

# INTERNATIONAL LAW AND INTERNATIONAL RELATIONS

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- The World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) sets minimum international standards for the protection of IP rights.
- The 1992 UN Convention on Biological Diversity (CBD), which originated in efforts to protect global biodiversity as a natural resource, simultaneously promotes the sharing of the economic benefits that arise from the use of genetic resources.

In addition to these five international institutions, the PGR regime complex has been influenced by activities at the domestic level, notably in the United States, and, to a lesser degree, in the EU. The United States has been a key driver of change in the IP field. Innovations that began in the United States, such as the patenting of life-forms, have subsequently been enshrined, partly as a result of U.S. insistence, in agreements such as TRIPs. U.S. firms are also the dominant innovators in both the pharmaceutical and agricultural industries.

Figure 26.1 illustrates these two dimensions of rules – ownership and allocative mechanisms – and summarizes the complicated story that we present below about the transformation from the common heritage system to sovereign and private property rights.

### The Common Heritage System

For most of human history, the rule of common heritage governed PGR. \*\*\* [Under this system] there were no property rights in PGR, nor did states bar access to genetic resources per se. As a result there was much international diffusion of PGR, particularly as long-distance trade expanded and imperial nations established central collections, such as Kew Gardens outside London, stocked with plants from around the globe.<sup>16</sup> To be sure, nations tried but often failed to maintain control over certain genetic resources; for example, China went to great lengths to preserve the silkworm monopoly, but ultimately lost it to two enterprising Nestorian monks.<sup>17</sup> Silkworms, rubber trees, and a few other special resources of obvious high value were the exception, however – otherwise, genetic resources were free for anyone who bothered to take them.

<sup>16</sup> Kloppenburg 1988.

<sup>17</sup> Stone 1994.

Ownership of Plant Genetic Resources and Mechanism for Allocating Benefits

		Common heritage	Property rights	
			Sovereign (state-controlled)	Private and community
Mechanism for allocating benefits from PGR	Market-based	Traditional 19th-century system		Late 20th-century national patents: U.S. EU  TRIPs  UPOV treaties
	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)

*Note:* The UN Food and Agriculture (FAO) Treaty distinguishes the rules that apply to both raw (“R”) and worked (“W”) plant genetic resources (PGR) for a core group of 35 staple food crops, denoted “R35” and “W35.” The Consultative Group on International Agriculture Research (CGIAR) gene banks 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 Convention on Biological Diversity (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.

**TRIPs:** Trade-Related Aspects of Intellectual Property Rights.

**UPOV:** International Convention for the Protection of New Varieties of Plants.

FIGURE 26.1. Two dimensions of debate.

Under the common heritage system there was little difference in treatment between what we term “raw” and “worked” PGR. In agriculture, the dividing line between raw and worked was (and often remains) indistinct because worked materials, as well as new raw materials collected in the field, are the source of new worked materials.<sup>18</sup>

The first moves toward propertizing PGR addressed worked resources. \*\*\* By the 1920s, a limited, industrial business of breeding emerged, and with it political pressure for protection arose. The most prominent innovative activity involved hybrid plants, which had their own built-in mechanism for protecting IP – hybrids lose their vigor after one generation, and thus farmers must purchase new seed every season.<sup>19</sup> But many other innovations were more difficult to protect, such as cuttings from fruit trees that propagate asexually. Governments responded by tailoring special rules to plant innovators. In 1930, the United States passed the Plant Patent Act, allowing innovators to claim patents for plants that reproduce asexually.<sup>20</sup> Most countries, however, stopped short of granting patents; if they granted IP protection at all they did so through a limited mechanism known today as “plant breeders’ rights.” These property rights barred plant breeders from [the] outright copying of innovations, but the rights did not prevent a breeder 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. \*\*\*

\*\*\* [The] 1961 UPOV agreement enshrined the concept of plant breeders’ rights into international law.<sup>21</sup> Plant breeders were concentrated in the industrialized states that had the largest influence over UPOV’s content, and the resulting UPOV agreement largely reflected their interests. Updated with new agreements in 1978 and 1991, fifty states eventually became parties to at least one of the UPOV agreements. \* While UPOV introduced property rights for worked PGR, 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 [raw genetic information could not be owned.]

