

## The Analytical Significance of Emergence in the Patent System

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### Contents

1. The Patent System	3
1.1. Institutional and Doctrinal Complexity	
1.1.1. Opacity	
1.1.2. Sticky	
1.1.3. Messy	
2. Emergence, Complexity and Learning Needs	12
2.1. Person Skilled in the Art	
2.2. Inventive Step	
2.3. Prior Art	
3. Bioethical Policy and Learning Constraints	24
4. Synthetic Biology as an Emerging Technology	30
4.1. De-skilling	
4.2. Sharing Innovation Platforms and Norms	
4.3. Integrally Multi-disciplinary	
4.4. Proprietary and Non-Proprietary Information	
4.5. Unpredictability and Risk	
5. Table 1 - Patents in Synthetic Biology	45

The extent and degree of the dysfunction of the patent system that was exposed and which set in during the last two decades is a matter of some debate. For the casual observer there is overall stability in the patent system, but for those using or working within the system deep and troubling aspects abound.<sup>1</sup> Tier 1

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\*This paper is informed by work done on an EPSRC Discipline Hopping Award on synthetic biology during 2011-12, when I was a visiting fellow at the Division of Molecular Biosciences, Imperial College.

<sup>1</sup> A selection of some persistent issues and recent attempts to address them is provided by the following: the vexed problem of patent enforcement (see Jackson's Review of Civil Litigation Costs 2009), continued controversy over patentability standards (*Human Genome Sciences v Eli Lilly* [2011] UKSC 51), the scope of gene patents (C-428/08 *Monsanto v Cefetra* [2010] All ER (D) 65 (Jul) (ECJ)) or indeed even purpose of the patent system (*Association for Molecular Pathology v USPTO* 94 USPQ2d 1683 (S.D.N.Y. March 29, 2010)), the fear of the chilling effect on research (C-34/10 *Brüstle v Greenpeace* [2011] ECR

biotechnology<sup>2</sup> raised a number of questions that were addressed largely as pure legal standards in the patent system. What should be the optimal standard of industrial application for speculative inventions? How to define inventive step standards for genomic data? Ought genes to be considered discoveries and therefore unpatentable? What degree of disclosure do we require to justify a product or process patent? We now have more or less functional answers to most of these questions but not without several trials and tribulations along the way. In the case of newly emerging technologies, it would seem wise to proactively attempt to minimise uncertainty and the resulting transactional costs.

This paper is written for the Nuffield Bioethics Council's Working Group and analyses the best way for policy-makers to assess priorities in relation to the intellectual property protection of emerging biotechnologies. The paper reflects the author's view of analytical priorities by focusing on the decision-making process in the patent system and flagging opportunities to direct the patent protection of emerging biotechnologies in a desirable way. The paper is informed by a useful discussion with members of the working party in London on December 2<sup>nd</sup> 2012. The consultation paper<sup>3</sup> and notes on fact-finding meetings were also revealing.<sup>4</sup> The author is grateful to lecturers at Imperial College for access to scientific materials and permission to attend lectures and an interactive session on Synthetic and Systems Biology as part of their MRes program.

The analytical significance of 'emergence' for the future intellectual property protection of emerging biotechnologies is of central concern in this paper. The analysis is restricted to the general principles of patent law as applied in the UK.<sup>5</sup>

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I- 0000. This paper is based largely on UK and European Law but reference to US law and literature is made where a more general point may be valid.

<sup>2</sup> I define Tier 1 biotechnology as a period of time beginning with the case of *Diamond v Chakrabarty* 447 U.S. 303 (1979) and ending with the rather remarkable unsolicited brief from the US DOJ in the case of *Association for Molecular Pathology v USPTO* 653 F 3d 1329 (Fed Cir 2011), which questioned many established assumptions about the patent eligibility of genomic data. <<http://patentdocs.typepad.com/files/united-states-amicus-brief-1.pdf>> accessed 28<sup>th</sup> August 2012.

<sup>3</sup> Nuffield Council on Bioethics, 'Emerging Biotechnologies Consultation Paper' (April 2011).

<sup>4</sup> The meeting on 'Policy, Regulation and Governance' has one reference to 'patents' in the context of orphan drugs.

<sup>5</sup> For an insightful view of intellectual property rights, which may be relevant to synthetic biology as an emerging biotechnology, see A Torrance, 'Synthesizing Law for Synthetic Biology' (2010) 11(2) *Minnesota J of Law, Science & Technology* 629.

Comparative observations are made with aspects of the US legal system. The paper advocates neither more lenient nor stringent legal requirements to comparable inventions outside of emerging biotechnology.<sup>6</sup> The aim here instead is to focus on the quality of decision making in the patent system to help avoid ‘disaggregated solutions to individual problems that are not effective or lasting.’<sup>7</sup> The paper ends with an analysis of six aspects of synthetic biology as an emerging biotechnology with a view to supporting specific recommendations in this field.

## 1. The Patent System

When a new invention is protected, it is subject to qualitative assessment by a patent office; and by courts only if its validity is challenged in litigation. The invention, or rather the description of the invention<sup>8</sup> provided by the inventor, is checked against several desirable characteristics such as novelty, inventive step and industrial application. The qualitative threshold for each of these characteristics is applied from statutory provisions that are interpreted through a number of legal decisions from courts. The decisions of the courts and their view of what the legal statutes specify is made operable as ‘bright lines’ – clearly defined rules or legal standards comprising objective factors - by patent offices even if they are not presented with equal clarity in judicial language. These bright lines are intended to aid potential inventors in evaluating the patentability of their inventions. Needless to say, patent offices cannot always provide precision because the nature of the assessment of patentability at several axis points remains fact-specific and therefore subjective.<sup>9</sup>

Patents as intellectual property rights also differ from other rights such as copyright and trademarks in that the patent specifies the technological worth of the invention

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<sup>6</sup> This is one of five lessons from the history of technology that apply to the regulation of emerging technologies according to Marchant and others, ‘What Does the History of Technology Regulation Teach Us About Nano Oversight?’ [2009] J. Law, Medicine & Ethics 724.

<sup>7</sup> ‘Societal Issues Arising from Synthetic Biology: What lies Ahead’ Alfred P Sloan Foundation Workshop Report (U.S. Department of Energy) Nov 7-8 2010.

<sup>8</sup> There are several limitations to the effectiveness of a literal description of functionality in the specification of a patent application, compounded at times, by the unintended consequences of legal rules on disclosure. S Thambisetty, ‘Sufficiency of Disclosure in the Common Law: Complexity, Divergence and Confusion’ in Bentley and others, *The Common Law of Intellectual Property: Essays in Honour of David Vaver* (Hart Publishing 2010) 199.

<sup>9</sup> Manual of Patent Practice UKIPO Available here <[www.ipo.gov.uk/p-manual-practice](http://www.ipo.gov.uk/p-manual-practice)>accessed 28<sup>th</sup> August 2012

in detail and juxtaposes it with preceding inventions and occasionally, unmet technological and commercial needs. Except in the case of pioneering inventions, the technological merit of an invention is largely a matter of comparison with what already exists, known legally as the *prior art*.

The *claims* of a patent are legal statements informed by existing prior art and motivated by the desire to specify the full extent of control or ownership over the invention. Claims are included a part of the *specification* in a patent application. It is a requirement of most jurisdictions that a specification contain a description of the invention, allowing a person skilled in the art to practice, use or work the invention.<sup>10</sup> Even if the invention itself appears worthy of a patent, the description of the invention has to be supported by a level of detailed disclosure sufficient to fulfill the requirement that an averagely skilled person in the same field be able to ‘work’<sup>11</sup> what has been invented. In the first instance the patent examiner assesses the sufficiency of the disclosure, which is a function of the meaning of technical and non-technical terms used in the patent application. In the absence of established meanings, the description of an invention in the patent may be used as a dictionary for the terminology of the claims. Significantly, meanings are often ‘constructed’ rather than ‘discovered’ and frequently lead to expensive litigation with unpredictable outcomes.<sup>12</sup>

The description of the patent system here suggests the intensity with which knowledge and information is consumed in the interpretation and application of statutory provisions in this part of the legal system. Some of the convolution stems from the obvious complexity of scientific and technical advances. A further source of complexity is the structure of the patent system where disaggregated decision-making is the norm. Unlike most areas of the law, patent law is fashioned by both administrative rule-making by patent offices and legislative or judicial law making.<sup>13</sup>

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<sup>10</sup> S Thambisetty, ‘Sufficiency of Disclosure in the Common Law: Complexity, Divergence and Confusion’ in Bentley and others, *The Common Law of Intellectual Property: Essays in Honour of David Vaver* (Hart Publishing 2010) 199.

<sup>11</sup> Working an invention depends on the type of invention it is. *Merrell Dow Pharmaceuticals Inc v HN Norton and Co Ltd* [1996] RPC 76 (HL).

<sup>12</sup> For example see discussion of *Kirin Amgen Inc v Hoechst Marion Roussel Ltd and Transkaryotic Therapies (No 2)* [2004] UKHL 46 at [32] in S Thambisetty, ‘Patents as Credence Goods’ (2007) OJLS 27(4) 707, 714-715

<sup>13</sup> Phillip Leith, ‘Judicial or Administrative Roles: The Patent Appellate System in the European Context’ (2001) 1 IPQ (1) 50.

Courts work with established rules of legal interpretation and actively justify and reason outcomes – a characteristic of the judicial process that enables methodological and substantive scrutiny. The patent office, in contrast, is an administrative agency that operates overwhelmingly on documentary evidence via internal processes that are difficult to scrutinise. The ‘judges’ in patent offices are technically qualified to examine patents. However, procedural expertise in legal reasoning such as ‘evidence sifting’ or weighting of arguments, which may be routinely expected from judges of national courts, is rare. Yet patent law is as much a creature of patent office rules as legislative and judicial time.<sup>14</sup> As a consequence, the cognitive heuristics in this field of law can be exceptional and form the basis of the analytical significance of the ‘emerging’ nature of some technologies.

## 1.1 Institutional and Doctrinal Complexity

This section presents the sources and nature of institutional complexity in the patent system. The management of complexity is a key preoccupation within the decision-making process.<sup>15</sup> Unusual heuristics developed in this field in turn give rise to several strategic possibilities that may be exploited in policy-making. The three features discussed below, and that may be ascribed to the patent system, may be inferred from the patent system’s response to key emerging technologies of the last two decades – genomic and digital technologies. The features draw on several insights, from our knowledge of how institutions and organizations work, to how substantive legal content in the patent system is produced.

### 1.1.1 Opacity

The opacity in patent systems comes about in at least three different but related ways – the uncertainty in the quality of patents, uncertainty in the property boundaries of individual patents and in the commercial and technical prognosis of unprecedented technologies (that may be disruptive or creative of new industries).

