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PUBLIC ACCESS TO SCIENCE: THE NEW POLICY OF THE NATIONAL INSTITUTES OF HEALTH IN LIGHT OF COPYRIGHT PROTECTIONS IN NATIONAL AND INTERNATIONAL LAW

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Science is built upon the shoulders of giants. Hence, advancement in this field relies on knowledge exchange and open scientific communication. This has led to the development of a publishing model whereby scientists submit their communications to publishers for publication in journals. Commercial scientific journals have become the main communication channel for science. Today, lofty and increasing journal subscription costs are becoming prohibitive and leading to serious obstructions in accessing scientific literature.

In an effort to recalibrate the system, and motivated by the desire to grant the public access to publicly funded medical and scientific research, the United States has recently established a new policy regarding scientific research funding. Since 2008, publications resulting from research funded by the National Institutes of Health (NIH) must be made freely available no later than one year following publication.

In this article, the NIH Public Access Policy (Policy) will be evaluated with a particular focus on the domestic goals of intellectual property and the international mechanism designed to allow states to pursue these goals, namely, the Three-Step Test. These particular provisions of the Policy and the peculiar case of research in the biomedical sciences lead to a finding that the Policy is compatible with the broader policy environment in which it resides—both at the national and international level.

PUBLIC ACCESS TO SCIENCE:

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Eve Heafey[†]

I. INTRODUCTION

In the United States, intellectual property (IP), in the form of patents and copyrights, is constitutionally sanctioned for the purpose of promoting science and the useful arts. Today, one of the most hotly contested issues in the field of IP is the extent to which these legally created rights may be inhibiting, rather than promoting, scientific research.[1]

This concern, accentuated by the desire to make publicly funded research freely accessible to the public, has catalyzed legislative intervention. In 2008, the United States Congress adopted the National Institutes of Health Public Access Policy (Policy), which directs the National Institutes of Health (NIH) to require that published author manuscripts resulting from NIH grants be made freely available to the public after one year.

The Policy has been received with some apprehension, notably by commercial publishers who rely on scientific publications generated from NIH funded research for much of their

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[1] Robin Feldman & Kris Nelson, *Open Source, Open Access, and Open Transfer: Market Approaches to Research Bottlenecks*, 7 NW. J. TECH. & INTELL. PROP. 14, 14 (2008).

revenue. Opponents contend that the Policy violates copyright law and infringes on the exclusive rights of copyright holders. [2]

In this article, the Policy will be examined as a case study for publicly funded scientific research publications in the United States.[3] Section II will explore the benefits of scientific research and its need for knowledge exchange, as well as the traditional publishing model, its successes, modern failures and the current trends it has catalyzed. In Section III, the new Public Access Policy of the NIH will be presented in light of the purposes for its enactment and the NIH mandate. To understand the legal significance of the Policy, the framework of copyrights in national and international law will be examined in Section IV. Against this background, the NIH Policy will be evaluated in Section V, followed by some concluding remarks in Section VI.

II. SCIENTIFIC RESEARCH & EXCHANGE: PAST, PRESENT, AND FUTURE

a. Science is a Global Public Good

It would be difficult to argue that science does not advance the well-being of humanity. Life sciences, for instance, can produce information and products that fight hunger and disease.[4] Medical research can significantly improve the quality of life for patients and can ultimately save lives.

[2] Letter from Allan Adler, Vice President for Legal & Governmental Affairs, Ass'n of Am. Publishers, to Nat'l Insts. of Health (May 30, 2008), *available at* http://publicaccess.nih.gov/comments2/files/AAP_NIH_Submission_05_30_08.pdf.

[3] Interestingly, the United States' conduct may have global repercussions in the field of scientific publications since the U.S. dominates the science, technology and medical publications market. *See* Charles Oppenheim, *Electronic Scholarly Publishing and Open Access*, 34 J. INFO. SCI. 577, 578 (2008) (stating that in 2005, the U.S. was estimated to account for 58 % of the global STM literature market).

[4] David W. Opderbeck, *The Penguin's Paradox: The Political Economy of International Intellectual Property and the Paradox of Open Intellectual Property Models*, 18 STAN. L. & POL'Y REV. 101, 158 (2007).

Advances in science, technology, and medicine, however, depend largely on the sharing of research information.[5] Accordingly, scientific research is a cumulative enterprise where today's research builds on previous work and the existing continuum of knowledge. In other words, scientific progress is the work and innovation of today's scientists, standing on the shoulders of giants that predate them.

b. Knowledge Exchange and the Invisible College

The collegial and communicative nature of scientific discovery and innovation permeates the scientific field. Indeed, science flourishes most when ideas, methods, and findings are freely and publicly exchanged.[6] This exchange not only avoids redundancy in scientific efforts, it also promotes accurate conclusions by allowing others to scrutinize findings and build upon them in their own research. [7]

Almost 400 years ago, a group of natural philosophers, known as "the Invisible College," came together to advance science through experimental investigation and knowledge exchange.[8] The Invisible College eventually became the Royal Society of London (Royal Society), a place of scientific research and discussion, which is celebrating its 350th anniversary last year.[9] The Royal Society published and distributed "accounts of experiments and lectures for the benefit of far-flung members and interested laymen who could not attend regular meetings."[10] These compilations evolved into scholarly journals that have since been the lifeblood of the scientific

[5] David Michaels, *Foreword: Sarbanes-Oxley for Science*, L. & CONTEMP. PROBS., Summer 2006, at 1.
[6] *Id.*
[7] *See* Michael B. Eisen & Andy Gass, *Public Access to Public Science: Recommendations for the California Stem Cell Institute's Policies Regarding Grantee-Produced Journal Articles*, 21 BERKELEY TECH. L.J. 1177, 1179 (2006).
[8] The Royal Society, History, at http://royalsociety.org/about-us/history (last visited Feb. 7, 2011).
[9] The Royal Society, 350th Anniversary, at http://350.royalsociety.org (last visited Dec. 12, 2010).
[10] Eisen & Gass, *supra* note 7, at 1179.

community and have provided a communication channel enabling knowledge exchange and dissemination of scientific information.[11]

c. The Traditional Publishing Model

Scholarly journals have four central functions. First, they certify the origin and date of the article. Second, they manage the peer-review process to ensure the reliability of the published information. The third and fourth functions of journals are distribution and archiving of the articles they publish. Beyond these functions, journals provide the means for success in the "publish or perish" world of scientific research. Indeed, scientists' careers depend largely on journals, as funding is granted partly based on publications[12] and universities often require publication in high impact journals for promotion and tenure.[13]

Furthermore, the carefully selected content of journals has particular value for scientists. Indeed, articles published in a journal are not only selected for their soundness, but also because they are interesting, important and relevant in the view of the editorial team for that particular journal, whose opinion the readers respect. This editorial selection restricts the flood of articles into the market in general, and leads to journals that have a reputation for providing a certain type of scientific communication. Moreover, a hierarchy of scholarly communications has evolved, resulting in scientists placing great trust in some journals and less in others.

The publication process is fairly straightforward. Once researchers have completed their experiments and drawn conclusions from the results, they write a manuscript describing their findings. This manuscript is submitted to a journal publisher. The particular journal is usually

[11] Leslie A. Harmel, *The Business and Legal Obstacles to the Open Access Publishing Movement for Science, Technical and Medical Journals*, 17 LOY. CONSUMER L. REV. 555, 562 (2005).
[12] *Id.* at 560.
[13] Christine Lamb, *Open Access Publishing Models: Opportunity or Threat to Scholarly and Academic Publishers?*, 17 LEARNED PUBLISHING 143, 144 (2004).

selected by the author for its field or topic, and for its impact factor. The publisher then takes over the management of the peer-review process, though volunteer reviewers conduct the actual peer-review.[14]

Reviewers are scientists with expertise in the relevant field.[15] They are employees of universities, public colleges and even corporations; their salaries are not part of the financial obligations of the publishers. The publisher role in peer-review involves the administrative coordination between reviewers and authors.[16] The peer-review process is a crucial element of publication, as it ensures that the manuscript reports sound science and reliable results.

After scientific review is complete, the final revised author manuscript is copyedited by the publisher before publication. Finally, the publisher oversees printing and distribution of paper journals, posts completed electronic articles on the web, and undertakes article archiving. As a condition of publication, it is standard for traditional publishers to require that authors transfer their copyrights in the works to the publisher.[17]

Indeed, publishers protect their subscription revenues by ensuring that the articles they publish are not available elsewhere. As researchers do not consider article publication as a direct source of funding and have no expectation of financial payment for their publication, authors generally agree to these copyright transfers.[18] One survey has even reported that almost half of the authors take no interest whatsoever in the copyright aspects of their publishing agreements

[14] MARK WARE & MICHAEL MABE, THE STM REPORT: AN OVERVIEW OF SCIENTIFIC AND SCHOLARLY PUBLISHING 25 (2009), *available at* http://www.stm-assoc.org/2009_10_13_MWC_STM_Report.pdf.
[15] *Id.* at 13.
[16] *See Fair Copyright in Research Works Act: Hearing on H.R. 6845 Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the Comm. on the Judiciary H.R.*, 110th Cong. 85 (2008) [hereinafter *Hearing*] (testimony of Heather Dalterio Joseph, Executive Director, Scholarly Publishing and Academic Resources Coalition).
[17] WARE & MABE, *supra* note 14, at 12–13.
[18] *Id.* at 5.

with journals.[19] Thus, the willingness of scientists to publish the results of their research in scholarly journals without payment, for the sake of science and knowledge, lives to this day.

d. Technology Changes Everything: The New Invisible College

The traditional publishing model, which arguably originates from the communications of the Invisible College, was reasonably efficient and justified when publishers needed to recoup their investments in such things as paper, printing, and postage. In the past, scientists were unable to publish on their own; for the publisher's service, authors transferred copyrights to the publisher or granted them an exclusive right to publish. [20]

Today, the Internet is the most cost efficient and useful way to disseminate and access articles.[21] Electronic journal publishing provides fast, cheap, and environmentally friendly ways to distribute research results and scientific publications.[22] Technology has enabled researchers to communicate their results and users are therefore harnessing the capabilities of the Internet to distribute and use information.[23] This has led to a *New Invisible College*, consisting of a global network of scientists connected over the Internet, sharing and discussing new science.[24] Yet their vehicle of communication, their language, is still administered by journal publishers.

e. The Communicators Impeding Communication[25]

[19] Ian Rowlands, Dave Nicholas & Paul Huntington, *Scholarly Communication in the Digital Environment: What Do Authors Want?*, 17 LEARNED PUBLISHING 261, 265 (2004).
[20] Eisen & Gass, *supra* note 7, at 1181.
[21] *Id.*
[22] *See, e.g.*, Oppenheim, *supra* note 3, at 577 (Scholarly publishers gradually "made the move to digital format, seeing it as a cheaper, faster and more effective method of getting their titles to their readers.").
[23] Daniel J. Gervais, *The Purpose of Copyright Law in Canada*, 2 U. OTTAWA L. & TECH. J. 315, 328 (2005).
[24] *See Generally* CAROLINE S. WAGNER, THE NEW INVISIBLE COLLEGE: SCIENCE FOR DEVELOPMENT (Brookings Institution Press 2008) (examining the emergence of global research networks and the increasing collaboration among scientists).
[25] For further reading, see THE WELLCOME TRUST, ECONOMIC ANALYSIS OF SCIENTIFIC RESEARCH PUBLISHING (2003), *available at* http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd003182.pdf, which provides an analysis of whether scientific research publishing operates in the interests of scientists

Commercial science, technology and medicine (STM) publishers essentially control scientific communications in the form of scholarly publications, which have become highly lucrative.[26] This is due, in part, to the generally inelastic demand for articles.[27] Publishers are therefore in the position of selling research to a high market demand.[28] For-profit STM journal revenues are typically quite high—generally in the 20% to 30% range.[29] More particularly, large publishers like Reed Elsevier PLC (Elsevier) publish core titles that generate as much as a 37% profit margin.[30]

Not only are publisher profits high, but a report by the Association of Research Libraries, the American Association of Universities, and the Pew Higher Education Roundtable estimates that the subscription cost of scholarly journals increased by almost 150% between 1986 and 1996, while the consumer price index increased by only 44%.[31] Subscription prices continue to climb, with recent academic and medical journal prices increasing by approximately 9% annually.[32]

While publishers continue to perform the same highly important functions (certification of the date and origin of articles, management of peer-review, distribution, and archiving), the

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and the public good. This report concludes that it does not. It further concludes that scientific publishing is dominated by commercial interests striving to improve their market position.

[26] MARK WARE & MICHAEL MABE, THE STM REPORT: AN OVERVIEW OF SCIENTIFIC AND SCHOLARLY PUBLISHING 5 (2009), *available at* http://www.stm-assoc.org/2009_10_13_MWC_STM_Report.pdf.

[27] PAUL GOODEN, ET AL., MORGAN STANLEY SCIENTIFIC PUBLISHING: KNOWLEDGE IS POWER 7(2002), *available at* http://www.econ.ucsb.edu/~tedb/Journals/morganstanley.pdf.

[28] JUDITH M. PANITCH & SARAH MICHALAK, THE SERIALS CRISIS: A WHITE PAPER FOR THE UNC-CHAPEL HILL SCHOLARLY COMMUNICATIONS CONVOCATION (2005), *available at* http://www.unc.edu/scholcomdig/whitepapers/panitch-michalak.html.

[29] *Reshaping Scholarly Communication: The Economics of Publishing*, U. CALIFORNIA, http://osc.universityofcalifornia.edu/facts/econ_of_publishing.html (last visited Dec. 12, 2010).

[30] GOODEN, *supra* note 27, at 13.

[31] Samuel E. Trosow, *Copyright Protection for Federally Funded Research: Necessary Incentive or Double Subsidy?*, 22 CARDOZO ARTS & ENT. L.J. 613, 624 (2004).

[32] Karen M. Albert, *Open Access: Implications for Scholarly Publishing and Medical Libraries*, 94 J. MED. LIBR. ASS'N. 253, 254 (2006), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525322/pdf/i1536-5050-094-03-0253.pdf.

costs associated with these functions have not increased. For instance, printing costs have not increased with respect to the past, whereas the cost for electronic distribution, which has largely replaced paper based distribution, is very low and independent of the number of readers.[33] The distribution and archiving costs today consist mostly of data hosting, information infrastructure maintenance, and electronic data refinement.

