing requirements for pesticides.<sup>43</sup> These developments in biotechnology had two effects. One was to cement the perception that raw PGR was extremely valuable—the Merck-Inbio deal became a symbol for the multimillion dollar revenues that every tropical government hoped to reap. The simultaneous emergence of engineered crops also created the impression that the entire industry was poised to change to a new, more profitable business model. Subsequent economic analyses—as well as a dearth of realized profits—suggest that the value of rainforest genetic resources was considerably overestimated, but in the 1990s the hopes for transformation were a more powerful elixir than the econometrics.<sup>44</sup> The other effect was that engineered crops became entangled in political controversy—opposed by many environmentalists, who feared their impact on ecosystems, but also by many developing countries who feared that if they allowed any engineered crops in their soils that all of their

<sup>&</sup>lt;sup>40</sup> Tilford 1998.

<sup>&</sup>lt;sup>41</sup> Reid 1993.

<sup>&</sup>lt;sup>42</sup> Ibid; Blum 1993.

<sup>&</sup>lt;sup>43</sup>Lurquin 2001; see also Pardey, ed., 2001.

<sup>&</sup>lt;sup>44</sup>See Peters et al. 1989: Godov et al. 1993:

agricultural products might be barred from markets where engineered crops carried a stigma. While this debate is complex and ongoing, it became enmeshed in the PGR regime complex through the inclusion, in the CBD, of a provision calling for the negotiation of a protocol on "biosafety." The CBD became a "christmas tree" treaty on to which governments and NGOs hung many controversial ornaments—no matter how tangential to the issue of biological diversity. 46

The Legalization of the Sovereign Rights and Intellectual Property Rights System

The early 1990s represented a watershed period in the development of the PGR regime complex. The CBD negotiations underscored the value of PGR to the industrialized world and also revealed that the developing countries would seek to control access to their PGR as a new form of leverage. Yet the CBD was a broad agreement that had been negotiated by relatively weak environment ministries and had little capacity to alter the rules that governments adopted to control the flow of genetic resources. At the same time that the CBD was finalized, governments—represented by more powerful trade ministers—were also in the final stages of negotiating a new round of international trade rules. These negotiations included a novel set of rules on intellectual property—put on the trade agenda because firms in software, pharmaceuticals and other "knowledge industries" insisted on better international protection of intellectual property. By itself, agribusiness would not have been able to advance this agenda, but with powerful industrial allies their concepts arrived at the center of the WTO negotiations. Backed by the power of the U.S. government they were codified into TRIPs. TRIPs sets minimum standards for intellectual property protection that forced parties to approximate an industrialized country model, and in practice these standards were closely modeled on U.S. or E.U. law. 47 Moreover, TRIPs was folded into the new WTO structure, which included a powerful, retooled dispute settlement system. Thus a large number of developing countries joined the WTO seeking greater access to markets, but their membership also required a transformation in their domestic rules for intellectual property.

TRIPs contains specific language on genetic resources, which mandates that countries must grant patents for microorganisms, and in Article 27.3b requires *either* patents or a "<u>sui generis"</u> system for worked PGR. The UPOV system of plant breeder rights was the concept that some TRIPs drafters had in mind for <u>sui generis</u> system, but not all states wanted to endorse UPOV. Lingering resistance to the notion of protecting living things through intellectual property rights, and concern about the North-South dimensions of the plant breeders' rights issue, forced the drafters to leave this provision open-ended

<sup>&</sup>lt;sup>45</sup> Paarlberg 2002.

<sup>&</sup>lt;sup>46</sup> For more on the "christmas tree" diplomatic processes that characterized global environmental summits, such as the 1992 Rio summit, see Brenton (1994).

<sup>&</sup>lt;sup>47</sup> Maskus 2000.

<sup>&</sup>lt;sup>48</sup> A "sui generis" system simply means a unique system tailored, in this case, to the needs of PGR.

and subject to review in 1998. (As of 2003 this review has barely commenced, though the statement launching the Doha Round of trade talks suggested that the review process will continue.) Unable to agree, negotiators kept Article 27.3b vague and then sought clarity from the bottom up—through the process of implementation, interpretation and review. A serious review of Article 27.3b, leading perhaps to revisions, would be a cumbersome process—evident in the slow pace so far—and renegotiation of Article 27.3b would upset the delicate balance struck when the larger TRIPs agreement (and the WTO itself) were forged in the early 1990s.

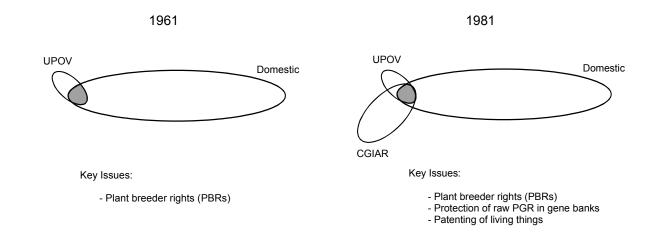
Within the FAO, a major change also occurred in the early 1990s: the negotiation of an additional Annex to the 1983 FAO Undertaking. The 1991 Annex signaled a fundamental shift in the terms of debate over PGR protection within that institution and, subsequently, in others. The Annex stated that "the concept of mankind's heritage, as applied in the [1983 Undertaking], is subject to the sovereignty of states over their plant genetic resources." This transformation was highlighted by an additional statement that flatly asserted that "nations have sovereign rights over their plant genetic resources"—a complete reversal of the 1983 Undertaking that sought to establish that no nation owned PGR. This reference to sovereign rights as the governing international rule, rather than common heritage, was almost the exact language in the draft texts, then-circulating, of the CBD. 49 The CBD also made clear that states controlled access to PGR and that the openaccess norm of the past was gone. Through this assertion of sovereign rights, a new approach to PGR, in which state sovereignty and intellectual property rights were the core norms, coalesced. Mindful that biological diversity could be extremely valuable and wary of outside interference in their sovereign freedom, developing countries sought to assert sovereign rights over plant genetic resources.