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<sup>14</sup> S Thambisetty, ‘Timing, Change and Continuity in the Patent System’ Haunss and others *The Politics of Intellectual Property: Contestation Over the Ownership, Use and Control of Knowledge and Information* (Edward Elgar 2009) 211.

<sup>15</sup> For instance, complex legal assessments made through nominally objective legal tests but incorporating subjective elements through multiple steps or stages. The *Windsurfing/Pozzoli* test of inventive step and the *Aerotel* four step test of patentability. Manual of Patent Practice <[www.ipo.gov.uk/practice-sec-003.pdf](http://www.ipo.gov.uk/practice-sec-003.pdf)> and <[www.ipo.gov.uk/practice-sec-001.pdf](http://www.ipo.gov.uk/practice-sec-001.pdf)> accessed 28<sup>th</sup> August 2012.

The following is a discussion of the different ways in which patents obscure the value of the invention or information<sup>16</sup> enclosed.

The quality of a patent comprises technological value and commercial significance.<sup>17</sup> A patent application tells us very little about the quality of the underlying invention. An invention passes a minimum threshold of novelty and inventiveness; the legal test itself does not convey the degree of inventiveness or what that may mean for commercial success.<sup>18</sup> Indeed, the successful exploitation of an invention can often depend on external factors unrelated to the technical merit, such as efficient business models and the presence of supporting ancillary technologies.

Since patents contain information in varying amounts and degrees of quality they are lumpy<sup>19</sup> indicators of underlying quality. Patent counts are therefore poor proxies for the underlying value of patents.<sup>20</sup> The inability to quantify the effect of novelty, inventive step, disclosure and breadth on a patent's economic value is exacerbated by immature markets associated with emerging technologies. There is thus a constant demand for other proxies of economic value. Empirical studies seem to support the idea that association with scientific literature can be used as a value determinant.<sup>21</sup> Breadth of a patent, represented by the various fields under which a

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<sup>16</sup> In UK law there is no definition of invention and the non-definition is subject to legal controversy. Lord Hoffman in *Merrell Dow* defined invention as information. *Merrell Dow Pharmaceuticals Inc* (n 11). Also see J Pila, 'On the European Requirement for the Invention' (2010) 4 IIC

<sup>17</sup> D Bosworth, D Filou and M Longland, 'Measuring the 'Quality' of Patents' (2003) Draft Report to the UK Patent Office <[www.patent.gov.uk/about/ippd/ipresearch/qualityofpatents.pdf](http://www.patent.gov.uk/about/ippd/ipresearch/qualityofpatents.pdf)> accessed 28<sup>th</sup> August 2012

<sup>18</sup> 'When a patent examiner scrutinizes a patent application, he has very little idea of whether he is looking at the technological cutting-edge equivalent of sliced bread, or looking at one of the applications that make up the staggering statistic of inventions that are never commercially exploited'. See Thambisetty, 'Patents as Goods' (n 12) 712 (footnote omitted).

<sup>19</sup> Clarisa Long, 'Patent Signals' (2002) 69 U Chi L Rev 625, 654

<sup>20</sup> BH Hall, A Jaffe and M Trajtenberg, 'Market Value and Patent Citations: A First Look' (2001) NBER Working Paper no. 7741, National Bureau of Economic Research <[www.card.iastate.edu/research/stp/papers/hall-jaffe-trajtenberg.pdf](http://www.card.iastate.edu/research/stp/papers/hall-jaffe-trajtenberg.pdf)>, 28<sup>th</sup> August 2012.

<sup>21</sup> M Carpenter and others, 'Linkage Between Basic Research Literature and Patents' (1980) 13(2) Research Management 30; Subramanian and Soh, 'An Empirical Examination of the Science and Technology Relationship in the Biotechnology Industry' (2010) 7 J of Engg and Tech Management 160.

patent may be categorised, as per the four-digit International Patent Classification (IPC) system is also used as a predictor of value.<sup>22</sup>

In recent years, the quality of patents has also suffered from the public's perception of patent office laxity in the examination of patents. The perception is fed by reports of patents on trivial advances where prior art has been overlooked, either individually or systematically, in order to grant patents in a particular field.<sup>23</sup> This has led some commentators to question the strong presumption of validity of a patent<sup>24</sup> and has led to measures such as 'validity opinions' at the UKIPO.<sup>25</sup> In this context, non-proprietary scientific publications have gained prominence by providing a transparent and verified source of information about a firm's actual and potential knowledge assets.<sup>26</sup>

Patents as property rights have always been notoriously ill-defined. It is in this context that Lemley and Shapiro suggest that a patent is no guarantee of exclusion of competitors, but more precisely a right to *try to exclude*.<sup>27</sup> The uncertainty in proprietary parameters means that it is often difficult to precisely resolve whether a particular act is infringing of a patent or not. In emerging technologies, this kind of uncertainty is partly a function of the rapidity of technological change and the consequent evolution of meanings of technical terms that makes it difficult to predict infringing acts. For instance, if new developments produce a new way of making a product that has already been patented, ought the patent to cover rights to this new way, even though the patent holder could not have conceived of it when making his patent application? In the US it is a question of application of the notoriously complicated *doctrine of equivalents*. In the UK the same doctrine applies in a limited way – in the final analysis infringement is matter of fairness to the inventor and

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<sup>22</sup> J Lerner, 'The Importance of Patent Scope: An Empirical Analysis' (1994) 25 RAND J Econ. 319.

<sup>23</sup> See RP Merges, 'As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform' (1999) 14 Berkeley Tech L J 577; K Dam, 'Some Economic Considerations in the Intellectual Property Protection of Software' (1991) 24 J Leg Stud 321, 369–71.

<sup>24</sup> Scott Kief, 'Economic Perils of US Patent Reform: Flexibility's Achilles Heel' Pymont and others, *Patents and Technological Progress in a Globalized World* (MPI Studies in Intellectual Property, Competition and Tax Law Springer 2008) 793

<sup>25</sup> See empirical observations in S Thambisetty, 'Patent Litigation in the UK: Solutions in Search of a Problem?' *European Intellectual Property Review* (2010) 32(5) 238

<sup>26</sup> Publications in peer-reviewed journals can be expected to act as a 'credence verifier'. See Thambisetty, 'Patents as Credence Goods' (n 12).

<sup>27</sup> Lemley and Shapiro, 'Probabilistic Patents' (2005) 19(2) J Econ Pers 75.

adequate notice to third parties about the property boundaries of inventions.<sup>28</sup> Technologies that move rapidly, in particular, can create considerable difficulty in assessing the true scope and value of patents.

New technologies can also create a period of doctrinal uncertainty that can colour the way the industry regards such rights. Brad Sherman wrote in 1990 of a ‘period of openness’ in interpretation in the case of biotechnology patents, especially in the context of the standard of non-obviousness.<sup>29</sup> On a macro level, it can take a few years for this period of openness to become converted to a ‘closed’ form of interpretation that is more common in law. On a micro level, it can mean patents of uncertain validity and scope.<sup>30</sup>

The opacity of patents described here makes it very difficult to predict the role, value and influence that different requirements of patentability may have on capital and labour markets as well as the research environment. This characteristic of patents has contributed to the development of epistemic communities in patent law<sup>31</sup> and a general ‘hands off’ approach from external policy-makers, who are loath to influence and create unintended outcomes in such an unpredictable field. Internationally, an epistemic community acts to develop consensus regarding technical issues within their professional ambit, then takes this consensus back to their national contexts, so ‘increasing the likelihood of convergent state behaviour and international policy coordination’.<sup>32</sup> Formal and informal interactions among patent offices appear to

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<sup>28</sup> For a useful discussion please see Ian Karet, ‘Construction of Patents’ in Roughton and others, *The Modern Law of Patents* (Lexis Nexis 2010).

<sup>29</sup> B Sherman, ‘Patent Law in a Time of Change: Non-Obviousness and Biotechnology’ (1990) 10 OJLS 278.

<sup>30</sup> For example, a new standard of industrial application used by the UKIPO for the first time in 2005 was finally resolved in 2011 when the Supreme Court rejected the standard as not appropriate under UK law. In the interim the UKIPO would have applied the standard, resulting in patents that may now be found invalid if litigated. See *Human Genome Sciences* (n 1).

<sup>31</sup> As applied to international relations, epistemic communities refer to ‘a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain of issue area’. P Haas, ‘Introduction: Epistemic Communities and International Policy Coordination’. (1992) *International Organization* 46(1) 1, 3. Although this community can also be domestic, the special interest of the concept arises in translational epistemic communities. Candler, ‘Epistemic Community of Tower of Babel: Theoretical Diffusion in Public Administration’ *The Australian Journal of Public Administration* 67(3) 294.

<sup>32</sup> Haas (n 31) 4.

generate normative emulation and engineered diffusion of legal standards.<sup>33</sup> In this context, scrutinising the decision-making processes in the patent system, including the workings of epistemic communities, provides the best leads for policy-makers to direct the system towards optimal solutions.

### 1.1.2 Sticky

The sticky-ness of the patent system comes about as a result of the density of the institutional cluster and incomplete information. Solving problems such as optimal patent standards for new kinds of subject matter is resource-intensive, and the temptation to rely on analogy and incremental solutions that satisfice can be very high.<sup>34</sup> This leads to the disproportionate importance of early solutions or legal standards that can then foreclose other more appropriate options that may come to light as the technology matures.

An example is presented by the way in which guidelines prepared by the USPTO (1998) tackled the speculative nature of uses disclosed in patent applications for full or partial gene sequences. The guidelines specified that a valid application must include *specific, credible* and *substantive* uses for gene and protein sequences in order to be eligible for a patent.<sup>35</sup> This particular permutation of terms had not explicitly been used before in US case law and European patent law had a different terminology – that of industrial application to be disclosed as part of a valid patent application.

However, for a period between 1998 and 2011 the specific, credible and substantial standard was successfully championed and transplanted into UK and European law through means that suggest adaptive behaviour.<sup>36</sup> Stock markets are highly sensitive

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<sup>33</sup> Thambisetty, ‘Timing, Continuity and Change’ (n 14) 221-222. For an illustration of such diffusion see Thambisetty, ‘Legal Transplants in Patent Law: Why “Utility” is the New “Industrial Applicability”’ (2009) 49 *Jurimetrics J* 155.

<sup>34</sup> Where the intention is to gain adequacy rather than fully theorised solutions, see ‘Timing, Continuity and Change’ (n 14).

<sup>35</sup> See discussion in S Thambisetty, ‘Legal Transplants in Patent Law’ (n 33). The 1998 Nuffield Bioethics Council Report was one of the first voices to endorse the use of the SSC standard in UK law. Nuffield Bioethics Council, ‘The Ethics of Patenting DNA’ (1998).

