Ownership of Inventions and Executive Order 10096

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It is well established policy and procedure for universities to require written "invention assignment agreements" from all involved in their research activities, including graduate students and visiting scholars. For instance, Stanford University's policy provides that faculty, staff, student employees, graduate students and postdoctoral fellows, as well as "*non-employees who participate or intend to participate in research projects*" at the university are bound by the policy.[1] In addition to its faculty, students and staff, the Massachusetts Institute of Technology policy on ownership of intellectual property applies to visitors participating in MIT programs or using MIT funds or facilities.[2] These visiting scientists, fellows or others are "required" to sign MIT's Personnel Inventions and Proprietary Information Agreements.[3] Courts have upheld the validity of such agreements that assign all rights in intellectual property to the university as well as of the institutional policies that require such assignments.[4]

But what about visiting research scientists who work for the Federal Government? As this paper explores, ownership of their inventions belongs to the Federal government pursuant to an Executive Order that conflicts with a specific statutory enactment, The Bayh-Dole Act. Accordingly, extra special care is necessary to identify these individuals and to address the various possibilities and implications for the ownership of inventions made or assisted in by these Federal employees while participating in sponsored programs at universities.

Executive Order 10096

Executive Order 10096, entitled *Providing for a Uniform Patent Policy for the Government with Respect to Inventions Made by Government Employees and for the Administration of Such Policy*, was signed by President Truman in January 1950.[5] The Order was modified by President Eisenhower in January 1957 to remove a provision relative to the so-called Government Patents Board's indexing of inventions owned or controlled by the United States and directing the GPB to transfer its records to the Department of Commerce.[6] In March of 1961, President Kennedy further amended Executive Order 10096 to abolish the Government Patents Board and to transfer all of its functions to the Department of Commerce.[7]

It has been reported that Executive Order 10096 "was the culmination of extensive study of the patent ownership policies of government agencies, private industry, educational institutions, private research organizations, and foreign governments that was conducted by the Attorney General of the United States and submitted to the President in a three-volume report in 1947."[8] It was not, however, the first instance when the Federal government sought to claim the patent rights of its employees.[9] While the scope, purpose and constitutionality of the Executive Order and the policy it initiated has been the subject of some debate, the policy seems firmly embedded within the Federal government.[10]

What Does the Executive Order Provide?

Section 1 of the Executive Order, which is now codified at 37 C.F.R. §501.6,[11] provides that the various agencies of the Federal government[12] "shall obtain, except as herein otherwise provided, the entire right, title and interest in and to any invention made[13] by any Government employee:[14]"

- "during working hours," or

- with a contribution by the government of facilities, equipment, materials, funds or information, or of time or services of other government employees on official duty, or

- which bears a direct relation to, or is made in consequence of, the official duties of the inventor.[15]

The regulations go on to establish a presumption that the above criteria are satisfied as to any particular invention when the government employee is employed or assigned:

- to invent or improve or perfect any art or process, machine, design, manufacture or composition of matter;

- to conduct or perform research, development work, or both;

- to supervise, direct, coordinate or review government financed or conducted research, development work, or both; or

- to act in a liaison capacity among governmental or non-governmental agencies or individuals engaged in such research or development work.[16]

Importantly, the regulations also provide that when the government's contribution to the invention is "insufficient equitably to justify a requirement of assignment to the government of the entire right, title and interest in the invention" or when the government has "insufficient interest in an invention to obtain the entire, right and interest therein," the government agency concerned shall "leave title to such invention in the employee."[17] In such cases, the government reserves a "non-exclusive, irrevocable, royalty-free license in

the invention with power to grant licenses for all government purposes."[18] The regulations also create a presumption that inventions made by any employee whose employment is not covered by the four categories of employment that permit the government to claim the entire right, title and interest to an invention (see text accompanying note 16 *supra*), fall within the scope of this section.[19]

It is important to note, that the regulations implementing Executive Order 10096 specifically reference the Federal Technology Transfer Act of 1986[20] which provides that when a Federal agency does not "intend to file for a patent application or otherwise promote commercialization" of an invention it either owns or has the right to own, it "shall allow" the inventor to obtain or retain title to the invention.[21] Provided, however, that the government reserves a "nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the government."[22] The end result here sounds remarkably like the result under Bayh-Dole.[23]

