The Political Economy of Data Protection

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INTRODUCTION

Information is the lifeblood of a knowledge-based economy. The control of data and the ability to translate them into meaningful information is indispensable to businesspeople, policymakers, scientists, engineers, researchers, students, and consumers. Having useful, and at times exclusive, information improves productivity, advances education and training, and helps create a more informed citizenry. As the National Information infra-

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structure Taskforce of the Clinton Administration observed:

Information is one of the nation’s most critical economic resources, for service industries as well as manufacturing, for economic as well as national security. By one estimate, two-thirds of U.S. workers are in information-related jobs, and the rest are in industries that rely heavily on information. In an era of global markets and global competition, the technologies to create, manipulate, manage and use information are of strategic importance for the United States.¹

To underscore the growing importance of information in the New Economy and the high economic value of data, Nicholas Negroponte recounted his visit to a leading U.S. integrated circuit manufacturer in the beginning of his book, *Being Digital*:

I was asked to sign in and, in the process, was asked whether I had a laptop computer with me. Of course I did. The receptionist asked for the model and serial number and for its value. “Roughly, between one and two million dollars,” I said. “Oh, that cannot be, sir,” she replied. “What do you mean? Let me see it.” I showed her my old PowerBook and she estimated its value at $2,000. She wrote down that amount and I was allowed to enter the premises. The point is that while the atoms were not worth that much, the bits were almost priceless.²

Although data have always been valuable, their value was not as greatly appreciated as it is today. In the past, data were protected primarily for their ability to enhance the value of other goods or services, rather than for their inherent value. Secrecy, family control, or the use of physical devices, like locks and safes, often protected valuable data, such as those contained in customer lists, inventory files, and sales records. As the legal system became more developed and as sophisticated technologies emerged, trade secret, misappropriation and unfair competition laws, contracts, and technological protection measures were being deployed to offer additional protection.

In the past two decades, those who collected or obtained access to a large amount of data began to explore ways to use the collected data as an income stream. Because the then-existing laws did not offer adequate protection for that particular purpose, they began to lobby for new *sui generis* rights to protect uncopyrightable collections of data. Meanwhile, pharmaceutical and agrochemical manufacturers were seeking to use their control of clinical trial data as an offensive strategy to protect markets and investment. As part of this effort, these manufacturers lobbied for the protection of test data submitted to regulatory authorities for the marketing approval

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¹ INFO. INFRASTRUCTURE TASK FORCE, NATIONAL INFORMATION INFRASTRUCTURE: AGENDA FOR ACTION 7 (1993).
of pharmaceutical and agrochemical products.

At the international level, the development of laws to protect data assets, which this article will collectively describe as data protection laws, has become even more intriguing. Because data can flow freely and easily from one country to another, countries that offer strong data protection tend to attract investment from data providers, such as database producers, pharmaceutical and agrochemical manufacturers, and other businesses that consider data an important asset. Meanwhile, countries that offer weaker protection provide equally attractive environments for businesses whose operations depend on the wide availability of free or cheap pre-existing data. If protection is minimal, these countries can also serve as havens for data pirates.

In light of the very different protection offered in these countries, businesses have engaged in regulatory arbitrage by relocating their operations to jurisdictions that offer more favorable legal environments. To attract foreign investment and to retain local businesses, countries now actively participate in a "race" to either the top or the bottom. Although this article focuses mainly on the "race to the top," which has resulted in the ratcheting up of intellectual property protection, it is important to remember that the reform efforts needed for either race often incur significant costs. By adopting an intellectual property system that ignores the balance between access and protection, countries will ultimately harm their economies by introducing laws that are not tailored to their interests, goals, and local conditions.

Part I of this article recounts the development of two new forms of data protection. It begins by examining the development of *sui generis* database protection. It discusses the protection of the EC Database Directive, the United States' resistance to *sui generis* database protection, and the eventual failure of the proposed World Intellectual Property Organization (WIPO) Database Treaty. Part I then focuses on the development of data exclusivity laws in less developed countries. In particular, it examines

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3. Although commentators have used the term "data protection" to describe the protection of personal data as viewed from the standpoint of consumers and policymakers, the term is used throughout this article to describe the protection of data assets as viewed from the standpoint of data providers and intellectual property rights holders. To emphasize the intersectionality between data protection and other areas, such as privacy, the term refers to both the protection of personal data and the protection of data assets in *infra* Part III.C.

the United States' use of free trade agreements to transplant data exclusivity laws abroad and highlights the many problems brought about by such transplantation.

Part II discusses the concerns raised by the undemocratic processes used to develop these laws and treaties. Focusing on "policy laundering" and "backdoor lawmaking," this Part explains why these efforts are harmful to both the United States and the larger international community. To help alleviate these problems, Part III then offers suggestions on how to recalibrate the balance of the intellectual property system. Part IV concludes with a plea for caution concerning the development of new intellectual property rights to protect data, drawing on the European Commission's recent evaluation of the EC Database Directive.

I. DATA PROTECTION

A. Database Protection

To help explain the emerging development of data protection at both the domestic and international levels, this article begins with two stories. The first story began in 1996, when the European Community promulgated the EC Database Directive. The Directive requires all the then fifteen (and now twenty-seven) member states to offer sui generis protection to databases that are created as a result of "substantial investment" by database producers. In addition, the Directive protects databases against unauthorized extraction and reutilization for a renewable term of fifteen years regardless of their eligibility for copyright protection.