<sup>36</sup> It is now applied beyond Europe via bilateral trade agreements that incorporate the standard. See AUSFTA Art 17.9

to adverse patentability signals from policy-makers and the legal system. Given the risk and resources required for creating new patentability standards for ill-understood technologies, there was, in the years subsequent to 1998, an inevitable short-term benefit to following the first formulation of a solution to a complex problem. The proliferation of the standard cannot be attributed to the optimality of the standard – in fact robust legal analysis would have demonstrated its unsuitability under UK law, a view recently shared by the UK Supreme Court,<sup>37</sup> as well as damage to the coherence of lateral legal doctrines in UK patent law.<sup>38</sup>

Sticky-ness in the patent system is exacerbated by the failure of litigation as an efficiency filter. Ideally inappropriate legal standards will be weeded out through litigation, for:

(Common) law evolves towards efficient rules because, inter alia, judges favour efficient rules, inefficient rules are litigated more often than efficient ones, litigants advocating efficient rules have greater incentives than those advocating inefficient rules to incur legal expenses that increase the likelihood of a favourable decision, and resorting to court settlement is more likely in cases in which legal rules governing the dispute are inefficient.<sup>39</sup>

This view of litigation as ‘efficiency facilitator’ is not supported empirically in the patent system.<sup>40</sup> Unlike a purely private legal dispute, the economics of patents often create a grave imbalance of incentives between a patentee and a potential challenger to the validity of the patent, with obvious repercussions not just for patent enforceability but also for the creation and continuance of appropriate legal doctrine.<sup>41</sup> It is also in the public interest to have an effective means of invalidating patents that ought not to have been granted.

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<sup>37</sup> *Human Genome Sciences v Eli Lilly and Company* (n 1) [40]. The SC referred to ‘significant and fairly fundamental differences’ between US patent law and the EPC that made alignment of the law in this regard ‘not currently practicable.’

<sup>38</sup> Thambisetty, ‘Legal Transplants’ (n 33).

<sup>39</sup> Oona Hathaway, ‘Path Dependence in the Law: The Course and Pattern of Change in a Common Law Legal System’, (2001) 86(2) *Iowa L Rev* 601.

<sup>40</sup> Jean O Lanjouw and J Lerner, ‘The Enforcement of Intellectual Property Rights: A Survey of the Empirical Literature’, (1997) NBER Working Paper 6296.

<sup>41</sup> Thambisetty, ‘Timing, Change and Continuity’ (n 14) 229-232

A patentee's incentive to defend his patent grossly exceeds an alleged infringer's incentive to challenge it. In the case of multiple infringers, patent invalidity judgments result in patents being turned into public goods; thus removing the ability of a patent holder to exclude others from appropriating the benefits of a successful attack.<sup>42</sup> Secondly, when multiple infringers compete in a product market, royalties are often passed through at least in part to consumers downstream. Therefore, there is no economic reason to expect direct infringers to have appropriate incentives to challenge a patent, even if they act collectively. Losing a challenge can be a very different outcome from uncomplainingly paying non-discriminatory royalties, as challengers often find themselves subject to injunctions or less favourable licensing terms. Patentees can also charge differential royalties to penalise firms that do not settle early - all of which weaken the infringer's incentive to challenge in the first place. Typically a gap of 7-12 years between a patent grant and commencement of litigation is likely. Further, patent litigation is inaccessible to many users of the system, due to eye-watering costs of litigation. This picture of patent litigation suggests that litigation in patent law on its own cannot be relied upon to weed out sub-optimal doctrine<sup>43</sup> or indeed safeguard public interest.

### 1.1.3 Messy

Current fragmentation of rights in Europe and the need to litigate across several national jurisdictions adds considerably to costs and complexity of patent litigation. It is a very significant time for patent litigation in Europe due to the proposed centralised European Patents Court. However, legal and institutional heterogeneity and the need for common procedural rules are some of the obstacles that have to be overcome.<sup>44</sup>

The messy nature of the patent system refers to the disaggregation of decision-making bodies and the fragmented and incremental results this can give rise to.

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<sup>42</sup> In the pharmaceutical sector US laws attempt to combat this problem by granting the first generic company that challenges a brand firm's patent US law exclusivity for a period of 180 days, during which period other authorised generics are prohibited. Unfortunately, this raises incentives to collude and settle between the brand pharma and first generic company leading to unintended consequences. See Michael Carrier, 'Solving the Drug Settlement Problem: A Framework for Presumptive Illegality' (2009) 108 *Michigan L Rev* 37.

<sup>43</sup> S Thambisetty, 'Patent Litigation in the UK: Solutions in Search of a Problem?' (2010) 32(5) *European Intellectual Property Review* 238.

<sup>44</sup> *ibid*

Decisions in the patent system are actualised through a complicated feedback loop between courts, patent offices and users, that often exacerbates the stickiness of early formulations of policy or doctrine. Messiness, as defined here, is a key institutional factor that impacts on the patent system's ability to make bioethical decisions, for instance. This is discussed in greater detail below.

## 2. Emergence, Complexity and Learning Needs

Any technology marked by scientific and technical uncertainty as well as indeterminate commercial prognosis is an 'emerging' biotechnology for the patent system. What is 'emerging' about the technologies under discussion is greater information about scientific viability, technical possibilities and commercial implications. The pace at which new information emerges may be different - in fits and starts or accelerating. Each new piece of information or understanding can have unpredictable outcomes, altering existing perceptions of knowledge; making something, which was previously thought impossible, reasonable to try; or even opening up or exacerbating gaps in knowledge. Available information is marshalled by the patent system to make legal decisions of great importance for individual inventors as well as for entire fields of study. As prior art is a key part of many patent decisions by courts and patent offices, the state of play in a technological field has continual relevance in every individual case.

Incomplete or evolving technical knowledge combined with the institutional characteristics of the patent system result in a complex environment that amplifies the difficulty in making appropriate decisions. Ideas, which grew out of studies of the social acceptance of technology, convey many aspects of institutional function<sup>45</sup> relevant to patent law, particularly to the management of complexity. It takes time and resources to learn new things, and we often learn by trial and error. People are more likely to do something that many others are also doing and may adapt their own behaviour based on what they expect other people to do.<sup>46</sup> *Learning effects* (where knowledge gained in the operation of a complex system leads to higher returns from continuing use); *coordination effects* (when the benefits received from choosing a particular standard increase as others adopt the same option); and

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<sup>45</sup> DC North, *Institutions, Institutional Change and Economic Performance* (Cambridge University Press 1990).

<sup>46</sup> BW Arthur, *Increasing Returns and Path Dependence in the Economy* (University of Michigan Press 1994).

*adaptive expectation* (derived from the self-fulfilling character of certain kinds of expectations) are all to be expected.<sup>47</sup>

Adaptive behaviour in patent law may also be actively engineered, as demonstrated by the establishment in 1983 of the 'Trilateral Office' – an entity comprising the European, US and Japanese patent offices, which share expertise through working groups and study reports<sup>48</sup>, and even take common positions in international negotiations, such as those related to the WIPO's Substantive Patent Law Treaty. The Office functions as an epistemic community that is not amenable to external oversight given the technical nature of patent law. The chance of policy or legal standards being inadvertently created through operational or procedural rules, which once set would be too difficult to change, is very high. Strategically, there is considerable loss of learning autonomy, and sub-optimal solutions to legal problems are likely, in order to reconcile all the implicit and explicit interests represented by this institutional cluster.

It has also been argued that actors, who operate in complex and opaque contexts, are heavily biased in the way they filter information into existing 'mental maps'<sup>49</sup>; 'confirming information tends to be incorporated and disconfirming information is filtered out'.<sup>50</sup> This in turn puts disproportionate importance on early events that may go on to have a decisive impact on the substantive content of legal doctrine, not because it is the best or most appropriate standard, but because it came first. Given the risks of formulating law under new and complex technological circumstances, learning behaviour, adaptive expectations, satisficing and the development of mental maps appear to be prominent among members of the knowledge network in the patent system.<sup>51</sup> For the rest of this paper, these constraints, or features of decision-making in the face of complexity, uncertainty and limited resources, are defined collectively as the *learning needs* of the patent system. It is the incompleteness

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<sup>47</sup> Pierson effectively builds on Arthur and North's work in the context of political institutions. For an in-depth discussion of these authors and the relevance of their insights to patent law see 'Timing, Continuity and Change in the Patent System' (n 14).

<sup>48</sup> <[www.trilateral.net/index.html](http://www.trilateral.net/index.html)>. Also see Louise Davies, 'Technical Cooperation and the International Coordination of Patentability of Biotechnological Inventions' (2002) 29(1) *J of Law and Society* 137.

<sup>49</sup> A Denzau and DC North, 'Shared Mental Models: Ideologies and Institutions' (1994) 47(1) *Kyklos* 3.

<sup>50</sup> P Pierson, 'Increasing Returns, Path Dependence and the Study of Politics' (2000) 94(2) *American Political Science Review* 251, 259.

<sup>51</sup> See discussion in 'Timing, Continuity and Change' (n 14) and 'Legal Transplants' (n 33).

of information and the consequent learning needs generated in the early part of a technology cycle that is of key relevance for the patent system.

The disproportionate significance of early solutions makes the patent system prone to agenda-setting and capture by vested interests. Conversely, policy-makers and government bodies should be prepared to exploit strategic opportunities, if backed by sound policy commitments, while being reflexive of others' attempts to do the same. The first jurisdiction to decide a case on the patentability of in silico modelling in synthetic biology, or the first patent office to come up with viable solutions to the problem of prior art in that field, will gain predominant influence in shaping doctrinal standards in an emerging technology.

In order to further illustrate the analytical significance of the 'emerging' nature of some biotechnologies, it is necessary to evaluate methods of managing incomplete information in the decision-making process within the patent system. The person skilled in the art, collating prior art and studying the means of adjudicating the inventive step standards are three methods discussed below.

#1: Institutional complexity is a challenge to appropriate policy making in the patent system. Rapid technological change can often outstrip the clock speed of the legal system. Ideally, policy-makers should anticipate strategic inflection points in emerging technologies and plan for disruptive scenarios where severe learning needs will be the norm. Exploring early ways of influencing debates within the existing characteristics of the patent system, before legal and policy options foreclose, would be worthwhile.

## 2.1 Person Skilled in the Art

The legal standard of the *person skilled in the art* (PSA) allows the law to capture technological specificities. The value of this standard lies in it being an objective formula that ensures legal certainty with discretionary spaces to achieve the purported aims of patent law. Conventionally, this notional person is presumed to be skilled at repetitive processes that produce expected results. The more skill the PSA is deemed to have, the less information a patentee has to disclose but the more difficult it becomes to be inventive enough to warrant a patent.

