Featured Article

Getting It Right: Intellectual Property Management Strategies Within the Academic Health System

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ABSTRACT: Academic health systems are innovation hubs that foster advancement in care through their research and innovation arms. In doing so, health care intellectual property (IP) may arise that includes patents, trademarks, copyrights, and trade secrets, all of which may originate within the health system or its academic partner(s). Under the Bayh-Dole Act of 1980, federal research grant recipients were allowed to obtain IP that protected their inventions when working with private sector partners to further develop inventions for commercialization. Unfortunately, in practice the activities of many technology transfer offices can work against the goals of the Bayh-Dole Act through unintentionally creating commercialization barriers. As a result, many organizations are focused on developing appropriate IP governance and supporting policies and procedures to minimize these impediments to effective tech transfer, i.e., efficient commercialization of inventions stemming from federal funded scientific research. This article will highlight the best practices associated with managing academic IP, including a review of the benefits and risks in commercializing research and innovation.

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IP Management Strategies Within the Academic Health System

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THE BAYH–DOLE ACT: INTRODUCTION

The Bayh-Dole Act,[1] enacted during the Carter Administration, was an effort to promote economic development in the aftermath of the economic slowdown in the late 1970s. Seeking ways to jump-start the economy, Senators Birch Bayh of Indiana and Bob Dole of Kansas spearheaded an initiative to reform how researchers supported by federal grant money—primarily those working in academia—could protect their inventions. While patenting such inventions was not proscribed by law, any patents that were obtained were owned by the federal government and thus there was no economic incentive for grant recipients, including universities and academic medical centers, to obtain them. While there were certain exceptions, such as the Wisconsin Alumni Research Foundation, very few technology transfer offices existed in American universities. Most university research was available for free to anyone keeping track of research published in scientific journals.

There was also a cultural prejudice against patents and technological research, which was thought to be the province of companies, such as those arising from the nascent biotechnology industry (e.g., Amgen, Genentech). If technology is "when you know the answer," academic research was believed to be properly limited to fundamental questions and "blue sky" science (i.e., scientific research where "real world" applications are not immediately apparent), with little applicability to technological advancement.

The passage of the Bayh-Dole Act (the Act) was instrumental in changing this perspective for several reasons. Under this legislation, universities and nonprofits obtaining federal research funds were required to pursue patent protection. If they did not, they were required to notify the federal funding agency to give the government the opportunity to obtain patent protection as it had prior to the passage of the Act. In addition, individual researchers were now able to apply for a patent themselves if both their organization and the government declined the opportunity. In situations where the university did obtain patent protection, it could be licensed (and licensing efforts were also anticipated in the Act), and any such license fees would be shared by the university, the department in which the researchers held faculty positions, and the researchers themselves. As a result, most entities pursuing and procuring federal research grants established technology transfer offices to help with the task of applying for and obtaining patents and licensing them to commercial concerns.

The Bayh–Dole Act: Provisions

The Bayh-Dole Act was the product of bipartisan efforts prompted by the recognition of risks to innovation in the 1970s which, by the early 1980s, had cultivated the popular view that other countries—most notably West Germany and Japan—were outcompeting the U.S.

1 Bayh–Dole Act, Pub. L. No. 96-517, 94 Stat. 3015, later codified under tit. 35 U.S. Code Part II Ch. 18, §§ 200-212.

The provisions of the Act, which are briefly discussed below, were intended to provide incentives and a framework for universities and other not-for-profit institutions to patent and license inventions. The Act also contained provisions with preference to U.S. industry, recognizing that some of the problems motivating the Act would not be addressed if licensees were foreign companies.

1. Section 200: Policy and Objectives[2]

The governmental policies and objectives aim to:

a. Use the patent system to promote the utilization of inventions arising from federally supported research or development;

b. Encourage maximum participation of small business firms in federally supported research and development efforts;

c. Promote collaboration between commercial concerns and nonprofit organizations, including universities;

d. Ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery;

e. Promote the commercialization and public availability of inventions made in the United States by U.S. industry and labor;

f. Ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and

g. Minimize the costs of administering policies in this area.

These principles embody the motivations of the Act's drafters and illustrate the perceived need for universities and nonprofit entities to utilize the patent system to promote and encourage commercialization of federally funded technologies. In addition, this section highlights other no-less-important policy goals, including facilitating small business involvement (illustrated in practice by numerous spin-out companies started by university

2 35 U.S.C. § 200 (2023). It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

professors/entrepreneurs since enactment of the Act[3]) and collaboration with existing businesses; promoting the use of U.S. industry; retaining for the U.S. government access to federally funded inventions and avoiding "non-use" thereof; and averting unnecessary bureaucracy and related costs as much as possible.

2. Section 201: Definitions[4]

This section, while being something of a formality, also provides important limits on the meaning of terms like "practical application," which contains quite specific meanings for the statutory categories of patentable subject matter under 35 U.S.C. § 101; "made," which encompasses the conventional definition of inventing as "the conception or first actual reduction to practice of such invention"; and "contractor," which defines the entities whose efforts can fall within the scope of the Act.

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3 The biotechnology company Genentech is a prime but hardly the only example; *see* Sally Smith Hughes, Genentech: The Beginnings of Biotech (University of Chicago Press; reprinted. 2013).

4 § 201. As used in this chapter—

(a) The term "Federal agency" means any executive agency as defined in section 105 of title 5, and the military departments as defined by section 102 of title 5.

(b) The term "funding agreement" means any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined.

(c) The term "contractor" means any person, small business firm, or nonprofit organization that is a party to a funding agreement.

(d) The term "invention" means any invention or discovery which is or may be patentable or otherwise protectable under this title or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 *et seq.*).

(e) The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: *Provided*, That in the case of a variety of plant, the date of determination (as defined in section 41(d)1 of the Plant Variety Protection Act (7 U.S.C. 2401(d))) must also occur during the period of contract performance.

(f) The term "practical application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

(g) The term "made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(h) The term "small business firm" means a small business concern as defined at section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(i) The term "nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

3. Section 202: Disposition of Rights[5]

This section sets forth the rights of each party to the relationships falling within the scope of the Act.

Section 202(a) sets forth the requirements for nonprofit organizations and small businesses to retain the rights to their federally funded inventions by affirmatively electing to do so within "a reasonable time (defined in Section 202(c) as within two years of disclosure of the invention to the government, which itself must be done within a "reasonable time"). This section also enumerates exceptions, including instances where the contractor is not located in the U.S. or is subject to the control of a foreign government, or where the federal government determines a national security need arising therefrom; "exceptional" circumstances wherein restricting or eliminating the contractor's rights to the invention "will better promote the policy and objectives" of the Act; or instances when the invention is related to research by the Department of Energy having to do with "naval nuclear propulsion or weapons."

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5 § 202. (a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention: *Provided, however*, That a funding agreement may provide otherwise (i) when the contractor is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, (ii) in exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of this chapter (iii) when it is determined by a Government authority which is authorized by statute or Executive order to conduct foreign intelligence or counter-intelligence activities that the restriction or elimination of the right to retain title to any subject invention is necessary to protect the security of such activities or, (iv) when the funding agreement includes the operation of a Government-owned, contractor-operated facility of the Department of Energy primarily dedicated to that Department's naval nuclear propulsion or weapons related programs and all funding agreement limitations under this subparagraph on the contractor's right to elect title to a subject invention are limited to inventions occurring under the above two programs of the Department of Energy. The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter.

(b)(1) The rights of the Government under subsection (a) shall not be exercised by a Federal agency unless it first determines that at least one of the conditions identified in clauses (i) through (iv) of subsection (a) exists. Except in the case of subsection (a)(iii), the agency shall file with the Secretary of Commerce, within thirty days after the award of the applicable funding agreement, a copy of such determination. In the case of a determination under subsection (a)(ii), the statement shall include an analysis justifying the determination. In the case of determinations applicable to funding agreements with small business firms, copies shall also be sent to the Chief Counsel for Advocacy of the Small Business Administration. If the Secretary of Commerce believes that any individual determination or pattern of determinations is contrary to the policies and objectives of this chapter or otherwise not in conformance with this chapter, the Secretary shall so advise the head of the agency concerned and the Administrator of the Office of Federal Procurement Policy, and recommend corrective actions.

(2) Whenever the Administrator of the Office of Federal Procurement Policy has determined that one or more Federal agencies are utilizing the authority of clause (i) or (ii) of subsection (a) of this section in a manner that is contrary to the policies and objectives of this chapter, the Administrator is authorized to issue regulations describing classes of situations in which agencies may not exercise the authorities of those clauses.

(3) If the contractor believes that a determination is contrary to the policies and objectives of this chapter or constitutes an abuse of discretion by the agency, the determination shall be subject to the [1] section 203(b).

Section 202(b) retains for the federal government through the Secretary of Commerce the supervisory role of evaluating which provisions of Section 202(a) apply in each instance.

Section 202(c) sets forth the timing requirements for contractor invention disclosure and election under Section 202(c)(1), which can be shortened under circumstances where there is public use, disclosure, or sale that would lessen the period for filing for patent protection under Section 202(c)(2). Section 202(c)(3) mandates that any contractor who elects to retain rights to an invention file a patent application prior to any statutory bar dates in the U.S. and abroad, with the federal government retaining rights to file abroad in any country the contractor fails to do so. Section 202(c)(4) retains for the federal government "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world" with there being the proviso

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(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time.

(2) That the contractor make a written election within two years after disclosure to the Federal agency (or such additional time as may be approved by the Federal agency) whether the contractor will retain title to a subject invention: *Provided*, That in any case where publication, on sale, or public use, has initiated the one year statutory period in which valid patent protection can still be obtained in the United States, the period for election may be shortened by the Federal agency to a date that is not more than sixty days prior to the end of the statutory period: *And provided further*, That the Federal Government may receive title to any subject invention in which the contractor does not elect to retain rights or fails to elect rights within such times.