How Executive Order 10096 Works in Practice

The federal agency employing the inventor is delegated authority to determine "whether the results of research, development, or other activity in the agency constitute an invention[24] within the purview of [the] Executive Order" and "to determine the rights in and to the invention."[25] The result of this "agency determination" will either be a finding that the government is entitled to obtain title to the invention or that title should be left with the employee. The policy of Executive Order 10096, as set forth in 37 C.F.R. Part 501, is incorporated into the regulatory framework of the various Federal agencies.[26]

It is important that the procedure mandated in the regulations be followed. For instance, after an employee of the Picatinny Arsenal and its Warheads and Special Projects Laboratory conceived and developed an invention, he executed and

forwarded to the Picatinny legal office three forms: a record of invention, the patent disclosure date sheet and the invention rights questionnaire.[27] Because Heinemann signed the "Invention Rights Questionnaire" directly underneath at statement that read: *I desire to assign to the United States Government the entire right title and interest in and to the above identified invention*," no formal determination of rights was held.[28] However, upon judicial review, the court found that the "assignment" had not been knowingly and freely given"[29] and the case was remanded to Picatinny Arsenal for a final determination of the respective rights of inventor and government in accordance with Army's version of the implementing regulations for Executive Order 10096.[30]

Likewise, where the inventor was chief of nuclear medicine at an Illinois Veterans Administration hospital when he conceived and first reduced his invention to practice, the general counsel of the VA embarked upon the procedure set forth in VA regulations[31] to determine the rights of the government and inventor in the invention.[32] The general counsel obtained the hospital administrator's report that indicated that the invention was made during duty hours and with contributions of VA facilities, equipment, funds as well as the services of other VA employees on official duty. The administrator also reported that the inventor had spent perhaps 25 percent of his official time on the development of the invention and that he was expected to engage in research pertinent to his medical specialty.[33] Accordingly, the VA general counsel advised the inventor that government ownership was likely to be the result. In response, the inventor indicated that 85 percent of the work was performed at non-VA facilities and that only six percent of the total project time occurred during regular working hours at the VA hospital.[34] Accordingly, the inventor asserted that the government contribution, as measured by the criteria of Executive Order 10096, was "insufficient to equitably justify the assignment to the government of the entire title to the patent."[35] Nonetheless,

the general counsel made a determination of rights to the invention that concluded that the inventor had failed to rebut the presumption of government ownership set forth in Executive Order 10096 and sustained the government's ownership.[36]

Effects of Agency Determination

If the agency determines that it is entitled to title to the invention and the employee does not appeal, the matter is concluded.[37] If, however, the agency determines that title should be retained by the inventor, it must notify the employee and, in those cases where its "insufficient interest in the invention is evidenced by its decision not to file a patent application," the agency may impose any one or all of the following conditions:

- that a patent application be filed in the United States and/or abroad if the government has determined that it has or may need to practice the invention;

- that the invention not be assigned to any foreign-owned or controlled corporation without the written permission of the agency; and

- that any assignment or license of rights to use or sell the invention in the United States shall contain a requirement that any products embodying the invention or produced through the use of the invention be substantially manufactured in the United States.[38]

Appeal by Employee Inventor

A government employee aggrieved by an agency's rights determination may obtain a review by filing, within thirty days after receiving notice of the determination, an appeal with the Under Secretary of Commerce for Technology.[39] At the appeal, the patentability of the invention is not in issue.[40] Rather, the focus is on whether or not the employee fits within the categories set forth in the Executive Order (as codified) and

whether or not the invention (which is defined as something that "is or may be patentable") was created, essentially, within the scope of the inventor's employment.[41] Judicial review of the Under Secretary's decision, although deemed "final" in the regulations, is available, as was any decision of the Commissioner of Patents and Trademarks whose determinations were deemed "final agency action reviewable under the Administrative Procedure Act (5 USC § 704)."[42]