Resolving the level of ‘ordinary skill in the art’ in UK and US law reveals a two-dimensional aspect – what the PSA knows and how he behaves. What the PSA is expected to know is based on the *common general knowledge* in the field. Distinguishing the *state of the art* from what is common general knowledge is a significant material fact.<sup>52</sup> For instance, a PSA is not expected to have knowledge of all patents in his field – only those that have filtered into the consciousness of the average person skilled in the art and what he would take for granted.<sup>53</sup> In the case of technology sectors populated by corporations with large and well-organised R&D units, the degree and level of information systematically circulated can skew notions of common knowledge.<sup>54</sup>

A second dimension refers to the creative attributes and prejudices of the average PSA - a mixed question of law and fact subject to the pace and manner of change in a technology. For example, in a technology that moves slowly and is less prone to technological revision, a PSA may be subject to prejudices that constrain his creativity. The inventor who came up with the first bag-less vacuum cleaner was able to show that his machine was inventive because, in spite of intense competition, nobody in the field of vacuum cleaner manufacture had commercially proposed or sold a bag-less one. Using bags in vacuum cleaners had become *de rigueur* and therefore a matter of technical prejudice among average persons skilled in the art.<sup>55</sup>

Patentees frequently seek to defend their inventions from a charge of non-inventiveness by arguing that even if the skilled person might conceive of the invention, he would reject the idea because he would believe it would not work for some reason. These ‘technical prejudice’ arguments, however, can only work in the UK if the information in the patent would enable the skilled person to overcome the prejudice. Thus:

[p]atentability [in the face of a technical prejudice] is justified because the prior idea which was thought not to work must, as a piece of prior art be taken as it would be understood by the person skilled in the art. He will read it with the prejudice of such a person. So that which forms part of the state of the art really consists of two things in combination, the idea and the prejudice that it would not work or be impractical. A patentee who contributes

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<sup>52</sup> *Wheatley v Drillsafe* [2001] RPC 7

<sup>53</sup> *Angiotech Pharmaceuticals v Conor Medsystems*, 2008 UKHL 49

<sup>54</sup> *Beloit v Valmet (No.2)* [1997] RPC 489 per Aldous LJ

<sup>55</sup> *Dyson v Hoover* (2002) RPC 465.

something new by showing that contrary to the mistaken prejudice, the idea will work or is practical has shown something new. He has shown that an apparent 'lion in the path' is merely a paper tiger. Then his contribution is novel and non obvious and he deserves a patent.<sup>56</sup>

Often, the person skilled in the art is portrayed as 'cautious' – one who ponders every experimental move against the backdrop of what is known in the field. He would neither go against an established prejudice nor try to enter into 'sacrosanct' or unpredictable areas nor take incalculable risks.<sup>57</sup> However this caution must not be mistaken for reluctance or opposition to scientific progress in the form of minor adjustments and tweaks. Courts use experts in the field to educate them about the PSA. The analysis is often historical, as it takes several years from the date of a patent application for it to find its way to the courts - an aspect that creates further cognitive complexity.

There are at least three points about the manner in which the notional PSA is used in patent law that are directly relevant to emerging biotechnologies. First, early perceptions about the capabilities of the average person in the field often become precepts that are applied as rules of law in specific contexts. If assessments are made on the basis of inadequate or immature technical knowledge, then the law may be stuck with rules based on 'technological misconceptions' with potential impact on entire fields of technology.

For instance many biotechnology molecular products are products obtained by entering known information into a known process.<sup>58</sup> On this basis, as biotechnology matured, many inventions ought to have been considered non-inventive. However, initial findings on level of skill of the PSA have proven sticky and hard to shift. For instance, in US law, structural dissimilarity between gene sequences and the protein sequences they code for, can deem one or the other of them novel and inventive, even though we now know that a PSA can decode one from the other. This technological misconception has worked in favour of inventors and increased the patenting of genomic inventions (which has consequently reduced their incentive to litigate the ruling).<sup>59</sup>

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<sup>56</sup> *Pozzoli SpA v BDMO SA and Moulage Industriel de Perseigne SA* (2006) EWHC 1398 (Pat)

<sup>57</sup> Genentech et al (Expression in yeast) OJ EPO. 1995, 684 (T 0455/91) [5.1.33]

<sup>58</sup> Conceptualised by Ducor as 'translation inventions'. Ducor, *Patenting the Recombinant Products of Biotechnology and Other Molecules* (Kluwer Law International 1998).

<sup>59</sup> National Research Council Committee on Intellectual Property Rights in Genomic and Protein

A misconception that has worked against inventors in US patent law required full structural description of gene sequences, even where the molecule may have been described functionally or via the method used to obtain it.<sup>60</sup> US courts believed that the degeneracy in genetic sequences did not allow the PSA to reliably isolate the target sequence despite well-known methods of searching large quantities of molecules with an established likelihood of success. Only in 2001 after a few cases had been tried and tested in higher appellate courts did the US patent office begin to accept ‘functional characteristics when coupled with a known or disclosed correlation between function and structure.’<sup>61</sup>

Secondly, the skilled person should be taken to be a worker who is aware of everything in the state of the art and who has the skill to adapt and change but not to exercise inventive ingenuity ‘which would be wrong in principle.’<sup>62</sup> In emerging technologies with high degrees of unpredictability and relatively small numbers of scientists or research groups, demarcating routine experiments from inventiveness can be complicated given the average profile of a researcher/PSA.

A person skilled in the art is an external reference point practising an established art, but sometimes technical circumstances may find this person to be actively seeking to innovate within it.<sup>63</sup> Such a development is not necessarily about making it harder to get patents but should rather be viewed as a function of emergence in the case of a technology that is advancing rapidly. In the early 90s the European Patent Office observed that a skilled person in the field of genetic engineering in 1978 was not to be seen as a Nobel Prize laureate but rather as a graduate scientist or a team of scientists of that skill, researching in laboratories that worked from molecular genetics to genetic engineering techniques.<sup>64</sup>

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Innovation, *Reaping the Benefits of Genomic and Proteomic Research* (National Academies Press 2006).

<sup>60</sup> D Burk and M Lemley, ‘Biotechnology’s Uncertainty Principle’ in Scott Kieff, *Perspectives on the Properties of the Human Genome Project* (Academic Press 2003) 305-353.

<sup>61</sup> USPTO, ‘Guidelines for Examination of Patent Applications Under 35 U.S.C. 112, 1, “Written Description” Requirement’ (Jan 5 2001) 66 Fed Reg 1099 1104, 1106. Note that in the interim period all patent applications will have continued to be tested against the technological misconception.

<sup>62</sup> *Molnlycke Health Care AB vs Brightwake Ltd* [2011] EWHC 376 (Pat)

<sup>63</sup> The legal evolution of the attributes of the PSA at least in US law may have resulted in unreal levels of ‘averageness’ that commentators have identified as bordering on ingenuity. J Darrow, ‘The Neglected Dimension of Patent Law’s PHOSITA Standard’ (2009) 23(1) Harvard J of Law and Tech 227.

<sup>64</sup> Case T-0060/89 *Harvard / Fusion Proteins* (1992) OJ EPO 268.

Ordinarily, in an emerging field, a lower level of skill of the PSA would open up greater possibilities of commercial exploitation. As technology matures, the PSA could be attributed with more common knowledge, making it harder to get patents. However, in synthetic biology, modularity<sup>65</sup> has allowed graduate scientists to be fêted as innovators via highly publicised events like the iGEM. One way to exclude patents on trivial inventions in the early stages of such a technology would be to condone an upward creep of the standard of PSA, ensuring that patent offices and courts allow the standard to fall back to normal levels as the technology matures. Arguably, the structural characteristics of the patent system make such nuanced responses unlikely without explicit policy intervention.

Thirdly, since the introduction of biotechnology, it has been recognised that the person skilled in the art may comprise a multidisciplinary team rather than a single individual.<sup>66</sup> But, rather confusingly, a normal person skilled in the art may be expected to consider the state of the art, not just in his field, but also in neighbouring or related fields. However, in UK/European law, if a problem prompts the skilled person in the art to seek a solution in another technical field, the assessment of whether the solution was inventive must be based on the knowledge and ability of the skilled person from that other field.<sup>67</sup>

Team composition can also fluctuate, depending on the problem at hand. In a recent case a key question was whether a person familiar with coating silicone was part of the skilled team that routinely adapted wound dressings. In a decision that appears circular, the court decided that although a team concerned with wound dressings in general would not include a silicone specialist, the team would immediately seek and acquire such a specialist at the point at which they ‘wanted to seriously contemplate employing silicone for the technical problem at hand.’<sup>68</sup>

Describing the average PSA and delineating what he knows or how he behaves can be a very complex task, given accelerating change in an emerging technology where technical meanings, perceptions and expectations tend to be fluid. In the context of the structural characteristics of the patent system, once technological mistakes or

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<sup>65</sup> For a discussion of modularity and its implications see Alain Pottage, ‘Too Much Ownership: Bio-Prospecting in the Age of Synthetic Biology’ (2006) 1 Bioscieties 1 137, 146-147.

<sup>66</sup> *Genentech* (n 57) above, See also Manual of Patent Practice <[www.ipo.gov.uk/practice-sec-003.pdf](http://www.ipo.gov.uk/practice-sec-003.pdf)> 7

<sup>67</sup> Trilateral Comparative Study Report (2008) Inventive Step.

<sup>68</sup> *Molnlycke* (n 62) para 54

misconceptions occur, they are likely to persist. Ideally, legal standards such as inventiveness are under constant revision and reflect the gains made in a field. However, neither the institutional characteristics nor the doctrinal complexity of the patent law allow for reflexivity in the law's response to technology life cycles. It is this institutional and doctrinal inadequacy that makes the case for explicit policy intervention to oversee legal standards in emerging technologies. Oversight can take many forms, from guidelines to mandatory rules, which are worth exploring further, at least in the early years of an emerging technology.

**#2:** Explicit policy interventions in the patent system may occasionally be justified in order to direct legal standards. Such input is a common aspect of regulatory design when technical standards have to be set. In contrast, the patent system does not normally have recourse to the views of contemporaneous scientists. If we regard the patent system as a significant aspect of the regulation of emerging biotechnologies, then there is a strong case to be made for such oversight that is also sympathetic to the institutional structure of the patent system. Such oversight could take the form of a technical standing committee or opinion group that is independent of and interacts with the patent office.

## 2.2 Inventive Step

Unpredictability or uncertainty in an emerging field can work in favour of the inventor, as the invention can indicate the overcoming of obstacles and therefore make it easier to establish patentability. Factors such as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them, the expectation of success<sup>69</sup> and the credibility of scientific claims can all be investigated by the law through the inventive step standard. Inventiveness internalises the multitude of decisions that must be taken in order to cope with the risk and promise of scientific enquiry as a process.

'Inventiveness' is the technological distance between what existed before and what has been newly made. It helps to think of the inventive step/non-obviousness standard as an evaluation of what is not patentable rather than what is patentable.

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<sup>69</sup> *Generics UK v Daiichi Pharmaceutical Co Ltd* [2008] EWHC 2413 (Pat)

The reverse ‘defining the precise degree of ingenuity or the character of the inventive step that is requisite to endow an invention with patentable subject matter’<sup>70</sup> is probably impossible.