(3) [T]hat a contractor electing rights in a subject invention agrees to file a patent applications prior to any statutory bar date that may occur under this title due to publication, on sale, or public use, and shall thereafter file corresponding patent applications in other countries in which it wishes to retain title within reasonable times, and that the Federal Government may receive title to any subject inventions in the United States or other countries in which the contractor has not filed patent applications on the subject invention within such times.

(4) With respect to any invention in which the contractor elects rights, the Federal agency shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement, may provide for such additional rights, including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency as necessary for meeting the obligations of the United States under any treaty, international agreement, arrangement of cooperation, memorandum of understanding, or similar arrangement, including military agreement relating to weapons development and production.

(5) The right of the Federal agency to require periodic reporting on the utilization or efforts at obtaining utilization that are being made by the contractor or his licensees or assignees: *Provided*, That any such information as well as any information on utilization or efforts at obtaining utilization obtained as part of a proceeding under section 203 of this chapter shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

that the government may have additional rights abroad under circumstances where such rights are "necessary for meeting the obligations of the United States under any treaty, international agreement" and otherwise.

Sections 202(c)(5) and 202(c)(6) set forth two important requirements for contractors who elect to retain title to a federally funded invention. The former sets out the right of the government to require "periodic reporting on the utilization or efforts at obtaining utilization" by the contractor, and the latter requires any U.S. patent application filed by the contractor to contain a notice of the federal funding, identifying its agency source, and affirmatively stating that "the government may retain certain rights to the invention."

Section 202(c)(7) governs how patent rights are shared, including the requirements that nonprofit organizations, such as universities, obtain approval from the federal agency before assigning the rights to a third party; royalties from licensing by the contractor be shared with the inventors; any excess profits be applied to support scientific research or education; and licensing to small businesses be pursued unless not feasible, as well as other provisions.

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(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

(7) In the case of a nonprofit organization, (A) a prohibition upon the assignment of rights to a subject invention in the United States without the approval of the Federal agency, except where such assignment is made to an organization which has as one of its primary functions the management of inventions (provided that such assignee shall be subject to the same provisions as the contractor); (B) a requirement that the contractor share royalties with the inventor; (C) except with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, a requirement that the balance of any royalties or income earned by the contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, be utilized for the support of scientific research or education; (D) a requirement that, except where it proves infeasible after a reasonable inquiry, in the licensing of subject inventions shall be given to small business firms; and (E) with respect to a funding agreement for the operation of a Government-owned-contractor-operated facility, requirements (i) that after payment of patenting costs, licensing costs, payments to inventors, and other expenses incidental to the administration of subject inventions, 100 percent of the balance of any royalties or income earned and retained by the contractor during any fiscal year up to an amount equal to 5 percent of the annual budget of the facility, shall be used by the contractor for scientific research, development, and education consistent with the research and development mission and objectives of the facility, including activities that increase the licensing potential of other inventions of the facility; provided that if said balance exceeds 5 percent of the annual budget of the facility, that 15 percent of such excess shall be paid to the Treasury of the United States and the remaining 85 percent shall be used for the same purposes described above in this clause; and (ii) that, to the extent it provides the most effective technology transfer, the licensing of subject inventions shall be administered by contractor employees on location at the facility.

(8) The requirements of sections 203 and 204 of this chapter.

Under circumstances where a contractor does not elect to retain title, Section 202(d) provides that the inventor(s) may retain title subject to a first right belonging to the federal government.

When a federal employee is a coinventor, the federal agency may, under Section 202(e), either assign its rights to the nonprofit organization, small business firm, or nonfederal employee inventor *or* acquire the rights of the nonprofit organization, small business firm, or nonfederal employee (but only when such acquisition is voluntary by the nonprofit organization, small business firm, or nonfederal employee).

Finally, Section 202(f) prevents the government (subject to necessity) from requiring a contractor to license nonsubject inventions to a third party.

The provisions under Section 202(c) also carry penalties for noncompliance, such as the federal government receiving title to the invention if time periods are not satisfied.

(d) If a contractor does not elect to retain title to a subject invention in cases subject to this section, the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder.

(e) In any case when a Federal employee is a coinventor of any invention made with a nonprofit organization, a small business firm, or a non-Federal inventor, the Federal agency employing such coinventor may, for the purpose of consolidating rights in the invention and if it finds that it would expedite the development of the invention—

(1) license or assign whatever rights it may acquire in the subject invention to the nonprofit organization, small business firm, or non-Federal inventor in accordance with the provisions of this chapter; or

(2) acquire any rights in the subject invention from the nonprofit organization, small business firm, or non-Federal inventor, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction and no other transaction under this chapter is conditioned on such acquisition.

(f)(1) No funding agreement with a small business firm or nonprofit organization shall contain a provision allowing a Federal agency to require the licensing to third parties of inventions owned by the contractor that are not subject inventions unless such provision has been approved by the head of the agency and a written justification has been signed by the head of the agency. Any such provision shall clearly state whether the licensing may be required in connection with the practice of a subject invention, a specifically identified work object, or both. The head of the agency may not delegate the authority to approve provisions or sign justifications required by this paragraph.

(2) A Federal agency shall not require the licensing of third parties under any such provision unless the head of the agency determines that the use of the invention by others is necessary for the practice of a subject invention or for the use of a work object of the funding agreement and that such action is necessary to achieve the practical application of the subject invention or work object. Any such determination shall be on the record after an opportunity for an agency hearing. Any action commenced for judicial review of such determination shall be brought within sixty days after notification of such determination.

4. Section 203: March-In Rights[6]

In perhaps the most controversial section of the Act, Section 203 provides that in limited circumstances, the federal government can "require the contractor, an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances." Importantly, the circumstances under which the government has such "march-in rights" under Section 203(a) are more limited than many, including members of Congress, appreciate them to be:[7]

1. The contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
2. The action is necessary to alleviate health or safety needs that are not reasonably satisfied by the contractor, assignee, or their licensees;
3. The action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

6 § 203. (a) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right, in accordance with such procedures as are provided in regulations promulgated hereunder to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself, if the Federal agency determines that such—

(1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;

(3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or

(4) action is necessary because the agreement required by section 204 has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement obtained pursuant to section 204.

(b) A determination pursuant to this section or section 202(b)(4)1 shall not be subject to chapter 71 of title 41. An administrative appeals procedure shall be established by regulations promulgated in accordance with section 206. Additionally, any contractor, inventor, assignee, or exclusive licensee adversely affected by a determination under this section may, at any time within sixty days after the determination is issued, file a petition in the United States Court of Federal Claims, which shall have jurisdiction to determine the appeal on the record and to affirm, reverse, remand or modify, as appropriate, the determination of the Federal agency. In cases described in paragraphs (1) and (3) of subsection (a), the agency's determination shall be held in abeyance pending the exhaustion of appeals or petitions filed under the preceding sentence.

7 *See, e.g.*, Joseph Allen, *President Biden: Don't Misuse Bayh-Dole March-in Rights*, STAT, Sept. 17, 2021, https://www.statnews.com/2021/09/17/president-biden-dont-misuse-bayh-dole-march-in-rights/.

4. The action is necessary because the agreement required by Section 204 (preference for U.S. industry) has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the U.S. is in breach of its agreement obtained pursuant to Section 204.

Section 203(b) sets forth the procedures for adjudicating whether the contractor is entitled to a waiver of the requirements of Section 204.

5. Section 204: Preference for U.S. Industry[8]

This section limits the right of a contractor who has retained title to a federally funded invention to grant an exclusive license to anyone who has not agreed in writing to manufacture any products "substantially" in the U.S. This requirement can be waived by the federal agency under circumstances where the nonprofit organization, small business firm, or assignee has made "reasonable but unsuccessful" efforts to find a U.S. manufacturer willing to manufacture substantially in the U.S. under similar terms as willing manufacturers outside the U.S. or where "under the circumstances domestic manufacture is not commercially feasible."

6. Section 205: Confidentiality[9]

This provision gives the federal funding agencies the ability to withhold from disclosure information about the invention "for a reasonable time in order for a patent application to be filed." The Act also does not impose an obligation for the federal government to release copies of any document that is part of an application (although U.S. patent and trademark practices or the patent statute may so compel).

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8 § 204. Notwithstanding any other provision of this chapter, no small business firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

9 § 205. Federal agencies are authorized to withhold from disclosure to the public information disclosing any invention in which the Federal Government owns or may own a right, title, or interest (including a nonexclusive license) for a reasonable time in order for a patent application to be filed. Furthermore, Federal agencies shall not be required to release copies of any document which is part of an application for patent filed with the United States Patent and Trademark Office or with any foreign patent office.

7. Section 206: Uniform Clauses and Regulations[10]

This section gives the Secretary of Commerce the authority to promulgate rules and regulations to implement the earlier provisions of the Act as well as establish standard funding provisions and agreements.

8. Section 207: Domestic and Foreign Protection for Federally Owned Inventions[11]

This section provides the statutory authority for agencies of the federal government to "apply for, obtain, and maintain patents or other forms of protection" in the U.S. or abroad for inventions in which the government has "an" interest, and the right to grant licenses therefore, as well as transfer interests to other agencies. The Secretary of Commerce is expressly empowered to oversee these efforts.

9. Section 208: Regulations Governing Federal Licensing[12]

This section empowers the Secretary of Commerce to promulgate regulations for licensing federally owned inventions.

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10 § 206. The Secretary of Commerce may issue regulations which may be made applicable to Federal agencies implementing the provisions of sections 202 through 204 of this chapter and shall establish standard funding agreement provisions required under this chapter. The regulations and the standard funding agreement shall be subject to public comment before their issuance.