<sup>18</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>19</sup> Griliches 1957.

<sup>20</sup> Rories 2001.

<sup>21</sup> Barton 1982. The United States also passed the Plant Variety Protection Act in 1970, which extended the 1930 Act to sexually reproducing plants.

### The Demise of the Common Heritage System

While change was already afoot by the early 1960s, the major shock to the common heritage system was the invention of recombinant DNA technology in the 1970s.<sup>22</sup> By allowing innovators to work directly at the genetic level, the scope for innovation in plant resources increased dramatically. This technological change stimulated interest in creating stronger protection for worked PGR and ultimately in creating property rights for raw PGR as well. In Demsetzian fashion, actors demanded property rights in response to the possibility of increasing the value of plant genetic resources and the desire to appropriate that value for themselves. Most of the early changes in property rights occurred in the United States, but this domestic activity created pressure for changes in international rules.

The biotechnology revolution that began in the 1970s led to the creation of many new firms engaged in genetic engineering. These firms' business models required secure property rights to reap the benefits of their costly investments in research and development. A critical breakpoint in this story was the U.S. Supreme Court's 1980 decision, in the landmark case of *Diamond v. Chakrabarty*, extending patent protection to living modified organisms – in that particular case, genetically engineered bacteria.<sup>23</sup> Before *Chakrabarty*, the patentability of living innovations outside the narrow confines of the 1930 Plant Patent Act was unclear. After *Chakrabarty*, and subsequent cases that reaffirmed and extended it, U.S. firms could receive complete utility patent protection for a panoply of genomic techniques. 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 short, these two changes – one judicial and one legislative – transformed the U.S. domestic playing field with regard to property rights in genetic resources. Since 1980, the conventional wisdom in the United States has been that strong property rights – patents, in particular – are essential to the modern biotechnology-based innovation system. U.S. firms and the U.S. government sought to extend this new system globally.<sup>24</sup>

<sup>22</sup> Evenson 2002,

<sup>23</sup> *Diamond v. Chakrabarty* (1980). Some doctrinal uncertainties remained that are not germane to our argument; see *Ex Parte Hibberd* (1985), and *JEM Ag Supply v. Pioneer Hi-Bred* (2001).

<sup>24</sup> Ryan 1998.

The increasing protection of worked PGR under the domestic laws of industrialized nations 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 placed on the FAO agenda by a coalition of developing countries, mainly from Latin America, and a small number of sympathetic industrialized countries. Often rich in biodiversity, developing countries have been the source of many commercially valuable genetic samples. Yet the open access regime gave them little compensation, even as arrangements such as UPOV forced them to pay for innovations built (in part) on their own genetic heritage. These concerns resonated with the then-recent effort to establish a New International Economic Order, aimed at redistributing global wealth through new international institutions and reining in the powers of multinational corporations.<sup>25</sup>

The FAO Undertaking attempted to counter the emergence of property rights in worked PGR – such as in the UPOV agreements – 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;” PGR should be available “free of charge . . . or on the most favorable terms.” \*\*\* [The industrialized countries refused to accept the Undertaking’s demand for open access to worked PGR.] Eight industrialized countries issued formal reservations to the Undertaking. In 1989, FAO adopted an Annex to the Undertaking to provide a general “agreed interpretation” that papered over this conflict and allowed most of these hesitant countries to join.<sup>26</sup> \*\*\*

### **Biodiversity and Bioprospecting**

The uneven but accelerating dissolution of the common heritage 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 animals (such as whales) were politically expedient choices for the first efforts at global environmental cooperation in the 1960s and 1970s. By the 1980s, however, conventional wisdom was that a broader approach was needed. This conceptual shift was rooted in ideas

<sup>25</sup> Gilpin 1987, 298–301.