The standard of judicial review for administrative determinations is the customary standard and the court can set aside agency action, findings or conclusions only if they are found to be arbitrary or capricious.[43] Moreover, the employee bears the burden of showing why the agency's findings of fact are arbitrary or capricious.[44]

Interestingly, at least one court has held that there is no requirement that an employee appeal an agency's initial rights determionation, even if the employee then seeks judicial review.[45] Accordingly, the doctrine of exhaustion of administrative remedies is discretionary, and a court can exercise subject matter jurisdiction of the employee's complaint concerning the agency determination.[46]

Constitutionality

Executive Order 10096 changed the nature of ownership for federal employees and the legal principles that defined the respective patent rights of employer and employee. The seminal case was *United States v. Dubilier Condenser Corp.,*[47] wherein the United States Supreme Court held that the common law of invention rights was controlling.[48] At issue was an invention made by two employees of the federal Bureau of Standards. The Court held that if the employees were employed to make an invention, and they succeed during the term of their service, then they must assign the invention to their employer; the rationale being that they produced the precise subject of their employment.[49] On the other hand, "if the employment be general, albeit it cover a

field of labor and effort in the performance of which the employee conceived the invention for which he obtained a patent, the [employment] contract is not so broadly construed as to require an assignment of the patent."[50] The *Dubilier* opinion states that the government's rights in and to inventions of its employees are governed by the same rules enforced in private employment and that assignment is required.[51]

In *Kaplan v. Johnson*,[52] a federal district court investigated the constitutionality of Executive Order 10096 – a document that the court declared to be a "significant departure from previously established common law principles that arose through a series of Supreme Court cases covering the better part of sixty years."[53] *Citing Youngstown Sheet & Tube v. Sawyer*, 343 U.S. 579 (1972), the court found "no basis for the promulgation of Executive Order 10096 in the President's array of constitutional powers," finding that the Order did not relate to his role as Commander in Chief nor does it relate to his duty to see that the laws are properly executed.[54] In response to the government's contention that Presidential authority was based upon various statutes, such as 5 U.S.C. §7301,[55] the district court held that Executive Order 10096 "goes beyond a simple condition of employment and entails the expropriation of a potentially valuable property right."[56]

On appeal, the Seventh Circuit stated that whether or not the President had implied powers to promulgate Executive Order 10096 need not be addressed if there was statutory authority from Congress.[57] The court then found such statutory authority to exist[58] and deemed the statutes adequate guidance for formulation of government policy concerning the rights in patents developed by government employees.[59] Accordingly, the court found Executive Order 10096 consitutional.

A subsequent case, *Heinemann v. United States*, addressed the allegation that Executive Order 10096 violated the Fifth Amendment. [60] This court also relied upon the fact that statutes enacted subsequent to the *Dubilier* decision had authorized the

President "to prescribe regulations concerning the conduct of Government employees and the ownership of Government property." As such, it too affirmed the constitutionality of Executive Order 10096.[61] The court in *Heinemann* also noted (as had the *Kaplan* court[62]) that "congressional acquiescence in the order [is] shown by the failure of Congress to modify or disapprove it."[63] There can be no "taking" of private property because, under the provisions of the Executive Order, the entire right, title and interest in the invention vests in the government by virtue of the fact that, as found at the invention rights determination, that the "invention bore a direct relation to and was made in consequence of the official duties of the inventor."[64]

Effects Upon the University and its Ownership

How can Executive Order 10096 affect a university's obligations to the sponsors of its research programs as well as the implementation of its own policies? What can a university do when its researchers have joint appointments with or employed by federal agencies? Consider these situations.

