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UNCTAD-ICTSD Dialogue on *Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning*
Bellagio, 29 November – 3 December 2004

Rights in Basic Information: A general perspective

DRAFT

Summary

This note attempts to map cross-cutting developments in the contemporary law of intellectual property rights that give rise to a risk that as intellectual property rights become more far-reaching in their scope and persistent in their application, they may increasingly frustrate the end they were originally intended to promote: innovation to benefit the public at large. Powerful economic and political pressures toward the increasing commodification of information are at work at both the national and international levels in today=s legal environment. Among the many potential adverse consequences is the enclosure of basic information essential to continued cultural production. As basic inputs to the innovation process are privatized, it becomes increasingly likely that legal rights will be misused in efforts to intentionally impede competition. It is just as likely, however, that the generation of new knowledge will be chilled by the commercial rationing of existing stores of information.

In the pages that follow, four trends are briefly explored:

- The experiment with intellectual property rights in non-original databases, in the European Union and (potentially) beyond;
- The movement toward data exclusivity rules relating to test information on pharmaceuticals and agricultural chemicals;
- Patent protection for basic research tools (including equipment, reagents, and biological compounds); and
- Anti-circumvention provisions that create an additional layer of legal protection for copyrighted works in digital formats.

The instances that constitute each trend operate, in various ways, to impede access to basic information. Each trend has been a response to the demands of rights holders, with little or no critical attention from policy makers to likely consequences for the innovation process. The resulting schemes of legal protection tend to be relatively absolute and unqualified, rather than (as in the case of traditional IPRs) porous and conditional. Although each trend has a different history, they tend to converge in the new space for norm-setting that has been created by the convergence of intellectual property and international trade. Thus, they are reinforced by provisions in bilateral, regional and (in some cases) multilateral agreements. Of particular concern are the terms of Free Trade Agreements recently negotiated (or under negotiation) between the United States and various trading partners.

Various measures should be considered to counter these trends and the larger

development they help to constitute. In particular, concerned governments and NGOs should

- Resist, where possible, the proliferation of IPRs that threaten access to basic information;
- Develop model provisions for meaningful exceptions and limitations into those international agreements and domestic laws that reflect the trends described above; and
- Monitor closely the effects of the new wave of IPRs on the innovation process.

Introduction: a fundamental tension

A high-level overview of intellectual property law today suggests that a fundamental tension is emerging between the generally-understood purpose of IPR regimes in general, on the one hand, and prominent trends in national and international law regimes, on the other. Succinctly put, this tension is between the public purposes of intellectual property and the tendency toward the commodification (and attendant rationing) of more and more forms of basic information. Although this emerging conflict is observable when particular domains of intellectual property are considered in isolation, it is even more noticeable B and of even greater concern B when these sectoral developments are compared and correlated with one another. It is the objective of this paper to map the present situation, to sketch some of its consequences, and to suggest ways in which it could be relieved through various policy initiatives.

There is a general theoretical and political consensus that although IPRs may serve other functions (such as fulfilling the economic and moral interests of individual contributors to general culture[1]), their primary and overarching purpose is a public one: to promote economic and social progress by promoting innovation.[2] Traditionally, this idea about the purposes of IPRs has been expressed through the metaphor of a social bargain between the individual who offers the fruits of mental labor and the collective that accepts and grants in return a limited period of conditional legal protection. Related discourses include that of incentives: It has been widely assumed, although not empirically demonstrated, that there is a positive relationship between the existence of reasonable levels of IPR protection and the willingness of individuals to engage in productive intellectual work leading to valuable innovation.

[1] Throughout this discussion, the term "culture" will be used in its broadest sense, to refer not only to the arts and letters, but also to other domains of intellectual activity, including science and technology.

[2] For a general discussion of the theme of public interest in the context of copyright law, *see* Gillian Davies, Copyright and the Public Interest (2d ed. 2002).

Implicit in this account of IPR=s is the proposition that for the enterprise of which IPRs are a part to succeed, it is crucial that rights in information be permeable rather than absolute, and that some fundamental items of information should be beyond the reach of legal protection. This proposition was made explicit (with respect to copyright) by the U.S. Supreme Court in 1991:

> The primary objective of copyright is not to reward the labor of authors, but "to promote the Progress of Science and useful Arts."... To this end, copyright assures authors the right to their original expression, but encourages others to build freely upon the ideas and information conveyed by a work.[3]

This is true whether the ideas and information in question are generally well-known or have been discovered through researchers' efforts. If IPRs restrict the flow of such ideas and information, the likely will result will be to chill rather than to encourage innovation. Thus, in all branches of intellectual property law, there traditionally have been threshold requirement for protection (originality, novelty, etc.) that protect basic information from monopolization; these, in turn, are backed up and reinforced by various exceptions and limitations on protection designed to assure information access.