11 § 207. (a) Each Federal agency is authorized to—

(1) apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(2) grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of this title as determined appropriate in the public interest;

(3) undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract, including acquiring rights for and administering royalties to the Federal Government in any invention, but only to the extent the party from whom the rights are acquired voluntarily enters into the transaction, to facilitate the licensing of a federally owned invention; and

(4) transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(b) For the purpose of assuring the effective management of Government-owned inventions, the Secretary of Commerce is authorized to—

(1) assist Federal agency efforts to promote the licensing and utilization of Government-owned inventions;

(2) assist Federal agencies in seeking protection and maintaining inventions in foreign countries, including the payment of fees and costs connected therewith; and

(3) consult with and advise Federal agencies as to areas of science and technology research and development with potential for commercial utilization.

12 § 208. The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.

10. Section 209: Licensing Federally Owned Inventionsw[13]

Section 209(a) provides federal agencies the authority to grant exclusive or "partially exclusive" (e.g., field of use) licenses for federally owned inventions, subject to a need to obtain investment capital or "otherwise promote the invention's utilization by the public," but with the extent of exclusivity being only those reasonably necessary to promote these ends. The agency also has the right to base such licenses on an agreement by a licensee to "achieve practical application of the invention within a reasonable time." Such licenses must be compliant with antitrust law and, for foreign patents, must enhance the interests of the federal government in foreign commerce.

13 § 209. (a) Authority.—A Federal agency may grant an exclusive or partially exclusive license on a federally owned invention under section 207(a)(2) only if—

(1) granting the license is a reasonable and necessary incentive to—

(A) call forth the investment capital and expenditures needed to bring the invention to practical application; or

(B) otherwise promote the invention's utilization by the public;

(2) the Federal agency finds that the public will be served by the granting of the license, as indicated by the applicant's intentions, plans, and ability to bring the invention to practical application or otherwise promote the invention's utilization by the public, and that the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public;

(3) the applicant makes a commitment to achieve practical application of the invention within a reasonable time, which time may be extended by the agency upon the applicant's request and the applicant's demonstration that the refusal of such extension would be unreasonable;

(4) granting the license will not tend to substantially lessen competition or create or maintain a violation of the Federal antitrust laws; and

(5) in the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.

(b) Manufacture in United States.—A Federal agency shall normally grant a license under section 207(a)(2) to use or sell any federally owned invention in the United States only to a licensee who agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

(c) Small Business.—First preference for the granting of any exclusive or partially exclusive licenses under section 207(a)(2) shall be given to small business firms having equal or greater likelihood as other applicants to bring the invention to practical application within a reasonable time.

(d) Terms and Conditions.—Any licenses granted under section 207(a)(2) shall contain such terms and conditions as the granting agency considers appropriate, and shall include provisions—

(1) retaining a nontransferable, irrevocable, paid-up license for any Federal agency to practice the invention or have the invention practiced throughout the world by or on behalf of the Government of the United States;

(2) requiring periodic reporting on utilization of the invention, and utilization efforts, by the licensee, but only to the extent necessary to enable the Federal agency to determine whether the terms of the license are being complied with, except that any such report shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5; and

Section 209(b) contains provisions analogous to the U.S. industry preference for contractors under Section 204, and Section 209(c) grants a "first preference" to U.S. small businesses.

Section 209(d) contains provisions for the U.S. government to retain "a nontransferable, irrevocable, paid-up license for any federal agency to practice the invention" (or have a third party practice the invention on the government's behalf); to have periodic reporting on utilization of the invention by government licensees; and to terminate the license should a licensee fail to satisfy its commitment to utilize the invention, be in breach of the license agreement regarding the preference for U.S. manufacturing, violate the antitrust laws (as determined by a court of competent jurisdiction), or fail to satisfy requirements for public use arising after the date of the license.

11. Section 210: Precedence of Chapter[14]

This section enumerates other statutes for which the Act takes preference and details the extent to which the authority of a federal agency would be limited regarding the disposition of rights in an invention or a requirement to disclose intelligence sources.

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(3) empowering the Federal agency to terminate the license in whole or in part if the agency determines that—

(A) the licensee is not executing its commitment to achieve practical application of the invention, including commitments contained in any plan submitted in support of its request for a license, and the licensee cannot otherwise demonstrate to the satisfaction of the Federal agency that it has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the invention;

(B) the licensee is in breach of an agreement described in subsection (b);

(C) termination is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license, and such requirements are not reasonably satisfied by the licensee; or

(D) the licensee has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under the license agreement.

(e) Public Notice.—No exclusive or partially exclusive license may be granted under section 207(a)(2) unless public notice of the intention to grant an exclusive or partially exclusive license on a federally owned invention has been provided in an appropriate manner at least 15 days before the license is granted, and the Federal agency has considered all comments received before the end of the comment period in response to that public notice. This subsection shall not apply to the licensing of inventions made under a cooperative research and development agreement entered into under section 12 of the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3710a).

(f) Plan.—No Federal agency shall grant any license under a patent or patent application on a federally owned invention unless the person requesting the license has supplied the agency with a plan for development or marketing of the invention, except that any such plan shall be treated by the Federal agency as commercial and financial information obtained from a person and privileged and confidential and not subject to disclosure under section 552 of title 5.

14 § 210. (a) This chapter shall take precedence over any other Act which would require a disposition of rights in subject inventions of small business firms or nonprofit organizations contractors in a manner that is inconsistent with this chapter, including but not necessarily limited to the following: (*followed by list of other provisions of U.S. law*).

12. Section 211: Relationship to Antitrust Laws[15]

The provisions of this section ensure that the Act cannot be used to contravene or provide a defense for violations of the antitrust laws.

13. Section 212: Disposition of Rights in Educational Awards[16]

This section precludes the federal government from asserting any ownership rights to inventions made awardees of scholarships, fellowships, training grants, or funding for educational purposes.

The Act, like most Acts of Congress, contains a potpourri of provisions that address how the Act must or should be executed (in many instances by administrative agencies like the National Institutes of Health and the Patent and Trademark Office). While in practice, the important actions that contractors (universities, academic medical centers, and health systems, as well as their technology transfer offices) must take are relatively few, failure to perform them can put rights at risk; it is therefore important to enumerate those actions succinctly.

Somewhat chronologically, the first requirement is that the contractor provide notice to the funding agency for inventions made using federally funded grants and other support sources. While the administrative requirements for notice are contained in the documents executed by the university in accepting a grant of federal monies for research, satisfaction of this requirement entails making sure that principal investigators (PIs) obtaining such grants are aware that the requirement exists and that these scientists are made to understand the importance of its satisfaction, a task usually undertaken by technology transfer personnel. Discussing the possible practical applications of the invention's goals and milestones, which is usually part of the grant application, can facilitate this process, as well as ensuring that all lab personnel, including postdoctoral fellows, graduate students, and technical staff, understand their obligations.

Next, the organization must determine whether it wishes to exercise its first right of pursuing protection (usually by patenting). Because the expenses involved in applying for patents are not trivial and come from the technology transfer office's budget, not all invention disclosures are pursued.[17] For those that are not, the Act requires the contractor provide timely notice to the federal funding agency using procedures adopted by each funding agency

15 § 211. Nothing in this chapter shall be deemed to convey to any person immunity from civil or criminal liability, or to create any defenses to actions, under any antitrust law.

16 § 212. No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee.

17 While the costs for a patent application can vary, preparation and filing costs generally range from $3,000 and $15,000, depending on the technology and complexity of the invention.

that contain at a minimum the application number and filing date of any such patent. Because these rights can be lost or severely compromised by disclosure prior to filing a patent application (for example, through publication of a scientific paper, presentation at a public meeting, or a lab's or individual scientist's website), technology transfer offices need a system to ensure diligence. Only when the government declines the opportunity for filing patent applications does the right to do so devolve to the individual scientist, and while this could under the right circumstances provide motivation to those individuals to comply, the contingent nature of these rights can reduce the probability that enlightened self-interest will be enough to make compliance sufficiently certain so as to satisfy the requirements of the statute in this regard.

For instances where the contractor decides to pursue patent protection, the statute requires that any patent application (and if successful, patent) provide notice to the public in any patent application filing and subsequently obtained patent that the invention was made using funding from a federal agency and that the government has certain rights to the invention. Satisfaction of this requirement is usually best achieved by including said notice in the first filing (such as a U.S. provisional application) wherein it will be present as such an application is revised, expanded upon with new disclosure, and converted into a U.S. or a foreign or international (PCT) application.

The remaining requirements have to do with licensing the patented technology (although there are opportunities for know-how and other nonpatent intellectual property invented under federally funded research grants and agreements to fall within the Bayh-Dole purview). The first and perhaps most important of these is the preference that patents and other intellectual property be licensed to U.S. industry. This requirement is almost entirely satisfied by the contractor and technology transfer office, although there can be instances where a PI is involved in a start-up that involves foreign-based companies (e.g., when there are foreign-based scientific collaborators and the start-up is based or has significant commercial activities abroad). While the strength of the innovation economy and availability of venture and other investment capital generally renders U.S. companies competitive, there have been areas where U.S. companies have substantially abandoned certain aspects of a market. Ironically, until the COVID-19 pandemic, vaccines were one such area due to potential liability, reduced opportunities for new vaccines, and, to some extent, anti-vaccine sentiment from prominent celebrities. In circumstances where there are no viable commercial opportunities, the Bayh-Dole Act permits exceptions, but the burden is on the contractor to prove the exception is warranted under the commercial circumstances.