<sup>26</sup> FAO Annex I 1989.

from conservation biologists that stressed the need to protect entire ecosystems and was consummated in the CBD \*\*\*.<sup>27</sup>

[In the late 1980s, when the CBD was taking shape,] developing countries began to see property rights in PGR as a mechanism for securing sovereignty and wealth, rather than solely as a device that “biopirates” from the North had rigged against them. \*\*\* The conceptual touchstone for this new political coalition in favor of property rules was the notion of “bioprospecting.” Firms could prospect for valuable genetic resources just as miners had prospected for gold in centuries past. A famous 1991 deal, in which a U.S.-based pharmaceutical giant (Merck) contracted with a Costa Rican conservation institute (INbio) for bioprospecting rights in the Costa Rican rain forest, signaled to many the dawn of a new era of bioprospecting.<sup>28</sup> This conceptual innovation aligned the interests of environmentalists, biotechnology firms, and developing countries that were seeking to extract greater value from their biodiversity riches.<sup>29</sup> [Subsequent economic analyses – as well as a dearth of realized profits – suggest that the value of rain forest genetic resources was considerably overestimated, but in the 1990s the hopes for transformation were a more powerful elixir than the econometrics.<sup>30</sup>]

\*\*\* [The] realization by developing countries that they could benefit from asserting sovereign ownership over raw PGR was reflected much more rapidly in the FAO’s Commission on Plant Genetic Resources. Unlike the omnibus CBD, the FAO commission was focused solely on the issue of PGR and thus could change course more nimbly \*\*\*. [In 1991, the FAO adopted a new Annex stating 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.” It also 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 almost exactly mirrored language in the draft texts, then circulating, of the CBD.<sup>31</sup>] The draft CBD text also made clear that states controlled access to PGR and that the open access norm of the past was

<sup>27</sup> On the intellectual shift toward the “ecosystem” concept see Golley 1993; on the history of wildlife protection, which until the late 1980s focussed on specific activities, regions and ecosystems, see Lyster 1985.

<sup>28</sup> See Tilford 1998 and Blum 1993.

<sup>29</sup> Reid 1993.

<sup>30</sup> See Peters et al. 1989; and Godoy et al. 1993.]

<sup>31</sup> The only difference being that the CBD language referred to all biological resources, not just genetic resources.

gone. Through these simultaneous assertions of sovereign rights in the CBD and the FAO, a new approach to PGR coalesced.

### The Legalization of Property Rights

The early 1990s represented a watershed in the development of the PGR regime complex – the final break from the primacy of common heritage. \*\*\* Yet the CBD was a broad agreement that had been crafted through a process dominated by relatively weak environment ministries; likewise, the FAO was dominated by agriculture ministries who also had limited influence. Although abundant in symbolism, the CBD and FAO had only minimal impact on the rules and practices that actually affected the flow of genetic resources.

At the same time that the new FAO Annex and CBD were finalized, nearly all the same states – represented by their 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 IP, which were placed on the trade agenda because firms in entertainment, Pharmaceuticals, and other “knowledge industries” insisted on stronger international protection of IP. \*\*\* Backed by the power of the United States, these rules were codified into TRIPs. TRIPs sets minimum standards for IP protection; in practice these standards were closely modeled on U.S. or EU law.<sup>32</sup> Moreover, TRIPs was folded into the new WTO structure, which included a powerful, retooled system for enforcing dispute settlement. The large number of developing countries that joined the WTO seeking greater access to markets found that their membership also required a transformation in their domestic rules for IP. \*

TRIPs contains specific language on genetic resources, which mandates that countries must grant patents for microorganisms and, in Article 27.3b, expressly requires either patents or a “*sui generis*” system for worked PGR.<sup>33</sup> The UPOV system of plant breeder rights was the concept that some TRIPs drafters had in mind for a *sui generis* system, but not all states wanted to endorse UPOV, forcing the drafters to leave this provision vague. These states instead sought clarity from the bottom up – each state would interpret and implement Article 27.3b as it saw fit, and a later systematic review would take stock of the experience. \*\*\*

<sup>32</sup> See Maskus 2000; Ryan 1998; and Sell 1995.

<sup>33</sup> A “*sui generis*” system simply means a unique system tailored, in this case, to the needs of PGR.



