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"Beyond the Scope of Ordinary Training and Knowledge": The Argument for Droit Moral, U.S. Research Science Intellectual Property Moral Rights

Joan Elise Jackson
researchsciencelaw@aol.com

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"Beyond the Scope of Ordinary Training and Knowledge": The Argument for *Droit Moral*, U.S. Research Science Intellectual Property Moral Rights

Joan Elise Jackson, PhD, JD, Esq.*

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ABSTRACT

Research science intellectual property law has undergone tremendous change within the past two decades.[1] In particular,

* Joan Jackson has a J.D. from the University of Massachusetts-Dartmouth School of Law; B.S. and M.S. in Biology from Tulane University; and Ph.D. in Zoology from the University of Nebraska-Lincoln. She spent twenty-seven years as a senior research scientist/laboratory director/program manager/inventor, identifying new drugs and diagnostics for orphan diseases, and designing- and conducting preclinical new drug efficacy studies; twenty years as Deputy Tropical Medicine Course Director/Adjunct faculty, teaching M.D., and medical students. Acknowledgments: This Article would not exist but for years of kind mentorship and patient correction of numerous drafts by Ralph D. Clifford, Esq., Professor of Law and Former Associate Dean, University of Massachusetts-Dartmouth School of Law; and Frances Howell Rudko, Esq., Professor of Law, University of Massachusetts-Dartmouth School of Law. Any mistakes or errors are to be solely attributed to the Author. Contact: Joan E. Jackson, email: researchsciencelaw@aol.com; cell: 301-661-9002; or joanjacksonlaw.com. The phrase, "Beyond the Scope of Ordinary Training and Knowledge," borrowed from 35 U.S.C. § 103 (2006), refers herein to novel research science achievement, arguably qualifying its natural creator for moral rights under international standards.

1. "Research science" and "scientific research" are used interchangeably. "Science" is defined herein broadly to include traditional laboratory sciences and social sciences. "Research" has been defined by the National Institutes of Health (NIH) as:

> A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Glossary & Acronym List, U.S. DEP'T HEALTH AND HUM. SERVICES, http://grants.nih.gov/grants/glossary.htm#S (last visited July 14, 2012). David L. Faigman et al. distinguished "applied research" from "basic research" as follows:

> "Basic research" is performed in order to provide a theoretical understanding of a phenomenon of interest. . . . [I]n science [a theory] means an explanation for a set of observed facts. Theory is not contrary to fact, it is the abstract or conceptual account [composed of hypotheses] for why the observed facts exist as they do. These [conceptual explanations] may or may not lead to a practical application. The steps in the process of theory development

research science procedure and focus has shifted dramatically

> and testing – hypothetico-deductive research [include] . . . .
> 1. Observations of some phenomenon are made. . . .
> 2. Possible explanations [theories] are proposed for what is observed. . . .
> 3. Hypotheses [conceptual propositions] are logically derived from the theories.
> 4. Studies are designed to test [the validity] of the hypotheses. In essence, the [research] study makes news observations that might disconfirm the hypothesis and thereby falsify the theory.
> 5. The results of such empirical tests lead to the revision or abandonment of older theories or the creation of still newer and hopefully better [more accurate] theories.
> 6. The process repeats itself as more empirical tests are conducted and theories undergo continued re-evaluation.

DAVID L. FAIGMAN ET AL., SCIENCE IN THE LAW: STANDARDS, STATISTICS AND RESEARCH ISSUES 120-21 (2002). "'Applied research' is aimed at answering immediate, practical questions. . . . Some [applied] research [e.g., a research survey] is conducted to provide a thorough description of something," to "try to explain patterns or similarity and variation that had been found." *Id.* at 120. To be disclosed or published, most research science must be subject to peer review. The NIH defines "peer review" as:

> The process that involves the consistent application of standards and procedures that produce fair, equitable, and objective examinations of [research funding] applications [and research findings submitted for publication or disclosure] based on an evaluation of scientific or technical merit or other relevant aspects of the application [or research manuscript submitted for publication]. The review is performed by experts (Peer Reviewers) in the field of endeavor for which support [or professional journal publication] is requested. Peer review is intended to provide guidance and recommendations [e.g. commentary on research to prospective research scientist authors] . . . .

NIH Grants Policy Statement, U.S. DEP'T HEALTH AND HUM. SERVICES, http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch1.htm#definitions_of_terms (last visited July 14, 2012); *see also* Peter W. B. Phillips & Camille D. Ryan, *The Role of Clusters in Driving Innovation*, *in* 1 INTELLECTUAL PROPERTY IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 281, 281-94 (Anatole Krattiger et al. eds., 2006). *See generally* AM. LAW INST., *Introduction* to PRINCIPLES OF THE LAW: INTELLECTUAL PROPERTY PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES 3-7, §§ 101-103 (2008) [hereinafter ALI] (ALI's model principles regarding current global intellectual property law and law practice).

from local to global.[2] Historically, prior to Internet communication, science generally focused on solutions to problems impacting local, regional, or national populations.[3] The scientific research (and, hence, the law governing intellectual property) similarly was largely circumscribed within the nation-state: professional research societies (science quality and ethics), state law (contractual and licensing agreements enforcement), and federal law governing copyright and patent.[4]

With the twenty-first century reliance on Internet communications, there was a marked shift in focus from local research science to global research science.[5] The Internet opportunities to draw from worldwide scientific talent and diverse expertise in real-time became an irresistible siren's song for research scientists to address global problems that only a few years ago were deemed unsolvable.[6] Today, the typical modern research laboratory is virtual, via the Internet, and composed of all existing international scientific expertise considered necessary to tackle major problems facing world populations.[7] Both undergraduate science education[8] and

2. Phillips & Ryan, *supra* note 1, at 281-94; *see also* COMM. ON NEW GOV'T-UNIV. P'SHIP FOR SCI. AND SEC., NAT'L RESEARCH COUNCIL, SCIENCE AND SECURITY IN A POST 9/11 WORLD: A REPORT BASED ON REGIONAL DISCUSSIONS BETWEEN SCIENCE AND SECURITY COMMUNITIES 61 (2007) [hereinafter NEW GOV'T-UNIV. P'SHIP] ("[L]ife sciences research is now nearly borderless and is a global collaborative activity."); ALI, *supra* note 1, at 6 ("The internationalist perspective also requires the Principles to envision a future in which coordination among [nation states'] courts evolves from the exceptional to the expected.").

3. *See generally* Phillips & Ryan, *supra* note 1, at 281-94.

4. *See* ALI, *supra* note 1, at 3-7, §§ 101-103.

5. Teri Melese, *Building and Managing Corporate Alliances in an Academic Medical Center*, 15 RES. MGMT. REV., Winter/Spring 2006, at 17, *available at* http://www.ncura.edu/content/news/rmr/docs/v15n1.pdf ("Moreover, there is an increased desire for companies to engage in strategic research partnerships reflecting a general trend for companies to move away from licensing arrangements and toward building partnerships.").

6. *See* ALI, *supra* note 1, at 3-7, §§ 101-103.

7. *See* Phillips & Ryan, *supra* note 1, at 281-94; Melese, *supra* note 5, at 14:

> The practice of biomedical research is changing. It is evolving towards a bigger enterprise involving multiple investigators from multiple institutions, both academic and

university education are also embracing the virtual international laboratory research model.[9] The result is that research science intellectual property law is struggling to keep

> corporate. No single investigator can assemble all the required technologies and expertise to understand complex disease mechanisms and to translate that scientific knowledge into disease treatment. To move discoveries effectively between bench and bedside requires close ties among the basic [academic fundamental biological/biochemical processes], clinical [patient management], and corporate research enterprises.

Id. (citations omitted). *See generally* ALI, *supra* note 1, at 3-7 (illustrating that ALI recognized that modern global commerce strains existing global intellectual property (IP) regulation because existing IP regulation lacks fully harmonized international legal standards).

8. Stephen K. Ritter, *Reengineering the Undergraduate Laboratory*, CHEMICAL AND ENGINEERING NEWS, Sept. 19, 2011, at 34-35. Students at Boston-based Simmons College conduct hands-on basic polymer research in collaboration with other institutions, including one university in Argentina. *Id.*

9. *See generally* UK/US STUDY GROUP, HIGHER EDUCATION AND COLLABORATION IN GLOBAL CONTEXT, BUILDING A GLOBAL CIVIL SOCIETY, A PRIVATE REPORT TO PRIME MINISTER GORDON BROWN 15, 20 (2009), *available at* www.aau.edu/WorkArea/showcontent.aspx?id=9222. This Study Group stated:

> Political systems – which remain resolutely national – have a notoriously hard time effectively addressing the world's greatest problems, which are transnational and global in nature. . . . [University-to-University] [t]ransnational HE [higher education] collaboration can elude the roadblocks that make it difficult to effectively address big global problems. . . . [O]ne possible vehicle is multilateral and multi-member collaborations. Universities must leverage their longevity and stability, and their ability to forge international bonds to create entities that have as their explicit mandate to take on the long-term, multilateral study of the most threatening global issues. . . . Increasingly, universities are relied upon for a huge range of research activities that used to be shared or shouldered by the private sector. "*Blue sky" research – research undertaken for knowledge's sake, to probe theoretical boundaries* but without immediate applied value – *is the driver of innovation*. . . . [W]hile we may know what *today's* "marketable areas" are, we don't know those of *tomorrow* – and only open ended research leads there. Now the locus of innovative research is, and will increasingly be, the university.

Id. (emphasis added).

abreast of the intertwined research science global network relationships.[10] National intellectual property law is being rapidly subsumed within global intellectual property law, simply because the research science parties involved even in unitary research projects span the globe.[11]

Global research proceeds logically into global commerce and both exert tremendous leverage on nations to conform to international intellectual property norms.[12] Absent the United States' consensus to be bound by majority global intellectual property agreements and regulatory authority, U.S. scientists face material disadvantages in modern global scientific research.[13]

I. Introduction

Moral rights' significance may perhaps be summed from an ancient truism: writers write, composers compose, painters paint, inventors invent, and so on, so that more often than not what one considers important in life is reflected in how one spends his life.[14] Moral rights evolved over centuries to grant recognition under law of the intangible essence of one's person inexorably reflected in one's creative tangible work product(s).[15]

This Article focuses on research scientists' moral rights: first, what these are and why formal recognition is essential to scientists' production of research benefiting the public, to the integrity of the scientific endeavor, and to sustain the research

10. *See* Phillips & Ryan, *supra* note 1, at 281-94; Melese, *supra* note 5, at 13, 14. *See generally* ALI, *supra* note 1, at 3-7, §§ 101-103.

11. *See generally* ALI, *supra* note 1, at 3-7, §§ 101-103.

12. *Id.* at 4-7.

13. *Id. at* 3-7, §§ 101-103; *see also* Jason Koebler, *Demand, Pay for STEM Skills Skyrocket*, U.S. NEWS & WORLD REP., Oct. 20, 2011, http://www.usnews.com/news/blogs/stem-education/2011/10/20/stem-competency-a-foundational-skill-jobs-expert-says. "[T]here's a problem with 'attracting homegrown American talent to science and engineering in the face of increasing supplies of highly qualified students and workers from lower-wage countries.'" *Id.* "For every 100 students who graduates with a bachelor's degree, 19 graduate with a degree in STEM, but only eight are working in a STEM occupation 10 years down the line . . . ." *Id.*

14. GOD'S LITTLE DEVOTIONAL BIBLE 1111 (1997).

15. *See generally* GILLIAN DAVIES & KEVIN GARNETT, MORAL RIGHTS 3-64 (2010).

science profession in the United States. Specifically germane to intellectual rights control and government rights in research science are the impact of post-9/11 federal security measures,[16] the 2011 Supreme Court decision in *Stanford University v. Roche Molecular Systems, Inc.*[17] regarding the Bayh-Dole and Stevenson-Wydler Acts,[18] and federal action to curb "science misconduct."[19] Second, the Article will address the current status of moral rights recognition in law in the United States; in other words, why the lack of U.S. moral rights for research scientists presages material disadvantage to U.S. scientists conducting research in modern global virtual laboratories. Third, United States moral rights legal recognition for research science is proposed, i.e., recognition and enforcement in federal law by non-waivable assignment to scientists of non-economic moral rights: attribution, integrity, retraction and disclosure. The latter moral rights are essential to research scientists' careers, to research science quality, and to ensure public disclosure. Moral rights are distinct from potentially alienable economic rights, allegedly important to research scientists' employers and government.

16. *See also Research Compliance: A Faculty Handbook, Research Security in the Post-9/11 Environment*, UC BERKLEY, http://rac.berkeley.edu/compliancebook/post911.html (last visited June 10, 2012); Allison Chamberlain, *Science and Security in the Post-9/11 Environment, Export Controls: Grants, Contracts, and Publishing*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., *available at* http://www.aaas.org/spp/post911/grants/ (last visited June 10, 2012). *See generally* NEW GOV'T-UNIV. P'SHIP, *supra* note 2.

17. Bd. of Trs. Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 583 F.3d 832 (Fed. Cir. 2009), *aff'd*, 131 S. Ct. 2188 (2011).

18. University and Small Business Patent Procedures Act of 1980 (Bayh-Doyle Act of 1980), Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200-212 (2006)) (controls allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in federally assisted programs); Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701-3714 (2006)) ("[T]he Federal Government shall strive where appropriate to transfer owned and originated technology to State and local governments and to the private sector.").

19. *See generally* DHHS Policies on Research Misconduct, 42 C.F.R. pts. 50, 93 (2011) (effective June 16, 2005).

II. Problem: Ostensibly to Promote Economic Enterprise, U.S. Law Is Failing to Preserve the Link Between the Scientist and His/Her Investigative Findings and Discoveries

A. *Why Research Scientists' Professional Activities Directly Depend on Recognition of Moral Rights*

A scientist's professional activities directly depend on the recognition of moral rights because these rights are essential to ensure science validity[20] (including transition into the marketplace for public benefit); to the integrity of the research process and profession; to prompt public research disclosure; and, to sustain the individual research scientist's career.[21] Research paternity (or right of attribution of the actual creator to be identified with his own work, *contra* plagiarism),[22]

20. Valid science is considered synonymous with reproducible results, using the exact materials and methods initially reported. Results reproduction requires precise, complete disclosure to research peers (scientific peer review), capable of replicating the innovative discovery to evaluate scientific validity in fact.

21. Sean B. Seymour, *How Does My Work Become Our Work? Dilution of Authorship in Scientific Papers, and the Need for the Academy to Obey Copyright Law*, 12 RICH. J.L. & TECH. (ISSUE 3, ARTICLE 11) 1, 2-3 (2006); *see also* Mark L. Meyer, *To Promote the Progress of Science and Useful Arts: The Protection of and Rights in Scientific Research*, 39 IDEA J.L. & TECH. 1, 33-34 (1998). *See generally* COMM. ON SCI., ENG'G, AND PUB. POLICY, RISING ABOVE THE GATHERING STORM: ENERGIZING AND EMPLOYING AMERICA FOR A BRIGHTER ECONOMIC FUTURE 70, 83-84, 104-105, 186-192 (2007) [hereinafter GATHERING STORM]; MEMBERS OF THE 2005 "RISING ABOVE THE GATHERING STORM" COMM., RISING ABOVE THE GATHERING STORM, REVISITED: RAPIDLY APPROACHING CATEGORY 5 (2010) [hereinafter STORM REVISITED].

22. David Nimmer, *The Moral Imperative Against Plagiarism (Without A Moral Right Against Reverse Passing Off)*, 54 DEPAUL L. REV. 1, 67 (2004) (quoting the Modern Language Association's four-prong definition of plagiarism). The definition is as follows:

> Plagiarism is the use of another person's ideas or expressions in your writing without acknowledging the source.
>
> Simply put, plagiarism is using another person's words or ideas without appropriate acknowledgement.
>
> In short, to plagiarize is to give the impression that you have written or thought something that you have in fact borrowed from someone else.

research integrity (or right of respect, right to object to distortion, mutilation or unauthorized modification of his work), right of retraction (right to withdraw the work from circulation and public use based on, for example, later specific contrary findings),[23] and right of disclosure (right to control first publication of the work) control research science in fact.[24] The right to divulge and retract allows the author to decide

> IV.[P]lagiarism is:
> a. reproducing someone else's sentences more or less verbatim, and presenting them as your own;
> b. repeating another's particularly apt phrase;
> c. paraphrasing someone else's argument;
> d. introducing another's line of thinking;
> e. failing to cite the source for a borrowed thesis.

Id.; *see also* K. R. ST. ONGE, THE MELANCHOLY ANATOMY OF PLAGIARISM 39, 54 (1988) ("academic plagiarism is a capital offense, punishable by academic death for student or faculty. With or without warnings."); Lisa G. Lerman, *Misattribution in Legal Scholarship: Plagiarism, Ghostwriting, and Authorship*, 42 S. TEX. L. REV. 467, 475 (2001); Jaime S. Dursht, *Judicial Plagiarism: It May Be Fair But Is It Ethical?*, 18 CARDOZO L. REV. 1253, 1260 (1996).

23. *See, e.g.*, Steve Ritter, *Metal-Oxo Papers Retracted*, CHEMICAL AND ENGINEERING NEWS, June 18, 2012, at 9 (Although the data published were correct, the authors retracted because later experiments proved their earlier interpretation of the data was wrong); Robert H. Silverman, et al., *Letter: Partial Retraction*, 334 SCI. 176, 176 (2011) (published Oct. 14, 2011).

24. DAVIES & GARNETT, *supra* note 15, at 5-6. Moral rights are:

> [G]enerally understood as the rights accorded the author of a work and related to the personality of the author, and the integrity of the author and the work, as opposed to the *economic rights*; the main moral rights are those of divulgation (right to disclose the work), paternity (right to be identified as the author of the work), integrity (right to maintain the integrity of the author in relation to the work, and the integrity of the work itself), and right of retraction (right to retract the work from circulation when the author changes views). Only the paternity and integrity rights are recognized in the Berne Convention: civil law jurisdictions may recognize the four rights, but common law jurisdictions [e.g. U.K. and U.S.A.] tend to limit recognition to the rights of paternity and integrity, as required by the Convention.

Id. (emphasis in original); s*ee also* SIGMA XI, THE SCIENTIFIC RESEARCH SOC'Y, HONOR IN SCIENCE 39 (2000); SIGMA XI, THE SCIENTIFIC RESEARCH SOC'Y, THE RESPONSIBLE RESEARCHER: PATHS AND PITFALLS 22 (1999).

when, where, and in what form the work will be disclosed (this is often equated with right of first publication).[25] Moral rights are distinct from and legally distinguishable from economic rights in the intellectual products of research science.[26]

Albeit an over-simplification, it has been said that the common law countries (e.g. U.S. and U.K.) are more concerned with protection of economic rights, whereas civil law countries concentrate on the moral rights of the creators, authors, and artists.[27] Also, it was argued that moral rights in common law countries were superfluous, being protected by federal, state, or common law (e.g. unfair competition, contract, defamation, and privacy).[28] The United States currently restricts moral rights

25. GRAHAM DUTFIELD & UMA SUTHERSANEN, GLOBAL INTELLECTUAL PROPERTY LAW 90-91 (2008).

26. "Economic rights" is a

> term generally used to describe rights related to the economic exploitation of protected material, as distinct from *moral rights*. The main economic rights are those of reproduction (copying), adaptation, communication and distribution. In French law, the economic rights are referred to as "patrimonial rights". [sic] Economic rights are usually established separately from moral rights in those laws which recognise both species of protection.

J.A.L. STERLING, WORLD COPYRIGHT LAW, PROTECTION OF AUTHORS' WORKS, PERFORMANCES, PHONOGRAMS, FILMS, VIDEO, BROADCASTS AND PUBLISHED EDITIONS IN NATIONAL, INTERNATIONAL AND REGIONAL LAW 1225 (3d ed. 2008) (emphasis in original).

27. 1 DAVID T. KEELING, INTELLECTUAL PROPERTY RIGHTS IN EU LAW, FREE MOVEMENT AND COMPETITION LAW 263 (2003); *see also* Gilliam v. Am. Broad. Cos., 538 F.2d 14, 24 (2d Cir. 1976) ("American copyright law, as presently written, does not recognize moral rights or provide a cause of action for their violation, since the law seeks to vindicate the economic, rather than the personal, rights of authors.").

28. STERLING, *supra* note 26, at 408; *see also* Nimmer, *supra* note 22, at 16-24 (citing MELVILLE B. NIMMER & DAVID NIMMER, 3 NIMMER ON COPYRIGHT § 1.12[A] (2004)):

> The Berne Implementation Act of 1988 expressly states that U.S. law then in existence sufficed to comport with all the requirements of the Berne Convention. Article 6*bis* [moral rights] was foremost on Congress's mind in that regard-fully a third of the enactments thirteen sections are designed to forestall a claim that Berne adherence creates a direct cause of action under U.S. law for the enforcement of moral rights.

recognition and enforcement to visual arts, performance and broadcasting professionals, and certain software creators.[29] In the U.S., research scientists' discoveries and disclosures are currently accorded no moral rights legal protection comparable to artistic creations.[30]

Id.

29. GILLIAN DAVIES, COPYRIGHT IN THE PUBLIC INTEREST 88-89 (2d ed. 2002):

> The Berne Convention implementation Act of 1988 paved the way for U.S. adherence to the Berne Convention on March 1, 1989, an "epochal event" bringing the United States of America into the major multilateral copyright Convention. Moral rights, which had never gained statutory recognition in the United States of America but which Member States of the Berne Convention are bound to respect, were stated to be provided for "under the confirmation of a great many common law precedents, several state statutes, and federal laws." In 1990, however, Congress enacted the Visual Artists' Rights Act, which affords limited rights of attribution and integrity to a narrowly defined class of visual artists with respect to certain artistic works and photographs. In the same year, the Computer Software Rental Agreements Act was adopted, granting authors or producers of software the right to authorize or prohibit rental of copies, even after sale.

Id. (internal citations omitted).

30. ROBERTA R. KWALL, THE SOUL OF CREATIVITY, FORGING A MORAL RIGHTS LAW FOR THE UNITED STATES 37 (2010).

> As the close of the First decade of the twenty-first century, the United States appears to be rather isolated in its failure to recognize explicitly adequate moral rights. The existence of more substantive moral rights protections in both civil and common law jurisdictions not only creates a disparity between law in the United States and many other countries, but also results in the situation in which American authors find substantially more protection for violations of their moral rights abroad than at home.

Id. (internal citations omitted); *see also* Cyrill P. Rigamonte, *Deconstructing Moral Rights*, 47 HARV. INT'L. L.J. 353, 354 (2006) ("the adoption of civil-law-style moral rights legislation is a major shift in terms of copyright theory, because it eliminates the key features that distinguished common law from civil law copyright systems"); Nimmer, *supra* note 22, at 19-20 (raising the question whether countries like England "have augmented their moral rights

David Nimmer, copyright authority, recognized that the right of attribution, with preclusion of its negative (plagiarism or reverse passing off), is essential to academic research:

> [T]here remains one locale where the *prohibition* on reverse passing off [in research science: plagiarism, fraud, and misrepresentation] serves *an essential role*, which *could legitimately arise to affect the legal rights of those caught within its net*. That legal domain is academe, with particular emphasis on the customs of higher education. . . . "Ideas, research, and writing are the currency of academe. *Originality of written work* is essential to the integrity of the academic system. A professor who claims the work or another as his own-even if it is part of an article-is engaged in academic fraud."[31]

In the U.S., research science intellectual property ownership may affect both attribution and control, to include what is disclosed (integrity) and whether research findings are disclosed to the public or not.[32] Employers, including certain federal agencies, want monopoly control over the products of their employees' intellectual property, and a variety of legal doctrines, agencies' policies and practices allow them to get it.[33]

protection" since the United States joined the Berne Convention in 1988 "in a way that leaves the United States isolated.")

31. Nimmer, *supra* note 22, at 66, 74 n.437 (emphasis added) (citations omitted).

32. *See* Seymour, *supra* note 21, at 11 ("Publication is the key to recognition, success, and advancement in science. Thus, every publication decision is necessarily decisive."). *See generally* Roberta R. Kwall, *The Attribution Right in the United States: Caught in the Crossfire Between Copyright and Section 43(a)*, 77 WASH. L. REV. 985, 985 (2002). The underlying theme of this article is that because the United States' copyright law and section 43(a) of the Lanham Trademark Act (codified at 15 U.S.C. 1125(a)) are grounded in objectives other than the personality and non-monetary interests with which the right of attribution is concerned, the federal enactment of a right of attribution applicable to a broad category of copyrightable works is vital. *See id.*

33. Catherine L. Fisk, *Removing the 'Fuel of Interest' from the 'Fire of Genius': Law and the Employee-Inventor 1830-1930*, 65 U. CHI. L. REV. 1127, 1128 (1998).

In particular, the law governing ownership or control of copyright and patents often results in employer intellectual property ownership (and thus control).[34] Fisk aptly summarized:

> The modern law was forged in the crucible where patent law's egalitarianism collided with the hierarchical premises of the law of master and servant. The law of employee inventions is an unstable mixture of the two bodies of law, the former honoring the rights of the inventor as employee and the latter being skeptical of the rights of the employee as inventor. . . . As Abraham Lincoln famously observed, "In anciently inhabited countries, the dust of the ages—a real downright old-foggyism—seems to settle upon, and smother intellects and energies of man." But in America, he asserted, we had broken the "shackles" of the "slavery of mind" and had established "a habit of freedom of thought" that was necessary to the "discovery and production of new and useful things." The patent law nourished this habit of free thought by allowing the ingenious to profit; it added "the fuel of interest to the fire of genius."[35]

The current United States deference to "hierarchical premises of the law of master and servant," coupled with denial of recognition for mere non-economic moral rights to attribution, integrity, retraction, and disclosure, essential to research scientists' careers and necessary to ensure research science quality, places U.S. research science in jeopardy in the modern global laboratories.[36]

34. *Id.* at 1128; *see* Allison Chamberlain, *Science and Security in the Post-9/11 Environment Export Controls: Grants, Contracts and Publishing*, AAAS, http://www.aaas.org/spp/post911/grants/ (last visited July 14, 2012).

35. Fisk, *supra* note 33, at 1128-29.

36. *Id.* at 1128; *see, e.g.*, GATHERING STORM, *supra* note 21, at 104-05:

> [S]ome measures put in place in the wake of September 11,

B. *Public Benefit Flowed from Personal Ownership of Intellectual Property*

1. Why Does It Matter Who Owns and Controls ScientificResearch?

In *Weinstein v. University of Illinois*, Judge Easterbrook summarized historic intellectual property ownership and control for research scientists:

> The University concedes in this court that a professor of mathematics who proves a new theorem in the course of his employment will own the copyright to his article containing that proof. *This has been the academic tradition since copyright law began* . . . a tradition the

2001, seeking to increase homeland security, will be ineffective at best and could in fact hamper US economic competitiveness and prosperity. . . . Of principal concern now are other forms of disincentive: expansion of the restrictions on "deemed exports," . . . . Expanded or new categories of "sensitive but unclassified" information [both] could restrict publication or other forms of dissemination. . . . Both approaches could undermine the protections for fundamental research established in National Security Decision Directive 189 (NSDD-189), the Reagan Administration's 1985 executive order declaring that publicly funded research . . . be unrestricted. . . . The NSDD-189 policy remains in force and has been reaffirmed by senior officials of the [then] current [George W. Bush] administration, but it appears to be at odds with other policy developments and some recent practices.