The identification of the prior art is an important first step in the process of comparing the invention in a patent application with the technological knowledge that existed before that application. The prior art in the case of inventive step (unlike novelty) calls for a qualitative appraisal because of the possibility of ‘mosaicing’ – putting two or more citations together where they would naturally lead from one to the other as a way of gauging what the PSA can be expected to infer. The combination can cover treacherous ground because an invention that was non-obvious ‘at the time the invention was made’ might subjectively and with hindsight appear obvious or uninventive when prior art citations are combined.

A sector-specific assessment of ‘inventiveness’ is extremely difficult to make ex ante. Legally, inventiveness is a function of the feasibility and credibility of technological claims at a given point in time. The patent office gathers information about an invention, and how inventive it appears is based on an appreciation of prior art. If the matter comes to be litigated, then courts can choose to have access to expert evidence. The expert will speak to what the average person skilled in the art would have imagined possible or feasible at the time the invention was first invented. On the one hand, making the threshold bar too high can mean fewer patents, but those that are patented will be more inventive. A low threshold, on the other hand, can lead to trivial inventions being patented – something that can quickly transform into industry expectations around which capital markets coalesce. Many of the controversies of genomic patenting, for instance, could have been avoided by specifying a higher standard of inventiveness that would have seen patents being rejected on full or partial gene sequence information when that information was easily attainable from the public domain.<sup>71</sup> Similarly, current standards in computer-

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<sup>70</sup> Swan Committee 1946-47 [127] as cited in A Monotti, ‘Divergent Approaches in Defining the Appropriate Level of Inventiveness in Patent Law’ in Ng and others, *The Common Law of Intellectual Property* (Hart Publishers 2010) 177, 179.

<sup>71</sup> ‘Patent Offices now lay emphasis on the standard requirement of inventive step (non-obviousness) as the requirement which will do most to retain genetic patenting within acceptable bounds ... With the growth of bioinformatics techniques to achieve automated comparison of gene functions between different species, it becomes increasingly difficult to characterise the work as anything other than routine.’ W Cornish, M Llewelyn and M Adcock ‘Intellectual Property Rights (IPRs) and Genetics’ (2003) 32 Report for the Department of Health UK.

implemented technologies have been criticised as placing the inventive step threshold too low.<sup>72</sup>

Confusion about how inventive is inventive enough is a direct result of lack of consensus about the goals of the patent system. Patents, in one conception of its aim, are to be granted only for technically worthy inventions that would not have been invented but for the incentive effect of the patent system. Such a view recognises the social cost of a monopolistic tool that must be used with restraint and discretion. Others argue that patents must function as a form of protection for investment.

One of the main arguments for the patenting of gene sequences in the early 1990s was the large front-end cost of sequencing, which required upfront investment. Without the promise of patents, venture capitalists would have no incentive to invest upfront.<sup>73</sup> This argument appears to give greater weight to early patents over the quality of technology. The fallacy in this argument is that investors will be satisfied or respond to early patents on inventions of unknown technological worth, rather than to credible and sound research paths.

Raising the inventive step standard will give rise to a level playing field and delay gratification for all by moving the incentive further up the chain of innovation – ensuring that only inventions of a certain quality are patented. Thus, though the venture capitalist bears the risks of investment, the degree of risk to reward is the same for all potential investors.

**#3:** It would be a mistake to attempt *ex ante* to set inventive step standards in any emerging technology because the technology is immature and unintended outcomes are likely. However, paying greater attention to the PSA heuristic will allow policy oversight of the level of inventiveness in the early years of an emerging technology. Scientists must see their role in setting legal standards as similar to technical standard-setting or credible peer review. An understanding of trivial inventions, around which a consensus for non-patentability can be built

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<sup>72</sup> See discussion in H Moir, 'How High is the Inventive Step? Some Empirical Evidence' (2009) Centre for the Governance of Knowledge and Development Working Paper <<http://cgkd.anu.edu.au/menus/workingpapers.php>>

<sup>73</sup> See Department of Justice Brief (n 2).

could be a fruitful strategy for an emerging technology like synthetic biology.

### 2.3 Prior Art

The type and quantum of prior art that is cited in patent applications is often an indication of the ‘emerging’ nature of some technologies<sup>74</sup>. For example, it has long been known that many biotechnology patent applications showed a higher than average number of citations to non-patent references (NPR), implying the absence of a corpus of technical advances to build on. The more scientific references there are in patents the closer it is considered to basic research. On average, international patents reference 15% NPR. For the period 1990-2004 about 55% of citations in biotechnology-related international patents were to NPR.<sup>75</sup> A more recent study of biotechnology firms found that on average a biotechnology patent cites 18 NPR, a majority of which are scientific publications.<sup>76</sup>

Given the short history of synthetic biology, we can expect patents here to refer to prior art only within the last few years. An important patent on protein logic gates, for example, references only 7 scientific publications, none earlier than 2001,<sup>77</sup> and no patent references. Between pioneering inventions, inventions in emerging technologies and trivial advances lies a huge swathe of inventions that are differentiated by the type and quantum of prior art cited. Emergence may thus be tangibly inferred by a small number of recent prior art citations (See Table 1).

Historically, patent offices have struggled with technologies that come from unprecedented backgrounds due to the difficulty in collating prior art. When the patent office ‘examines’ patents, it tends to rely on previously granted patents, pending applications and scientific journals or other technical materials that are systematically made available in databases. There is a bias towards documented prior art, although clearly science and technology interactions are not limited to documents. ‘Informal, non-traceable flows of tacit knowledge’ do not figure in

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<sup>74</sup> Elsewhere I have used the term ‘immature technologies’ in the context of legal doctrine to refer to the same. ‘Patents as Credence Goods’ (n 12).

<sup>75</sup> OECD *Patent Statistics Manual* (OECD Publishing 2009) 117-118.

<sup>76</sup> Subramanian and Soh (n 21) 165.

<sup>77</sup> US Patent US7604805B2 2009-10-20 Protein Logic Gates.

patent office examinations.<sup>78</sup> With software-implemented inventions, a large proportion of programming information was embodied in the programs written or the inventions that the programs implemented, making it hard to identify prior art against which patent applications could be tested.<sup>79</sup> Further 'de-skilling' of programming meant that the technology was not limited to a small number of 'experts'. This exacerbated the difficulty in gaining access to prior art for patent offices in the 80s and 90s.

The grant of the Amazon 1-click patent was widely seen and criticised as an instance of the US patent office missing information that was widely known in the field among programmers, even if not documented in a way that would be accessible to patent examiners. Former Amazon.com developer Barton-Davis stated in the aftermath of the grant of the patent, that it was just one example of the way in which the company has benefited enormously from ideas circulating in the open and/or free software world of the middle 1990s. '1-click is a simple, logical and obvious use of the cookie system pioneered by Netscape and others.'<sup>80</sup>

In conventional biotechnology, too, the availability of vast quantities of genomic data in the public domain has been slow to filter through to the patent office. Chin notes that this is because patent offices invoked a model of DNA discovery that insists on explicit structural formulae for specific nucleic acid molecules, whereas genetic research literature often reports on advances that apply to general classes of nucleic acids.<sup>81</sup> This misreading results in significant discrepancy between the prior art that is recognised as effective by the patent system and the scientific community's understanding of the state of the art. The resulting errors in the level of skill of the person skilled in the art are typical of the problems faced by patent offices when responding to unprecedented technologies that have unusual means of generating and disseminating knowledge. In fact, as discussed below, the 'open' nature of some aspects of the development of synthetic biology may impair the ability of patent offices to preclude patents on trivial and obvious technological advances.

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<sup>78</sup> J Callaert and others, 'Traces of Prior Art: An Analysis of Non-Patent References Found in Patent Documents' (2006) 69(1) *Scientometrics* 3.

<sup>79</sup> J Park, 'Evolution of Industry Knowledge in the Public Domain: Prior Art Searching for Software Patents' (2005) 47 2 *SCRIPTed* 1.

<sup>80</sup> S L Jarvenpaa and E H Tiller, 'Protecting Internet Business Methods: Amazon.com and the 1-click Checkout' <<http://btl.mcombs.utexas.edu/IBM%20Course%20modules/bizmethpatents1.pdf>> accessed 28<sup>th</sup> August 2012.

<sup>81</sup> A Chin, 'Artful Prior Art and the Quality of DNA Patents' (2006) 57 *Alabama L Rev* 57 975.

**#4:** Prior art in emerging biotechnologies may be found in unexpected locations and formats. Conservative patent offices, which rely only on formally documented prior art, risk granting patents that ought not to be granted. Scientists in the field must be consulted in order to map all possible variations in format and sources of prior art in an emerging technology.

### 3. Bioethical Policy and Learning Constraints

In its 1998 report, the Nuffield Council chose to report on patentability of DNA as an 'ethical issue'.<sup>82</sup> The question of the ownership of DNA sequences can certainly be considered an entirely ethical question in the same sense as all ownership, use and exploitation of property for profit could be. However, legally the ethical question is limited to specific provisions that are called into question infrequently.<sup>83</sup> Ethical decision making, which involves the application or interpretation of existing statutory provisions to hitherto unprecedented phenomena or subject matter, fits well within the general paradigm presented here, of formulating legal standards in the context of emergence and learning needs.

Ethical questions often touch upon other laws such as human rights law, international obligations and the notion of human dignity, as well as less clear policy constraints. Therefore, a body that decides on the ethical question, as a part of the question of patentability, may be expected to have access to or utilise several sources of law and policy, wherefrom it can discover the right approach, particularly when unprecedented subject matter is in question. Higher appellate courts that are generalist in nature have recourse to a greater variety of approaches to a legal problem. They are more likely to adopt a 'purposive' approach to interpretation<sup>84</sup>, where the appropriateness of an exclusion from patentability is explored. Such courts may identify issues that are best left to legislatures. In contrast, specialist

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<sup>82</sup> 'The Ethics of Patenting DNA' (n 35).

<sup>83</sup> The EPO countenances the use of Art 53(a) EPC only in 'rare and exceptional' circumstances. *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)).

<sup>84</sup> In purposive interpretation, the text's 'purpose' is the criterion for establishing which of the semantic meanings yields the legal meaning. For more see A Barak, *Purposive Interpretation in Law* (Princeton University Press 2011).

courts often take the purpose of a statute as given and proceed to address legal questions as a matter of literal or semantic interpretation.

Patent law in Europe (and to a lesser extent in the US) exhibits a curious disaggregated decision-making process<sup>85</sup> because of the dominance of the European Patent Office (EPO), which functions as a specialist ‘court’. Due to the pressures of harmonization, the EPO has considerable influence on the interpretation of the ethical implications of the commercialization or exploitation of inventions. This role comes at the cost of greater involvement of generalist national appellate courts that may be more suited to making broadly conceived ethical decisions. The EPO is a specialised administrative body with quasi-judicial functions and a corporate structure geared towards customer service (to actual and potential patent holders). In the past the EPO has cast its role as one of granting patents<sup>86</sup> and has generally interpreted all exclusions to patentability narrowly in a growing body of case law.<sup>87</sup> Such precedents signal a self-perception that is not in keeping with the EPO’s role in safeguarding the public interest by denying patents that are inappropriate or rightly excluded by law.