Two of the three inventors for the nicotine patch, Drs. Murray Jarvick and Jed Rose, were employed by the Veterans Administration and the Regents of the University of California while they were developing the underlying patent (the third inventor, also Dr. Karce Rose, was in private practice).[65] The university, presumably with signed invention assignments from its two employees, and being the recipient of funding from the Department of Health and Human Services and National Institute for Drug Abuse for at least some portion of the work done by Drs. Jarvick and Rose,[66] and aware of the implications of Executive Order 10096, contacted the VA concerning its interest in the invention and suggested that VA assign its rights to the employees - the inventors.[67] In making the request, the university noted its obligations under Bayh-Dole and its intention to license the invention.[68]

Notwithstanding the invention disclosure of Drs. Jarvick and Rose that they had produced the invention during their employment with the VA, using VA facilities, during working hours and using VA equipment, the Veterans Administration determined that it had made an "insignificant contribution" to the patent's development.[69] Accordingly, the VA disclaimed any right it had to the invention; except, that is, for its non-exclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes.[70] The university then obtained assignments from the inventors for all of their rights in the invention, and then, moved forward with an exclusive license with Ciba-Geigy to manufacture and market the nicotine patch.[71]

Would the license agreement have occurred without a release of the VA claim to all right, title and interest in the subject invention? Probably not. Why not? The University of California would not be in a position to license the invention; while it might have received an assignment from the two inventors in its employ, the fact of their employment by the VA essentially meant that they had nothing to assign unless the VA relinquished its rights under Executive Order 10096. If the VA had retained all right, title and interest to the invention, would Ciba-Geigy have licensed the invention from the agency? Probably not since it was the inability of the Federal government to effectively license the technologies that it owned gave rise to the passage of Bayh-Dole.[72] What did the University of California do right? Request that the VA release its rights to the inventors, who, hopefully had already assigned their rights in the invention to the University pursuant to the University's standard invention assignment agreement, before they went too far down the licensing road with Ciba-Giegy.

For another example, consider the complex litigation concerning the patents concerning use of AZT in treating HIV. In this case, Burroughs Wellcome Company owned and controlled six patents.[73] When Barr Laboratories, and others, filed applications

with the Food and Drug Administration to manufacture and distribute generic equivalents of Burrough's patented product, they asserted that the BW patents were either invalid or not infringed by their products.[74] Barr Laboratoties, who held a non-exclusive license from National Institutes of Health to exploit any patent rights held by the NIH (which included an obligation to represent the interests of the United States in any litigation), argued that two NIH scientists were un-named co-inventors of the Burrough patents and that NIH, as the scientists' employer, either owned or had a right to practice the patent.[75]

While the court rejected Barr's argument that the NIH scientists were co-inventors, it nonetheless went on to address how the Federal government could obtain rights in the patent. First, stating that "the patent right initially vests in the inventor,"[76] the court opined that since the government is not a natural person, it cannot be an inventor and patent rights cannot vest automatically in the government; the government must derive patent rights from an inventor.[77] The court then noted that "although a formal assignment is not necessary in order for the government to obtain ownership rights in the inventions of its employees" (citing Executive Order 10096), the federal regulations provide for procedures "to be followed when a government employee seeks to establish patent rights."[78] Since the alleged NIH co-inventors never filed an employee invention report or undertook any action to establish their status as co-inventors, there was no basis to find that the government had any rights in the Burroughs patents.[79]

Practical Advice to Universities

In considering how to deal with federal employees in a university, it is important to remember that they – as the actual inventor – are initially vested with the rights to their invention.[80] Accordingly, getting visitors or others who work for the Federal government to sign invention assignment agreements

when they first present themselves for participation in university research activity is wise and prudent. However, these visitors may have a conflict with the customary explicit transfer to the university of all right, title and interest in inventions conceived or first reduced to practice during their time at the university. Accordingly, Stanford University, for example, has an alternative agreement for individuals coming to the Univeristy who have a conflicting obligation concerning intellectual property. This document provides:

> - that the individual agrees to abide by the policies concerning patents and copyright;
>
> - that the individual will disclose to Stanford all potentially patentable inventions conceived or first reduced to practice in whole or part in the course of the individuals' participation in activities at Stanford;
>
> -that all right, title and interest in such patentable inventions are assigned jointly to Stanford and the individual's non-Stanford employer;
>
> - that the assignment is not inconsistent with the terms of the individual's non-Stanford employment or any other agreement.[81]

This alternative form also requires that the individual's non-Stanford employer "acknowledge and accept" the provisions of the document.[82] While obtaining an authorized signature to bind the United States government may be problematic, by making the university a co-owner with the Federal government, each is entitled to exercise the full panoply of rights (albeit subject to the other's right to do so as well). This procedure does, however, eliminate the need to obtain a post-invention assignment from the Federal inventor or co-inventor in the event that the

Federal agency can be persuaded to release its claim to all right, title and interest in the invention. Accordingly, individual universities would be well advised to specifically require that individuals being asked to sign patent and copyright assignment agreements indicate whether or not they are an employee of the Federal government (or any other institution) and a warranty that the individual is not currently under an obligation to any entity that would conflict with the provisions of the university's agreement.

