Intellectual property rights in synthetic biology: an anti-thesis to open access to research?

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Abstract Synthetic Biology is a surging area of contemporary life science based research that is rapidly evolving by virtue of its multidisciplinary composition and applications. Biology never before has seen such a gold rush and demonstrated potential for knowledge based economy. The area of synthetic biology is in a nascent and tender stage, however issues pertaining to open access to research versus the monopolistic intellectual property regime (specifically patents) have already started raising concerns in the emerging bio-based economy. The present study critically analyses the comparative benefits as well as lacunas of open access to research and patenting issues. It is noteworthy that both approaches for synthetic biology development have to co-exist in order to optimally benefit the society at large.

Keywords Knowledge sharing · Life science industry · Monopoly · Patent · Societal benefits

Introduction

Research in the field of biological sciences has been taken by a storm since the inception of the Human Genome Project. The synthesis of the first microbial genome leads to the next logical step of revolutionizing the existing

genetic engineering technology in order to delve into the microcosms of living systems. Academic endeavor has always driven such research. However, it is only when such research culminates into its applicability in the commercial sense, does it validate the investment (financial as well as human capital) which has been incurred. It is an accepted fact that since the beginning of the millennium, biological sciences has been directed towards not only understanding elements of living systems, but to transform such knowledge into commercially potential application which find use in day to day life. The concerns pertaining to sustaining life on earth has brought in the realization that mankind needs to develop more viable as well as sustainable technologies whose negative impact is minimal. The creation of artificial life appears to be the most daring offshoot of such research. To create artificial systems which have a multitude of applications in almost every discipline is nothing more than the inevitable outcome of intuitive character of scientific research.

Synthetic biology exemplifies a discipline that has allowed diverse disciplines to intermingle and co-exist in order to promote this niche area of technology to ultimately realize its inherent potential (SynbioSafe 2007). The best example of such consensus between the scientific community as well as regulatory bodies is within the European Union with the initiation of the SYNBIOSAFE project by the European Community in 2007 to deal with the ethical and safety issues concerning the use of technology developed and the resultant implications. The European Community has taken a pro-active approach towards dealing with the prospective impact of the outcome from research in new areas of scientific research. The NEST (New and Emerging Science and Technology)—PATHFINDER Initiatives have been in the forefront in dealing with synthetic biology research in particular (NEST 2005). The United

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States Department of Defense has been actively involved in developing strategies to counter the possible misuse of research in this field (CIA 2003). OECD has also initiated projects to forge a common understanding in the policy community of the issues to be aware of (research needs, community building, safety and security concerns, regulatory implications, market pathways, public understanding) (OECD 2010).

The advantages of scientific endeavors such as synthetic biology has therefore not only expanded the paradigm of biological research but has also made professionals from different areas of science, business, law, including the regulating and governing bodies to actively take part in not only promoting synthetic biology but also in understanding its ramifications on society. It is clear from the aforementioned examples that research in a niche discipline such as synthetic biology presents itself as a two-edged sword which needs a conscientious effort to not only be used responsibly, but also be made available without unreasonable restrictions hindering its potential. The present paper discusses one such aspect of synthetic biology where intellectual property rights and free access to research outcomes have been the bone of contention before different fora. The present paper acknowledges that the field of synthetic biology even while in its infancy reflects not only a new era in scientific research but also seeks to bring a paradigm shift in the legal and socio-ethical front. The open and free access to research also has a profound influence upon the discussion as to the social and ethical impact of the ultimate result of synthetic biology research. The present paper attempts to draw a consonance between the monopolistic nature of intellectual property and the open access research. The paper seeks to understand whether the intellectual property regime actually limits access to research by taking into consideration the foundation on which the law has evolved, especially in the field of patent law.

‘Open access to research’ in synthetic biology

Synthetic biology has opened the vistas of new and unexplored areas of use and manipulation of biological systems. Even while the basic tenet remains to understand the intricacy of the functioning of such systems, the research ultimately seeks to create novel organisms which can be tinkered at human will to suit need and applicability. Synthetic systems also provide the opportunity for researches to explore new arenas of commercial exploitation of such organisms in order to serve as efficient alternatives to conventional technology in fields such as energy production and medicine. Keeping in view the positive aspects of synthetic biology, the possible negative use of such research has opened the debate as to options for governance to

regulate and control the misuse of the tools of synthetic biology research (Garfinkel et al. 2007). Considering the mechanisms through which the plausible hazardous impact of such artificial organisms can occur is a matter of discussion by various international organizations (IRGC 2009) and national bodies (RAE Report 2009). The issues have specific significance in relation to safety and security which extends from biological containment to microbial weapons for use in biological warfare (Cho et al. 1999). Security issues are pertinent to understand as they are a matter of concern to the States world over (Church 2004).