Rising journal subscription costs have outpaced academic library budgets, which has led to what is commonly known as the "Serials Crisis," resulting in libraries being forced to cancel subscriptions.[34] For instance, Duke University's Medical Center Library cancelled 525 of its 1,753 titles because of subscription fees. [35] Similarly, Cornell cancelled more than 200 journals from Elsevier alone.[36] Library organizations have studied the Serials Crisis and concluded that high subscription prices did not result from increased publishing costs, but are likely caused by publishers seeking to increase profits.[37]

The publishers, who traditionally provided a distribution channel for research results, now seem to be impeding that communication.[38] Unfortunately, perverse motivations exist for publishers to limit the access to the scientific information they publish, in order to increase profits.[39] As a result of high subscription costs, access to scientific literature in research

[33] Eisen & Gass, *supra* note 7, at 1181.
[34] *See* Nicholas Bramble, *Preparing Academic Scholarship for an Open Access World*, 20 HARV. J.L. & TECH. 209, 216 (2006).
[35] Robert C. Denicola, *Copyright and Open Access: Reconsidering University Ownership of Faculty Research*, 85 NEB. L. REV. 351, 352 n.4 (2006).
[36] *Id.*
[37] *See* Maarten Cornet & Ben Vollaard, *Tackling the Journal Crisis: When Authors Pay with Money Instead of Copyright* (CPB Neth. Bureau for Econ. Policy Analysis, Working Paper No. 121, 2000), *available at* http://www.cpb.nl/sites/default/files/publicaties/download/tackling-journal-crisis-when-authors-pay-money-instead-copyrights.pdf.
[38] *See* Trosow, *supra* note 31, at 623.
[39] Pritpal S. Tamber et al., *Open Access to Peer-reviewed Research: Making it Happen*, 362 THE LANCET 1575, 1576 (2003).

institutions can be seriously obstructed.[40] Researchers outside of major research institutions will find themselves even more limited.[41]

The current state of affairs allows publishers to hold a quasi-monopoly over the distribution of scientific research. Indeed, authors are under pressure to publish for career advancement and funding applications.[42] While authors are free to negotiate, most publishers require transfer of copyright as a condition to acceptance.[43] Moreover, it appears that the loss to publishers caused by canceled subscriptions is insignificant compared to the gain from continuing subscribers.[44] Indeed, the permanent record of scientific progress and discoveries is now owned and controlled by these publishers, rather than by the scientific community or the public, which forces readers to continue their subscription.[45]

According to some authors, the continuing prevalence of STM journal publishers is "a vestige of a time when the economics of the publishing process were very different than they are today."[46] The balanced relationship that existed in the days of the Invisible College has been disturbed by the New Invisible College, triggering new ideologies in knowledge exchange and information access.

f. 21st Century Trends: The Open Access Movement

In 2001, over 30,000 scientists from 177 countries manifested their displeasure with commercial for-profit journals. They pledged to publish in, edit and review for, and personally

[40] *See* Trosow, *supra* note 31, at 615.
[41] Eisen & Gass, *supra* note 7, at 1179.
[42] MARK WARE & MICHAEL MABE, THE STM REPORT: AN OVERVIEW OF SCIENTIFIC AND SCHOLARLY PUBLISHING 5 (2009), *available at* http://www.stm-assoc.org/2009_10_13_MWC_STM_Report.pdf.
[43] P. Bernt Hugenholtz, *Copyright vs. Freedom of Scientific Communication*, 13 LEARNED PUBLISHING 77, 77 (2000).
[44] Tamber et al., *supra* note 39.
[45] Eisen & Gass, *supra* note 7, at 1180.
[46] *Id.* at 1181.

subscribe to only the journals that allowed free access to articles six months after their publication.[47] These scientists were fighting against the publisher protectionism occurring at the expense of educational and research uses.

Three landmark documents soon followed: the Declaration of the Budapest Open Access Initiative,[48] the Bethesda Statement on Open Access Publishing,[49] and the Berlin Declaration on Open Access to Knowledge in the Sciences and the Humanities.[50]

The open access (OA) movement was echoed by the Public Library of Science (PLoS), which launched its first peer-reviewed journal—PloS Biology—a nonprofit scientific and medical publication under the OA model.[51] PLoS was founded by the Scholarly Publishing and Academic Resources Coalition (SPARC) and operates as an "international alliance of academic and research libraries working to correct imbalances in the scholarly publishing system."[52] PLoS now publishes seven online peer-reviewed scientific and medical journals.[53]

In 2003, the United States Congress came face to face with OA issues when Rep. Martin Olav Sabo introduced the Public Access to Science Act (commonly referred to as the Sabo Bill), which aimed to force scientific publishers into the OA model, making all federally funded

[47] Denicola, *supra* note 35, at 351–52.
[48] BUDAPEST OPEN ACCESS INITIATIVE, http://www.soros.org/openaccess (last visited Dec. 12, 2010). As of December 2010, there were over 5,900 signatories to this Declaration, including many universities and library associations. *See View Signatures*, BUDAPEST OPEN ACCESS INITIATIVE, http://www.soros.org/openaccess/view.cfm (last visited Dec. 12, 2010).
[49] BioMed Central, *Bethesda Principles: Summary of the April 11, 2003, Meeting on Open Access Publishing*, OPEN ACCESS NOW, http://www.biomedcentral.com/openaccess/bethesda/ (last visited Dec. 12, 2010) (recognizing a right to access and grants to all users a license to "copy, use, distribute, transmit and display the work") [hereinafter *Bethesda Principles*].
[50] *Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities*, OPEN ACCESS MAX PLANCK SOC'Y, http://oa.mpg.de/lang/en-uk/berlin-prozess/berliner-erklarung/ (last visited Dec. 12, 2010). The signatories to this Declaration intend to urge their researchers and grant recipients toward the open access model.
[51] *See Open Access License*, PUB. LIBR. SCI., http://www.plos.org/journals/license.php (last visited Dec. 12, 2010).
[52] *About SPARC*, SCHOLARLY PUBL'G & ACADEMIC RES. COAL., http://www.arl.org/sparc/about/index.shtml (last visited Dec. 12, 2010).
[53] PUB. LIBRARY OF SCI., http://www.plos.org/journals/journals.php (last visited Dec. 12, 2010).

published results available for anyone to freely access and republish.[54] While this bill has not yet passed, it has been followed in 2006 and more recently in 2009, by the Federal Research Public Access Act, which would require any federal agency with external research expenditures exceeding $100 million to implement an OA publishing policy.[55]

Some universities have also joined the open access movement. For instance, in 2003, the Cornell University Senate recognized that the increasing control of commercial publishers over academic and scholarly communication "threatens to undermine core academic values promoting broad and rapid dissemination of new knowledge and unrestricted access to the results of scholarship and research . . . ."[56] The Cornell University Senate therefore encouraged the University to "vigorously" explore and support alternatives.[57]

More recently, **t**he Harvard University Faculty of Arts and Sciences adopted an open-access publishing policy.[58] Other Harvard schools and many other institutions, colleges, and universities have followed suit and since adopted similar resolutions in the United States and abroad.[59]

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[54] *See* Public Access to Science Act, H.R. 2613, 108th Cong. § 3(a)(2) (2003).
[55] *See* Federal Research Public Access Act of 2009, H.R. 5037, 111th Cong. (2010) (referring to House Committee on Oversight and Government Reform on Apr. 15, 2010); Federal Research Public Access Act of 2009, S. 1373, 111th Cong. (2009) (referring to Senate Committee on Homeland Security and Governmental Affairs on Jun. 25, 2009); Federal Research Public Access Act of 2006, S. 2695, 109th Cong. (2006).
[56] Cornell Faculty Senate, Resolution Regarding the University Library's Policies on Serials Acquisitions, with Special Reference to Negotiations with Elsevier (Dec. 17, 2003), *available at* http://www.library.cornell.edu/scholarlycomm/resolution2.htm (last visited Dec. 12, 2010).
[57] *Id.*
[58] Press Release, Harvard Faculty of Arts & Scis., Harvard To Collect, Disseminate Scholarly Articles For Faculty (Feb. 12, 2008), *available at* http://www.fas.harvard.edu/home/news-and-notices/news/press-releases/release-archive/releases-2008/scholarly-02122008.shtml; *see also* Josh Wilner, *Open Access to Legal Scholarship*, 2 MCGILL J.L. & HEALTH 1, 3 (2008).
[59] *See Registry of Open Access Repository Material Archiving Policies*, EPRINTS, http://www.eprints.org/openaccess/policysignup (last visited Dec. 12, 2010); *see also* Concordia Univ., Senate Resolution on Open Access (Apr. 16, 2010), *available at* http://library.concordia.ca/research/openaccess/SenateResolutiononOpenAccess.pdf (resolving to join the open access movement by requiring that faculty members who are authors of scholarly articles accepted for publication peer-reviewed journals deposit an electronic copy in the Concordia University Research Repository, unless

In Canada, the National Research Council of Canada's (NRC) Senior Executive Committee has recently established a policy making it mandatory for NRC institutes to deposit copies of all peer-reviewed publications in the NRC Institutional Repository.[60] In 2009, the University of Ottawa became the first Canadian university to adopt "a comprehensive open access program that supports free and unrestricted access to scholarly research."[61] The open access program includes a commitment to make the University's scholarly publications freely available through the University's online repository, as well as a financial support to help researchers defray open access fees charged by publishers.[62]

This section has shown that universities and research institutions are often initiators of OA declarations because they find themselves paying at several levels of the traditional publishing process: salaries and research costs leading to the published results, submission fees and page charges paid to publishers, and subscription fees to access these results and those of others. As an example, the University of California (UC) paid $8 million in the 2002–03 academic year solely for online access to scientific journals published by Elsevier, amounting to one sixth of the UC materials budget that year. [63] Despite this massive direct cost to the UC, it still supports almost 1,000 faculty members serving on Elsevier journal editorial boards. [64] In fact, almost 50% of UC subscribed Elsevier journals have at least one UC faculty member on

publishers, co-authors or other rights holders disallow such a deposit). In the international sphere, the United Nations World Summit on the Information Society has recently endorsed the open access movement by declaring the intention to promote the dissemination of scientific and technical information. United Nations World Summit on the Info. Soc'y, Declaration of Principles § 28 (Dec. 12, 2008), *available at* http://www.itu.int/wsis/docs/geneva/official/dop.html.

[60] Press Release, Nat'l Research Council, Extending the Reach and Increasing the Impact of NRC Research (July 23, 2008), *available at* http://cisti-icist.nrc-cnrc.gc.ca/eng/news/cisti/2008/nparc.html .

[61] Press Release, Univ. of Ottawa, University of Ottawa Among North American Leaders as it Launches Open Access Program (Dec. 8, 2009), *available at* http://www.media.uottawa.ca/mediaroom/news-details_1824.html.

[62] *Id.*

[63] *Scholarly Communication: Elsevier, a Case Study*, U. CAL., BERKELEY LIBR. COLLECTIONS, http://www.lib.berkeley.edu/Collections/elsevier_case_study.html (last visited Jan. 15, 2011).

[64] *Id.*

their editorial board. [65] Furthermore, UC has estimated that 10% to 15% of Elsevier content is written by UC Faculty.[66]

A similar relationship exists between American taxpayers who fund research the traditional publishing system that charges for access to the publications communicating the results of that research. In light of this situation, Congress adopted provisions to restore the balance. These are embodied in the 2008 Appropriations Bill and reflected in the NIH Public Access Policy described below.

III. THE ISSUE: THE POLICIES OF THE NIH

The NIH, an agency under the United States Department of Health and Human Services, is "the Federal focal point for health research," and "the steward of medical and behavioral research for the Nation,"[67] with the ultimate objective of healthy living and reduced burdens of illness and disability for the American people.[68] In pursuit of these objectives, NIH appropriations have grown from $2.3 billion (1976) to almost $30 billion (2008).[69] In 2008, around half of those resources ($15 billion) were distributed to over 36,000 individual scientists as Research Project Grants for extramural research.[70] The NIH estimates that the research it

[65] *Scholarly Communication: Elsevier, a Case Study*, U. CAL., BERKELEY LIBR. COLLECTIONS, http://www.lib.berkeley.edu/Collections/elsevier_case_study.html (last visited Jan. 15, 2011).*Ibid.*
[66] *Id.*
[67] *Almanac*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/almanac/ (last visited Dec. 12, 2010).
[68] *Mission*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/index.html (last visited Dec. 12, 2010).
[69] *Almanac: Appropriations*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/almanac/appropriations/part2.htm (last visited Dec. 12, 2010).
[70] *Research Portfolio Online Reporting Tools, Budget and Spending*, NAT'L INSTS. HEALTH, http://report.nih.gov/budget_and_spending/index.aspx (last visited Dec. 12, 2010) (extramural research based on investigator-initiated applications that originate from individual scientists: $15 billion for 36,000 Research Project Grants in 2008).

supports generates about 80,000 scientific and medical journal articles annually.[71] These publications act as an unofficial record of NIH funded research. which act as a *de facto* record of NIH funded results.

a. The New NIH Public Access Policy

As the primary source of government funding in medical research, the NIH aims to ensure a high return on this significant public investment.[72] To maximize returns, and for the benefit of science and health, it was deemed important to make the record of NIH funded research publicly accessible.[73] Indeed, the U.S. House Appropriations Committee stated that it was "very concerned that there is insufficient public access to reports and data resulting from NIH funded research" and that this situation was "contrary to the best interests of the U.S. taxpayers who paid for this research."[74] This view echoed the opinion of 25 Nobel Prize Laureates who sent a letter to Congress, in support of public access to works funded by NIH.[75]

Congress endorsed NIH efforts for increased public access to publicly funded research in the conference report that accompanied the 2005 Consolidated Appropriations Act.[76] The report referred to the NIH policy proposal to make research articles based on NIH funding publicly available through PubMed Central (PMC) within six months after publication in a peer-reviewed

[71] Ass'n of Research Libraries & Scholarly Publ'g & Academic Res. Coal., NIH Public Access Policy Does Not Affect U.S. Copyright Law (July 2008), *available at* http://www.arl.org/sparc/bm~doc/nihpolicy_copyright_july2008.pdf (last visited Dec. 12, 2010).
[72] *See generally* Timothy L. Faley & Michael Sharer, *Technology Transfer and Innovation: Reexamining and Broadening the Perspective of the Transfer of Discoveries Resulting from Government-Sponsored Research*, 3 COMPUTER TECH. TRANSFER & SOC'Y 109, 112 (2005) (discussing the Bayh-Dole Act as a mandate for publicly funded researchers to incorporate their results into commercial products or services).
[73] *See Hearing*, *supra* note 16, at 15–16, 21 (testimony of Dr. Elias A. Zerhouni, Director, National Institutes of Health).
[74] H.R. REP. NO. 108-636, at 104 (2004); *see also Action at the U.S. Congress*, THE ALLIANCE FOR TAXPAYER ACCESS, http://www.taxpayeraccess.org/issues/nih/action-at-the-us-congress.shtml (last updated May 4, 2005).
[75] Open Letter to the U.S. Congress Signed by 25 Nobel Prize Winners (Aug. 26, 2004), *available at* http://www.fas.org/sgp/news/2004/08/nobel082604.pdf.
[76] *See* Consolidated Appropriations Act 2005, H.R. 4818, 108th Cong. (2004) (enacted).

journal.[77] On May 2, 2005, the voluntary NIH Policy became effective and the NIH requested the submission of manuscripts to PMC within 12 months of their publication.[78]

Despite the enthusiasm it generated, the voluntary NIH Policy was only moderately successful. The NIH reported in January 2005 that less than 4% of the estimated eligible manuscripts were submitted to PMC.[79] Two years later, provisions making the Policy mandatory were included in section 218 of the 2008 Consolidated Appropriations Act, which was signed by President Bush on December 26, 2007 and became Public Law No. 110-161. Section 218 stated that:

> The Director of the National Institutes of Health **shall require** that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law. [80]

The Policy became permanent through the Omnibus Appropriations Act of 2009, signed into law by President Obama on March 11, 2009.[81] The Policy as it now stands requires manuscripts developed through funding by the NIH to be made available to the public, free of

[77] *See* H.R. REP. NO. 108-792, at 104 (2004).
[78] Notice of Nat'l Insts. of Health, Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research (Feb. 3, 2005), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html [hereinafter NIH Public Access Policy].
[79] ELIAS A. ZERHOUNI, REPORT ON THE NIH PUBLIC ACCESS POLICY 4 (Jan. 2006), *available at* http://www.mlanet.org/government/gov_pdf/2006_nihrpt_pubaccessplcy.pdf.
[80] Consolidated Appropriations Act of 2008, H.R. 2764, 110th Cong. § 218, at 344 (2007) (enacted) (emphasis added).
[81] Omnibus Appropriations Act of 2009, H.R. 1105, 111th Cong. § 217, at 259 (2009) (enacted) (renews the NIH Public Access Policy for the 2009 fiscal year and "thereafter").

charge, within one year after publication. The author is required to deposit the final submitted manuscript rather than the published, copyedited version that includes the stylistic edits of the publisher.