Consistently with the view of their purposes described, IPRs (whether copyright, patent or various *sui generis* regimes) historically have confined their subject matter to the outcomes of knowledge-generating processes. Now, increasingly, we see modifications in the law of IPRs which have the effect of extending private control to the basic or essential tools by which knowledge is generated which are themselves the building blocks of future cultural production. Examples (to be considered at somewhat greater length below) include trends toward protection of non-original databases, patenting of basic research techniques and findings, data exclusivity requirements with respect to pharmaceuticals and agricultural chemicals, and legal reinforcement of digital rights management technology.

At the outset, it is fair to ask whether anxiety over this development may be overstated. Obviously, to the extent that IPRs are employed abusively, to deny some group of potential innovators access to basic tools, or to suppress competition generally, the results could be devastating.[4] But this is not the only scenario with which we should be concerned. It is equally and perhaps even more likely that these new forms of legal control will be used not to prevent information access altogether but to regulate in ways that maximize the economic rents derived from its disclosure. In other words, the legal

[3] Feist Publications v. Rural Tel. Serv. Co., 499 U.S. 340, 349-50 (1991).

[4] This risk is one aspect of "information feudalism", the increasing risks of which have been so persuasively suggested by leading critics of globalized IPR norms. *See* Peter Drahos with John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy (2002).

developments with which this paper is concerned provide the legal infrastructure for a scheme in which access to basic information would be available primarily through a pay-per-use model. Accordingly, traditional ways of accessing basic data (either from free sources or through the one-time purchase of information compendia) no longer would be widely available. In their place, market access to data would be efficiently available on an as-needed basis.

This possibility should be a matter of particular concern in itself. Historically, the wide accessibility of basic information most of it beyond the reach of IPRs has served the general cause of innovation precisely because it has supported uses of that information that are profligate, redundant and sometimes even non-productive. Opportunities to pursue inspiration, even when they lead down blind alleys, or to mine large quantities of information for patterns and significances that may not appear when smaller information sets are considered, has been essential in the history of innovation. The importance of legal norms that support such inefficient information use is intimately related to the Newtonian aphorism. If I have seen farther, it is by standing on the shoulders of giants a familiar cliche in discussions of innovation policy.[5] It is obviously true that innovation comes from somewhere rather than from nowhere; that, in other words, Romantic concepts of cultural production (focusing the heroic struggles of individual authors and inventors) fundamentally and dangerously misstate the nature of the innovation process.[6] But the OTSOG trope also implies an important cautionary: Innovators do not know, until after the fact, which bodies of prior knowledge will be productive ones on which to base future work. Only by preserving the ability to hop, more or less gracefully, from the shoulders of one giant to those of another can we assure that innovation will have a future as impressive as its distinguished past.

Database protection

As has already been indicated, conventional IPRs (especially copyright) have long provided a shield against commodification of the factual contents of information products, as such. Although there have been some temporary breaches of this barrier (in the form of a so-called "sweat of the brow" approach to copyrightability analysis, these have been transitory episodes; thus, U.S. flirtation with this approach came to an end, for example, with the previously-referenced *Feist* decision in 1991. Since that time, however, there has been increasing militation, primarily on the part of a few multi-national enterprises with large investments in electronic databases, collections of scientific and technical journals and related information products, for the creation of a new free-standing form of

[5] Familiar enough, in fact, to have merited an entire volume devoted to its pedigree and geneology: Robert K. Merton, On the Shoulders of Giants (1965).

[6] *See* Peter Jaszi & Martha Woodmansee, The Construction of Authorship: Textual Appropriation in Law and Literature (1994).

intellectual property i.e. *sui generis* protection for non-original databases.