In light of the various concerns, one approach which has been propounded and is slowly gaining wide spread acceptance is that of adopting an “open-research” approach. The proponent of this theory of countering the possible misuse of synthetic biology research was Prof. Drew Endy, who was of the opinion that rather than contributing to the burgeoning body of genetic knowledge, companies doing basic research were restricting access to crucial parts of the human genome thought to contain genes implicated in a host of diseases. He therefore believed that as scientists develop such material that could help other scientists who depend on the information encoded in genetic material, there should be an open mechanism to work together to share generated genetic information (Endy and Thomas 2008). Also, NSF funded and multi-partnered International Open Facility Advancing Biotechnology (BioFab) supports open technology platform and aims at providing free availability of genetic constructs that can be customized for specific applications by academia and industry.

Proponents of the ‘open access to research’ concept believe that it will not only increase the transparency in research, thereby promoting only those scientists who really seek to use such information productively and simultaneously aid in subduing the misuse of synthetic biology. It shall also create a common consortium wherein there is free exchange of information without any hindrance as to access or the need to pay royalty. Open source reflects a new approach adopted by scientists wherein the intention of allowing the free flow of information is not only to work towards securing common benefit, but is a mode through which reliability and security can bring the scientific community together in order to realize the actual potential of value-added research (Endy 2005). Further, open source sharing of information and results in the field of synthetic biology was initiated by the establishment of the BioBricks Foundation by engineers and scientists from MIT, Harvard, and University of California, San Francisco. The Foundation has opened MIT’s Registry of Standard Biological Parts for use so that any synthetic biologist or biological engineer can to some extent, program living organisms in the same way a computer scientist can

program a computer (The BioBricks Foundation 2007). The Registry is believed to be able to allow scientists to contribute and access standard genetic components whereby the need for large investments can be reduced. Further, it is considered to be an option against intellectual property protection wherein scientific data is often secured at a rate of royalty (Brown 2004). However, it still remains to be assessed whether the open access to research approach will be sustainable and will aid in governance of synthetic biology by taking due consideration of socio-ethical and legal issues associated with this emerging area of science.

Scope of intellectual property regime (patent law)

The ideology of intellectual property encompasses the need to grant privileges to nurture ingenuity as well as meet societal obligations. The intangible character of intellectual property has been conferred a legally enforceable character in the form of a right in the property contained therein (Prager 1944). Patents as a form of intellectual property rights have in effect been realised to be a value asset and trade currency which promote expansion and dissemination of innovative ideas in tangible form through commerce (Bentley and Sherman 2001). This has as a result brought about rapid advancement in technology, trade mechanisms and development of a robust and competitive market.

The rights conferred with the grant of a patent have been traditionally recognized as providing exclusive privileges for using/selling newly developed technologies, goods and services for the stipulated statutory period. Further, the grant of patents has been justified based on their role in the generation, empowerment and circulation of technical information. Economists have come to believe that it is socially essential to provide wide access to new technologies and products (Lerner 2002). This is because, when patented technologies are successfully made available to the public, they in turn gain market value and ultimately fuel the economy. Once the term elapses other market players are free to enter thereby generating healthy competition. This ultimately not only benefits the consumer but also allows inventions cater to diverse markets. The high economic value of patents have made them assume a form of assets, which can generate the capital for a company, assigned, licensed, traded and valued in monetary terms (Comanor and Scherer 1969).

It must however be noted that while such monopoly is the impetus for an inventor to further his intellectual abilities by realising the potential therein in terms of a limited monopoly, the same is not absolute and unrestricted. Justice Story adopting a utilitarian approach observed that inventions need to be disclosed to the public at the earliest, to

benefit society in general.¹ Justice Learned Hand in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*² stated, “it is a condition upon the inventor’s right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly.” With this premise it can be inferred that patents as a component of intellectual property rights assume multi-dimensional character wherein balance between rights of the inventor and the needs of the public is often regulated by the governing law. This jurisprudence was evolved in early English cases such as *Darcy v. Allein*³ and *Liardet v. Johnson*.⁴ The United States Supreme Court later established that keeping the view that the Constitution promoted new and useful scientific and technological arts, it is also necessary to validate the grant of patent in compliance to statutory requirements.⁵ As observed in *Seymour v. Osborne*,⁶ “Letters patent are not to be regarded as monopolies, created by the executive authority at the expense and to the prejudice of all the community except the persons therein named as patentees, but as public franchises granted to the inventors of new and useful improvements.... as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress”.