## III. The Regime Complex in Action

The 1990s offer a snapshot of the evolution of a regime complex. During this critical decade, propertization triumphed. The FAO process abandoned common heritage for PGR, and the CBD explicitly and centrally proclaimed genetic resources to be sovereign property by 1992. Both TRIPs and the CBD entered into force in 1994 (though their negotiations took years) and patent protection for PGR, as well as other life forms, continued to be extended incrementally in US and EU domestic law throughout the 1990s. Figure 2 depicts the evolution of the regime complex graphically—over time, the rules have become more elaborate, the number of international institutions involved in the area has grown, and the boundaries between the elemental regimes have blurred.

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<sup>&</sup>lt;sup>49</sup> The only difference being that the Biodiversity language referred to all biological resources, not just genetic resources.



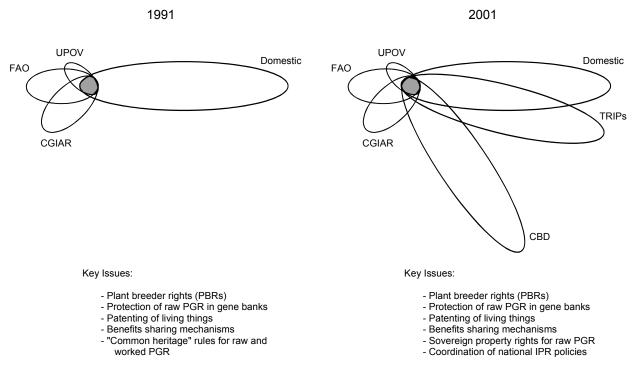


FIGURE 2: Evolution of the regime complex.

As the varied international agreements began to be implemented, such as through national capacity building programs in the biodiversity context that included model legislation on sovereign ownership of resources, the debate over rules of ownership-common heritage vs. property-was largely put to rest. By the early 1990s rules over

ownership had broadly recognized sovereign, private or community property rights, although the extent of the shift was still hotly contested. For example, in the TRIPs review process as well as in the negotiation of a "Biosafety Protocol" to the CBD, developing countries, sometimes joined by the EU, evinced a strong desire to limit the scope of protection for worked PGR. This effort was opposed by the US, which sought to treat genetic innovations like other innovations, and sought the widest possible ambit for intellectual property law.

With the question of ownership largely settled, the new front line was the allocation of benefits from PGR—the second dimension in figure 1. Should the market be left to itself to allocate the benefits of PGR, or should governments regulate the allocation of benefits? Developing countries were wary of market mechanisms and sought rules that would force PGR innovators to share the benefit stream with those states that provided the raw PGR—property rights alone would not be enough to force "bio-pirates" to disgorge a proper share of profits to those who now, thanks to the new normative framework of sovereign property rights, owned and controlled access to raw PGR. The CBD in particular became a focal point for the elaboration of benefit-sharing schemes. The scope of the CBD was the widest of all the elemental regimes, and thus the architects of the CBD were forced to paper over the widest range of diverging views with broad rules—deferring until later decisions on what was actually meant by the broad rules that were codified in the treaty.

Having transformed the core norms governing PGR, states and NGOs now focused on the many remaining, and more fine-grained, differences over the precise scope and nature of PGR protection. Real and perceived conflicts in these rules in turn animated searches for solutions that would reconcile the varied strands of the regime complex. The search process occurred through a wide array of institutions—the numerous working groups within the CBD, TRIPs, FAO, and, most recently, the World Intellectual Property Organization. Depending on how you count, by the 1990s more than a dozen intergovernmental committees worked on the PGR issue, spread across all disparate elemental regimes. Moreover, governments were also fragmented in their representation within each of these regimes. Agriculture ministries dominated the FAO, plant breeders UPOV, environment ministries the CBD, and intellectual property lawyers along with trade negotiators concentrated on TRIPs.

Viewed in totality, however, a common pattern of rule evolution emerged. Where views were diverse and conflicting, negotiations nonetheless proceeded and yielded "agreements." The pressure to move forward stemmed, in part, from the fact that negotiations on PGR-related matters were linked to a much larger array of issues that could not be held hostage easily—for example, the wider trade regime in TRIPs and the WTO, and the broader effort (with a deadline of the 1992 conference in Rio) to craft an overarching agreement on biodiversity. The pressure to move to agreement was greatest in the areas where PGR-related rules had the deepest linkages to other (more important) issues.