Id.; *see*, *e.g.*, Letter from Condoleezza Rice, Assistant to the President for Nat'l Sec. Affairs, to Dr. Harold Brown, Ctr. for Strategic & Int'l Studies (Nov. 1, 2001), *in* COMM'N ON SCI. AND SEC., SCIENCE AND SECURITY IN THE 21ST CENTURY 111 (2002) 111 (reaffirming the NSDD-189); John Marburger, Dir., Office of Sci. and Tech. Policy, Remarks at the Roundtable on Scientific Communication and National Security (June 19, 2003), *available at* http://www.fas.org/sgp/news/2003/06/ostp061903.html. *See also* Philip H. Hulme, *Biosecurity and the Politics of Fear*, 334 SCI. 176, 177 (Oct. 14, 2011) ("Since the 2011 anthrax mailings shocked the public, the United States has substantially increased its funding for research and development of biodefense countermeasures. . . . These funds could be better spent. Biodefense research focuses on pathogens of high biodefense value but low public health significance.").

> University's policy purports to retain. The tradition *covers scholarly articles and other intellectual property . . . .*[37]

As Judge Easterbrook aptly noted, historically there exist numerous examples of United States scientists who built successful professional research careers making monumental health and economic contributions as envisioned by the constitutional framers. More often than not, scientists are professionally enabled because of unchallenged ownership and control of their own creative research intellectual property. Scientists' careers, including mobility and the freedom to change employment,[38] are established on research science disclosure. There is no logical incentive for any scientist to refuse to disclose his research discoveries. Ownership by scientist creators historically fulfilled the constitutional purpose of Art. I, Sec. 8: "To promote the progress of science and the useful arts." Representative examples of countless similar scientist creators include: from industry, Thomas A. Edison; from academia, George Washington Carver; and from medicine, Thomas E. Starzl, each promoting "progress of science."

An early industrial research scientist, Thomas Alva Edison, held over 1093 patents as actual inventor-creator.[39] Edison was born February 11, 1847 and died October 18, 1931.[40] Edison sold his initial patents, which he created as a

37. Weinstein v. Univ. of Ill., 811 F.2d 1091, 1094 (7th Cir. 1987); *see also* Seymour, *supra* note 21, at 5 ("[I]t has been the prevailing academic practice to treat the faculty member as the copyright owner of the works that are created independently and at the faculty members own initiative for traditional academic purposes.") (quoting AAUP, STATEMENT ON COPYRIGHT (1999)); Seymour, *supra* note 21, at 5 ("Because professors choose the subject matter, intellectual approach, and direction of their scholarship, the university exerts little to no control and thus is not entitled to ownership.") (citing Sunil R. Kulkarni, *All Professors Create Equally: Why Faculty Should Have Complete Control Over the Intellectual Property Rights in Their Creations*, 47 HASTINGS L.J. 221, 240 (1995)).

38. NEW GOV'T-UNIV. P'SHIP, *supra* note 2, at 3 ("The global scientific enterprise thrives on the movement of students and scholars across borders and among institutions.").

39. *Edison's Patents*, RUTGERS U., http://edison.rutgers.edu/patents.htm (last updated Feb. 20, 2012).

40. *Detailed Biography*, RUTGERS U., http://edison.rutgers.edu/bio-

telegrapher, using money from the sales to eventually set up his own research and development laboratory in Menlo Park, New Jersey.[41] In Menlo Park, Edison led a team of inventors, numbering over 10,000 during the first World War, credited with hundreds of inventions associated with bringing electricity to the U.S. public via his company, General Electric.[42] Edison's modest goals still mirror those of a majority of today's research scientists: "Having one's own shop [laboratory], working on projects of one's own choosing, making enough money today so one could do the same tomorrow . . . ."[43]

George Washington Carver was an academic, inventor, botanist, and fast friend of Thomas Edison.[44] Professor Carver was born on July 12, 1864 and died on January 5, 1943. [45] The son of a Missouri slave, Carver attended Iowa State University, earning a bachelor's degree in 1894 and a master's degree in 1896. [46] He then joined the faculty of Booker T. Washington University's Tuskegee Institute.[47]

Carver viewed the scientist as a person who "unlocked the mysteries of the universe in order to improve the quality of life for everyone, particularly the poor and underprivileged."[48] Through the years, Professor Carver gained international stature, working with scientists from China, Japan, Russia, India, Europe, and South America. In 1916, he was elected a member of the Royal Society for the Encouragement of the Arts in England.[49] Carver also consulted with the U.S. War

long.htm (last updated Feb. 20, 2012).

41. RANDALL STROSS, THE WIZARD OF MENLO PARK: HOW THOMAS ALVA EDISON INVENTED THE MODERN WORLD 20-21 (2007).

42. *The Making of Modern America: The Wizard of Menlo Park*, DIGITAL HIST., http://www.digitalhistory.uh.edu/database/article_display.cfm?HHID=339 (last updated July 14, 2012); HOWARD B. ROCKMAN, INTELLECTUAL PROPERTY LAW FOR ENGINEERS AND SCIENTISTS 129-134 (2004).

43. STROSS, *supra* note 41, at 13.

44. GEORGE WASHINGTON CARVER, IN HIS OWN WORDS xiii-xiv, 7, 11 (Gary R. Kremer ed. 1987).

45. *Id.* at xiii-xiv.

46. *Id.* at xiii, 6, 24, 45, 46, 50, 84, 112, 129.

47. *Id.* at 47.

48. *Id.* at 102.

49. *See Dr. Carver is Dead; Negro Scientist*, N.Y. TIMES, Jan. 6, 1943, http://www.nytimes.com/learning/general/onthisday/bday/0712.html.

Department.[50] Having developed about 100 commercial products from the sweet potato and over 145 products from the peanut, Professor Carver argued southern U.S. poverty could be eliminated by agricultural products diversification: peanuts, pecans, and sweet potatoes as cash crop replacements for cotton.[51] Professor Carver published his science research in a series of 50 bulletins. Upon his death, he established the George Washington Carver Foundation at Tuskegee Institute to perpetuate research in agriculture and chemistry.[52]

Thomas Starzl, the medical father of liver transplant surgery, was born in 1926.[53] Dr. Starzl, spent his life from 1947-1959 in college, medical school, surgical residencies and surgical fellowship programs.[54] He began his research career by developing a method to track and record deep brain responses to sensory stimuli, earning a Ph.D. in neurophysiology at the same time he received his medical degree with distinction in 1952.[55] Starzl continued surgical training at Johns Hopkins University Hospital in Baltimore for four years. Thereafter, Starzl continued surgical training in open-heart surgery and blood vessel surgery at Jackson Memorial Hospital in Miami, work that later proved critical to liver transplantation. While in Miami, he set up a research laboratory in his garage and experimented with transplanting the livers of dogs.[56]

In 1958, Dr. Starzl moved to Northwestern University, passed the thoracic surgery boards (1959), and was awarded two research grants, one from the National Institutes of Health (NIH) and one, a Markle Scholarship, which together allowed him to resume research on liver transplants for four years.[57] Starzl subsequently relocated to the Colorado School of Medicine, where he performed more than 1,000 kidney transplants and improved post-operative therapies to control non-twin organ rejection, using combinations of irradiation,

50. CARVER, *supra* note 44, at 102.

51. *Id.* at 114.

52. *Id.* at 102-126, 148-170.

53. THOMAS E. STARZL, THE PUZZLE PEOPLE: MEMOIRS OF A TRANSPLANT SURGEON 6 (1992).

54. *Id*. at 25-69.

55. *Id*. at 37-46.

56. *Id*. at 47.

57. *Id*. at 62-69.

immunosuppressant drugs, and the synthetic corticosteroid suppressant, prednisone.[58]

Starzl's primary interest was liver transplantation, which due to the dual problems of uncontrolled bleeding and organ rejection, presented more difficult surgical problems than kidney transplantation. He returned to liver transplantation surgery in March and May of 1963, and both patients died.[59] Over the years, Starzl was able to gradually increase post-operative survival of his liver transplant patients, patients who were already terminal due to their own liver's failure.[60] Although Starzl tried alternative approaches to counter post-operative rejection, his ultimate success would lie in his identification of new anti-rejection therapies, anti-lymphocyte globulin and the immunosuppressants, cyclosporine and tacrolimus, the solutions making liver transplantation a "standard procedure" today.[61] Starzl summed up his career by stating, "[*p*]*eople who have an intellectual objective dream large and build castles*."[62] "[O]ur mutual goal, and especially mine, was to bring liver transplantation to clinical use."[63] Furthermore, "[d]uring those years. . .the [transplant] surgeons and physicians also changed-not so rapidly because their lives were not at stake, but inexorably, because the lives of others were in their hands. Some were corroded or destroyed by the experience, some were sublimated, and none remained the same."[64] Starzl continues to speak throughout the world and has published four books, 2130 scientific articles, and 292 book chapters.[65]

The key takeaway from these representative research scientists is that the overwhelming majority did not elect research science as a profession having any reasonable vision

58. *Id*. at 83-95.
59. *Id*. at 96-117.
60. *See id*. at 243-333.
61. *Id.*
62. *Id.* at 86 (emphasis added).
63. *Id.* at 87.
64. *Id*. at 4.
65. *See Alum Thomas Starzl to Receive National Medal of Science*, NW. U. FEINBERG SCH. MED., http://www.feinberg.northwestern.edu/news/2005/2005A-December/starzl.html (last visited July 10, 2012).

of tremendous wealth. Scientists do elect scientific research because of elusive scientific answers or heretofore "unsolvable" problems that often become personal professional quests, personal passion and require personal dedication unrelated to and beyond any economic return but subsistence to continue the work. Best practices of scientific research reflect these latter principles.[66]

66. COMM. ON SCI., SEC., AND PROSPERITY, COMM. ON SCIENTIFIC COMMC'N AND NAT'L SEC. DEV., SEC., & COOPERATION POLICY & GLOBAL AFFAIRS, BEYOND "FORTRESS AMERICA": NATIONAL SECURITY CONTROLS ON SCIENCE AND TECHNOLOGY IN A GLOBALIZED WORLD 47-48 (2009):

> *Best Practices that Enable Success in Fundamental Research* [include:] . . .
> *Freedom in inquiry*. . . . [S]cientists are generally free to pursue any question that is of interest. It is often visionary scientific teams that discover paradigm-shifting advances leading to whole new fields of inquiry.
> *Freedom to pursue knowledge at the scientist's own discretion.* Many scientists are interested in unraveling the mysteries of the natural and physical worlds without regard to practical application. Others pursue opportunities driven by technological shifts, but without a defined end goal. Yet others choose to tackle and solve problems that confront mankind . . . opportunity driven research, often leads to products and processes of great significance . . . in ways that were never anticipated by those conducting the initial research. . . .
> *Freedom to collaborate without limitation.* Open communication among scientists can provide insights into problems and their solutions . . . . Rapid advances often occur at the interface between fields or from the application of advances in one field to a related field. . . .
> *Pluralistic and meritocratic support of science.* . . . Science . . . not guided by a master plan that constrains scientific activity to defined avenues. . . . Similarly, most scientific research funding is administered under a meritocratic review system designed to support the best researchers who propose the best ideas.
> *Freedom to publish.* Science is a cumulative subject in which each scientist builds on the work of others. The fundamental error-correction mechanism of science arises from the replication of work that has been conducted by others, thus enabling mistakes to be exposed. This approach depends on the wide dissemination and open communication of scientific results and methods.

Id. (emphasis in original).

However, as illustrated in the three examples, each scientist at every stage of the research *required* intellectual property ownership and control for his research continuation to the next improvement and, finally, to successful achievement. Had the telegraph companies claimed Edison's initial patents; had the University claimed Carver's publications' copyrights or censored or denied publication disclosure by him; had the various hospitals and university medical facilities claimed Starzl's preliminary surgical advances denying basic moral right, respectively, would the U.S. electricity network, Southern poverty alleviation by crop rotation and new product derivatives marketing, or the surgical procedure and drug-protocols essential to liver transplantation survival exist? The answer is obvious, and Judge Easterbrook's decision in *Weinstein v. University of Illinois* upholds U.S. science tradition, that is, that a research scientist who does the work at a minimum retains the moral rights of attribution, integrity, retraction, and disclosure. These four moral rights are essential to research scientists' careers and are essential to ensure research science quality if scientific research is to survive as a profession in the United States.[67]

2. Who Owns and Controls Scientific Research in the United States?

The answer to who owns or controls scientific research depends on a complex body of national and international (treaties) law, governmental regulatory policy regarding the administration of federal research funding awards, research science professional ethical standards, and individual academic institutions' or commercial firm's administrative policies.[68]

67. 811 F.2d 1091, 1094 (7th Cir. 1987).

68. *See* Seymour, *supra* note 21, at 12-20; *see also* Meyer, *supra* note 21; DAVIES & GARNETT, *supra* note 15, at 3-67, 857-954, 1012, 1128-33. 42 C.F.R. § 93.103 provides:

> Research misconduct means the fabrication, falsification, or plagiarism in proposing, performing or reviewing research or reporting research results. (a) Fabrication is making up data or results and recording or reporting them. (b) Falsification is manipulating research materials,

> equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. (c) Plagiarism is the appropriation of another's ideas, processes, results, or words without giving proper credit [attribution]. (d) Research misconduct does not include honest error or difference of opinion.

42 C.F.R. § 93.103 (2011); *see also* SIGMA XI, HONOR IN SCIENCE, *supra* note 24, at 39 ("Truthfulness may or may not be the cement that holds together society as a whole, but certainly it is essential to science.") (emphasis added); SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 22 ("Experimental results are property that someone owns. The ownership of ideas is important; it has a bearing on promotion, and ideas [copyrights, patents] sometimes can be sold for profit. Conflicts of interest exist."). Regarding institutional policies, see, for example, Seymour, *supra* note 21, at 8 n.40 (quoting professors' publications policy, i.e., whether the academic investigator-author or university owns intellectual property created by professors) (emphasis added) (internal citations omitted), stating that at Brown University:

> It is the policy of Brown University that ownership of the copyright in a work shall belong to the author or authors of the work, with certain stated exceptions. The exceptions to this policy that shall vest ownership of the copyright in a work with Brown University, rather than with the author or authors of the work are: (1) if the work is a work-made-for-hire as defined in the U.S. copyright law; (2) if the work is defined as an "Institutional work" under Section 2.4 below . . . *Copyrightable works of scholarly research, course materials or artistic works made by faculty members would not be considered works-made-for-hire and are property of the author and authors.*

Id. But see Seymour, *supra* note 21, at 8 n.41 (emphasis added) (regarding Cornell University's policy):

> This default position [that copyright ownership initially vests with the author] is based largely on the practices at peer institutions. *This is a policy determination and not one based on legal precedent.* Under U.S. copyright law, employers own the copyright to works created by their employees. Faculty are legally employees of the University. Despite a widely held belief among academics that there is a "faculty exception" to the work-for-hire-doctrine, the reality is there are very few cases (none in our jurisdiction) recognizing an exception and then only with respect to scholarly publications (and all pre-date the latest (1976) revision to the copyright statute). There are, therefore, no legal constraints on the University in formulating this policy position.

An apparent modern legal fiction is to effectively develop intellectual property for commercial use and public benefit; the intellectual property rights of the individual scientist must be transferred to the employer, entrepreneur or government.[69] One may legitimately ask: under what precedent or authority did this modern "legal fiction" evolve and persist?

For federally funded research, there is no basis in law or statute for the answer that by default an employer owns research he did not personally conceive, direct or create, but rather this "policy" evolved as a solution to a Congressional mandate to the Public Health Service (PHS) to address science misconduct related to federally funded research.[70] This latter

Id.(quoting Comm. on Intellectual Prop., Cornell Univ., Draft Report from Intellectual Property Committee 3 n.1 (Mar. 27, 2003) (unpublished draft), *available at* http://theuniversityfaculty.cornell.edu/forums/pdfs/CopyrightReportRev.pdf); Dow Chem. Co. v. Allen, 672 F.2d 1262, 1275 (7th Cir. 1982):

> [T]he heart of the system consists in the right of the individual faculty members to teach, carry on research, and publish without interference from the government, community, the university administration, or his fellow faculty members. . . . [W]e think it clear that whatever constitutional protection is afforded by the First Amendment extends *as readily to the scholar in the laboratory* as to the teacher in the classroom.

Id. (emphasis added).

69. Fisk, *supra* note 33, at 1127-29.

70. Howard Waldeman, *Ownership, Access, Retention, and Sharing of Research Data Produced by PHS Grants or Contracts and CRADAS*, *in* DATA MANAGEMENT IN BIOMEDICAL RESEARCH: REPORT OF A WORKSHOP APRIL 1990, at 86-89 (1990). Mr. Waldeman states:

> III. Grants: (1) Ownership:
> When PHS awards a research grant, the data developed by the grantee institution is owned by the grantee institution unless there is a specific condition to the contrary inserted in the grant award statement. *This legal principle is a matter of PHS practice and policy; there are no regulations which explicitly prescribe it.*

Id. at 86 (emphasis added); *see also Appendix A: Summary of Breakout Session*, *in* DATA MANAGEMENT IN BIOMEDICAL RESEARCH: REPORT OF A WORKSHOP APRIL 1990, at 96(1990):

PHS "policy" is directly contrary to research science practice in fact.[71] The Public Health Service (PHS) offices involved in "research integrity," solely as a function of a PHS policy of convenience,[72] appear to have conflated legitimate regulatory

> The group also dealt with the question of *data ownership*, namely whether the university or the investigator should retain the data. There was strong consensus that the investigator has the primary responsibility for data retention, maintenance, and *appropriate sharing* [disclosure]. The university shares responsibility for maintaining the data, *but custody should reside with the investigator*.

Id. (emphasis added); *NIH Grants Policy Statement*, U.S. DEP'T HEALTH AND HUM. SERVICES, http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch8.html#_Availability_of_Research (last updated Oct. 20, 2011).

71. Michael Jackson & Felix Khin-Maung-Gyi, The George Washington Med. Ctr., *Perspective of an Academic Institution*, *in* DATA MANAGEMENT IN BIOMEDICAL RESEARCH: REPORT OF A WORKSHOP APRIL 1990, at 23 (1990). Jackson and Khin-Maung-Gyi state: "[T]he view that *investigators' interest in their data are primary* is a widely accepted principle of the biomedical research culture, and one that is subscribed to by the editors of scientific journals who solicit copyright transfer from individual authors without requirement of institutional approval." *Id.*

72. *See also* Waldeman, *supra* note 70, at 91:

> The following issues related to the Federal government were noted:
> The PHS requirement that institutions must retain grant records for three years was evidently written to apply principally to financial records. Recently, and *not in accord with common institutional practices*, *PHS has interpreted this regulation to apply also to all data and materials relevant to a research project. This extrapolation is viewed as inappropriate and unwarranted, and should be corrected.*

Id. (emphasis added); *cf.* 45 C.F.R. § 74.53 (2011):

> (a) This section sets forth requirements for record retention and access to records for awards to recipients.
> (b) Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report . . . .
> (g) Paragraphs (g)(1) and (g)(2) of this section apply to the following types of documents, and their supporting records:

financial responsibility of the grantee organization to account for federal grant awards expenditure with actual scientific research data records generated by the research scientist.[73] This latter arguably aberrant PHS "policy and practice"[74] seems to have evolved coincidently with several political events: the Congressional "Science Misconduct" hearings led by Congressional Representative John D. Dingell and the Bayh-Dole Act, University and Small Business Patent Procedures Act of 1980[75] for private institutions, and its counterpart for government agencies, the Stevenson-Wydler Technology Innovation Act.[76] Third, U.S. security concerns exacerbated by 9/11 have resulted in science community concern of federal government restriction of even "unclassified but sensitive [UBS]" scientific research as an express condition of receipt of federal grant or contract support or simply via unspecified peer journal editorial decision.[77] The first delegated to institutions receiving federal research funds a new responsibility to "police" science misconduct allegations pertaining to their research science staff.[78] The second, Bayh-Dole, encouraged institutions

> Indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates) . . . . (2) . . . the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

Id.

73. 45 C.F.R. § 74.53.

74. *Id.*

75. University and Small Business Patent Procedures Act of 1980 (Bayh-Dole Act of 1980), Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200-212 (2006)). Bayh-Dole controls allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in federally assisted programs. *Id.*

76. Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701-3714 (2006)) ("[T]he Federal Government shall strive where appropriate to transfer owned and originated technology to state and local governments and to the private sector.").

77. *See generally* NEW GOV'T-UNIV. P'SHIP, *supra* note 2.

78. *See* Waldeman, *supra* note 70, at 91; 45 C.F.R. § 74.53 (2011); Public Health Services Policies on Research Misconduct*,* 42 C.F.R. pts. 50, 93 (2011)

receiving federal funds to *acquire intellectual property ownership* in their research staff's work ostensibly to facilitate technology transfer of federally funded research discovery to commercial benefit of the public and also share license and royalties with both the academic institution and research scientist inventors.[79] Stevenson-Wydler was amended by the Federal Technology Transfer Act in 1986.[80] This amendment "attempted to institutionalize technology transfer in government [research] laboratories, by among other things, making technology transfer a component of employee evaluation."[81] "Homeland security" legislation, Executive Orders of the George W. Bush Administration and policies promulgated by executive agencies post-9/11, have had an arguably "chilling," if not in fact research censorship impact on scientific research in the U.S. supported by federal funding.[82] The latter United States Executive post-9/11 security action is a broad complex topic. Discussion of post-9/11 executive action

(effective June 16, 2005).

79. 35 U.S.C. §§ 200-212 (2006).

80. Federal Technology Transfer Act, Pub. L. No. 99-502, 100 Stat. 1785 (1986).

81. Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 311, 353 (2008).

82. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA Patriot Act) § 1016, Pub. L. 107-56, 115 Stat. 272 (codified at 42 U.S.C. § 5195c(e) (2006)); Homeland Security Act of 2002, §§ 301-313, Pub. L. 107-296, (codified at 6 U.S.C. § 185 (2006)); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. 107-188, (codified at 42 U.S.C. § 201); Homeland Security Presidential [George W. Bush] Directives/HSPD 1-14 [unclassified versions], *in* NATIONAL SECURITY ISSUES IN SCIENCE, LAW, AND TECHNOLOGY 543-634 (Thomas A. Johnson ed. 2007); *see* Julie E. Fischer, STEWARDSHIP OR CENSORSHIP, BALANCING BIOSECURITY, THE PUBLIC'S HEALTH, AND THE BENEFITS OF SCIENTIFIC OPENNESS (2006), *available at* http://www.stimson.org/images/uploads/research-pdfs/Stewardship.pdf; *see also* Steven E. Miller, *After the 9/11 Disaster: Washington's Struggle to Improve Homeland Security*, AXESS STOCKHOLM, Mar. 2003, at 8-11, *available at* http://belfercenter.ksg.harvard.edu/publication/254/after_the_911_disaster.html; TANIA SIMONCELLI & JAY STANLEY, SCIENCE UNDER SIEGE: THE BUSH ADMINISTRATION'S ASSAULT ON ACADEMIC FREEDOM AND SCIENTIFIC INQUIRY, THE AM. CIVIL LIBERTIES UNION (2005); Donald Kennedy, *Science and Secrecy*, 289 SCI. 724, 724 (Aug. 4, 2000). *See generally* Harold C. Relyea, *Presidential Directives: Background and Overview*, CONG. RES. SERV. (Nov. 26, 2008), *available at* http://www.llsdc.org/attachments/wysiwyg/544/CRS-98-611.pdf.

is limited herein to its impact on intellectual property rights of research scientists to claim creative authorship and to freely divulge the results of "unclassified" scientific investigative findings and discoveries; the scientists' copyright first publication; and, related First Amendment free speech rights such as patent inventorship and patent "secrecy" classification.

a. *Public Health Service (PHS) Research Science Misconduct Policy Provides for Research Ownership to the Grantee Institution, Removing from the Research Scientist Author-Creator-Inventor*

Scientists, unlike their professional counterparts in medicine and law, do not answer to any formal scientific professional regulatory body for violations of ethical and moral professional standards.[83] There is no regulatory counterpart, "American Scientific Research Association," for practice of scientific research, to the American Medical Association (AMA) for license and practice of medicine, or the American Bar Association (ABA) for license and practice of law. Rather, by neglecting to formally organize and regulate themselves, research scientists arguably have fostered default federal executive agency regulation.[84]

Historically, professional research scientists (PhD and M.D.-researchers) have been assumed to be "self-regulated" by their employer-institution and via prepublication peer review

83. *See, e.g.*, COMM. ON RESEARCH STANDARDS AND PRACTICES TO PREVENT DESTRUCTIVE APPLICATION OF BIOTECHNOLOGY, NAT'L RESEARCH COUNCIL, BIOTECHNOLOGY RESEARCH IN AN AGE OF TERRORISM 63 (2004) [hereinafter FINK REPORT], *available at* https://download.nap.edu/openbook.php?isbn=0309089778 ("There is a deep and long-standing foundation of scientific *self-regulation, voluntary standards, and associated accreditation*. Given the fundamentally international character of research in the life sciences, any serious attempt to prevent the misuse of research must include efforts at improving and harmonizing standards and practices internationally.") (emphasis added); COMM. ON NEW GOV'T-UNIV. P'SHIP, *supra* note 2, at 63.

84. FINK REPORT, *supra* note 83, at 63 ("There is a deep and long-standing foundation of scientific self-regulation, voluntary standards, and associational accreditation.").

of their research work-product.[85] Peer review regulates science publication but lacks investigative or enforcement authority to address fraud, plagiarism, or misappropriation.[86] Society membership is for all practical purposes *pro forma*.[87] While ostensibly promoting personal and institutional responsibility, such *laissez-faire* ethics by research scientists prompted government action; where research scientists' professed "professional self-regulation" failed to create standards, proper investigative procedures, and disciplinary enforcement.

Prior to the early 1980s Congressional involvement, professional societies, government research grant (funding) agencies, and nongovernmental review agencies, while promoting education in ethical behavior, had no legal authority or power to regulate research scientists' professional acts, even those in transparent violation of written ethical behavior standards (*e.g.* plagiarism, misappropriation of another's ideas/work product, fraud, or retaliation for reporting of unethical behavior).[88] The result has been that, absent formal ethics adjudication standards, investigative processes, and disciplinary enforcement processes, the scientists are now facing piecemeal standards drafted by government officials in fourteen executive agencies.[89] Research scientists have, via inaction, largely forfeited authority to self-regulate as a unified body of professionals.[90]

b. *Political Considerations Fostering Government and Institution "Oversight Ownership" of U.S. Research Science*

Science misconduct came into the political spotlight when "Albert Gore, Jr., Chairman of the Investigations and

85. *Id.*

86. *Id.* at 116.