Although it met with considerable (and continuing) resistance in the United States, this initiative was more hospitably received in Europe, where in 1996 the European Union adopted its Directive on the legal protection of databases, which provides in part for a new right against the unauthorized extraction and/or reutilisation of substantial parts (evaluated qualitatively or quantitatively) of databases reflecting a substantial investment on the part of the compiler.[7] This new database right has provoked enormous concern, both within Europe and beyond it; although it is too soon to say with any certainty how much documentable harm this privatization of basic knowledge will do to the research enterprise, it is hard to see how the costs to innovation (although perhaps difficult to measure) can be other than significant. Nor is there any indication that Europe is drawing back significantly from this dubious policy.

Recently, the European Court of Justice decided several cases involving the interpretation of the database right, and each of which involved an organizer of sporting events sought database right protection for sporting event against providers of off-site betting services. The ECJ, however, refused to find 'substantial investment' as required by the Database Directive. An official press release of the Court put it this way:

> Although a football fixture list may be considered to be a database within the meaning of the directive, finding and collecting the data which make up such a list do not require any particular effort on the part of the professional leagues. Those activities are indivisibly linked to the creation of those data, in which the leagues participate directly as those responsible for the organisation of football league fixtures. Obtaining the contents of a football fixture list thus does not require any investment independent of that required for the creation of the data contained in that list.

Certainly, the effect of this decision is to limit the applicability of the new data right where one form of information compilation (those which result incidentally from the performance of a different function) is concerned. But protection for most kinds of compilations which have been a special focus of policy concern (including observational data and collections of scientific and technical articles) are likely to be unaffected by the decision.

In some respects, the first major encounter between the ECJ and the database right has served to reinforce preexisting doubts about the wisdom of privatizing basic data. In its judgment in one of the recent cases, the Court goes on to say:

> The terms "extraction" and "re-utilisation"... must be interpreted as

[7] Directive 96/9/EC (OJ 1996 L 77/20). For a comprehensive discussion of the Directive and legislation implementing it in various European countries, *see* Institute for Information Law, University of Amsterdam, "The Database Right File", http://www.ivir.nl/files/database/.

> referring to any unauthorized act of appropriation and distribution to the public of the whole or a part of the contents of a database. Those terms to do imply direct access to the database concerned.... The fact that the contents of a database were made accessible to the public by its maker... does not affect the right of the maker to prevent acts of extraction and/or re-utilisation.[8]

In other words, the proprietor of a database right now has the unquestioned legal authority not only to condition access to the contents of such a collection, but to ration and meter its use after such access has occurred a right that is foundational to pay-per-use information commerce.

The database right has not been widely imitated outside of Europe. The United States, Canada, China, Japan and other states have considered but so far resisted its adoption. However, there remains a significant risk that, in the future, database protection may be pressed as a candidate for recognition as an international legal norm within the framework of IPR/international trade law. The countries of Europe, with early support from the United States, attempted to achieve this result at the December 1996 WIPO Diplomatic Convention, although they fell short of their objective.[9] Although there has been no subsequent action, the protection of non-original databases remains on the agenda of the WIPO Standing Committee on Copyright and Related Rights.[10]

To date, the issue of database protection has not figured in other international negotiations. The issue is, for obvious reasons, absent from the texts of recently concluded free trade agreements (FTAs) between the United States and various trading partners. Perhaps significantly, however, Art. 2.1 of the draft text of the Subsection B.2.c. of the draft Free Trade Area of the Americas Agreement chapter on Intellectual Property provides a negative definition of the subject-matter of copyright which would appear to permit the

[8] British Horseracing Board Ltd. v. William Hill Organization Ltd. C-203/02, Nov. 9, 2004).

[9] *See* Jörg Reinbothe & Silke von Lewinski, The WIPO Treaties 1996: Commentary and Legal Analysis 486-88 (2002). Reinbothe and von Lewinski repeat the conventional account of the fate of the proposed database treaty that it was shelved when the Diplomatic Convention ran out of time to consider it, although they also acknowledge that the failure of the United States to follow through on its early support of the treaty was also inimical to its changes of success. In fact, the story was even more complicated, and featured prominently a number of less developed countries expressing significant skepticism about the desirability of a new international norm conferring a high level of new protection on information products that are characteristically associated with the most developed nations.

[10] *See* the Report on the Eleventh Session, June 7-9, 2004, SCCR/11/4 (Sept. 16, 2004), at paras. 9-23.

extension of protection under that rubric to many forms of factual information.[11] Of even more immediate concern is the possibility that protection for the contents of non-original databases may find its way onto the agenda for the eventual revision on the World Trade Organization's TRIPS agreement.