At the Massachusetts Institute of Technology the problems potentially attributable to the implementation of Executive Order 10096 have yet to be addressed in any formal policy. Nonetheless, MIT's experience with the priority given to Executive Order 10096 by the Department of Commerce has resulted in its Office of Intellectual Property Counsel recommending that Federal employees be denied participation in any on-going research activity or in a new research project that involves a sponsored research agreement that grants the research sponsor an exclusive option to license the inventions developed during the research.[83] Moreover, MIT would not permit a Federal employee whose agency may claim sole ownership to inventions developed or co-developed by the Federal employee while at MIT to participate in a federally funded program since MIT would not be able to comply with Bayh-Dole, especially if that Federal funded program had other non-government sponsors.[84]

Open Questions

The approach of MIT essentially seeks to avoid the problems attributable to the potential reach and affect of Executive Order 10096. The Stanford policy discussed above, on the other hand, seeks to grant Sanford co-ownership rights – a result that may or may not be achievable in advance of an actual invention – especially with the Federal government. This latter situation begs the question: Can a "release" of the Federal government's right, title and interest be obtained in advance, for instance,

when the federal agency seeks to involve its employee in a new or on-going sponsored research program?

The Executive Order and its implementing regulations do not contemplate such an event. Nonetheless, assuming an agreement can be negotiated between the Federal government and the university whereby the university agrees to assume title to any inventions pursuant to Bayh-Dole and to license such inventions in the "public interest," and recognizing the Federal government's royalty-free, irrevocable, nontransferable and non-exclusive license in any inventions, the release of the Federal government's claim would appear to fulfill the objectives of the Federal government as manifested in Executive Order 10096, the Federal Technology Transfer Act and Bayh-Dole. Clearly, such agreements will need to be negotiated on a case-by-case basis but in the face of a policy such as that being proposed by MIT, such an approach may well be the only means to involve Federal researchers in the sponsored programs being conducted at American universities.

NOTE: Author is engaged in the private practice of law in Camden, Maine. The paper was prepared for course "Non-Profit Technology Transfer" taken as part of LL. M. curriculum.

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[1] Inventions, Patents and Licensing, Research Policy Handbook, Document 5.1, Stanford University (July 15, 1999).

[2] Guide to the Ownership, Distribution and Commercial Development of MIT Technology (June 1999), Section 2.1 (page 5).

[3] *Id.* at Section 5.1(b)(page 20).

[4] *See, e.g., Chou v. University of Chicago*, 254 F.3d 1347, 1357 (Ct. App. Fed. Cir. 2001).

[5] Exec. Order No. 10096, 15 F. R. 389 (1950); currently codified at 37 C.F.R. §501 *et seq.*

[6] Exec. Order No. 10695, 22 F. R. 365, 1957 WL 8001 (Pres.).

[7] Exec. Order No. 10930, 26 F. R. 2583, 1961 WL 8183 (Pres.).

[8] *Kaplan v. Corcoran,* 545 F.2d 1073, 1076-77 (7th Cir 1976).

[9] *See United States v. Dubilier Condenser Corporation*, 289 U.S. 178, 205-06 (1933)(discussion of various efforts by the executive departments to regulate the taking of patents by government employees and imposition of requirement that patents so obtained be assigned to the government).

[10] *Halas v. United States*, 28 Fed. Cl. 354, 364 (Ct. Fed. Cl. 1993)(policy set forth in Executive Order 10096 applies to all government agencies with respect to inventions made by any government employee; government as whole owns rights to invention not just the particular agency for which employee works).