87. *Id.* at 62-64.

88. Public Health Services Policies on Research Misconduct, 70 Fed. Reg. 28,370 (May 17, 2005) (codified at 42 C.F.R. pts. 50, 93).

89. FRANCIS L. MACRINA, SCIENTIFIC INTEGRITY: TEXT AND CASES IN RESPONSIBLE CONDUCT OF RESEARCH 14 (3d ed. 2005).

90. Public Health Services Policies on Research Misconduct, 70 Fed. Reg. at 28,370.

Oversight Subcommittee of the House Science and Technology Committee, held the first hearing on the emerging problem. The hearing was prompted by the public disclosure of research misconduct cases at four major research centers in 1980."[91] Prior to 1986, reports of scientific misconduct had been reported directly to the PHS agencies funding the research in question. In 1986, NIH directed the reporting of science misconduct be done through the NIH Institutional Liaison Office.[92] In 1985, Congress passed the Health Research Extension Act.[93] This Act required the Secretary of Health and Human Services to issue a regulation requiring applicant of awardee institutions of federal research grant funds to establish "an administrative process to review reports of scientific fraud"[94] and "to report to the Secretary any investigation of alleged scientific fraud which appears substantial."[95]

In the 1980s, U.S. Congressional oversight of scientific fraud in federally funded biomedical research was under intense legislative and public scrutiny primarily due to Representative John D. Dingell, Chairman of the House Energy and Commerce Committee.[96] Representative Dingell's House Committee funded the National Institutes of Health (NIH), one, if not the largest, of several sources of federal research grant support.[97] Federal funding for science research

91. *Historical Background*, OFF. OF RES. INTEGRITY (Nov. 9, 2011, 3:17 pm), https://ori.hhs.gov/historical-background.

92. *Id.*

93. Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (codified as amended in scattered sections of 42 U.S.C.).

94. Health Research Extension Act § 493, 42 U.S.C. § 289(b) (2012).

95. *Id.*; *see* NIKOLAS KONTARATOS, DISSECTING A DISCOVERY, THE REAL STORY OF HOW THE RACE TO UNCOVER THE CAUSE OF AIDS TURNED SCIENTISTS AGAINST DISEASE, POLITICS AGAINST SCIENCE, NATION AGAINST NATION 158-162(2006).

96. JUDY SARASOHN, THE DAVID BALTIMORE AFFAIR, SCIENCE ON TRIAL: THE WHISTLEBLOWER, THE ACCUSED, AND THE NOBEL LAUREATE 60 (1993).

97. *Id*. at 60-61 (On April 12, 1988, Representative John D. Dingell convened a hearing entitled "Scientific Fraud and Misconduct and the Federal Response" before the House Energy and Commerce Subcommittee on Oversight and Investigations. Dingell noted he was shocked that National Institutes of Health (NIH) relied on institutions to investigate allegations of science misconduct among their own staff. Dingell went on to liken this process to a "fox actively investigating the chicken coup." This hearing began

was increasing and Dingell considered NIH and university mechanisms for dealing with science fraud inadequate.[98] In particular, several cases, including the Robert Gallo and the David Baltimore cases, of alleged scientific misconduct by prominent U.S. senior research scientists, had attracted negative international attention to U.S. federally funded scientific research.[99]

In March 1989, the PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, National Institutes of Health (NIH), and the Office of Science Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH).[100] In 1992, OSI and OSIR were consolidated into the Office of Research Integrity (ORI) in OASH; and HHS established a Research Integrity Adjudications Panel of the Departmental Appeals (DAB).[101]

Dingell's own formal investigation of the Baltimore case of alleged scientific misconduct.); *see also* OFFICE OF RESEARCH INTEGRITY, U.S. DEP'T OF HEALTH AND HUMAN SERVS., ANNUAL REPORT 2009, at 32 (2010), *available at* http://ori.hhs.gov/images/ddblock/ori_annual_report_2009.pdf (Research misconduct activity has increased from 159 allegations, inquiries or investigations in 1993, to 230 in 2008.); LAWRENCE J. RHOADES, OFFICE OF RESEARCH INTEGRITY, NEW INSTITUTIONAL RESEARCH MISCONDUCT ACTIVITY: 1992-2001, at 11 (2004), *available at* http://ori.dhhs.gov/documents/NewInstitutionalResearchMisconductActivity.pdf ("The number of institutions responding to allegations of research misconduct has grown steadily from 1992-2001 and is expected to continue to do so."); Sarah Glazer, *Combating Science Misconduct, Are Government Investigations Unfair?*, CQ RESEARCHER, Jan. 10, 1997, at 5, 6, 11, *available at* http://library.cqpress.com/cqresearcher/document.php?id=cqresrre1997011000#Sidebar1REF[1] ("Science fraud became an even bigger issue in April 1988, when Rep. Dingell launched hearings on the [David] Baltimore case before his Energy and Commerce Subcommittee on Oversight and Investigations.").

98. DANIEL J. KEVLES, THE BALTIMORE CASE: A TRIAL OF POLITICS, SCIENCE, AND CHARACTER 136 (1998); *see also* JOHN CREWDSON, SCIENCE FICTIONS: A SCIENTIFIC MYSTERY, A MASSIVE COVER-UP, AND THE DARK LEGACY OF ROBERT GALLO 13 (2002); Lawrence B. Altman, *Discoverers of AIDS and Cancer Win Nobel*, N.Y. TIMES, Oct. 7, 2008, http://www.nytimes.com/2008/10/07/health/07nobel.html.

99. KONTARATOS, *supra* note 95, at 155-157; *see also* CREWDSON, *supra* note 98, at 13; SHANE CROTTY, AHEAD OF THE CURVE, DAVID BALTIMORE'S LIFE IN SCIENCE (2001); KEVLES, *supra* note 98; SARASOHN *supra* note 96; Altman, *supra* note 98.

100. *Historical Background*, OFF. OF RES. INTEGRITY, http://ori.dhhs.gov/about/history.shtml (last updated Nov. 9, 2011).

101. *Id.*

Although having different outcomes, these two cases, David Baltimore and Robert Gallo, are of particular import because both illustrate the intrinsic conflict of interest of institution or agency self-investigation PHS mandated process: absence of "due process," politically motivated misrepresentation, economic self-interest of the investigative executive agency trumping established U.S. patent law, government mandated retraction of scientific findings subsequently found valid, and irreparable harm, irrespective of innocence or guilt, resulting to accused and plaintiff research scientists.[102] The Baltimore case is egregious: ruined careers, financially devastating legal costs for defense against the U.S. government's "abuse of process," a process devoid of any pretense of due process or merit, before total vindication of two innocent scientists ten years later.[103]

The David Baltimore Case is summarized as follows:

David Baltimore (born March 7, 1938), PhD,[104] 1975 Nobelist for reverse transcriptase discovery: RNA-transcription-into-DNA, refuting the DNA Dogma, DNA-to-RNA-to-protein-never the reverse;[105] age 52 in 1990 when formal allegations (informal, made in 1986)[106] were made that he and Dr. Thereza Imanishi-Kari had committed science misconduct.

102. SARASOHN, *supra* note 96, at 7:

> Over the next few years, [Margot] O'Toole [Baltimore and Imanisishi-Kari's accuser] would find her scientific career in shreds; Imanishi-Kari's reputation would be in ruins; even the president of Rockefeller University, Nobel-prize winner David Baltimore, who put his personal stamp of approval on the publication of the study, would be dragged into the controversy and eventually forced to resign.

Id.

103. CROTTY, *supra* note 99, at 205 (quoting Bernadine Healy, the former Director of NIH).

104. SARASOHN, *supra* note 96, at 77-78; *Autobiography*, NOBELPRIZE.ORG, http://www.nobelprize.org/nobel_prizes/medicine/laureates/1975/baltimore-autobio.html (last visited Aug. 24, 2012).

105. CROTTY, *supra* note 99, at 114-15; KEVLES, *supra* note 98, at 9; SARASOHN, *supra* note 96, at 78-80.

106. KEVLES, *supra* note 98, at 67, 138.

Affliation: President, Rockefeller University, faculty forced Dr. Baltimore's resignation Dec. 2, 1991.[107]

Current: Robert A. Millikan, Professor of Biology, Calfornia Institute of Technology (Caltech).[108]

Charge: Data fabrication, scientific misconduct, by Thereza Imanishi-Kari, a David Baltimore mentee and coauthor collaborator of the research in question; accuser was Margot O'Toole, a postdoctoral fellow in Imanishi-Kari's laboratory.[109] Initially, he tried to explain the results, but under continued intense legal pressure, Dr. Baltimore retracted the paper in question.[110] Note: A retraction is a complete repudiation of the content of a scientific publication. A retraction is the legal equivalent of a "no contest" admission the science misconduct allegation is valid.

Law: After the University had investigated and cleared Baltimore and Imanishi-Kari,[111] this case was "pursued" by various federal agencies, including: repeated investigations by various National Institutes of Health (NIH) agencies, a Congressional investigation headed by Representative John D. Dingell, a self-appointed Congressional science "fraud-buster" who recruited Federal Bureau of Investigation (FBI) Secret Service forensics in his "investigation."[112] It was noted that Baltimore used the resources of the Whitehead Institute, the Massachusetts Institute of Technology (MIT) affiliate, he directed to hire a team of high-powered attorneys, from two firms, one in Boston, one in Washington, D.C., to represent himself. Thereza Imanishi-Kari's defense was handled primarily *pro bono* by Bruce Singal, a former federal prosecutor and partner in the firm of Ferriter, Scobbo, Sikora, Caruso & Rodophele, Holyoke, Massachusetts.[113] Shane Crotty indicated

107. *Id.* at 10, 287; SARASOHN, *supra* note 96, at 248-249.

108. KEVLES, *supra* note 98, at 12.

109. KEVLES, *supra* note 98, at 67-95, 208, 216; SARASOHN, *supra* note 96, at 269.

110. SARASOHN, *supra* note 96, at 107, 217-220, 265.

111. *Id.* at 217.

112. CROTTY, *supra* note 99, at 158; KEVLES, *supra* note 98, at 223; SARASOHN, *supra* note 96, at 86-87.

113. SARASOHN, *supra* note 96, at 82-83, 95; *Handling Misconduct – Inquiry Issues*, OFF. OF RES. INTEGRITY, http://ori.hhs.gov/ori-responses-issues (last updated Apr. 19, 2011).

Dr. Baltimore contributed more than $100,000 for an attorney to defend Thereza Imanishi-Kari, a Brazilian scientist he had mentored.[114] Dr. Imanishi-Kari was investigated by a grand jury in Baltimore for the science misconduct charges. However, on July 13, 1992, the U.S. Attorney Richard D. Bennet declined to prosecute because he did not believe he could persuade a jury *beyond a reasonable doubt*.[115] Both Dr. David Baltimore, a Nobel Laureate, and Dr. Thereza Imanishi-Kari were finally *cleared of wrong-doing 10 years after the first accusations* were brought against them.[116] *[T]he public damage to these two scientists' personal lives and science careers fills several books*

> ORI permits, but neither requires nor provides counsel for respondents, complainants, and other participants in misconduct proceedings. An institution must decide to whom it should provide counsel, and if counsel should be provided. . . . [W]hile parties may arrange for their own counsel, reimbursement is not available from the Federal government under the Equal Access to Justice Act in hearings before the Departmental Appeals Board [DAB].

Id. See also KEVLES, *supra* note 98, at 330. Imanishi-Kari was defended on appeal by Joseph Onek, of the Washington D.C. firm of Crowell & Moring. Onek concluded:

> This case has been a nightmare for Dr. Imanishi-Kari for almost a decade. *During this same decade, a number of other scientists have been falsely accused of misconduct.* This panel's decision will not only vindicate Dr. Imanshi-Kari, but will bring to an end an ignoble chapter in the history of American science.

Id. (emphasis added).

114. CROTTY, *supra* note 99, at 148, 150, 201.

115. SARASOHN, *supra* note 96, at 264 (This burden of proof for finding of science misconduct has since been reduced by DHHS to mere "preponderance of the evidence."); Stanley G. Korenman, *8: Malfeasance and Misconduct*, OFF. OF RES. INTEGRITY, http://ori.dhhs.gov/education/products/ucla/chapter8/Chapter8.pdf (last visited July 16, 2012) ("A finding of research misconduct requires that – (a) There be a significant departure from accepted practices of the relevant research community; and (b) The misconduct be committed intentionally, or knowingly, or recklessly; and (c) The allegation be proved by a preponderance of the evidence.").

116. CROTTY, *supra* note 99, at 205; *see also* Imanishi-Kari, No. 1582, 1996 WL 399931, at *1 (D.A.B. June 21, 1996).

and reams of published scientific professional journal commentary.[117]

Consequences: One point upon which everyone involved agrees is that all of the preliminary investigations, including the one by Congress, were sorely mishandled in that the scientific issues at the heart of the controversy were never properly investigated by *unbiased, scientifically competent personnel until almost 10 years after initial charges were brought*.[118] The question of possible science misconduct and or fraud early became "politically charged" both by the stature of Dr. Baltimore and the sums of public health service funding that had supported these two scientists' research. The several initial NIH oversight agencies tasked with "research integrity oversight" were admittedly tainted by overt bias going to lack of objectivity in their investigations and the fraud investigators' findings were eventually discounted.[119]

Finally, in 1996 the NIH Appeals Board held "a trial-like hearing," amassing "over 6500 pages of hearing transcript, [seventy] laboratory notebooks, the entire collection of Secret Service evidence, Imanishi-Kari's supporting documents, and the ORI's [Office of Research Integrity's] obsessive list of thousands of 'findings of fact and conclusions of law.'"[120] The Departmental Appeals Board (DAB) is available to scientists accused and found guilty of misconduct by their employer-institutes and ORI. It is composed of one to three judges.

> *The appeals panel demolished the Office of Research Integrity, ORI's findings. "The panel cleared Imanishi-Kari's name in their opening comments*: 'Because the history of this case involved a direct attack on Dr. Imanishi-Kari's honesty, we evaluated her statements carefully, and relied primarily on evidence in the record other than her testimony. . . The credibility of her testimony before us was bolstered, however,

117. CROTTY, *supra* note 99, at 139-220; *see also* Glazer, *supra* note 97.

118. CROTTY, *supra* note 99, at 201-20; KELVES, *supra* note 98, at 11-12.

119. CROTTY, *supra* note 99, at 201; *see also* Imanishi-Kari, 1996 WL 399931, at *110.

120. CROTTY, *supra* note 99, at 201.

> when much of the evidence in the record, and in particular, some of the document examination evidence, corroborated her statements and directly contradicted representations made by ORI.' They continued, 'ORI's description of the forensics findings were not always dependable. For example, as described by ORI, one type of Secret Service analysis seemed to provide support (albeit limited) for ORI's position on two important issues. . . . The actual results, however, were not as described and were consistent with (indeed, arguably substantiated) Dr. Imanishi-Kari's version of events (which was also corroborated by other evidence.)' . . . The Secret Service and the ORI could ascribe no motive for Imanishi-Kari to fabricate such useless [unpublished] data, and most of their examples of 'fraud' centered on unpublished data, falsification of which made no sense. The ORI's logic baffled the appeals panel. . . . In particular, the panel found that the infamous seventeen pages of data that obsessed O'Toole [Imanishi-Kari's accuser], Feder and Stewart contained nothing fraudulent or unseemly. . . But the appeals panel concluded that the Secret Service techniques didn't work even on laboratory notebooks whose veracity was unchallenged, including Margot O'Toole's. . . The appeals panel became even more skeptical of the Secret Service work when it became clear that Dingell's aides had met with them and told them what data were 'good' and what were suspicious. . . Ironically, the panel also noted that the ORI's statistician, Dr. Dahlberg, who accused Imanishi-Kari of data selection, engaged in data selection and interpretation of his own. Under intensive investigation, Imanishi-Kari's data selection technique was corroborated by other immunologists who analyzed the data. Dahlberg's [PHS-ORI] own data selection technique held up less well; he had strayed from

> what other statisticians noted were 'more accurate' techniques. . . [Re: Margot O'Toole, the accuser's, partisan stand] Such involvement can compromise both the ability of the investigators to maintain objectivity and the ability of the whistleblower to avoid becoming too vested in the outcome. We [the appeal panel] think that happened here."[121]

Bernadine Healy, the former Director of NIH, summed up the Imanishi-Kari & Baltimore case as follows: "'*There was a lot of cruelty and abusive behavior tolerated in the name of rooting out fraud,' when actually, 'the fraud, the abuse, the dishonesty, was in the [federal government's] process.*'"[122]

The Robert Gallo case resulted in tremendous economic gain for the U.S. government by defending Robert Gallo, a NIH research scientist's, contested claim of first discovery and, thereby, means to detect and screen patients for HIV/AIDS infection. The Gallo case illustrates well PHS agency self-investigation conflict-of-interest given high economic intellectual property right's stakes.

The Robert Gallo case is summarized as follows:

Robert Charles Gallo, M.D. (born 1937)[123] initial

121. *Id.* at 201-04 (emphasis added).

122. *Id.* at 205 (emphasis added); *see also* KEVLES, *supra* note 98, at 11-12, stating:

> This book is also about the civil rights of scientists, particularly Thereza Imanishi-Kari. Once I [Kelves] started studying the record of this case, several points became quickly evident:
>
> - Imanishi-Kari had not had a fair trial.
> - She had been convicted in the court of public opinion and nowhere else.
> - Those who condemned Baltimore for defending his colleague over-looked or were indifferent to crucial aspects of the case, among others.
>
> . . . In June 1996 [a decade after allegations were made] Thereza Imanishi-Kari was officially exonerated on all the counts that had been brought against her.

123. *Gallo, Robert Charles*, ACADEMIC DICTIONARIES AND ENCYCLOPEDIAS, http://scientists.enacademic.com/539/Gallo_,_Robert_Charles (last visited Aug. 24, 2012).

allegations surfaced about 1985.[124]

Affiliation: National Cancer Institute (NCI), National Institutes of Health (NIH) when allegations made,[125] now (2012) Professor of Medicine, Director, Institute of Human Virology, an institution affiliated with the University of Maryland Biotechnology Institute;[126] also, cofounder of Profectus BioScience, Inc., Baltimore, MD; and member of its Scientific Advisory Board.[127]

Allegation: Misappropriated virus, claiming he made first isolation of HIV/AIDS viral agent, from samples obtained from Dr. Luc Montagnier, a collaborator at the Pasteur Institute, Paris, France. U.S. and foreign patent issues regarding HIV/AIDS blood test developed from isolated virus were consequently in question.[128]

Issue 1: *Not discussed, herein*: whether Gallo misappropriated Montagnier's HIV/AIDS virus sent to him as a professional courtesy, claiming the French virus as his own discovery?

Issue 2: Whether Gallo *et al*. submitted to the U.S. Patent and Trademark office as a novel "invention" an HIV/AIDS diagnostic test patent application, ignoring the Montagnier, *et al*.- prior filed two patent applications? Neither Gallo nor any of Gallo's laboratory research team were named co-inventors on the two prior 1983 patent applications filed by filed Montagnier *et al*..[129]

124. KONTARATOS, *supra* note 95, at 135.

125. KONTARATOS, *supra* note 95, at 46.

126. *About Dr. Gallo*, INST. OF HUMAN VIROLOGY, http://www.ihv.org/about/robert_gallo.html (last visited Aug. 21, 2012); *Robert C Gallo M.D.*, UNIV. OF MD. SCH. OF MED., http://medschool.umaryland.edu/facultyresearchprofile/viewprofile.aspx?id=4901 (last visited Aug. 24, 2012).

127. *Scientific Advisory Board*, PROFECTUS BIOSCIENCES, INC., http://profectusbiosciences.com/about_scientific.html (last visited Aug. 21, 2012).

128. KONTARATOS, *supra* note 95, at 135-36, 351-52, 354-55.

129. The French team filed two patent applications (Great Britain provisional Sept. 15, 1983; U.S. provisional Dec. 5, 1983) cited within a European Application (filed Sept. 9, 1984), claiming the Great Britain Sept. 15, 1983 priority date, 4 and 7 months, respectively, before Gallo filed his first application on April 23, 1984 in the United States. *See* KONTARATOS, *supra* note 95, at 350-352.

Law: Gallo's and his US co-inventors or the patent counsels representing Gallo *et al.* in failing to acknowledge Dr. Luc Montagnier's *et al.* prior patent applications, GB 8324800 filed over 7 months (September 15, 1983) and U.S. 06/558,109 (provisional, filed Dec. 5, 1983) filed over 4 months, prior to Gallo's *et al*. (4,520,113, filed April 23, 1984) appear to have violated Manual of Patent Examining Procedure (MPEP) Chapter 2000-Duty of Disclosure, 2001 Duty of Disclosure, Candor and Good Faith (codified at 37 CFR § 1.56). In particular MPEP 2001.06(a) Prior Art Cited in Related Foreign Applications [R-2]. MPEP 2121 Prior Art: General Level of Operability/Enabling: "When the reference relied on clearly anticipates or makes obvious all the elements of the claimed invention, the reference is presumed to be operable." (The right of foreign priority is codified at 35 U.S.C. § 119 and the right of U.S. priority is codified at § 120).[130]

130. 35 U.S.C. §§ 102 (a), (f), (g)(1) (2010):

> A person shall be entitled to a patent unless-
> The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent, or…
> (f)he did not himself invent the subject matter sought to be patented, or
> (g)(1) during the course of any interference conducted under section 135 or section 291, another inventor establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed . . .

Id.; PETER D. ROSENBERG, PATENT LAW BASICS § 15.10 (2002). Rosenberg explains the violation Gallo is alleged to have committed:

> Because the grant of a patent is affected with a public interest, an applicant owes uncompromising duty to report to the Patent & Trademark Office all facts concerning possible fraud or inequity underlying the applications in issue [Interlego A.G. v. F.A.O. Schwartz, Inc., 191 U.S.P.Q. 129, 136-37 (N.D. Ga. 1976)]. The defense of fraud is generally made in two formulations. The first is in terms of equivalent to common-law fraud. The second formulation is in terms of the equity doctrine of unclean hands. The latter is used when not all the elements of the common-law fraud are available [Coal Processing Equip., Inc. v. Campbell, 211

Given the facts of this case, Gallo *et al.* attorneys knew or should have known of the prior Montagnier, *et al.* patent applications filed September 1983 in Great Britain and related U.S. application filed Dec. 5, 1983, and clearly failed to disclose the prior patent applications' existence to the U.S. PTO, a required material fact, as probable "prior art."[131]

> – "Both the [NIH] attorneys and the PTO examiner told the [Representative John D. Dingell] subcommittee staff that numerous aspects of the IP [French-Institute Pasteur, Luc Montagnier, *et al.* foreign and US prior filed patent applications] and LTCB work [with the Institute Pasteur virus] were material to the claims of Gallo *et al.* and should have been disclosed. . . ."[132]

> – "The Gallo *et al.* patent was issued in record time . . . At the time the Gallo *et al.* patent issued, the IP [Institute Pasteur] patent application, submitted over four months prior to the submission of the Gallo *et al.* patent invention application, had not been touched. . . The different handling of two applications for the same invention has never been satisfactorily explained. . . ."[133]

U.S.P.Q. 986, 1000 (S.D. Oh. 1981)]. . . . There is a two-prong test for establishing inequitable conduct before the Patent & Trademark Office:

(1) The information withheld must be *material*; and
(2) The misrepresentation must have been *intentional*.

Id. (emphasis in original).

131. *See* U.S. Patent No. 4,520,113 (filed Apr. 23, 1984) (issued May 28, 1985); *Investigation of the Institutional Response to the HIV Blood Test Patent Dispute and Related Matters: Hearing before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, §§ III-IV (1988) (statement of Rep. Dingell, Chairman, H. Comm. on Energy and Commerce), *available at* http://www.virusmyth.com/aids/hiv/gallo/ExeSum.html.

132. *Id.* at § IV.

133. *Id.* at § III.

> – According to the [U.S.] examiner, when she first saw the IP [Institute Pasteur] application, within two weeks of issuing Gallo *et al.*, she recognized immediately that PTO had "screwed up" in issuing the Gallo *et al.* patent.[134]
>
> – "The HHS response to the IP [Institute Pasteur] challenge . . . was immediate and reflexive. The response was to defend—at all costs and irrespective of the evidence—the claims of Gallo *et al*. The Subcommittee investigation showed that HHS officials and attorneys conducted a parody of an investigation; they did not seek the truth, but rather sought to create an official record to support the claims of Gallo *et al*."[135]
>
> – HHS officials accepted uncritically everything they were told by Dr. Gallo and his colleagues, incorporating the LTCB scientists' information unqualifiedly and without confirmation into official reports of the Department. When these officials encountered hard evidence that contradicted the NCI [National Cancer Institute-Gallo's employer]/HHS claims, the evidence was ignored, discarded, and/or suppressed.[136]

Factual dated evidence in the patent applications on public record in the U.S. Patent and Trademark Office (PTO) and European Patent Office (EP) today support the Congressional Subcommittee's (reconstructive) analysis for the second issue of the conflicting patents filed.[137]

134. *Id.*

135. *Id.*

136. *Id.*

137. Antigenes, moyens et method pour le diagnostic de lymphadenopathie et du syndrome d'immuno-depression acquise, European Patent No. 0,138,667 A2 (filed Sept. 14, 1984) (citing as priority patent application, GB 8,324,800, filed Sept. 15, 1983) (issued April 24, 1985) (inventive entity listed as Luc Montagnier, Francoise Barre-Sinoussi, Francoise V[e]zinet-Brun, Christine Rouzioux, Willy Rosenbaum, Charles

Consequences: Without including Gallo or any of Gallo's colleagues, Luc Montagnier filed his patent application first, twelve (12) claims total, "GB [Great Britain] 8,324,800, *filed Sep. 15, 1983.*"[138] Without including Montagnier or any of

Dauguet, Jacqueline Gruest, Marie-Therese Nugeyre, Francoise Ray, Claudine Axler-Blin, Solange Chamaret); Human Immunodeficiency Viruses Associated with Acquired Immune Deficiency Syndrome (AIDS), a Diagnostic Method for AIDS and Pre-AIDS, and a Kit Therefore, U.S. Patent No. 4,708,818 (filed Oct. 8, 1985) (citing as priority Gr. Brit. Patent Application No. 8,324,800, filed Sept. 15, 1983) (issued Nov. 24, 1987) (attributing invention to Luc Montagnier, Jean-Claude Chermann, Francoise Barre-Sinoussi, Francoise Brun-Vezinet, Christine Rouzioux, Willy Rozenbaum, Charles Dauguet, Jacqueline Gruest, Marie-Therese Nugeyre, Francoise Rey, Claudine Axler-Blin, Solange Chamaret, (and purportedly added in 1987 interference settlement) Robert C. Gallo, Mikulas Popovic, and Mangalasseril G. Sarngadharan) (specifically listing Great Britain Patent Application No. 8,324,800 under the "Foreign Application Priority Data" heading).