Internationally, similar undertakings have also surfaced, notably at the Canadian Institutes of Health Research (CIHR), the governmental agency responsible for funding health research in Canada.[82] Its mission is to create new scientific knowledge and to catalyze its translation into improved health.[83] In September 2007, CIHR unveiled its Policy on Access to Research Outputs, whereby grant recipients must "make every effort" to ensure that their CIHR-funded peer-reviewed manuscript is freely accessible through either the publisher's website or an online repository (such as PMC), as soon as possible and no later than six months after publication.[84] In support of this new policy, Dr. Alan Bernstein, the CIHR President at the time, stated that as a publicly funded organization CIHR has "a responsibility to ensure that new advances in health research are available to those who need it and can use it – researchers world-wide, the public and policy makers."[85] The CIHR Policy, however, is arguably a softer requirement because it only requires that authors "make every effort" to make their manuscript accessible, without explicitly requiring it.[86]

[82] *See* Press Release, Nat'l Research Council Can., Canada Joins International Effort to Provide Access to Health Research (July 6, 2009), *available at* http://www.nrc-cnrc.gc.ca/eng/news/nrc/2009/07/06/pubmed-cisti.html.
[83] *Our Mission*, CANADIAN INSTS. HEALTH RES., http://www.cihr-irsc.gc.ca/e/7263.html (last visited Dec. 12, 2010).
[84] *Policy on Access to Research Outputs*, CANADIAN INSTS. HEALTH RES., http://www.cihr-irsc.gc.ca/e/34846.html (last visited Dec. 12, 2010) [hereinafter *CIHR Policy*].
[85] Press Release, Canadian Insts. of Health Research, CIHR Unveils New Policy on Open Access (Sept. 4, 2007), *available at* http://www.cihr-irsc.gc.ca/e/34916.html.
[86] *CIHR Policy*, *supra* note 83.

Overseas, the Wellcome Trust, the largest non-governmental source of funds for biomedical research in the UK,[87] has joined in the efforts of making health research results publicly accessible. Since October 2006, it requires that all peer-reviewed journal articles resulting from Wellcome Trust research grants be deposited to PMC within six months of publication.[88]

b. The Rationale Behind the NIH Policy[89]

Generally, the broadest possible dissemination of peer-reviewed manuscripts encouraged by the Policy is intended to advance science and improve human health.[90] More particularly, the Policy is motivated by the desire to increase the integration and accessibility of biomedical research results and to speed discoveries, hopefully resulting in the prevention of death and disability.[91] As stated in the Bethesda Principles, removing access barriers to information accelerates research and makes the information as useful as it can be.[92] The Human Genome Project, a forum established to promote the free flow of pre-published data on gene sequences, is an exemplar of information sharing in order to advance science more efficiently and with greater speed. [93]

[87] *Frequently Asked Questions*, THE WELLCOME TRUST, http://www.wellcome.ac.uk/News/Media-office/Fact-file/index.htm (last visited Jan. 16, 2011).
[88] *Position Statement in Support of Open and Unrestricted Access to Published Research*, THE WELLCOME TRUST, http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002766.htm (last visited Dec. 12, 2010).
[89] It should be noted that this article will not assess whether the NIH Policy achieves the objectives it pursues.
[90] *See* NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., ANALYSIS OF COMMENTS AND IMPLEMENTATION OF THE NIH PUBLIC ACCESS POLICY 1 (2008), *available at* http://publicaccess.nih.gov/analysis_of_comments_nih_public_access_policy.pdf [hereinafter NIH COMMENT ANALYSIS].
[91] *Hearing*, *supra* note 16, at 25 (statement of Dr. Elias A. Zerhouni, Director, National Institutes of Health).
[92] *Bethesda Principles*, *supra* note 49.
[93] *See* Summary of the Report of the Second International Strategy Meeting on Human Genome Sequencing (Feb. 27–Mar. 2, 1997), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml; *see also* Eliot Marshall, *Bermuda Rules: Community Spirit, With Teeth*, 291 SCIENCE 1192 (2001), *available at* http://www.sciencemag.org/content/291/5507/1192.full (discussing the impact of the Human Genome Project's

The NIH has articulated three specific aims for the Public Access Policy.[94] First, the Policy enables a public archive of NIH funded research publications, preserving these results for the future.[95] Second, this archive is a central resource and compendium for scientists to research information and for NIH to manage research investments.[96] Third, the archive provides free access to publicly funded results for health care providers, educators, scientists and the public in general.[97]

Making federally funded research publicly accessible for the benefit of the people of the U.S. is undoubtedly a compelling cause. Each year, American taxpayers contribute over $40 billion in federal funding to support scientific and medical research.[98] The U.S. funds this research with the belief and intention that new ideas and discoveries will improve the lives of the American people. Be that as it may, publicly funded results are published mainly in for-profit journals, which charge a subscription fee to view their contents. Thus, taxpayers must pay twice to obtain the information: once to fund the research and a second time to have access to it, either by directly purchasing articles, or indirectly through the public library system for instance. The Policy is based on the belief that taxpayers should have free access to the results of research paid for by their tax dollars.[99]

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public access rules on the genomics industry); NATL RESEARCH COUNCIL OF THE NAT'L ACADS., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 135 (Stephen A. Merrill & Anne-Marie Mazza eds. 2006), *available at* http://www.nap.edu/openbook.php?record_id=11487 (concluding that free exchange and information sharing is in the best interest of all science).

[94] NIH COMMENT ANALYSIS, *supra* note 90, at 5.

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] Harmel, *supra* note 11, at 555.

[99] Kristopher Nelson, *The Impact of Government-Mandated Public Access to Biomedical Research: An Analysis of the New NIH Depository Requirements*, 19 ALB. L.J. SCI. & TECH. 421, 426 (2009).

The public will not only benefit from direct access to results, but also from an indirect trickle-down effect. For instance, patients will indirectly benefit from more informed health care providers. Easier access to information will also drive down research costs, which will allow researchers to reinvest these savings into other research tools such as better instruments, leading to more efficient and higher quality research. [100]

Federal research and development expenditures have more than tripled since 1976, from $20 billion to nearly $70 billion in 2000.[101] It is now, more than ever, becoming a priority to maximize taxpayer investment by increasing the dissemination of knowledge produced from public funding. The NIH Policy supports the interest of the people to have access to information that is created at the government's (and taxpayers') expense.[102] This is by no means a new concept, as the U.S. Copyright Act denies the copyrightability of U.S. Government works, such that they immediately fall into the public domain and are freely available for the benefit of the American people.[103]

It is important to emphasize the immense power of knowledge integration rendered possible by PMC and the large-scale submission of information to the archive. Given the current accelerating growth of knowledge, the connectivity of all available sources of scientific information and their functional integration is required for their efficient exploitation.[104] Indeed,

[100] *Id.* at 446.
[101] *See* U.S. Census Bureau, *R&D Expenditures: 1960–2000*, *in* STATISTICAL ABSTRACTS OF THE UNITED STATES: 2001, 507 tbl.767 (2001), *available at* http://www.census.gov/prod/2002pubs/01statab/science.pdf; *see also* U.S. Census Bureau, *Federal R&D Obligations to Selected Universities and Colleges: 1981 to 1999*, *in* STATISTICAL ABSTRACTS OF THE UNITED STATES: 2001, 511 tbl.775 (2001), *available at* http://www.census.gov/prod/2002pubs/01statab/science.pdf (showing an increase in the dollar amount of federal R&D obligations to certain educational institutions).
[102] *See Hearing*, *supra* note 16, at 14 (statement of Hon. Darell Issa, Member, Subcommittee on Courts, the Internet, and intellectual property).
[103] 17 U.S.C. § 105 (2010).
[104] *See Hearing*, *supra* note 16, at 16 (testimony of Dr. Elias A. Zerhouni).

it is not sufficient to have a passive and disordered database. The real value lies in data being connected and linked, which is now made possible by technology. For instance, a PubMed search will link an article with the chemical structure described in it, as well as the chemical structure, the related chemical proteins, and any other known relevant information.

IV. LEGAL AND POLICY BACKGROUND OF IP IN NATIONAL AND INTERNATIONAL LAW

It is generally accepted that the modern notion of copyrights, and patents for that matter, has derived from the state-issued privileges of 15th century Venice.[105] These privileges were exclusive rights granted by royal prerogative to individuals as a reward or to encourage them in the pursuit of useful activities.[106] The Venetian system of privileges was adopted throughout 16th century Europe and remained largely unchanged until the 18th century.[107]

At that time, Enlightenment currents were sweeping through Europe and exposing the need for learning. As a result, the English Statute of Anne, which entered into force in April 1710, proclaimed a new purpose for the protection of original works: the encouragement of learning.[108] To promote this objective, the Statute granted copyrights to authors and publishers, which prevented reuse of their works by other publishers.[109] This statute, generally considered

[105] PAUL GOLDSTEIN, COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES 219–21, 552–53 (4th ed. 1997) (providing a brief overview of history of trademark and copyright law).
[106] *Id.*
[107] *Id.*
[108] Statute of Anne, 1710, 8 Ann., c. 19 (Eng.) [hereinafter Statute of Anne]; *see also* Reto M. Hilty, *Five Lessons About Copyright in the Information Society: Reaction of the Scientific Community to Over-Protection and What Policy Makers Should Learn*, 53 J. COPYRIGHT SOC'Y U.S.A. 103, 107 (2006).
[109] Daniel J. Gervais, *Towards a New Core International Copyright Norm: The Reverse Three-Step Test*, 9 MARQ. INTELL. PROP. L. REV. 1, 4 (2005).

the first copyright statute, "closed the period of experiment and tentative administration of literary property and opened the period of modern copyright law."[110]

Generally speaking, copyrights are state-granted rights that bestow upon authors of creative works certain exclusive rights over those works. Authors may transfer or license those rights to another party. Due to advances in technology and the new forms of creation it has made possible, the traditional copy right has morphed into what is known today as the "copyright bundle."[111] The bundle now includes rights such as reproduction, public performance, communication to the public, and adaptation.[112]

Although works must be creative to be protected, the measure of creativity in copyright law is not very strict and admits almost any original creation, including scientific reporting. Despite protection extending to the expression of scientific information, it is important to remember that scientific facts cannot be protected by copyright. This fundamental notion of copyright law, often referred to as the "idea-expression dichotomy," establishes that only the expression of an idea can be protected, rather than the idea itself.[113]

a. National Perspectives

Copyrights, and intellectual property rights in general, are a matter of domestic law. In the United States, copyrights are established in and governed by the Copyright Act, first enacted by Congress in 1909 and most recently fully revised in 1976.[114] The Act notably describes the

[110] HARRY H. RANSOM, THE FIRST COPYRIGHT STATUTE: AN ESSAY ON ACT FOR THE ENCOURAGEMENT OF LEARNING, 1710, at 106 (1956).
[111] Gervais, *supra* note 109, at 5 (the "copyright bundle" bundle is composed of "copyright rights," a list of specific rights in respect of particular forms of exploitation of works (reproduction, public performance or communication to the public, and adaptation)).
[112] Gervais, *supra* note 109, at 5.
[113] *See* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 411–16 (rev. 4th ed. 2006) (explaining the idea-expression dichotomy).
[114] MELVILLE B. NIMMER & DAVID NIMMER, NIMMER ON COPYRIGHT § 1-TL (rev. ed. 2008).

protected subject matter, the nature of the rights conferred, assignments, licenses and other transfers of rights, the duration of protection, copyright infringements, and exceptions to infringement. By granting protection to authors, Congress aimed to encourage the production of literary works of lasting benefit to the world.[115]

The economic basis for granting such exclusive rights is the conviction that personal gain is the best way to encourage creators and inventors to produce new works.[116] In spite of this reward, intellectual property law makes reward to the author a secondary consideration.[117] This has been repeatedly confirmed by the Supreme Court, which observed that the "monopoly privileges that Congress may authorize are neither unlimited nor primarily designed to provide a special private benefit. Rather, the limited grant is a means by which an important public purpose may be achieved."[118]

This public purpose and the power of Congress to pursue it, is bestowed upon Congress by the Constitution through article I, section 8 which states that Congress shall have the power to: "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[119] This constitutional mandate empowers Congress to grant intellectual property rights (IPRs). The constitutional language reveals that the Framers intended to limit IPRs and congressional power

[115] Washingtonian Co. v. Pearson, 306 U.S. 30, 36 (1939).
[116] Mazer v. Stein, 347 U.S. 201, 219 (1954); *see* David W. Opderbeck, *A Virtue-Centered Approach to the Biotechnology Commons (Or, the Virtuous Penguin)*, 59 ME. L. REV. 316, 317 (2007); *see also* MERGES, *supra* note 113, at 11 (describing the "incentive theory" to justify intellectual property); ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS 7 (2003).
[117] Mazer v. Stein, 347 U.S. at 219; United States v. Paramount Pictures, 334 U.S. 131, 158 (1948); *see also* NIMMER & NIMMER, *supra* note 114, at § 1.03[A].
[118] Sony Corp. of Am. v. Universal City Studios, 464 U.S. 417, 429 (1984); *see also* Twentieth Century Music Corp. v. Aiken, 422 U.S. 151, 156 (1975) ("Creative work is to be encouraged and rewarded, but private motivation must ultimately serve the cause of promoting broad public availability of literature, music and the other arts.").
[119] U.S. CONST. art. I, § 8, cl. 8.

to ends that promote progress. This intention is manifested by the identification of specific categories of intellectual goods (writings and discoveries) that could be subject to exclusive rights and particular persons who could secure these rights (authors and inventors) for a limited time.[120]

Interestingly, the Court of Customs and Patent Appeals has commented that the Constitution's intellectual property clause is unusual in stating a reason for bestowing this power to Congress. According to the Court, this unusual inclusion was undoubtedly caused by the Framers' apprehension of the historical granting of monopolies by the English Crown purely for financial gain, and the Framers' attempt to avoid such monopolies, which served no public purpose. [121] The Court noted that "any Government grant of a monopoly for even a limited time should be limited to those things that serve in the promotion of science and the useful arts."[122]

Thus, the Constitution is the *raison d'être* of copyrights and of limits to their scope. Indeed, copyrights grant exclusive rights but are nevertheless limited in nature and must ultimately serve the public good by promoting progress.[123] It is therefore a worthwhile exercise to determine what the constitutional mandate to promote progress entails. In the language of the Constitution, "science" is understood as copyrightable works and the "useful arts" as patentable inventions.[124] Despite this differentiation, the constitutional mandate calls for a unitary purpose—to promote progress.[125] The Supreme Court has consistently recognized this unified purpose, observing that "both patent law and copyright law seek to increase the store of human

[120] Trosow, *supra* note 31, at 642.
[121] *In re* Yuan, 188 F.2d 377, 380 (C.C.P.A. 1951)
[122] *Id.*
[123] Fogerty v. Fantasy, Inc., 510 U.S. 517, 526 (1994).
[124] Graham v. John Deere Co., 383 U.S. 1, 5–6 (1966); NIMMER & NIMMER, *supra* note 114, § 1.03 n.11.2.
[125] Lazercomb America, Inc. v. Reynolds, 911 F.2d 970, 975–76 (4th Cir. 1990); *see also* Mazer v. Stein, 347 U.S. 201, 219 (1954).

knowledge and arts by rewarding inventors and authors with the exclusive rights to their works for a limited time."[126]

The protection of intellectual goods prompts creators and inventors to share their work immediately rather than keeping it secret, by giving them a right of action against imitations and forgeries. This incentive, combined with the constitutional limitation on the period of protection, reveals that the Framers had broad public dissemination of works in mind. The public benefits both immediately from the disclosure of the work, and later from its incorporation to the public domain at the expiration of copyright protection. Hence, the objective is not confined to an increase in quantity of works; it also extends to an improvement in the dissemination of works.[127]

It is also revealing that the Framers chose to mandate the promotion of progress rather than using the language of the Statute of Anne, enacted for "the encouragement of learned men to compose and write useful books . . . ."[128] The particular constitutional phrasing suggests that the Framers intended to give Congress a broader power to foster dissemination. Requirements of copyrightability also reflect this desire to foster dissemination. In particular, creative efforts must be materially supported, by expressing in it writing for instance, in order to become copyrightable subject matter. This requirement pressures creators to record their work, thereby making it more easily disseminated. Such requirement additionally facilitates the preservation of works for the benefit of future generations.

