Bayh-Dole
THE GOOD, THE BAD AND THE UGLY

Understanding what the Bayh-Dole Act does and does not require of inventors, agencies and universities is a critical pretext to any informed debate. IPAO sat down with Dr. Gerald Barnett, a technology transfer veteran of over 25 years to discuss the Bayh-Dole Act and to develop an understanding of what it really requires of university and inventor.

IPAO interviews Gerald Barnett, PhD, Director, Research Technology Enterprise Initiative (RTEI) University of Washington.

IP ADVOCATE: Can you lay out the groundwork assumptions of Bayh-Dole before we delve into the particulars of the Act?

DR. BARNETT: It is important to acknowledge from the start of this discussion that Bayh-Dole applies only to instances of research performed with federal funds and not to any other circumstance of invention. Just because research is done at a university - that doesn't necessarily mean that Bayh-Dole is in play. For that matter, Bayh-Dole only applies to work done within the "planned and committed" scope of federal support. It doesn't apply to fellowships, scholarships, or closely related work that falls outside the "planned and committed" activities of a federal award.

THE GOOD - WHAT BAYH-DOLE WAS INTENDED TO DO

IP ADVOCATE: Understood. We're framing our discussion around the best and worst of Bayh-Dole - from intent to implication. Let's start with what's good. What was Bayh-Dole designed to do?

DR. BARNETT: Bayh-Dole was and is all about establishing the role of universities as stewards of patentable inventions produced with federal funds. Universities that receive federal awards should serve as trustees on behalf of the intended beneficiaries of the awards. Bayh-Dole lays out who these are: the general public, American manufacturers and small businesses, inventors, scientists, and educators, and the federal government. Universities are not named beneficiaries. That's because they are the stewards.

IP ADVOCATE: Does that mean that the university automatically owns inventions made with federal funds? That the inventor is required to assign their invention to their university?

DR. BARNETT: No - Bayh-Dole does not require assignment of inventor's patent rights to his or her university for federally funded research.

IP ADVOCATE: Why is that?

DR. BARNETT: Because, at a minimum, Bayh-Dole was drafted to recognize the existing diverse practices that were in play at the time. Some universities had their own patent licensing offices, others used affiliated research foundations, and others contracted for patent management services as needed. The law did not aim to eliminate some of these practices. In that regard, it is rather deftly drafted to give universities a lot of range in what they can do. The aim of the law is to bring coherence to the federal side of the relationship.

More importantly, the broad objective of Bayh-Dole, to use patent rights to promote the use of federally supported inventions, has little to do with the university hosting the research.

It's only when a university has a reason to advance the government's interest that Bayh-Dole gives it the opportunity to step into a management role with regard to inventions and patents.

IP ADVOCATE: Was Bayh-Dole intended to benefit universities?

DR. BARNETT: Whatever the motivations that prompted folks to support Bayh-Dole, the law as it stands aims to protect the government's interest in an invention - there is no language or intent that suggests that a university is to operate in its own best interest to exploit the invention or patent rights. While self-interest is not a bad thing in itself, there's nothing in Bayh-Dole that makes this a requirement. If there is a weakness in Bayh-Dole, perhaps it is that the law underestimated how susceptible university personnel can be to self-interest, even while engaged in publicly funded research with express claims that the results are in the public interest. One has to end up with the equation institutional self-interest = public interest for this to work. It's not a workable equation. It's certainly not in Bayh-Dole.

IP ADVOCATE: Dr. Barnett, take us into the letter of the law. Where does it specify all of this?

DR. BARNETT: The actual language relating to what written agreements are required is found in Section 37 of the Code of Federal Regulations, Part 400. The standard contract clauses are set out in 401.14(a), and it is these that form the obligations on a university contractor when a federal award is made. Part 401.14(a) (f) is headed clearly "Contractor Action to Protect the Government's Interest". This is very important - again - the Act is not about university profit - it is about advancing the public interest in research it funds. Certainly there is provision for a university to profit from the licensing patents (whether done directly or through an invention management agent). But even when that happens, the Act makes it clear that the royalties are to be shared with inventors and the remainder used for "scientific research or education" (see 37 CFR 401.14(a) (k) (3).

This provision has been generally read to set up a squabble between inventors and the university administration over how licensing revenue over costs will be handled. This also is a faulty assumption propagated by administrators. Actually, Bayh-Dole allows all the proceeds from licensing to be treated as an expense "incidental to the administration of subject inventions" and allocated to the inventors entirely. One can see that universities are called out as stewards.