In this context, two recent decisions on stem cells provide an interesting demonstration of the institutional messiness in Europe. Biotechnology is unusual in that the EPO uses the Biotechnology Directive<sup>88</sup> (which is a European Union document, unlike the European Patent Convention, which predates the European Union) as a supplement to the interpretation of the European Patent Convention (EPC). This means that biotechnology questions can be referred to the European Court of Justice (ECJ) – an appellate court with broad jurisdiction. The involvement of the ECJ provides the possibility of a broad-based ethics approach to patentability

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<sup>85</sup> A unique contrast in approaches can be seen in the case of the patentability of the genetically-modified onco-mouse at the European Patent Office, a body with specialist quasi-judicial functions, and the Canadian Supreme Court, a generalist appellate body. See S Thambisetty, ‘The Institutional Nature of the Patent System and its Impact on Bioethical Decision-Making’, in Christian Lenk, Nils Hoppe and Roberto Andorno, *Studies in the Legal, Ethical and Political Impact of Intellectual Property* (Aldershot: Ashgate Publishing House 2007) 247.

<sup>86</sup> As per the EPO’s reading of Art 4(3) EPC in G 1/04 *Diagnostic Methods* 2006 OJ EPO 334

<sup>87</sup> The EPO has recently claimed there is no such general rule to read exclusions narrowly. But see Bently and others, ‘Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights’ *WIPO Standing Committee on the Law of Patents* SCP 15/3.

<sup>88</sup> Directive 98/44/EC on the Legal Protection of Biotechnological Inventions [1998] OJ L213/13

of biotechnological inventions, but not so in other areas (such as digital processing or nanotechnology).

The WARF case involved several pertinent questions regarding the patentability of stem cells and was referred to the enlarged board of appeal of the EPO.<sup>89</sup> Arguably the most salient of these questions was whether stem cells that can only be developed by destroying the human embryo from which they are derived, be patented? This question of patentability rests on the correct interpretation of a rule that applies the general prohibition against the patenting of immoral inventions embodied in Art 53(a). The rule reads: [Under] Article 53(a), European patents shall not be granted in respect of biotechnological inventions which in particular, concern the following ... 'uses of human embryos for industrial or commercial purposes.'<sup>90</sup> The EPO had to interpret whether 'uses' of human embryos included the destruction of them. The EPO found that :

Rule 28(c) ... EPC forbids the patenting of claims directed to products which - *as described in the application* (emphasis added) - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.<sup>91</sup>

The limited way of narrowly analyzing the wording of the Rule means the following criticism is a legitimate one:

On the face of it, it was a hearteningly moral decision. Closer inspection however is needed. Patent attorneys will read these words carefully. If a product for example an hES cell culture, is produced by a production method which *initially* involves the destruction of a human embryo, then if *further* production (e.g. by incubation of the derived hES cell culture) need not involve further destruction of human embryos after the patent application filing date, it could be argued that patentability is *not* excluded by the wording quoted above. A patent applicant may readily ensure that such further production without destruction is possible by depositing a sample of the culture at a recognised depository no later than the filing date of the patent application. Our conclusion is that the Enlarged Board of Appeal may

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<sup>89</sup> G-2/06: *Use of embryos/WARF* (2009) OJ EPO 306.

<sup>90</sup> Rule 28(c) *Convention on the Grant of European Patents* (European Patent Convention).

<sup>91</sup> *Use of Human Embryos/WARF* (n 89) 331-332.

again have pointed out to patent applicants how they may circumvent a patenting prohibition of the EPC, viz. by what we term the “deposit loophole”.<sup>92</sup>

The above comment is by no means an unjust criticism of the EPO attempting to do a difficult job, but a tried and tested method whereby exclusions from patentability are reduced to linguistic silos that can be side-stepped by avoiding or specifying certain terms in patent applications. At least three instances come to mind. The European Patent Convention excludes animal varieties from patentability but the narrow interpretation of the term by the EPO means that genetically modified animals may be patented. Applicants have only to ensure that the term ‘animal variety’ is not used in the application.<sup>93</sup> Similarly, computer programs explicitly excluded in the EPC may be patented so long as the patent description incorporates ‘technical’ components as banal as servers or other general-purpose equipment.<sup>94</sup> Thirdly, most ‘diagnostic methods’ are now patentable provided at least one step in the process of diagnosis is practised away from the human or animal body which can be easily incorporated into the description of the diagnostic method invention.<sup>95</sup> These decisions can be seen as a result of taking the purpose of a statute as a given - that is to grant patents. Any provision that derogates from it is therefore read narrowly in a manner that does not allow for policy-based analysis and in fact blows a hole through many exclusions.

An even greater problem with the EPO’s decision was that it never undertook an analysis of the relationship between Rule 28(c) and Art 53(a) and, rather remarkably, avoided discussion of the implication of the latter general exclusion on morality. The EPO felt that, given its interpretation that Rule 28(c) prohibited ‘uses’ of human embryos involving destruction [as such use was an integral and essential part of the industrial or commercial exploitation of the claimed invention that violates Rule 28(c)], it was:

... not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard

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<sup>92</sup> S Stercx and J Cockbain, ‘Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO’s WARF Decision’ (2010) 7(1) SCRIPTed 92.

<sup>93</sup> Case T-315/03 *Harvard/Transgenic animal* [2005] EPOR 31 (EPO (Technical Board of Appeal)).

<sup>94</sup> Case T-258/03 *Hitachi/automatic auction method* [2004] OJ EPO

<sup>95</sup> G 1/04 *Diagnostic Methods* (n 86).

of *ordre public* or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess *ordre public* or morality under Article 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre.<sup>96</sup>

Art 53(a) would have required a broad-based and detailed analysis of the interpretation of this provision in light of public morality among member states – arguably an agenda that is resource intense and would have entailed considerable commitment on the back of a root-and-branch analysis of several legal options. The EPO arguably has not invested in the capability to undertake generalised policy or ethics-based analysis. Indeed, by not undertaking such an analysis, the EPO is able to preserve its propensity to make it easier rather than more difficult to obtain patents. The EPO's choice of decision-making paradigm here can be seen, at best, as a typical example of incomplete decision making or satisficing and at worst as capture by special interests.

The decision of the European Court of Justice in *Brustle v Greenpeace*<sup>97</sup> concerned the question of patentability of an invention involving the production of neural precursor cells that presupposes the use of stem cells at the blastocyst stage – a process that entails the destruction of the human embryo. In contrast to the EPO's approach, the argument that the absence of any reference to the prior destruction of human embryos in the patent application would mean that products of such embryos would be patentable, was subsequently explicitly addressed by the court and rejected. In a statement that seems directed specifically at all the things that the EPO did not say, the ECJ noted that:

Not to include in the scope of the exclusion from patentability set out in Article 6(2)(c) of the Directive technical teaching claimed, on the ground that it does not refer to the use, implying their prior destruction, of human embryos would make the provision concerned redundant by allowing a patent applicant to avoid its application by skillful drafting of the claim.<sup>98</sup>

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<sup>96</sup> *Use of embryos/WARF* (n 89) 327.

<sup>97</sup> C-34/10 (n 1).

<sup>98</sup> *ibid* 50

The ECJ also exhibited a degree of comfort with the use in interpretation of the nebulous legal notion of ‘human dignity’. It observed that:

the context and aim of the Directive thus show that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense.<sup>99</sup>

Both of these statements highlight the ECJ’s capacity for purposive interpretation. In contrast, the EPO appears ill-equipped and constitutionally disinclined to follow a similar approach. The ECJ cannot be expected to intervene frequently as such appeals are rare and can only involve the interpretation of the Biotechnology Directive. There is of course no guarantee that emerging biotechnologies, which include as an integral part other related non-biotechnological techniques such as digital circuit design or nanotechnologies, will fall under the remit of the Directive. Such inventions may nonetheless raise moral or ethical questions.

**#5:** Learning needs and institutional inclinations make the EPO a poor venue to address bioethical concerns supporting the rejection of patent applications. The ECJ is better suited to policy-based analysis of patentability but can only do so for cases that call into question some aspect of the Biotechnology Directive. However, there is no guarantee of the timely involvement or intervention of the ECJ. Additionally, technologies that are associated with or incorporated into inventions (such as digital circuitry or nanotechnology) in emerging biotechnologies may take such inventions out of the purview of the Biotechnology Directive. There is an urgent need to evaluate the bioethical decision-making infrastructure in the patent system, including analysis of the scope of the Directive for emerging technologies like synthetic biology. Influential bodies like the European Parliament and national appellate courts could, given the right context, fulfil anticipated learning needs in the patent system in the context of ethically problematic inventions.

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<sup>99</sup> *ibid* 34

#### **4. Synthetic Biology as an Emerging Technology**

This section focuses on five unprecedented features of synthetic biology that will determine the future management of legal complexity. These features do not exhaustively define this new technology(ies), but identify pressure points in the management of intellectual property given the heuristics described in this paper. Prof. Kitney likens the current stage of development of synthetic biology to early stages of synthetic chemistry, from which it took 30-50 years before successful industrial application was possible.<sup>100</sup> However, the availability of powerful computers, broadband networks and high-speed DNA sequencing and the coming together of biological, engineering and physical sciences are key differences that could speed up advances in unpredictable ways. In the next phase we can expect proprietary and non-proprietary information to proliferate further, limiting the current window of analytical and strategic policy-making opportunities presented by emergence.

Synthetic biology has been described as a new engineering discipline<sup>101</sup> and one that requires an unprecedented level of collaboration and coordination between several disciplines. Synthetic biology as a whole brings together opposite but symmetrical scientific cultures – the ‘deconstruction of life’, where biological systems are dissected in the search for simplified and minimal forms, and the ‘construction of life’, where the goal is to build systems inspired by general biological principles and to reproduce the behaviour of live systems.<sup>102</sup>

Essentially, the field comprises of four different approaches.<sup>103</sup> The bottom-up approach focuses on reconstruction of chemically synthesised genomes after they have been fully sequenced. The reconstructions can take place in sets that are then put together. Metabolic engineering looks at ways of modifying metabolic pathways – an ambition that holds considerable promise including the possibility of producing biofuels in viable commercial forms. The development of ideal cell chassis that produce desirable responses to bacterial DNA currently focuses on neutral minimal cells. However, it is possible that in the near future different versions and strains

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<sup>100</sup> Imperial College MRes course lectures (Jan 2012).

<sup>101</sup> Andrianantoandro and others, ‘Synthetic Biology: New Engineering Rules for an Emerging Discipline’ (2006) *Molecular Systems Biology* 1.