Data exclusivity

There is considerable debate over the proper classification of this important new category of IPRs, which are being strongly advocated for inclusion in international agreements by the international trade bureaucracy of the United States. In some accounts, data exclusivity rules are described as an outgrowth of trade secrecy. If so, however, they incorporate a significant departure from the traditional principles of this body of law: whereas, historically, trade secrecy and disclosure were inimical, data exclusivity rules enable the disclosure of information for certain purposes (including regulatory approval) while a umbrella of legal protection is preserved to prevent its use by third parties. But if data exclusivity is a new form of intellectual property, then it is a very peculiar one, for it does not require any level of inventive or creative activity on the part of the person or entity enjoying legal protection.

One things is clear: The provisions for data exclusivity (with respect to both pharmaceuticals and agricultural chemicals) contained in various FTAs go well beyond anything requirement under the TRIPS Agreement, where countries only must protect "undisclosed" pharmaceutical test data from "unfair commercial use." On its face, this TRIPS provision is intended only to cover the literal misappropriation of test data from (for example) regulatory agency files. Moreover, TRIPS parties have substantial discretion to decide what kinds of protection they provide and are not obligated to exclude other parties from using the data. By contrast, under most of the recent FTAs to which the U.S. is a party

- Countries are required to provide five years of data protection from the moment any pharmaceutical product was given regulatory approval in their country, and 10 years from the time of approval of any agricultural product. This amounts to an effective five - or 10-year bar on creation of generic versions of these products, whether pursuant to compulsory licenses or in cases where full patent protection may not be available for them.

- In general, these restrictions also apply where the product in

[11] *See* the Third Draft Agreement, FTAA.TNC/w/133/Rev.3 (November 21, 2003). The implications of Art. 2.1 are discussed in "FTAA: IPJustice Whitepaper" at http://www.ipjustice.org/FTAA/whitepaper.shtml.

> question has granted regulatory approval elsewhere in the world, even though it may not have yet have been marketed in the country where data exclusivity is claimed. Tacking of protection periods appears to be a possibility (for example, five years from the date of a drug's approval for marketing outside the target country followed by another five years following its eventual approval in that country).[12]

Self-evidently, data exclusivity rules are a threat to achieving reasonable levels of public access to affordable versions of essential medicines and agricultural products. But they are something more as well: a threat to the research process itself. Increasingly, the process of creating functional generic equivalents (in the form of follow-on proteins) for existing biotechnology agents will require that potential competitors have reasonable access to confidential data filed by the original developer with regulatory authorities. These are, of course, precisely the sorts of filings to which data exclusivity applies. Thus, perpetuation and intensification of existing regimes of data exclusivity are likely to delay or frustrate this important dimension of applied research.[13]

Patents on basic research tool and inputs[14]

This is an issue of a somewhat different character from those just discussed, each of which involve the creation of what are effectively new IPRs to enclose information that was formerly available to innovators at large. Here, by contrast, the focus is on the development (particularly in the United States) of traditional patent law in ways that can dramatically circumscribe the future course of innovation by making research tools and other necessary research inputs subject to patent licensing. Although the rest of the world still may lag somewhat behind the U.S. in the patent protection of research tools and related subject-matter, there is room for concern that as standards of patent protection increase under the pressure of international agreements, the result may be further restrictions on access to the equipment, supplies and other materials required to perform basic research.

[12] This analysis is drawn from Robert Weissman, "Dying for Drugs: How CAFTA Will Undermine Access to Essential Medicines", 25 The Multinational Monitor (No. 4) (April 2004), at http://multinationalmonitor.org/mm2004/04012004/april04corp2.html.

[13] Meir Pugatch, "Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access", Third Bellagio Dialogue on Development and Intellectual Property (October 2004), at 13-14.

[14] I am grateful to my colleague Joshua Sarnoff for helping me to formulate this section; all errors are my own; a not insignificant disclaimer from a copyright specialist daring to discuss patent law issues!