If an agency allows university inventors to retain their personal rights to inventions, the Act does not require any such allocation of income for scientific research or education. It is only when the university shorts the inventors the full amount of the income less their other costs that the Act steps in to guard against the steward dipping into the funds for its own purposes. One may note, as well, that the Act does not even restrict the "scientific research or education" to the host university's own accounts. I don't know of a university, however, that actually tries to support research or education using Bayh-Dole income other than in its own operations. It's all very narrow and selfish, from a public perspective.

IP ADVOCATE: Where it says "contractor action" - contractor refers to the university?

DR. BARNETT: Exactly. It's worth quoting in full. Subsection 2 of (f) reads:

"The contractor agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel

identified as responsible for the administration of patent matters and in a format suggested by the contractor each subject invention made under contract in order that the contractor can comply with the disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on subject inventions and to establish the government's rights in the subject inventions. This disclosure format should require, as a minimum, the information required by (c) (1) [disclosure of subject inventions to the government], above. The contractor shall instruct such employees through employee agreements or other suitable educational programs on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars."

IP ADVOCATE: Under Bayh-Dole, what happens when and if a researcher assigns rights to their university?

DR. BARNETT: When a faculty inventor assigns patent rights to the contractor, the university becomes a trustee of that intangible property.

This is important - the university is not a corporate owner. Any rights and interest in that intellectual property, specifically patent rights, are conditional on its safeguarding the rights for the beneficiaries, not for itself. You can find statements of this in Circular A-110, which provides the governing regulations for federal support of university research generally. Bayh-Dole shows up in Circular A-110 as .36 (2). That's a tough message a lot of university folks want to ignore.

When I bring this up, they start to fight about it rather than affirm it. It's really quite remarkable.

IP ADVOCATE: If the patent does generate royalties, what then?

DR. BARNETT: If an invention developed with federal funds happens to make money, that's a great side benefit and Bayh-Dole does specify how these funds may be used if the licensor is the university or its assignee of Bayh-Dole interest. But nowhere in Bayh-Dole is there a statement that an objective of the law was to generate funds for universities. That certainly can be a university goal, and again it can be a worthy goal at that. Just don't say Bayh-Dole requires it. It's something universities have decided to do.

IP ADVOCATE: Can you take us into the law itself and show us the intent?

DR. BARNETT: Sure. It's a bit of a fiction to say the law is capable of intention. Instead, we can look at the Act's statement of objectives. This gets a little lengthy, but if you go into the US Code Title 35, Part II, Chapter 18, § 200 titled "Policy and objective"; it spells out Bayh-Dole's objectives:

"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."

Whatever the private motivations and whatever the issues at debate in deciding on the final language, this is the best expression of what actually is the law of the land. One can work to be clever about it, or focus on a small bit of the whole, but why not just read this piece and start with the entire passage. University licensing folk, for the most part, show no evidence of having read this piece of the law, or if they have, remembering any more of it than "commercialization of patent rights for money"—which is only a bit of one objective, down the list always.

IP ADVOCATE: There's nothing there about raising funds for universities.

DR. BARNETT: There's not there, and I don't think it was an oversight. This Act was drafted to say what it needed to say, state the intent and what isn't there - isn't there for a reason.

> If the idea was to give universities first crack at suing American industry for fat royalty checks to supplement their budgets, don't you think that would be right there in the foreground as a primary objective?

Well, perhaps not as overt as that. But that's essentially what universities are claiming by their actions, justifying this as ensuring "respect" for their intellectual property rights. Indeed it may be, but it's not a purpose in Bayh-Dole. For that matter, if American industry is using inventions supported with federal funds, license or not, university royalties or not, one could argue quite reasonably that the government's interest in the invention has been addressed.

THE BAD - HOW BAYH-DOLE HAS BEEN MISUSED

IP ADVOCATE: Sounds good. Would you say then that Bayh-Dole has been used as it was intended?

DR. BARNETT: Yes and no. Some approaches have been great, some good and then some have really misused the Act for their own purposes.

IP ADVOCATE: Can you give us an overview of the types of misuse you've seen over the years?

DR. BARNETT: The biggest problem is that universities take shortcuts to their own self-interest and ascribe this to Bayh-Dole, when it's really their own "bureaukleptic" behavior. I call it that because that's what it comes down to. Claim everything and release only those things that don't matter later. It's what one would expect if an organization was greedy and uncertain about the future. It's also what one would expect if the way to deal with uncertainty was to impose some sort of process to give things the appearance of order, even if there was no idea what kind of judgment should be used.