In contrast, in elemental regimes that were specialized for PGR purposes—such as the FAO Undertaking—serious negotiations sat in a holding pattern until the broader negotiating processes set basic norms. This process of framing norms under pressure produced both synergies and conflicts. In some instances the interactions between elemental regimes were supportive--as in the FAO Annex employing the exact language drafted for the CBD. But in many other cases the norms in the different elemental regimes were in conflict. The CBD, for example, contained language on the scope of intellectual property rights and requirements that governments adopt schemes to share the benefits of worked PGR—language that the US government saw as aimed at undermining TRIPs.

Although it involved many disparate actors, the process of adjusting the rules in the PGR regime complex had a common focus: the inconsistencies at the boundaries between the elemental regimes—the "joints" in the regime complex. Inconsistencies focused the agenda for policy reform, which actors in these disparate institutions pursued in two different ways. First, diplomats and stakeholders sought to resolve differences in the treatment of PGRs through practice and the interpretation of existing rules—what might be called a "bottom up" approach. Second, simultaneously, they sought to change the rules as well—through both new and continuing international negotiations on PGR. Here we illustrate both modes of change—interpretation and legalization.

The practices of the CGIAR system in the 1990s manifest the first approach. CGIAR attempted to resolve the conflict between its practices—which had been based on open access and common heritage—with the new rules that called for sovereign ownership by attempting to keep separate the pre-1992 and post-1992 collections in its gene banks—with the pivotal date set at the year when the CBD was finalized. The pre-1992 collection would be able to travel under open-access rules, whereas samples from the later collection would require some form of compensation if they yielded useful products. In practice, that distinction was impossible to maintain, so CGIAR also sought to create special "material transfer agreements (MTAs)" in which the supplier of genetic material would agree to allow free access—in essence, superseding the CBD and restoring the pre-1992 status quo. <sup>50</sup> In recent years, the World Intellectual Property Organisation (WIPO) has sought to coordinate standard terms and conditions for MTAs. <sup>51</sup>

This bottom-up approach is also evident in several debates that continued unresolved through the 1990s, such as over the assignment of "farmers' rights." Farmers' rights are "rights arising from the past, present and future contribution of farmers in conserving, improving, and making available plant genetic resources..." The underlying idea was to compensate farmers for the incremental, collective innovations they create through their normal agricultural practices—as a counter to the plant breeder rights

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<sup>&</sup>lt;sup>50</sup> Barton& Seibeck 1994.

<sup>&</sup>lt;sup>51</sup> Helfer 2003.

<sup>&</sup>lt;sup>52</sup> FAO 1995.

assigned to commercial innovators by UPOV. At issue was the dividing line between raw and worked PGR—the farmers' rights movement asserted that much of what is taken to be raw is in fact worked. This debate continued through floor speeches at UN fora and through efforts to challenge the expansion of PGR patentability in many industrialized states—in particular the US. Having lost the debate over whether life forms could be patented at all, opponents, which included many NGOs, shifted their arguments and claimed that patent rights were too broad—"novel" products were not novel but, rather, built on traditional knowledge accumulated over generations. The property rights that might be applied to such knowledge—known previously as "farmers' rights"—now acquired a broader term, "traditional knowledge (TK)."

The second approach—the commencement, at the international level, of new negotiations and the continuation of older negotiations, is manifested in TRIPs, the CBD, and the new FAO treaty. In TRIPs, the major issue has been the review of Article 27.3b, which addresses PGR. In particular, states have been grappling with the meaning of an "effective sui generis system" (the language used in 27.3b) for protecting plant innovations. In the CBD, the focus has mainly been on the development of rules for sharing the benefits of PGR. The CBD has provided a general forum for these discussions and also allowed governments to address this issue through negotiations on the Biosafety Protocol, which does not directly address PGR issues but does attempt to limit the marketing of genetically-modified organisms. In so doing, countries opposed to gene engineering were, in part, attempting to adjust the allocation of benefits from worked PGR—favoring traditional "working" of PGR over gene engineering.

Another example of new negotiations is found in the wreckage of the FAO Undertaking. As international norms shifted in the early 1990s toward systems of private property, the original Undertaking (hostile to private ownership) was left as a glaringly inconsistent and thus increasingly irrelevant elemental regime. Yet, over the same period the experience in CGIAR had demonstrated that the complete shift to propertization would be harmful to efforts to improve the limited number of crops that were most essential to poor farmers. Across-the-board rules, such as in the CBD, were backfiring because all crops could not be treated alike. Yet the practice of negotiating individual or even standardized MTAs—as had been pursued by CGIAR as a way to resolve the problem of treating pre- and post-1992 collections differently—proved cumbersome and raised the specter of a fragmented system of gene banks in which the property rules and benefits sharing schemes would vary by shipment. Through the same dispersed search process, a solution was crafted in the context of negotiations that updated the FAO Undertaking to make it consistent with other international norms—in particular, CBD and TRIPs culminating in the 2001 FAO Treaty. The 2001 Treaty's aim is to facilitate the exchange of seeds and other germplasm between member states. It creates a special "multilateral system" for core crops—in a sea of sovereign and private property, it carves out a special collective property right for a limited number of food and feed crops:

In essence, the multilateral system is a communal seed treasury composed of 35 food and 29 feed crops now held by governments...and by CGIAR...in exchange for access to this common seed pool, those who commercialize products that incorporate plant genetic resources received from the multilateral system must pay a percentage of their profits into a fund to be administered by the Treaty's Governing Body. That fund will be used to promote conservation and sustainable use of plant genetic resources, particularly by farmers and indigenous communities, whose rights and contributions to genetic diversity the [2001 Treaty] expressly recognizes. 53

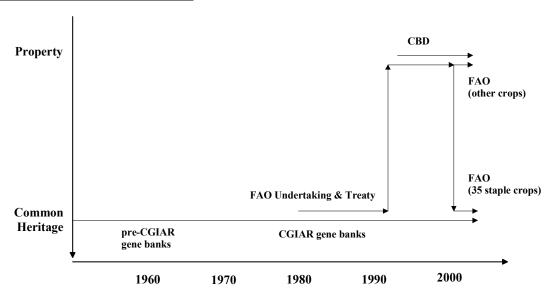
The 2001 FAO Treaty embodies many of the themes that are woven through the PGR debate: the desire to share the benefits of propertization collectively; the concern with food security; the need to keep the CGIAR system open; the rights of farmers. The core of the new PGR order, nonetheless, remains unchallenged: for all but a few major food crops, property rights and sovereign control are the rule.

In sum, by the end of the 1990s the international rules governing PGR were radically different from those that existed 50 years earlier. The common heritage principle, which had persisted for so long, had been replaced by a system of sovereign control over genetic resources. While states now owned and controlled access to PGR, private entities could obtain intellectual property rights in PGR. Figure 3 summarizes this shift—for raw PGR (panel a) as well as "worked" PGR (panel b). Our claim is that the development of a property rights system is best understood as a Demsetzian transition. As new plant breeding techniques and recombinant DNA technology transformed the scope of plant innovation, the value of PGR, both raw and worked, rose dramatically. As Demsetz suggested, this rise in value significantly increased the incentives to create property rights. Decisions such as the US Supreme Court's in *Diamond* paved the way, as they both recognized and substantially reinforced the rise in value associated with PGR. Yet even landmark events such as *Diamond* did not erase existing political controversies, such as over the patentability of living things. Thus international norms were cast broadly to allow some diversity in local circumstances. The E.U., for example, only allowed plant breeder's rights—never patents—for plant innovations. And in some cases, such as the core crop plants addressed by the 2002 FAO Treaty, the costs of administering property rights were so high that states reverted to the common heritage concept--an outcome consistent with sophisticated versions of the Demsetzian thesis.<sup>54</sup> On the whole the demands for property rights in PGR were largely met by the mid-1990s; enclosure triumphed over common heritage and open-access.

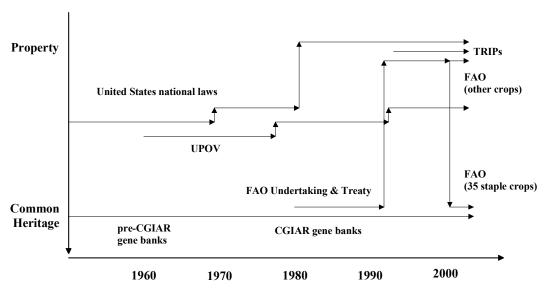
<sup>&</sup>lt;sup>53</sup> Helfer 2002.

<sup>&</sup>lt;sup>54</sup> Merrill. 2002: Levmore. 2002

#### Panel A: "Raw' Plant Genetic Resources



#### Panel B: "Worked" Plant Genetic Resources



**Figure 3:** Changes in Property Norms for Raw and Worked PGR. Institutions shown only on panels for which they have relevant rules; UPOV, for example, related only to worked PGR. CGIAR gene banks are shown as "raw" although perhaps two-fifths of their collections have been working in some way. CBD is not shown on panel B, although the CBD does include a clause that pertains to worked PGR. Lines shift at major events that alter the rules within a given institution. Major events for raw PGR: the Annex to the International Undertaking (1992); the FAO Treaty that distinguished rules for 35 staple crops from those for non-staples (2001). Major events for worked PGR: the PVPA (1970) and the *Diamond* case in the U.S. (1980); revisions to UPOV (1978, 1991); the annex to the International Undertaking (1991).

## IV. Regime Complexes and the Study of Regimes

Many studies have noted the tremendous rise in the number of international treaties and organizations, particularly since 1945. The implications of increasing institutional density nonetheless have received little systematic attention. There has been some concern among international lawyers with rising "treaty congestion." More recently, Oran Young and Olav Schram Stokke have explored what they term "institutional interplay." <sup>56</sup> But for the most part scholarship on international cooperation has proceeded as if increasing institutional density is largely immaterial for theories of international regimes.

As the PGR case illustrates, one outcome of higher density is overlapping regimes (see figure 2), often with conflicting rules. Consequently, rather than a single discrete regime governing PGR, we argue the PGR issue-area is best conceptualized as a regime complex comprised of elemental regimes. In the remainder of this article we use the PGR story to illustrate and probe the conjectures about regime complexes described in the introduction. Our argument is not that existing regime theory is fatally flawed, but rather that it is implicitly oriented around a model of regime development that is increasingly outdated.