Another requirement contained in the Act regarding licensing are related to the allocation of profits. The inventors generally share in provisions that encourage researcher participation, and financial benefits for research labs, academic departments, and the organization as a whole are intended to provide incentives for compliance and participation in technology transfer. Importantly, the use of moneys distributed to institutional recipients (departments, etc.) is limited to research and teaching. For example, Princeton University's use of profits for

licensing faculty patents for Eli Lilly and Company's Alimta anticancer drug were used to build a new chemical engineering building (and not, for example, a new football stadium).

Limitations to the Act: *Stanford v. Roche*

In 2011, the U.S. Supreme Court limited the scope of the provisions of the Bayh-Dole Act mandating assignment of rights to inventions made incident to a federally funded research grant in its decision in *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems Inc.*[18] The Court's decision was based on a fundamental premise of U.S. patent law: "[s]ince 1790, the patent law has operated on the premise that rights in an invention belong to the inventor." The question, according to the Court, was whether Congress acted to overrule that principle for federally funded inventions under the Bayh-Dole Act and automatically vest title in the federal contractor. The Court decided it did not.

The dispute arose when a research scientist at Stanford, who had signed an "agreement to assign" (in future) all federally funded inventions to Stanford, performed research at the biotech company Cetus (later acquired by Genentech) and, as a condition for performing that work, signed an agreement that assigned to Cetus any inventions made from this research. The inventions in question were methods for detecting HIV in patient samples, which are then used to assess the effectiveness of AIDS treatments. Stanford later obtained several patents on these inventions and sued Roche Molecular Systems (which had acquired Cetus) when the company marketed a diagnostic test that incorporated these methods. The Federal Circuit made a distinction between the "agreement to assign" to Stanford and the agreement to Cetus, which read that the scientist "will assign and hereby assigns" all inventions to the company. For the appellate court, the language that the scientist "agreed to assign" to Stanford amounted to a promise to assign inventions not yet made and thus, under contract law, was insufficient to divest Cetus of title under the "will assign and hereby assigns" language of that agreement.

The Supreme Court affirmed in an opinion by Chief Justice Roberts, who was joined by all but Justices Breyer and Ginsberg (Justice Sotomayor filed a concurring opinion). In doing so, the Court focused on the preclusive effect, if any, of the Bayh-Dole Act on the inventor's interests in the invention. The court recited the several provisions of the Patent Act that require that an inventor is entitled to a patent (subject to the specific provisions of Section 101); that the inventor must sign an oath or declaration attesting to inventorship (Section 115); and that a patent is issued to the inventor or the inventor's assignee (Sections 151, 152, and 261). The primacy of the inventor as patentee is supported by precedents cited by the Court,[19] as well as under treaty. While much of these same precedents support the right of an

18 Bd. Trs. Leland Stanford Junior Univ. v. Roche Molecular Sys., 563 U.S. 776 (2011).

19 Including Gayler v. Wilder, 51 U.S. 477 (1851); Solomons v. United States, 137 U.S. 342, 346 (1890); and United States v. Dubilier Condenser Corp., 289 U.S. 178, 188 (1933).

inventor to assign title to an invention to another, the patent right, ultimately, "must trace back to the inventor" according to the Court's decision. Mere employment is not enough to convey title to an invention from an inventor-employee to the employer "unless there is an agreement to the contrary," and thus, the issue before the Court was whether (or which of) the agreements was effective in transferring title.

The Court characterized the position taken by Stanford and the federal government as amicus curiae to be that Congress altered this traditional relationship regarding title to inventions made using moneys from the federal government. The Court rejected this view, saying that when Congress intended to do so in the past it had done so expressly, citing statutory provisions regarding nuclear energy,[20] NASA,[21] and the Department of Energy[22] as examples of such express vesting of title of private patents to the U.S. Such express language is "notably absent" from the Bayh-Dole Act, according to the Court, which stated that:

> Nowhere in the Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions. Instead, the Act provides that contractors may "elect to retain title to any subject invention." (35 U.S. C. § 202(a)).

The court noted that, under Section 202(e), "[a] 'subject invention' is defined as 'any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.'" The Court explicitly rejected Stanford's reading of the phrase "invention of the contractor" to perform the vesting function, saying that to do so would "assume that Congress subtly set aside two centuries of patent law in a statutory definition" and would render the phrase "of the contractor" superfluous. By this interpretation, the Act is limited to those inventions "owned by or belonging to the contractor," which would require assignment from the inventor to the university in order to be satisfied. While noting that Stanford's reading of the phrase "the invention of the contractor" to mean "all inventions made by the contractor's employees is 'plausible in the abstract,'" the opinion expressly rejected the analogy with the products of other employees in other contexts (such as automobile manufacturing), saying that "patent law has always been different." The Court also rejected the idea that employment is enough, absent an agreement, to vest ownership of a patented invention in the employer. According to the Court, the language of the Act specifying that the contractor can elect to retain title supports this view, with its ruling stating "you cannot retain something unless you already have it" and citing as an example *Alaska v. United States.*[23] In the

20 42 U.S.C. § 2182.
21 51 U.S.C. § 20135(b)(1).
22 42 U.S.C.§ 5908.
23 Alaska v. United States, 545 U.S. 75, 104 (2005).

Court's opinion, "[t]he Bayh-Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have."

The opinion contains two other important statements. First, in a footnote, the Court rejected the dissent's assertion that Executive Order 10096 acts to vest title in the government, saying that this order applies to federal employees, and that recipients of federally funded contracts are *not* federal employees. The Court further rejected the interpretation that Section 210 of the statute, which states that "it 'take[s] precedence over any other Act which would require a disposition of rights in subject inventions . . . that is inconsistent with' the Act" displaces the inventor's rights in favor of the university. This can happen only with regard to "subject inventions," which the Court interprets to mean "inventions of the contractor" (i.e., only *after* an inventor has assigned rights in the invention to the university). This argument leads to the second statement, which is that the court finds that the Act is limited to the "order of priority rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor. Nothing more." The court says that this interpretation is supported by the absence of any provisions regarding third parties "that have neither sought nor received federal funds" such as Roche. The absence of such remedies "would be deeply troubling," according to the opinion, "[i]n a world in which there are frequent collaboration[s] between private entities, inventors, and federal contractors." The opinion also states that Stanford's interpretation would vest title in inventions "even if the invention was conceived before the inventor became a University employee, so long as the invention's reduction to practice was supported by federal funding," and that title would vest in the university "even if only one dollar of federal funding was applied towards the invention's conception or reduction to practice."

Finally, the opinion reviews other portions of the Act, such as Section 202(d), that are related to the inventor "retaining" rights to the subject invention if the university declined to retain title. The use of the word "retention" in the statute "would be odd," says the Court, if the inventor did not have rights in the invention to retain.

In practice, the consequences of the Court's decision have been minimal; in response, universities and other institutional grant recipients became more diligent in obtaining present assignments from inventor-employees for future inventions. The Court's decision did not increase the burden on universities to protect such inventions, but it did increase the vigilance exercised by technology transfer offices and university officials to prevent the loss of rights to third parties.

PATIENT DATA AND HOW IT CAN BE USED

The practice of respecting a patient's confidences and prohibiting the unauthorized disclosure of medical information dates back centuries.[24] Today, these traditional privacy concerns become complicated to the extent disclosure is required by insurers (both public and private) to justify and coordinate coverage for medical care.[25] In the context of the Bayh-Dole Act, such medical information arises as data generated from medical and scientific research, which if resulting from federal funding, must at least be considered for its practical applications and if possible protected by patenting and other intellectual property regimes. But in this context, the intellectual property is also (usually) licensed, and between public disclosure of inventions and licensing, privacy concerns and accommodations thereto protect against situations where patient medical data may be inadvertently and inappropriately disclosed. The following sections detail both previous and ongoing efforts to enhance protection for medical information, particularly with regard to electronic databases.[26]

Medical Records Privacy: A HIPAA Primer

The principal federal law protecting patient privacy with respect to their medical records is the Health Insurance Portability and Accountability Act of 1996, or HIPAA.[27] This Act was initially concerned with the accessibility of medical records tied to insurance reimbursement[28] and is administered under the Office of Civil Rights for HIPAA as part of the U.S. Department of Health and Human Services.[29] As technology has developed, the Act has evolved to outline national standards for electronic health care transactions and codifies responsibility for maintaining the confidential status of patient electronic medical records.[30] These provisions also apply to medical research data produced from federally funded medical research.

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24 "Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private." *See Greek Medicine: "I Swear by Apollo Physician . . .": Greek Medicine from the Gods to Galen*, Nat'l Libr. Med., Nat'l Insts. Health, https://www.nlm.nih.gov/hmd/greek/greek_oath.html (last updated Feb. 7, 2012).

25 *See Improve Care Coordination: The Need for Better Improved Care Coordination*, HealthIT.gov, https://www.healthit.gov/providers-professionals/improved-care-coordination (last reviewed Sept. 15, 2017).

26 An additional regulatory route for protecting patient privacy and medical information is via the Federal Trade Commission pursuant to Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45). Under this section, unauthorized disclosure of medical information is a consumer protection violation prohibited by the Act as an unfair or deceptive act or practice. An example of such an action is *Easy Healthcare Corp. v. U.S.*, recently settled with the district court entering a permanent injunction prohibiting disclosure, imposition of a mandatory privacy and information security program by the company, a $100,000 civil penalty, and other provisions. *See* Stipulated Order for Permanent Injunction, Civil Penalty Judgment, and Other Relief, United States v. Easy Healthcare Corp (2023), https://www.ftc.gov/system/files/ftc_gov/pdf/2023.06.22_easy_healthcare_signed_order_2023.pdf.

27 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) [hereinafter HIPAA].

28 *Id.* at tit. II.

29 *See Office for Civil Rights*, U.S. Dep't Health & Human Servs., https://www.hhs.gov/ocr/index.html (last visited Oct. 2, 2023).