IP ADVOCATE: What did Bayh-Dole intend for inventors?

DR. BARNETT: Bayh-Dole has a built-in respect for inventors. As far as I can tell, the drafters of the law understood that it is the faculty investigators that propose the research, control the research, that may invent, and that report and publish.

Finally, it should also be the faculty investigators that report their inventions and discoveries directly to the funding agencies.

University administrators are not innovators. It's these expert scientists, engineers, doctors, and scholars that the government seeks access to, for what they can do, not as employees of a corporation that assigns them their work and pays them to give up control of their results for corporate decision-making.

IP ADVOCATE: What should the university be doing in this process?

DR. BARNETT: Bayh-Dole never intended that the university act as a corporate employer for federal awards, but rather as a service intermediary. Simply, a university should serve as a contracting service for federal agencies working, otherwise directly, with research personnel. University services should make these interactions efficient for the agencies and the faculty researchers, not a breeding ground for controversy by inserting institutional self-interest.

IP ADVOCATE: Is there any flexibility, or is the Bayh-Dole Act rigid in its performance requirements?

Dr. Barnett: There is a great flexibility designed into Bayh-Dole. Flexibility that universities have largely ignored. It's amazing that given all the possibilities for patent practice, U.S. universities overwhelmingly have designated themselves as owners, and have focused on using patents to create products rather than standards or specialty internal uses.

I suppose that products sold in huge markets are where the money is, such as a new drug. It's a little sad, really, that the biggest social goal university licensing offices commit themselves to is helping drug companies turn acute conditions into chronic ones. It doesn't appear to be the same thing, say, as a cure.

For all that, there's nothing in Bayh-Dole that requires universities to designate themselves and they don't have to do this to comply fully with the Act. Simply put, Bayh-Dole requires that the university (the contractor) agree to require its employees to disclose promptly each subject invention and to execute all papers necessary to file patent applications and to establish the government's rights. Beyond that, there is a lot of possibility. The university could designate the faculty principal investigator to receive invention disclosures. The university could allow the inventor to identify an appropriate invention management organization. The university could assign its interest in managing its obligations under the Act to multiple foundations, depending on subject matter or simply to have a range of possible future partners to better match inventions with opportunities.

None of this has happened, though. It's really quite a pity that universities have fallen to what amounts to the lowest common denominator practice. It's uniform, process-ridden, and largely ineffective.

IP ADVOCATE: These are the details that should be in IP policies, correct?

DR. BARNETT: Yes - but most university intellectual property policies go way beyond what Bayh-Dole requires... For that matter, Bayh-Dole does not even require an institutional IP policy. That's another assumption made by university administrators. It just isn't there in the Act. Bayh-Dole is essentially self-implementing. All one needs are the written agreements with research personnel to protect the government interest and designation of personnel responsible for patent matters. University "bureaukleptic" IP policies that require faculty inventors to assign their inventions over don't have anything to do with Bayh-Dole. That says something about a university's impulse, but says next to nothing about compliance with Bayh-Dole, innovation, or public service.

IP ADVOCATE: Sounds simple.

DR. BARNETT: It should be, at least at the policy level. The federal funding agency depends on the university to have a written agreement with its research employees to protect government interests. Beyond that, it is up to the funding agency to stipulate those interests directly to the faculty principal investigator through the funding announcement and the statement of work, and through these documents and the Act itself, to any inventor working within the scope of the federal funding agreement. The inventor is then obligated to those stipulations through their written agreement with their university.

Think of it as making a public, irrevocable, enforceable commitment in the form of a written agreement, in which the university serves as the public registrar of the commitment. This is the essence of federal contracting. You agree to the terms as these are set forth by the agency within the scope of its authority. That's what the written agreements in Bayh-Dole do. It's all very nicely done, though most of the niceness is apparently wasted on university administrators.

IP ADVOCATE: Then what about all of the other requirements universities force inventors to agree to under the guise of compliance?

DR. BARNETT: Anything else the university asks of its researchers is deal play and has really nothing to do with Bayh-Dole compliance. A university can claim ownership of inventions. Bayh-Dole indeed allows this to happen. But the reasons for taking ownership are not compliance with the law, but something else. The stakes can be money, power, notoriety, faculty rights, officiousness, fear, sense of public purpose, or whatever - but it ain't Bayh-Dole!