The dissemination of knowledge has been a major focus of American copyrights, at least until 1976. Until that time, the Copyright Act attached copyrights to works only upon

[126] *Lazercomb America, Inc.*, 911 F.2d at 976.
[127] Orrin G. Hatch & Thomas R. Lee, *"To Promote the Progress of Science": The Copyright Clause and Congress' Power to Extend Copyrights*, 16 HARV. J.L. & TECH. 1, 7 (2002). *See generally* SCHECHTER & THOMAS, *supra* note 116, at 5–6 (describing the importance of the limited lifetime of IP protection to the enrichment of the public domain).
[128] Statute of Anne, *supra* note 108.

publication, rather than immediately following creation.[129] Congress was therefore focused not on stimulating creation, but on providing incentives for publication.[130] The Canadian perspective is a similar one, which views copyrights as incentives to increase not only the production of works, but also the availability of knowledge.[131] Industry Canada, the federal agency responsible for IP administration, has remarked that while copyright protection rewards the creation and publication of knowledge, it also facilitates access to this knowledge.[132]

Essentially, IPRs reflect a balancing act whereby the state creates incentives that maximize the benefits of creating and promulgating writings and discoveries, taking into account the social cost of their creation, including the cost of administering the system and limiting access.[133] Knowledge accessibility and dissemination should become an even greater focus of copyright law in the current digital environment. Limits placed on copyrights will avoid depriving some groups of information, which could stretch the digital divide of society and lead to somber social and political repercussions.[134] In general, limitations on copyrights typically seek to maintain the delicate balance required by the constitutional mandate by keeping state granted monopolies in check with public interest objectives. Statutory exceptions, such as the

[129] Hatch & Lee, *supra* note 127, at 12.
[130] Hatch & Lee, *supra* note 127, at 4, 12.
[131] *See generally* Graeme B. Dinwoodie, *Private Ordering and the Creation of International Copyright Norms*, 160 J. INSTITUTIONAL & THEORETICAL ECON. 161 (2004), *available at* http://www.kentlaw.edu/depts/ipp/publications/privateordering15july05.pdf.
[132] Balanced Copyright, A Framework for Copyright Reform (2002), *available at* http://www.ic.gc.ca/eic/site/crp-prda.nsf/eng/rp01101.html; *see also* Gervais, *supra* note 23, at 318.
[133] Stanley M. Besen & Leo J. Raskind, *An Introduction to the Law and Economics of Intellectual Property*, 5 J. ECON. PERSP. 3, 5 (1991); William M. Landes & Richard A. Posner, *An Economic Analysis of Copyright Law*, 18 J. LEGAL STUD. 325, 326 (1989).
[134] MARTIN SENFTLEBEN, COPYRIGHT, LIMITATIONS AND THE THREE-STEP TEST IN INTERNATIONAL: AN ANALYSIS OF THE THREE-STEP TEST IN INTERNATIONAL AND EC COPYRIGHT LAW 30 (2004).

fair use defense,[135] facilitate the access and use of works by the general public in appropriate situations.[136]

As Daniel J. Gervais elegantly reflected, "copyright is not a dam, it is a river."[137] Copyright law is a means to direct use (and optimize exploitation), rather than a tool to fend off users. In this light, the wise words of Justice Brennan resurface: "The zealous defense of the copyright owner's prerogative will, I fear, stifle the broad dissemination of ideas and information copyright is intended to nurture."[138]

Such malfunctions of the intellectual property system have at times become apparent. Faced with this situation, the state may adjust the way rightholders manage their IPRs, such as it did by enacting the Bayh-Dole Act.[139] Prior to this Act, it was very difficult to protect publicly funded discoveries using patents.[140] Therefore, under the earlier legal regime, inventions were rarely being commercially exploited because they could not be turned over to the private sector.[141] As a result, the taxpayer money that was invested in these inventions was not benefiting the public. The enactment of the Bayh-Dole Act enabled the commercial exploitation

[135] *See* 17 U.S.C. § 105; NIMMER & NIMMER, *supra* note 114, § 13.05. *See generally* KENNETH D. CREWS, COPYRIGHT, FAIR USE AND THE CHALLENGE FOR UNIVERSITIES: PROMOTING THE PROGESS OF HIGHER EDUCATION 30 (1993).
[136] Iowa State Univ. Research Found., Inc. v. American Broad. Cos., 621 F.2d 57, 60 (2d Cir. 1980) (statutory exceptions allow courts to "avoid rigid application of the copyright statute when, on occasion, it would stifle the very creativity which that law is designed to foster"); *see also* Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 577 (1994) (using the same language as *Iowa State University Research Foundation* in applying the fair use doctrine); Sarah E. Henry, *The First International Challenge to U.S. Copyright Law: What Does the WTO Analysis of 17 U.S.C. § 110(5) Mean to the Future of International Harmonization of Copyright Laws Under the TRIPs Agreement?*, 20 PENN. ST. INT'L L. REV. 301, 303 (2001).
[137] Gervais, *supra* note 109, at 7.
[138] Harper & Row Publishers, Inc. v. Nation Enters, 471 U.S. 539, 579 (1985) (Brennan, J., dissenting).
[139] Bayh-Dole Act, 35 U.S.C. §§ 200–12 et seq. (2010).
[140] Mary Eberle, *March-In Rights Under the Bayh-Dole Act: Public Access to Federally Funded Research*, 3 MARQ. INTELL. PROP. L. REV. 155, 157 (1999).
[141] *Id.* at 158.

of publicly funded inventions, by allowing grant recipients to obtain patents on them.[142] In essence, the Act employed incentives of the patent system to persuade private companies to develop publicly funded inventions into products serving the public.[143] Not surprisingly, in the unwavering pursuit of its mission, the NIH had long since recommended that NIH funded research tools patented by grant recipients be widely disseminated.[144]

b. International Copyright Framework

Although copyright law, and IP law in general, is a domestic affair, states must comply with international law to avoid facing sanctions from the international community. In the 19th century, international copyright protections were established by bilateral treaties, which provided mutual recognition of rights but lacked uniformity.[145] In an effort to increase homogeneity, the Berne Convention for the Protection of Literary and Artistic Works was adopted in 1886 and established uniform international standards of copyright protection.[146] The United States has been a party to the Convention since 1989.[147]

Through the 1970's and 1980's however, massive technology advances disturbed the IP landscape. As developed countries moved toward knowledge-based economies, IP gradually became a central concern in international trade negotiations.[148] In addition, the Berne Convention enabled states to self-regulate the enforcement of Berne requirements by avoiding the

[142] *Id.* §§ 202–203; *see also* Gary Pulsinelli, *Share and Share Alike: Increasing Access to Government-Funded Inventions Under the Bayh-Dole Act*, 7 MINN. J. L. SCI. & TECH. 393, 394 (2006).
[143] 35 U.S.C. § 200.
[144] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 (Dec. 23, 1999).
[145] WORLD INTELLECTUAL PROP. ORG., WIPO INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW AND USE ¶ 5.165 (2d ed. 2004), *available at* http://www.wipo.int/about-ip/en/iprm/ [hereinafter WIPO HANDBOOK].
[146] Berne Convention for the Protection of Literary and Artistic Works pmbl., Sept. 9, 1886, S. Treaty Doc. No. 99-27, 1161 U.N.T.S. 3 [hereinafter Berne Convention]; *see also* WIPO HANDBOOK, *supra* note 145, ¶ 5.166. *See generally* SCHECHTER & THOMAS, *supra* note 116, at 273–74.
[147] *Contracting Parties > Berne Convention*, WORLD INTELLECTUAL PROP. ORG., http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=15 (last visited Jan. 16, 2011).
[148] Haochen Sun, *Overcoming the Achilles Heel of Copyright Law*, 5 NW. J. TECH. & INTELL. PROP. 267, 274 (2007).

jurisdiction of the International Court of Justice through the escape clause of article 33.[149] At the end of the 1980's, it was recognized that uniform international protection standards were necessary.[150]

The issue was taken up within the General Agreement on Tariffs and Trade (GATT) in the framework of the Uruguay Round negotiations from 1986 to 1994, as well as by the World Intellectual Property Organization (WIPO) in 1996.[151] The Uruguay Rounds led to a major multilateral instrument for the globalization of IP laws, the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement.[152] The Uruguay Rounds also gave rise to the Marrakech Agreement whereby the GATT, organized to promote the reduction of tariff barriers to the international movement of goods,[153] was replaced by the World Trade Organization (WTO) to deal with the regulation of trade between states.[154] The United States, member of the defunct GATT, has been a member of the WTO since its establishment on January 1, 1995.[155]

The insertion of IP in the framework of international trade relations through the WTO in 1994 was a manifestation of the growing importance of IP in the stimulation of economic growth in industrialized countries, which became increasingly vulnerable to free riding and piracy.[156] Beyond offering minimum standards of protection to intellectual property, TRIPs also undertakes

[149] Berne Convention, *supra* note 146, art. 33(1) (giving jurisdiction to the International Court of Justice (ICJ) in case of dispute, but by virtue of art. 33(2), member states may declare that they are not subject to ICJ jurisdiction).
[150] WIPO HANDBOOK, *supra* note 145, ¶¶ 5.208–5.209.
[151] *Id.* ¶ 5.210.
[152] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 7, Apr. 15, 1994, 33 I.L.M. 1197, 1869 U.N.T.S. 299 (1994) [hereinafter TRIPs]. *See generally* MICHAEL BLAKENEY, TRADE ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A CONCISE GUIDE TO THE TRIPS AGREEMENT (1996); SCHECHTER & THOMAS, *supra* note 116, at 277–78.
[153] General Agreement on Tariffs and Trade, Oct. 30, 1947, T.I.A.S. No. 1700, 55 U.N.T.S. 194.
[154] *What is the WTO?*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Jan. 16, 2011).
[155] *Members and Observers*, WORLD TRADE ORG., http://www.wto.org/ english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 16, 2011).
[156] J.H. Reichman, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 VAND. J. TRANSNAT'L L. 747, 762–763 (1989).

to "reduce distortions and impediments to international trade . . . and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[157]

TRIPs incorporates articles 1 through 21 of the Berne Convention and, contrary to the Berne Convention escape clause, makes them unavoidable by attaching to them the WTO dispute resolution mechanisms.[158] Indeed, TRIPs avoids the self-regulation enabled by the Berne Convention and creates mandatory international IP norms. These norms must be implemented by any state seeking to gain access to international markets, which are opened by the WTO, as membership requires ratification of TRIPs.[159]

The WTO is also the primary body charged with enforcing WIPO-administered international treaties, such as the Berne Convention.[160] WIPO was established in 1974 to "promote the protection of intellectual property throughout the world through cooperation among States."[161] As one of the United Nation's specialized agencies, WIPO aims at homogenizing national IP protections.[162]

After the adoption of TRIPs, the WIPO Diplomatic Conference on Certain Copyright and Related Rights Questions addressed issues that had been neglected by the Agreement.[163] As a result, the WIPO Copyright Treaty (WCT) was adopted in 1996 to "develop and maintain the

[157] TRIPs, *supra* note 152, pmbl.
[158] Thomas E. Volper, *TRIPs Enforcement in China; A Case for Judicial Transparency*, 33 BROOK. J. INT'L L. 309, 309 (2007).
[159] Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U.J. INT'L L. & POL'Y 769 (1997).
[160] Jo Oliver, *Copyright in the WTO: The Panel Decision on the Three-Step Test*, 25 COLUM. J.L. & ARTS 119, 129, 133 (2002).
[161] Convention Establishing the World Intellectual Property Organization art. 3, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3.
[162] Henry, *supra* note 136, at 306.
[163] WIPO HANDBOOK, *supra* note 145, ¶ 5.211.

protection of the rights of authors in their literary and artistic works in a manner as effective and uniform as possible."[164]

Evidently, WCT objectives are compatible with the Berne Convention. The opening lines of the WCT provide that the Treaty is a "special agreement" within the meaning of article 20 of the Berne Convention.[165] This provision of the Berne Convention enables members to enter into special agreements amongst themselves as long as these agreements "grant to authors more extensive rights than those granted by the Convention, or contain other provisions not contrary to this Convention."[166] In other words, the WCT leaves no doubt that its interpretation may not reduce the level of protection granted by the Berne Convention.[167] The WCT addresses the need to define the international IP law as a result of modern information technology advancements.