30 HIPAA § 201, 42 U.S.C. 1320a-7c.

With the advent of electronic medical records and telehealth, HIPAA mandates that a clinician involved in telemedicine has the same duty to safeguard a patient's medical records and keep their treatments confidential as traditional physicians.[31] Operationally, this involves ensuring that the location in which the confidential information resides and how it is stored must be secure, and that no confidential patient information is exposed inadvertently or otherwise.[32] This is particularly relevant when certain factors present elevated exposure risk, such as research and technical personnel who can act more independently of the medical team than in traditional medical settings (i.e., where records are conventionally kept on site in a physician's locked office or in a hospital records repository that includes all the security provisions attendant to them). In addition, and unique to electronic medical records, a patient's confidential medical information is subject to potential exposure from hackers during transmission or storage;[33] this risk requires, at a minimum, some form of encryption to prevent information from being inappropriately accessed.[34]

HIPAA identifies three groups of individuals who have responsibility for maintaining the confidentiality of patient medical records and other information:

- A covered healthcare provider, who is a person, business, or agency that furnishes, bills, or receives payment for healthcare in the normal course of business and transmits any covered transaction electronically.[35]
- A healthcare clearinghouse, which is a business or agency that processes or facilitates the processing of health information from a nonstandard format or content into standard format or vice versa, or the business or agency that performs this function for another legal entity.[36]
- A private benefit plan, which is a plan for an individual, group, or some combination thereof, that provides or pays for the cost of medical care, has greater than 50 participants, and is not self-administered.[37]

31 HIPAA tit. II.
32 *Id*.
33 *See Summary of the HIPAA Security Rule*, HHS, https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html (last reviewed Oct. 19, 2022).
34 *See* Elizabeth Snell, *Breaking Down HIPAA: Health Data Encryption Requirements*, HealthITSecurity (Mar. 20, 2015), https://healthitsecurity.com/news/breaking-down-hipaa-health-data-encryption-requirements.
35 HIPAA § 262, 42 U.S.C. §§1320d(3), 1320d-1.
36 HIPAA § 262, 42 U.S.C. §§1320d(2), 1320d-1.
37 HIPAA § 262, 42 U.S.C. §§1320d(5), 1320d-1.

Also included under the umbrella of HIPAA responsibility for maintaining patient confidentiality are "business associates," which comprise anyone that:

- Creates, receives, maintains, or transmits protected health information (PHI) to perform certain functions or activities on behalf of a covered entity;
- Provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to, or for, a covered entity in situations where PHI is involved;
- Provides data transmission services to a covered entity and has access to PHI on a routine basis;
- Offers personal health records to one or more individuals on behalf of a covered entity; and/or
- Operates as a subcontractor of the business associate who has been delegated a function, activity, or service in a capacity other than as a member of the business associate's workforce.[38]

Genetic Information Privacy

A particular facet of patient information related to health and subject to inadvertent disclosure is genetic information, which has become available and greatly increased in scope over the past 40 years.[39] The significance and scope of genetic information resulting from research, including elucidation of the genetic bases for disease and genetic approaches to therapeutic interventions, cannot be emphasized enough. Today, there are many more examples of diseases having a known genetic basis as well as diseases for which the risk—and especially, increased risk—of developing such diseases has been elucidated.[40] Concerns that this information could be used to discriminate against individuals in employment or other social contexts, including access to health insurance, motivated the passage of the Genetic Information Nondiscrimination Act (GINA) of 2008.[41] This Act prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members or using it for decisions regarding coverage, rates, or preexisting conditions.[42] The law also prohibits most employers from using genetic information for hiring,

38 *See* 45 C.F.R. §§ 164.502(e), 164.504(e) (2023).

39 Previously, only a handful of illnesses and propensities were known to have a genetic basis. These include diseases related to chromosomal abnormalities, such as Down's Syndrome, Turner's Syndrome, and Klinefelter's syndrome, and those related to genetic mutations, including sickle cell anemia, cystic fibrosis, Duchenne's muscular dystrophy, and Tay-Sachs disease. *See* Heidi Chial, *Rare Genetic Disorders: Learning About Genetic Disease Through Gene Mapping, SNPs, and Microarray Data*, 1 Nature Educ. 192 (2008).

40 These diseases include (most (in)famously) increased risk for breast and ovarian cancer associated with mutations in the BRCA gene, as well as Huntington's chorea and familial adenomatous polyposis.

41 Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881.

42 *Id.*

termination, or promotion decisions, as well as any decisions regarding terms of employment.[43] Despite these safeguards, the potential liability to individuals from improper disclosure is still very present, as GINA's health coverage nondiscrimination protections do not extend to life insurance, disability insurance, or long-term care insurance,[44] nor does GINA mandate coverage for any particular test or treatment.[45] Moreover, GINA does not prohibit health insurers or health plan administrators from obtaining and using genetic test results in making health insurance payment determinations, which could form an economic basis for such discrimination.[46]

Privacy Concerns

Personal medical records fall well within the modern expansion of privacy protected under the First Amendment,[47] as well as under interpretations—both conventional and modern—of the Third, Fourth, Fifth, and Fourteenth Amendments.[48] Due to the sensitive nature of their content, a patient's medical records and other health information involve equivalent concerns regarding protections against the publicizing of this information as motivated by protection of other areas of individual privacy. These protections are expressly directed to a citizen's right to be free from government intrusion. Protections from private actors (including employers and the press, among others) must rely on other powers of Congress, such as its power over interstate commerce, because the behavior of private actors is not restricted by privacy considerations as governments (local, state or federal) are recognized to be. The citizenry's interest in privacy from intrusion by private actors certainly applies to the use of medical information regarding employment and, particularly in view of the reach of nationwide insurance providers (despite local control thereof state-by-state) and similar consolidation of the medical provider industry (hospitals, for example). These privacy rights can be functionally, if not legally, restricted when pitted against free speech and press freedom rights under the First Amendment, and remedies for unauthorized disclosure in such cases may be limited to traditional libel, slander, rights of publicity, and breach of confidentiality actions (albeit these will be more attenuated for individuals in the public eye such as actors, musicians, and politicians).[49]

43 *Id.*; there can be exceptions where a genetic condition or propensity is directly related to an individual's ability to perform the tasks required for the job.
44 *Id.*
45 *Id.*
46 *Id.*
47 *See, e.g.*, Loving v. Virginia, 388 U.S. 1 (1967); Griswold v. Connecticut, 381 U.S. 479 (1965).
48 All these amendments more or less directly implicate the privacy right for an individual to be secure in her home or in her possessions and to restrict the government's ability to intrude on that privacy by requiring due process of law to do so.
49 *See* New York Times Co. v. Sullivan, 376 U.S. 254 (1964).

Ownership of Patient Medical Record Databases and Related Patent Protection

These days, patient medical information is almost exclusively contained in electronic databases. Yet even in the analog age, there was a recognition that the accumulation of individual items of data in a collection was not only valuable but could be protected as a form on intellectual property.[50] Books of phone listings and maps (particularly for cities and towns) could be protected by copyright, and more specific lists, such as a company's client or customer list, were valuable trade secrets.[51] The value of this intellectual property came not from the individual items but from the collection as a whole. In this way, such traditional databases—which is what we would recognize them to be, especially when reduced to electronic media—differ from collections of patient medical information, wherein each item represents a person's medical history and, in some instances, propensity for developing a disease.[52] The technology involved in creating or storing information (either per se or related to physical samples) can be protected by patenting[53] or, less productively, as a trade secret;[54, 55] however, databases themselves are difficult to protect, because each new entry creates a new database not previously described.[56]

Like traditional trade secret collections, protecting medical information databases involves restricting access, which is the key property right (but it should be recognized this property right belongs to the complier of the database, not the individuals whose data makes up the database).[57] This can be limited to granting access to a portion or subset of the items in the database or providing access to the entirety of the information therein.[58] One of the

50 *See* Julie E. Cohen & William M. Martin, *Intellectual Property Rights in Data*, *in* Information Systems and the Environment (Deanna J. Richards et al. eds., 2001), https://www.nap.edu/read/6322/chapter/5; protecting databases has traditionally not been a particularly attractive option, because among other things it relied on trade secret legislation enacted state-by-state. This changed when Congress enacted the Defend Trade Secrets Act in 2016 (Pub. L. No. 114-153, 130 Stat. 376 (2016), codified at 18 U.S.C. § 1836 *et seq.*); see also Josh Rich, *President Obama Signs Defend Trade Secrets Act*, Patent Docs (May 11, 2016, 11:59 PM), http://www.patentdocs.org/2016/05/president-obama-signs-defend-trade-secrets-act.html#comments.

51 *See* Timothy K. Sendek, *Customer Lists as Trade Secrets*, Nat'l Law Review (Dec. 30, 2009), https://www.natlawreview.com/article/customer-lists-trade-secrets.

52 This value being demonstrated by the protections for these items as discussed above; vide infra.

53 Patenting and trade secret protection are not necessarily mutually exclusive. Most inventions are kept confidential (i.e., are trade secrets) until a patent application is published. Moreover, a product can have some aspects patented and others kept as trade secrets (provided the best mode requirement of 35 U.S.C. § 112(a) (2023) is not violated); *see* Christianson v. Colt Indus. Operating Corp., 486 U.S. 800 (1988).

54 Although trade secret protection can lead to substantial judgments. *See, e.g.*, Epic Systems Corp. v. Tata Consultancy Services Ltd., No. 14-cv-748-wmc (W.D. Wis. Apr. 27, 2016) ($240 million compensatory damages, $700 million punitive damages); Robyn Meredith, *VW Agrees to Pay G.M. $100 Million in Espionage Suit*, N.Y. Times, Jan. 10, 1997 ($1.1 billion judgment: $100 million cash, $1 billion products); and Pacesetter v. Nervicon, No. BC424443 (Cal. Sup. Ct. June 20, 2011) ($947 million judgment).