To the detriment of U.S. database producers, the Directive includes a reciprocity provision that denies protection to databases produced in countries that fail to offer comparable protection. To maintain the competitive advantage of U.S. database producers, Congress considered many legislative proposals in the mid-to-late 1990s to strengthen database protection. Nevertheless, all of these proposals failed, and the United States, as of this writing, has yet to offer sui generis database protection.

The cold reception of database protection can be largely attributed to the 1991 case of *Feist Publications, Inc. v. Rural Telephone Service Co.*, a key United States Supreme Court decision that disqualified the white pages

6. Id. art. 7.
7. Id. arts. 7, 10.
8. Id. art. 11.
of a telephone directory for copyright protection.\textsuperscript{10} As the Court declared, "[o]riginality is a constitutional requirement."\textsuperscript{11} A compilation is therefore not worthy of copyright protection unless information in the compilation is selected, coordinated, or arranged in an original manner.\textsuperscript{12} Under the Court’s reasoning, nonoriginal, noncreative databases would not qualify for copyright protection even if a substantial amount of labor and capital had been expended to create those databases. Because the proposed \textit{sui generis} database protection legislation sought to offer protection under this rejected "sweat of the brow" theory, it was very unlikely to pass constitutional muster under the Copyright Clause.\textsuperscript{13} Such legislation also raised serious constitutional questions under both the Commerce Clause and the First Amendment.\textsuperscript{14}

To make things worse, many considered \textit{sui generis} database protection to be bad public policy whose costs were likely to outweigh its benefits.\textsuperscript{15} For example, the protection would confer far broader and stronger exclusive rights on database contents than necessary to provide the needed incentives for database producers. By granting a monopoly over collected data, such protection would also allow private entities to lock up information that was essential to basic scientific research and future creative endeavors. In addition, \textit{sui generis} protection would make information products more expensive by creating an anti-competitive environment that would make it difficult for valued-added products and services to enter the market. Finally, the additional protection was considered unnecessary because database producers already enjoyed significant protection under state contract, misappropriation, and unfair competition laws as well as through the use of technological protection measures.

\textsuperscript{10} Id. at 364.
\textsuperscript{11} Id. at 346.
\textsuperscript{12} See id. at 358–59.
\textsuperscript{13} See id. at 352–56, 360.
The biggest stumbling block to the passage of *sui generis* database protection legislation, however, was politics. At the time the bills were proposed, only one of the three major stakeholders in the database industry, McGraw-Hill, was an American company. The other two, Reed-Elsevier and Thomson (now Thomson Reuters), were European and Canadian companies, respectively. As a result, the proposed legislation did not get much traction on Capitol Hill. Instead of providing substantial facts on the harm that the lack of Congressional responses would cause to the U.S. database industry, the sponsors and proponents of this legislation were able to make only generalized claims of potential foreign competition and piracy in European markets. Because many businesses were both producers and users of data, they remained reluctant to support stronger database protection until they were certain that the proposed legislation would strike the appropriate balance between the production of databases and the use of collected information.

Notwithstanding the immense controversy surrounding the domestic proposals, the U.S. administration skillfully circumvented the domestic legislative process by actively pushing for the adoption of a draft treaty proposal by the WIPO. Modeled after the EC Database Directive, the proposed treaty called for the protection of databases for a term of twenty-five years, which could be renewed indefinitely upon the showing of substantial changes to the database contents. Although WIPO considered the draft treaty in the 1996 diplomatic conference, along with the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty, the strong disagreement among the member states and the active participation of academics and nongovernmental organizations successfully prevented WIPO from adopting such a treaty.

**B. Data Exclusivity**

The second story concerns the increasing international protection of undisclosed information, which "has never been the subject of any multila-
teral agreement" until the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement). Article 39(3) of the TRIPs Agreement requires member states to protect against unfair commercial use of the undisclosed information submitted for the marketing approval of products that utilize new chemical entities. The protected information includes the clinical trial data that regulatory agencies collect as part of the effort to evaluate the efficacy, quality, and safety of new pharmaceutical and agrochemical products.

Notably, Article 39(3) does not offer broad protection of these test data. Instead, it includes two very narrow conditions. First, the provision offers protection against unfair competition; it does not create exclusive rights in the collected data. Second, the protection applies only to products utilizing new chemical entities; it was not intended for "existing chemical entities that have been reformulated or sold for a new indication." Notwithstanding the limited scope of Article 39(3), the United States, the European Community, and their pharmaceutical and agrochemical industries have broadly interpreted the provision to cover a new data exclusivity regime that is similar to those currently in place in those regions.

To transplant data exclusivity laws abroad, the United States, in recent years, has entered into bilateral or regional free trade agreements with many less developed countries. These agreements require countries to prohibit the use by third parties of clinical trial data that have been submitted to regulatory authorities for the marketing approval of pharmaceutical and agrochemical products. Article 15.10.1 of the Central America-Dominican Republic Free Trade Agreement, for example, requires each signatory country to offer exclusive protection of undisclosed test data "for at least five years for pharmaceutical products and ten years for agricultural


26. The United States is not the only country that has aggressively pushed for these bilateral or regional trade agreements. Nevertheless, this article focuses on the U.S.-initiated agreements because of their representativeness for the recent bilateral and regional efforts, their considerable implications for public health, and their differences from similar agreements initiated by the European Community, which are often filled with more compromises among its many member states.
chemical products.” Similar provisions can be found in the United States–Australia Free Trade Agreement, the United States–Singapore Free Trade Agreement, and many other recently-negotiated free trade agreements.