#### No Clean Slate

Existing scholarship on international regimes has generally, if implicitly, assumed that the process of regime formation begins with an institutional clean slate. In most empirical studies of regime formation negotiators arrive at the task of forming a regime without any explicit international rules in place.<sup>57</sup> States with different interests vie to shape the outcomes, and institutions are crafted to serve the political agreement. In cases where negotiations occur within an already existing institutional framework, negotiations tend to focus on the same issue-area—often merely extending and adjusting agreements that already exist. Thus the international trade regime evolved through 8 rounds of GATT negotiations—and as GATT proved inadequate for the enormity of the task, the parties created a new institution, the WTO. Similarly, negotiators crafted the Chemical Weapons Convention and created a tailored international organization to act as secretariat and engage in investigations. In these examples, negotiators could largely operate against an institutional clean slate, creating rules and organizations as needed within the political confines set by the structures of interests, power, and ideas.

<sup>&</sup>lt;sup>55</sup> Weiss 1998.

<sup>&</sup>lt;sup>56</sup> Young, 2002; Stokke, ed. 2001.

<sup>&</sup>lt;sup>57</sup> To be sure, in some cases regimes are "nested" and one agreement builds on another (Young 2002). In those cases, however, lines of hierarchy are clear and available to resolve conflicts between rules.

In a regime complex, by contrast, negotiations over rules commence with an elaborate and dispersed institutional framework already in place. The institutional slate is not clean. Several overlapping regimes exist, each of which addresses some aspect of the issue in question. Negotiations that proceed within an existing institutional context often address topics far outside the scope of the original institutions. Ideas, interests and expectations are already aligned around some set of existing rules and concepts, though these rules and concepts can and often do contradict one another. Power, interests and ideas as a result do not directly map to outcomes in the rules and behavior in the regime, and analysts cannot therefore trace rule content or evolution neatly back to changes in these underlying driving forces. We expected that the complexity of interests and the existence of overlapping rules and norms would lead to distinctive processes of institutional development. In many respects this expectation was borne out.

The best example of how prior expectations and institutional accretion affect outcomes in a regime complex is the provision on PGR protection in TRIPs, known as Article 27.3b. When negotiators in TRIPs began crafting rules on intellectual property for PGR in the late 1980s there were several sets of rules and expectations already firmly in place. For decades, the community of plant breeders had built up the concept of a "plant breeder's right" and enshrined it into both international and domestic law. Some who opposed even this weak form of intellectual property right, predominantly concentrated in the developing world, had already established a marker in the 1983 FAO Undertaking. Yet these opponents to propertization were fragmented by the early 1990s: at the very time that TRIPs was taking shape many of the governments in developing countries were shifting positions on property rights, at least for raw PGR. Newly aware of the rising value of PGR, they sought to assert sovereign rights and to reverse the long-standing principle of treating raw PGR as the common heritage of mankind.

In this state of flux it was impossible to gain consensus on a single approach to property rights. Yet the TRIPs negotiation, part of the omnibus Uruguay Round, could not be halted, so the negotiators agreed by necessity on a broad umbrella approach. TRIPs decreed that plant varieties must be protected either by patents or by an "effective sui generis system," and this compromise would be reviewed after four years. This approach, which in turn focused subsequent efforts to clarify the meaning of article 27.3b, traces directly to the multiple interests, rules and expectations that already existed in the PGR regime complex. It contrasts sharply with more familiar cases such as that of the Montreal Protocol on ozone depletion, where negotiators had diverging interests but the negotiation process was unconstrained by existing rules on ozone depleting chemicals. Faced with a clean institutional slate, the Montreal Protocol negotiators could strike a political compromise that directly reflected relative power, interests, and knowledge. Indeed, when negotiators in the Montreal Protocol regime inserted language about trade measures with regard to non-parties, they were not much constrained by existing trade rules or

expectations about the use of sanctions to enforce environmental agreements.<sup>58</sup> The negotiators of PGR provisions in TRIPs, the 2002 FAO Treaty, and the CBD faced a quite different situation. A multiplicity of overlapping rules and norms existed, against which they crafted new rules. As we discuss further below, the preference for consistency, in particular legal consistency, played a major role in constraining rule choices. Occasionally, however, negotiators deliberated embraced legal inconsistency, employing what we term "strategic inconsistency" as a way to shift rules across fora. In both situations, however, the existence of overlapping and inconsistent elemental regimes plays an important role in the development of the regime complex.

#### Forum Shopping

The defining characteristic of a regime complex is the existence of multiple, overlapping elemental regimes. Given the availability of multiple fora, we expected to observe countries and interest groups selecting the forum that best suited their interests, and pursuing rule development there. The PGR case study is consistent with this expectation.

The FAO, for example, served as the negotiating forum for the 1983 Undertaking that sought to declare both raw and worked PGR to be the common heritage of all mankind. The FAO was a favorable site for assertions of redistribution and had, as part of the UN system, open access rules that permitted many states to participate. By contrast, the WTO served as the site for negotiation of new intellectual property rules for PGR. The US and to a lesser extent the EU used the omnibus nature of the WTO to force developing countries to accept a wide array of intellectual property rules that were arguably detrimental to their interests. The U.S., especially, was able to link IPR issues (important to powerful interests in the U.S.) to broader market access (a key interest of developing countries) and thus integrate TRIPs into the wider array of agreements that formed the WTO.<sup>59</sup> To be sure, the acceptance of stronger intellectual property protection was part of a broader shift toward economic liberalization in the 1990s. Moreover, the US did not get everything it wanted with regard to PGR: rather than clear patent protection, as noted above TRIPs merely requires an "effective sui generis system."