Today, the essence of the international intellectual property framework is the harmonization of protections to fortify international trade. To this end, international IP law establishes minimum protection standards and regulates the permissible exceptions and limitations to copyrights.

i. Minimum Copyright Protections

As stated above, uniform standards of national protection facilitate the free flow of trade in copyright markets.[168] To this end, TRIPs gives effect to the minimum protection standards of the Berne Convention, which grant authors of literary and artistic works "the exclusive right of

[164] World Intellectual Property Organization: Copyright Treaty pmbl., Dec. 20, 1996, S. Treaty Doc. No. 105-17, 36 I.L.M. 65 [hereinafter WCT]. *See generally* Julie S. Sheinblatt, *The WIPO Copyright Treaty*, 13 BERKELEY TECH. L.J. 535 (1998).
[165] WCT, *supra* note 164, art. 1(1).
[166] Berne Convention, *supra* note 146, art. 20.
[167] WIPO HANDBOOK, *supra* note 145, ¶ 5.212.
[168] *See* Ruth Gana Okediji, *Symposium on Globalization at the Margins: Perspectives on Globalization from Developing States*, 7 IND. J. GLOBAL LEGAL STUD. 117, 119–20 (1999).

authorizing the reproduction of these works, in any manner or form."[169] It should be noted that the Berne Convention tends to reflect the natural law foundations of copyright law, emphasizing an author-centered approach. The WCT also favors an author-centered approach, granting authors "the exclusive right of authorizing the making available to the public of the original and copies of their works through sale or other transfer of ownership."[170] TRIPs, on the other hand, focuses upon utilitarian considerations and the protection of right holders.[171]

ii. Allowing States to Restrict Copyrights (Limitations and Exceptions in International Copyright Law)

The IP balancing act calls for limitations and exceptions to copyrights. The international protection regime supports this need and allows states to restrict copyrights.[172] As a matter of fact, the international regime homogenizes not only the minimum copyright protections, but also the copyright limitations and exceptions which are permitted. Prior to these provisions, initially incorporated to the Berne Convention in 1967, the allowed limitations or exceptions to copyright varied greatly from one state to another.[173] The Berne Convention, which solely considered the existence of reproduction rights, consequently only permitted limitations to these rights.[174] Later agreements, such as TRIPs, accepted the existence of a copyright bundle and therefore mirrored the permission for all exclusive rights.[175]

Besides allowing limitations and exceptions, TRIPs also explicitly recognizes public interest considerations by accepting that members "adopt measures necessary to protect public

[169] Berne Convention, *supra* note 146, art. 9(1).
[170] WCT, *supra* note 164, art. 6(1).
[171] SENFTLEBEN, *supra* note 134, at 17.
[172] *See generally* Sam Ricketson, *The Boundaries of Copyright: Its Proper Limitations and Exceptions: International Conventions and Treaties*, 1999 INTELL. PROP. Q. 56.
[173] Oliver, *supra* note 160, at 134.
[174] Berne Convention, *supra* note 146, art. 9.
[175] TRIPs, *supra* note 152, art. 13.

health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."[176]

In the context of the NIH Policy dissemination objectives, it is interesting to note that TRIPs also establishes that the "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[177] Similarly, the WCT preamble recognizes "the need to maintain a balance between the rights of authors and the larger public interest, particularly education, research and access to information as reflected in the Berne Convention."[178]

Although copyright limitations and exceptions[179] are undoubtedly permitted in the international regime, they are subject to certain conditions. The Berne Convention provides criteria to assess the validity of copyright limitations in domestic law. Indeed, limitations are permitted "in certain special cases," provided that they did not "conflict with a normal exploitation of the work" and did "not unreasonably prejudice the legitimate interests of the

[176] *Id.* art. 8(1); *see also* ICTSD-UNCTAD CAPACITY BLDG PROJECT ON IPRS AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT: AN AUTHORITATIVE AND PRACTICAL GUIDE TO THE TRIPS AGREEMENT 127 (Pedro Roffe et al. eds. 2005), *available at* http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (stating that TRIPs article 8 gives substantial discretion to states regarding the measures they may be adopt to address public health, nutrition and matters of vital importance; and suggesting that article 8 accords such measures a presumption of consistency with TRIPs, such that WTO Members seeking to challenge the measure bear the burden of proving inconsistency: "so long as sectors and measures are identified in good faith, the sovereign discretion of the Member adopting such measures should be accepted.").

[177] TRIPs, *supra* note 152, art. 7.

[178] WCT, *supra* note 164, pmbl.

[179] For simplicity, "limitations and exceptions" will be shortened to "limitations" for the purposes of this discussion.

author."[180] This assessment structure, now commonly referred to as the "Three-Step Test," has been included in later agreements, notably in the WCT as well as TRIPs for limitations to copyrights and patents.[181]

The Three-Step Test (Test) has been subject to a great deal of discussion and misunderstanding regarding its interpretation. This is likely due to the history of the Test's development. Indeed, when the Test was introduced to the Berne Convention, the domestic copyright law of member states had developed in various directions and already granted distinct limitations to the right of reproduction. [182] As a result, the wording of the Test was designed to be sufficiently vague to accommodate the various national limitations and exceptions.[183] Vague as it was, the Test was incorporated into TRIPs regarding limitations to not only reproduction rights, which were the sole rights protected by the Berne Convention, but on the whole bundle of copyrights secured by TRIPs:

> Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.[184]

While the escape clause contained in the Berne Convention allowed states to self-regulate (recall Berne Convention article 33), the Test's incorporation into TRIPs eliminated this option and subjected states to the WTO dispute settlement procedure in case of disagreement between states regarding the validity of a limitation. To date, states have availed themselves of this

[180] Berne Convention, *supra* note 146, art. 9(2); *see also* Kamiel J. Koelman, *Fixing the Three-Step Test*, 8 EUR. INTELL. PROP. REV. 407, 407 (2006).
[181] WCT, *supra* note 164, art. 10; TRIPs, *supra* note 152, arts. 13, 30.
[182] SAM RICKETSON, BERNE CONVENTION FOR THE PROTECTION OF LITERARY AND ARTISTIC WORKS: 1886-1986, at 482 (1987).
[183] *Id.*
[184] TRIPs, *supra* note 152, art. 13.

dispute settlement mechanism only once with regards to copyright limitations. That case was brought before the WTO Dispute Settlement Panel by the European Union regarding the United States Fairness in Music Licensing Act of 1998, which allowed restaurants, bars and shops to play radio and television broadcasts without paying licensing fees.[185] An interpretative analysis of the Three-Step Test led the Panel to rule that the U.S. legislation failed each step.[186] Although the decision is not binding on other member states, on domestic courts, and even arguably on a later WTO Panel,[187] it continues to be an important reference in the interpretation of the Three-Step Test and will serve as a guide in the discussion that follows.

iii. Understanding the Three-Step Test

It is generally understood that the Test contains three cumulative conditions. Each of the conditions must be met and failure to do so results in the exception being held invalid.[188] The Three-Step Test can be viewed as a basic rule (allowing limitations and exceptions in certain special cases), complemented by two criteria that delimit its scope (no conflict with normal exploitation of the work and no unreasonable prejudice to the legitimate interests of the right holder).[189] These criteria will be explained in more detail in the sections below.

A. Certain special cases

[185] Jane C. Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the "Three-Step Test" for Copyright Exceptions* 3 (Columbia Law Sch. Pub. Law & Legal Theory Working Paper Grp., Paper No. 19, 2001), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=253867.
[186] *Id.* at 5.
[187] Oliver, *supra* note 160, at 132–33.
[188] Panel Report, *United States – Section 110(5) of the US Copyright Act*, ¶ 6.107–6.109, WT/DS160/R (June 15, 2000) [hereinafter WTO Panel, *U.S. Copyrights*], *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds160_e.htm (click "Panel Report"; then click the first "E" in the "Original Format" column); *see also* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter WTO Panel, *Canada Patents*], *available at* http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (holding that failure to meet the requirements of one of the three steps will necessarily result in a violation of article 30 of TRIPs).
[189] SENFTLEBEN, *supra* note 134, at 125.

The first criterion of the Three-Step Test is relatively undisputed. Discussions regarding the possible meaning of "certain" as "sure" can be dismissed by an investigation of the French and Spanish versions of the TRIPs Agreement.

It is relevant to mention here that the French, English, and Spanish versions of WTO Agreements carry equal weight, as these are the official languages of the WTO.[190] Indeed, all WTO agreements, including TRIPs, are drafted in these three languages, none of which prevails over any other. In this regard, it is helpful to evoke the Vienna Convention on the Law of Treaties, which codifies customary international law, including treaty interpretation law.[191]

The Vienna Convention states that treaties authenticated in several languages are equally authoritative in each language.[192] Furthermore, terms of a treaty are presumed to have the same meaning in each authentic text.[193] Finally, when a comparison of authentic texts reveals a difference of meaning (which is not removed by the general rules of treaty interpretation), the meaning that best reconciles the texts, having regard to the object and purpose of the treaty, must be adopted.[194] This interpretation mechanism has notably been applied by the Court of Justice of the European Communities.[195] More to the point, it has also been employed by a WTO Panel in the interpretation of a WTO Agreement: "the terms of a treaty authenticated in more than one

[190] *See* HAMMOND SUDDARDS SOLICITORS, AN ANATOMY OF THE WORLD TRADE ORGANIZATION 51 (Konstantinos Adamantopoulos ed., 1997); Hiro Iwamura, *Memoir of International Trade Law: Issues of Translating WTO Safeguard Provisions into Japanese*, 5 ASIAN-PAC. L. & POL'Y J. 188, 193 (2004); Gerard de Graaf & Matthew King, *Towards a More Global Government Procurement Market: The Expansion of the GATT Government Procurement Agreement in the Context of the Uruguay Round*, 29 INT'L LAW. 435, 439 n.18 (1995).
[191] Vienna Convention on the Law of Treaties arts. 26–38, May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679 [hereinafter Vienna Convention], *available at* http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf.
[192] *Id.* art. 33(1).
[193] *Id.* art. 33(3).
[194] *Id.* art. 33(4).
[195] *See* Case 283/81, Srl CILFIT v. Ministry of Health, 1982 E.C.R. 3415, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61981J0283:EN:PDF.

language – like the WTO Agreement – are presumed to have the same meaning in each authentic text."[196]

This type of analysis is required if a treaty, such as TRIPs, is adopted without providing for the prevailing text in case of a divergence.[197] The Berne Convention on the other hand, did provide for the French text to prevail in case of differences of opinion on the interpretation of different versions.[198]

To return to the interpretation of the first criterion of the Three-Step Test, the French "certains" and the Spanish "determinados," leave no doubt that the term "certain" was not intended to mean "sure." In fact, the analysis of the three official texts of TRIPs supports Jane C. Ginsburg's interpretation that the first criterion of the Three-Step Test requires that the scope of the copyright limitation be well-defined ("certain") and narrowly limited to pursue an exceptional policy objective ("special").[199] This interpretation of certain special cases of copyright limitations and exceptions is usually summarized as requiring a narrow scope of application, in a quantitative as well as qualitative sense.[200] Although limitations and exceptions must be well defined, it is unnecessary to identify or enumerate their every possible application. It suffices that their scope of application is "known and particularized."[201] This is an important feature of permissible limitations, as it guarantees some degree of legal certainty.

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[196] Appellate Body Report, *United States – Final Countervailing Duty Determination with Respect to Certain Softwood Lumber from Canada*, ¶ 59, WT/DS257/AB/R (Jan. 19, 2004), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds257_e.htm (click "Appellate Body Report"; then click "E" in the "Original Format" column); *see also* Panel Report, *Argentina – Safeguard Measures on Imports of Footwear*, ¶ 8.166 n.530, WT/DS121/R (June 25, 1999), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds121_e.htm (click "Panel Report"; then click "E" in the "Original Format" column).
[197] Vienna Convention, *supra* note 191, art. 33(1).
[198] Berne Convention, *supra* note 146, art. 37(1)(c).
[199] Ginsburg, *supra* note 185, at 5.
[200] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.109.
[201] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶¶ 6.108, 6.113.

While Sam Ricketson, a leading authority on the Berne Convention, has held that copyright limitations must be justified by some "clear reason of public policy or some other exceptional circumstance,"[202] the WTO Panel rejected this view.[203] This follows WTO Appellate Body decisions that rejected the subjective aims pursued by national legislation as an interpretative tool for other WTO Agreements.[204] In brief, the legitimacy and efficacy of a policy objective is for the member state to decide.[205]

B. Normal exploitation of the work

Ricketson explains that the meaning of the second criterion of the Test is simply understood by "common sense," as "the ways in which an author might reasonably be expected to exploit his work in the normal course of events."[206] It is certainly clear that "normal exploitation" cannot be interpreted as the full use of all exclusive rights, as this interpretation would leave the provision permitting limitations devoid of meaning. As a result, "normal" must mean something less than the full use of exclusive rights.[207]

The WTO Panel dealt with the interpretation of the second criterion of the Three-Step Test in the similar context of TRIPs-allowed limitations to patent rights.[208] The Panel ruled that "exploitation" refers to the commercial activity by which right owners employ their exclusive

[202] RICKETSON, *supra* note 182, at 482.
[203] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶¶ 6.112–6.113.
[204] *See* Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, 19–23, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Oct. 4, 1996), *available at* http://www.worldtradelaw.net/reports/wtoab/japan-alcohol(ab).pdf (rejecting the "aims and effects" test in the context of the national treatment clause of article III of GATT 1994); *see also* Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, ¶¶ 241, 243, 246, WT/DS27/AB/R (Sept. 9, 1997) (*adopted* Sept. 25, 1997), *available at* http://www.law.georgetown.edu/iiel/cases/EC-Bananas(abr)(ab).pdf (rejecting the aims and effect test in the context of the national treatment clause of article XVII of GATS).
[205] Oliver, *supra* note 160, at 149 (discussing the WTO Panel's rejection of the view that a legitimate public policy is required to pass the first step of the Test).
[206] RICKETSON, *supra* note 182, at 482–83.
[207] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.167.
[208] WTO Panel, *Canada Patents*, *supra* note 188 (reporting on Canada's patent protection regime of pharmaceutical products).

rights to extract economic value from them.[209] The Panel ruled identically in the case of musical works.[210]

Beyond the fairly uncontested meaning of exploitation, the presence of the term "normal" raises more substantive questions. Although the Vienna Convention handles treaty interpretation, its provisions generally prescribe that treaties must be interpreted in accordance with the ordinary meaning of words used in their context, in light of the treaty's object and purpose,[211] and that special meanings can be given if it is established that the parties so intended.[212] The WTO Panel found no special meaning that was intended by the parties and explained that what is generally understood by "normal" can lead either to an empirical conclusion denoting the way in which a work is in fact exploited in the relevant community or to a normative standard of entitlement, related to potential, permissible or desirable exploitations.[213]

This difference in connotations is significant. Indeed, under the auspices of the empirical approach to defining normalcy, uses from which an owner would not ordinarily expect to receive compensation (such as researchers reporting their results in manuscripts) would not be considered part of normal exploitation.[214] On the other hand, the normative approach would ban uses that have, or are likely to acquire, considerable economic importance; commercial gain for the work being reserved to their authors.[215]

[209] *Id.* ¶ 7.54.
[210] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.165.
[211] Vienna Convention, *supra* note 191, art. 31(1).
[212] *Id.* art. 31(4).
[213] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.166.
[214] *Id.* ¶ 6.177.
[215] *Id.* ¶ 6.179 (following the suggestion of the Government of Sweden, with the assistance of the Bureaux for the Protection of Intellectual Property, the predecessor organization of WIPO, that the exception should not enter into economic competition with the right holder).