138. Absent inclusion of Gallo or any member of Gallo's research team, Montagnier and his French co-inventors' team filed in Great Britain (GB), patent application GB 8,324,800, on Sept. 15, 1983, which is cited as foreign priority on all subsequent patent applications this research team filed in 1983 through 1984. Montagnier's team filed a second U.S. patent application, 06/558,109 on Dec. 5, 1983, so that Montagnier *et al.* in fact filed two (provisional?) patent applications before Gallo, *et al.* filed on April 23, 1984. The U.S. PTO website, http://www.pto.gov/patents/resources/types/provapp.jsp, states:

> A provisional application for patent is a U.S. national application for patent filed in the USPTO under 35 U.S.C. § 111(b). It allows filing without a formal patent claim, oath or declaration, or any information disclosure (prior art) statement. It provides the means to establish an early effective filing date in a later filed non-provisional patent application filed under 35 U.S.C. § 111(a). It also allows the term "Patent Pending" to be applied in connection with the description of the invention . . . . In accordance with 35 U.S.C. § 119(e), the corresponding non-provisional application must contain or be amended to contain a specific reference to the provisional application.

Id. The U.S. Patent and Trademark Office (PTO) Manual of Patent Examining Procedure (MPEP) 2138.05 "Reduction to Practice," states:

> Reduction to practice may be an actual reduction [e.g. laboratory data proof] or a constructive reduction to practice which occurs when a patent application on the claimed invention is filed. The filing of a patent application serves as conception and constructive reduction to practice of the subject matter described in the application. *Thus the*

Montagnier's research team, Gallo filed on *Apr. 23, 1984*, after Montagnier's filing dates, Gallo's patent being essentially a duplicate of Montagnier's 1983 application minus two claims, ten (10) claims total.[139] According to U.S. and international patent law, first filed becomes "prior art," which precludes "novelty" of later essentially similar inventions.[140] Gallo's 1984 patent application should never have been issued since it apparently violates U.S. patent law.[141]

> Section 102(e) is a codification of a Supreme Court case [Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (1926)] which held that a United States patent is effective as a reference against a subsequently filed United States patent application of another as of its filing date, and not as of the date it issued as a patent. Thus, the date as of which the specifications of United States patents become prior art relates back to their filing dates – a date on which their disclosures were not actually available to the public.[142]

A 1987 settlement of the patent interference claims by the French inventors ongoing two years-purportedly was as follows:

> *inventor need not provide evidence of either conception or actual reduction to practice when relying on the content of the patent application. Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). A reduction to practice can be done by another on behalf of the inventor. *De Solms v. Schoenwald*, 15 USPQ2d 1507, 1510 (Bd. Pat. App. & Inter. 1990). "While the filing of the original application theoretically constituted a constructive reduction to practice at the time, the subsequent abandonment of that application also resulted in an abandonment of the benefit of that filing as a constructive reduction to practice. The filing of the original application is, however, evidence of conception of the invention."

Id.

139. '113 Patent (emphasis added).
140. ROSENBERG, *supra* note 130, at § 7.11 (citing 35 U.S.C. § 102(e)).
141. *See id.*
142. *Id.*

> The names of Luc Montagnier, Franciose Barre-Sinousse, Jean-Claude Chermann, Francoise Brun, and the rest of the Pasteur [Institute] group would be added as inventors on Gallo's patent, and the names of Gallo, Popovic and Sarngadharan to the Pasteur still-pending application, which the [U.S.] patent office, hopefully, would agree to issue. Rather than the two competing but co-existing patents envisioned by Salk [Jonas Salk polio vaccine inventor, a mediator between Gallo and Montagnier], there would be two shared patents. The deal depended on the PTO's [U.S. Patent and Trademark Office] *willingness to overlook the existence of two patents for the same invention*, which might be made easier by the fact that both would be owned jointly by HHS [U.S. Health and Human Services] and the Pasteur [Institute, Paris, FR]. Because the Red Cross had been using the Gallo test almost exclusively, the $4 million in annual royalties being collected by the HHS was several times the $500,000 earned by the French. After redistribution imposed by the settlement, HHS would end up with some $2 million a year, and the Pasteur with about $1.5 million. The French would hold the short end of the money stick.[143]

143. CREWDSON, *supra* note 98, at 294-95 (emphasis added); Human Immunodeficiency Viruses Associated with Acquired Immune Deficiency Syndrome (AIDS), a Diagnostic Method for AIDS and Pre-AIDS, and a Kit Therefore, U.S. Patent No. 4,708,818 (filed Oct. 8, 1985) (Gr. Brit. Patent Application No. 8,324,800 (filed Sept. 15, 1983)) (issued Nov. 24, 1987) (attributing revised post-1987 settlement invention to Luc Montagnier, Jean-Claude Chermann, Francoise Barre-Sinoussi, Francoise Brun-Vezinet, Christine Rouzioux, Willy Rozenbaum, Charles Dauguet, Jacqueline Gruest, Marie-Therese Nugeyre, Francoise Rey, Claudine Axler-Blin, Solange Chamaret, Robert C. Gallo, Mikulas Popovic, and Mangalasseril G. Sarngadharan). The Great Britain Patent No. 8,324,800 that is cited as priority was filed absent any of Gallo's team. *Id. But see* Serologic Detection of Antibodies to HTLV-II in Sera of Patients with AIDS and Pre-AIDS Conditions, U.S. Patent No. 4,520,113 (filed Apr. 23, 1984) (issued May 28, 1985) (attributing invention to Robert C. Gallo, Mikulas Popovic, and Mangalasseril G. Sangadharan) (an indication that the 1987 settlement did not in fact reciprocally co-attribute Gallo's April 23, 1984-filed patent

Besides the evidence in the two disputed patents, an advanced search of the PTO website shows Luc Montagnier has been named lead inventor on almost twice as many issued U.S. patents as Robert Gallo.[144]

In 2008, Drs. Luc Montaignier and Franciose Barre-Sinousse received the Nobel Prize for discovery of the virus causing AIDS; Dr. Robert Gallo was not mentioned.[145]

The late 1980's-2001 was a time period when Congress increased science research money, in particular to fund HIV/AIDS and cancer research, but most research programs also benefited.[146] Then, abruptly after 9/11 in 2001, the research budget devoted to life science research funding was

application to include the French team of Montagnier *et al*.).

144. *Results of Search in U.S. Patent Collection Database for Luc Montagnier*, USPTO PATENT FULL-TEXT AND IMAGE DATABASE, http://patft.uspto.gov/netahtml/PTO/search-adv.htm (submit "in/montagnier-luc" in Query field and then follow "Search" link) (last visited Aug. 1, 2012) (returning 106 patents total); *Results of Search in U.S. Patent Collection Database for Robert C. Gallo*, USPTO PATENT FULL-TEXT AND IMAGE DATABASE, http://patft.uspto.gov/netahtml/PTO/search-adv.htm (submit "in/gallo-robert-c" in Query field and then follow "Search" link) (returning 54 patents total) (last visited Aug. 1, 2012).

145. Altman, *supra* note 98.

146. Eugenie Samuel Reich, *Science After 9/11: How Research Was Changed by the September 11 Terrorist Attacks*, SCI. AM., Sep. 1, 2011, *available at* http://www.scientificamerican.com/article.cfm?id=how-research-was-changed-by-september-11-terrorist-attacks&page=2:

> A major conduit for the shifts is the availability of money: The U.S. Department of Homeland Security (DHS), created by consolidating 22 federal services and agencies in 2002 in direct response to September 11, had a science budget that peaked at $1.3 billion in 2006 before falling again to about $700 million in 2011. Key science-funding agencies including the National Science Foundation, the National Institutes of Health and the U.S. Department of Energy, also put money into research motivated by security concerns (amounting to a total homeland security (this number does not refer to DHS but to homeland security funding across all agencies) *research budget of $7.3 billion in 2011*) and a small amount of the U.S. Department of Defense money associated with wars in Afghanistan and Iraq ended up in the hands of researchers as well-for example, by funding work on explosives detection and weaponry.

Id. (emphasis added).

proportionately reduced due to the billions of U.S. dollars spent to fund military operations in Afghanistan and Iraq and the new "Homeland Security."[147] Both political situations, Representative Dingell's scrutiny and proportionately reduced federal expenditure for life sciences research after 9/11, stimulated more investigation of possible fraud by U.S. scientists.[148]

In the late 1980's, the PHS-NIH-ORI,[149] accused a university research scientist funded by NIH, professor of neurology at the University of Wisconsin, James H. Abbs, of

147. NEW GOV'T-UNIV. P'SHIP, *supra* note 2, at 71-72:

> Gregory J. Pottie, UCLA School of Engineering and Applied Science, commented at the September 2006 regional meeting that in the context of national security sensor networks, he has already witnessed examples of research domains [biochemical sensors] where short-term thinking on security has "directly damaged long-term research of direct benefit to our national security." . . . Several university officials expressed concern about the direction research funding in the life sciences has taken. Over the past five years, there has been a remarkable increase of funding for bioterrorism-related research, *while long-standing research budgets in the life sciences have been cut or have remained stagnant*.

Id. (emphasis added) (citing *R&D Funding Update on R&D in NIH FY 2007 House Appropriations*, AM. ASS'N FOR THE ADVANCEMENT OF SCI., http://www.aaas.org/spp/rd (last visited Aug. 18, 2012); Gregory J. Pottie, Remarks Made at the Committee on a New Government-University Partnership for Science and Security Western Regional Meeting at Stanford University (Sept. 27, 2006)), *available at* www7.nationalacademies.org/stl/202006.pdf.

148. *Investigation of the Institutional Response to the HIV Blood Test Patent Dispute and Related Matters*, *by the Subcommittee on Oversight and Investigations*, pt. VI, Committee on Energy and Commerce (Representative John D. Dingell, Chairman, April 1988); *see also* Glazer, *supra* note 97, at 11 ("Science fraud became an even bigger issue in April 1988, when Rep. Dingell launched hearings on the [David] Baltimore case before his Energy and Commerce Subcommittee on Oversight and Investigations."); RHOADES, *supra* note 97, at 11 ("The number of institutions responding to allegations of research misconduct has grown steadily from 1992-2001 and is expected to continue to do so."); OFFICE OF RESEARCH INTEGRITY, *supra* note 97, at 32. *See generally* SARASOHN, *supra* note 96, at 56, 60-61.

149. These abbreviations stand for, respectively, Public Health Service-National Institutes of Health-Office of Research Integrity. *See* KEVLES, *supra* note 98, at 290.

scientific misconduct.[150] Professor Abbs' laboratory was the only one of its kind studying human speech using x-ray microbeam analysis. The court noted that scientific fraud is much "in the news these days; and this case, the government advises us in its brief, 'is of far-reaching national significance.'"[151] The charge was that a recent article co-authored by Abbs contained graphs that had been traced from graphs in a previous publication rather than generated by data from the NIH grant research, as the article claimed.[152] The University of Wisconsin self-investigated the matter, clearing Abbs.[153]

150. Abbs v. Sullivan, 963 F.2d 918, 927, 928 (7th Cir. 1992), *vacating* 756 F. Supp. 1172 (W.D. Wis. 1990) (The appellate court held that while the government had violated the Administrative Procedure Act, Abbs may not appeal an executive agency's violation of administrative procedure absent showing of personal injury, specifically under Administrative Procedure Act § 10(c) "irreparable harm, the judicial remedy therefore [being] inadequate.").

151. *Abbs*, 963 F.2d, at 928 (citing Patricia K. Woolf, *Deception in Scientific Research*, 29 JURIMETRICS J. 67 (1988)).

152. *Id.* at 921.

153. Abbs v. Sullivan, 756 F. Supp. 1172, 1176-1177 (W.D. Wis. 1990). The trial court found the following undisputed facts:

> In 1987, a committee of the University of Wisconsin-Madison conducted an inquiry into allegations that plaintiff Abbs had engaged in scientific misconduct, specifically, that he had published certain curves in the Journal *Neurology* that were traced from curves he had published previously, rather than being from two different patients as plaintiff represented. The university committee determined that there was no need for formal investigation into the allegations of scientific misconduct against Abbs and so advised NIH's Office of Extramural Research, in June 1987 . . . [None-the-less t]he Office of Extramural Research of NIH conducted additional inquiries into the Abbs matter and obtained a report from a panel of experts questioning the University of Wisconsin-Madison's prior determination that the allegations against Abbs did not warrant a formal investigation. On January 12, 1990, the Acting Director of the Office of Scientific Inquiry advised plaintiff Abbs that his name and the fact that he was the subject of an investigation had been entered into the Public Health ALERT system, which serves to communicate information about investigations and final determinations of [science] misconduct to all Public Health Service agencies.
>
> *Id.*

Nonetheless, prior to beginning its own investigation, the Office of Scientific Integrity (OSI-NIH-PHS) placed "in the Public Health Service's 'ALERT' system a notice that Dr. James Abbs of the University of Wisconsin was being investigated for scientific misconduct.[154] The ALERT system distributes such notices to all agencies of the Public Health Service that make research grants."[155] Under the OSI-PHS investigative procedure, Dr. Abbs: (1) would not have complete access to the investigative file; (2) would not be allowed to attend interviews with other witnesses; and (3) would not be entitled to full evidentiary hearing before a finding of misconduct was made.[156]

The issue before the *Abbs* court was: "whether the policies and procedures governing such investigations comply with the Administrative Procedure Act and the due process and equal protection clauses of the Fifth Amendment[?]"[157] The University was a co-plaintiff with Abbs, citing its economic stake in Abbs' NIH million-dollar-grant's overhead, and both sides moved for summary judgment.[158] "In an accompanying opinion the [district court] judge explained that while the procedures employed by the Office of Scientific Integrity *were indeed invalid* because adopted in violation of the Administrative Procedure Act . . . Abbs *has no liberty or property interest* in continued funding by NIH, so even if the proceedings were inadequate he had no constitutional claim."[159]

154. *Id.*

155. *Abbs*, 756 F. Supp., at 1177-78.

156. *Id.* at 1176.

157. *Id.* at 1176.

158. *Id.* at 1176.

159. *Abbs*, 963 F.2d at 922 (emphasis added); *Abbs*, 756 F. Supp. at 1182-1183. The trial court stated:

> Plaintiff Abbs contends that he has a constitutionally protected property interest that derives from the interrelationship of federal funding with his career advancement and income. . . . As important as such funding is to plaintiff Abbs, however, *it does not constitute a constitutionally protected property interest unless* his claim to it is legally enforceable by contract or under state or federal law. . . . As to future federal funding, plaintiff Abbs has no enforceable right to receive grants or awards, whatever his status as researcher. . . . *As to current grants,*

Abbs challenged the lack of a constitutional claim on appeal.[160]

The U.S. Seventh Circuit dismissed Abbs' appeal.[161] The court reasoned that:

> Section 493(b) of the Public Health Service Act, 42 U.S.C. § 289b(b), directs NIH to establish a "process" for responding to complaints of scientific fraud. Pursuant to this directive, but without notice or opportunity for public comment, the predecessor of the Office of Scientific Integrity had announced "Policies and Procedures for Dealing with Possible Misconduct in Science" in the July 18, 1986, issue of an NIH publication called *NIH Guide for Grants and Contracts*.[162]

The Appeals court in its conclusion noted:

> Of course no one likes to be accused of misconduct. The district court judge remarked that "the fact that Abbs might ultimately be cleared of the accusations against him . . . is as unconvincing as arguing that persons charged with felonies have no cognizable interest in the trial procedures afforded them because they might be acquitted." But a criminal defendant cannot bring a suit to enjoin the procedures under which he is to be tried. No more can Dr. Abbs.[163]

> *he is not the grantee [see page 1176, University of Wisconsin-Madison, his employer, the legal grantee] and [Abbs, therefore,] can claim no property rights in the funding for these grants.*

Id. (emphasis added).

160. *Abbs*, 963 F.2d at 921.

161. *Id.* at 928.

162. *Id.* at 921.

163. *Id.* at 928 (citing *Abbs*, 756 F. Supp. at 1181.)

The verdict in *Abbs* aptly illustrates both the need for moral rights non-waivable assignment to research scientists (not the grantee institution) as well as the need for a research scientists regulatory body (an impartial body equivalent to the ABA for lawyers), and not PHS, to promulgate, adjudicate, and enforce scientific research ethical standards. The *Abbs* courts noted that the existing PHS policy violated the Administrative Procedure Act, but held Abbs had no liberty or property interest in his own scientific research, so Abbs lacked a constitutional claim.[164]

Further, as the *Abbs* court noted, a default PHS policy that the grantee institution *owns the research data*[165] further places the research scientist at disadvantage in court regarding standing, because the scientist is simply deemed under PHS policy (arguable, as discussed below in conflict with federal intellectual property law) to have no intellectual property ownership or control of his own creative research accomplishments.[166]

In short, U.S. scientists have lost, via (allegedly) unchallenged executive agency abuse of authority, the "fuel of interest" from their own "fire of genius" that Abraham Lincoln had celebrated.[167] Absent U.S. adoption of inalienable moral attribution (paternity), integrity, retraction, and disclosure

164. *Abbs*, 963 F.2d at 921 ("[T]he district judge never entered an injunction against its [Office of Scientific Integrity] conducting the investigation [science misconduct alleged against Dr. Abbs] by the procedures she had held invalid."); *Abbs*, 756 F. Supp. at 1182-1183 ("As to current grants, he *[Dr. Abbs] is not the grantee* [University of Wisconsin-Madison, Abb's employer, the legal grantee] *and [Dr. Abbs, therefore,] can claim no property rights in the funding for these [Abbs' personally conceived and personally authored research grants]*") (emphasis added).

165. *Abbs*, 756 F. Supp. at 1176 ("[T]he University of Wisconsin-Madison . . . is the legal entity that applies for research grants.); *see* Waldeman, *supra* note 69.

166. *Abbs*, 963 F.2d at 922 (emphasis added); *Abbs*, 756 F. Supp. at 1182-1183 ("As to current grants, he *[Dr. Abbs] is not the grantee* [University of Wisconsin-Madison, Abb's employer, the legal grantee] *and [Dr. Abbs, therefore,] can claim no property rights in the funding for these [Abbs' personally conceived and personally authored research] grants*") (emphasis added).

167. Fisk, *supra* note 33, at 1128-29 (citing Abraham Lincoln, Second Lecture on Discoveries and Inventions (Feb. 11, 1859), *in* 3 COLLECTED WORKS OF ABRAHAM LINCOLN 356, 363 (Roy P. Basler ed., 1953)).

(divulgation) rights, American research scientists often lack standing to sue for non-economic intellectual rights in their own research discoveries.

In the U.S., the percentage of independent inventors (those who have not assigned their patent rights to an employer or the government) is relatively low (about 25%); such independent individuals are typically viewed negatively by corporations, creating material pressure for a research scientist to comply to gain or to retain employment.[168] Consequently, even in the 1980s, the majority of patents issued (84%) go to corporations.[169] This latter fact, presumed true, largely vitiates the federal government's rationale for technology transfer legislation in 1980, Bayh-Dole, Stevenson-Wydler, in 1986 for The Federal Technology Transfer Act, and PHS policy mandating control by federal scientific research grantee organizations.[170]

Like the U.S. in 1916,[171] independent inventors tend to be much higher in developing countries, about 66% in Brazil and 25-50% in European countries.[172] In the U.S., then, the majority, three-quarters (75%), of research scientist inventors assign their ownership of their creative inventions to their employers, usually as a mandate of their employment. This situation results in business managers' practical control of scientific research, both science direction toward marketable products as well as research disclosure, via peer-reviewed

168. MICHAEL GOLLIN, DRIVING INNOVATION: INTELLECTUAL PROPERTY STRATEGIES FOR A DYNAMIC WORLD 99 (2008) (citing WORLD INTELLECTUAL PROP. ORG. & INT'L FED'N OF INVENTORS' ASS'NS, HOW CAN PATENT OFFICES ENCOURAGE INVENTIVE AND INNOVATIVE ACTIVITIES? (2000), *available at* http://www.wipo.int/edocs/mdocs/innovation/en/wipo_ifia_bue.00/wipo_ifia_bue.11.doc; Farag Moussa, *The Role of Innovation*, INT'L FED'N OF INVENTORS' ASS'N, http://www.invention-ifia.ch/role_of_innovation.htm (last visited July 17, 2012)).

169. Fisk, *supra* note 33, at 1129 n.9 (citing *Rights of Employed Inventors: Hearing on H.R. 4732 and H.R. 6635 Before the H. Subcomm. On Courts, Civil Liberties, and the Administration of Justice*, 97th Cong. 1 (1982) (remarks of Rep. Robert Kastenmeier)) (stating that "[eighty-four] 84% percent of U.S. patents go to corporate assignees, 'usually the employer of the actual inventor.' As recently as 1916, three-quarters [75%] of the patents in the United States were issued to individuals.") (internal citations omitted).

170. *See supra* Part II.B.2.

171. Fisk, *supra* note 33, at 1129 n.9.

172. GOLLIN, *supra* note 168, at 99.

scientific publications, upon which the scientists' careers depend (matters for which business managers are generally not competent).[173] Research scientists' creativity is the foundation

173. Melese, *supra* note 5, at 17:

> Moreover, there is an increased desire for companies to engage in strategic research partnerships reflecting a general trend for companies to move away from licensing arrangements and toward building partnerships. . . . [M]ost contract officers . . . that negotiate research and collaborative agreements for acquiring technology resources are commonly not trained to make science or business decisions and are not experts in intellectual property. Consequently, they lack the skills required to balance science and intellectual property risk against the potential benefits of a business opportunity.

Id. (citation omitted); *see also id.* at 14:

> The practice of biomedical research is changing. It is evolving towards a bigger enterprise involving multiple investigators from multiple institutions, both academic and corporate. No single investigator can assemble all the required technologies and expertise to understand complex disease mechanisms and to translate that scientific knowledge into disease treatment. To move discoveries effectively between bench and bedside requires close ties among the basic [academic fundamental biological/biochemical processes], clinical [patient management], and corporate research enterprises.

Id. (citations omitted); Thomas J. Roberts & Jess House, *Profile of a Research Administrator*, 15 RES. MGMT. REV., Winter/Spring 2006, at 41 ("The general profile of a research administrator is: . . .bachelor's degree . . . 6-10 years [experience as research administrator]."); GOLLIN, *supra* note 168, at 120-21:

> I [Gollin, Esq., IP Partner, Venable, LLP] have never met anyone who is an expert in all three areas-creativity (technology or art), (2) intellectual property law, and (3) business. . . . Engineers and scientists engage in basic research and product development, and operate in a situation of high technical complexity[,] . . . high information intensity[,] . . . [and] high aesthetic sophistication. . . . *They* [*research scientists*] *understand the innovation and its relation to the state of the art*. . . . Unfortunately, senior managers in some organizations are not proactive and [specifically scientifically] knowledgeable, and may make unwise decisions about intellectual property or otherwise thwart good work by [research scientists] staff-

for the quality and quantity of marketable products; such U.S. policies and statutes arguably remove control and exploitation of scientific researchers' intellectual endeavors and accomplishments to business administrators least likely to have the scientific acumen to further develop U.S. intellectual property.[174] In 1968 the executive branch commissioned a report from Harbridge House, which reported commercial utilization of government funded research was low.[175] The Harbridge report also found that "the evidence does not indicate that either title or nonexclusive licensing [to the employer] is uniformly the best way to promote utilization" of academic research.[176] The PHS policies of ownership by grantees are inextricably intertwined by the dual justifications of "policing" science misconduct and facilitating "technology transfer," both justifications having highly questionable merit and questionable effectiveness in fact and in practice.[177]

> investing unnecessarily to protect worthless projects, failing to take measures necessary to protect valuable projects, or structuring unworkable relationships with collaborators.

Id. (emphasis added).

174. Greenbaum, *supra* note 81, at 359:

> More often than not, technology transfer offices drain university resources, promising the sky but delivering little. Further, they drain the resources and time of the researchers who must cooperate with the TTOs [technology transfer offices] to draft and license patents. With their monopolistic hold on all licensing efforts in the university, technology transfer offices may also inhibit many entrepreneurial efforts by the researchers themselves-stunting the growth of a patent-friendly environment in academia and hampering independent academia-industry collaboration.

Id.

175. *Id.* at 338-39 nn.86, 90, 91 (citing ANDREW Z. MICHAELSON, THE LAW OF THE LAB: USING ZERIT TO INFORM TECHNOLOGY TRANSFER 21, 22 (2002), *available at* http://leda.law.harvard.edu/leda/data/512/michaelson.pdf).

176. *Id.* at 339.

177. *See, e.g.*, Dov Greenbaum, *Research Fraud: Methods For Dealing With An Issue That Negatively Impacts Society's View of Science*, 10 COLUM. SCI. & TECH. L. REV. 61, 75 (2009) ("Has the prevalence of fraud in science risen to problematic level? . . . [T]here is little in the way of hard empirical data one way or the other.").

c. *The Courts' Disagreement with Agencies' Policies and Practice:* Stanford v. Roche *and Bayh-Dole*

Nonetheless, the PHS "default intellectual property employer ownership policy" has *neither* been generally embraced by the courts *nor* accepted in practice by the research science community.[178] In *Forsham v. Harris*, the U.S. Supreme Court held that data developed under a federal grant did not constitute an "agency record."[179] As previously noted, editors of scientific journals solicit copyright transfer from individual authors *without requirement of institutional approval*, an indication that journal editors, as well as prior noted scientist researchers, deem research scientist authors own copyright in their own research, not their employers.[180] In its June 6, 2011, 7:2 decision, *Board of Trustees of the Leland Stanford University v. Roche Molecular Systems, Inc.*, the U.S. Supreme Court affirmed that "[t]he Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions."[181] Chief Justice Roberts wrote for the

178. *Id.* at 74; *see* Bd. of Trs. Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 583 F.3d 832 (Fed. Cir. 2009), *aff'd*, 131 S. Ct. 2188 (2011); *see also* Waldeman, *supra* note 70; Jackson & Khin-Maung-Gyi, *supra* note 71.