At the same time TRIPs was being debated the CBD was taking shape. Whereas TRIPs was crafted by trade diplomats, the CBD was negotiated in UNEP—a forum dominated by environment ministries. The focus of the CBD originally centered on conservation—a key issue especially for greener industrialized countries. But developing countries were wary of new agreements that could impose obligations to protect natural areas—which could be costly and might constrain development and intrude on

<sup>&</sup>lt;sup>58</sup> The Montreal protocol was negotiated before the GATT *tuna-dolphin* case catapulted the trade-environment linkage to the front of the international agenda.

<sup>&</sup>lt;sup>59</sup> Sell 1995; Jackson 1998.

sovereignty—so they grafted the intellectual property agenda onto the negotiations. What they were unable to achieve in other fora—such as TRIPs—the developing countries tried to gain through linkages to biodiversity. As the biodiversity negotiations proceeded from their origins in conservation they expanded to include an ever-larger array of diverse and vaguely linked issues. The result was two diverging and distinct sets of rules, with the CBD's rules on intellectual property in genetic resources directly undercutting those in TRIPs. This divergence in substantive rules occurred despite the fact that the CBD and the WTO have roughly the same membership. The two institutions offered two distinct fora, with different linkages. One, dominated by environment ministries, was attractive to those who wanted sovereign property rights and regulation of the benefits of PGR. The other, populated by finance and trade ministers, was willing to craft a broad rule for PGR in order to achieve greater benefits through trade in other goods and services. The same governments were adopting seemingly different positions, depending on the forum. The result was norms that were general enough so that most interpretations could flourish—in effect, pushing to the process of interpretation and implementation what uncoordinated formal negotiations across multiple international fora were not able to achieve.

#### Legal Consistency

One of the signal attributes of the PGR regime complex is a concern on the part of negotiators with legal consistency, both within each elemental regime and among the various elemental regimes. Assuring legal consistency, by which we mean a lack of overt legal conflict among overlapping rules, is a recurring and difficult problem because the international legal system has no formal hierarchy of treaty rules. While the WTO may be more politically significant than the CBD, as a matter of international law the two are on an equal plane. Nor are there are clear super-mechanisms or principles for resolving inconsistencies among legal rules. The ongoing effort within the WTO to address conflicts between trade and environment rules --through the creation of the Committee on Trade and Environment, among other actions--evidences the concern states have with resolving such legal conflicts.

The PGR case suggests that legal consistency matters for substantive outcomes because areas of persistent inconsistency serve as a focal point for efforts at reconciliation. This occurs both through attempts at inventing ways to implement or interpret international norms such that inconsistencies would be resolved and, if such efforts fail, through formal renegotiations. Efforts to resolve inconsistencies are focused, initially, within each elemental regime—through the adoption of broad rules if it is not possible to agree on more specific commitments. As these inconsistencies at the core of elemental regimes are

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<sup>&</sup>lt;sup>60</sup> There are several doctrines in international law that aim to resolve inconsistencies, such as temporality (later in time principle) and the concept of *lex specialis*. In practice, however, these rules are often vague in application and as a result substantial controversy exists over the result when international treaties conflict. <sup>61</sup> Shaffer 2001.

sorted out, those that remain at the "joints" between the elemental regimes remain as more persistent challenges.

The concern with achieving or increasing legal consistency in the PGR regime complex is illustrated in several conflicts. One is the evolution of the FAO Undertaking. The original 1983 Undertaking declared all PGR to be common heritage, but as attitudes shifted during the 1980s and developing countries favored a new approach based on sovereign rights the inconsistencies between the Undertaking and shifting norms of international law became apparent. Those inconsistencies then set the scene for the major battles over intellectual property rules concerning PGR. The Undertaking itself was ultimately renegotiated—and through that negotiation process diplomats were forced to elaborate how the new scheme of sovereign rights over PGR could be applied in detail, such as in the gene banks that housed raw PGR. Similarly, when diplomats took up the task of negotiating a protocol to the CBD—the Biosafety Protocol—they did so against the backdrop of TRIPs, which required countries to impose stricter systems for protecting intellectual property in worked PGR. The result was extensive debate over so –called "savings clauses": clauses in the Biosafety Protocol that purport to immunize TRIPs from any inconsistency with the Biosafety Protocol's provisions. (Whether the text achieves this or merely highlights the intractability of legal consistency is a debated proposition). 62

The PGR case illustrates that states also attempt to create what we term strategic inconsistency—to force change in rules by explicitly crafting rules in one elemental regime that are inconsistent with those in another. They do this because they know that inconsistencies focus diplomatic and implementation effort. Developing countries led the establishment of the original FAO Undertaking in a radical attempt to refocus the agenda toward a broad common heritage principle for all PGR. The CBD's rules on intellectual property rights are another example—the treaty included language that made intellectual property rights subservient to environmental protection and development objectives, which appeared to contravene the content of TRIPs, which was already taking shape in the Uruguay Round. Indeed, this conflicting language was part of the reason the US refused to sign the CBD. These examples contrast sharply with the single-issue nature of the ozone regime, where the issue of legal consistency with other regimes did not arise until several years after the Montreal Protocol was first negotiated—when compatibility between environmental regimes and trade regimes was the subject of intense debate. (Even then, the debate over compatibility between trade and environment regimes was mostly hypothetical.)

