

NIH Public Access Policy Does Not Affect U.S. Copyright Law *Analysis*

The U.S. National Institutes of Health (NIH) is one of the largest funders of biomedical research in the world. In FY2008, NIH's operating budget is \$29 billion and the agency distributes most of its research dollars through grant agreements to outside researchers. In FY 2007, NIH awarded approximately 47,000 research grants, with annual funding averaging \$432,714.¹ NIH estimates that the research it supports generates approximately **80,000 scientific and medical journal articles per year**. To ensure that the scientific and social impact of this research is maximized, NIH maintains an online digital archive called PubMed Central (PMC) to provide researchers and the public with long term access to peer reviewed biomedical journal articles and manuscripts arising from NIH funds. Importantly, this archive also permits NIH to better manage their research portfolio and provides accountability through this taxpayer funded research investment.

Following several years of congressional consideration, NIH *requested* that investigators submit their peer reviewed manuscripts to PMC and grant NIH a license to make these publicly accessible within 12 months after the date of publication. Despite the policy being in place for almost three years, data showed that compliance with this request never exceeded 10%. As a result, Congress gave NIH explicit instructions:

SEC. 218. 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.

- Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008)

Although NIH was not required by law to proceed with a notice-and-comment rulemaking to implement this directive, NIH nevertheless invited public comment on **three** separate occasions to receive the benefits of the public's views. Over six thousand comments were filed with the agency – the vast majority in strong support of this policy.²

A minority of the comments filed came from a subset of the publishing community who oppose the NIH Public Access Policy. In the most recent comment period, the Association of American Publishers (AAP) submitted an Opinion Letter that makes misleading and incorrect assertions about the relationship between the NIH Public Access Policy and U.S. Copyright law.³ These assertions are not supported by the law or the facts.

¹ See http://report.nih.gov/award/Research/Research_Average_Award_Dollars.xls

² See <http://publicaccess.nih.gov/comments.htm> and http://publicaccess.nih.gov/comments/Overview_Context.pdf.

³ Online at http://publicaccess.nih.gov/comments2/files/AAP_NIH_Submission_05_30_08.pdf.

I. The NIH Final Policy is fully consistent with the United States Copyright Act.

Assertion: The AAP Opinion Letter suggests that NIH may be violating the provision of U.S. law against “involuntary transfers” (17 U.S.C. § 201(e)) by “forcibly extract[ing] rights from the author prior to their later transfer to a publisher.” [AAP Opinion Letter page 7.]

FACT: Section 201(e) does not apply to voluntary government grants, cooperative agreements or contracts. *Copyright is an author’s right.* Researchers who conduct research and report on that research in scientific and medical journals voluntarily agree that, in return for taxpayer funding, the researchers will grant NIH a copyright license to make the author’s final version of these articles publicly accessible within 12 months of publication. Section 201(e) applies to statutes and regulations that by their own force transfer rights under copyright against the author’s will, not to voluntary contracts and grant agreements.

The attempt to characterize these contracts as “involuntary” makes no sense; authors routinely enter into agreements with other entities that fund the creation of a copyrighted work in exchange for some or all of the rights under copyright. For example, under the logic of the AAP argument, the contract between a first-time novelist and Random House providing an advance and a promise of royalties in exchange for a transfer of copyright would be an “involuntary transfer” of copyright.

Like other entities that fund the creation of copyrighted works, NIH requires something in return. While most other entities, such as the members of the AAP, require a transfer of exclusive rights by the author when they provide financial support to the creation of a copyrighted work, the NIH policy requires **only** the grant of a non-exclusive license. This policy leaves the author free to transfer some or all of the exclusive rights under copyright to a journal publisher or to assign these anywhere they so choose.

There is no derogation of the importance of copyright or any rights thereunder for the U.S. government to abide by the longstanding and well-established principle that a party who funds an author's creation of a copyrighted work is entitled to require some agreement with the author about the management of copyrights that arise from such funding. For this reason there is no involuntary transfer of a copyright created with government funding nor does the NIH policy in any way affect U.S. Copyright law.

II. The Berne Convention and the TRIPS Agreement have no relation to the NIH Public Access Policy

Assertion: The AAP Opinion Letter suggests that the NIH Public Access Policy may violate U.S. obligations under the Berne Convention and the TRIPS Agreement because the policy concerning contractual terms governing copyrighted works created with federal support “is indistinguishable from a legislative *exception* to copyright term and rights.” [AAP Opinion Letter page 10.]

