

Bayh-Dole Act: Rights and Responsibilities

John Raubitschek
NAS – STEP Briefing
June 30, 2008

B-D Rights

- Under B-D (1980), universities and small businesses have right to own inventions made with federal funds – grants, contracts or cooperative agreements; amended in 1984 to remove GOCO exemption and exclusive license term limits
- Not an administration supported bill; agency patent counsel drafted another bill giving all contractors an exclusive license but that bill never voted on
- Universities no longer had to request rights from funding agency; such requests took time and inhibited licensing by universities
- Prior to B-D, universities having a tech transfer program could own their inventions if they had an IPA with NIH ('68) or NSF ('72); Boyer-Cohen recombinant DNA patent licensed by Stanford under NIH/NSF IPAs; IPAs formed basis for many terms in Bayh-Dole
- Universities and small businesses may assign or receive rights in joint inventions with USG employees (35 USC 202(e))
- Inventors may own with permission of employer/funding agency

B-D Exceptions

- An agency may limit rights in inventions by doing a Determination of Exceptional Circumstances but rarely done (NIH/Energy) – must be reported to Commerce which may comment but does not approve; NIH no longer reports DEC to DoC
- Other Transactions (DoD and Energy) and ATP (NIST) grants not covered by B-D

B-D Duties

- Report invention to funding agency – 2 months after reported by inventor to patent administrator– replaced 6 mo. from conception or first actual reduction to practice – both complex legal issues
- Problem – disclosure by inventor may not be complete
- Elect rights w/i 2 years from reporting to agency but may request additional time
- File w/i 1 year of election – USG support statement required in spec; universities defer patent costs by filing provisional application
- Submit confirmatory license to be recorded in PTO (not for provisional applications) – “free” license may not save USG any money when buying from patent owner or its licensee nor be used by university grantee
- Agency may request utilization reports on licensed inventions

Reportable Inventions

- Invention or discovery which is or may be patentable or a plant variety – 35 USC 201(d)
- Includes software and biological materials
- These inventions may present a problem if a university does not want to patent them
- Software usually copyrighted and licensed
- Biological materials usually licensed under a MTA
- If university does not file a patent application, agency has residual ownership rights
- Inventing party may ask funding agency not to exercise those rights
- NIH policy permits ownership w/o patenting if biological materials are made available to non-profit research community

Statutory Restrictions on Universities in 35 USC 202(c)(7)

- Cannot assign inventions w/o agency approval unless to a patent management organization
- Must share royalties with inventors – no specific percentage unlike at least 15% for USG inventors; Platzer (Sloan–Kettering employee) case argued for a minimum share which was not accepted
- Royalties must be used for scientific research or education
- 5% cap on royalties after covering expenses imposed on university GOCOs with 75% of surplus going to US Treasury – last Congress unsuccessful effort to raise cap for mid-sized GOCOs
- Small business preference in licensing by universities and most licenses are with small businesses

Other Limitations

- March-in rights (35 USC 203) – agencies may require licensing of inventions if not being commercialized or for health and safety
- Never exercised although NIH had 2 requests in 2004 (reasonable pricing for 2 specific drugs) and one in 1997 (infringer wanted license)
- Domestic manufacture (35 USC 204) – exclusive licensees required to substantially manufacture in the US for products sold in US but may get an exception with agency approval for unsuccessful efforts; violation enforced by march-in

Penalties

- Universities may lose title if they fail to report, elect or file application w/i stated time limits
- Campbell v. Army (CAFC 2004) – small business lost patent because it refused to report an invention to Army which claimed that it was a joint inventor
- See 2002 suit against IBM by MIT licensee where a patent was held to be unenforceable because MIT refused to give Navy a confirmatory license
- Avoid timeliness problem by requesting extension of time, which agencies usually grant, even retroactively
- Failure to comply with B-D does not invalidate patent or license (several district court cases held this)

Implementation of Act

- Implementing B-D regs in 37 CFR Part 401 and FAR Part 27; slight differences because of updating FAR in December 7, 2007 but one standard clause, 52.227-11 or 401.14 (see also OMB Circular A-110)
- Only NSF has B-D regs although NIH gives guidance on research which may impact IPR
- Under 401.1(e), agency supplemental regs must be sent to DoC for approval prior to OMB
- Bayh-Dole policy oversight assigned to Commerce (35 USC 206)
- DoC delegated this to Technology Administration (37 CFR 401)
- TA was abolished in September 2007
- NIST will be assigned B-D oversight

Personal Thoughts

- Act does not need major changes which could destroy balance of public and private rights – PCAST 2003 report
- Some want to limit free license for USG and make march-in optional
- Return to case-by-case determination of rights by agencies will slow down commercialization (NSF and DOE)
- Ownership of inventions by USG not desirable because it is not an effective licensor but is improving; creator of technology has more knowledge and incentive in licensing
- Prohibition on patenting in Human Genome Project may require a DEC and shows distrust of patent system
- Tension between universities and business over IP in sponsored projects; sponsor requiring a free license inhibits commercialization by others – GUIRR 3-year Congress
- Tension between universities and small business over IP in STTR involving participation of both
- Any questions?
- 703-704-0667