179. 445 U.S. 169, 186-187 (1980) (internal citations omitted); *see also* Weinstein v. Univ. of Ill., 811 F.2d 1091, 1094 (7th Cir. 1987); 23 AM. JUR. PROOF OF FACTS 2D, 203 § 18 (Westlaw 2010) ("the mere fact that an invention was conceived and developed while the inventor was employed entitles the employer to *no* right or title to the invention") (emphasis in original). However, once employer contribution has been established, the existence of an employer's right may be presumed; McKeen v. Jerdone, 34 App. D.C. 163, 6 (1909) (the employer has the burden of showing both that it was aware of and communicated to the employee a specific means of accomplishing the desired result, and that the employee's work consisted of mere improvement that could have been carried out by any skilled technician); Burton v. Burton Stock-Car Co., 171 Mass. 437, 50 N.E. 1029 (1898); Deane v. Hodge, 35 Minn. 146, 27 N.W. 917 (1886) (the employer has the burden of proving that the employee intended to permit the employer to make gratuitous use of the employee's invention). *But see* Pedersen v. Akona, 429 F. Supp. 2d 1130, 1143 (D. Minn. 2006) (finding implied-in-fact contract and 'shop right by estoppel' of employer to use employee's invention).

180. Jackson & Khin-Maung-Gyi, *supra* note 71, at 23.

181. *Leland Stanford Univ.*, 131 S. Ct. at 2190 (citing University and

majority:

> Since 1790, the patent law has operated on the premise that rights in an invention belong to the inventor. [*See, e.g*,. Gayler v. Wilder, 51 U.S. 477, 493 (10 How. 1850).] The question here is whether the University and Small Business Patent Procedures Act of 1980-commonly referred to as the Bayh-Dole Act-displaces that norm and automatically vests title to federally funded inventions in federal contractors. *We hold it does not*.[182] . . . [U]nless there is an agreement to the contrary, an employer does not have rights in an invention "which is the original conception of the employee alone."[183]

The Chief Justice further stated that:

> Although much in intellectual property has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not.[184] . . . We have *rejected the idea that mere employment is sufficient to vest title to an employee's invention in the employer*.[185]

In *Stanford*, the Supreme Court strongly affirmed (7:2) that, absent clear contractual waiver to the contrary, research scientists both own and control research science they creatively bring into being.[186] It is too soon to anticipate what impact

Small Business Patent Procedures Act of 1980 (Bayh-Doyle Act of 1980), Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200-212 (2006)) (Bayh-Dole controls allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in federally assisted programs)) (quotation is found in the syllabus of the opinion).

182. *Id.* at 2192 (emphasis added).

183. *Id.* at 2195 (citation omitted).

184. *Id.* at 2194.

185. *Id.* at 2196 (emphasis added).

186. *Id.*

Stanford will have on United States research science. However, it seems clear that many federal agencies' policies and practice, prior reviewed herein, may require substantive revision in light of the *Stanford* holding.

III. Why Is Absence of Moral Rights for Scientists a Problem: Adverse Impact on Scientific Progress and Achievement

A. *U.S. Agencies' Policies Legal Deficiencies in General*

In 2005, it was estimated there were at least fourteen (14) U.S. federal agencies or departments that fund scientific research.[187] Some of these have established policies implementing the Federal Policy on Research Misconduct mandated by the Office of Science and Technology Policy (a part of the executive branch of the U.S. government)."[188] The latter office, Office of Science and Technology Policy, of the President established a "Uniform Policy for Research Misconduct" with which individual agencies are to comply.[189] Less than forty percent of U.S. federal agencies have drafted science misconduct policies. Most existing science misconduct policies provide very broad, general requirements in brief statutory form. "The remainder [of the relevant federal agencies] are either drafting policies or are in the process of establishing policies through formal channels."[190] Agencies having science misconduct guidelines include: Department of Health and Human Services (DHHS);[191] Department of Defense (DoD);[192] Department of Energy (DoE);[193] National Aeronautics

187. MACRINA, *supra* note 89, at 14-15.

188. *Id.*

189. Uniform Policy on Research Misconduct, Notification of Final Policy, 65 Fed. Reg. No. 235, 65 Fed. Reg. 76,260 (Dec. 6, 2000).

190. MACRINA, *supra* note 89, at 14.

191. Public Health Services Policies on Research Misconduct, 42 C.F.R. pts. 50, 93 (2011).

192. *Research Integrity and Misconduct*, DEP'T OF DEFENSE INSTRUCTION 3210.7, at 1, 5 (2004), *available at* www.dtic.mil/whs/directives/corres/pdf/321007p.pdf:

> (a)DoD Directive 3216.2, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported

and Space Administration (NASA).[194] In 1995, the Department of Health and Human Services (DHHS) published a sixty eight page booklet of guidelines and recommendations entitled, "Integrity and Misconduct in Research."[195] In contrast to the comparable ABA's LEGAL ETHICS: THE LAWYER'S DESKBOOK ON PROFESSIONAL RESPONSIBILITY is 1697 pages excluding additional Index Tables.[196] Scientific professional journals occasionally publish review articles on science misconduct, most highlighting the devastation to scientific careers and reputation of both the scientists and their institution-employers.[197] One may reasonably conclude that professional

Research," March 25, 2002
(b)Federal Register, Volume 65, page 76262, December 6, 2000, "Federal Policy on Research Misconduct" current edition
(c)Title 32, Code of Federal Regulations, Part 22, "DoD Grant and Agreement Regulations (DoDGARS)," current edition
(d)Title 48, Code of Federal Regulations, Chapter 2, "Defense Federal Acquisition Regulation Supplement (DFARS)," current edition
(e)Section 2409 of title 10, United States Code, "Contractor Employees: Protection from Reprisal for Disclosure of Certain Information"
(f)Section 552 of title 5, United States Code, "Freedom of Information Act"
(g)Section 552a of title 5, United States Code, "Privacy Act"

Id.

193. Interim Final Rule & Opportunity for Comments, Department of Energy Policy on Research Misconduct, 70 Fed. Reg. 123 (proposed July 28, 2005) (to be codified at 10 C.F.R. pts. 600, 733, 48 C.F.R. pts. 935, 952, 970).

194. Grant and Cooperative Agreement Handbook—Research Misconduct, 70 Fed. Reg. 96 (May 19, 2005) (to be codified at 14 C.F.R. pts. 1260, 1273, 1274).

195. U.S. DEP'T OF HEALTH AND HUMAN SERVICES, COMM'N ON RESEARCH INTEGRITY REPORT, INTEGRITY AND MISCONDUCT IN RESEARCH (1995) [hereinafter RYAN REPORT], *available at* http://ori.hhs.gov/documents/report_commission.pdf.

196. *See* RONALD D. ROTUNDA & JOHN S. DZIENKOWSKI, LEGAL ETHICS, THE LAWYER'S DESKBOOK ON PROFESSIONAL RESPONSIBILITY (2012).

197. Rennie Drummond, *Dealing with Research Misconduct in the United Kingdom and An American Perspective of Research Integrity*, 316 BRIT. MED. J. 1726-33 (1998); *see also* Herbert N. Nigg & Gabriela Radescu, *Science Misconduct in Environmental Science and Toxicology*, 272 J. OF THE AM. MED. ASS'N 168-70 (1994).

ethical guidance for research scientists is fragmented between governmental agencies, guidelines *drawn using very broad strokes*; for the most part, lacking objective procedural process and enforcement authority, comparable to the American Medical Association or American Bar Association.[198]

Macrina aptly notes another common issue, that is, science misconduct often does not occur in a vacuum.[199] Science misconduct is frequently accompanied by charges under various civil and criminal laws.[200] Scientific experts, specific to the accused's research specialty and without conflict of interest, should be recruited to fully adjudicate offenses perpetrated by the individual or group.[201] The latter is rare given the ORI's mandate for institutions to "self-investigate" alleged science misconduct of their own (to include institution administrators), particularly if misconduct involves economic or commercial matters of science germane to the institution's functions.[202]

198. The "Ryan Report" recommendations for research misconduct are not unchallenged in the scientific community. RYAN REPORT, *supra* note 195; *see, e.g.*, *Debate*, *Should the Department of Health and Human Services Adopt the Ryan Commission's Recommendations? Pro and Con*, CQ RESEARCHER (Jan. 10, 1997), *available at* http://library.cqpress.com/cqresearcher/document.php?id=cqresrre199701100 0#Sidebar1REF[1]; Jennifer Kulynych, *Intent to Deceive: Mental State and Scienter in the New Uniform Federal Definition of Scientific Misconduct*, 1998 STAN. TECH. L. REV. 2, *available at* http://stlr.stanford.edu/pdf/kulynych-intent-to-deceive.pdf ("The legal principle of 'innocent until proven guilty,' which might be rephrased, 'assume correct until proven wrong,' does not apply to scientific work; the burden of proof remains with those claiming new findings.") (internal citation omitted); Jesse A. Goldner, *The Unending Saga of Legal Controls Over Scientific Misconduct: A Clash of Cultures Needing Resolution* 24 AM. J.L. & MED. 293 (1998).

199. *See* MACRINA, *supra* note 89, at 15.

200. *Id.*; *see infra* Section III.B. Criminal penalties for scientific research disclosure or "export" of sensitive but unclassified research science, absent a license to disclose, may include both incarceration and/or substantial fines.

201. Kulynych, *supra* note 198, at ¶¶ 48-49.

202. *See, e.g.*,United States v. Butler, 429 F.3d 140, 144-45 (5th Cir. 2005); *see also* Barbara E. Murray, Karl E. Andersen, Keith Arnold, John G. Bartlett, Charles C. Carpenter, Stanley Falkow, J. Ted Hartman, Tom Lehman, Ted W. Reid, Frank M. Ryburn, Jr., R. Bradley Sack, Marc J. Struelens, Lowell S. Young & William B. Greenough III, *Destroying the Life and Career of a Valued Physician-Scientist Who Tried to Protect Us from Plague: Was It Really Necessary?*, 40 CLINICAL INFECTIOUS DISEASES 1644-48, 1646 (2005), *available at* http://cid.oxfordjournals.org/content/40/11/1644.full.pdf+html.

Both the National Institutes of Health (NIH, United States Public Health Service, USPHS) and National Science Foundation (NSF) require all grantee institutions to have infrastructure in place for dealing with scientific misconduct.[203] When the economic or political stakes are sufficient, such legal delegation for intramural misconduct investigation functions tantamount to placing the "fox in charge of oversight of the chicken coup" for the majority of grantee institution scientists in both academic and government institutions.[204] Appellate process to the NIH, Office of Research Integrity (ORI), results in formal extramural investigations less than ten percent of the time despite apparent statutory mandate for federal funds scientist recipients.[205] The end result of this flawed system for research science public disclosure is often: (i) frequent and admitted denial of due process; (ii) forced retraction or government denial of public disclosure against public interest; (iii) arguable denial of First Amendment free speech; and, (iv) given PHS policy for grantee institution ownership, lack of standing for any impartial court challenge by the research scientist.

Summarizing modern government conflation of economic and security issues, the Association of American Universities notes: "Export control laws, long a mechanism to control transfer of goods having *military* applications, became [after 9/11 also] a means to limit export of goods or technologies having *commercial* value. This dual focus contributes to some of the difficulties experienced in university research administration today."[206]

203. MACRINA, *supra* note 89, at 15.

204. *See, e.g.*, SARASOHN, *supra* note 96, at 60; CREWDSON, *supra* note 98, at 294-95.

205. *Annual Report*, OFFICE OF RESEARCH INTEGRITY, http://ori.hhs.gov (last visited Feb. 16, 2012).

206. Alice P. Gast, *The Impact of Restricting Information Access on Science and Technology* 3 (2003) (emphasis in original), *available at* http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=1602.

B. *Delayed or Denied Public Disclosure of Research Findings Against Public Benefit*

In a survey from 2001-2006, AAAS found that intellectual property concerns significantly delayed, or precluded both research advancement and research disclosure to the public from government, nonprofit, healthcare, academic, industry and business organizations.[207] Research science disclosures, to include intellectual property, perceived as implicating U.S. national security are generally handled via "a complex combination of statutes, regulations, and procedures that govern control of classified information, public access to governmental information, and maintenance of government records."[208] Post-9/11, President George W. Bush "extended classification authority to several departments and agencies that had not previously been involved . . . e.g. the Department of Agriculture, the Environmental Protection Agency, and the Department of Health and Human Services."[209]

Post-9/11 security restrictions on disclosure of federally funded research were instituted under three new legal doctrines: export restrictions, a term of art broadly including any "sensitive" [research science] disclosure to any non-U.S. citizen [latter, "deemed export"]; "unclassified but sensitive" federal agencies' policies determinations; "dual use" research findings disclosure which may apply when basic life science

207. STEPHEN A. HANSEN, AMANDA BREWSTER, JANA ASHER & MICHAEL KISIELEWSKI, THE EFFECTS OF PATENTING IN THE AAAS SCIENTIFIC COMMUNITY 8-9 (2d ed. 2006), *available at* http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf.

208. GATHERING STORM, *supra* note 21, at 475-78, 475 n.1:

> With two exceptions, the government has no authority to designate information produced outside this legal framework as classified. The first exception is through the Atomic Energy Act; information related to nuclear weapons may be "born classified" without any prior involvement of the government in its generation. The second exception, under the Invention Secrecy Act of 1951, permits information received as part of the patent-application process to be classified.

Id.

209. *Id.* at 475.

research findings may have alternative applied use; and arguable self-censorship chilling by the scientific community (e.g. peer-reviewed research science journal editors) for any science deemed to have potential national security implications.[210]

Detailed review of security issues is beyond the scope of this review except as these may impact research science intellectual rights of attribution, integrity, disclosure and retraction. Research science security issues reflect the present the national security environment, currently in flux in response to rapidly changing global situations and executive policy.[211]

210. FINK REPORT, *supra* note 83, at 96:

> Until recently, there were very few cases of problems related to the publication of research results in the life sciences that attracted significant public attention. Some specialists in bioterrorism, however, had warned that, given continuing advances in biotechnology, open publication could provide information of use to terrorists…The public perception led to calls for scientific journals to refrain from publishing "dangerous" research or *to delete some data from published research results in order to preclude others from replicating the results* . . . . In addition to the results of fundamental research, the compilation, synthesis, and assessment of already published results in review articles may provide an understanding of a field that could guide or assist terrorists. Even more difficult are the concerns raised by reports that result when scientists are assembled to render their judgment as experts about particular problems.

Id. (emphasis added). *See generally* NEW GOV'T-UNIV. P'SHIP, *supra* note 2; James B. Petro, *Intelligence Support to the Life Science Community: Mitigating Threats from Bioterrorism*, CENT. INTELLIGENCE AGENCY (June 26, 2008, 3:02 PM), https://www.cia.gov/library/center-for-the-study-of-intelligence/csi-publications/csi-studies/studies/vol48no3/article06.html.

211. *See, e.g.*, *Research Compliance*, *supra* note 16:

> The U.S.A. Patriot Act and related legislation have altered the landscape for research at U.S. universities. Driven by a concern that research-generated information and materials used in research experiments could be used by terrorists to attack the American population, the Federal government has extended its regulation of research activities at universities and private laboratories. The effects of this new regulatory regime will be felt especially by the biological sciences, and some branches of chemistry, computer science,

1. "Export Restrictions": Publication, Peer-to-Peer Communication, and Patent Secrecy Orders

Federal export restrictions may affect intellectual property rights of U.S. scientists' research disclosure, to include: peer-reviewed journal publication; peer-review by U.S. scientists of research by scientists in certain foreign countries; scientific communication with research science colleagues in the U.S. and overseas; collaborative research science with "foreign" scientists to include naturalized U.S. university faculty and students (under the "deemed exports" policy restriction);[212] and patent secrecy orders.[213]

a. *Export Controls*

Export Controls control the flow of both information and materials.[214] Most, but not all, information subject to export control is of United States origin, in whole or in part, and proprietary.[215] The Department of Commerce implements the export information and materials licenses under the Export Administration (Regulations) Act of 1979 (EAR).[216] Information

> and physics . . . . *The regulatory atmosphere since 9/11 remains volatile and subject to change.*

Id. (emphasis added).

212. JULIE NORRIS, ASS'N OF AM. UNIVS./COUNCIL ON GOV'T RELATIONS, RESTRICTIONS ON RESEARCH AWARDS: TROUBLESOME CLAUSES, *available at* www.aau.edu/WorkArea/showcontent.aspx?id=1634 (citing the text of the laws, regulations and policies).

213. The Invention Secrecy Act of 1951, 35 U.S.C. §§ 181-188 (2006) (implemented by 37 C.F.R. § 5.1 (2011)).

214. *See* GENEVIEVE J. KNEZO, CONG. RESEARCH SERV., RL 31845, "SENSITIVE BUT UNCLASSIFIED" AND OTHER FEDERAL SECURITY CONTROLS ON SCIENTIFIC AND TECHNICAL INFORMATION: HISTORY AND CURRENT CONTROVERSY 3-6 (2004), *available at* http://www.fas.org/sgp/crs/RL31845.pdf.

215. FINK REPORT, *supra* note 83, at 105 n.41.

216. Export Administration Act of 1979, Pub. Law 96-72, 93 Stat. 503 (codified as amended in scattered sections of 50 U.S.C. app.) (amended by International Emergency Economic Powers Enhancement Act, Pub. L. No. 110-96, 121 Stat. 1011 (2007)). The Act lapsed on August 20, 2001 and the President (George W. Bush), through Executive Order 13,222 of August 17, 2001 (66 Fed. Reg. 44,025 (Aug. 22, 2001)), has continued the Regulations in effect under the International Emergency Economic Powers Act. 50 U.S.C. § 35 (2006). *See also* IAN F. FERGUSSON, CONG. RESEARCH SERV., RL 31832,

and technical data export is also controlled by the Department of State, under the International Traffic in Arms Regulations (ITAR).[217] The EAR defines "technical data" as:

> *Technology*. (General Technology Note)—Specific information necessary for the "development", "production", or "use" of a product. The information takes the form of "technical data" or "technical assistance". Controlled "technology" is defined in the General Technology Note and in the Commerce Control List (Supplement No. [One] to part 774 of the EAR).
>
> N.B.: Technical assistance—May take forms such as instruction, skills training, working knowledge, consulting services.
>
> Note: "Technical assistance" may involve transfer of "technical data".
>
> *Technical data* —May take forms such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals and instructions written or recorded on other media or devices such as disk, tape, read-only memories.[218]

In contrast to EAR,[219] the 2011 ITAR definition of "technical data" explicitly excludes "general scientific,

EXPORT ADMINISTRATION ACT: EVOLUTION, PROVISIONS, AND DEBATE (2009), *available at* http://www.fas.org/sgp/crs/secrecy/RL31832.pdf.

217. International Traffic in Arms Regulations, 22 C.F.R. §§ 120-130 (2011).

218. 15 C.F.R. § 772.1 (2012) (emphasis added). The Commerce Control List is part of the EAR, 15 C.F.R. § 774, Supplement No. 1-15, and is available at http://www.gpoaccess.gov/cfr/index.html and http://www.access.gpo.gov/bis/ear/ear_data.html. *See generally* IAN F. FERGUSSON, CONG. RESEARCH SERV., RL 31832, THE EXPORT ADMINISTRATION ACT: EVOLUTION, PROVISIONS, AND DEBATE (2009), *available at* http://www.fas.org/sgp/crs/secrecy/RL31832.pdf.

219. FINK REPORT, *supra* note 83, at 105 n.41 ("Unlike the EAR [under the ITAR], however, 'publicly available scientific and technical information and academic exchanges and information presented at scientific meetings are not treated as controlled technical data.").

mathematical or engineering principles,"[220] and information within the "public domain," (including newspapers, subscriptions, library materials, patents, conferences, meetings or seminars, released by government agency), or products of "fundamental research. . .ordinarily published and shared broadly in the scientific community."[221] The 2011 ITAR, however, provides an exception to "fundamental research" disclosure if: "(i) The *University or its researchers accept other restrictions* on publication of scientific or technical information resulting from the project or activity, or (ii) The research is *funded by the U.S. Government* and specific access and dissemination controls protecting information resulting from the research are applicable."[222] Another exception to the fundamental research "export exception" is fundamental proprietary research, even if sponsored by private commercial interests and conducted at public and private universities.[223] Since fundamental research may not, at its onset, envision any

220. Technical Data, 22 C.F.R. § 120.10(a)(1)-(5) (2011).

> (a) Technical data means, for purposes of this subchapter:
> Technical data means, for purposes of this subchapter:
> (1) Information, other than software as defined in § 120.10(a)(4), which is required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance or modification of defense articles. This includes information in the form of blueprints, drawings, photographs, plans, instructions or documentation.
> (2) Classified information relating to defense articles and defense services;
> (3) Information covered by an invention secrecy order;
> (4) Software as defined in § 121.8(f) of this subchapter directly related to defense articles;
> (5) This definition *does not include information concerning general scientific, mathematical or engineering principles commonly taught in schools, colleges and universities or information in the public domain as defined in § 120.11*. It also does not include basic marketing information on function or purpose or general system descriptions of defense articles.

Id. (emphasis added).

221. 22 C.F.R. § 120.11(a)(1)-(8) (2011).

222. *Id.* at § 120.11(a)(8) (emphasis added).

223. FINK REPORT, *supra* note 83.

proprietary outcome, this exception is indeed problematic for academic institutions' export compliance. Exports, defined in the ITAR, expressly includes any form of disclosure, "oral or visual or transfer."[224]

b. *"Deemed Exports"*

Deemed exports are generally intangibles, broadly defined as delivering information or allowing access or use of export-controlled components by non-U.S. persons within the U.S.,[225] or abroad.[226] Sensitive information subject to non-disclosure or license to disclose includes information non-U.S. persons:

> might be expected to take . . . with them in their heads or personal notes when they leave the United States at some future time, providing the information or access to them was "deemed" to be an export for regulatory purposes. In this way, the reach of the [various federal agencies' export control] lists was extended to many activities conducted entirely within the United States, and not just to activities of exporting goods and services.[227]

Deemed exports have their origin in The National Defense Authorization Act for Fiscal Year 2000,[228] authorized by the Inspectors General of the Departments of Commerce, Defense, Energy, and State, in consultation with Directors of the CIA (Central Intelligence Agency) and FBI (Federal Bureau of Investigation), to conduct a multiyear assessment of the

224. 22 C.F.R. § 120.17(a) (2011).

225. COMM. ON SCI., SEC., AND PROSPERITY ET AL, BEYOND FORTRESS AMERICA: NATIONAL SECURITY CONTROLS ON SCIENCE AND TECHNOLOGY IN A GLOBALIZED WORLD 22 nn.11, 32-33, Appendices F, H (2009).

226. 22 C.F.R. § 120.17(a)(4) (2011) ("(a) Export means: (4) Disclosing (including oral or visual disclosure) or transferring technical data to a foreign person, whether in the United States or abroad.").

227. COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225, at 33-34.

228. National Defense Authorization Act for Fiscal Year 2000, Pub. L. 106-65, 113 Stat. 512 (1999).

adequacy of current controls and counterintelligence measures to prevent acquisition of sensitive U.S. technology and technical information by countries and entities.[229] Many of these agencies' reports remain either classified or publicly unavailable.[230]

In 2006, Arthur Bienenstock, Past-President of the American Physical Society, Director of the Wallenburg Research Link and professor at the Stanford Synchrotron Radiation Laboratory [among his numerous titles], reviewed the impact of the "deemed export" Policy on Stanford to the Deemed Export Advisory Committee (DEAC), of the Association of American Universities (AAU), concluding: "negative consequences [of deemed export policies] for the nation [are] far greater than positive."[231]

229. Memorandum from Michael C. Kane, Assoc. Adm'r for Mgmt. and Admin., to Alfred K. Walter, Acting Assistant Inspector Gen. for Inspections and Special Inquiries, (Mar. 31, 2004), *in* OFFICE OF INSPECTIONS AND SPECIAL INQUIRIES, U.S. DEP'T OF ENERGY, INSPECTION REPORT: CONTRACTOR COMPLIANCE WITH DEEMED EXPORT CONTROLS 10-11 (2004), *available at* http://energy.gov/ig/downloads/inspection-report-contractor-compliance-deemed-export-controls-doeig-0645:

> The National Defense Authorization Act for Fiscal Year 2000 requires that between 2000 and 2007[,] the President shall submit to Congress and annual report to include a review that examines export control issues by the Offices of Inspector General (OIGs) of the Departments of Energy, Commerce, State, and Defense. For 2004, the OIGs for these agencies and the Department of Homeland Security and the Central Intelligence Agency reviewed compliance by contractors and universities with deemed export controls for access to unclassified technologies. Release to a foreign national of technology or software that is subject to the Export Administration Regulations is "deemed to be an export" to the home country of the foreign national. Release includes visual access by foreign nationals to United States-origin equipment and facilities and oral exchange of information.

Id.; COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225, at 22 n.11.

230. COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225, at 22 n.11.

231. *Arthur Bienenstock (Profile)*, STANFORD UNIV., http://fsi.stanford.edu/people/arthurbienenstock (last visited Apr. 12, 2012); Arthur Bienenstock, Stanford Univ., Presentation to the Deemed Export Advisory Committee: Deemed Exports: An Academic's View (Jan. 22, 2006),

In assessing the negative impact of "deemed exports," Professor Bienenstock noted that thirty three percent of Stanford's graduate students are non-U.S. from ninety four foreign countries; that Stanford's contracts and grants cannot restrict publication nor limit participants in research based on nationality, religion, gender, etc.; both faculty advisors and students working on integrated research projects must have access to confidential data to participate fully in the research; and Department of Commerce must provide an accurate and readily available list of technical manuals "not publicly

available at www.aau.edu/WorkArea/DownloadAsset.aspx?id=1536 (follow "Bienenstock Presentation at DEAC Meeting," dated January 22, 2006). Among the negative consequences of "deemed export controls" Bienenstock listed are: foreign students treated as second-class on campus: readily identifiable (badges, etc.), limited access to controlled instruments; will discourage students from US universities; will discourage faculty with controlled equipment from supervising foreign students; U.S. is dependent on foreign students for its S & T (science and technology) workforce; students on temporary visas earned about one-third (32%) of all S & E (science and engineering) doctorates awarded in the U.S. in 2003; more than half (55%) of engineering doctorates were awarded to students on temporary visas; historically, half or more of students on temporary visas have stayed in the United States immediately after degree conferral, with this percentage increasing in recent years. *See also* Jacob N. Shapiro & David A. Siegel, *Is This Paper Dangerous? Balancing Secrecy and Openness in Counterterrorism*, 19 SECURITY STUD. 66, 94, 98 (2010) (emphasis added), *available at* http://www.princeton.edu/~jns/publications/Is%20This%20Paper%20Dangerous.pdf:

> [Federal] officials do not generally believe changes in the level of security have increased security. Sixty-seven percent of our respondents report secrecy has increased since 2000, and [thirty] percent report it has remained the same. At the same time, [sixty] percent of our respondents report that the changes in information control have had no effect *or a negative effect* on the safety of society from terrorism. This perception is not consistent with the hypothesis that changes have been driven by a well-reasoned effort to increase security. . . . One federal official neatly summarized a more nuanced approach: "Secrecy does not necessarily increase security. Although it may deny information to our adversaries, it also denies information to those who need access; perhaps decreasing our ability to protect ourselves; perhaps decreasing the level of trust our citizens have in government."