[11] The current codification is substantially the same as the previous codification at 37 C.F.R. §100 *et seq.* with the exception that the Under Secretary of Commerce for Technology is given the decision making authority and responsibility to hear appeals that was previously given to the Commissioner of Patents and Trademarks; additionally, the individual agency heads are now given advance approval to make determinations of rights concerning government employee inventions). *See* Final Rule, Uniform Patent Policy for Domestic Rights in Inventions Made by Government Employees, 53 F.R. 39734 (October 11, 1988).

[12] 37 C.F.R. §501.3(b)(*Government agency* means "any Executive department or independent establishment of the Executive branch of the government (including any independent regulatory commission or board, any corporation wholly owned by the United States, and the Smithsonian Institution), but does not include the Department of Energy for inventions made under the provisions of 42 U.S.C. §2182, the Tennessee Valley Authority, or the Postal Service").

[13] 37 C.F.R. §501.3(e)(*made* means "the conception or first actual reduction to practice of [any] invention as stated in *In re King*, 3 USPQ 2d (BNA) 1747 (Comm'r Pat. 1987").

[14] 37 C.F.R. §501.3(c)(*government employee* "means any officer or employee, civilian or military, of any government agency, including any special government employee as defined in 18 U.S.C. §202 or an individual working for a Federal agency pursuant to the Intergovernmental Personnel Act, 5 U.S.C. §1304 and §§3371-3376, or a part-time consultant or part-time employee as defined in 29 U.S.C. §2101(a)(8) except as may otherwise be provided by agency regulation approved by the [Under] Secretary [of Commerce for Technology].

[15] 37 C.F.R. §501.6(a)(1).

[16] 37 C.F.R. §501.6(a)(3).

[17] 37 C.F.R. §501.6(a)(2).

[18] *Id.*

[19] 37 C.F.R. §501.6(a)(3).

[20] 15 U.S.C. §3710 *et seq.* (policy of Federal government to ensure full use of nation's investment in research and development and to strive to transfer Federally owned or originated technology to State and local governments and to the private sector).

[21] 15 U.S.C. §3710d.

[22] *Id.*

[23] 35 U.S.C §202 (nonprofit organization may, within reasonable time after disclosure to Federal government, elect to retain title to any subject invention, subject to nonexclusive, nontransferable, irreovocable, paid-up license to practice or have practiced for or on behalf of the Unites States); *see* 35 U.S.C. §206 (authority to promulgate regulations now codified at 37 C.F.R. §401 et seq.).

[24] Under 37 C.F.R. §501.3 *invention* means any art or process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the patent laws of the United States.

[25] 37 C.F.R. §501.4

[26] *See, e.g.*, 7 C.F.R. §1250.542 (patents, copyrights, trademarks and information accruing from work pursuant to any plan or project undertaken by any person on behalf of the Egg Board [of the Department of Agriculture] … shall become the property of the U.S. Government …. Ownership of inventions made by employees of the [Egg] Board shall be determined in accordance with Executive Order 10096). *Also see* 14 C.F.R. §1245.501 (General Counsel of NASA delegated authority to make determinations of the

respective rights of the government and of the inventor in and to inventions made by employees under the administrative jurisdictions of the NASA).

[27] *Heinemann v. United States*, 4 Cl. Ct. 564, 567 (1984).

[28] *Id.* at 568.

[29] *Id.* at 571.

[30] *Id.*

[31] 38 CFR §§1.650-1.663.

[32] *Kaplan v. Johnson*, 409 F. Supp 190, 192 (N.D. Ill. 1976).

[33] *Id.* at 193.

[34] *Id.*

[35] *Id.*

[36] *Id.* at 194.

[37] 37 C.F.R. §501.7(a).

[38] 37 C.F.R. §501.7(b).

[39] 37 C.F.R. §501.8(a).

[40] *Zacharin v. United States*, 43 Fed. Cl. 185, 195 (1999).

[41] 37 C.F.R. §501.8(b)(2) and (3).