The economic rationale behind these data exclusivity provisions is simple and easy-to-understand. As the pharmaceutical industry has claimed, “[t]he development and bringing to market of a new drug requires the originator to conduct extensive chemical, pharmacological, toxicological and clinical research and testing, at an average cost of US$800 million, and taking 10 to 15 years to complete.” Because of the high costs of data collection and the large amount of time involved, additional protection, other than what pharmaceutical manufacturers already received under the patent system, is necessary to protect their investment. Such protection would also prevent third parties, in particular generic competitors, from free riding on the originator’s efforts in collecting data during clinical trials. Viewed in this light, data exclusivity laws are less important as a means to generate incentives than for its ability to effectively erect a market entry barrier that extends the originator’s limited monopolies.

Notwithstanding these justifications, commentators have found the need for data exclusivity laws economically dubious. Although the costs of clinical trials remain high and could make up for a major portion of the research and development costs of new drugs, companies already have considerable incentives under the current patent system. They also have received significant support from public funding to conduct research and development. While pharmaceutical manufacturers may still need incentives to obtain marketing approval for their products, most of the marketing costs are already included in the total costs that are used to justify stronger

31. See Carlos M. Correa, Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements, in NEGOTIATING HEALTH, supra note 24, at 81, 82 (noting that “[t]he development of test data typically represents more than 60 percent of the research and development . . . costs of new drugs”).
patent protection. Unless the regulatory authorities in foreign countries require different clinical trials during the approval process, additional incentives seem to be unnecessary. Indeed, if data exclusivity laws are to be adopted, one has to wonder whether existing patent rights need to be curtailed proportionally to reflect the additional incentives.

Moreover, even if one can make a strong case for data exclusivity laws in developed countries, the case for similar laws in less developed countries is rather weak. There is simply no evidence that pharmaceutical manufacturers cannot recoup their investment if data exclusivity is provided only in developed countries. In fact, ratcheting up protection in the form of data exclusivity in less developed countries is unlikely to result in greater research and development worldwide or increased foreign direct investment in the affected countries. After all, these poor countries “provide a small share of the global pharmaceutical market and their policy choices have a minimal impact upon the R&D investment decisions of multinational pharmaceutical companies.”

Even worse, there are serious moral and ethical implications for introducing data exclusivity laws. If pharmaceuticals become readily available at the end of the patent term, it will be inhumane to delay the entry of competitive drugs, whether on-patent or generic. Such delay, along with the reduced price competition, is likely to prolong, or even exacerbate, the massive public health crises in less developed countries. It is also wasteful and highly undesirable to require duplicative testing in countries that have very limited economic resources. Moreover, it is simply immoral to require the use of human subjects and animals to retest drugs that are considered bioequivalent to those that have already been approved for the market.

If the protection is strengthened to the point that the public disclosure of clinical trial data is forbidden, such protection would even create serious public health and environmental risks. As Aaron Fellmeth has explained:

Disclosure of marketing approval data honors the public’s interest in being informed about the safety and effectiveness of an approved drug and allows independent observers, such as academics and public interest groups, to conduct further testing and to verify or dispute the accuracy and impartiality of the data submitted by the registrant. It is sometimes observed that drug developers have an incentive to suppress unfavorable results from their drug testing or to exaggerate their efficacy findings. The lack of access to testing data seriously impedes third parties from uncovering bias, inaccurate or incomplete results, and false claims based on that data. The public may thereby be defrauded and public health ex-

33. Weissman, supra note 24, at 154.
34. See Correa, supra note 31, at 93.
posed to unnecessary danger.\textsuperscript{35}

In countries suffering from rampant corruption and a lack of government transparency, the public availability of these data and the possibility of using them to conduct independent evaluation are likely to be very important. Such availability not only will meet the countries' public health needs, but will also reduce the opportunity for collusion and anticompetitive behaviors.

In sum, even if there is a strong need for providing incentives for pharmaceutical manufacturers to develop new and better drugs, that need has to be balanced against the socioeconomic costs of having data exclusivity laws, the nation's public health needs, and the moral and ethical concerns that such protection raises. Therefore, it is not surprising that many commentators have proposed compromise solutions using the alternative cost-sharing approach that will enable pharmaceutical manufacturers to receive compensation for the high costs of the clinical trials used to obtain marketing approval for their products.\textsuperscript{36} To many of these commentators, the latter's approach, although not necessarily desirable, is still far better than the introduction of data exclusivity laws.

II. THE DYNAMICS OF INTERNATIONAL LAWMAKING

A. Policy Laundering

While these two stories provide important insights into the process of creating new intellectual property rights to protect data, they also help us better understand the political economy of data protection. Taken together, they describe vividly what commentators have termed "policy laundering."\textsuperscript{37} As two commentators defined:

Policy laundering" is a term that describes efforts by policy actors to have policy initiatives seen as exogenously determined, or even seen as requirements imposed by powerful others. The United States and the United Kingdom are identified as policy actors that routinely push for the establishment of regulatory standards in international policy venues

\begin{itemize}
\item \textsuperscript{36} See, e.g., id. at 482–99; Jerome H. Reichman, \textit{The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?}, in \textit{Negotiating Health}, supra note 24, at 133, 144–48; Weissman, \textit{supra} note 24, at 155–63.
\end{itemize}
so that domestic policies can be brought into line with those policies "under the requirement of harmonization and the guise of multilateralism."