<sup>102</sup> Victor de Lorenzo, Louis Serrano, Alfonso Valencia, ‘Synthetic Biology: Challenges Ahead’ (2006) 22 (2) *Bioinformatics* 127-128.

<sup>103</sup> Prof. Kitney, Imperial College MRes course lectures (Jan 2012).

may be pre-developed for specific applications. The fourth approach is to focus on parts, devices and systems where modularity, characterization and standardization are key challenges. This systemic approach to design aims to produce systems and networks that perform tasks and accurately reproduce same part for same function.

#### 4.1 De-skilling

The key end point of synthetic biology is industrial application.<sup>104</sup> One of the methods to arrive at successful applications is to master the modularity of parts and devices. However, a key challenge is unpredictability and problems in scaling up. Prof. Kitney describes this effort as akin to moving from laborious processes for the production of elegant Chippendale furniture to the industrial production of Ikea pieces, involving at its core, a process of de-skilling.<sup>105</sup> While only limited creativity may be possible with a given Ikea piece, the elegance derives from the process of standardization itself and the management of unpredictability that it involves.

The de-skilling within biological networks and systems will allow those with limited knowledge to use the parts. Where successful, no great expertise will be necessary to put modules together once they have been predictably standardised. This opens up the possibility of innovative behaviour to almost everyone who can order components online, akin to software programming in the 1980s. Location of experimentation and innovation will become defused with the result that prior art will be difficult to locate or document. Like the early computing machines, prior art can be expected to be embedded within the innovations themselves much like programming code.

Drawing analogy with the open source software effort, modular technologies may be made available through *open access* or *open source*. The former will only allow usage of a standardised part whereas the latter will support future innovations as it involves the disclosure of the internal workings of the part. Extending the Ikea furniture analogy, open access would provide only the right amount of nuts and screws and panels with a highly ordered set of instructions. Open source will provide multiple versions of different components like multiple kinds of hinges and provide avenues for producing something different from the instruction sheet.

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<sup>104</sup> *ibid*

<sup>105</sup> *ibid*

## 4.2 Sharing Innovation Platforms and Norms

Synthetic and systems biology today has a number of platforms where information is shared by users and contributors to improve upon innovations and find technical solutions and fixes to bugs. These platforms are web based and powered by accelerating functionality on the Internet. Given the history of the open source movement it seems obvious to share bioinformatics tools, but such platforms and databases unusually go beyond software-driven information to include wetware.<sup>106</sup> The main motivation for such sharing appears to be to reduce transaction costs for downstream research which is similar to the impetus behind publicly available genomic databases albeit with a closer amalgam of open and commercial science.<sup>107</sup> An additional motivation is directed towards solving problems collaboratively and the avoidance of duplicated effort. Rai has found that biomedical research in the last 30 years has become increasingly proprietary and secretive. Collaborative models here, therefore, go against the norm, thus raising the potential need for public funding for 'open biology' in contrast to open source software.<sup>108</sup>

One example worth exploring further is standard-setting for synthetic biology.<sup>109</sup> Standards are the result of the recognition of the practical value of choosing to do the same task in the same way and are a crucial part of supporting infrastructure in a technical field. The synthetic biology community led by the BioBricks Foundation has started working on an integrated approach to standards that could be key to industrial applications.<sup>110</sup> Explicitly modelled on the process used by the Internet Engineering Task Force to support and publish the development of Internet Protocol Standards, the effort borrows the 'Request for Comments' (RFCs) mode. The original 'Request For Comments', suggesting Internet protocols, were never intended to be

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<sup>106</sup> See for instance, <[http://openwetware.org/wiki/Main\\_Page](http://openwetware.org/wiki/Main_Page)> accessed 28<sup>th</sup> August 2012.

<sup>107</sup> See RP Merges, 'A New Dynamism in the Public Domain' (2004) 71 U Chicago L Rev 203 and T Caulfield 'Open Science versus Commercialization: A Modern Research Conflict' *Genome Med* 2012 4(2) 17.

<sup>108</sup> AK Rai, 'Open and Collaborative Research: A New Model for Biomedicine' (2005) 131 <[http://scholarship.law.duke.edu/faculty\\_scholarship/882](http://scholarship.law.duke.edu/faculty_scholarship/882)> accessed 28<sup>th</sup> August 2012.

<sup>109</sup> Standard-setting is of primary importance to build infrastructure and make industrial applications possible. 'Towards Standards in Synthetic Biology: A Exploratory Workshop of the EU-US Task Force on Biotechnology Research' (Segovia, June 2010)

<sup>110</sup> A technical introduction to the challenges of standard-setting is provided by Adam Arkin, 'Setting the Standard in Synthetic Biology' (2008) 26 *Nature Biotechnology* 771.

finished products but deliberately exposed internal architecture to make it easy for subsequent innovators.<sup>111</sup>

However, the mimicking of standard-setting on the Internet can potentially differ in at least three very significant ways. In 1968, when the first RFC was written, there was no financial incentive to control Internet protocols through patents. Early pioneers of the Internet were steeped in a hacker culture that existed in federally-funded labs and were motivated by the communal enterprise of producing knowledge.<sup>112</sup> Synthetic biology is an infant of the patent age. Rai cites a report by Walsh that only 13% of biologists felt comfortable talking to people outside their lab<sup>113</sup>, emphasizing the role of secrecy in biomedical research. This is partly because the publication or credit model is very strong in biology and limits motivations to share information.<sup>114</sup> Thirdly, over the years the community that contributes to Internet protocols has built up strong reputational incentives to do so. Unless similar norms develop in biology, shared innovation platforms are unlikely to succeed. In biology this would require that contributions to standard-setting and integration technologies be supported by research councils, the tenure process and universities, as valuable knowledge contributions that evidence skill and calibre. Additionally, public funding in the early years for shared innovation platforms may suppress the desire to gain exclusive rights and support the development of new norms of sharing.

### 4.3 Integrally Multi-disciplinary

Biology has benefited greatly from paradigms derived from artificial intelligence, in silica modelling and digital circuitry and this is being actively played out in synthetic biology. For example, the field of nanoscale biocoordination polymers<sup>115</sup> brings nanotechnology to synthetic biology. Artificial gene circuits have been

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<sup>111</sup> Stephen Croker, 'How the Internet Got Its Rules' *New York Times* (New York 6 April 6 2009) <[www.nytimes.com/2009/04/07/opinion/07crocker.html?\\_r=1](http://www.nytimes.com/2009/04/07/opinion/07crocker.html?_r=1)> accessed 28<sup>th</sup> August 2012.

<sup>112</sup> Or Mertonian modes of production. See Rai (n 109) endnote 12.

<sup>113</sup> Rai (n 109). Also see Rai, 'Open Source Biology: The Role of Law' Duke University 2/17/2005 Available here <[www.youtube.com/watch?v=Gydv6oieBE8](http://www.youtube.com/watch?v=Gydv6oieBE8)> accessed 28<sup>th</sup> August 2012.

<sup>114</sup> *ibid*

<sup>115</sup> Liu and Tang, 'Nanoscale Biocoordination Polymers: Novel Materials from an Old Topic' (2012) 18 *Chem. Eur. J.* 1030 proposes the construction of nanoscale biocoordination polymers through replacement of synthetic organic molecules with natural biomolecules as building blocks, with potential breakthrough biological applications.

proposed to be embedded into microbial cells that function as switches, timers, oscillators, and Boolean logic gates. Understanding complicated networks, such as cellular phenomena that arise from the interactions of genes with proteins, features that make cells operate reliably in diverse conditions, and how cells are responsible for reliable operations are fundamental questions. The idea is to separate complicated networks into many simpler ones that resemble the modules of gene regulation. Building more complex systems from these basic gene circuit components is a key goal for biologic circuits design even though the in silica modelling remains unstable and uncertain.<sup>116</sup>

The integral multi-disciplinarity in synthetic biology sets up the legal problem of delineating the PSA - what does he know and how does he behave? Given the levels of unpredictability in synthetic biology, is he more tolerant of risk and uncertainty than can be expected in other fields? Must we expect the early synthetic biologist to behave unexpectedly in making research decisions? How fluid is the team of scientists that almost certainly will make up the PSA in synthetic biology?

Peer-reviewed publications in these early years will certainly be used to give content to the characteristics and knowledge of the PSA in the next decade and it may be beneficial to encourage a more reflexive archival function. For example, it would be interesting to know whether journals reporting on advances in synthetic biology are more tolerant of unpredictability and instability in experimental results. Are they more open to conceptual analysis to fill in gaps in knowledge than in other fields and what would this mean for the PSA standard in 10 years time? We can expect current attitudes in peer review to inform the 'credibility' of scientific claims made in litigation over the next decade. If contemporary scientists and peer-reviewed journals were more reflexive about the information they generate, there is a strategic possibility that they could direct the future content of the law now.

The reliance on digital technologies brings the troubling aspect of the patentability of computer-implemented inventions - a possibility in synthetic biology that Rai and Boyle describe as the 'perfect storm', as it has the potential to bring together the worst aspects of legal controversies in patenting biotechnology and computer programs.<sup>117</sup> Patentability of computer-implemented inventions is notoriously

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<sup>116</sup> Chen and others, 'Robust Design of Biological Circuits: Evolutionary Systems Biology Approach' (2011) *J of Biomedicine and Biotechnology* doi:10.1155/2011/304236

<sup>117</sup> Rai and Boyle, 'Synthetic Biology: Caught Between Property Rights, the Public Domain and the Commons' (2007) 5(3) *PLoS Biol* 389.

complicated even after 20-30 years of sustained litigation (or perhaps because of it). In essence, the complication arises from the near impossibility of separating pure mathematical or computing methods (that are not patentable) from the application that it drives (that ought to be patentable).

The assessment of the patentability of ‘computer-implemented inventions’ is particularly relevant to bioinformatics. In trying to develop ways to analyse eligibility for patents, the Boards of Appeal of the EPO have developed legal principles that lower the threshold bar of patentability through watered-down definitions of ‘technical’, and move the focus instead to inventive step. To all intents and purposes, this development co-opts the PSA heuristic in deciding which inventions ought to be patentable. The question of what ought to be patentable requires a purposive understanding of why certain inventions are excluded from patentability in the first place. The use of the PSA in fact-specific assessments makes limited allowance for discussion about inherent patentability. A good example of how this heuristic is co-opted in a bioinformatics context at the cost of policy-based reasoning is provided by a recent case.<sup>118</sup>

The principal claim in this patent is directed to a five-step method of determining the genotype at a locus within genetic material obtained from a biological sample. In step A the genetic material produces a reaction value, steps B to E are mental activities performed, based on the application of mathematical methods. The core of the invention as claimed by the patentee is about establishing a set of probability distributions, and applying the reaction value to each pertinent probability distribution and determining the genotype based on this data.