Id.(emphasis added).

available," subject to deemed export restriction [over 30,000 instruments at Stanford would need to be examined as possibly deemed export-restricted].[232]

Deemed exports have been broadly defined to include disclosure of materials and methods in peer-reviewed scientific journal research articles; peer review of scientific research manuscripts for peer-reviewed journal publication (to include mere correction of faulty English grammar); peer review by U.S. scientists of research by scientists in certain foreign countries; scientific communication with research science peers in the U.S. and overseas (for example, at seminars or scientific meetings); collaborative scientific research with "foreign" scientists to include naturalized U.S. university faculty and students (under the "deemed exports" policy restriction).[233] In short, most activities intrinsic to scientific research, to include all the most common forms of scientific disclosure, may be deemed by one of several federal agencies' various policies to violate certain export restrictions.[234]

232. Presentation to the Deemed Export Advisory Committee: Deemed Exports: An Academic's View, *supra* 231; *see also* COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225, at 32-37. The sharply rising Export Control Classification Numbers (ECCNs, numbering close to 500 in 2008) are taken from the annual editions of the Code of Federal Regulations: 15 C.F.R. 774 Supplement 1 (2011).

> The relationship between the number of ECCNs and number of controlled goods is neither direct nor proportional and is influenced by several variables, including the breadth of products and goods controlled and the list of destination countries defined for each ECCN. The [Department of Commerce] Control List (CCL) is not in fact an explicit list of commercial items to be controlled and is instead a list of technology descriptions that may qualify a product for export [restriction]. A cross-reference between the ECCN and common product types is included with the current CCL, but it clearly states *it is not an exhaustive list*.

COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225, at 33 (emphasis added).

233. NORRIS, *supra* note 212 (this AAU/COGR report cites the text of the laws, regulations and policies).

234. COMM. ON SCI., SEC., AND PROSPERITY, *supra* note 225, at 32-37.

> Our former unilateral strategy of containment and isolation of our adversaries is, under current conditions, a self-

c. *Patent Secrecy Orders: The Invention Secrecy Act of 1951*[235]

The Invention Secrecy Act of 1951 permits the federal government to place "secrecy orders" on a patent application.[236] The latter results in both restricted disclosure of the invention and withholding the grant of the patent.[237] There are several types of secrecy orders, ranging lowest to highest, from prohibitions on export (but allowing other "business purposes" disclosure), to classification or prohibition of all disclosure.[238] Since the Invention Secrecy Act's effective date, invention secrecy orders have steadily increased to a high of 5241 in effect in FY (fiscal year) 2011.[239] The Invention Secrecy Act is not restricted to public interests in government inventions but applies broadly also to private inventions which "might in the opinion of the Commissioner of Patents, be detrimental to the

> destructive strategy of obsolescence and declining economic competitiveness. A strategy of international engagement is a path to prosperity that can be coupled with a smart approach to security using an adaptive system of government regulation and incentives.

Id. at 81.

235. The Invention Secrecy Act of 1951, Pub. L. No. 82-256, 66 Stat. 3 (codified at 35 U.S.C. §§ 181-188 (2006)).

236. 35 U.S.C. § 181 (2006) provides that:

> Whenever publication or disclosure by the publication of an application or by the grant of a patent on an invention in which the Government has a property interest might, in the opinion of the head of the interested Government agency, be detrimental to the national security, the Commissioner of Patents upon being so notified shall order that the invention be kept secret and shall withhold the publication of the application or the grant of a patent therefore under the conditions set forth hereinafter.

Id.

237. *Id.*

238. *See generally* STEVEN AFTERGOOD, FED. OF AM. SCIENTISTS, INVENTION SECRECY (2011), *available at* http://www.fas.org/sgp/othergov/invention/index.html (contains cross-links to official government documents' references).

239. *Id.*

national security."[240]

The Invention Secrecy Act limits a secrecy order time period to a period of one year, but provides for additional renewal of secrecy status "for additional periods of one year upon notification by the head of the department or the chief officer of the agency who caused the order to be issued."[241] There are substantial penalties for the inventor who discloses by publication or by filing overseas in violation of a secrecy order, including the U.S. Patent and Trademark Office holding the patent "abandoned"; "a forfeiture by the applicant, his successors, assigns, or legal representatives, or anyone in privity with him or them of all claims";[242] and possible criminal penalties.[243]

2. "Sensitive but Unclassified" ("Controlled Unclassified Information"): Executive Agency and/or Academic Institution Publication Preclusion

Albeit not defined in statutory law,[244] "Sensitive But Unclassified" information, or SBU, was technically defined in 2009 "to refer collectively to [the approximately 117] designations used within the Federal Government for documents and information that are sufficiently sensitive to warrant some level of protection, but do not meet the standards for National Security Classification."[245] "Controlled But Unclassified Information," or CUI, was defined as:

> A category designation that refers to unclassified information that does not meet the standards for National Security Classification under Executive Order 12,958, as amended, but is (i) pertinent to

240. 35 U.S.C. §§ 181-188 (2006).

241. *Id*. at § 181.

242. *Id*. at § 182.

243. *See id.* at § 186.

244. KNEZO, *supra* note 214, at 2.

245. PRESIDENTIAL TASK FORCE ON CONTROLLED UNCLASSIFIED INFO., REPORT AND RECOMMENDATIONS 1 n.2, 33-34 (2009) (SBU definition given on first page and"SBU Markings Currently in Use" in Appendix), *available at* http://www.justice.gov/ag/cui_task_force_rpt.pdf (last visited July 12, 2012).

> the national interests of the United States or to the important interests of entities outside the Federal Government, and (ii) under law or policy requires protection from unauthorized disclosure, special handling safeguards, or prescribed limits on exchange or dissemination.[246]

Publication restrictions precluding research science disclosure based on increasing government classification and non-classified denial of disclosure predate 9/11.[247] While detailed information security history is beyond the scope of this review, a brief security history overview is material to the current status of attribution, integrity, retraction, and disclosure intellectual rights restrictions pertaining to U.S. scientific research.[248]

President Ronald Reagan's Executive Order 12,356, signed by the President on April 2, 1982, greatly broadened authority to classify information.[249] As previously discussed, however, President Reagan's National Security Decision Directive 189, National Policy on the Transfer of Scientific, Technical and Engineering Information, ostensibly remains in force post-9/11:[250]

246. *Id.* at1 n.2

247. *See* Austin Harris, *Square Information, Round Characterization: Executive Order 13,556 and Its Implementation Challenges*, 1 UNIV. MIAMI NAT'L. SECURITY & ARMED CONFLICT L. REV. 150, 158-61 (2010-2011); *see also* KNEZO, *supra* note 214.

248. PRESIDENTIAL TASK FORCE, *supra* note 245, at 6-7 n.12; *see* KEVIN R. KOSAR, CONG. RESEARCH SERV., RL 97-771, SECURITY CLASSIFICATION POLICY AND PROCEDURE: E.O. 12958, AS AMENDED (2009), *available at* http://www.fas.org/sgp/crs/secrecy/97-771.pdf.

249. Exec. Order No. 12,356, 47 Fed. Reg. 14,874, 14,875 (1982):

> If there is reasonable doubt about the need to classify information, it shall be safeguarded as if it were classified pending a determination by an original classification authority . . . . If there is reasonable doubt about the appropriate level of classification, it shall be safeguarded at the higher level of classification . . . .

Id.; *see also* National Security Information, 47 Fed Reg. 27,836 (June 25, 1982) (to be codified at 32 CFR pt. 2001).

250. GATHERING STORM, *supra* note 21, at 104-06 ("The NSDD-189 policy

> It is the policy of this Administration that, to the maximum extent possible, the *products of fundamental research remain unrestricted*. It is also the policy of this Administration that, where the national security requires control, the mechanism for control of information generated during federally-funded fundamental research in science, technology and engineering at colleges, universities and laboratories is classification. *Each federal government agency is responsible for*: a) determining whether classification is appropriate prior to the award of a research grant, contract, or cooperative agreement and, if so, controlling the research results through standard classification procedures; b) periodically reviewing all research grants, contracts, or cooperative agreements for potential classification. *No restrictions may be placed upon the conduct or reporting of federally-funded fundamental research that has not received national security classification*, except as provided in applicable U.S. Statutes.[251]

Post-9/11, the freedom to publish scientific research often seems to turn on each agency's interpretation of whether science research is "fundamental research,"[252] rather than on

remains in force and has been reaffirmed by senior officials [Condoleeza Rice] of the [then] current [George W. Bush] administration, but it appears to be at odds with other policy developments and some recent practices.").

251. National Security Decision Directive 189 (Sep. 21, 1985), *available at* http://www.fas.org/irp/offdocs/nsdd/nsdd-189.htm (emphasis added).

252. *See, e.g.*, Letter from John J. Young, Dir., Def. Contract Audit Agency, to Sec'ys of the Military Dep't (June 26, 2006), *available at* http://www.ogrd.wsu.edu/documents/DOD.pdf. This letter defines "fundamental research" as follows:

> "Fundamental research" means basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production, and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons . . . .

whether "research that has not received a national security classification."[253]

> The definition of "contracted fundamental research" in a DoD grant or contractual context is established by References (a) and (b) and is defined as follows:
>
> "'Contracted Fundamental Research' includes research performed under grants and contracts that are (a) funded by budget Category 6.1 ("Research"), whether performed by universities or industry or (b) funded by budget Category 6.2 ("Exploratory Development") and performed on-campus at a university. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2 funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the contract or grant."
>
> The terms "budget category 6.1" ("Research") and "budget category 6.2" ("Exploratory Development") have been replaced by Research, Development, Test, and Evaluation Budget Activity 1 (Basic Research) and 2 (Applied Research). With this clarification, these references continue to define national and DoD policy on the transfer [including publication] of the products of contracted fundamental research.

Id. See generally KNEZO, *supra* note 214 (There appears to be lack of consensus whether SBU should be classified; and whether SBU controls adversely affect scientific communication.).

253. KNEZO, *supra* note 214, at 1; *see also Defense Federal Acquisition Regulation Supplement*, *DFARS Procedures, Guidance and Information*, PGI 204(3)(ii), *available at* http://www.acq.osd.mil/dpap/dars/dfars/changenotice/2008/20080721/pgi-changes-07212008.pdf:

> (i) NSDD 189 establishes a national policy that, to the maximum extent possible, the products of fundamental research shall remain unrestricted. NSDD 189 provides that no restrictions may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification, except as provided in applicable U.S. statutes. As a result, contracts confined to the performance of unclassified fundamental research generally do not involve any export-controlled items, information, or technology.
>
> (ii) NSDD 189 does not take precedence over statutes. NSDD 189 does not exempt any research, whether basic, fundamental, or applied, from statutes that apply to export controls such as the Arms Export Control Act, the Export Administration Act of 1979, as amended, or the U.S.

Restriction on disclosure, to include research science, may be divided into two broad categories: classified, denoted by the government with specific markings; and unclassified, which includes about 117 "*ad hoc*, agency-specific" subtypes, defined by individual agencies' policies.[254] It is the latter, most often restricting modern U.S. research science disclosure, i.e. the broad category designated either as: "unclassified but sensitive" ("UBS"), or "Controlled Unclassified Information" ("CUI").[255] Modern CUI/UBS may include, but is not limited to, such executive agency "inefficient, confusing patchwork"[256] as: "attorney client, IT [Information Technology] security-related, trade secret [and other intellectual research science property], bomb tech sensitive, controlled nuclear information, chemical-terrorism vulnerability information, and protected infrastructure information."[257] It is the *ad hoc* agency-specific denial of research science disclosure invoking UBS or CUI restriction blamed for harm to U.S. research innovation, particularly post-9/11.[258]

In Executive Order 13,526, dated December 29, 2009,

> International Emergency Economic Powers Act, or the regulations that implement those statutes (the ITAR and the EAR). Thus, if export-controlled items, information, or technology is used to conduct research, the export control laws and regulations apply to the controlled items, information, or technology.

Id.

254. PRESIDENTIAL TASK FORCE, *supra* note 245, at app. 2, 33-34; *see also* Harris, *supra* note 247, at 157.

255. Harris, *supra* note 247, at 158-61. Federal employee job performance rating for conformance with CUI Framework policies may be a material factor promoting research science disclosure self-censorship or "chilling" factor; *see also* PRESIDENTIAL TASK FORCE, *supra* note 245, at 23-24.

256. Exec. Order No. 13,556, 75 Fed. Reg. 68,675 (Nov. 4, 2010).

257. Harris, *supra* note 247, at 158 (internal citations omitted); *see also* PRESIDENTIAL TASK FORCE, *supra* note 245.

258. Exec. Order No. 13,556, 75 Fed. Reg. 68,675, § 1 (Nov. 4, 2010) ("This inefficient, confusing patchwork has resulted in inconsistent markings and safeguarding of documents, led to unclear or unnecessarily restrictive dissemination policies, and created impediments to authorized information sharing. The fact that *these agency-specific policies are often hidden from public view only aggravated these issues*.") (emphasis added). *See generally* GATHERING STORM, *supra* note 21, at 70, 83-84, 104-05, 186-92; REVISITED STORM, *supra* note 21.

President Barack Obama revoked prior more restrictive executive orders regarding national security information.[259] Executive Order 13,526 does not specifically address "unclassified but sensitive" scientific research. In Executive Order 13,556 of November 4, 2010, President Obama recently addressed the research science publication problem of the non-classified publication preclusion, i.e. "Controlled Unclassified Information."[260] It is too soon after the 2009-2010 executive policy changes to evaluate the impact on U.S. scientific research innovation, the latter severely harmed by post-9/11 disclosure restrictions.[261]

259. Exec. Order No. 13,526, 75 Fed. Reg. 707 (Dec. 29, 2009):

> Section 1.1 Classification Standards
> (b) If there is significant doubt about the need to classify information, it shall not be classified . . . .
> Sec. 1.5 Duration of Classification
> (d) No information may remain classified indefinitely . . . .
> Sec. 1.7 Classification Prohibitions and Limitations
> (b) Basic scientific research information not clearly related to the national security shall not be classified . . . .
> Sec. 1.8 Classification Changes
> (c) Documents required to be submitted for prepublication review or other administrative process pursuant to an approved nondisclosure agreement are not covered by this section [Classification Challenges].

Id.

260. Exec. Order No. 13,556, 75 Fed. Reg. 68,675, § 1 (Nov. 4, 2010); *see also* Harris, *supra* note 247.

261. EXEC. AGENCY, CONTROLLED UNCLASSIFIED INFORMATION (CUI) OFFICE NOTICE 2011-01: INITIAL IMPLEMENTATION GUIDANCE FOR EXECUTIVE ORDER 13,556 (2011), *available at* www.archives.gov/cui/.../2011-cuio-notice-2011-01-initial-guidance.pdf; *see also CUI Chronology*, CONTROLLED UNCLASSIFIED INFO., http:/www.archives.gov/cui/chronology.html (last visited Apr. 4, 2012) ("[I]n May 2008, the Archivist of the United States established the CUI Office within NARA [National Archives and Records] to act as the CUI Executive Agent (EA)."). *See generally* GATHERING STORM, *supra note* 21, at 70, 83-84, 104-105, 186-192; REVISITED STORM, *supra* note 21; COMM. ON SCI., SEC., AND PROSPERITY, s*upra* note 225; PRESIDENTIAL TASK FORCE, *supra* note 245.

3. "Dual Use": When Basic Life Sciences Research May Have Applied Use

"Dual use" has been defined as scientific research that has both civil and military applications and is subject to one or more agencies' policy control regimes.[262] The Bureau of Industry and Security (BIS) within the Department of Commerce is charged with regulating dual use exports.[263] The BIS licensing is accomplished in consultation with, e.g. review by Defense Technology Security Agency in the Department of Defense, and referral by Depart of State.[264] For research scientists, "dual use" is a broad and ill-defined research category,[265] admittedly failing to reflect advances in technology, and failing to reflect foreign availability of dual use items.[266] Shared responsibility for dual use determination further creates uncertainty as to which agency controls licensing determination.[267] Finally, research scientists and research organizations may not appeal denial, because there is no judicial review of licensing decisions.[268]

262. FINK REPORT, *supra* note 83, at 105; *see also* NAT'L INSTS. OF HEALTH, OFFICE OF BIOTECHNOLOGY ACTIVITIES, NAT'L SCI. ADVISORY BD. FOR BIOSECURITY, FREQUENTLY ASKED QUESTIONS No. 14 [hereinafter NSABB], *available at* http://oba.od.nih.gov/oba/ibc/FAQs/FAQs%20about%20the%20National%20Science%20Advisory%20Board%20for%20Biosecurity.pdf:

> The NSABB has proposed defining "dual use research of concern" as research that, based on current understanding, *can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others* to pose a threat to public health, agriculture, plants, animals, the environment or materiel. The NSABB has also proposed a series of experimental outcomes that should be given special consideration for their dual use potential.

Id. (emphasis added).

263. FERGUSSON, *supra* note 216, at 26.

264. *Id.*

265. NSABB, *supra* note 262, at No. 14.

266. FERGUSSON, *supra* note 216, at 26.

267. *Id.*

268. *Id.*

4. "Self Censorship Chilling" by Peer Reviewed Journal Editors of Scientific Findings Deemed to Pose Potential Security Risk by Disclosure

Self-regulation of "sensitive" research science disclosure post-9/11 was initially based on the 1970s 3-prong model for self-regulation of recombinant DNA research:

> (1) personal responsibility and accountability of the researcher to conduct his or her research safely;
>
> (2) deliberations by a nationally convened advisory group to provide recommendations regarding biosafety with recombinant DNA research; and
>
> (3) local oversight by the institution through a committee of peer researchers and biosafety professionals to assure that appropriate facilities, practices, personnel, and training were in place.[269] Post-9/11, the National Academies of Sciences published findings and recommendations of the 2003 "Fink Report," after the committee chairman, Gerald Fink.[270]

The 2004 Fink Report advocated "expanded self-governance by researchers toward issues of biosecurity, as well as the formation of a national advisory board to help guide both the government and research community in addressing issues involving dual use." [271] The National Science Advisory Board on Biosecurity, NSABB, was chartered by the Executive Office of the President [George W. Bush] and became fully operational in 2005.[272] Currently, the mandate of the NSABB, located

269. NEW GOV'T-UNIV. P'SHIP, *supra* note 2, at 59-60 ("Although all these [3-prong model] components of self-governance and local assurance were recommended for all U.S. researchers regardless of affiliation, the practical outcome of this system is that only institutions accepting federal funding for DNA research are obligated to use this model of oversight.").

270. FINK REPORT, *supra* note 83, at 115.

271. NEW GOV'T-UNIV. P'SHIP, *supra* note 2, at 60.

272. *Id*. at 60-61.

within the National Institutes of Health (NIH), Office of the Director NIH, Office of Biotechnology Activities, has been restricted to "oversight of dual use biological research,"[273] and a limited renewable charter of two-year intervals.[274] The NSABB mandate has been increasingly narrowed in scope from that initially proposed in the "Fink Report" of 2004.[275]

The Fink Report also recommended peer-reviewed science journals "refrain from publishing 'dangerous' research or delete some data [to include materials and methods] from published research results in order to preclude others from replicating the results." [276] The Fink Report further broadly recommended virtually every aspect of research science disclosure be subjected to restriction:

> In addition to the *results of fundamental research*, the compilation, synthesis, and assessment of already published results in *review articles* may provide an understanding of a field that could guide or assist terrorists. Even more difficult are concerns raised by reports that result *when scientists are assembled* [e.g. at professional scientific society meetings] to render their judgment as experts about particular problems, even when they rely completely on

273. NSABB, *supra* note 262, at No. 14.

> The NSABB has proposed defining "dual use research of concern" as research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment or materiel. The NSABB has also proposed a series of experimental outcomes that should be given special consideration for their dual use potential.

Id.

274. *Id.*

275. *Id.*; *see also* FINK REPORT, *supra* note 83, at 95 (The NSABB meeting pertains to "insider threats at facilities that conduct research with highly pathogenic agents").

276. FINK REPORT, *supra* note 83, at 96.

open sources of information.[277]

Professional peer-reviewed journals' responses to the Fink Report recommendations appear guardedly negative. For the eleven journals it publishes, the American Society for Microbiology (ASM) rejected restriction on material and methods information section of peer reviewed research articles.[278] The ASM did institute formal procedures as part of the peer-review process to allow reviewers to "address potential risks of the research results to national security." [279] Other science peer-reviewed journals have also "moved to develop [a security] review procedure of their own." [280]

An executive agency, Department of Defense (hereinafter, DoD), proposed in 2002 "that researchers be required 'to obtain DoD approval to discuss or publish findings of all military-sponsored unclassified research.'"[281] The scientific research community response severely criticized the latter DoD proposal prompting DoD withdrawal.[282] Department of Defense 5230.27 and 5230.29, affirmed on May 2010 and January 2009, respectively, reflect ostensible intent to adhere to the principle of public access to unclassified government research, while apparently retaining [by reference] prior agency policies and/or processes, restricting unclassified science disclosure.[283] The

277. *Id.* at 96-97 (emphasis added).

278. *Id.* at 97.

279. *Id.*

280. *Id.*

281. *Id.* at 101 n.1.

282. *Id.*

283. Presentation of DoD-Related Scientific and Technical Papers at Meetings, Instruction 5230.27 (Dep't of Def. Oct. 6, 1987) (affirmed May 24, 2010), *available at* http://www.ogrd.wsu.edu/documents/DOD.pdf; Security and Policy Review of DoD Information for Public Release, Instruction 5230.29 (Dep't of Def. Jan. 8, 2009), *available at* http://www.dtic.mil/whs/directives/corres/pdf/523029p.pdf; *see also* NORRIS, *supra* note 212; KNEZO, *supra* note 214, at 47:

> [T]he Depart of Defense reportedly plans to reissue its guidelines relating to pre-publication review of extramural research it funds outside of its own laboratories. Recently several university groups wrote a letter to the Director of the Office of Science and Technology Policy complaining that more agency program officials are inserting pre-

federal agencies push for—with unquestionable push back-resistance of the research community–to allow "voluntary" or federal research support "contract clauses" to limit open and full scientific disclosure continue post-9/11 and to the profound detriment of U.S. research innovation.[284]

Continually-shifting policies regarding science disclosure post 9/11, coupled with the vague broad definitions of "fundamental" and "unclassified sensitive" research science, have served to profoundly "chill" science innovation and to discourage scientists from the pursuit of research affected by U.S. government nondisclosure policies mandated nondisclosure .[285]

> publication review clauses into contracts, including fundamental research, without explanation as to their justification. This has "pernicious effects," they said, "not only with regard to the freedom to publish but also with regard to employment of foreign-born students and researchers on the federally funded research projects."

Id.

284. Instruction 5230.27, *supra* note 283; Instruction 5230.29, *supra* note 283; NORRIS, *supra* note 212; KNEZO, *supra* note 214, at 47; *see also* REVISITED STORM, *supra* note 21; COMM. ON SCI., SEC., AND PROSPERITY ET AL., *supra* note 225; PRESIDENTIAL TASK FORCE, *supra* note 245; Simoncelli & Stanley, *supra* note 82, at 33 ("[N]o administration should use its power to censor, obstruct, tamper with of distort the findings of scientists to fit its political agenda. Federal science-based agencies must retain the capacity to carry out independent scientific research and should not be subjected to political influence in establishing peer-review standards."). *See generally* GATHERING STORM, *supra* note 21, at 70, 83-84, 104-05, 186-92.

285. DoD 5230.27 , *supra* note 283; DoD Instruction 5230.29, *supra* note 283; NORRIS, *supra* note 212; KNEZO, *supra* note 214, at 47; SIMONCELLI & STANLEY, *supra* note 82, at 33.

C. *Constitutional and Federal Law: U.S. Moral Rights Denial Creates Legal Anomalies and Apparent Conflict of Law Regarding Intellectual Property Created by Research Scientists*

1. U.S. Government and Industry Practice Appears to Violate Scientists' First Amendment Rights and Article I, § 8, cl. 8, and May Place Scientists in Potential Catch-22 Situation: Either to Violate Professional Ethical Standards or to Abruptly Foreclose Employment

There is no copyright in works of the United States.[286] "[C]opyright law prohibits any copyright in works of the U.S. government."[287] One reason given for the prohibiton is the concern for government censorship of information in violation of the First Amendment.[288] Professor Pollack argues that the founding fathers intended the Constitution's art. I, sec. 8, cl. 8, copyright and patent provisions to be read *in pari materia* with the First Amendment.[289] The copyright clause when so read, would equate "progress" with "dissemination" and could have no potential to support censorship because "Congress was empowered only to enact copyright statutes that disseminated knowledge." [290] Restriction on research a scientist's First Amendment disclosure for the public benefit may also be limited by commercial sources providing scientific research support.[291]

286. 17 U.S.C. § 101(iii)(C) (2006).

287. 2 WILLIAM F. PATRY, PATRY ON COPYRIGHT § 4:54 (2009) ("Current copyright law prohibits any copyright in works of the U.S. government (a defined term). The origin of this prohibition may be traced back to the 19th century, when both statutory and judicial opinions began to shape the area."); *see also* 17 U.S.C. § 101(iii)(C).

288. Malla Pollack, *The Democratic Public Domain: Reconnecting the Modern First Amendment and the Original Progress Clause (A.K.A. Copyright and Patent Clause)* 45 JURIMETRICS J. 24, 45 (2004).

289. *Id.*

290. *Id*. at 30.

291. Melese, *supra* note 5, at 15 ("[T]he high costs and risks associated with discovering and bringing a new drug to market and the potential financial rewards for doing so encourage pharmaceutical companies to retain, sequester, and control enabling intellectual property.").

One familiar challenge for federal scientists occurs when the scientist's research findings contradict a strongly held position of senior supervisors, who may include political appointees.[292] Professional ethical standards expressly require the scientist to "give the decision-maker a frank, understandable description of the science."[293] However, such situations often in fact place the government researcher in the position of acquiescing in clear professional breach of research integrity (e.g. knowing fraudulent distortion of research record in acquiescence to a superior's order).[294] Any knowing distortion of the research record (even to placate a supervisor) if/when revealed would terminate the scientist's career in disgrace or, depending on source of research support, could subject him to devastating "science misconduct" action.[295] The alternative, is the scientist immediately quits his/her job to foreclose the scientist's supervisor-coerced participation in knowing scientific fraud.[296]

Modern research networks linking federal government and

292. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 41-43:

> In recent years, the federal national laboratories have been subject to reviews which have recommended reduction in size, narrowing scope, and, in some cases, closing. These pressures, not common in academia, lead to implicit and sometimes explicit demands of loyalty to the organization. One pressure can be less-than-objective regarding results which may go against the desires of the leaders or funders of the organization….A more difficult challenge comes when a scientist's position, based on his or her research, contradicts a strongly held position of senior political appointees. These situations, while perhaps rare, can place the government researcher in a dilemma: acquiesce or leave.

