ILLINOIS LAW

Implementation Issues in IP for Synthetic Biology

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Overview

- Basic law
- Directive 2018-26 (Enabling Modernization Through the Management of Intellectual Property)
- Implementation issues in SynBio, specifically
- Further considerations

Intellectual Property

- Patents
- Copyright
- Trademarks
- Trade Secrets
- Sui Generis Protections
  - Mask works
  - Vessel hulls

Intellectual Property

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Patents

- Protect inventions
  - e.g., machines, manufactures, compositions of matter &c.
- Applications examined by U.S. patent office
  - Must be new, useful, nonobvious, and disclose the invention
- Infringement
  - Making, using, selling, offering to sell, or importing
  - Contributory infringement (components)
  - Damages usually reasonable royalty
    - Applies to government, including military (28 U.S.C. § 1498)
- Licensing crucial to avoid infringement

Patents

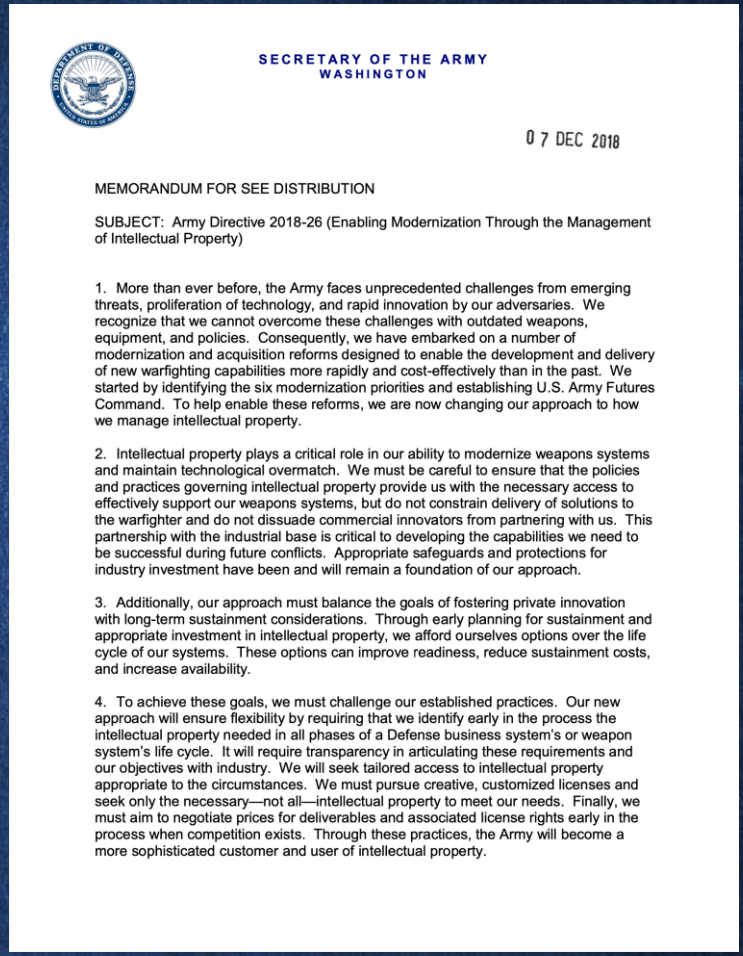
- Bayh-Dole Act
  - *Allows*, but does not require, extramural grant recipients to patent inventions made under federal funding, e.g., universities
    - Must be licensed to government as "nonexclusive, nontransferable, irrevocable, paid-up license…on behalf of the United States"
  - Stevenson-Wydler Act same for *intramural* grant recipients
  - Echoes of Vannevar Bush, *Science: The Endless Frontier*

Trade Secrets

- Protect *information* that "derives independent economic value" from being kept secret
- No examination; no registration
  - Must be subject of "reasonable efforts" at secrecy
  - Must not be readily ascertainable
- Infringement is "misappropriation"
- Defenses to infringement
  - Reverse engineering
  - Independent invention
- Hybrid state–federal regime
- Damages = value of loss (or, often, injunction)
- Can be licensed just like patents

Directive 2018-26 (the "ASA(ALT) IP Directive")

- Using IP to balance "fostering private innovation" with "long-term sustainment"
- Applies to all FAR/DFARS contracts, and even beyond (e.g., CRADAs)
- Requires early negotiations as to ownership of IP rights
  - Obligation to consider priced contract options (where competitive)



SECRETARY OF THE ARMY
WASHINGTON

07 DEC 2018

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Army Directive 2018-26 (Enabling Modernization Through the Management of Intellectual Property)

1. More than ever before, the Army faces unprecedented challenges from emerging threats, proliferation of technology, and rapid innovation by our adversaries. We recognize that we cannot overcome these challenges with outdated weapons, equipment, and policies. Consequently, we have embarked on a number of modernization and acquisition reforms designed to enable the development and delivery of new warfighting capabilities more rapidly and cost-effectively than in the past. We started by identifying the six modernization priorities and establishing U.S. Army Futures Command. To help enable these reforms, we are now changing our approach to how we manage intellectual property.

