Synthetic Biology: A Whole Bunch of Balancing Acts

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Synthetic Biology, a balance between the compartmentalization methodologies of engineering and the reproductive efficiency of biology, is a field reliant on balance. This need for balance is particularly evident in the area of intellectual property.

The multitude of papers suggesting that synthetic biology be protected via copyright laws instead of patent laws notwithstanding,[1] inventions within the field of synthetic biology tend to be covered by patent law under the current intellectual property regime in the United States.[2]

However, while statutory patent law in the United States is technology agnostic, the courts and the United States Patent and Trademark Office treat different technologies differently for a host of different patentability criteria, for example, the distinction between predictable arts such as electrical and mechanical related arts and unpredicatable art such as biology and chemistry.[3] These distinctions have political repercussions as well, as most recently shown by the longstanding concern over the appointment of the next patent commissioner.[4]

Relatively clear cut examples of this discrimination are the related but separate enablement and written description requirements wherein biological inventions are read with an eye to different standards than hi-tech innovations. The differences in enforcement of these criteria not only reflect different properties of the technologies, but also reflect the efforts of the courts and the USPTO to promote innovation through manipulation of these criteria as policy levers. [5]

Synthetic Biology presents a rather unique application of these discriminatory efforts by the courts and the USPTO, particularly since the component fields of synthetic biology, biology and engineering, are often treated differently. Synthetic biology's wide ranging applications across multiple different fields and technologies including health, environment, nanotechnology, materials science, and energy might also cause confusion as to how best approach the patenting of the technologies. [6] Moreover, synthetic biology is not simply just the insertion of genes or the construction of novel genomes, it incorporates a whole host of enabling technologies[7] that will innovate alongside innovations in synthetic biology itself.

As such, synthetic biology necessitates a more novel approach; an effort to balance competing concerns and factors to optimally promote further innovation. In lieu of a sui generis system, the courts and the patent office might look toward treating synthetic biology innovations differently depending on whether they lean more toward the predictable or unpredictable, albeit at the risk of predictability for the inventor. For example, basic biological parts might be relatively predictable by nature, particularly in vitro, whereas larger machines, and particularly in vivo machines may be highly unpredictable.

Another area where balancing is required relates to competing efforts within the synthetic biology community to establish open source like protection regimes and proprietary regimes, the two opposing efforts somewhat representative of the engineering and biology aspects respectively, [8] and not, as some may think, representative of public universities vs. private industry. [9]

Here too, rather than a blanket response for the entire field, it might be better to apply an open source ideology to the protection of say basic parts, and a proprietary philosophy to protection of larger and/or complicated systems that use multiple basic and not-so-basic parts.

Similarly, further distinctions could also be made between general workhorse-like parts necessary for use in many different types of machines versus very specialized parts that might be useful in only a handful of applications.

Additionally, as the US patent regime evolves to tighten up patentable subject matter, even eviscerating the statute and mashing up unrelated parts (e.g., subject matter and non-obviousness), synthetic biology could fall prey to the dragnets designed to rope in software patenting in particular. For example, the current law has become very restrictive on the patenting of methods intended to be implemented via one or a million processors, but conceivably possible to be implemented by a hypothetical human, similarly, a process intended to be implemented via one or a million manipulated genomes but conceivably possible to be implemented by a hypothetical mechanical machine must also become unpatentable.

Whether its practitoners and the courts can find an optimal balance in the intellectual property aspects of synthetic biology is not simply an academic quandary. The courts and the USPTO, which, when captured by an industry tend to work towards the benefit of that industry,[10] need to appreciate the necessary balances in synthetic biology: when patents promote and when patents hinder innovation in this field and to apply the law accordingly. At minimum this requires the non-trivial effort of those in the field to tease out when to apply what type of intellectual property regime and then help the courts and the USPTO learn more about applying those regimes to synthetic biology.

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[1] Rai A, Boyle J (2007) Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons. PLoS Biol 5(3): e58.

[2] Dov Greenbaum, Legal Concerns in Emerging Science: Synthetic Biology and Intellectual Property, Intellectual Property Law: Interdisciplinary Analysis (Miriam Bitton & Lior Zemer eds.) (Forthcoming 2014

[3] *In re Fisher*, 427 F.2d 833,839 (C.C.P.A. 1970).

[4] Klint Finley, Silicon Valley Wins! Obama Picks Ex-Google Lawyer to Head Patent Office, WIRED 10.17.14, available at http://www.wired.com/2014/10/michelle-lee-uspto/

[5] Greenbaum, Dov. "An Analysis of Federal Circuit Discrimination: The Evolution of the Written Description Requirement Vis-a-Vis DNA and Biotechnological Inventions Concerns for Synthetic Biology." *Recent patents on DNA & gene sequences* 5.3 (2011): 153-165.

[6] van Doren, Davy, Stefan Koenigstein, and Thomas Reiss. "The development of synthetic biology: a patent analysis." *Systems and synthetic biology* 7.4 (2013): 209-220.

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[8] Nelson B. Synthetic biology: Cultural divide. Nature. 509(2014):152-4.

[9] Marks and Clerk, New report reveals trends in genomic research, 24 June 2014. Available at http://www.marks-clerk.com/Home/Knowledge-News/News/New-report-reveals-trends-in-genomic-research.aspx#.VEL1tBZQF1E

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