The concept of “open source” in the area of biology propounds the “free access for all” theory, which perhaps on the face of it stands contrary to the long standing ideology of intellectual property being a restrictive monopoly. However, it must be understood that no intellectual property can supersede the need to serve the larger public interest. It is interesting to note that within the policy and legislative framework of patent law worldwide, the public interest perspective has been given emphasis. This emerges not only from the notion of patentable subject matter, but also determining the criteria for granting a patent as well limitations upon the monopoly may be utilized. English law was the first to lay down the qualification to the modern concept of novelty. Categorizing patent monopolies as exceptions, the construction of the statute had been restrictive and narrow. It is pertinent to note that at its inception English law under the Statute of Monopolies of

¹ *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829).

² *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (1946).

³ *Darcy v. Allein*, 77 E.R. 1260 (1601).

⁴ *Liardet v. Johnson*, 1 J. Oldham (K. B. 1778).

⁵ *Pennsylvania R. Co. v. Locomotive Truck Works*, 110 U. S. 490 (1884).

⁶ *Seymour v. Osborne*, 78 U.S. 516 (1870).

1623 regarded the ideology that monopoly was *prima facie* against the common law, statute law, and liberty of the subject because it damages not only those working in the trade but all other subjects of the realm as well by raising prices, reducing merchantability, and reducing employment.⁷

It is therefore taken into account that technology or an invention does not become entitled to patent protection because the inventor considers his invention to be novel or new. In the seminal case of *Baker v. Selden*,⁸ the United States (US) Supreme Court held that, “the claim to an invention or discovery of an art or manufacture must be subjected to the examination of the Patent Office before an exclusive right therein can be obtained, and it can only be secured by a patent from the government”. Therefore, prior to the grant, the invention has to satisfy criteria which include but are not limited to patentable subject matter, novelty, utility and non-obviousness. English Courts endorsed the same by opining that, “any man who by his own charge and industry, or by his own wit or invention doth bring any new trade into the realm, and that for the good of the realm: that in such cases the king may grant to him a monopoly patent for some reasonable time, until the subjects may learn the same, in consideration of the good that he doth bring by his invention to the commonwealth, otherwise not”.⁹

Skill, intellect, labour and persuasiveness form the fundamental tests for conferring exclusive rights to individuals who contribute to technological progress. The nature and extent of rights granted under patent monopoly are defined in their metes and bounds by the governing law. Even while considering the argument that the open access to the results of research in the area of synthetic biology will aid in its growth, the relevance of intellectual property rights cannot be sidelined. In a global economy it would act as detriment to the inventor as well as the public at large if innovative ideas do not serve their intended purpose. As observed by Lon Fuller, the common law “projects its roots more deeply and intimately into human interaction than does statutory law” (Fuller 1969). Patent law also relies on its effectiveness based on socio-economic, cultural and political factors, rather than mere compliance to statutory language. Therefore, even while considering the fact that free access shall aid in the growth of synthetic biology, it must be accepted that patents have contributed positively in terms of generating the impetus to innovate and transcend the traditional limits of scientific research. Through patents it is not only possible to protect inventions that are valuable

as end products, but also secure the precursors and research tools which are the result of ingenuity and human effort.

It is therefore to be noted that while conferring intellectual property protection may in circumstances seek to slow down the progress of research, to adopt a completely opposite approach of open access may seek to generate reluctance on the part of inventors to disclose their research results. This is very pertinent in a scenario where the success of synthetic biology research largely relies upon commercial application of the artificial systems (Trichi and Chugh 2010). This in turn involves large-scale monetary investment wherein profits derived determine the future of propagation of such technology. Therefore, while a proprietary system may create an expensive option to promote research, it cannot be completely ignored. Striking a balance between proprietary rights and public interest is one of the supervening goals of the intellectual property regime. The BioBricks Foundation is an example of allowing individual researchers and small scale teams to access standardized modules. The consortium can be used to create common ownership in the technology thereby promoting the interests of all the stakeholders. It is therefore necessary to consider the option wherein intellectual property management mechanisms are adopted to bring the scientific community and business together. Licensing mechanisms and models of developing consortiums wherein cross-licensing can be explored in situations wherein critical technology is involved.

Further, patentability of living organisms or any component thereof has more recently seen Courts take a more restricted view. The *Myriad* decision by the United States District Court of New York in May, 2010 is one such example. It must therefore be considered that the law around the world may in time see consensus in terms of not granting patents in the field of biological sciences. However, in the current scenario, open access to research and intellectual property rights must co-exist and strike a balance to ultimately promote and boost the hidden potential of synthetic biology.

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⁷ *Darcy v. Allein*, 77 E.R. 1260 (1601).

⁸ *Baker v. Selden*, 101 U.S. 99 (1879).

⁹ *The Clothworkers of Ipswich*, 78 Eng. Rep. 147 (K. B. 1615).

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