The problem is especially acute not only because patents based on a disclosed non-research related utility can be applied to bar research uses, but also because patents are now routinely allowed for compositions and machines having a disclosed utility only for research.[15] As a result, the range of patentable subject-matter that potentially falls under the heading of "research tools" is impressive, including equipment (the microscope and its analogues), chemical reagents, cell lines, specialized animal species (such as the Harvard onco-mouse), DNA and other protein sequences, and more. Indeed, almost anything that is patented and that can be used in research is properly considered a "research tool". Two examples of patents that could have been but were not impediments to innovation in research, because they were made available through low-cost, widespread, non-exclusive licenses (without reach-through royalties on the products of research) are those on the Cohen-Boyer method vector-based cloning and the PCR (polymerase chain reaction) enzyme protein that, which reproduces precisely and on a large scale particular DNA sequences.

An early discussion of this dilemma, as it is manifested in the critical field of molecular biology, captured the difficulty surrounding it:

> Participants from the three sectors academia, industry, and government made it clear that they are not opposed to patenting of research tools. By and large, they expressed the view that broad access to research tools is important for the continued vigor of the research enterprise.... At the same time, the specter of patents that could stifle research permeated many of the discussions.[16]

The key, then, may not be to bar the patenting of research tools as such (a goal that would be both politically and conceptually difficulty to achieve), but to assure reasonable that reasonable levels of access to such tools are available, through codified research exemptions, compulsory licenses or other mechanisms. Here, however, FTAs may stand in the way. Thus, for example, Art. 16.7.6 of the U.S.-Singapore FTA (like equivalent provisions of other agreements) restricts the parties' ability to grant compulsory licenses to

[15] This approach to patentability is demonstrated in Madey v. Duke Univ., 307 F.3d 1351(Fed. Cir., 2002) (a decision that also limits severely the scope of the non-statutory "research exemption" in U.S. law). As a result of this approach, reagents (having no discernible use to the original inventor), ESTs and SNPs, DNA and protein sequences, and other inventions having principal use for research are patentable. Notably, provisions in recent international agreements may be read to compel a similar approach to the patentability of research tools in those jurisdictions. *See, e.g.,* TRIPS Art. 27.1 and fn. 5, U.S.-Singapore Free Trade Agreement 16.7.1.

[16] National Research Council, Intellectual Property Rights and Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, February 15-16, 1996 (1997)

situations where they are needed to counteract anti-trust violations, or to deal with national emergencies and other situations of extreme urgency, or for public non-commercial purposes.[17] Literally understood, such TRIPS plus provisions would appear to limit the ability of states bound by such agreements to create significant research exemptions or other otherwise restrict the scope of patents in research tools to benefit the enterprise of innovation.

Digital rights management and anti-circumvention

Traditional copyright law incorporates a number of mechanisms designed to harmonize the means of private intellectual property protection with the goal of public benefit. Broadly speaking, these are limiting or exceptional doctrines which, though they are referred to by different terms in different national law systems, all combine to play the same role: to assure the availability of reasonable levels of access, with or without license, to protected works. The list of such mechanisms includes copyright term limitation, the distinction between a work's protected expression and its unprotected content (sometimes termed its idea), the exhaustion doctrine, specific educational and cultural exemptions, compulsory licensing (for purposes such as signal redistribution or the making of sound recordings), and catchall or residual access-oriented doctrines such as "fair use" or "fair dealing" (depending on local copyright terminology). Although some of these doctrines (e.g. term limitation) are threatened in the modern copyright environment, and recent international agreements (i.e Article 13 of TRIPS) make some effort to check or control the growth of others, the dynamic balance they represent has survived more or less intact into our era. Broadly speaking, we may say that this array of balancing mechanisms exists to assure that a legal regime intended to promote cultural progress by providing incentives to authors will not be used to monopolize materials necessary to assure reasonable levels of follow-on creativity. The need for such balancing mechanisms became increasingly acute as the protections afforded by copyright became more intense and the range of subject-matter to which copyright applied became broader. In particular, the decision to protect computer programs in machine-readable format under copyright generated new urgency around the goal of ensuing the access required to enable subsequent generations of innovation in software engineering.[18]

To a significant extent, the balance just described has been founded on the existence of a relatively stable distinction between public (typically commercial and consumptive) uses of copyrighted works, as to which copyright owners have an intense and legitimate interest in exercising strict control, and private (typically productive and non-commercial) ones as to which copyright owners have had fewer reasonable grounds of

[17] United States-Singapore Free Trade Agreement, Art. 16.7.6.

[18] *See, e.g.*, Sega Enterprises Ltd. v. Accolade, Inc., 977 F.2d 1510 (9th Cir. 1993) (applying "fair use" to decompilation in connection with reserve engineering of software).

practical concern. In the electronically networked communications environment, the public/private distinction has come to been as a less and less reliable guide to policy choice, just as the anxieties of copyright owners (especially companies with large inventories of protected material) have become more acute.