Fact: The Berne Convention and the TRIPS Agreement do not apply to the NIH Policy. These international treaties require that Member States adhere to certain minimum standards in their copyright laws. The NIH Final Policy concerns **contract terms** between authors and a funding agency, not exceptions to copyright law. As such, the NIH Final Policy in no way implicates Article 13 of TRIPS or Article 9 of the Berne Convention, which address permissible copyright limitations and exceptions. *These treaty provisions do not apply to the terms of contracts that authors enter into in exchange for valuable consideration.*

The implications of the AAP Opinion Letter's analysis are staggering. If that analysis were correct, it would require a finding that portions of **all U.S. government procurement law and not simply the NIH policy** are in conflict with treaty obligations. It has been longstanding policy of the United States that whenever a federal agency enters into a contract, cooperative agreement, or grant that contemplates the creation of copyrighted works and other intellectual property, the agency *must* reserve a license to use such intellectual property. From the perspective of the U.S. Copyright Act, there is no difference between the copyright licenses granted in these government contracts and the license that authors are required to grant to the NIH under its policy.

Surely the United States did not understand itself to be required to amend all of federal procurement law when it enacted Section 201(e) of the Copyright Act or when it became a member of the Berne Convention, the TRIPS Agreement, or any other international instrument concerning copyright.

III. The NIH Public Access Policy is consistent with the trend among the United States' trading partners to make publicly funded research articles freely available on the Internet

Assertion: The AAP Opinion Letter suggests that the NIH Final Policy gives the appearance that the United States is weak on intellectual property protection and may set a precedent that other countries will abuse. [AAP Opinion Letter page 13.]

Fact: The NIH Public Access Policy does not amend or in any way affect the rights granted to authors under the United States Copyright Act so cannot set any precedent with respect to international standards on copyright law. Quite to the contrary, the NIH Final Policy fully supports copyright law by recognizing and respecting the rights of authors, including the longstanding and well-established right of authors to grant licenses in exchange for financial support in the creation of copyrighted works.

The weak-on-IP assertion is an attempt to direct attention away from the relevant international precedent regarding online, public access to peer reviewed journal articles reporting the results of publicly funded scientific and medical research. Prominent public and private biomedical research funders in Europe, Canada, and Australia have amended their funding contracts and grant agreements to require, as a condition of support, that authors deposit their final manuscripts into publicly accessible, online digital repositories. For example, In October of 2006, the UK Medical Research Council (MRC), amended their contracts to require online public access as a condition of funding. MRC's policy requires researchers to make papers freely accessible in an online database within 6 months of publication in a journal. Similar policies have been enacted

by the European Research Council, The Canadian Institutes of Health Research, and the Agence nationale de la recherche in France, among others.

All of these policies covering government contracts for scientific and medical research have been implemented consistent with copyright law. All of these funding bodies have taken into consideration the role that scholarly journal publishers play in communicating scientific and medical research. The policies of these countries uniformly require an embargo period of 6 months before the results are publicly accessible. When initially proposed, the NIH Public Access Policy also had an embargo period of 6 months. In response to thousands of public comments, including those from a small group of publishers who argued that 6 months was too short, the NIH adopted an embargo period of up to 12 months instead. Far from setting the bar in this arena, the U.S. policy deviates from the international standard by being far more conservative.

IV. The NIH's procedure for adopting and implementing its Final Public Access Policy is fully consistent with the Administrative Procedures Act (APA)

Assertion: The AAP Opinion Letter asserts that the NIH Public Access Policy is a “legislative rule” requiring notice and comment rulemaking under the APA because the policy amends HHS procurement regulations. [AAP Opinion Letter page 5.]

Fact: The NIH Policy implements a specific statutory provision and is therefore an “interpretive rule” that does not require notice-and-comment rulemaking under the APA.

The very case on which The AAP Opinion Letter relies makes this distinction clearly, by differentiating between “cases where a rule is ‘based on specific statutory provisions’ (interpretive), and where one is instead ‘based on an agency's power to exercise its judgment as to how best to implement a general statutory mandate’ (legislative).” *American Min. Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110 (D.C. Cir. 1993).

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