In the first story, database protection was considered both unconstitutional and inexpedient on American soil. Such protection, by contrast, was viewed more favorably outside the United States, thanks to the warm reception of *sui generis* database protection in Europe. Had the U.S. administration been able to push WIPO to adopt the draft database treaty, it would have succeeded in laundering an unpopular and ill-advised policy through the international process. When the policy returned to the home soil for deliberation, that policy would be likely to become more legitimate as a result of the new-found need for international harmonization. As Pamela Samuelson surmised:

Had this effort succeeded in Geneva, Clinton administration officials would almost certainly have then argued to Congress that ratification of the treaties was necessary to confirm U.S. leadership in the world intellectual property community and to promote the interests of U.S. copyright industries in the world market for information products and services.

Moreover, the administration’s laundering effort has upset the dynamics of the domestic lawmaking process. When Congress deliberates treaty-implementing legislation, the main focus of the policy debate may no longer be whether the policy would benefit the American economy—or, better, the American people. Instead, the focus may become whether the failure to adopt such a policy would isolate the country from the international community. The tone of the debate and the congressional committees involved may change. Even if the same committees are involved, they may have a difficult time adapting to new international issues, which are often quite different from the domestic issues that they are used to handling.

Similar policy-laundering activities took place in the second story. Although governments of less developed countries entered into the free trade agreements based on their internal assessment, the use of the bilateral (or regional) negotiation process successfully transformed an unpopular, ill-advised policy to one that less powerful countries had to accept due to their limited bargaining power in one-to-one situations. If a sufficient number of less developed countries adopt these unpopular proposals, the pres-

39. See Hosein, supra note 37, at 188 (noting the general notion that “international cooperation is inherently good” and the general belief that international cooperation is “seen as benign and . . . for the most part uninterrogated”).
41. See The Policy Laundering Project, supra note 37.
sure would be on the remaining holdouts in the international community to agree to new global standards that would not have been adopted had the policy been deliberated at the multilateral level.

This development is rather unfortunate because less developed countries, to date, have achieved significant success in pushing for reforms of the international intellectual property regime. The Doha Declaration on the TRIPS Agreement and Public Health, for example, delayed the mandatory introduction of patent protection for pharmaceuticals and the protection of undisclosed clinical trial data until January 1, 2016.42 If ratified, the proposed article 31bis will amend the TRIPs Agreement to allow countries with insufficient or no manufacturing capacity to import generic versions of on-patent pharmaceuticals.43 In addition, less developed countries successfully pushed for the establishment of the WIPO Development Agenda.44 They were also able to slow down the patent harmonization process by delaying the adoption of the proposed Substantive Patent Law Treaty.45

Outside the intellectual property regime, the economic plight of less developed countries has earned great sympathy in the human rights, public health, biological diversity, and information and communications fora, and among academics and non-governmental organizations.46 There has also been a growing awareness of the protection of traditional knowledge and cultural expressions and increasing recognition of the need to develop such protection.47 In sum, the bilateral and regional free trade agreements were a major setback to the many achievements less developed countries have made at the multilateral level both within and outside the intellectual property regime.

B. Backdoor Lawmaking

While policy laundering is undesirable and would result in the adop-
tion of ill-advised policies, it is particularly problematic from the standpoint of democratic governance. If left unchecked, policy laundering would result in what I have described as "backdoor lawmaking"—"a process of outsourcing the legislative process to an international forum of unelected representatives in an effort to create laws that the domestic legislature would not have otherwise enacted."48 This backdoor process represents rent-seeking at its best, and the laws created through the process will eventually haunt the American people.

The first story shows a failed attempt by the U.S. administration to engage in backdoor lawmaking. Noticing that Congress was unlikely to offer *sui generis* database protection at the domestic level, the administration went to a multilateral forum—WIPO in this case—to create new international standards based on laws that its domestic legislature was reluctant to adopt. Should the draft WIPO Database Treaty be adopted, the resulting standards will travel back to the United States in the form of international obligations. These obligations would likely provide both the needed momentum and new-found justifications for enacting laws that the domestic legislature initially found unappealing. By presenting the treaty as a *fait accompli*, the administration therefore might be able to make an end run around Congress and the domestic deliberative process.49

The second story illustrates a different type of backdoor lawmaking, but one that would hurt both the United States and less developed countries. Through the use of free trade agreements and forum-shifting strategies,50 the administration successfully sidestepped the multilateral process to select a more desirable negotiating forum. In doing so, the United States forced less developed countries to reopen the TRIPs debate in an undesirable forum without the support of other less developed countries. As Jerome Reichman noted in the context of data exclusivity, "[t]o ignore the clear evolution of the text in favour of quasi-exclusive rights in regulatory data... would in effect amount to imposing unbargained-for trade concessions beyond what was agreed in TRIPS."51

The backdoor lawmaking process is equally damaging to the American people. Because clinical trial data are currently protected in the United

49. See Hosein, supra note 37, at 189–90; Samuelson, U.S. Digital Agenda, supra note 18, at 374.
50. For discussions of "forum shifting" or "regime shifting" strategies, see JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION 564–71 (2000); Laurence R. Helfer, Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking, 29 YALE J. INT’L L. 1 (2004); Yu, Currents and Crosscurrents, supra note 21, at 408–16.
51. Reichman, supra note 36, at 140.
States, the European Community, and many other countries, there is no guarantee that those who signed onto the free trade agreements would always embrace the U.S. model, as compared to, say, the EC model. In fact, those agreements at times have called for a higher level of protection than what is currently offered in the United States. Under those scenarios, the higher standards required by these agreements would eventually flow back to the United States to further affect the domestic legislative process.