Thus from the mid-1980s, the number of international institutions within the regime complex grew, and the boundaries between the elemental regimes blurred. This expansion was driven by the large number of new issues that touched on PGR – such as protection of biological diversity and the expanding agenda of international trade policy – as well as the desire by key stakeholders to codify the emerging consensus in favor of property rights. \*\*\*

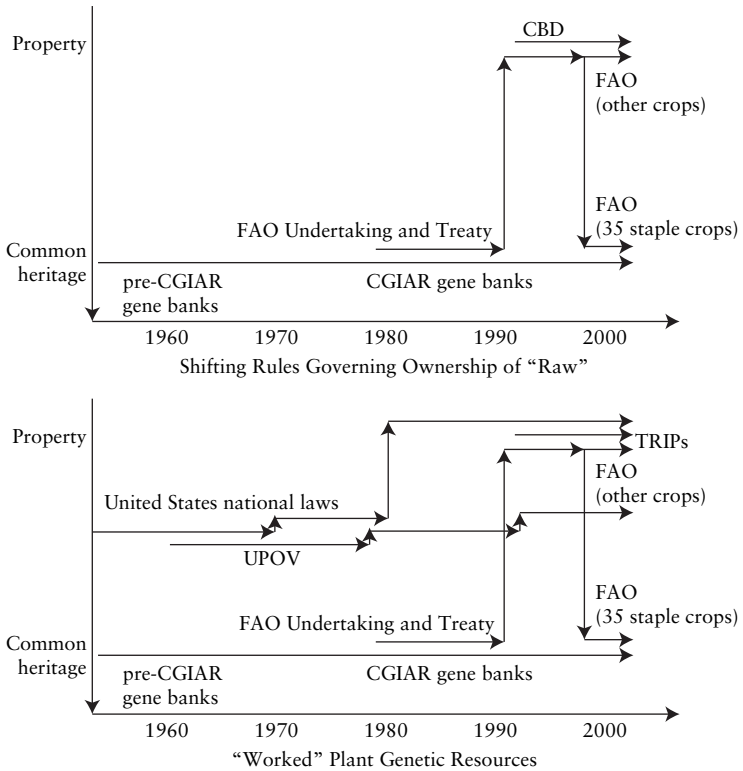
The seismic change in property rules rippled through the rest of the regime complex, affecting how key stakeholders saw their interests served in many other rules. The main front line was now the allocation of benefits from PGR – the second dimension in Figure 26.1. Should the market be left to itself to allocate the benefits of PGR, or should governments regulate the allocation of benefits? Distributional issues often confound efforts to secure property rights. As Libecap argues, “all things equal, skewed rights arrangements lead to pressure for redistribution through further negotiations.”<sup>34</sup> The history of PGR exemplifies this pattern. Wary of market mechanisms, developing countries sought to create special mechanisms that would force innovators to share the benefit stream with the states that provided the raw PGR. Property rights alone, these countries argued, would not be enough to force biopirates to disgorge a fair share of profits.

These efforts to elaborate an international benefit-sharing scheme arose mainly in the CBD \*\*\*. The widest in scope of all the elemental regimes, the CBD was a convenient forum for actors who wanted to expand the debate. At the same time, powerful states that wanted to insulate the normative structure of other (in their view, more important) elemental regimes – notably the WTO – often found it convenient to allow the CBD to become a holding pen for these new concerns \*\*\*. The CBD addressed the benefit-allocation issue through several controversial provisions. Most notably, it obligated each party to enact measures aimed at “sharing in a fair and equitable way . . . the benefits arising from the commercial and other utilization of genetic resources with the [state] providing such resources.”<sup>35</sup> This redistributive language was strongly opposed by the United States, and contributed to the U.S. decision not to ratify the CBD.

\* \* \*

<sup>34</sup> Libecap 2003.

<sup>35</sup> Article 16. Similar language appears in Article 8(J) of the CBD. On the use of CBD as a holding pen and the incentives to shift between regimes see Helfer 2004.



Note: Institutions shown only on panels for which they have relevant rules. The International Convention for the Protection of New Varieties of Plants (UPOV), for example, relates only to worked plant genetic resources (PGR). Consultative Group on International Agricultural Research (CGIAR) gene banks are shown as "raw," although perhaps two-fifths of their collections have been worked in some way. The Convention on Biological Diversity (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 (1991); the UN Food and Agriculture (FAO) treaty that distinguishes rules for 35 staple crops from those for nonstaples (2001).