The concern with legal consistency in the PGR regime complex is emblematic of a more general trend toward legalization in world politics.<sup>63</sup> International relations are

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<sup>&</sup>lt;sup>62</sup> Safrin 2002.

<sup>&</sup>lt;sup>63</sup> Goldstein et al. 2001.

increasingly legalized; legal arguments and legal concepts play a greater role in international cooperation.

#### Regime Development through Implementation

In the traditional model of regime development, parties who seek a change in regime rules press their cause through formal negotiations leading to new rules; the implementation process follows thereafter in a "top down" fashion. As many studies on the design and implementation of international commitments have noted, however, the actual practice of implementation is not linear and does not proceed according to a single plan or measure of performance to which all governments adhere. Governments have diverging interests and varied constraints on their freedom of action; it is more difficult for them to plan and anticipate the process of implementation as international rules become more complicated, intrusive and demanding. Governments can avert some of these problems by building in flexibility for the interpretation and implementation of international commitments, but that strategy is itself constrained—a shift to more complicated, intrusive and demanding international rules implies the need for substantial coordination that excessive flexibility would undermine.<sup>64</sup>

We hypothesize that the existence of a regime complex resolves this tension in favor of a "bottom up" style of implementation. Negotiators know that in the efforts to resolve incompatible interests and constraints on domestic action they are inclined to adopt broad rules. They adopt broad rules nonetheless because it is extremely difficult to work out the fine detail for all contingencies and local situations ex ante. The lack of a an institutional clean slate accelerates this tendency toward broad general rules, especially in periods when the regime complex is expanding to encompass new elemental regimes—as it did in the early 1980s with the addition of the FAO Undertaking and, again, in the 1990s with the creation of the CBD and the conclusion of the WTO's TRIPs Agreement. The addition of new nodes in the network makes it harder to coordinate and avoid inconsistencies. We do not argue that broad rules and flexibility in interpretation and implementation are used merely to avoid conflicts; rather, we suggest that the difficulty of working out inconsistencies in the formal rules leads to a style of regime change in which the implementation process is increasingly relied upon as a "laboratory" for experimenting with different solutions to incompatible interests and inconsistent rules. The parties are not content just to allow different interpretations to flourish through the implementation process. Rather, they use the experience in implementation as a direct guide for subsequent formal changes and clarifications of the rules. Three episodes in the history of the PGR regime complex reveal this process: one episode has now largely run its course, and two are still in motion.

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<sup>&</sup>lt;sup>64</sup> Lawrence et al. 1996;

First, the evolution of rules for the CGIAR gene banks shows how incompatible interests led diplomats to adopt broad and conflicting rules, with more durable solutions worked out through implementation. The origins of that episode were the shift in preferences in the late 1980s by developing countries in favor of sovereign rights over raw PGR. These countries inserted language into the CBD underscoring that approach, knowing that it would conflict directly with the FAO Undertaking as well as longestablished practice in the gene banks, which explicitly operated according to the principles of open access and common heritage. At first the CGIAR gene banks attempted the easiest solution to this inconsistency: ignore the CBD's rules or segregate their collections into pre-1992 (open access) and post-1992 (regulated access). Segregation proved expensive, contrary to the open-access culture that pervaded CGIAR, and extremely complicated. Modern crop varieties are built from dozens of strains preserved in seed banks; allocating the improvements based on the national origin of the material was nearly impossible. But the strategy of simply ignoring the new CBD-driven rules did not prove sustainable. It directly conflicted with the CBD and was controversial with developing country governments and NGOs that sought regulated access as a way to channel some of the benefits of raw PGR back to the countries of origin, thereby halting "biopiracy." Ultimately, diplomats in the FAO concluded that a change in the rules would be required. Such a change was relatively easy to codify because the same government representatives who knew the most about this problem—agriculture and development experts—were also the lead players in crafting the new FAO Treaty on Plant Genetic Resources that resulted.

In that forum the developing countries stuck to the principle of sovereign rights for raw PGR, but they returned to the common heritage principle for a limited group of 35 staple food crops. For these 35 crops the gains from sovereign ownership were small and strong property rights would undercut the goal of food security. Consequently, the new FAO Treaty on Plant Genetic Resources explicitly exempts these 35 crops from the principle of sovereign ownership. In sum, attempts at implementation of the conflicting rules in the original FAO Undertaking, the CGIAR gene banks, and CBD revealed the need for a change in rules; yet the general principle of sovereign ownership remained intact. The parties started with broad and conflicting rules and then tried to work out the problems—with the strategies that were easiest to implement first, followed by those that required progressively greater legal coordination. After doing so, they negotiated a new solution that sought to reconcile as best as possible the various interests and goals.