Id.; see, e.g., MARK BOWEN, CENSORING SCIENCE, INSIDE THE POLITICAL ATTACK ON DR. JAMES HANSEN AND THE TRUTH OF GLOBAL WARMING (2008) (detailing the James Hansen case).

293. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 41-43.

294. *Id.* at 42-43.

295. *See* SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 10 (Applying any or all of the DHHS, NAS, NSF, Commission on Research Integrity, and Medical Res. Council-England definitions of "misconduct in science," a scientist's distortion of the research record, even under supervisor's order, could render the scientist subject to misconduct charges.)

296. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 41-46; *see* BOWEN, *supra* note 292.

industry with academic science research have brought restrictions on publication that are arguably unconstitutional.[297] Corporate and/or agency support may similarly come with implicit or mandated restriction that only scientific research findings furthering private or executive agency interest be disclosed.[298] This latter restriction directly impacts research science quality and integrity via corporate or government agency preclusion against disclosure limited to research findings favorable to corporate-, or business- with agency collaborative interest, a process arguably risking First Amendment challenge as a prior restraint[299] against the public interest.

The Commission on Research Integrity proposed definition of research misconduct would preclude any

> significant behavior that improperly appropriates the intellectual property or contributions of others, that intentionally

297. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24 , at 50; s*ee also* Aaron S. Kesselheim et al., *Whistle-blowers' Experiences in Fraud Litigation Against Pharmaceutical Companies with Supplemental Appendix*, NEW ENG. J. MED., May 13, 2010,at 1832, 1839 (a study of "relators" in *qui tam* suits filed under the Federal False Claims Act).

298. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 50:

> The increasing involvement of industry, through grants and other support, has been encouraged by universities. While financially advantageous, and bringing faculty into contact with practical problems, these industrial links have brought restrictions on publication and other challenges to academic freedom. An early proponent has cautioned that "the price of corporate support is eternal vigilance."

Id.

299. *See generally* IOANNIS G. DIMITRAKOPOULOS, INDIVIDUAL RIGHTS AND LIBERTIES UNDER THE U.S. CONSTITUTION: THE CASE LAW OF THE U.S. SUPREME COURT 531-32 (2007) (citing Alexander v. United States, 509 U.S. 544, 550 (1993)) (["The term prior restraint is used] . . .' to describe administrative and judicial orders forbidding certain communications when issued in advance of the time that such communications are to occur.'"); *see also* Freedman v. Maryland, 380 U.S. 51, 58 (1965) ("[A non-criminal prior restraint upon expression] . . .'avoids constitutional infirmity only if it takes place under procedural safeguards designed to obviate the dangers of a censorship system.'").

> impedes the progress of research, or risks corrupting the research record or compromising the integrity of research practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in [peer] reviewing the proposals and research reports of others.[300]

However, the PHS policy of asserting institutional control over intellectual property of research scientists working under federal grants as property of the grantee institution, and not the research scientist creator-inventor, arguably facilitates the sort of detrimental restrictive disclosure that the policy was supposed to prevent.

The latter DHHS research misconduct definition in accord with 42 C.F.R. §§ 50 and 93 appears to preclude both the latter government and commercial industry practices, posing material risk to distort or preclude science disclosure. While distortion of and preclusion of research science disclosure, violate scientific research professional ethical standards, published policy of DHHS, and international law's *droit moral* doctrine re science authors, arguably against public benefit, currently there exists no direct or explicit private cause of action for such science misconduct in the United States.[301] David Nimmer, citing St. Onge's definition of plagiarism,[302] sums this situation as follows:

> Plagiarism is an intentional fraud committed by the psychologically competent that consists of copying significant and substantial uncredited written materials for unearned advantages with no significant enhancement of materials copied. That definition does not purport to set forth the elements for a tort at law. Rather, it expresses

300. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 10 (quoting RYAN REPORT, *supra* note 195).

301. Nimmer, *supra* note 22, at 76-77 n.453.

302. ONGE, *supra* note 22, at 39 ("[A]cademic plagiarism is a capital offense, punishable by academic death for student or faculty. With or without warnings.").

> "house rules" that certain guilds –notably academics [to include research scientists]-but other domains as well. . .have accepted upon themselves. Those who cross the line risk not liability in court to the general public, but rather being defrocked from the particular priesthood which maintains its special rules. . ..even there, it is only the extreme case. . .that will lose her job (although one who habitually cribs from other's writings may, over time, develop a deserved reputation for academic shoddiness).[303]

The message from Nimmer is clear: absent inalienable moral rights to attribution, integrity, and first disclosure (which confer standing), there exists no recognized cause of action in fact under law for research science misconduct plagiarism, or right to attribution for actual authors. [304]

2. U.S. Work Made for Hire (Copyright)

In the U.S.A., under the "work made for hire doctrine" of the 1976 Act, the employer is considered the author of an employee's creative work.[305] The latter doctrine distinguishes

303. Nimmer, *supra* note 22, at 69-70 (internal quotation marks omitted).

304. *Id.*

305. 17 U.S.C. §§ 101, 201(a)-(b) (2006). Section 101 states:

> A "work of the United States Government" is a work prepared by an officer or employee of the United States Government as part of that person's official duties. A "work made for hire" is (1) a work prepared by an employee within the scope of his or her employment; or (2) a work specially ordered or commissioned for use as a contribution to a collective work,…if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire. 17 U.S.C. §§ 201(a)-(b) provide: (a) Initial Ownership. Copyright in a work protected under this title vests initially in the author or authors of the work. The authors of a joint work are coowners of copyright in the work. (b) Works Made for Hire. In the case of a work made for hire, *the employer* or other person for whom the work was prepared *is considered the*

the U.S.A., from every other nation, because the U.S.A.'s "work for hire" doctrine effectively grants the "whole bundle of sticks" of intellectual property rights (all moral and all economic rights) of an employee's creation to the employer.[306] The Copyright Act at 17 U.S.C. §§ 104(c) expressly precludes expansion or reduction of either Title 17 or common law rights in reliance on the provisions of the Berne Convention. However, the 1976 Copyright Act significantly modified the definition of "work made for hire" to modify or eliminate the presumption of the 1909 Act favoring rights in the employers. The changes, however, will not be applied retroactively.[307]

Whether a person is an employee for purposes of 17 U.S.C. § 101 of the 1976 U.S. Act is determined by principles of the common law of agency.[308]

> A work made for hire is defined in 17 U.S.C. § 101 of the 1976 U.S. Act as:
>
> (1) a work prepared by an employee within the scope of his or her employment; or

author for purposes of this title, and, unless the parties have expressly agreed otherwise in a written instrument signed by them, *owns all of the rights comprised in the copyright*. (emphasis added).

Id.

306. STERLING, *supra* note 26, at 1209; Dennis Angel & Samuel W. Tannenbaum, *Works Made for Hire Under S. 22*, 22 N.Y.L. SCH. L. REV. 209, 210-11 ("An established principle of both common law and statutory copyright in the United States is the presumption that the copyright in the work produced by an employee in the course of his employment vests in his employer. By securing copyright in a work, the employer acquires all rights under the Copyright Act.") (citations omitted).

307. *See* Roth v. Pritikin, 710 F.2d 934, 939 (2d Cir. 1983), *cert. denied*, 464 U.S. 961 (1983) (retroactive application of the 1976 Act's "work made for hire" to pre-1978 transactions would raise a due process violation and be a taking of property [from the employer] without just compensation); *see also* 1 DAVID NIMMER, NIMMER ON COPYRIGHT § 1.11 (2012) (Retroactive application of the 1976 Act, effective January 1, 1978, would be a violation of the Fifth and Fourteenth Amendments and a violation of the Fifth Amendment limitation on the federal government's right to take private property for public use absent just compensation).

308. *See* 18 C.J.S. *Copyrights* § 23 (2011).

> (2) a work specially ordered or commissioned for use as;
>
> > (i) a contribution to a collective work;
> >
> > (ii) part of a motion picture or other audiovisual work;
> >
> > (iii) a translation;
> >
> > (iv) a supplementary work (i.e. a work for publication as a secondary adjunct to a work by another author, the term being fully defined in the Act);
> >
> > (v) a compilation;
> >
> > (vi) an instructional text (term defined in the section);
> >
> > (vii) a test;
> >
> > (viii) answer material for a test; or
> >
> > (ix) an atlas,
>
> if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire.[309]

The 17 U.S.C. §102(2) is silent on the issue of whether there must be a pre-creation writing for assignment of copyright. Consequently, courts are split.[310] Once a work is

309. STERLING, *supra* note 26, at 1253.

310. Schiller & Schmidt, Inc. v. Nordisco Corp., 969 F.2d 410, 412 (7th Cir. 1992) (holding that the writing must precede the creation of the work); *see also* Armento v. Laser Image, Inc., 950 F. Supp. 719, 750 (W.D.N.C. 1996) (requiring the explicit words, "work made for hire"), *aff'd*, 134 F.3d 362 (4th Cir. 1998). *But see* Playboy Enters., Inc. v. Dumas, 53 F.3d 549, 560 (2d Cir.

presumed "made for hire," the burden shifts so that only a written agreement signed by both parties will rebut the assignment of rights to the employer, and even then *only the rights are reassigned*; *the employer is still considered "the author."* [311]

In contrast to the United States of America, if assignment of employee rights to an employer is permitted, most civil law nations both limit the category of employer (e.g. broadcasters, motion picture producers, computer programs) to those specifically involved in commercial works involving collective endeavors, and also narrowly define rights granted such employers to less than all property rights.[312]

The USA "work for hire doctrine" is arguably inherently in conflict with: (i) the Fifth and Fourteenth Amendments' preclusion of government takings of private property for public use without just compensation;[313] (ii) 17 U.S.C. § 201(e) which forbids "involuntary transfer;" [314] (iii) international treaties

1995), *cert. denied*, 516 U.S. 1010 (1995) (post-creation writing acceptable when confirms prior agreement oral or implied).

311. Mark L. Meyer, *To Promote the Progress of Science and the Useful Arts: The Protection of and Rights in Scientific Research*, 39 IDEA 1, 5 n.24 (1998) (citing Angel & Tannenbaum, *supra* note 306, at 209, 210 n.5 (1976)).

312. STERLING, *supra* note 26, at 1209.

313. U.S. CONST. amend. V ("No person shall…be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."); U.S. CONST. amend. XIV, § 1:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges and immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Id.

314. 17 U.S.C. § 201(e) (2006) states:

> When an individual author's ownership of copyright, or of any of the exclusive rights under a copyright, has not been previously transferred *voluntarily by that individual author*, no action by any governmental body or other official or organization purporting to seize, expropriate, transfer, or exercise rights of ownership with respect to the copyright, or

binding the U.S.A. as federal law;[315] (iv) research science professional and regulatory "science misconduct" ethical restrictions on authorship to natural authors;[316] and (v) subsequent patent prerequisites for proof of patent inventor and priority in written works.[317]

Such plain language conflicts of intellectual property law as applied to research science and research scientists would not exist but for U.S.A.'s exclusion of research scientists from moral rights of attribution and integrity, accorded visual and

> any of the exclusive rights under a copyright, shall be given effect under this title, except as provided under title 11. [Title 11 of the United States Code is entitled "Bankruptcy."]

Id. (emphasis added).

315. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, UN. Doc. A/RES/810 (III) (Dec. 10, 1948); *see also* U.S. CONST. art. VI, cl. 2:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and *all treaties made, or which shall be made, under authority of the United States*, shall be *the supreme law* of the land; and the judges of every state shall be bound thereby, anything in the Constitution or laws of any state to the contrary notwithstanding.

Id. (emphasis added). The U.N. Charter, a self-executing treaty, would preempt state laws by virtue of the Supremacy Clause, which gives treaties the same status as federal law. The Universal Declaration of Human Rights, if viewed as an extension of the U.N. Charter, would grant individuals progressive economic, cultural and social rights (e.g. potential for U.S. economic liability under federal law). *See also* MARY ANN GLENDON, A WORLD MADE NEW: ELEANOR ROOSEVELT AND UNIVERSAL DECLARATION OF HUMAN RIGHTS 172, 174 (2001).

316. SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 10 (citing RYAN REPORT, *supra* note 195, at 15).

317. U.S. CONST. amend. V ("No person shall…be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."); U.S. CONST. amend. XIV :

> No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Id.

phonographic artists.[318] Professor Kwall summed the U.S. current position in refusal to recognize moral rights:

> The existence of more substantive moral rights protections in both civil and common law jurisdictions not only creates a disparity between the law in the United States and other countries, but also results in situations in which *American authors find substantially more protection for violations of their moral rights abroad than at home*.[319]

The latter situation, United States research science lack of moral rights recognition in law for research scientists, is deemed one, if not the, fundamental factor for current American innovation decline, i.e. *lack of talent in the U.S.A.*, and not merely lower operating cost outside the U.S.[320]

318. Nimmer, *supra* note 22, at 24-25.

319. KWALL, *supra* note 30, at 37 (emphasis added) (internal citations omitted).

320. *See* STORM REVISITED, *supra* note 21, at 46:

> Turning to research and development [R&D]-where the United States ranks eighth among nations on a per-GDP [gross domestic product] basis-government investment has declined from two-thirds of the nation's total expenditure to less than one-third. *Over half of the United States federal R & D spending is defense-related*. China has a relatively low R&D to GDP ratio-but has more than doubled the figure over the past decade, even while growing its GDP substantially. Viewing such trends United States research universities are increasingly creating ties to what they view as the more highly regarded overseas universities. . . . United States industrial firms are increasingly adopting much the same strategy, building new research facilities outside the country. *Although this was initially driven by the lower cost of operations abroad, it now is often motivated by the relative availability of talent*. The National Science Foundation reports that *U.S.-based companies now have* [*twenty-three*] *percent of their R&D employment located abroad*.

Id. (emphasis added) (citations omitted).

3. Intrinsic Conflict of Law Between Title 17 and Title 35 for Scientific Research Progressing from Unpublished-to-Patent

In research science creative sequence, copyright normally precedes a patent filing on the subject matter of an invention. Unlike copyright in the U.S.A., however, irrespective of ownership assignment, a patent by law must be filed and issue only in the *actual inventor's* name, and not the name of a potential assignee of patent rights, e.g. an employer.[321]

The patent attribution standard, 35 U.S.C. §§ 102(a) and 102(f), limit to the natural person inventor, is a higher standard than that allowed under copyright to authors under title 17 (17 U.S.C.), particularly that given in the "work for hire" doctrine. Assuming initial copyright authorship were assigned to an employer under "work for hire," the required priority evidentiary proof of first conception and reduction to practice, then, is unlikely to reflect the natural person inventor. Such a scenario via work for hire would break a scientist's attribution to his creation during the research sequence from unpublished labnotes-to-patent-to-manuscript-publication legally would preclude patent protection. Patent

321. 35 U.S.C. § 102(a) (2006) (essential to prove "known or used" actual inventor's patent priority); 35 U.S.C. § 102(f) (2006) (patent may be filed only in name of *actual inventor*.); *see also* Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F. 3d 1223, 1230-31 (Fed. Cir. 1994) ("That is not to say, however, that the NIH scientists [defendant-employer] merely acted 'as a pair of hands' [testing the new anti-HIV/AIDS drug, azidothymidine (AZT)] for the Burroughs Welcome inventors…[E]nabling disclosure does suffice in this case to confirm the inventors [BW] had concluded the mental part of the inventive process-that they had arrived at the final, definite idea of their inventions [before committing to NIH investigators' AZT efficacy testing], leaving only the task of reduction to practice to bring the inventions to fruition…the NIH scientists were not joint inventors of these inventions."). The recent patent reform act, the Leahy-Smith America Invents Act, H.R. 1249, passed by the Senate on September 8, 2011, signed into law by President Obama on September 16, 2011, broadens filing to allow filing by the employer or assignee of the actual inventor. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011). Various changes in patent law implemented by provisions of the America Invents Act, will take effect on differing dates. *America Invents Act: Effective Dates*, U.S. PAT. AND TRADEMARK OFF. (Oct. 5, 2011), http://www.uspto.gov/aia_implementation/aia-effective-dates.pdf. The details for implementation of the America Invents Act are being formulated, so are outside the time scope of this review.

priority in the U.S.A. is determined by "first to conceive." [322] First conceptions, typically unpublished but copyrighted by fixation in a tangible medium of expression, logically precede "reduction to practice of the operative invention."[323]

Were *in arguendo* the conception and reduction to practice research sequence steps assigned via work for hire authorship to an employer, any resultant inventive product or process should be legally precluded patent protection by 35 U.S.C. § 102(a) & (f), requiring the actual inventor-creator be named inventor on the patent. In contrast, given accord with Berne art. 6 *bis*, UDHR art. 27, International Covenant on Economic, Social and Cultural Rights (ICESCR) art. 15, intellectual property rights granted to the scientist continuously remain attributed to the actual scientist creator-inventor during the entire research-to-product or research to–process sequence so no conflict of title 17 and title 35 would exist.[324]

4. Patent "Shop Right," Employer Paid-Up Use License vs. Patent Work Made for Hire, Employer Ownership

Under common law, absent agreement to the contrary, the inventor-employee owns the right to an invention even if conceived during the course of employment.[325]

Work for hire theory provides at least three exceptions to the latter rule:

(1) an express agreement assigning employee inventions to the employer exists;

(2) an implied agreement is found because:

322. 35 U.S.C. §§ 102(a), (f) (2006); *see* 17 U.S.C. § 102 (2006). Among its many new provisions, the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b), passed by the Senate on September 8, 2011, signed into law by President Barak Obama on September 16, 2011, changes U.S. patent law from a "first to invent" to a "first to file," thereby harmonizing U.S. patent law with the global majority. *See also* Glenn Hess, *Senate to Revisit Patent Reform*, CHEMICAL AND ENGINEERING NEWS, Sept. 5, 2011, at 44, 44-46 (2011).

323. 35 U.S.C. § 102(a), (f) (2006).

324. STERLING, *supra* note 26, at 1248, 1267.

325. KATHLEEN L. DAERR-BANNON, CAUSE OF ACTION TO ENFORCE PREINVENTION ASSIGNMENT AGREEMENTS, CAUSES OF ACTION 2d § 269 (2010) (citing Univ. Patents, Inc. v. Kligman, 762 F. Supp. 1212, 1219 (E.D. Pa. 1991)).

(a) employee was "hired to invent;"[326]

(b) employee was tasked to solve a specific problem;[327]

(c) employee served in a fiduciary capacity to the employer.[328]

326. *See, e.g.*, Pedersen v. Akona, LLC, 429 F. Supp. 2d 1130, 1141 (D. Minn. 2006) (discussing the test to determine whether an employee is "hired to invent"):

> Although there is a presumption that an inventor owns his invention, "employers may still claim employee's inventive work where the employer specifically hires or directs the employee to exercise inventive faculties." . . . "When the purpose for employment thus focuses on invention, the employee has received full compensation for his or her inventive work." . . . To apply the hired-to-invent doctrine, a court must "examine the employment relationship at the time of the inventive work to determine if the parties entered into an implied-in-fact contract to assign patent rights." . . . "[S]tate contract principles provide the rules for identifying and enforcing implied-in-fact contracts."… "The implied-in-fact contract to assign inventive rights is a question of fact."

Id.

327. *See, e.g.*, McKeen v. Jerdone, 34 App. D.C. 163, 172 (D.C. Cir. 1909) (citing Robinson v. McCormick, 29 App. D.C. 98, 109 (D.C. Cir. 1907)) (provides the test ("beyond the scope of ordinary training and knowledge") for distinguishing when an employee or his employer is entitled to patent claim(s) as inventor based on alleged input from the employer):

> It is a well-established principle of the patent law that where an inventor [employer] employs another to embody his conception in a drawing or in a practical form, he is entitled to any improvement thereon due to the mechanical skill of the employee….But while an employer is to be protected from bad faith of his employee, the employee is equally entitled to protection from his employer. If, therefore, he goes further than mechanical skill enables him to do and makes an actual invention, he is entitled to its benefit. "To claim the benefit of the employee's skill and achievement, it is not sufficient that the employer had in mind a desired result, and employed one to devise means for its accomplishment. He must show that he had an idea of the means to accomplish the particular result, which he communicated to the employee in such detail as to enable the latter to embody the same in practical form."

McKeen, 34 App. D.C. at 172 (quoting *Robinson*, 29 App. D.C. at 109).

328. B. Jean Weidemier, *Ownership of University Inventions: Practical*

Where no contractual agreement, express or implied exists, shop right may operate to grant an employer a royalty-free license to use the employee's patent, when the invention was made with the employer's resources or facilities.[329]

a. *Patent "Shop Right," Employer Paid-Up Use License*

Unlike copyright work for hire doctrine, the patent "shop right" grants the employer only limited rights in an employee's invention. Shop right was defined as the non-exclusive right to practice any invention made by an employee; patent title still remains with the employee.[330]

Shop right is not a statutory right, but rather a form of implied license, a common law right, determined by the court factual analysis of equitable principles, an employer may to freely use the subject of a patent if an employee uses his

Considerations, *in* 1 INTELLECTUAL PROPERTY IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES, ch. 5.4, 495-505, 495 (Anatole Krattiger, Richard T. Mahoney, Lita Nelsen, Jennifer A. Thomson, Alan B. Bennett, Kanikaram Satyanarayana, Gregory D. Graff, Carlos Fernandez & Stanley P. Kowalski eds. 2006).

329. *Id.* at 495.

330. C.T. Drechsler, Annotation, *Application and Effect of "Shop Right Rule" or License Giving Employer Limited Rights in Employees' Inventions and Discoveries*, 61 A.L.R. 2d 356, § 6[b] (2010) (citing Consol. Vultee Aircraft Corp. v. Maurice A. Garbell, Inc., 204 F.2d 946, 950 n.1 (9th Cir. 1953), *cert. denied* 346 U.S. 873 (1953)); *see also* Stanley P. Kowalski, *Making the Most of Intellectual Property: Developing and Institutional Policy*, *in* 1 INTELLECTUAL PROPERTY IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES, ch. 5.3, 485-94, *supra* note 328:

> A shop right is an "implied-in-law nonexclusive license of a patent from an employee to an employer. A shop right is generally implied when an employee *who is not specifically hired to invent* uses the employer's facilities to invent, usually while on the job. The shop right rule grants to such an employer the royalty-free right to use the invention of the employee. It is based on the employer's presumed contribution to the invention through materials, time, and equipment."

Id. (emphasis added). *See generally* C.C. BJORKLUND, EMPLOYEE'S RIGHT TO COMPENSATION FOR EMPLOYER'S USE OF EMPLOYEE'S INVENTIVE IDEA, 23 AM. JUR. PROOF OF FACTS 2d § 203 (2010).

employer's time, money, tools and materials to produce a useful result.[331] Shop right is distinct from an express license, the latter given by consent of the parties, whereas a shop right is created by operation of law.[332]

b. *Patent Work Made for Hire, Employer Ownership*

In contrast to shop right, work for hire operates to divest the employee-inventor of patent title, based on the three common law exceptions prior noted.[333] Albeit no state has yet adopted a similar position, federal law mandates that the federal employee-inventor divested of his patent rights under work for hire be afforded a minimum 15% of any royalties or income received by the U.S. government.[334] The current state [non-federal][335] majority view is given in the Utah statute

331. Drechsler, *supra* note 330, at § 18.

332. *Id.*

333. Weidemier, *supra* note 328, at 495.

334. The Uniform Patent Policy for Rights in Inventions Made by Government Employees, 37 C.F.R. §§ 501.1-501.10 (2011), is applied in tandem with the Technology Transfer Act of 1986, 15 U.S.C. § 3710 (2006), which established a minimum compensation scheme, fifteen percent of any royalties or income received, for inventors employed by the U.S. government. 15 U.S.C.A. § 3710(d) (2006) further "requires a government agency to allow the inventor to retain title to any covered invention when the agency does not intend to file a patent application or otherwise promote commercialization." *See also* DAERR-BANNON, *supra* note 325, at subsec. 5.

335. W.W. Allen, Annotation, *Comment Note.-Rights and Remedies (Independently of Patent Laws) of One who Makes an Invention or Discovery, or Conceives an Idea or Plan, as Against One who Utilizes It Commercially, or Discloses It, or Threatens to Do So*, 170 A.L.R. 449 (2011) (citing Becher v. Contoure Laboratories, 29 F.2d 31 (2d Cir. 1928), *aff'd* 279 U.S. 388, 390, 391 (1929)):

> A suit in respect of wrongful manufacture, use, or disclosure of a secret invention, discovery, process, etc., being founded in the common law, or the ordinary equity jurisdiction, and not on the patent laws, may of course be maintained in a state court. Such a suit is not affected by the collateral circumstance that plaintiff has filed an application for a patent, nor by the granting of a patent to plaintiff subsequently to the matter complained of.

Allen, *supra* note 335, at § II.

regarding employer's rights to employee-inventor's patents.[336] The Utah statute "clearly states the employer's right to require preinvention agreements as a condition of employment or the continuation of employment, making it clear that adequate consideration from employment-based inventions is employment or continuation of employment in the at will situation." [337] Thus state court majority, in upholding employer preinvention patent assignment agreement on a take-it-or-leave-it-basis allows the employer to avoid difficult contract questions re "adhesion and unconscionability, adequacy of consideration, freedom of contract, and structural difficulties implicit in *ex ante* bargaining for speculative rights." [338]

A recent case *DDB Technologies v. MLB Advanced Media L.P*, has further defined "work for hire." [339] On appeal, the

336. DAERR-BANNON, *supra* note 325, at subsec. 5.

337. *Id.*

338. *Id.* at subsec. 7.

339. DDB Tech., L.L.C. v. MLB Advanced Media L.P., 517 F.3d 1284 (Fed. Cir. 2008), *remanded to* 676 F. Supp. 2d 519 (W.D. Tex 2009), *denying leave to appeal*, Misc. No. 925, 2010 WL 675689 (Fed. Cir. Feb. 24, 2010) (employer's legal title to employee's invention depends on whether employment agreement states that employee assigned future inventions or merely agreed to assign future inventions); *see also* Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc. 131 S. Ct. 2188, 2192 (2011) (holding: "The patent law has operated on the premise that rights in an invention belong to the inventor." The Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.)