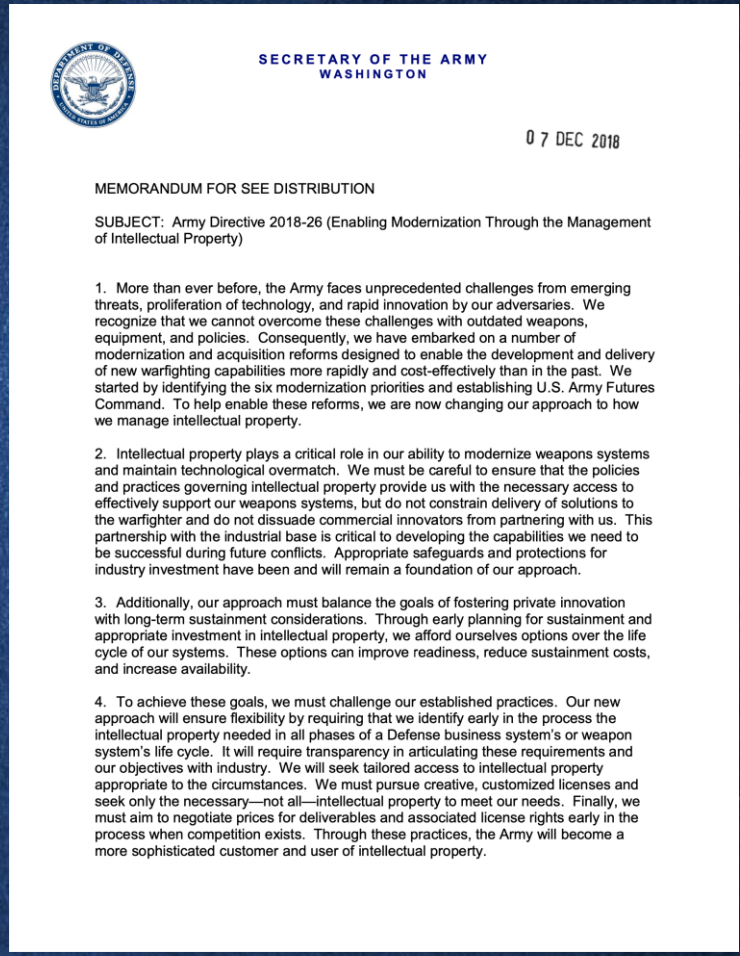
2. Intellectual property plays a critical role in our ability to modernize weapons systems and maintain technological overmatch. We must be careful to ensure that the policies and practices governing intellectual property provide us with the necessary access to effectively support our weapons systems, but do not constrain delivery of solutions to the warfighter and do not dissuade commercial innovators from partnering with us. This partnership with the industrial base is critical to developing the capabilities we need to be successful during future conflicts. Appropriate safeguards and protections for industry investment have been and will remain a foundation of our approach.

3. Additionally, our approach must balance the goals of fostering private innovation with long-term sustainment considerations. Through early planning for sustainment and appropriate investment in intellectual property, we afford ourselves options over the life cycle of our systems. These options can improve readiness, reduce sustainment costs, and increase availability.

4. To achieve these goals, we must challenge our established practices. Our new approach will ensure flexibility by requiring that we identify early in the process the intellectual property needed in all phases of a Defense business system's or weapon system's life cycle. It will require transparency in articulating these requirements and our objectives with industry. We will seek tailored access to intellectual property appropriate to the circumstances. We must pursue creative, customized licenses and seek only the necessary—not all—intellectual property to meet our needs. Finally, we must aim to negotiate prices for deliverables and associated license rights early in the process when competition exists. Through these practices, the Army will become a more sophisticated customer and user of intellectual property.

Directive 2018-26 (the "ASA(ALT) IP Directive")

- Requires new programs to establish an IP Strategy
- Encourages use of "modular programs"
- Promotes in-licensing and out-licensing
  - Encourages review of Army Regulation 70-57 ("Army Technology Transfer") to calculate royalties
    - One patent = one invention



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Issues for Synthetic Biology Specifically

- Components not typically patented
  - Genetic sequences difficult to patent
  - OSF principles
    - (+) Freedom to operate
- Where components are patented, contributory infringement
  - 35 U.S.C. § 271(c)
    - "Offers to sell or sells…a component of a patented machine…constituting a material part of the invention…and not a staple article of commerce"
- Government not a "person" for purposes of post-issuance challenges (*Return Mail Inc. v. USPS*)
- One patent, one invention rule liable to raise costs
  - Royalties can be significant
    - Synthetic biology, often fewer components than hardware (per patent damages higher)
  - Even where royalties low, Army scale is enormous
    - *Liberty Ammunition Inc.*, $15 million on 1.4¢/round (1.1 billion rounds)

Issues for Synthetic Biology Specifically

- Trade secrecy difficult
  - Unclear degree to which genetic sequences are trade secrets
    - But see *In re Certain Botulinum Toxin Products*
  - Reverse engineering often easy; or readily accessible
- Secrecy without national security?
  - Conflict between Directive 2018-26 and Army Reg. 70-57
- State law conflicts with DTSA
- Injunction threat serious

Further Considerations

- Shifting law during procurement, implementation
- Update 2018-26?
  - Focuses primarily on data, software
  - More concrete guidance for IP licensing in SynBio space
- Royalties *very* difficult to calculate
- Injunctions potentially problematic
- Offensive reverse engineering
  - Deployed SynBio easy to R.E.—can't keep secret (*Orfeo* principle)
  - Makes trade secret negotiations difficult

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