Two other examples of evolution through implementation in the PGR case are still unfolding, and we mention them only briefly. One is reconciling the various weak forms of intellectual property that can be asserted over improved plant varieties—such as the different types of plant breeder rights that are embodied in the different UPOV agreements—with the strong, patent-based rights that many countries, led by the U.S., are now allowing for innovators. TRIPs accepts all of these systems but envisions that several years after the creation of the WTO (in 1995) a review would take stock of the various

efforts and propose a coherent route forward. The architects of TRIPs built in to the agreement the very process that is a hallmark of a regime complex because they knew that the many varied interests and competing schemes made it impossible for them to adopt a precise and shared rule ex ante. They enshrined a general approach and then hoped that the implementation process would lead to a specification of international rules that were more precise yet still compatible with the diverse interests involved. The review is proceeding slowly—more slowly than envisioned—which reveals another point about the dynamics of a regime complex: the codification of international norms is driven by credible deadlines, but the implementation process often drags on because politically the easiest solution in the face of rule conflict is to keep the rules broad and then defer the details until later.

The third example involves "traditional knowledge." Modern systems for protecting intellectual property are organized to protect discrete innovations that occur at a moment in time by specified persons; they are generally unable to protect innovations that reflect the slow accumulation of novel concepts by many (unknown) members of a community.<sup>65</sup> This fact has led advocates for indigenous peoples to fear that traditional knowledge will be incorporated into discrete innovations and patented—with the stewards of such knowledge not rewarded for their long efforts and, perhaps, even forced to pay for the innovation constructed on their work. This movement spawned the effort to create and assert "farmers rights"—as a counterpart to plant breeder rights—that would recognized and reward traditional farmers for their improvements to crops. That effort has not yielded much practical change—mainly because key advanced industrialized countries are opposed but also because critics of strong intellectual property rights rail about the failures to reward traditional knowledge but have generally failed to propose viable rules with which to do so. Now the World Intellectual Property Organization, which has been a peripheral actor in this story, has convened a new working group to generate property rights rules and benefits sharing schemes that will recognize traditional knowledge. This development is part of the decentralized adjustment process that has occurred in the PGR regime complex as new conflicts in rules are revealed.

#### V. Conclusion

Genetic resources are increasingly an arena of global conflict in world politics. The struggle over the control of plant genetic resources is at the core of this battle. Over the last century, the international rules for PGR protection shifted--quite dramatically--from a common heritage, open access system to a system of sovereign resource rights and private intellectual property rights. We have argued that this transition was driven by the perception—and the reality—of the rising value of PGR, in particular as new techniques of genetic manipulation permitted innovators to add substantial value to plants.

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<sup>&</sup>lt;sup>65</sup> Boyle 1997.

Propertization, initially resisted by the plant-rich developing world, has triumphed over common heritage.

This transition to an international property rights system did not occur smoothly. Rule evolution in the PGR case involved several distinct but overlapping international regimes interacting with each other as well as the domestic practices of key states. Whereas existing studies of international regimes have generally focused on regimes as single, self-contained entities, often built around a single treaty, the hallmark of the regime complex in PGR is the lack of any central, hierarchical international institution. The principles, norms, rules and decision-making procedures that govern plant genetic resources have not arisen or changed in ways that are fully consistent with the existing body of theory about international regimes. Consequently, the PGR case is best characterized as a regime complex rather than a regime. The horizontal, overlapping structure and the presence of divergent rules and norms are the defining characteristics of a regime complex.

The regime complex for plant genetic resources is unlikely to be the first or the last such institution in world politics. Indeed, there are good reasons to believe that regime complexes will become much more common in coming decades as international institutions proliferate and inevitably bump against one another. Examples include the many elemental regimes related to the production, control and release of chemicals into the environment—such as on organic pollutants, trade in chemicals, and standardized methods for testing chemical safety. Looser regime complexes may be found in other areas, such as energy, where a myriad of elemental regimes addresses various forms of air pollution caused by consumption of energy as well as oil spills, investment, and production sharing agreements. As one looks closely, with this new conceptual lens, regime complexes built on complex interactions between elemental regimes may be found in many places. It might be useful to develop a typologies of regime complexes that span from tightly bound arrangements (e.g., chemicals) to the very loose (e.g., energy).

Despite a clear rise in institutional density in the international system, there has been surprising little research into the implications of density for the evolution of international cooperation. In this article we have advanced several hypotheses about the dynamics of a regime complex in order to highlight how the process of rule evolution in a regime complex differs from the processes identified by mainstream regime theory. In a regime complex rules evolve against a thick backdrop of existing rules: there is no clean institutional slate upon which actors pursue interests or wield power. This backdrop defines the regime complex but also generates its distinctive dynamics. In an increasingly legalized world, the lack of legal consistency that flows from differing and overlapping rules pushes states to seek resolutions and to negotiate broad rules. At times, states also create strategic inconsistency as they seek to move the rules in one or another direction.

In all these circumstances the primary locus of action is not formal negotiations but instead more complicated processes of implementation and interpretation, which in turn feed back at times to formal negotiations. As the scope of the regime complex grows, the style of rule change shifts ever more to this more messy and complicated "bottom-up" style and away from the top-down system that is implicitly assumed in the dominant approach to the study of regimes. While regime theory has advanced significantly since its start in the early 1980s, more research on regime complexes and their evolution will, we believe, both reflect a growing empirical reality and contribute to the increasing number of studies on the relevance of law, legalization and institutions to world politics.

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