The Panel concluded that the word "normal" was being used in a sense that combined both meanings.[216] The Panel also took care to note that not all uses that involve commercial gain necessarily conflict with a normal exploitation of the work, showing tendencies toward a more empirical approach. According to the Panel, limitations to an exclusive right in domestic legislation "rises to the level of a conflict with a normal exploitation of the work if uses, that are in principle covered by that right but exempted under the limitation, enter into economic competition with the ways that right holders normally extract economic value from that copyright and thereby deprive them of significant or tangible commercial gains."[217]

Martin Senftleben makes sense of this finding by explaining that only loss to actual or potential modes of exploitation that typically constitute a major source of income are prohibited, leaving copyright limitations possible on forms of exploitation that generate only relatively few revenues.[218]

C. Unreasonable prejudice to legitimate interests

The third and last criterion is arguably the most nebulous of the three steps. "Prejudice" is likely the easiest notion to define, according to the ordinary meaning and what is generally understood in legal jargon as damage, harm or injury.[219]

The third step aims to protect the legitimate interests of the right holder, which are defined by the Panel as "legal rights to a property, or the use or benefits of a property."[220] The Panel further explains that the term "may also refer to a concern about a potential detriment or advantage, and more generally to something that is of some importance to a natural or legal

[216] *Id.* ¶ 6.166; *see also* WTO Panel, *Canada Patents*, *supra* note 188, ¶ 7.54.
[217] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.183.
[218] SENFTLEBEN, *supra* note 134, at 193–94.
[219] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.220.
[220] *Id.* ¶ 6.223.

person."[221] Interestingly the Panel's language tempers the notion of prejudice by allowing potential harm, and extends the interpretation of this step beyond economic harm, despite the fact that TRIPs did not incorporate the non-economic interests handled by article 6 of the Berne Convention.[222]

Although the criterion requires that the protected interests be legitimate, legitimacy of the authors' interests in economic gain is manifest. Note, however, that this language does restrict author interests in some manner. For instance, an author would not have a legitimate interest in preventing the publication of an unfavorable book review.[223] Thus, given that any limitation imposed on exclusive rights must necessarily result in some degree of prejudice to the legitimate interests of the right holder, the key question is: how much prejudice is unreasonable? The very existence of the provision permitting limitations undoubtedly presupposes that a certain amount of prejudice must be reasonable.[224] The WTO Panel deemed that a prejudice is unreasonable if it causes or has the potential to cause an unreasonable loss of income to the copyright owner.[225]

Though this conclusion may appear unavailing, some useful illations may be derived. First, the conclusion suggests that the copyright holder must be extracting income from the use seeking to be restricted in order for the limitation to result in loss of income. Second, it allows some degree of flexibility as the limitation may be invalid even if it is not certain that such limitation would cause prejudice. Lastly, the Panel's wording implies that at least some loss of income must be deemed reasonable.

[221] *Id.*
[222] *Id.* ¶ 6.220.
[223] Ginsburg, *supra* note 185, at 9.
[224] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.220.
[225] *Id.* ¶ 6.229.

V. ANALYSIS: THE RECALIBRATION OF COPYRIGHTS

Copyrights must exist in equilibrium with a matrix of social, legal, and technical elements. Changes or developments in the matrix have the potential to perturb the copyright balance and lead to perverse consequences that are out of line with the basic objectives of the IP protection system.[226] These changes may also open the door to new avenues that may serve the IP system goals better. When this type of perturbation arises, the legislator may step in to restore the balance and further the goals of IP.

The NIH Policy is an example of such legislative intervention, catalyzed by technological change. In this regard, Dr. Elias Zerhouni (Director of NIH, 2002 to 2008)[227] announced before a House Judiciary Committee discussing the Fair Copyright in Research Works Act: "We wouldn't be here unless the world of information technology had not changed."[228]

Legislatures must bear their international obligations in mind when recalibrating the national copyright landscape. In times of upheaval and change, the Three-Step Test acts as an appraisal of validity for any limitations or exceptions envisaged by states. The abstract nature of the criteria imparts stability to the Test, which remains unaffected by changes in the matrix.[229] The following will examine whether the legislative action taken by the United States government, and embodied in the NIH Policy, is valid with respect to the Three-Step Test. Before advancing any further, it should be noted that national legislative action must first be a "limitation or exception to exclusive rights," in order to even trigger the Three-Step Test.

a. Limitation or Exception to Exclusive Rights

[226] SENFTLEBEN, *supra* note 134, at 35.
[227] News Advisory, Nat'l Insts. of Health, Elias A. Zerhouni to End Tenure as Director of the National Institutes of Health (Sept. 24, 2008), *available at* http://www.nih.gov/news/health/sep2008/od-24.htm.
[228] *Hearing*, *supra* note 16, at 16 (testimony of Dr. Elias A. Zerhouni).
[229] SENFTLEBEN, *supra* note 134, at 35.

Some authors explain that the seemingly duplicated inclusion of "limitations" and "exceptions" is caused by the circumstances of TRIPs negotiations, which were conducted against the backdrop of common law ("limitations") and civil law ("exceptions") traditions.[230] The WTO Panel has nonetheless interpreted the two terms differently; the former as a reduction of an exclusive to some extent, and the latter as a derogation from such right in some respect.[231]

In light of the above definitions of the terms "limitation" and "exception," it remains unclear whether the NIH Policy is a limitation to copyrights. In fact, the Policy can be viewed as implicitly reaffirming exclusive rights by forcing authors to efficiently manage their copyrights.[232] Indeed, to comply with the Policy authors must negotiate with publishers to include an agreement clause ensuring that the author retains the right to provide a copy of the final manuscript to NIH. Thus, the author's copyright is left intact; the Policy only creates a contractual obligation between the author and the NIH regarding the management of a copyrighted work generated by NIH funding.[233] The copyright therefore continues to be held by the author. As a result, there is no involuntary transfer of copyright ownership: the Policy calls for a non-exclusive license in exchange for funding.[234]

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[230] *Id.* at 22.
[231] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.107–6.109.
[232] Scholarly Publ'g & Academic Res. Coal., *NIH Public Access Policy Does Not Affect U.S. Copyright Law*, ASS'N RES. LIBR. 3 (July 2008), http://www.arl.org/sparc/bm~doc/nihpolicy_copyright_july2008.pdf.
[233] Nelson, *supra* note 99, at 443.
[234] If the NIH Public Access Policy were considered an involuntary transfer, it could be equated to a "taking," as provided in the U.S. Constitution. Although unlikely to succeed, the Policy could therefore become the basis for compensation claims under the Takings Clause of the U.S. Constitution. This Clause forces the government to pay just compensation when it takes private property. U.S. CONST. amend V ("Nor shall private property be taken for public use, without just compensation."). As intellectual property is a form of private property, the Policy could be portrayed as a taking, thereby forcing the government to compensate. However, it is generally accepted that IP takings law is virtually non-existent in the United States. In fact, IP taking cases are very rare and have been limited to patent takings; no copyright taking case has yet been brought before the courts.

A recent case before the U.S. Court of Appeals for the Federal Circuit, *Zoltek Corp. v. United States*, 442 F.3d 1345, 1350–51 (2006), confirmed the Supreme Court's ruling in *Schillinger*, rejecting the argument that a patentee could sue the government for patent infringement as a Fifth Amendment taking. Schillinger v. United States, 155

This type of contractual exchange is not new in the sphere of intellectual property. In fact the Office of Management and Budget (OMB) Circular A-110 sets out that federal funding agencies in the United States shall reserve a license to use works that are generated from federal grant money by institutions of higher education, hospitals, and other non-profit organizations.[235] While grant recipients are permitted to copyright these works, the agency "reserve[s] a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so."[236]

Although routinely ignored by other agencies,[237] OMB Circular A-110 has been implemented by the National Science Foundation (NSF).[238] The NSF is an independent federal agency created by Congress to promote the progress of science.[239] The Foundation is charged with "initiating and supporting basic scientific research"[240] and fostering "the interchange of scientific information among scientists and engineers in the United States and foreign countries .

U.S. 163, 169 (1894). *Zoltek* likely closes the door on patent takings, perhaps unless the governmental action lacks public purpose, which would violate the Fifth Amendment. *Cf.* Christina Bohannan & Thomas F. Cotter, *When the State Steals Ideas: Is the Abrogation of State Sovereign Immunity from Federal Infringement Claims Constitutional in Light of Seminole Tribe?*, 67 FORDHAM L. REV. 1435, 1507 (1999) (discussing whether state infringement of intellectual property could be a violation of substantive due process and observing that "it is unlikely that intellectual property is a 'fundamental' property interest in modern constitutional parlance"). *But see* Justin Torres, Note, *The Government Giveth, and the Government Taketh Away: Patents, Takings, and 28 U.S.C. § 1498*, 63 N.Y.U. ANN. SURV. AM. L. 315 (2007) (arguing that patentees should be provided with just compensation for infringement by the government).

[235] Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 HARV. J. ON LEGIS. 369, 369 (2000).

[236] Circular from the Office of Mgmt. & Budget, The White House, to Heads of Exec. Dep'ts & Establishments (Sept. 30, 1999) *available at* http://www.whitehouse.gov/omb/circulars/a110/a110.html (concerning the uniform administrative requirements for grants and agreements with institutions of higher education, hospitals, and other non-profit organizations).

[237] Trosow, *supra* note 31, at 631.

[238] OFFICE OF BUDGET, FINANCE & AWARD MGMT., NAT'L SCI. FOUND., GRANTS POLICY MANUAL, at I-5 (2005) [hereinafter NSF GRANTS MANUAL], *available at* http://www.nsf.gov/pubs/manuals/gpm05_131/gpm05_131.pdf.

[239] National Science Foundation Act of 1950, Pub. L. No. 81-507, 64 Stat. 149 (codified at 42 U.S.C. §§ 1861–1887 (2006)).

[240] 42 U.S.C. § 1862(a)(1) (2006).

. . ."[241] To this end, it supports almost half of the non-medical, basic research conducted at colleges and universities.[242] NSF grant recipients may own or permit others to own copyrights, but those copyrights are subject to a non-exclusive, nontransferable, irrevocable, royalty-free license belonging to the federal government, to be used for federal purposes.[243]

Similar practices are also emerging for patent licenses in exchange for funding. According to recent studies, a growing number of governmental funding agencies are requiring that patented inventions resulting from grants be made widely available by grant recipients for purposes of noncommercial research.[244]

Generally speaking, research funding is often subject to conditions. In the cases discussed in this section, these conditions involve licensing of publicly funded IP to the funding agencies, for the benefit of the public. In other words, the NIH Policy addresses contractual terms between researchers and a funding agency, rather than copyright limitations. If a researcher does not wish to enter into such an agreement, he is free to turn down NIH funding.

Opponents of the Policy might argue that researchers do not have this freedom, because of the preeminent role of NIH funding in the biomedical research sector. Following this reasoning, it would be difficult to defend publisher copyright transfer agreements that are often conditional to publication, given the crucial importance of publication in this sector. Yet manuscript copyrights are commonly transferred to publishers and such transfers are a well-accepted fact of life for researchers.

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[241] *Id.* § 1862(a)(3).
[242] Trosow, *supra* note 31, at 635.
[243] NSF GRANTS MANUAL, *supra* note 238, at VII-17.
[244] *See* Peter Lee, *Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 889, 893 (2009).

The American Association of Publishers (AAP), however, insists that the NIH Public Access Policy is unlawful. In response to the NIH invitation for public comment regarding the Policy,[245] the AAP submitted an opinion letter, which implies that the NIH Policy is a limitation or exception to copyrights. [246] The AAP Opinion Letter also contends that the Policy fails every step of the Three-Step Test.[247] Before coming to any conclusions regarding the validity of the NIH Policy under the Three-Step Test, the Policy details will be examined.

b. The Particular Provisions of the NIH Policy

The NIH Public Access Policy was specifically designed to heighten the integration and accessibility of biomedical research results, as discussed above. To this end, the Policy contains specific provisions, which direct and contain the application of its public access requirements:

1. Manuscripts that are directly funded by an NIH grant or cooperative agreement in 2008 and beyond are subject to the Policy.[248]
2. The Policy requires that authors deposit the final, peer-reviewed author manuscript (not the copy edited version that is published by the journal).
3. Following publication, authors have 12 months to comply with the Policy, thereby leaving journals publishing NIH funded works one full year of publication exclusivity.

[245] *Notice of Public Meeting: Seeking Comments on Implementation of the NIH Public Access Policy*, NAT'L INSTS. HEALTH (Mar. 7, 2008), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-057.html; *see also Request for Information: NIH Public Access Policy*, NAT'L INSTS. HEALTH (Mar. 28, 2008), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-060.html.
[246] Letter from Allan Adler, Vice President for Legal & Governmental Affairs, Ass'n of Am. Publishers, to Nat'l Insts. of Health (May 30, 2008), *available at* http://publicaccess.nih.gov/comments2/files/AAP_NIH_Submission_05_30_08.pdf.
[247] *Id.*
[248] *Determine Applicability*, NAT'L INSTS. HEALTH, http://publicaccess.nih.gov/determine_applicability.htm (last visited Jan. 16, 2011). It should be noted that as a result of the limited wording of this requirement, all research articles submitted for publication outside of NIH grants or cooperative agreements remain untouched by the policy.

Beyond the particularities of the NIH Policy itself, the subject matter of NIH funded research manifests distinctive characteristics.

c. The Peculiar Case of Research in the Biomedical Sciences

Legally speaking, all original works are protected by copyright, whether the work is artistic or scientific.[249] Even so, a fundamental distinction is instinctively perceived between the publication of scientific articles and that of poetry. The rationale behind this distinction lies at the very heart of the unique ethos of science. According Robert Merton, the first great sociologist of science, the "institutional goal of science is the extension of certified knowledge."[250]

On this topic, the Access to Knowledge (A2K) Draft Treaty recognizes the peculiarity of science in its section regarding digital rights management, which would allow broader restrictions on technological protection measures for works of medical and scientific literature.[251] Interestingly, the Draft Treaty would also weaken these restrictions for works that are substantially financed by national governments.[252] The Draft Treaty was developed by an international coalition of intellectual property activists,[253] in response to the call from Brazil and Argentina for establishing a development agenda for the World Intellectual Property Organization.[254]

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[249] SAM RICKETSON & JANE C. GINSBURG, INTERNATIONAL COPYRIGHT AND NEIGHBORING RIGHTS: THE BERNE CONVENTION AND BEYOND 406, 413 (2d ed. 2005) (noting that scientific articles are subject to copyright: "written description of an experiment, process, device or the like"); *see also* MERGES, *supra* note 113, at 372 (stating that only a modicum of originality is required).

[250] ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267, 270 (Norman W. Storer ed., 1973) (further describing science as comprised of four basic norms: communalism, universalism, disinterestedness and organized skepticism).

[251] Draft Treaty on Access to Knowledge art. 3-6(b)(v)(2), May 9, 2005, *available at* http://www.cptech.org/a2k/a2k_treaty_may9.pdf (last visited Apr. 21, 2010).

[252] *Id.* art. 3-6(b)(v)(3).

[253] Madhavi Sunder, *IP*^{3}, 59 STAN. L. REV. 257, 310 (2006).

[254] *See* WIPO General Assembly, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11 (Aug. 27, 2004), *available at* http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_11.pdf; *see also* WIPO General Assembly

i. Nature and use of scientific scholarly communications

Science is the exercise of continually seeking "closer approximations to the truth."[255] To be sure, scientific research aims to discover the fundamental laws that govern the physical and natural world; scientific articles communicate advancements in this quest.

Consequently, the value of scientific scholarly communication lies mostly in the results obtained, the experimental procedures used and the interpretation and analysis of observations; much less value lies in the written expression of this information. It is the raw information expressed in scientific articles that users seek out. In other words, scientific research leads to the discovery of "knowledge goods that have intrinsic value."[256] Without suggesting that scientific articles are not subject to copyright, it could be argued that the communication of scientific research results in journals are akin to the communication of "ideas," rather than the customary expression of ideas which usually protected by copyright.

The value of scientific information emphasizes the importance of the "New Invisible College" in science, whereby research occurs within a global network of scientists, interconnected by the internet and communicating through journal publications. In support of this, studies have shown that scientists turn to published articles in their research to a much greater extent than researchers in other fields, such as arts and the humanities. For instance, the number of articles read by faculty members in medicine is almost three times that in the

Draft Report, *Inter-Sessional Intergovernmental Meeting on a Development Agenda for WIPO*, IIM/3/3 Prov. (Aug. 12, 2005), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/iim_3/iim_3_3_prov.pdf.