[42] *Heinemann v. Unites States*, 796 F.2d 451, 454 (Fed. Cir. 1986) *cert. denied* 480 U.S. 930 (1987); *Halas*, 28 Fed. Cl. at 363. *See* note 11 (prior to current codification appeals were taken to the Commissioner of Patents and Trademarks).

[43] *Heinemann*, 796 F.2d at 454; *also see Kaplan*, 409 F. Supp at 196 (administrative action regarded as arbitrary and capricious only where action not supportable on any rational basis).

[44] *Halas*, 28 Fed. Cl. at 363.

[45] *Halas*, 28 Fed. Cl. at 361.

[46] *Id.*

[47] *Dubilier*, 289 U.S. at 187.

[48] *See* G.K. Smith, *Faculty and Graduate Student Generated Inventions: Is University Ownership A Legal Certainty?* 1 VIRGINIA JOURNAL OF LAW & TECHNOLOGY 4 (1997).

[49] *Dubilier*, 289 U.S. at 187; *cited* in *Kaplan*, 545 F.2d at 1076.

[50] *Id.* at 187; *cited* in *Kaplan,* 545 F.2d at 1076.

[51] *Id.* at 192; *cited* in *Kaplan*, 545 F.2d at 1076.

[52] 409 F. Supp. 190 (N.D. Ill. 1976).

[53] *Id.* at 203.

[54] *Id.* at 204.

[55] Cited statute authorizes the President to prescribe regulations governing the conduct of, and conditions of employment for, employees of the executive branch.

[56] 409 F. Supp at 204.

[57] *Kaplan*, 545 F.2d at 1077.

[58] *Id.* *Citing* for the basis of its conclusion:

5 U.S.C. §301 (the head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property).

5 U.S.C. §3301 (The President may (1) prescribe such regulations for the admission of individuals into the civil service in the executive branch as will best promote the efficiency of that service).

5 U.S.C. §7301 (The President may prescribe regulations for the conduct of employees in the executive branch).

[59] *Kaplan*, 545 F.2d at 1077.

[60] *Heinemann*, 796 F.2d at 451.

[61] *Id.* at 455 *citing*, e.g., 5 U.S.C. §§ 301, 3301 and 7301.

[62] *Kaplan*, 545 F. 2d at 1077.

[63] *Heinemann*, 796 F.2d at 455.

[64] *Id.* at 455-56.

[65] *Ciba-Geigy Corp. v. Alza Corp.*, 804 F.Supp. 614, 616 (D. N.J. 1992).

[66] The trial court subsequently questioned whether the invention at issue was "conceived or first actually reduced to practice" during the pendency of these Federal grants, thereby questioning the applicability of Bayh-Dole obligations. *Id.* at 627.

[67] *Id.* at 616.

[68] *Id.* at 616. *See* 35 U.S.C. §202 (university obligated to promote commercialization of inventions).

[69] *Id.* at 617.

[70] *Id.* at 617.

[71] *Id.* at 617.

[72] 35 U.S.C. §200 (objective of Congress to use patent system to promote utilization of inventions arising from federally supported research and *inter alia* to promote commercialization and public availability of inventions made in Unted States by United States industry and labor).

[73] *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 828 F.Supp 1208, 1210 (E.D. N.C. 1993).

[74] *Id.*

[75] *Id.* at 1210.

[76] *Id.* at 1214.

[77] *Id.*

[78] *Id.* at 1214.

[79] *Id.* at 1215.

[80] *See* 37 C.F.R. §501.6(a)(4)(when government does not acquire title pursuant to criteria set forth herein, the Government "shall leave the entire right, title and interest in and to the invention in the Government employee); *see Dubilier,* 289 U.S. at 187 (a patent is property and title to it can pass only by assignment).

[81] Patent and Copyright Agreement for Personnel at Stanford Who Have a Prior Existing and Conflicting Intellectual Property Agreement with Another Employer, Stanford University Research Policy Handbook (January 1999).

[82] *Id.*

[83] Private communication dated November 23, 2004, with Ann M. Hammersla, Senior Counsel for Intellectual Property and Director of Office of Intellectual Property Counsel, Massachusetts Institute of Technology.

[84] *Id.*