55 *See* Class 707: Data Processing: Database and File Management or Data Structures, USPTO (Jan. 2010), https://www.uspto.gov/web/patents/classification/uspc707/sched707.htm.

56 Each iteration adding a new entry creates a new database and thus defeats an applicant's ability to satisfy at least the written description requirement of 35 U.S.C. § 112(a).

57 This is true even for collections of biological samples or organisms (which are often individually not patentable) such as those curated by the American Type Culture Collection (www.atcc.org).

58 This is true whether the collection is physical (such as biological or other specimens) or just lists (pure information).

negative consequences of such protection can be its impact on academic research, insofar as the database owner restricts access. Fortunately, this rarely happens.[59]

The commercialization incentives under the Bayh-Dole Act raise important implications for using patient medical information as part of an enabling disclosure to support patent protection.[60] While the extent and scope of these concerns will vary with each invention and the particular disclosure it entails, it must be generally recognized that these concerns add to the burden of compliance with the Act and the patient privacy protection laws discussed herein. Importantly, anyone privy to such confidential patient information would be well advised regarding the requirements for keeping such information confidential and the technological and human resources challenges to achieving these goals.

Special Case: The Uncertain Future of Patent Protection for Human Diagnostics

One advantage of accumulating databases of patient medical information is that, with sufficient size, patterns of relationships on inheritance[61] or environmental exposure[62] can become evident. This has been the experience of the past 40 years, particularly with regard to identifying genes (and in particular genetic mutations or other variants) that are involved with and provide predictive power for certain diseases.[63] The continued accumulation of this evidence is expected and intended to result in individual-centric medicine (termed "personal-

59 An example of how database access can provide competitive advantages even without patent protection is the Myriad Genetics database for BRCA gene mutations. As is well known, Myriad's patents on isolated human BRCA genes *BRCA1* and *BRCA2* were invalidated by the Supreme Court in 2013. Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576 (2013), and patent protection for methods of detecting such mutations lost when the Court of Appeals for the Federal Circuit invalidated such claims on appeal from consolidated actions for infringement brought by Myriad against several genetic diagnostic providers in the wake of the Supreme Court decision. BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014). Nevertheless, Myriad has been able to protect its competitive advantage in the BRCA testing market because its extensive database (estimated to contain the results from more than three million patients) enables Myriad to provide informative diagnostic information with regard to genetic variants that occur with sufficient infrequency (termed "variants of unknown significance" or "VUS") that their association with predicted disease is unclear without reference to Myriad's database.

60 *See* 35 U.S.C. §112(a); *see also,* Amgen Inc. v. Sanofi, 143 S. Ct. 1243 (2023).

61 Indeed, one advantage University of Utah researchers enjoyed in the competition between several laboratories to isolate the human BRCA genes was the records, going back more than 100 years of death and causes of death for generations of ancestors. Because breast and ovarian cancers were well recognized during this time period, classical genetic methods could be combined with modern molecular biological approaches to identify the portions of chromosome 17 (BRCA1) and chromosome 13 (BRCA 2) where these loci could be found.

62 *See, e.g.*, John B. Whitfield et al., *Genetic Effects on Toxic and Essential Elements in Humans: Arsenic, Cadmium, Copper, Lead, Mercury, Selenium, and Zinc in Erythrocytes*, 118 Env't Health Persps. 776 (2010).

63 For example, the BRCA genes for breast and ovarian cancer (U.S. Patent Nos. 5,747,282 and 5,837,492); repetitive motif expansion in Duchenne's muscular dystrophy (M. Koenig et al., *The Complete Sequence of Dystrophin Predicts a Rod-Shaped Cytoskeletal Protein*, 53 Cell 219 (1988); M. Koenig et al., *The Molecular Basis For Duchene Versus Becker Muscular Dystrophy: Correlation Of Severity With Type Of Deletion,* 45 Am. J. Hum. Genetics 498 (1989)) and Fragile X syndrome (Kathryn B. Garber et al., *Fragile X syndrome,* 16 Eur. J. Hum. Genetics 666 (2008)); and deletion of a specific amino acid (Phe508) in cystic fibrosis (Johanna M. Rommens et al., *Identification of the Cystic Fibrosis Gene: Chromosome Walking and Jumping,* 245 Sci. 1059 (1989)).

ized medicine"), meaning that knowing an individual's genotype as it relates to disease or treatment of disease will permit treatment of the individual rather than what has been developed for a population.[64]

Many of these diagnostic methods have been heretofore the subject of patent protection.[65] Patents in the U.S. are defined by statute; this includes what types of inventions are eligible for patenting, which is codified in the patent statute under Section 101.[66] Until recently, this statutory requirement has been construed broadly to include "anything under the sun that is made by man."[67] However, the scope of patent subject matter eligibility has always been constrained by exceptions recognized by the Supreme Court; these are "laws of nature, physical phenomena, and abstract ideas."[68]

Claims to diagnostic methods adopt a canonical format of reciting steps to "determine and infer": one or more steps involve detecting something (e.g., a biomarker) and from that inferring something related to what is detected (e.g., the presence or absence of a disease).[69] As a consequence, unlike industrial and chemical method claims,[70] diagnostic methods claims produce information—that is, the inference related to what is detected.[71] In addition, for medical diagnostics claims, patent protection implicates public policy concerns related to whether permitting patenting will inhibit the practice of medicine or interfere with a physician's treatment of a patient as a result of obtaining a diagnostic result.[72]

These concerns apparently prompted a series of decisions by the U.S. Supreme Court severely restricting patent eligibility of medical diagnostic methods.[73] These decisions mandate that claims that merely recite a law of nature and supply the direction to "apply it"

64 "[T]herapy with the right drug at the right dose in the right patient." Laviero Mancinelli et al., *Pharmacogenomics: The Promise of Personalized Medicine*, 2 AAPS Pharm Sci 29 (2000). Personalized medicine is expected to provide the ability to make more informed medical decisions and result in a higher probability of desired outcomes thanks to better-targeted therapies and a reduced probability of negative side effects. Unlike in traditional medicine, personalized medicine is focused on prevention and prediction of disease rather than reaction to it and earlier disease intervention than has been possible in the past. Another expected benefit is to reduce healthcare costs.

65 *See* U.S. Patent Nos. 5,747,282 (BRCA 1); 5,837,492 (BRCA 2); 5,187,063 (Duchenne's muscular dystrophy); and 6,107,025 and 6,180,337 (Fragile X syndrome), among others.

66 "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title," 35 U.S.C. § 101 (2023).

67 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

68 *Id.*

69 Kevin Emerson Collins, *Prometheus Laboratories, Mental Steps, and Printed Matter*, 50 Hous. L. Rev. 391(2013).

70 The practice of these types of method claims produce a device or other tangible product; *see* Diamond v. Diehr, 450 U.S. 175 (1981).

71 *See* Kevin E. Noonan, *Rapid Litigation Management Ltd. v. Cellzdirect, Inc. (Fed. Cir. 2016)*, Patent Docs (July 6, 2016, 11:44 PM), http://www.patentdocs.org/2016/07/rapid-litigation-management-ltd-v-cellzdirect-inc-fed-cir-2016.html.

72 Mayo Collaborative Servs. v. Prometheus Labs Inc., 132 S. Ct. 1289 (2012).

73 *Id.*

are not patent eligible.[74] The law, as interpreted by the Court, requires the claim to recite (and the specification to disclose) "something more" than the law of nature, and that "something more" must be more than what is routine, well-understood, and conventional in the relevant art.[75] According to the Court, "It is not enough to inform a relevant audience about certain laws of nature," and add steps that "consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."[76] Many lower courts have followed this reasoning to invalidate claims to medical diagnostic methods.[77]

In addition to the courts, the U.S. Patent and Trademark Office (USPTO) has adapted its practices for determining patent eligibility to be compliant with the Supreme Court's decisions. This has resulted in a two-step inquiry:[78]

1. Is the claim directed to a "natural law" that is subject to a Section 101 analysis?

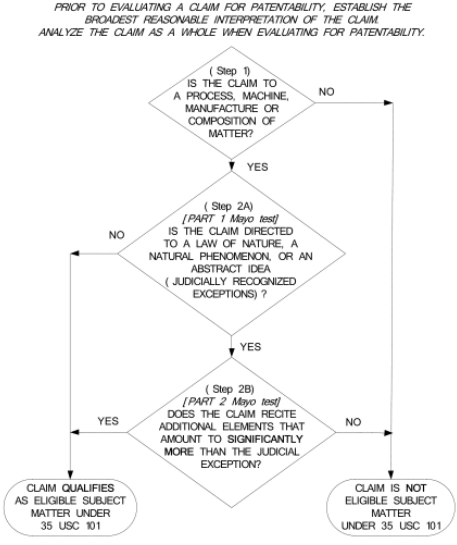
74 *Id.* at 72.

75 *Id.* at 73.

76 *Id.* at 79–80.

77 Particularly vulnerable have been claims that recite "a method for diagnosing disease X, by detecting the (presence/absence/changed amount) of marker (gene/protein/metabolite) Y." Approximately 70% of all patents challenged under the Alice-Mayo test are found invalid, comparison over 11,000 granted claims. The worst districts for patentees (10 or more §101 decisions) have been the Districts of Delaware, California (Northern), California (Central) (>70% invalid), while the best district for patentees has been the Eastern District of Texas (<35% invalid).

78 The test consists of three steps, designated by the USPTO as Step 1, Step 2a, and Step 2b:



2. Is the claim directed to a patentable "judicially recognized exception" under the Alice-Mayo test?[79] If yes, does the claim recite "additional elements that amount to significantly more than the judicial exception"?