[255] Cyril N. Hinshelwood, Nobel Lecture (Dec. 11, 1956), *available at* http://nobelprize.org/nobel_prizes/chemistry/laureates/1956/hinshelwood-lecture.pdf (Sir Hinshelwood was awarded the 1956 Nobel Prize in Chemistry for his research into the mechanism of chemical reactions).

[256] Michael J. Madison, *The Idea of the Law Review: Scholarship, Prestige and Open Access*, 10 LEWIS & CLARK L. REV. 901, 923 (2006).

humanities.[257] In general, faculty members in sciences, medicine and health, read significantly more scholarly journal articles than faculty members in social sciences and the humanities.[258] Likewise, scientists use journals to disseminate their work more than researchers in other fields.[259] These studies illustrate how scientists depend on the scholarly publication system, which may help explain the quasi-monopoly that journals publishers hold.

Since scientific knowledge is valuable when it is employed and applied, it follows that the communication of results is time sensitive.[260] Indeed, undisclosed results can cause redundant research efforts. Therefore, scientific information is in principle most useful immediately after its discovery. This is reflected in user behavior. While access to results is difficult immediately following discovery, users do have access after publication and it has been found that the majority of article readings come from articles no more than one year old.[261]

[257] MARK WARE & MICHAEL MABE, THE STM REPORT: AN OVERVIEW OF SCIENTIFIC AND SCHOLARLY PUBLISHING 29 (2009), *available at* http://www.stm-assoc.org/2009_10_13_MWC_STM_Report.pdf.
[258] Carol Tenopir et al., *Variations in Article Seeking and Reading Patterns of Academics: What Makes a Difference?*, 31 LIBR. & INFO. SCI. RES. 139, 142 (2009) [hereinafter Tenopir et al., *Variations*]; *see also* Donald W. King et al., *Patterns of Journal Use by Faculty at Three Diverse Universities*, D-LIB MAG., Oct. 2003, *available at* http://www.dlib.org/dlib/october03/king/10king.html; Carol Tenopir et al., *Medical Faculty's Use of Print and Electronic Journals: Changes Over Time and Comparison with Other Scientists*, 92 J. MED. LIBR. ASS'N 233, 237 (2004) [hereinafter Tenopir et al., *Medical Faculty*].
[259] THE UNIV. OF CAL. OFFICE OF SCHOLARLY COMMC'N & THE CAL. DIGITAL LIBRARY ESCHOLARSHIP PROGRAM, FACULTY ATTITUDES AND BEHAVIORS REGARDING SCHOLARLY COMMUNICATION: SURVEY FINDINGS FROM THE UNIVERSITY OF CALIFORNIA 83 (2007), *available at* http://osc.universityofcalifornia.edu/responses/materials/OSC-survey-full-20070828.pdf (reporting percentage of researchers by discipline that published to a subscription-based journal in 2006, by discipline: Physical Sciences - 95%; Life and Medical Sciences - 93%; Humanities - 83%; Arts - 64%).
[260] *See* Kevin L. Smith, *Open Access and Authors' Rights Management: A Possibility for Theology*, THEOLOGIAN LIBRARIANSHIP, June 2009, at 45, 47, *available at* http://journal.atla.com/ojs/index.php/theolib/article/view/73/243.
[261] Tenopir et al., *Variations*, *supra* note 258, at 141; Tenopir et al., *Medical Faculty*, *supra* note 258, at 238; *see also* King et al., *supra* note 258, at 134 (survey of five U.S. universities, which together have academic programs in all major areas, including: medicine and other health-related fields, engineering, life and physical sciences, social sciences, law, business, education, humanities, literature, and history).

In the fast paced world of science and medicine, one year is a long time.[262] Internationally, major funding agencies of scientific and medical research results (UK Wellcome Trust, UK Research Council, European Research Council, Canadian Research Council, Australian Research Council) are attuned to the time-sensitive nature of results and are already requiring public access to funded journal publications after a six-month delay.[263]

The NIH Policy also gives deference to these features of scientific information. In formulating the Policy, the NIH recognized the time-sensitivity of results and the importance of access, while respecting the journal publishing system by granting publishers a one-year time window.

ii. The concerns of the authors[264]

Scholarly journal publication is distinctive in its lack of royalty generation.[265] Scientists traditionally publish for impact and dissemination of results, rather than payment. They dream of publishing the kind of results that will be not only extensively used but also highly esteemed by peers, who are best qualified to assess its worth.[266] Publication of results also allows researchers to make a contribution to science and more importantly, to publicly designate this contribution as their own. Beyond career promotions and funding, publication gives rise to recognition of the source of the contribution by fellow scientists.

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[262] *Hearing*, *supra* note 16, at 58 (testimony of Ms. Heather Dalterio Joseph, Executive Director, Scholarly Publishing and Academic Resources Coalition).
[263] *Id.* at 91 (testimony of Dr. Elias A. Zerhouni).
[264] S*ee generally* DIANE HARLEY ET AL., ASSESSING THE FUTURE LANDSCAPE OF SCHOLARLY COMMUNICATION: AN EXPLORATION OF FACULTY VALUES AND NEEDS IN SEVEN DISCIPLINES (2010), *available at* http://escholarship.org/uc/cshe_fsc.
[265] Albert, *supra* note 32, at 255.
[266] Robert K. Merton, *Foreword* to EUGENE GARFIELD, CITATION INDEXING—ITS THEORY AND APPLICATION IN SCIENCE, TECHNOLOGY, AND HUMANITIES, at v, v–ix (ISI Press 1983), *available at* http://garfield.library.upenn.edu/ci/foreword.pdf.

As copyright is at least partly intended to foster the creation of works, it should be understood that even the complete denial of copyrights for scientific articles would not deter scientists from writing them and hoping to disseminate their results. Their only concern in this case would be proper attribution of work and protection against plagiarists. It could be argued that this is a limited view, since publishers would refuse to publish articles (or would charge authors to publish), if the works were not granted copyright.[267] This underlines the importance of the 12 month time window accorded by the NIH Policy, giving publishers the opportunity to capitalize on this exclusivity for one full year.

Importantly, publishers typically make the bulk of their sales in the first year of publication.[268] Moreover, some commercial publishers have embraced public access by voluntarily surrendering exclusivity while continuing to succeed financially. The Rockefeller University Press, for instance, publishes three biomedical journals (The Journal of Cell Biology, The Journal of Experimental Medicine, The Journal of General Physiology) and makes all research articles from its journals available on PMC after a six-month embargo.[269]

This model is compatible with author interests in the attribution of source, as well as in the broad availability of their work. Broad dissemination might even increase citations to their work, a sought after commodity in the harsh publish-or-perish world of research.[270] The NIH Policy operates in a similar fashion and similarly coincides with the aspirations of researchers.

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[267] *See generally* Steven Shavell, *Should Copyright of Academic Works Be Abolished?*, BERKMAN CENTER FOR INTERNET & SOC'Y HARVARD U., http://cyber.law.harvard.edu/sites/cyber.law.harvard.edu/files/Copyright%207-17HLS-2009.pdf (last visited Jan. 15, 2011).

[268] *See Hearing*, *supra* note 16, at 2 (statement of Hon. Howard Berman, Chairman, Subcommittee on Courts, the Internet, and Intellectual Property).

[269] *Copyright Policy*, ROCKEFELLER U. PRESS § 4, http://www.rupress.org/subscriptions/terms.dtl (last visited Jan. 15, 2011); *cf. University Overview and Quick Facts*, ROCKEFELLER U., http://www.rockefeller.edu/about (last visited Jan. 15, 2011) (showing the University's mantra: "Science for the benefit of humanity").

[270] Bramble, *supra* note 34, at 220–21.

iii. Manifest public interest in publicly funded products of scientific research

Researchers, especially in the medical and life sciences, also inevitably aspire to help humankind by furthering knowledge and understanding. NIH researchers handle a wide variety of topics affecting everyone in one way or another.[271] In 2009, scientific efforts funded by the NIH led to developments in a cocaine vaccine for treatment of drug addiction, gene therapy for eye conditions and deep brain stimulation to curb Parkinson's symptoms.[272]

Stem cell research also holds great promise for improved health, notably offering "the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions, and disabilities including Parkinson's disease, amyotrophic lateral sclerosis, spinal cord injury, burns, heart disease, diabetes, and arthritis."[273]

Benefits deriving from scientific and medical research, as well as the advancement of knowledge, are undeniable. This manifest public interest in the advancement of scientific knowledge is reflected in the NIH Policy that, as seen above, seeks to improve health by increasing the integration and accessibility of biomedical research results.[274] This also coincides nicely with researcher aspirations.

Finally, let it not be forgotten that the public itself funded these results. Many argue that the public has an inherent right to access the research that it has paid for.[275] In support of this, the

[271] *About the National Institutes of Health*, NAT'L INSTS. HEALTH, http://www.nih.gov/about/index.html (last visited Jan. 16, 2011).
[272] *Selected Research Advances of NIH*, NAT'L INSTS. HEALTH, http://history.nih.gov/about/timelines_research_advances.html#2009 (last visited Jan. 15, 2011).
[273] *Stem Cell Information: Stem Cells and Diseases*, NAT'L INSTS. HEALTH, http://stemcells.nih.gov/info/health.asp (last visited Jan. 15, 2011).
[274] *See* NIH COMMENT ANALYSIS, *supra* note 90.
[275] Nelson, *supra* note 99, at 426; *see also* Trosow, *supra* note 31, at 647. *See generally* Public Access to Science Act, H.R. 2613, 108th Cong. (2003) (excluding from copyright protection works resulting from federally-funded scientific research); Federal Research Public Access Act of 2009, H.R. 5037, 111th Cong. (2010) (providing free public access to federally-funded research); Eisen & Gass, *supra* note 7 (arguing for free public access to scientific journal articles).

Organization for Cooperation and Development (OECD) has called for a new international norm, compelling full and open access to scientific data from publicly funded research.[276]

d. Does the NIH Public Access Policy Pass the Test?

Despite the doubts surrounding whether the NIH Policy is a limitation or exception to copyrights, it is worthwhile to investigate whether the Policy would nevertheless be found justified in international law. To be sure, a public interest imperative might lead to legislative action imposing a limitation or exception to copyrights, which is nonetheless valid and compliant with international obligations.[277] The Three-Step Test, as stated above, acts as the validity assessment structure for limitations to copyrights.

The discussion that follows examines the Test, while bearing in mind the particular provisions of the NIH Policy (publicly funded research results, scientific and medical subject matter, one year embargo, deposit of final, peer-reviewed author manuscript).

i. Certain special cases

At the outset, a limitation must be clearly defined such that it is known and particularized, in order to pass the first step. This is the case for the NIH Policy, which applies only to publications that have been directly funded by the NIH.

It could be argued that day-to-day labwork might blur the line between those efforts that are NIH funded and those that are not. This would create uncertainty and therefore could render the exception less clearly identifiable. This view ignores the capabilities of research laboratories,

[276] ORG. FOR ECON. CO-OPERATION & DEV., OECD PRINCIPLES AND GUIDELINES FOR ACCESS TO RESEARCH DATA FROM PUBLIC FUNDING 11 (2007), *available at* http://www.oecd.org/dataoecd/9/61/38500813.pdf.
[277] Gervais, *supra* note 109, at 19 (reviewing the WTO Panel's interpretation of the second and third steps).

which are already in place. Indeed, research grants are generally directed toward a particular project and funding sources usually require that funds only be used for that project. As a result, researchers are well accustomed to managing research expenses with respect to the appropriate grants, as well as identifying the specific funding source for each of their efforts.

Thus, the NIH Policy therefore identifies specific works that are subject to public access requirements. The Policy restricts application only to future scientific and medical scholarly published works, which were directly funded by the NIH. In the vast realm of copyrights, these elements create a foreseeable, narrow, "discrete and discernible category of works separate and distinct from other works."[278]

The WTO Panel held that the legitimacy of public policy objectives pursued by legislation, and the efficacy of such legislation in attaining them, is not relevant to the application of the Three-Step Test; that the legislation must only be shown to pursue a particular objective.[279] Regardless, even if the legitimacy of the NIH Policy objectives were considered, it would be difficult to argue that these are not in legitimate pursuit of the public interest. Indeed, the Policy aims to benefit the public directly by granting free access to publicly funded research. Perhaps more importantly, the Policy also aims to benefit the public indirectly through improved science and medicine.

It has been suggested that the first step should not be dwelled upon in too great detail.[280] Accordingly, focus will now be shifted to the two criteria that delineate the scope of the first condition.

[278] Trosow, *supra* note 31, at 677.
[279] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶¶ 6.108–6.110; Gervais, *supra* note 109, at 14.

[280] DANIEL J. GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 144–47 (2d ed. 2003) (arguing that the Test is in fact a two-step test and that little attention should be paid to the meaning of "special").

ii. Normal exploitation of the work

Before moving forward with the analysis of this criterion, it should be noted that the NIH Policy is not retroactive and only applies to future NIH funded works that are written. Thus its effects on copyright owners only have bearing on authors and not on publishers, who do not yet own copyrights on works to be targeted by the Policy. In addition, the Policy requires only the deposit of the final, peer-reviewed author manuscript rather than the version that is copy-edited and published by the journal.[281] In this sense, the Policy does not affect publisher copyrights. This reveals that the assessment of the second step should be entirely focused on whether the Policy conflicts with researchers' normal exploitation of the work.

As stated above, interpretation of the second step leaves room for normative and empirical approaches. Despite this variance, it is generally agreed that economic loss to the author is decisive in finding a conflict with normal exploitation.[282] As we have seen, authors in the scientific field do not seek to profit directly from the publication of scholarly journal articles. They wish to share their discoveries and heighten their visibility, prestige and recognition by peers. Without existing profits to be lost, the two approaches must be examined more closely.

A. The empirical approach

The empirical approach to interpreting "normal exploitation" involves the appraisal of the authors' actual and current exploitation of the work. Following the WTO Panel ruling, the Policy would fail the second step if the public access requirement enters into "economic competition with the ways that right holders normally extract economic value from that copyright . . . ."[283]

[281] Consolidated Appropriations Act of 2008, H.R. 2764, 110th Cong. § 218, at 344 (2007) (enacted).
[282] Koelman, *supra* note 180, at 409 (discussing the various perspectives on determining the harm to right holders caused by national law limitations or exceptions to copyright).
[283] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.183.

For the reasons described above—namely that authors do not directly extract economic value from journal publications—the empirical approach points to the conclusion that the NIH Policy does not contravene the second criterion.

Having said that, it is important to remember that researchers do "exploit" their works in some sense by extracting benefits from the publication of their work, even though these benefits are not direct financial rewards. Indeed, publication in specific, often leading, journals is the normal way for authors to extract value from their work (indirectly, by using that publication as leverage in grant applications, for instance). At this point, it should be highlighted that the NIH Policy does not prohibit this use. Admittedly, the public access requirement is triggered if and only if the work is in fact published. It is true however that the Policy could motivate some journal publishers to reject concerned manuscripts for publication, arguably reducing the author's ability to publish.[284]

Could this potential effect of reducing the likelihood of a paper's acceptance for publication in a particular journal be considered as economically competing with the ways that right holders normally extract economic value from that copyright? It seems unlikely. The publishers' Policy-motivated refusal is an indirect consequence of the NIH Policy requirements. Indirect consequences, those that exhibit a link too tenuous with the alleged cause, are typically disregarded in both common and civil law systems. In cases of tort liability for instance, there must be a direct causal link between the action of the defendant and harm to the plaintiff.[285] The

[284] It should not be forgotten that even the refusal of some journals to publish will not prevent authors from submitting either to different journals or to consider alternatives to traditional publishing models, such as open access journals.