Even if Congress were able to resist the temptation of introducing harmonizing legislation, these laws might still enter the country in the form of customary international law when a sufficient number of countries adopt the controversial provisions in their bilateral or regional agreements and expressly and consistently recognize these provisions as legal norms governing their state conduct. Although Congress may override these customary laws through legislation, the potential of their influence on the domestic legislative and judicial processes and their ability to shape international discussion are not to be ignored.

Moreover, the international agreements and the network of bilateral and regional agreements might affect the country's international obligations by "form[ing] the context for" the interpretation of treaties the United States has ratified. Because of the growing overlap between intellectual property and other policy arenas, like international trade, human rights, public health, biological diversity, food and agriculture, and information and communications, governments and international organizations have increasingly looked to these agreements as part of a larger overall framework. In United States—Section 110(5) of the US Copyright Act, for example, the WTO Dispute Settlement Panel noted the need "to seek contextual guidance... when developing interpretations that avoid conflicts within this overall framework, except where these treaties explicitly contain different obligations."

Finally, the United States' obligations under the free trade agreements

52. See Pugatch, supra note 25, at 102–10.
may make it difficult and costly for the country to reduce protection in the future if it later finds the new standards detrimental to the local economy. As Anupam Chander reminded us in the context of anti-circumvention legislation:

FTA [free trade agreements] obligations, it must be remembered, generally apply equally to the United States. Thus, it is possible that the United States could run afoul of its own FTAs. The FTAs are not term-limited, though they do permit withdrawal. Should we conclude in the future that the DMCA anti-circumvention rules are too constricting, we will have to renegotiate the FTA, flout the FTA, or conform to an uncongenial rule. Our FTA partners may often lack the internal economic incentive to seek to enforce the FTA's strict anti-circumvention terms (though they may take it as a license to reduce their own anti-circumvention excess), yet they may seek to enforce the FTA once partnered with interested multinational corporations engaged in rent-seeking.57

In sum, the second story is as disturbing as, if not more disturbing than, the first. Both stories are troubling because the pressing international needs for higher international standards would likely not have existed had the administration not "outsourced" the legislative process in the first place. Policy laundering and backdoor lawmaking are dangerous; they are harmful to both the United States and the larger international community.

III. POLICY RESPONSES

So, what should policymakers do, especially in light of the growing pressure on the creation of new intellectual property rights to protect data and the increasing tendency of powerful governments to engage in policy laundering and backdoor lawmaking to circumvent the domestic deliberative process? This Part proposes four sets of policy recommendations: (1) focus on the local incentive structures; (2) establish internal and external maximum limits; (3) explore the intersectionality between intellectual property and related areas; and (4) develop a balanced policy debate.

A. Focus on the Local Incentive Structures

First, policymakers need to avoid focusing narrowly on the protection of investment. As I mentioned elsewhere, an emerging "incentive-investment divide" exists between national and foreign intellectual property policies.58 While developed countries are eager to protect the overseas investment of their nationals, less developed countries overly focus on

attracting foreign investment to the point that they ignore the adverse impact of new intellectual property laws on the local incentive structures. Because many policymakers consider intellectual property protection a mere bargaining chip among the many trade negotiation items, the one-size-fits-all standards they obtained through the package deal often fail to meet local needs, national interests, technological capabilities, institutional capacities, and public health conditions.

To bridge this incentive-investment divide, policymakers need to decouple intellectual property and trade in their policy assessment and carefully evaluate the need for new intellectual property standards outside the trade context. Here, I am not advocating the decoupling of intellectual property and trade in the international intellectual property system. Countries should be free to decide whether they want to link intellectual property with trade in the bargaining process; such bargain linkage may indeed benefit countries if made under the right conditions. Instead, I am arguing for the decoupling of intellectual property and trade in an assessment of the need for new intellectual property standards. Because bargain linkage would likely distort the analysis by ignoring important concerns and side effects while inducing policymakers to ask the wrong questions, the decoupling of intellectual property and trade would provide a more accurate assessment of the need for these new standards.

If additional incentives are found to be necessary, policymakers need to explore whether there is an alternative strategy that is less restrictive to the country’s social, economic, cultural, and developmental goals, including access to essential medicines, educational materials, computer software, and information technology; the protection of traditional knowledge and cultural expressions; the promotion of biological diversity; and the preservation of culture and free expression. This proposal calls for a “less restrictive” standard, as compared to the “least restrictive” standard that is often used in U.S. constitutional law, because the latter would impose too heavy a burden on those seeking protection and would therefore significantly reduce incentives for innovation.

As far as policy options are concerned, there is a misguided tendency for policymakers in both developed and less developed countries to assume that the property rights model is the only model, or the best one, that is compliant with the TRIPs Agreement or other commitments under the international intellectual property regime. However, other models, such as compensatory liability rules, awards and prizes, and non-property-based
moral rights-like protection, may be equally compliant. These alternative models may also be more efficient and economically attractive, and perhaps even less harmful. In addition, commentators have discussed the potential of using government procurement, publicly-funded research grants, public-private partnerships, and open source and collaborative models to generate incentives. Without evaluating all of these alternatives, it is hard to determine whether the property rights model is as superior as its advocates have claimed.