The USPTO then proceeds with examination for patentability, applying the "broadest reasonable interpretation" of the claims after conducting the subject matter eligibility analysis under these rubrics.[80] When applying the test of what satisfies the requirement for what is "significantly more," the USPTO applies the standard that the elements of the claim, considered both individually and as an ordered combination, are sufficient to ensure that the claim as a whole amounts to significantly more than the exception itself.[81] As in many USPTO analyses, the claims must be considered as a whole.[82] In practice, the USPTO's implementation of these Supreme Court decisions have severely limited patenting of diagnostic method claims[83] and hindered the progress of developing personalized medicine.[84]

Guidance from the USPTO advises that diagnostic methods using novel reagents or detection steps are patent eligible, as are novel treatment methods and specific treatment methods using particular administration routes or methods.[85] Somewhat controversially, the

79 The Court's *Mayo* decision was further explicated, and its reasoning explained, in a decision unrelated to patent eligibility of diagnostic method claims. *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 134 S. Ct. 2347, 2354 (2014).

80 Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, to the Patent Examining Corps., USPTO (May 4, 2016), https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-memo.pdf [hereinafter "Bahr Memo"].

81 *Id.*; the guidances for applying this standard include the note that "[i]ndividually-viewed elements may not appear to add significantly more, those additional elements when viewed in combination may amount to significantly more than the exception . . ." *Id.* at 3.

82 *Id.*

83 *See* Heidi Ledford, *US Personalized-Medicine Industry Takes Hit from Supreme Court*, 536 Nature 382 (2016) – Summary of Intellectual Property Scholars Conference, presenting data that after *Mayo*, USPTO was more than four times more likely to reject personalized medicine claims as ineligible and applicants were only half as likely to overcome the rejections. Statistically, 5.5% of applications were rejected under § 101 rejections in 2011 and the percentage of applications rejected under § 101 had risen to 22.5% in 2015. Before *Mayo*, 70.7% of § 101 rejections were overcome but that percentage had fallen to 29.7% by 2015. Assuming 1,000 claims, this corresponds to 55 claims being rejected, 39 rejections overcome and 16 maintained prior to the *Mayo* decision and 225 claims rejected, 67 overcome, and 158 maintained after the *Mayo* decision was rendered. This represents an almost tenfold increase in diagnostic method claims being rejected by USPTO.

84 Bernard Chao & Amy Mapes, *An Early Look at Mayo's Impact on Personalized Medicine*, 2016 Patently-O Patent L.J. 10 (2016). This report reviewed one of every ten applications in USPTO Art Unit 1634 (methods for measuring or testing processes involving enzymes or microorganisms). Only subject matter eligibility rejections were considered, and their results showed that of the 294 applications considered, 170 (58%) were abandoned, 53 patented, 3 allowed, and 2 on appeal (only 1 of which involved a §101 rejection). Since the time of the study, 196 (67%) have been abandoned, 64 granted, 1 allowed and 1 on appeal (the Examiner having been affirmed in the prior appeal). A random spot check of the newly abandoned and patented claims revealed that no continuing applications were filed in the abandoned applications and narrow claims (e.g., requiring very specific reagents or a treatment step) were allowed in the grated patents.

85 *See* Bahr Memo, *supra* note 80; *see also* Subject Matter Eligibility Examples: Life Sciences, USPTO (May 2016), https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf.

guidance also indicates that methods of detecting a biomarker that does not recite a diagnostic correlate would also be patent eligible, a policy decision seemingly at odds with at least one Federal Circuit opinion.[86] Patent ineligible methods, according to the USPTO's interpretation of the Supreme Court's *Alice-Mayo* test, are diagnostic treatment methods broadly reciting a natural law (defined as the correlation between a marker and disease); claims that recite mental steps of drawing the inference regarding the outcome of a diagnostic method and the diagnosis; or claims reciting a higher level of generality between the biomarker and a diagnosis.[87]

Related to the Supreme Court's views on medical diagnostic claims, the Justices have also rendered decisions on the patent eligibility of natural products.[88] There have been few court cases on this aspect; however, in addition to *UURF v. Ambry Genetics*,[89] the Federal Circuit invalidated claims to chimeric sheep in *In re Roslin Institute (Edinburgh)*[90] but declared patent-eligible claims for producing in vitro hepatocyte cultures.[91] These decisions are relevant to patenting biomarkers,[92] the prospects for which (at least with regard to unaltered embodiments thereof) have dimmed in the aftermath of the Supreme Court's decision in *Associate for Molecular Pathology v. Myriad Genetics Inc.* This is because by their nature, many of the relevant, diagnostically informative biomarkers are natural products,[93] and the

86 *See* Ariosa Diagnostics, Inc. v. Sequenom Inc., 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 579 U.S. 928 (2016).

87 Such claims are exemplified by claims invalidated by the district court and affirmed by the Federal Circuit. For example, claim 1 of U.S. Patent No. 5,709,999:

> A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

Ass'n for Molecular Pathology v. United States PTO, 702 F. Supp. 2d 181, 213 (S.D.N.Y. 2010).

88 Ass'n for Molecular Pathology v. Myriad Genetics Inc., 569 U.S. 576 (2013); surprisingly, the Court had not directly spoken on the question of subject matter eligibility for natural products until its *Myriad* decision.

89 BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp., 774 F.3d 755 (Fed. Cir. 2014); in this aspect of the decision the Federal Circuit invalidated claims to primer pairs for in vitro amplifying portions of the human BRCA genes informative for genetic diagnostics predicting the likelihood of developing breast or ovarian cancer.

90 *In re* Roslin Inst. (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014); the appellate court's decision relied on the fact that the claimed sheep were, indeed, sheep (albeit genetically identical to the sheep from which they were produced by in vitro nuclear transfer to enucleated eggs). It is undetermined whether other ways to distinguish the claimed product would be patent eligible (for example, a claim to a genetically identical *flock* of sheep).

91 Rapid Litig. Mgmt. v. Cellzdirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016); a non-trivial distinction between the claims at issue in this case and diagnostic method claims invalidated in other decisions is that these claims have a tangible outcome (the in vitro hepatocyte cultures produced by the claimed methods) as opposed to intangible diagnostic information produced by conventional medical diagnostic claims.

92 Examples of these molecules include those that are nucleic acid-based (e.g., single nucleotides polymorphisms or SNPs, and chromosomal rearrangements); protein-based (*e.g.*, sickle cell anemia); immunological (antigens, antibodies, cytokines); metabolites (endogenous or produced in response to drugs, diet, etc.); and more complex phenotypes.

93 While no court has rendered a decision affirming this characterization, the language of the Supreme Court's *Myriad* opinion suggests that conventionally patent-eligible molecules (antibiotic, antibodies, vitamins, vaccines, etc.) may not remain patent eligible.

reasoning behind the Court's *Myriad* decision suggests that mere isolation is not enough to confer patent eligibility to such molecules.[94] What may be needed, as suggested by the *Myriad* decision, is that whatever is claimed has somehow been changed from how it exists in nature;[95] the safest course may be by structural change to the biomarker, most typically by being conjugated or otherwise labeled with a detectable marker.[96]

Additional USPTO guidances[97] have set forth examples of what is considered patent eligible and what is not for both diagnostic methods claims and natural products.[98] For "products of nature," patent-eligible examples include products comprising alterations (e.g., mutations, chemical reactions, changes in structure or physical form) not found in nature; formulations (particularly with components not found together in nature) that change properties or functional characteristics of product of nature; and nonconventionality of other aspects of the claimed invention (microneedles used for vaccination being exemplified in the guidance).[99] On the other hand, products of nature per se (i.e., having no differences except concentration or specific activity from their presence in nature);[100] and combination of

94 The Supreme Court's *Myriad* decision held that genomic DNA (or indeed any DNA molecule that had the structure found in a human chromosome) was patent ineligible because it had not been sufficiently changed from how it occurred in nature to evidence the "hand of man" as set forth in the Court's *Chakrabarty* decision. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980). Complementary DNA (cDNA), produced by reverse transcription of messenger RNA could be eligible under the Court's decision, provided it showed such differences; in higher organisms like man, *for example*, most cDNAs differ from the corresponding genomic DNA progenitors because so-called intervening DNA (or introns) have been spliced out during mRNA maturation. It is clear that the Court recognized the need for human intervention to produce cDNA from mRNA; it is less clear that the Court appreciated that removing intron sequences (a process known as splicing; Dean H. Hamer & Philip Leder, *Splicing And The Formation Of Stable RNA*, 18 Cell 1299 (1979)) was naturally performed inside the cell.

95 Purification or increased concentration or potency may not be enough, however.

96 While such distinctions have formed the basis for USPTO policy on natural products patenting, it must be recognized that many structural alteration have the capacity or likelihood to alter relevant biological activity (binding specificity or affinity, biological half-life, antigenicity, etc.).

97 Earlier iterations of such guidances were criticized for being overly exclusive of patent eligibility. For example, gunpowder was deemed ineligible has being merely a mixture of elemental sulfur, charcoal and saltpeter (KNO^3), until it was pointed out that the mixture (but not combination of its components) had the capacity to explode. In addition, review of 1355 drugs approved by the FDA from 1980-2010 indicated that the majority of anticancer drugs (80%) and antibiotic drugs (75%) would be patent ineligible under the earlier standards promulgated by the USPTO in response to the Supreme Court's *Mayo* and *Myriad* decisions. *See* David J. Newman & Gordon M. Cragg, *Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010*, 75 J. Nat. Prods. 311 (2012).