THE UGLY - HOW BAYH-DOLE HAS BEEN ABUSED: LITIGATION, PROFIT-SEEKING & WORSE

IP ADVOCATE: Beyond misuse and misinterpretation, what is the worst you have seen?

DR. BARNETT: It comes down to money. Nowhere does it say that Bayh-Dole was intended to earn big bucks for universities. Yet many universities and corporations in the system skip right for the money, any way they can get it. Ironically, apart from some rare, substantial transactions over the nearly 30 years of Bayh-Dole, universities haven't got all that much of the money, and have done even worse at the other stuff, such as dealing with software and data.

The problems also show up with university inventors. I've seen money-driven behavior with federal funding that wouldn't do so well if it surfaced in the press. It isn't that money driven behaviors are themselves bad. It's just that within a university, in the conduct of science and other public interested research, it's the public interested part that gets squeezed out. Who advocates for the public interest in the push and pull between inventors and administrators over Bayh-Dole inventions?

IP ADVOCATE: Is Bayh-Dole to blame?

DR. BARNETT: Well, it comes in for its share of blaming, though I don't see how it is the cause. More to the point, Bayh-Dole has allowed us to see what universities would do if given a broad mandate to support American industry and public access to federal research results. After nearly thirty years, they have done a good job at becoming work-a-day, if not dull, at innovation. Corporate ownership of IP has not had a great ride for spinning out innovation that benefits the corporate owner.

Even as we see a resurgence of corporate interest in "open innovation", it is the universities, which should specialize in open innovation, that are standing as primary opponents. Much has been written blaming the Bayh-Dole Act for what really amounts to questionable or even unethical university behaviors. These behaviors often occur when a university ignores the provisions of Bayh-Dole, not because it is acting within its letter or intent.

IP ADVOCATE: What about the instances of mistreatment of inventors over the years?

DR. BARNETT: If a university acquires ownership of patent rights, the inventor then becomes another beneficiary under Bayh-Dole and should be treated accordingly. The university is there to shepherd inventions and associated patent rights on behalf of the beneficiaries of the award. One would think it immoral for a trustee to use the assets entrusted to it for its own advantage. That's another tough message for universities to deal with. I don't think, institutionally, administrators think any action they make could be subject to a claim of morality. That's an old, outmoded concept. At best, the compliance term is "ethics" and that involves coming up with technical reasons for doing things. It's all very sad, that personal judgment and responsibility is so drained out of innovation practice—and as a matter of policy!

IP ADVOCATE: Should inventors be allowed to participate in the fate of their innovation?

DR. BARNETT: Definitely. And so should principal investigators. The university should be careful in removing an inventor from the decision making process. Keep in mind that most inventions in university research are co-invented, and co-inventors may disagree on the course of action. Universities have a role in dealing with such disputes, because it is in the public interest to get on with getting an invention into use. One might argue that the inventors have a default right to be involved in the university disposition of the inventions, whether they assign their rights under Bayh-Dole unless and until they freely waive that right. Universities should deal with that. It would make for better innovation practice, even if it created administrative bother. It's beyond me why a love of process should dominate research innovation practices.

THE TAKEAWAY FROM ALL OF THIS

IP ADVOCATE: Can you sum this up for our readers?

DR. BARNETT: Sure - Federally supported inventions are meant to be deployed in support of public purposes. There are many ways to do it. Today we explored a tiny bit of the space. Changes in world research and investment economies mean it's not business as usual in the US. Changes need to be made in university innovation practice to diversify it, not to fix it or replace one autocratic system with another. University research and IP officers may see this as a criticism. They believe they are doing everything possible to implement best practices and do their professional best. All true.

It's just that the values that got you to this point of efficiency may not be the best ones to support you when times are changing. It's all very plausible for lemmings, until they reach the cliff. Even for self-interested reasons, universities should be reaching out for new strategies to extend their reach into community. Given the pull out by state governments in support of public research universities, especially, state schools should be deploying IP to win friends and build collaborations. Instead, we see business as usual in IP licensing. It's not a good leading indicator for IP management.

IP ADVOCATE: Any advice to universities about how to step up?

DR. BARNETT: Recognize what you are - a steward - and change your policy and practice behaviors accordingly.

Dr. Gerald Barnett is a thought leader in the arena of intellectual property and commercialization. He is a frequent contributor to multiple IP blogs and publications and has appeared as a Guest Expert on IPAO's Expert Opinion Forum.