As a final step, before intellectual property protection is strengthened or new sui generis rights are created, policymakers need to conduct impact studies to ensure a holistic evaluation of the ramifications of the proposed new standards. Those studies have been widely endorsed in the areas of human rights, public health, and biological diversity and within the WIPO Development Agenda. They become particularly important as intellectual property protection continues to affect other policy areas.

When I first proposed to decouple intellectual property and trade, a number of scholars suggested that the coupling of trade and additional policy areas, such as competition law, is likely to be more beneficial to less developed countries than the decoupling of intellectual property and trade. While I understand my colleagues' eagerness to tie the assessment to related policy areas and to undertake holistic policy analyses, I find this three-step process more protective of interests of less developed countries than a complex, gigantic one-step process that requires the consideration of


60. See, e.g., United Nations Convention on Biological Diversity art. 14(1)(a), opened for signature June 5, 1992, 1760 U.N.T.S. 143 (requiring contracting parties to “introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures”); U.N. Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He Is the Author (Article 15, Paragraph 1(c), of the Covenant), ¶ 35, U.N. Doc. E/C.12/GC/17 (Jan. 12, 2006) available at http://www.unhchr.ch/tbs/doc.nsf/898586b1dc7bc043c1256a450044f331/03902145edbe797c125711505f84e08/$FILE/G0640060.pdf (stating that “States parties should ... consider undertaking human rights impact assessments prior to the adoption and after a period of implementation of legislation for the protection of the moral and material interests resulting from one's scientific, literary or artistic productions”); WORLD HEALTH ORG., COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 10 (2006) (stating that “[h]ealth policies, as well as inter alia those addressing trade, the environment and commerce, should be equally subject to assessments as to their impact on the right to health”), available at http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf; WIPO Development Agenda Report, supra note 44, Annex I, ¶ 33–38 (outlining recommendations within the assessment, evaluation, and impact studies cluster).
all the related, yet incoherent, policies. The requirement of impact studies at this stage, hopefully, will provide the needed holistic analysis.

In undertaking such an analysis, the studies will provide important information that will help policymakers in less developed countries make informed judgments in the face of heavy lobbying by developed countries and their intellectual property industries. They will also ensure that the nationals and nongovernmental organizations of demandeur countries are aware of the development-related impact of the policies that their governments have been pushing abroad.

Even if policymakers decide to ignore adverse impact studies in their effort to strengthen intellectual property protection, the studies will serve as a warning about the potential danger to the public, relevant stakeholders, and nongovernmental organizations. They may also provide valuable information that can be used to design correction mechanisms should policymakers realize their missteps. If the impact studies are to be conducted by an international organization, such as the WTO or WIPO, or funded solely by developed countries, or at least those countries that push for stronger protection, the savings will further benefit less developed countries in the form of technical and legal assistance.

B. Establish Internal and External Maximum Limits

Second, policymakers need to pay close attention to the increased globalization of the intellectual property system. Although the focus on minimum standards makes good sense when a patchwork international system links the laws and customs of different countries together, the recent development of a global intellectual property system requires a greater emphasis on the development of maximum standards. Today, commentators have repeatedly criticized the one-size-fits-all system brought about by the TRIPs Agreement and WIPO-led harmonization efforts. While these commentators are correct in noting that one size does not fit all, a bigger problem is that the size is wrong. As James Boyle reminded us, the size of the current system is extra large—a size that is too large for less developed economies.61

More is not always better, and in the timeless words of Fritz Schumacher, "Man is small, and, therefore, small is beautiful."62 In the copyright context, authors need access to a richly endowed public domain to

participate in the creative process. The more protection society gives to a single author, the less access to the copyrighted works thousands, or even millions, of future authors (and many more consumers) will have. At some point, the lack of access to needed raw materials and the fear of copyright infringement lawsuits will prompt future authors to abandon their aspiring profession.

To strike the balance between access and protection in the intellectual property system, it is important to locate maximum limits to intellectual property protection. These limits can be found both internally and externally. Within the intellectual property system, it is important not just to strengthen the protection of public access rights but also to identify the smallest protectable unit (SPU). Identifying this SPU is likely to be very important, as protection continues to move upstream to cover data, gene fragments, and basic research tools.

Article 9(2) of the TRIPs Agreement makes it clear that copyright protection shall not extend to “ideas, procedures, methods of operation or mathematical concepts.” Article 10(2) also stipulates that the protection of compilations of data or other material “shall not extend to the data or material itself.” Although these provisions provide a good start, countries need to devote greater efforts to refine these limiting concepts and principles. What does an idea or a procedure mean? What is considered a method of operation? Is a mathematical concept the same as the one held by mathematicians and scientists?

In addition to internal limits, policymakers also need to locate external limits, which can be found in related regimes, such as those governing competition, human rights, and public health. Examples of these limits are the concept of “data protection misuse,” human rights-based compulsory licenses, and exceptions that are specially designed to respond to national

64. Several commentators have made similar observations. See, e.g., Justin Hughes, Size Matters (Or Should) in Copyright Law, 74 FORDHAM L. REV. 575, 620–35 (2005) (developing a framework for a “minimum size principle”); Pamela Samuelson, Randall Davis, Mitchell D. Kapor & J.H. Reichman, A Manifesto Concerning the Legal Protection of Computer Programs, 94 COLUM. L. REV. 2308, 2385 (1994) (“Features that consist of only one or a small number of elements are probably too small in relation to the software product as a whole to affect investment incentives. Hence, they should probably be exempt from regulation by a market-oriented legal regime.”).
65. TRIPs Agreement, supra note 23, art. 9(2).
66. Id. art. 10(2).
public health emergencies. With the increasing complexity of the international intellectual property regime, the need to understand the interactions between intellectual property rights and rights in other regimes can only become greater.