98 May 2016 Subject Matter Eligibility Update, 81 Fed. Reg. 27,381 (May 6, 2016), https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-10724.pdf [hereinafter "May 2016 Subject Matter Eligibility Update"]. *See* Kevin E. Noonan, *USPTO Releases Memorandum on Subject Matter Eligibility*, Patent Docs (July 18, 2016, 11:44 PM), http://www.patentdocs.org/2016/07/uspto-releases-memorandum-on-subject-matter-eligibility.html#comments; *see also* Kevin E. Noonan, *The Recent PTO Guidance on Subject Matter Eligibility: Lessons,* Patent Docs (May 25, 2016, 11:26 PM), http://www.patentdocs.org/2016/05/the-recent-pto-guidance-on-subject-matter-eligibility-lessons.html.

99 *See* Heidi Ledford, *US Personalized-Medicine Industry Takes Hit from Supreme Court*, 536 Nature 382 (2016).

100 It is unclear whether a specific preparation at a therapeutically useful concentration would be patent eligible without more; it may be presumed that a pharmaceutical composition comprising excipients or other components would be considered a specific subset of patent-eligible formulations but there is no decision affirming this expectation.

product of nature with other substances that do not change physical properties or other characteristics are not patent-eligible.[101] Diagnostic reagents per se are also likely to be ineligible, and according to the Court's *Myriad* decision, merely producing a reagent synthetically will not render claims to the reagent patent eligible, provided that the structure is the same as exists in nature.[102]

TECHNOLOGY TRANSFER OPERATIONS

As the technology transfer provisions arising under the Bayh-Dole Act have developed, most universities have established within their administrative organizational charts an Office of Technology Transfer or Management. Depending on the size and scale of the research portfolio, technology transfer functions can be managed entirely in-house, externally, or as is most often the case, through a hybrid model where external counsel provides legal expertise in securing the intellectual property rights to an organization. Typically, technology transfer offices not only manage the disclosures, patents, and licenses for commercialization, but also address intellectual property issues across material transfer agreements, confidential disclosure agreements, and clinical trial agreements. Regardless of their structure, and due to competing priorities, technology transfer offices are often perceived by researchers to be "black holes" hindering research innovation. This is not surprising when (1) academic institutions on average spend 0.6% of their research budgets on transferring the technology resulting from their research programs, split 45% on patent protection and 55% on operating costs; and (2) over half the technology transfer programs bring in less money than the costs of operating the program; only 16% are self-sustaining.[103]

Recently, however, the environment has changed. Universities and other research organizations are seeking to diversify their revenue streams, and commercialization of technology is often a top strategic priority. Beyond increased revenue, university and health system leaders are stressing the importance of creating jobs through start-ups; advancing care within their systems and across the world; and managing their data-rich functions, including those within health and health care. As investment increases in technology transfer, research organizations will need to measure the success of these offices.

The first area that will need to be measured is related to the financial support and operational roles and responsibilities of the technology transfer office. The primary function of licensing managers should be focused on licensing transactions, not on the other intellectual property issues that may filter through the office. Some organizations have started to

101 This reasoning relies expressly and heavily on the Supreme Court's 1948 *Funk Brothers Seed Co. v. Kalo Inoculant Co.* decision (Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948)), expressly reaffirmed in the Supreme Court's *Myriad* decision after more than a generation of being ignored.

102 Ass'n. Molecular Pathology v. Myriad Genetics Inc., 133 S. Ct. 2107, 2119 (2013).

103 Irene Abrams et al., H*ow are U.S. Technology Transfer Offices Tasked and Motivated—Is It All About the Money?*, 17 Mgmt. Research Rev. 1 (Jan. 2009).

segment activities such as material transfer agreements to dedicated personnel, while others have utilized internship-type programs to divert some of the less-critical activities from licensing managers. Turnover is relatively high for licensing managers, and some organizations find that moving to a deal-focused structure lowers this rate. Other front-end activities to be measured may include reviewing the deal flow related to licenses, performance on any innovation funds, and the number of researchers engaged by the office.

The second area to be measured relates to the office's productivity and impact. The number of license agreements completed remains the primary measurable outcome for most entities, while deal size and number of start-ups are also considered to be primary success metrics. Given the importance of increasing the number of new deals and building a diverse portfolio, organizations should consider leveraging support staff to manage existing patent and license portfolios. Another option is to mirror the industry by including a "stage gate" approach to the invention process to develop consistency across the commercialization process.

CONCLUSION

Congress has determined that there is a public policy imperative to promote innovation by encouraging and indeed mandating that inventions made with federal funding be protected by seeking and obtaining patents, which can then be licensed to commercial actors. In this way, universities and other non-profit federal funding recipients can participate in innovation without needing to exceed their more theoretical and "pure science" bounds by handing off these efforts to those whose expertise is in the practicalities of producing goods and services. Moreover, the benefits to the public are that grant monies received by universities can be focused on discovery and scientific development while those adept at raising money to bring products to market can best employ their strengths in this regard, with some measure of reward in the form of licensing royalties returning to the universities, departments, and individual scientists themselves.

However, to properly effectuate these goals and fulfill their roles in the Bayh-Dole regime, tech transfer offices must be aware of "best practices" and the need to avoid actions and activities contrary both to the statute and the policies it was enacted to achieve. These include:

- **Tech transfer offices need to be deal-focused and minimize turnover.** The purpose of the Bayh-Dole regime is to effectively transfer technology from university and other non-profit organizations to those who can commercialize inventions stemming from scientific discovery. This means that tech transfer managers and officers should always have licensing as top-of-mind and act to facilitate deal-making, while not permitting the scientists or organization to be shortchanged in the process.
- **Streamline the invention disclosure process.** Scientists are incredibly busy and time spent in the patenting process is time not spent pursuing their scientific endeavors. Accordingly, it is incumbent upon tech transfer offices to provide structure to the invention disclosure process that minimizes the distractions the process inevitably causes. Certain steps that can be taken include invention disclosure documents that

capture the necessary information while not requiring exhaustive disclosure that will come out in the patent drafting process. Also important is pairing the right patent counsel with their inventors, with regard to technical background, experience, and ability to converse with and understand the inventions being disclosed.

- **Implement transparent royalty sharing arrangements.** Licensing almost always involves royalties and there are rubrics with which sharing of royalty and milestone payments can be standardized (with fixed percentages going to the university, the department, and individual scientists). A better approach may be to tailor such standards to individual situations depending on factors like the number of inventors involved. And such consideration should also include the licensor—a royalty structure for a license with a large pharmaceutical company can be inappropriate (and even deleterious) for use with a start-up, for example.
- **Provide training on regulatory and licensing processes.** There are many sources for training and information on tech transfer, including the Association of University Technology Managers (AUTM) and the Licensing Executive Society (LES), among others. Outside counsel should not be overlooked as a source of such information; most patent lawyers having university and non-profit clients are more than happy to give seminars and tutorials on patent law and the requirements for compliance with the Bayh-Dole Act.
- **Licenses should be the primary productivity metric.** Money talks, and the tech transfer office's main job is not amassing patents put negotiating productive licenses that return royalties to the university.
- **Paralegals are key assets in managing patent portfolios.** The management of existing license and patent portfolios often pull licensing managers away from completing new deals. Paralegals and other support personnel should be utilized to manage and support post-license activities, invoicing, maintenance fees, and other duties that don't require licensing managers.
- **Biggest drawback is business inexperience of faculty.** It is unwise to ignore the human frailty that intelligent people often do not recognize those things they know little or nothing about. It is a common belief that because people of ordinary intelligence can be successful at business than university professors, being of extraordinary intelligence in comparison should be able to succeed at starting a company. Such beliefs must be tactfully but thoroughly extinguished.
- **Tech transfer folks, even if lawyers, are not tenured faculty (who usually want to direct development).** A corollary to the idea that faculty should be able to run a business is that they are capable of negotiating licenses and in other ways direct commercialization of their inventions. And because faculty can be tenured (and tech transfer people generally are not), the faculty can exert pressure inordinate to their actual ability to contribute to successful licensing. One of the only ways to inhibit this behavior is for the tech transfer manager to impress by performance that they are better suited to their role.

- **Properly licensed, faculty can provide benefits to the commercial developer through consultancy.** Information known (usually) only to the scientist/ inventor are those embodiments or approaches to an invention that do not work. This is because failures are not published, and this provides an opportunity for a faculty member to have a consultancy agreement with a licensee that can benefit commercial development (by avoiding dead ends) and provide additional income and incentive for the faculty member.
- **Conflict of interest is common—it is hard to wear both faculty and company executive hats (and best to avoid).** However, it is difficult for most faculty to be involved in a startup company based on their inventions while at the same time continuing to perform related federally funded research wherein the university (and ultimately the government) are the rights holders. Best practices involve delineating (contractually, or at least in writing) the roles and responsibilities to each entity the faculty member has and how to avoid conflicts of interest, usually involving conferring with academic department heads or deans.
- **Timing is important between patent filings and publications, particularly with students.** Most countries operate under an "absolute novelty" standard where publication prior to patent filing can preclude patenting the prematurely disclosed invention. Such outcomes can be avoided by communication between scientists and the tech transfer office, responsiveness by each to avoid delay in having an application drafted, reviewed, and filed, and making sure federally funded principal investigators recognize their responsibility for assuring compliance and the possible risk to future funding if they do not comply.
- **Institutional mission matters in commercialization activities.** Research organizations are often mission-driven, and the supporting commercialization functions should tie to not only the mission of the organization but also to the collective good. For example, many health care organizations understand that they have significant value in their data and care-delivery protocols, but at the same time have sought alternative methods of realizing value from their data (e.g., partnering with governmental agencies).

Complying with the provisions of the Bayh-Dole Act while upholding a university's commitment to scientific inquiry and the free flow of ideas can be challenging. Participation by an involved and effective tech transfer office has been the best way to maximize these competing priorities in ways that effectuate the goals of commercializing inventions stemming from federally funded research. It can be expected that such active participation will continue to be so.

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