In the last decade, one of copyright owners= most significant responses to the uncertainty of the new communications environment has been to develop digital rights management ("DRM") tools to control access and use of texts, images and sounds in electronic formats, with the aim of enabling new, and newly secure, forms of electronic information commerce on a "pay-per-use" model. Inevitably, however, the risk that such DRMs may be hacked has loomed large in the concerns of copyright owners. From this concern has grown domestic and international political pressure for the creation of a new species of intellectual property protection: the so-called anti-circumvention provisions that are the centerpiece of the 1998 Digital Millennium Copyright Act (DMCA) in the United States[19] and the 2001 European Union Directive on the harmonization of certain aspects of copyright and related rights in the information society,[20] as well as the two WIPO treaties concluded in 1996.[21] This new family of legal norms is not a development of copyright law, though it is superimposed on copyright; rather, it provides for new rights, new remedies and crucially a new and exclusive set exceptions; copyright's traditional limiting doctrines do not apply in this evolving legal space.

Although the WIPO treaties allow parties a good deal of latitude in choosing how to implement the general obligation to provide legal rights and remedies against the unauthorized evasion of DRMs, the various FTAs to which the United States is a party are far more specific: In effect, they mandate that parties follow the specific approach to anti-circumvention (or, as it is sometimes called, "paracopyright") legislation adopted by the U.S. This approach includes not only prohibitions against the circumvention of DTMs as such, but also against the making available of equipment or services that can be employed for purposes of circumvention. As a result, even when limited exceptions to the bar on circumvention activities may be available, they are likely to be unavailing since most information practitioners will not have the capability to take advantage of these access privileges without technological support or assistance.

One characteristic of the U.S. legislation that is becoming the international pattern in this area is that it makes few concessions to the access interests of follow-on creators and

[19] 17 U.S.C. Secs. 1201 et seq. For a discussion of the DMCA in context, *see* Micheal J. Madison, "Rights of Access and the Shape of the Internet", 44 B.C. L. Rev 433 (2003).

[20] Directive 2001/29/EC (OJ 2001 L 167/10)

[21] Anti-circumvention is treated in Art. 11 of the WIPO Copyright Treaty and Article 18 of the WIPO Performances and Phonograms Treaty. *See* Reinbothe and von Lewinski, *supra* note 9, at 135-47, 409-414.

innovators. This problem already is acute in fields (such as software development and encryption research) where basic information is incorporated in copyright works that are made available only in digital formats.[22] It will become increasingly significant in other fields (including scholarship, criticism and education) as literary texts and (especially) audiovisual works migrate to exclusive digital formats. The problem is exacerbated by the fact that, by design, anti-circumvention regimes are insensitive to the distinction between the protected and unprotected elements of copyright works. In other words, when a digital rights management technology is deployed to safeguard a work in its entirety, the general rules is that this technology fence cannot be breached even for the purpose of gaining access to what is otherwise public domain information. Again, this problem is currently sub-critical in fields other that software-related research, but is likely to become increasingly severe as the amount of "born digital" and "digital only" content increases.

It should be incumbent on states not already committed to U.S-style anti-circumvention legislation and interested NGOs to intervene in the future direction of legal protection for DRMs. The first such intervention occurred in Geneva in 1996, when various stakeholders successfully lobbied the WIPO Diplomatic Convention to adopt anti-circumvention provisions that would allow a reasonable latitude of choice in national law implementation.[23] That coalition now should be reconstituted to deal with the current efforts of the U.S. to impose a "one size fits all" approach to this important issue. To a certain extent, legislation of this kind may be an inevitable part of future IPRs. But the specific content of such legislation is an appropriate site for struggle within the general contest over the shape of the international information order.

Conclusion: first steps toward recovering balance

As threatening to the future of innovation and the cause of information justice the preceding parade of horribles may be, there are immediate actions that states, NGOs and international agencies concerned with innovation policy can take. Although most of these steps respond primarily to one or another of the particular expansionist tendencies in intellectual property law described above, some of them have cross-cutting relevance as well. An example is the move toward accessible open access journals for the presentation of scientific and technical information (both data and analyses). This international trend, which received a significant impetus from the Budapest Initiative of 2001,[24] foresees a world-wide movement by individual scholars (and their professional associations) away from publication in the proprietary journals maintained by the corporate information

[22] *See* Joseph P. Liu, The DMCA and the Regulation of Scientific Research, 18 Berkeley Tech. L.J. 501 (2003)

[23] *See* Pamela Samuelson, "The U.S. Digital Agenda at WIPO", 37 Va. J. Int'l L. 369 (1997).