**Major events for worked PGR:** The U.S. Plant Variety Protection Act (1970) and the *Diamond* case in the United States (1980); revisions to UPOV (1978, 1991); the annex to the International Undertaking (1991).

**TRIPs:** Trade-Related Aspects of Intellectual Property Rights.

FIGURE 26.2. Changes in property norms for raw and worked PGR.

In sum, by the end of the 1990s the international rules governing PGR were radically different from those that existed seventy-five years earlier. Figure 26.2 summarizes this shift – for raw PGR (top panel) as well as “worked” PGR (bottom panel).

\*\*\* [The realignment of the late 1990s did not erase existing political controversies.] Thus international norms were cast broadly to allow some diversity in local circumstances. \*\*\* In some cases, such as the core crop plants addressed by the 2002 FAO treaty (discussed below), the costs of administering property rights turned out to be so high that states collectively reverted to the common heritage concept – an outcome consistent with sophisticated versions of the Demsetzian thesis.<sup>36</sup> As property theorists have noted, a resource will operate without property rights as long as the cost of implementing and enforcing property rights is “higher than the value of the increase in the efficiency of utilization of the resource gained by the introduction of a property regime.”<sup>37</sup> This was the case for many common food crops because of the extreme difficulty of demarcating and enforcing property rights – and the relatively small gains from doing so in this area – and consequently the system revived the common heritage approach in this circumscribed domain.<sup>38</sup> On the whole, however, the demands for property rights in PGR were largely met by the mid-1990s. Enclosure had triumphed over common heritage and open access.

#### REGIME COMPLEXES AND THE STUDY OF REGIMES

Many studies of international cooperation have noted the tremendous rise in the number of international treaties and organizations, particularly since 1945.<sup>39</sup> Yet few studies have given systematic attention to the implications of this increase in institutional density.<sup>40</sup> \*\*\* This rise in density occurs against a backdrop of increasing legalization in world politics. The international legal system is, however, nonhierarchical: generally,

<sup>36</sup> See Libecap 1989; Merrill, 2002; and Levmore 2002.

<sup>37</sup> Benkler 2002, 402.

<sup>38</sup> See the list in the 2002 FAO Treaty on Plant Genetic Resources. As Libecap notes, the physical nature of an asset affects the cost of calculating and assigning value, in turn affecting the costs of marking and enforcing property rights. Libecap 2003, 150.

<sup>39</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>40</sup> Partial exceptions include Young 2002; Stokke 2001; and Leebron 2002.

no one regime is supreme over others as a legal matter. Moreover, the international legal system is disaggregated. Regimes and rules are developed in one forum that frequently implicate or even challenge regimes and rules developed in other forums.

As the PGR case illustrates, one result of rising density in this context is the development of overlapping but discrete regimes, often with conflicting rules during periods of transition to new interests and rules. \*\*\*

In the remainder of this article we use the PGR case 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 oriented around a model of regime development that fails to reflect the growing concentration and interconnection of institutions in the international system.

### 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 creating a regime without any explicit international rules in place; previous arrangements – if they exist at all – are readily discarded or adjusted. In these accounts, states with different interests vie to shape the outcomes, and institutions are crafted to serve the political agreement. \*\*\*

In a regime complex, by contrast, negotiations over most substantive rules commence with an elaborate and dispersed institutional framework already in place. The institutional slate is not clean. Ideas, interests, and expectations frequently are already aligned around some set of existing rules and concepts \*\*\*. Consequently, power, interests, and ideas do not directly map onto the norms that become enshrined in the agreements at the core of the regime; the content and evolution of rules does not trace neatly back to changes in the underlying driving forces. We expected that the lack of a clean slate would affect the development of the rules in the elemental regimes in a path-dependent manner – and, consequently, the evolution of regime complex as a whole. Despite the history of PGR being one of dramatic change – a normative shift, over many years, from common heritage to propertization – in many respects this expectation was borne out. We found path dependence at the meso scale, in that particular rules affected and constrained the architecture of subsequent rules. Yet at the macro scale the regime complex exhibited marked change.