[285] *See* CODE CIVIL [C. CIV.] art. 1382 (Fr.) (establishing the liability of a person who causes injury: "Tout fait quelconque de l'homme qui cause, un dommage, oblige celui par la faute duquel il est arrivé, à le réparer" or "Any act of man that causes damage, obliges the one by whose fault it happened to repair it"); Civil Code of Québec, S.Q. 1991, c. 64, art. 1457 (Can.) (a person is responsible for any injury he causes to another by his own fault); *see, e.g.*,

reduced likelihood of publication exhibits a link to NIH actions that could be considered broken by the superseding actions of the publisher.[286]

In any case, while publishers are protesting the NIH public access requirements, there is no solid evidence to indicate that they would in fact deny acceptance on that basis. The publishers have neither stated their intention to refuse concerned manuscripts nor would it be in their best interest to do so. First, the lack of cooperation on behalf of publishers might motivate authors to seek out other avenues for publication of their work, whether funded by NIH or not. Second, since NIH funded researchers are significant contributors to biomedical journals, it could be argued that publishers would be better off accepting NIH funded works and taking advantage of the one year embargo to capitalize on publication exclusivity and make some profits (recall that this period is typically the most profitable for publishers), rather than none.

B. The normative approach

On the other hand, normative interpretation calls for the evaluation of potential or permissible exploitations of the work by the author—uses that are not currently exploited, but conceivably could be exploited in the future. These yet unexploited uses must have, or be likely to acquire, *considerable* economic importance. Understanding this principle to signify that all unexploited uses might acquire economic importance would leave it devoid of meaning. In light of this interpretation, it seems likely that in the scientific research arena, authors will continue to write manuscripts without exploiting them for commercial gain and are not likely to actively

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Jorman v. Veterans Admin., 830 F.2d 1420, 1425 (7th Cir. 1987) (Affirming that the plaintiff's injuries were not fairly traceable to the defendant's actions, but rather to the response of other actors. The Court found that the actual and direct cause of resegregation of the plaintiff's neighborhood was in fact the increased black demand for housing coupled with whites' fear of declining property values.). *See generally* RESTATEMENT (SECOND) OF TORTS § 431(a) (2010) (the actor's negligent conduct is a legal cause of harm to another if his conduct is a substantial factor in bringing about the harm).

[286] RESTATEMENT (SECOND) OF TORTS § 440 (definition of superseding cause).

seek out uses with considerable economic importance, as this is beyond the objectives of researchers and scientists. Indeed, the economic concerns of researchers (such as funding and career advancement) are already addressed by the attribution of source and the broad dissemination of results provided by publication.

Notwithstanding the two approaches, the second criterion appears to exist in order to prevent the implementation of a limitation that deprives copyright holders of significant or tangible commercial gains.[287] In this respect, Senftleben argues that only limitations to exploitations that constitute, or are likely to constitute, a major source of income fail the Test. [288] Limitations therefore remain possible on modes of exploitation that generate only few revenues, such as the publication of scientific scholarly articles by researchers.

In fact, the most important economic benefit that authors extract from their work is research funding. Setting aside the possible (though unlikely) rejection of manuscripts by publishers, compliance with the NIH Policy seems unlikely to hinder funding while non-compliance is expected to curtail future NIH funding.[289]

iii. Unreasonable prejudice

The third step embodies a balancing act between protection for the "legitimate interests of the right holder" and the interests of the beneficiaries of the limitation or exception.[290] In other words, the prejudice to a right holder's interests must not be unreasonable.

A. The meaning of unreasonable

[287] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.183.
[288] SENFTLEBEN, *supra* note 134, at 194.
[289] *Frequently Asked Questions about the NIH Public Access Policy*, NAT'L INSTS. HEALTH, http://publicaccess.nih.gov/FAQ.htm (last visited Dec. 12, 2010) (stating that the NIH Public Access Policy is a term and condition of award; non-compliance may delay or prevent awarding of funds).
[290] Gervais, *supra* note 109, at 17 (arguing that the third step may be a balance of rights of copyright holders and users in the Berne Convention); *cf.* Ginsburg, *supra* note 185, at 15 (third step may reduce to balancing the legitimacy of the interests of the right holders and of the beneficiaries to the exception).

It follows that a proper understanding of the term "unreasonable" is necessary for an accurate application of the third step. Referring to the Oxford Dictionary, the WTO Panel ruled that "reasonable" means proportionate, within the limits of reason, not greatly less or more than might be thought likely or appropriate, and of a fair, average or considerable amount or size.[291] This interpretation therefore introduces a proportionality test, in the sense that the harm to authors must be proportionate to the user's benefit. This consideration and weighing of other interests is explicitly entrenched in the TRIPs Three-Step Test for limitations and exceptions to patent rights, which allows states to balance all interests involved:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[292]

This analysis reveals that "not unreasonable" might in fact be closely related to the need for justification. In fact, this interpretation may turn out to be the most accurate.

B. Not unreasonable, or rather, justified

As previously mentioned, the TRIPs Agreement comprises three official texts (French, Spanish, and English versions), which have equal authority, but can sometimes be interpreted differently. Indeed, while the English version of the Three-Step Test in TRIPs asserts "unreasonable prejudice," the French and Spanish texts suggest a requirement that resembles

[291] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.225.
[292] TRIPs, *supra* note 152, art. 30.

more closely "unjustified prejudice."[293] Interestingly, the French text of the Berne Convention, which prevails in case of dispute (according to article 37),[294] also includes the particular phrasing of "unjustified prejudice."[295] Although TRIPs does not explicitly incorporate article 37 of the Berne Convention,[296] it could be argued that the incorporation of articles 1 to 21 of the Berne Convention also entails the incorporation of their meaning, which would be defined by the prevailing French version. In support of this, while translators opted for "unreasonable prejudice,"[297] in the English version, the French text of TRIPs was not altered and maintained the "préjudice injustifié" phrasing, suggesting that the Members did not disagree with the interpretations it carried.

The examination of all versions is important, as the interpretation of only the English version may lead to a different conclusion. Indeed, "reasonable" has a closer relationship with elements of magnitude: how much? To what extent? Thereby leading to proportionality evaluations. In this regard, the WTO Panel used the Oxford Dictionary to define "reasonable" which also led to interpretations related to quantity or amount.[298] Note that in the context of the WTO dispute settlement system, WTO panels and the Appellate Body frequently consult the Oxford English Dictionary in the interpretation process of undefined terms of WTO

[293] *Id.* art. 13. (French: "préjudice injustifié"; Spanish: "perjuicio injustificado")
[294] Berne Convention, *supra* note 146, art. 37(1)(c).
[295] *Id.* art. 9(2).
[296] TRIPs, *supra* note 152, art. 9(1) ("Members shall comply with Articles 1 through 21 of the Berne Convention").
[297] Gervais, *supra* note 109, at 18–19.
[298] WTO Panel, *U.S. Copyrights*, *supra* note 188, ¶ 6.225 (defining reasonable as "proportionate, within the limits of reason, not greatly less or more than might be thought likely or appropriate, or of a fair, average or considerable amount or size." (citations omitted) (internal quotation marks omitted)).

agreements.[299] According to the Oxford Dictionary, "unreasonable" would be defined by what is excessive in amount or degree, recalling this notion of magnitude.[300]

The public access requirements of the NIH Policy are likely proportional in light of all interests involved. First, the public benefits are immense. Second, the Policy does not significantly prejudice the use that authors make of their works. Additionally, in the pursuit of balance, the NIH provides for a one-year embargo.[301] Finally, it is important to recognize that in the grand scheme of things, authors are also users. Indeed, researchers who publish manuscripts are also researchers who will benefit from the increased access to scientific information delivered by the NIH Policy.

In contrast, the term "justified" involves less consideration of the magnitude of the limitation and focuses on the basis for its existence. A justified limitation would entail that there is a good or legitimate reason for it. The Oxford English Dictionary defines "justified" as something that is warranted, or supported by evidence and "unjustified" as unwarranted, or not proved to be right or proper.[302] In particular, the Dictionary states that in law, a justification is "[t]he showing or maintaining in court that one had sufficient reason for doing that which [s]he is called to answer . . . ."[303] The most obvious justification of the NIH Policy is the pursuit of public interests. Without a doubt, the public holds interests in accessing publicly funded knowledge, for direct and indirect reasons, as discussed above.

C. A public interest justification

[299] *See, e.g.*, WTO Panel, *Canada Patents*, *supra* note 188, ¶¶ 7.30, 7.54 (defining "limited" and "normal"); Panel Report, *Canada Term of Patent Protection*, ¶ 6.34, WT/DS170/R (May 5, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/1391da.pdf (defining "subject matter").
[300] THE OXFORD ENGLISH DICTIONARY (2d. ed., 1989) (definition of "unreasonable.").
[301] Consolidated Appropriations Act of 2008, H.R. 2764, 110th Cong. § 218, at 344 (2007) (enacted).
[302] THE OXFORD ENGLISH DICTIONARY (2d. ed., 1989) (definitions of "justified," "unjustified," and "justification.").
[303] *Id.*

Scholars contend that the Test must be re-balanced and interpreted in high consideration of the public interest. According to them, the WTO Panel's recent interpretation of the Test leaves states with limited options to take public interests of fundamental importance into consideration. [304] The highly economic focus of the Panel ruling may even block public interest copyright exemptions such as private copying.[305] Interestingly, the Panel only cited the English version of the Test, which may be a determining factor in its imbalanced ruling.

In an effort to recalibrate the Test, a coalition of experts from the Max Planck Institute for Intellectual Property and the School of Law at Queen Mary (University of London) have produced a Declaration aiming to restore the Test to its initial role as a "relatively flexible standard precluding clearly unreasonable encroachments upon an author's rights without unduly interfering with the ability of legislatures and courts to respond to the challenges presented by shifting commercial and technological contexts in a fair and balanced manner."[306]

An interpretation of the Three-Step Test, which enables states to justify a limitation or exception by public interest objectives, is a welcome return to the fundamental objectives of intellectual property law. By focusing on the basis for the limitation's existence rather than on its magnitude, this approach allows states to manage their IP system by responding to modern

[304] Koelman, *supra* note 180, at 411; *see also* SENFTLEBEN, *supra* note 134, at 201–06; Christophe Geiger, *Right to Copy v. Three Step Test: The Future of the Private Copy Exception in the Digital Environment*, COMPUTER L. REV. INT'L, 2005, at 7–13.

[305] Geiger, *supra* note 304, at 7–13.

[306] Christophe Geiger et al., *Towards a Balanced Interpretation of the "Three-Step Test" in Copyright Law*, SOFT LAW NEWS 2–3, http://www.softic.or.jp/publication/SLN/intro.pdf (last visited Jan. 15, 2011). One author has also suggested that the three-step test should be reversed. The Reverse Test would be used to determine which uses of the copyright holder are protected (safe from national law limitations or exceptions), rather than using the Test to decide whether the copyright limitation or exception respects the Test's criteria. Thus, if a protected use was limited by national legislation, that legislation would be found to contravene the Test. The reversal is based on the assumption that what the three-step test does not allow, is what copyright intended to protect. The reverse test focuses on the effect of the limitation or exception on the copyright holders (recall that in the context of the NIH Policy, the rightholders are authors). *See also* Gervais, *supra* note 109, at 29 (concluding that the Internet may have changed what normal commercial exploitation means and that situations beyond commercially significant uses could be justifiably limited in pursuit of a public interest objective).

circumstances in an effort to maintain the delicate intellectual property balance and foster the worthy ends to which it aims.

VI. CONCLUSION

One of the pillars of scientific, technological and medical advancement is scholarly communication. Acting as the gatekeeper of STM scholarly communication, the traditional publishing system holds a quasi-monopoly over the flow of information within these fields. In addition, commercial publishers have perverse incentives to restrict this flow and the access to scientific information in order to maximize their profits.

The NIH Public Access Policy sets a limit to the control of publishers over scientific publications that are funded by the NIH, by releasing the publicly funded manuscripts for free access after one year. Importantly, the Policy does not terminate the ownership or existence of the copyright vested in the work. Should the Policy be found to constitute a limitation or exception to that copyright however, it must remain compliant with international legal obligations regarding minimum copyright protections by passing the Three-Step Test.

Many believe that a strong argument can be made regarding the compliance of the NIH Policy with the Test.[307] The above analysis shows that the scope of application is well-defined and limited to only those works that are funded by the NIH. This leads to a foreseeable and discernible category of works that fall subject to the NIH Policy.

The foreseeability and discernability of this distinctive category of works is one of the crucial elements that create a permissible carve out for limiting copyrights on publicly funded scientific communications. Scientific works exhibit particular characteristics that warrant the

[307] *See, e.g.*, Trosow, *supra* note 31, at 677.

distinction made between these and other copyrighted works. Indeed, the value of scientific scholarly communication lies in the raw information rather than the written expression of it. Furthermore, researchers in the natural sciences and medicine rely heavily on the information contained in these communications to share their findings, learn from others and make headway in their field of research.

Along with the discernible, predictable and limited application of the NIH Policy, the analysis contained in this work also reveals other factors that aid the Policy to pass muster under the Three-Step Test. Under the auspices of the second criterion of the Test, the extent of a limitation's impact on the copyright holder's normal exploitation of the work determines that limitation's likelihood of failing the Test. To support a finding of Test compliance, copyright limitations should have minimal effects on the actual and probable commercial exploitation of the work that produce significant or tangible commercial gains.

Importantly, the NIH Policy eliminates the consideration of publisher interests by requiring only the prospective application of the Policy to final author manuscripts. Thus, limitations should not permit uses that enter into economic competition with the ways authors extract considerable economic value from their work. Uses that provide only few or no revenues to authors, such as the publication of scientific scholarly communications, may be limited. While the NIH Policy might indirectly cause publishers to deny journal publication, thereby influencing the way by which authors extract value from their work, the Policy has reduced the likelihood of this consequence by granting publishers a 12-month exclusivity period.

Another factor that must be taken into consideration when assessing the validity of a copyright limitation under international law is the reasonableness or the justification of that limitation. Since the interpretation of "unreasonable prejudice" has not yet been established, it is

preferable to design a limitation that is both proportional and justified. The NIH Policy is an exemplary case, exhibiting balance between the prejudice to author interests, which is minimal, and the benefits to users, which is great, as well as a public interest justification. As many have already suggested, giving greater consideration to public interests, such as the NIH Policy objectives of improved human health and public access to results it has funded, may be key in recalibrating the Three-Step Test.

This work has undertaken to ground the NIH Public Access Policy in national and international copyright law, hoping to heighten its widespread acceptance by authors as well as publishers. Although it may not immunize the NIH Public Access Policy from all attacks, strengthening the legal validity of the Policy may protect it from being challenged before the courts.

Lastly and most important, the increased use of a public access system such as PubMed Central, stimulated by the NIH Policy, should encourage and facilitate the transition of scientific scholarly communication to new public access publishing models; reassuring authors and readers in their reliability as well as efficacy in the betterment of science and of access to knowledge.

> "*For also knowledge itself is power*."
>
> Francis Bacon (English lawyer, courtier, philosopher, and essayist, 1561-1626), in *Meditationes Sacrae*, 1597, 'Of Heresies'