[24] *See* Budapest Open Access Initiative: http://www.soros.org/openaccess/index.shtml.

conglomerates (who are not coincidentally the strongest advocates of new IPRs for databases and other compiled information products) in favor of new electronic publications and repositories such as (to cite only one example), the Public Library of Science.[25] This development involves nothing more or less than the decommodification of entire bodies of useful knowledge (at least going forward).[26]

A closely related initiative would be resistance, at the national and international levels, to further codification of *sui generis* data protection. Although, as outlined above, this battle has already been lost in Europe, it still is being waged in much of the rest of the world; in fact, in some countries alliances of public and private organizations have been effective in blocking the introduction of such measures.[27] It will be equally critical to assure that this item, which remains technically part of the WIPO intellectual property agenda, does not surface at any future Diplomatic Conference convened by that organization, nor as part the agenda for the next revision of TRIPS within the WTO. This is a goal that should be within the reach of states and NGOs concerned about the possibility dampening effect of database protection on the practice of innovation, especially in less development countries. But to assure that it is achieved, it is critical that the point that the database protection project is at best radically premature and at worst wholly misguided should be made in international fora on every possible occasion.

On the issue of data exclusivity, it is crucial to develop the technical legal argument that this new form of IPR is not required under any *existing* multilateral norm and to make efforts to resist its inclusion in new bilateral, regional and (especially) multilateral agreements. Immediate steps also should be taken to draft model alternative provisions on data exclusivity that can be proposed by less developed countries for inclusion in FTAs and regional trade agreements with the United States and Europe. In addition, it will be important to consider ways in which during future rounds of multilateral trade/IPR negotiations provisions may be devised to take better account of the access interests of innovators in confidential test data. These interests are likely to become increasingly acute, with the passage of time, as new efforts to create competitive equivalents to biotechnology agents become a more prominent aspect of research in pharmaceutical and agricultural fields.

Where patents for research tools and other essential research inputs are concerned, it is critical to put emphasis on the need to develop recognition at a global level for provisions designed to assure continued access for purposes of follow-on innovation. To

[25] *See* Public Library of Science: http://www.plos.org.

[26] *See* Budpaest Open Access Initiative: http://www.earlham.edu/~peters/fos/boaifaq.htm

[27] Declan McCullagh, "Anti-P2P bill may slip past legislative rush", CNET News.com**,** Nov, 18, 2004 (quoting Marybeth Peters, the U.S. register of copyrights: "I don't think you'll ever see database protection.")

the extent permitted under international agreements, states should attempt to avoid interpreting provisions of domestic patent law as providing comprehensive protection against research uses of patented inventions. In particular, there is an urgent need to develop and disseminate models for exemptions and compulsory licenses designed to facilitate research use. Governmental and institutional funders of research also can help assure future access to research tools through provisions in grants and contracts that require recipients to provide non-exclusive licenses on reasonable terms for the research use of inventions devised with their financial support.

On the issue of digital rights management and related anti-circumvention legislation, a multi-pronged response is urgently required. In particular, those who are concerned about the restrictive potential of "paracopyright" norms should:

- Support research and development around "smart DRM" technologies, which have the designed-in capability to recognize and accommodate traditional exceptions to copyright protection;[28]

- Campaign actively for the recognition of exceptions and limitations to anti-circumvention provisions that are appropriate to the needs and circumstances of countries actually implementing them; and
- Advocate for the inclusion in international agreements of so-called "encoding rules" (i.e. restrictions on the use of DRMs) applicable to digital objects which include high proportions of basic information to which there is a strong public interest in access.[29]

[28] *See* Daniel Benoliel, "Technological Standards, Inc.: Rethinking Cyberspace Regulatory Epistemology", 92 Calif. L. Rev. 1069 (2004).

[29] One example of such an "encoding rule" can be found in Sec. 1201(k)(2) of the U.S. Digital Millennium Copyright Act, which prohibits the encryption of free over-the-air broadcasts.