C. Explore the Intersectionality Between Intellectual Property and Related Areas

Third, policymakers need to pay greater attention to the interplay between the protection of data assets and other related issues, such as trade, agriculture, health, the environment, education, culture, competition, free speech, privacy, democracy, and the rule of law. In addition, they need to examine the potential adverse impact of such protection. They should also recognize that data responsibility goes hand in hand with data protection.

Data protection does not refer to the protection of intellectual property rights in data alone. In Europe, it refers to the protection of personal data or—as U.S. academics and policymakers would put it—individual privacy. Article 15(1) of the EC Data Protection Directive requires each EU member state to

grant the right to every person not to be subject to a decision which produces legal effects concerning him or significantly affects him and which is based solely on automated processing of data intended to evaluate certain personal aspects relating to him, such as his performance at work, creditworthiness, reliability, conduct, etc.

Article 8(1) also requires each member state to “prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.”

Making a similar wordplay, the abbreviation “IP” can stand for more than just intellectual property (or industrial profits!). It can also stand for individual privacy, information policy, international politics (and, of course, Internet protocol). It is important that policymakers look beyond just the protection of data as newly established intellectual property rights. After all, data protection can easily implicate education, culture, and

69. See Weissman, supra note 24, at 165–77.
70. See Jacqueline Lipton, Information Property: Rights and Responsibilities, 56 FLA. L. REV. 135, 165 (2004) (“If information property rights are here to stay, we should consider ways in which responsibilities of property ownership can be developed and imposed on right holders as part of our legal system.”).
science (in the case of database protection), as well as food and agriculture, biological diversity, public health, and human rights (in the case of data exclusivity).

In fact, the protection of data assets does not necessarily conflict with the goals of other policies—privacy, for example. The protection of data assets and that of personal data can easily coexist with each other. For instance, those who stand to benefit from stronger protection of data assets may also acquire more, and happier, customers if they are able to develop a stronger respect for personal data. The complementary nature of these two forms of protection makes good sense, because they involve similar interests, trade-offs, and challenges. As Jonathan Zittrain pointed out: “The elements of the information technology revolution that worry intellectual property holders carry parallel significance for individuals as personal data holders. After all, whether for profit or dignity, at the core each group desires the same end: control over information.”

Notwithstanding these similarities, there are significant differences between the two: their shifting roles and significantly different political economies. As Professor Zittrain continued:

There is . . . a fundamental shifting of roles. In the context of intellectual property, worry has come largely from well-organized corporate interests seeking protection against a death by a thousand cuts from “little guy” information pirates. With privacy, worry has come largely from individuals seeking protection against a whittling away of privacy by well-organized corporate interests.

Likewise, Lawrence Lessig noted:

The big difference between copyright and privacy . . . is the political economy that seeks a solution to each problem. With copyright, the interests threatened are powerful and well organized; with privacy, the interests threatened are diffuse and disorganized. With copyright, the values on the other side of protection (the commons, or the public domain) are neither compelling nor well understood. With privacy, the values on the other side of protection (security, the war against terrorism) are compelling and well understood. The result of these differences, as any political theorist would then predict, is that over the past ten years, while we’ve seen a lot of legislative and technical changes to solve the problems facing copyright, we’ve seen very few that would solve the problems of privacy.

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74. Id.
D. Develop a Balanced Policy Debate

Finally, policymakers need to understand and recognize the inherent challenge in finding the appropriate balance between protection and access in intellectual property and information policies. While rights holders and maximalists tend to focus on the absolute nature of property—the right to exclude, in particular—they ignore the many important limitations, safeguards, and obligations in the real property system, such as adverse possessions; easements; servitudes; irrevocable licenses; fire and building codes; zoning ordinances; the rule against perpetuities; and the eminent domain, waste, nuisance, and public trust doctrines.\textsuperscript{76}

Similarly, cyber-libertarians and the minimalists tend to emphasize the hackers' motto, "[i]nformation wants to be free," without even mentioning its diametrically opposite twin, "[i]nformation also wants to be expensive."\textsuperscript{77} This latter rallying cry (or, shall we say, the capitalists' motto) follows immediately from the hackers' motto in Stewart Brand's oft-quoted book, \textit{The Media Lab}. As Brand explained:

\begin{quote}
Information wants to be free because it has become so cheap to distribute, copy, and recombine—to too cheap to meter. It wants to be expensive because it can be immeasurably valuable to the recipient. That tension will not go away. It leads to endless wrenching debate about price, copyright, "intellectual property," and the moral rightness of casual distribution, because each round of new devices makes the tension worse, not better.\textsuperscript{78}
\end{quote}