> At that time [1988], patent law appears to have long specified that a patent assignment of future inventions . . . conveyed equitable, but not, legal title. *See, e.g.*, CURTIS, A TREATISE ON THE LAW OF PATENTS FOR USEFUL INVENTIONS §§ 170, 155 (3d ed. 1867) ("A contract to convey a future invention… cannot alone authorize a patent to be taken by the party in whose favor such a contract was intended to operate"); Comment, *Contract Rights as Commercial Security: Present and Future Intangibles*, 67 YALE L.J. 847, 854 n.27 (1958) ("The rule generally applicable grants equitable enforcement to an assignment of an expectancy but demands a further act, either reduction to possession or further assignment of the right when it comes into existence"). (Breyer, J. and Ginsburg, J. dissenting)

Id. at 2203. *See also* Filmtec Corp. v. Allied-Signal, Inc., 939 F.2d 1568, 1572 (Fed. Cir. 1991) ("[o]nce the invention is made and [the] application for [a]

Federal Circuit addressed two issues: (1) whether the patent assignment clause created an automatic assignment or merely an obligation to assign; and (ii) whether the patents fell within the scope of employee's employment agreement. As to the first issue the Court held federal (not state contract) law applied.[340] Under federal law, a patent assignment is automatic by operation of law when it expressly grants rights in future inventions and requires no further act on the part of the assignee to complete the transfer.[341] Alternatively, contracts merely obligating an inventor to grant rights in the future may vest equitable rights to the employer, but do not by themselves vest legal title to the patents on those inventions.[342] Therefore, despite the assignment language, the employee would still need to transfer legal title to his employer in an invention developed after a general assignment of "future rights."[343]

patent is filed,…legal title to the rights accruing thereunder would be in the assignee [words: "do hereby [post-invention] assign"]…, and the assignor-inventor would have nothing remaining to assign."); Ipventure, Inc. v. Prostar Computer, Inc., 503 F.3d 1324 (Fed. Cir. 2007) (holding that an agreement to assign future patent rights is not a present assignment, as would be indicated by present assignment language, "hereby conveys, transfers, assigns.").

340. *DDB Tech.*, 517 F.3d at 1296; *see also* DAERR-BANNON, *supra* note 325, at subsec. 3:

> Federal law determines how a patent is transferred, but state law governs the agreements to assign patents and state law governs preinvention agreements. With their origins in equity and in common law, such contracts:
> (i) usually are, but need not be, in writing;
> (ii) may be express, or within reasonable limitations, may be implied in fact.

DAERR-BANNON, *supra* note 325, at subsec. 3.

341. *DDB Tech.*, 517 F.3d at 1290.

342. *Id.*

343. *See* Brian Brunsvold & John C. Paul, *Recent U.S. Decisions and Developments Affecting Licensing,* 43 LES NOUVELLES: J. OF THE LICENSING EXECUTIVE SOC'Y INT'L 144, 145-46 (2008).

5. Lanham Act Sec. 43(a) Reverse Passing Off Cause of Action Reasonably Foreclosed After *Dastar*

In the United States, a common law country, copyright protects economic rights in a creator's work, and on its face the Act is silent regarding the actual author's attribution or other moral rights.[344] The United States became a party to the Berne International Copyright Convention, effective 1989, absent acceptance of its Art. 6*bis* moral rights, which would have given U.S. authors attribution rights under federal law under the Berne Implementation Act of 1988.[345] Hence, although with widely varying measures of success, numerous cases by actual authors to vindicate attribution in their works have been brought under Lanham Trademark Act's sec. 43(a) "proscribing

344. Roberta Rosenthal Kwall, *The Attribution Right in the United States: Caught in the Crossfire Between Copyright and [Lanham] Section 43(a)*, 77 WASH. L. REV. 985, 997 (2002). *But see* Chloe v. Fordham Univ. Sch. of Law, 920 F. Supp. 44 (1995) (holding that the Berne Convention is not self-executing, and cannot be used to support a separate copyright claim [author's claim of "mutilation" of his writing] outside of the rights accorded by domestic U.S. copyright law.)

345. Nimmer, *supra* note 22, at 22-23 n.119 (2004):

> [P]rotection of moral rights in the United States was significantly at odds with moral rights enforced in countries that incorporate Article 6*bis* into their domestic laws *in haec verba*. At the outset, all U.S. creators working in an employment relationship will, on account of that employment status, be most challenged to vindicate, under copyright law, any of the quasi moral rights [of attribution, integrity, retraction, and disclosure]…Ineligibility for employees to assert moral rights in their creations " is doubtless a legal position which is incompatible with the protection provided for under Article 6*bis* of the Berne Convention." …American law as of 1989 recognized the artist's right to object to "derogatory action in relation to" his work. Moreover, the fact that the United States subsequently implemented moral rights legislation-expressly limited to the very narrow category of works of visual art, and subject to innumerable exceptions even in that field-*merely highlights the contrast between our system and that of other Berne states [nation states], whose moral rights apply across almost all categories of copyrightable works*.

Id. (emphasis added).

'false designations of origin'" and "false descriptions or representations in connection with any goods or services."[346]

The 2003 landmark case of *Dastar Corp. v. Twentieth Century Fox Film Corp* is widely believed to have proscribed further reverse passing off cause of action for actual authors' attribution rights under Lanham 43(a).[347] In *Dastar*, the Court

346. Kwall, *supra* note 344, at 988 (citing 15 U.S.C. § 1125(a) (2006)). As amended via the Trademark Law Revision Act of 1988, § 1125(a) provides:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name or symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
> shall be liable in a civil action by any person who believes that he or she is likely to be damaged by such act.

15 U.S.C. § 1125(a).

347. 539 U.S. 23 (2003) stating:

> In sum, reading the phrase "origin of goods" in the Lanham Act in accordance with the Act's common-law foundations (which were *not* designed to protect originality or creativity), and in light of the copyright and patent laws (which *were*), we conclude that the phrase refers to the producer of the tangible goods that are offered for sale, and not to the author of any idea, concept, or communication embodied in those goods. Cf. 17 U.S.C. § 202(distinguishing between a copyrighted work and "any material object in which the work is embodied"). To hold otherwise would be akin to finding that § 43(a) created a species of perpetual patent and copyright, which Congress may not do. See Eldred v. Ashcroft, 537 U.S. 186, 208 (2003).

Dastar, 539 U.S. at 37. (emphasis in original). S*ee* Graeme W. Austin, *The Berne Convention as a Canon of Construction: Moral Rights After* Dastar, 61 N.Y.U. ANN. SURVEY AM. L. 111 (2005), *available at* http://www.law.nyu.edu/ecm_dlv3/groups/public/@nyu_law_website__journals

noted that Dastar copied film in the public domain, then manufactured and sold the video set as its own product with no mention of the original television series edited to comprise Dastar's video set.[348] The Supreme Court held that "as used in the Lanham Act, the phrase 'origin of goods' is in our view incapable of connecting the person or entity that originated the ideas or communications that 'goods' embody or contain." [349] Pre-*Dastar*, Lanham § 43(a) was touted as a legal option to address lack of attribution or plagiarism, now considered practically foreclosed.[350]

IV. Research Science Moral Rights: What Should Be Done

A. *Federal Law Should Recognize Research Scientists' Moral Rights of Attribution, Integrity, Retraction and Disclosure as Inalienable and Distinct from Associated Economic Rights*

1. U.S. Obligations to Research Scientists Under Treaties: Enforceable Under Article VI, cl. 2 of the U.S. Constitution as Federal Law

The authority for both copyright and patent law in the United States arises under the U.S. Constitution: "[The Congress shall have the power] [t]o promote the [p]rogress of [s]cience and the [u]seful arts, by securing for limited times *to authors and inventors* the *exclusive right* to their respective writings and discoveries."[351] Read literally, and in accord with

__annual_survey_of_american_law/documents/documents/ecm_pro_064627.pdf (arguing in favor of U.S. adherence to Berne Art. 6*bis* under *Murray v. Schooner Charming Betsy*, 6 U.S. 64, 118 (1804), requiring courts to interpret statutes consistently with both customary international law and treaties).

348. Nimmer, *supra* note 22, at 38-40.

349. *Dastar*, 539 U.S. at 31-32.

350. Nimmer, *supra* note 22, at 30-44.

351. U.S. CONST. art. I, § 8, cl. 8 (emphasis added); *see also* DUTFIELD & SUTHERSANEN, *supra* note 25, at 100-01 nn.41-42 (2008) (emphasis added) (quoting THE FEDERALIST NO. 43, at 271-72 (James Madison) (Clinton Rossiter ed. 1961)):

> The utility of [the copyright] power will scarcely be

the framers' intent and historic application to early U.S. research science authors and inventors, the Constitution appears to grant intellectual property rights to natural persons, the actual creators of scientific intellectual property.[352] The classic constitutional definition of an author is "he to whom anything owes its origin; originator; maker; one who completes a work of science or literature."[353]

Increasingly relevant for modern global research endeavors, Article VI, cl. 2 of the U.S. Constitution accords treaties of which the U.S. is party the status of federal law—"the supreme law of the land." [354] Modern research science intellectual property is, by the very nature of global investigative teams, often outside the sole jurisdiction of any one nation state and requires coordination of national courts.[355]

> questioned. The *copyright of authors* has been solemnly adjudged, in Great Britain, to be a right of common law. The right to useful inventions seems *with equal reason to belong to the inventors*. *The public good fully coincides in both cases with the claims of individuals*. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point, by laws passed at the instance of Congress.

Id. (emphasis added). *See* EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORIC PERSPECTIVE 59-77, 78-151 (2002) (Review of intellectual property law history, reflecting England's influence on early U.S. law to accord the actual author(s) and –inventor(s) legal rights to their work); Karl Fenning, *The Origin of the Patent and Copyright Clause of the Constitution*, 17 GEO. L.J. 109 (1929).

352. U.S. CONST.. art. I, § 8, cl. 8; THE FEDERALIST NO. 43, *supra* note 351, at 271-72.

353. 1 HOWARD B. ABRAMS, THE LAW OF COPYRIGHT § 4:2 (2011) (citing Burrow-Giles Lithographic Co. v. Sarony, 111 U.S. 53, 61 (1884)). In *Burrow-Giles*, the Court defined an author as one who "involves originating, making, producing, as the inventive master mind, the thing to be protected . . . the author is the man who really represents, creates, or gives effect to the idea, fancy, or imagination." *Burrow-Giles*, 111 U.S. at 61.

354. U.S. CONST. art. VI, cl. 2. ("[A]ll Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.")

355. *See, e.g.*, ALI, *supra* note 1, at 6 ("The internationalist perspective also requires the Principles to envision a future in which coordination among [nation states'] courts evolves from the exceptional to the expected").

a. *Authorship Attribution to Natural Person Creator: An Implicit Human Moral Right*

International treaties and declarations to which the United States is a party, when read *in pari materia* to the U.S. Constitution and federal law, appear in accord with the interpretation that natural person creators are the primary focus of legal intellectual property rights.[356] Professor Davies summarizes the purpose of copyright as follows:

> The copyright system guarantees the personal interests of the author in his work. It is also what Macaulay described as the "least objectionable" way of remunerating men of letters by providing mechanisms for authors and other rights owners to obtain economic rewards for their efforts. By securing such financial rewards, it stimulates creativity, thereby in the words of the Statute of Anne encouraging "learned men to compose and write useful books," and in the modern world. . .promoting the widest possible availability of copyright protected material to the public, thereby encouraging both learning and the progress of science.[357]

These treaties appear to imply moral rights, *droit moral*; namely that an actual author who invests time in creating the work also grants certain rights unique to creators.[358] Berne does not specifically define "author;" however, the Convention's text and historic context suggest "author" and "authorship" were meant to be defined as the "natural person who created the work."[359] The rule that the natural person who created the

356. DAVIES, *supra* note 29, at 235.

357. *Id.*

358. DUTFIELD & SUTHERSANEN, *supra* note 25, at 90-91.

359. PAUL GOLDSTEIN & BERNT HUGENHOLTZ, INTERNATIONAL COPYRIGHT: PRINCIPLES, LAW, & PRACTICE 245 (2010) ((quoting S. Ricketson, *The 1992 Horace S. Manges Lecture — People or Machines: The Berne Convention and the Changing Concept of Authorship*, 16 COLUM.-VLA J.L. & ARTS 1, 21(1991)).

work is the original owner is known as the "creator doctrine."[360] The creator doctrine is the doctrine followed by the global majority, including most civil law countries.[361] In marked contrast to civil law countries, common law countries (e.g. the U.S.A. and U.K.) broaden the definition of author to include not only the individual, but also a legal person such as a corporate body.[362]

Moral rights theories may be broadly divided into three categories: monist, dualist and reverse dualist (based on how the rights are enforced).[363] Germany represents a monist theory, in which the personal element of a work, as an extension of the creator's personality, may not usually (unless specifically waived) allow alienability of either moral or economic rights to a work.[364] In contrast, the French dualist law considers moral and economic rights theoretically separate, and moral rights are considered to protect personal interests in a work apart from the work's value.[365] Distinguished markedly from monists and dualists, common law countries' (e.g. U.K. and U.S.A.) reverse monist theory views works only in economic terms, enabling full alienability to deem non-natural creators the "authors" (e.g. employers, businesses, etc.) and granting only limited time monopoly.[366] Default authorship, by virtue of the mere act of hiring the actual author-creator, is directly contrary to the research science requirement to attribute works only to the true authors.[367] Attribution to the natural person author ensures proper attribution and personal accountability, positive or negative depending on science findings' merit, to the actual creator, both taken together to promote scientific integrity.[368]

Professor Belanger argues that U.S. federal copyright law "fails to meet the Berne Convention standards" for protection of

360. *Id.* at 245.

361. STERLING, *supra* note 26, at 1209.

362. *Id.*

363. Thierry Joffrain, Note, *Deriving a (Moral) Right for Creators*, 36 TEX. INT'L L. J. 735, 756-57 (2001).

364. *Id.* at 756.

365. *Id.*

366. *Id.* at 757.

367. *Id.* at 768-70.

368. *See, e.g.*, Nimmer, *supra* note 22, at 74.

moral rights in: (i) Section 106(A) applies only to works of visual art, as opposed to all literary [including scientific] and artistic works; (ii) Section 106(A) only provides the rights of attribution and integrity, as opposed to full rights of respect [faithful reproduction, rights of pseudonymity and anonymity], and Section 106(A) allows for waiver of moral rights, a concept outside of Berne.[369]

b. *Absence of Clear Legal Cause of Action or Adequate Remedies for Research Science Plagiarism*

Moral rights are distinct from and broader than copyright.[370] Rights norms and professional research science ethical mandates of research scientists and professional science research associations absolutely require attribution.[371] In the United States, research science attribution and integrity violations are rarely prosecuted or enforced, except as applied to research misconduct actions.[372] Federal government funding agencies often enforce research misconduct primarily to recoup federal research grant funds from an awardee committing fraud.[373] While most research scientists feel very strongly that federal law should allow courts to review science misconduct plagiarism and fraud,[374] some judges and federal grant agency

369. William Belanger, *U.S. Compliance With the Berne Convention*, 3 GEO. MASON INDEP. L. REV. 373, 399 (1995); *see also* Natalie C. Suhl, *Moral Rights Protection in the United States Under the Berne Convention: A Fictional Work?*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1203 (2002).

370. KWALL, *supra* note 30, at 55-57.

371. *See, e.g.*, 42 C.F.R. pts. 50, 93 (2011) (detailing U.S. federal grant funded research attribution requirements); *see also* SIGMA XI, HONOR IN SCIENCE, *supra* note 24, at 39 (in illustrating the research scientists' professional ethical requirements, the authors state that "[*t*]*ruthfulness* may or may not be the cement that holds together society as a whole, but certainly it *is essential to science*.") (emphasis added); SIGMA XI, THE RESPONSIBLE RESEARCHER, *supra* note 24, at 55 ("Experimental results are property that someone owns. The ownership of ideas is important; it has a bearing on promotion, and ideas [patents] sometimes can be sold for profit. Conflicts of interest exist.").

372. *See, e.g.*, SARASOHN, *supra* note 96, at 60-62; CREWDSON, *supra* note, 98, at 294-95.

373. 42 C.F.R. pts. 50, 93 (2011).

374. Nimmer, *supra* note 22, at 76-77 n.453 (citing Roberta Kwall, *Moral*

officials embrace David Nimmer's opinion that: "rather than altering the laws passed by Congress or state legislatures, the answer should be internal to the academic setting by the adoption of appropriate university policies, ratified by their respective academic senates, for application to professors and students alike." [375] Disadvantage of the latter court deference to internal agency- or internal institution self-investigation for the plaintiff research scientist, whose research has been misappropriated, or otherwise subjected to integrity trespass or disclosure denial outside science merit, is the practical problem of conflict of interest of self-investigation, e.g. "the [agency] fox guarding the henhouse" denial of due process or any impartial investigative process.[376] The current legal situation in the United States for research science places the U.S. in the unenviable position of a dwindling minority of developed countries regarding its research science attribution and integrity policies and practice.[377] As will be discussed in greater

Rights for University Employees and Students: Can Educational Institutions Do Better Than The U.S. Copyright Law?, 27 J.C. & U.L. 53,55 (2000)).

375. Nimmer, *supra* note 22, at 76-77 n.453.

376. *See, e.g.*, Jackson v. McHugh, 131 S. Ct. 280 (2010), *cert. denied*, Jackson v. Geren, 325 Fed. Appx. 213 (4th Cir. 2009), *aff'g* No. AW-07-851, 2008 WL 7728654 (D. Md. Nov. 14, 2008); *see* Robert A. Gorman, *Copyright Conflicts on the University Campus: The First Annual Christopher A. Meyer Memorial Lecture*, 47 J. COPYRIGHT SOC'Y U.S.A. 291, 303 (2000) ("Were the university to own the copyright in faculty-created works, the university can block publication, can decide where and when to place the professor's work for publication, and can abridge, revise and delete as it chooses.").

377. KWALL, *supra* note 30, at 37 (citing Nimmer, *supra* note 22, at 19-20) (raising the question whether countries like England "have augmented their moral rights protection" since the United States joined the Berne Convention in 1988 "in a way that leaves the United States isolated"):

> As the close of the First decade of the twenty-first century, the United States appears to be rather isolated in its failure to recognize explicitly adequate moral rights. The existence of more substantive moral rights protections in both civil and common law jurisdictions not only creates a disparity between law in the United States and many other countries, but also results in the situation in which American authors find substantially more protection for violations of their moral rights abroad than at home.).

Id.; *see also* Cyrill Rigamonte, *Deconstructing Moral Rights*, 47 HARV. INT'L. L.J. 353, 354 (2006) ("the adoption of civil-law style moral rights legislation is

detail in subsequent sections, the result of the United States' current failure to recognize in law the natural person research scientist's basic attribution, disclosure, retraction, and integrity moral rights to his work is arguably unconstitutional and against public interest.[378]

c. *Authorship Under the Universal Declaration of Human Rights (UDHR) Art. 27 and the International Covenant on Economic, Social, and Cultural Rights (ICESCR) Art. 15 Binds the U.S. via the UN Charter*

The Universal Declaration of Human Rights, of which Eleanor Roosevelt was a key proponent, provides in Article 27:

> (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
> (2) Everyone has the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[379]

The ICESCR imposes three obligations on member States:

a major shift in terms of copyright theory, because it eliminates the key features that distinguished common law from civil law copyright systems").

378. KWALL, *supra* note 30, at 37; U.S. CONST., art. I, § 8, cl. 8 ("The Congress shall have 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"); U.S. CONST. amend. IV; U.S. CONST. amend. V; U.S. CONST. amend. XIV.

379. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, art. 27, U.N. Doc. A/RES/217(III) (Dec. 10, 1948); *see also* U.S. CONST. art. VI, cl. 2 ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and *all Treaties made, or which shall be made, under the Authority of the United States*, shall be *the supreme Law* of the Land . . . .") (emphasis added). The U.N. Charter, a self-executing treaty, would preempt state laws by virtue of the Supremacy Clause, which gives treaties the same status as federal law. The Universal Declaration of Human Rights, if viewed as an extension of the U.N. Charter, would grant individuals progressive economic, cultural and social rights (*e.g.* potential for U.S. economic liability under federal law); GLENDON, *supra* note 315, at 172, 174.

to respect, to protect and to fulfill. [380] Although the U.S. signed the ICESCR in 1979, it has not been ratified.[381] However, the ICESCR Article 15 simply reiterates UDHR Article 27, so the U.S. may be bound via the U.N. Charter as previously noted.[382] Under the U.N. Charter incorporating the UDHR and ICESCR principles, the United States is bound to enforce human rights for research scientists implicitly, if not directly, mandating certain fundamental moral rights.[383]

380. MAREE SAINSBURY, MORAL RIGHTS AND THEIR APPLICATION IN AUSTRALIA 16 n.75 (2003) (internal citations omitted) ("The objective of this meeting was to elaborate on the Limburg Principles as regards the nature and scope of violations of economic, social and cultural rights and appropriate responses and remedies.").

381. KWALL, *supra* note 30, at 134 n.15.

382. International Covenant of Economic, Social, and Cultural Rights art. 15, Jan. 3, 1976, 993 U.N.T.S. 3:

> 1. The States Parties to the present Covenant recognize the right of everyone
>
> (a) To take part in cultural life;
>
> (b) To enjoy the benefits of scientific progress and its applications;
>
> (c) *To benefit from the protection of moral and material interest resulting from any scientific, literary or artistic production of which he is an author.*
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and diffusion of science and culture.
>
> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

Id. (emphasis added).

383. RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES, Introductory Note (1987):

> Virtually all states are members of the United Nations and parties to its charter. . . . In Articles 55 and 56 of the Charter, all member "pledge themselves to take joint and separate action in cooperation with [United Nations] Organization for the achievement of, *inter alia*, "universal respect for, and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language or religion." . . . Increasingly, the Charter provisions have been linked to the Universal Declaration of Human Rights . . . almost all states would agree that some

d. *What Is A "Scientific Work" Protected Under Law?*

The U.S.A. is bound as a party to The Berne Copyright Convention (absent Article 6 *bis* moral rights), the Uniform Copyright Convention (UCC), the World Trade Organization (WTO, and thereby of Trade Related Aspects of Intellectual Property Rights or TRIPS), and the World Intellectual Property Organization (WIPO) Performance and Phonograms Treaty (WPPT).[384]

> [T]he Berne Convention refers to "every production in the . . . scientific domain" and "works relative to . . .science" (Article 2(1)). The UCC refers in its preamble and Article I to "protection of . . . scientific . . . works". In these contexts the term scientific refers to works in the field of science (e.g. the physical or mathematical sciences) to make it clear that works that do not have a purely artistic appeal can be covered.[385]

Berne copyright extends protection to: "all countries of the Union. This protection shall operate for the benefit of the author and his successors in title." [386]

> infringements of human rights enumerated in the Declaration are violations of the Charter or of customary international law . . . . The United Nations Charter and Charter of the Organization of American States, both of which include human rights provisions are treaties of the United States.

Id. (alteration in original).

384. STERLING, *supra* note 26, at 1267.

385. *Id.* at 1248, 1267 (the Unites States is a member of the following international treaties: Berne 1989 (Paris); Universal Copyright Convention (UCC) 1955 (Paris 1972); World Trade Organization (WTO, and, thus, of TRIPS) 1995; WIPO Performance and Phonograms Treaty (WPPT) 2002).

386. Berne Convention for the Protection of Literary and Artistic Works art. 2, para. 6, Sept. 9, 1886, S. Treaty doc. no. 99-27 (1986) (as last revised in Paris on July 24, 1971 and amended Sept. 28, 1979). The U.S. signed and enacted into U.S. law via the Berne Convention Implementation Act of 1988, Pub. L. No. 100-568, 102 Stat. 2853 (Oct. 31, 1988) (codified at 17 U.S.C. § 101 note); *see also* ALI, *supra* note 1, at 4 ("Under the Berne Convention,

B. *Remedy: U.S. Accords Non-Waivable Moral Rights: Attribution, Integrity, Retraction, and Disclosure to Research Scientists, with Economic Rights Shared Equitably with Employers*

1. Is Constitutional: Promotes Rights Guaranteed Scientists for the Public Benefit

Were the United States to adopt dualist or French theory of *droit moral*, this would cause minimal disruption of existing copyright and associated law.[387] The United States already recognizes separation of economic rights from the actual author-creator.[388] Therefore, to separately recognize in federal law non-economic rights: attribution, integrity, retraction, and disclosure, for research scientists, would merely serve to harmonize these same rights operating *de facto* at the institutional and professional association level.[389] As discussed, there appears to be no Constitutional bar, but rather on its face and by evidence from the Founding Fathers, supported by recent Supreme Court decisions, remains consistent with copyright and patent law.[390]

2. Harmonizes U.S. Policy with Global IP Policies to Facilitate U.S. Scientists' Unfettered Research Collaboration in Modern Virtual Global Scientific Research Ventures in the Public Interest

As discussed herein, research scientists today face monumental challenges, challenges that are administrative and legal rather than primarily scientific.[391] Policies and procedures governing intellectual property and professional

copyrights arise simultaneously in all 163 (as of December 2007) member States [nation-states]. Furthermore, trademark and patent rights holder are increasingly relying on central prosecution of their applications through the Madrid Protocol, the Patent Cooperation Treaty (PCT), and the European Patent Convention (EPC).").

387. *See supra* Part IV A.1.a.

388. *Id.*

389. *See supra* Part II.

390. *See supra* Part IV; *see also* Fisk, *supra* note 33, at 1128.

391. *See, e.g.*, ALI, *supra* note 1; Phillips & Ryan, *supra* note 1.

ethics standards, historically uniform among research science institutions today vary dramatically, causing uncertainty absent uniform federal law.[392] The adoption of Berne's 6*bis droit moral*, particularly the French dualist theory, would fix in law professional ethics standards on which research relies in fact to maintain research quality and ensure procedural integrity.[393] The adoption of *droit moral* would also serve to harmonize United States intellectual property law of more than 157 countries worldwide, facilitating U.S.-global science research collaboration.[394]

V. Conclusion

Modern research science faces new challenges with the shift from national to global research efforts, funding, and legal jurisdiction problems inherent to scientific work products developed multi-nationally.[395] Current United States law and policy, which denies fundamental non-economic moral rights to research scientists—rights recognized in 157 nations overseas—has become an overwhelming disincentive to engage in scientific research in the U.S. Historic research science ethics standards, promulgated and enforced to ensure scientific research quality and professional accountability, of both research practice and reporting by the local institution or professional societies, have decreasing control of global research networks.[396] As the American Law Institute aptly describes for new world intellectual property, relevant principles of law must be harmonized among jurisdictions, between and among nation-states, for the scientific research benefits to accrue efficiently to the public's benefit.[397] To that end, it is urged that the United States adopt intellectual property moral rights recognition for research science. The rejection, thereof, is increasingly isolating our nation, and hence our scientific professional community, from the

392. *See, e.g.*, *supra* Part II.A-B.
393. *See supra* Part IV.
394. *Id.*
395. *See* ALI, *supra* note 1, at 3-7, §§ 101-103.
396. *See supra* Part II.A-B.
397. *See* ALI, *supra* note 1, at 3-7, §§ 101-103.

mainstream global research community and to America's innovative- and economic profound detriment.[398]

398. *See, e.g.*, KWALL, *supra* note 30, at 37.