The two phrases, "information wants to be free" and "information also wants to be expensive," therefore, go hand in hand with each other. Their tension, as Brand put it, "will not go away" even with a more advanced state of technology. In fact, as Jack Goldsmith and Tim Wu recently wrote in response to the hackers' motto, "information does not . . . want to be free. It wants to be labeled, organized, and filtered so it can be discovered, cross-referenced, and consumed."\textsuperscript{79} Writing from a very different perspective, Marci Hamilton also commented: "Information 'wants' nothing. Like technology, it is nothing more than a tool that can be used by humans for..."
It is high time that the two sides in the information policy debate engage each other in a continuous dialogue. Information does not want to be either free or expensive; it wants to be both. More than that, it wants to be exchanged—exchanged among the different stakeholders! The information policy debate is not just about the maximalists or the minimalists, copyright holders or cyber-libertarians, the pro-IP camp or the anti-IP camp. The debate is far more complex, dynamic, nuanced, and multifaceted than what a bipolar debate suggests. The positions taken by the various stakeholders vary from time to time and from market to market. Thus, stakeholders need to start exploring the common grounds they share while working to reconcile their differences. In doing so, they may be able to develop a mutually beneficial information policy.

IV. CONCLUSION: A CAUTIONARY NOTE

To conclude this article, it is instructive to return to the first story of data protection. Shortly before the presentation of this article in February 2006, the European Commission released its inaugural report on the EC Database Directive. Backed by empirical data, this report is both important and insightful; it represents the Commission’s first attempt to evaluate the ten-year-old directive. More importantly, within the context of the discussion here, the report’s findings and recommendations provide an instructive lesson on the growing efforts to establish new intellectual property rights to protect data.

The report found that the Directive not only failed to benefit the European Community much, but also might have harmed the European publishing and database industries. As the report stated, there were 4085 EU-based database “entries” in 2001, the time when most of the first fifteen EU member states had implemented the Directive into national laws, but the number of “entries” declined three years later by close to a quarter to


81. See Yu, Anticircumvention and Anti-anticircumvention, supra note 48, at 31.

Although the Directive aimed to create a level-playing field between U.S. and European database industries, "the European share decreased from 33% to 24% [between 2002 and 2004] while the US share increased from 62% to 72%. The ratio of European/US database production, which was nearly 1:2 in 1996, has become 1:3 in 2004." 84

Notwithstanding these disappointing results, the Commission offered three justifications for the retention of the Directive. 85 First, the Commission "has received strong representations from the European publishing industry that 'sui generis' protection is crucial to the continued success of their activities." 86 (Surprise! Surprise!) As the Commission explicitly acknowledged, "the attachment to the new right is a political reality that seems very true for Europe." 87 Second, a repeal of the sui generis right "would require withdrawing, or 'reverse', legislation and that might reopen the original debate on the appropriate standard of 'originality.'" 88 Similarly, a reformulation of the scope of the right would "require the Community legislator to revisit the compromise underlying the two-tier protection introduced by the Directive." 89 Third, "[r]emoving the 'sui generis' right and thereby allowing Member States to revert to prior forms of legal protection for all forms of 'non-original' databases that do not meet the threshold of 'originality', might be more costly than keeping it in place." 90

Although the Commission's analysis is pragmatic, one could only imagine how much better the European publishing and database industries would have been had the Directive not been introduced in the first place. 91 After reading this report, many Americans may be thankful that Congress did not hastily adopt sui generis database protection legislation in response

83. EUROPEAN COMMISSION REPORT, supra note 82, at 24.
84. Id. at 22.
85. In addition to maintaining the status quo, the Commission provided three other policy options: (1) repeal the Directive, (2) withdraw the sui generis right, and (3) amend the sui generis provisions. See id. at 25–27 (discussing the policy options).
86. Id. at 24.
87. Id. at 25.
88. Id. at 6.
89. Id. These two tiers refer to "a harmonised level of protection of 'original' databases under copyright and the introduction of a new 'sui generis' right to protect investments in databases." Id. at 10 (citations omitted).
90. Id. at 27.
91. But see Matthias Leistner, The Protection of Databases, in RESEARCH HANDBOOK ON THE FUTURE OF EU COPYRIGHT 427, 449 (Estelle Derclaye ed., 2009). Leistner points out that the Commission's analysis completely ignores the fact that in the first years after the enactment of the Database Directive the European database industry had indeed increased substantially and that the crucial decrease of database production from 2001 to 2004 might indeed rather be linked to the general crisis of the information industries in that period or other incidental factors.
to the EC Database Directive. They may also be grateful to those who worked hard to lobby against the adoption of the draft WIPO Database Treaty, which, if adopted, would no doubt sneak back into the country as laws made through the backdoor.

As a larger part of society migrates to the knowledge-based economy, information will only become even more valuable. As a result, data protection will become more important, and those who stand to benefit from such protection are likely to demand even stronger and more expansive intellectual property rights in data using novel, and often unproven, legal theories. While policymakers cannot ignore the need to protect the investment of those who produce, collect, verify, present, and handle data, they also need to think carefully about the original design of the intellectual property system, the scope of its protection, the collateral damage of overprotection (or underprotection), and the importance of the balance between access and protection.

The decision to introduce data protection laws needs to be guided not by faith or speculation, but by empirical data.92 After all, as the European Commission’s report has shown, laws can be politically entrenched, and amending these laws can be difficult even if they have proven to be ineffective or harmful.

92. See Yu, Anticircumvention and Anti-anticircumvention, supra note 48, at 60; Boyle, Two Database Cheers for the EU, supra note 82. This problem is actually more complicated. It is not just about the lack of empirical data; it also concerns whether the research is funded by non-self-interested parties.