Generally, when there is a mix of ‘technical’ (step A, because of the use of genetic material) and ‘non-technical’ features (steps B to E as they are mental activities), the invention is considered to be ‘technical’ as per the low threshold bar of the EPO. Once the threshold patentability question is summarily considered and answered in the affirmative, the analysis then moves on to the question of inventive step. Generally, if non-technical features interact with technical features they can also be considered when evaluating the ‘inventiveness’ of an invention. Thus here the crucial question is whether the mathematical methods provide a ‘tangible technical result’ because they are central to determining the genotype of the biological sample,

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<sup>118</sup> Case T-0784/06 *Beckman Coulter Inc. v Roche Diagnostics GmbH* [2010 (EPO (Technical Board of Appeal))

or whether they are just too general to provide any technical contribution beyond a trivial one.<sup>119</sup>

Based on the facts here, the TBA decided that the mathematical reasoning, starting from an actual experimental value and ending with the determination of a precise genotype, was not described in sufficient detail. Part of the process employs software called GetGenos, specifically developed by the inventors and which had not been reasonably described. The mathematical methods, taken on their own, therefore made no sense. The person skilled in the art would not know how to proceed from step A to step E, which in turn means that there is no interaction between the 'technical' and 'non-technical' aspects of the invention leading to a 'tangible technical result'. Hence the mental activities of steps B to E are to be disregarded in assessing inventive step. This leaves step A – comprising reacting the material at the locus to produce a first reaction value indicative of the presence of a given allele at the locus – a process that already exists in the prior art and is therefore unpatentable.

The case itself has implications for the patentability of *in silico* modelling, but the real implications lie in the choice of cognitive heuristics. It should have been possible and open to the EPO, based on the wording of Art 52(2), to exclude this particular invention as consisting largely of mental processes and/or mathematical methods, both of which are explicitly excluded as non-patentable inventions. Instead, the use of the inventive step standard and through it, the PSA, is significant. It allows the EPO to refer to a sort of 'higher authority' – the objective and reasonable (and therefore presumably, unprejudiced) PSA, rather than resort to innovation policy that would fit the purpose of the exclusions better but may prove controversial.

The increasing operationalization of legal principles also runs the risk of 'patentability by creep' where incremental changes to the attitudes or knowledge of the PSA leaves us with questionable standards of patentability that routinely bypass normative evaluations. However, as per the paradigm presented in this paper such learning constraints are to be expected. Closer policy oversight of patentability standards is therefore legitimate and may even be indispensable in the case of emerging biotechnologies.

#### 4.4 Proprietary and Non-Proprietary Information

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<sup>119</sup> *ibid* p 14.

Open-source synthetic biology represents a confluence of ideas from the open-source software and biology movements. The strategy borrows ideas like open technology platforms and technical standards to allow for greater collaborative work as well as the dissemination of data. Leading open science initiatives such as the BioBricks Foundation, the iGEM competition and the Bioconductor project, which seeks to ‘collaboratively create extensive software for computational biology and bioinformatics’, have received considerable attention from both scientists<sup>120</sup> and social science commentators.<sup>121</sup>

However, in synthetic biology there seems to be a level of comfort among scientists about biological parts, processes and information circulating in common but also being used privately and for exclusionary purposes, in contrast to the extreme version of the copyleft movement.<sup>122</sup> User-driven innovation creates multiple end points for the proliferation of exclusive intellectual property rights because legal frameworks currently governing open data and innovation in synthetic biology do not appear to have a viral element to them. For example, the Registry of Standard Biological Parts ([partsregistry.org](http://partsregistry.org)) does not oblige users who take the parts and make other devices with the parts or subject it to modifications to make their creations available on the same open basis:

The BPA [Biobricks Public Agreement] is a scaleable contract among parties, not a copyright-based license ... the BPA is a contract between one person who wants to make a genetically encoded function free to use and someone else who wants to use it freely. As a second major difference between the BPA and the GPL, there is no required ‘give back’ or ‘viral’ clause in the BPA.<sup>123</sup>

This hybrid openness does not thus preserve the open model for second or third generation biological parts or applications.

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<sup>120</sup> B Canton and others, ‘Refinement and Standardization of Synthetic Biological Parts and Devices Nature Biotechnology’ (2008) 26(7) 787.

<sup>121</sup> J Zhang, C Marris and N Rose, ‘The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the ‘Art’ of Governance’ (2011) BIOS Working Paper 4 1.

<sup>122</sup> Copyleft is a general method for making a program (or other work) free, and requiring all modified and extended versions of the program to be free as well <[www.gnu.org/copyleft/](http://www.gnu.org/copyleft/)> accessed 28<sup>th</sup> August 2012.

<sup>123</sup> <<http://biobricks.org/bpa/faq/#3>> accessed 28<sup>th</sup> August 2012.

Additionally, some technologies and processes have been made available in two different versions - the 'for profit' proprietary version and the 'for sharing' open version. For instance Tom Knight's BioBricks - a technology for stitching and assembling sequences - was redesigned by him for industrial applications. The proprietary version can assemble up to ten parts in a single reaction while the non-proprietary one could only link three.<sup>124</sup>

There are other reasons why an open strategy may appeal to synthetic biologists. There is now clear evidence of exclusionary behaviour among scientists, of withholding scientific data for either money or competition.<sup>125</sup> This problem of access has led to sustained efforts in the US to 'minimize exclusionary behavior by requiring scientists and research institutions to put data and certain types of research tools into the public domain or at a minimum license them widely and non exclusively for a reasonably fee.'<sup>126</sup>

At least in the US, due to the way the Bayh Dole Act is applied by universities, scientists are severely restricted in making use of intellectual property that has been produced in employment,<sup>127</sup> except if that intellectual product was non-exclusive in the first place. Contributing to public platforms allows scientists to take the information with them if they move from one university to another, or even to a private firm. Other commentators have noted that the excitement with which open source biology is being received is largely because it is seen as solving the problem of access to intellectual goods that we have seen develop in biotechnology.<sup>128</sup>

In the UK too, there is considerable uncertainty about the true scope of the research use exception even in the case of publicly funded universities, as they are

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<sup>124</sup> M Baker, 'The Next Step for the Synthetic Genome' (2011) 473 Nature 473 403.

<sup>125</sup> J Walsh, 'For Money or Glory? Secrecy, Competition and Commercialization in Science' (2004) Presentation at American Sociological Association, cited in Rai (n 108) endnote 29.

<sup>126</sup> Rai (n 108). Arti Rai notes a number of initiatives such as National Research Council *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences* (National Academies Press 2003); NIH, 'Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice' (1999) *Federal Register* 64.

<sup>127</sup> *Madey v Duke* 307 F 3d 1351 (Fed Cir 2002)

<sup>128</sup> K Nolan-Steveaux, 'Open Source Biology: A Means to Address the Access and Research Gaps?' <[www.chtlj.org/sites/default/files/media/articles/v023/v023.i2.Nolan-Steveaux.pdf](http://www.chtlj.org/sites/default/files/media/articles/v023/v023.i2.Nolan-Steveaux.pdf)> accessed 28<sup>th</sup> August 2012.

increasingly conducting research in collaboration with private concerns.<sup>129</sup> Such research cannot therefore be regarded as ‘non commercial’. Gower in 2006 also pointed out that the additional requirement that research be ‘private’ (interpreted as ‘non-public’), in order for the exception to apply, is problematic. There is ‘concern that if research has to be ‘non-public’ to be exempt, then publicly funded research that is, as a condition of funding, disclosed may not also qualify for the research exception.’<sup>130</sup> The interpretation of ‘private’ as ‘non public’ clearly has direct impact on public databases as well as innovation platforms under both open access and open source constraints. Given judicial will and the right instance of litigation, it would be relatively simple for courts to clarify that ‘private’ research can result in public disclosure and still be within the scope of the research use exception. The legal resolution of this issue may be more difficult if that public disclosure results in or leads to profit (to establish employability or to seek commercial funding for instance).

Additionally, in the UK inventions made under an employment contract are owned by the employer; and the terms of the employment can evolve and extend beyond the contract of employment itself. This includes inventions even, arguably, in cases where the invention may not be patentable.<sup>131</sup> Potentially, this could encompass information such as pure computer programs or raw biological discoveries, which are ‘not to be regarded as inventions.’<sup>132</sup>

Research staff at publicly-funded universities in the UK, who engage in public platforms for synthetic biology run the risk of constrictive interpretation of the ‘research use’ exception and of uncertain rules that govern the ownership of ‘inventions’ made in the course of employment. In most universities copyright policy is clearly displayed near photocopiers and libraries. A similar drive to disseminate information about the scope of the research use exception, uncertain as it is, and rules of ownership of inventions when in employment, may prove beneficial and empower researchers to work around potential blocks.

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<sup>129</sup> For a comparative review of the experimental use exception see Mathew Rimmer, ‘Patents and Experimental Use’ Issues Paper, Advisory Council on Intellectual Property Enquiry.

<sup>130</sup> Gower’s Review of Intellectual Property (November 2006) 46

<sup>131</sup> This controversial point was alluded to but not fully resolved in *LIFFE Administration and Management v Pavel Pinkava* [2007] RPC 30 para 89.

<sup>132</sup> *ibid*

Synthetic biology patents so far appear not to have generated the same level of angst among academic scientists that we saw surrounding the patenting of raw genomic information.<sup>133</sup> A simple search for US patents on Google Patents in 2010 containing the phrase ‘synthetic genes’ showed at least 56 patents. There is also the possibility of synthetic gene copyright for ‘original works of authorship’; - a requirement that may be met by engineered DNA but not naturally-occurring DNA. Table 1 shows a selection of patents that encompass key technologies for synthetic biology. Note the profile of the prior art cited and the academic inventors.

Open source biology has several implications for the evaluation of inventive step standards in the US and UK/Europe. First, by making some and not other information openly available, platforms such as BioFab, the BioBrick Foundation and BioConductor are in effect making it harder to get patents that encompass basic technology but easier to develop more sophisticated technologies and processes. This will, whether by design or inadvertence, preserve patentability of subsequent generations of biological parts but raise the threshold bar of inventiveness. In effect it amounts to a ‘spoiler’ strategy of publishing patent-defeating prior art that is not uncommon in patent law.<sup>134</sup>

The second related point is that the spoiler strategy will only work if patent examiners are aware of what is transpiring in the field. The non-exclusive nature of the open strategy will mean an inevitable spread of prior art in unconventional locales, such as sophisticated web-based infrastructures, and embedded within a highly engaged global community of synthetic biologists from multiple disciplines. This spread of prior art projects problems with software programming code and genomic information to several degrees of complexity due to the range of technologies involved. Patent examiners trained perhaps in conventional biotechnology or computing may not be able to access information available in open or hybrid platforms in an unconventional format

#### 4.5 Unpredictability and Risk

Although there are claims that SB has grown exponentially in the last few years, the field has many fundamental macro-level problems as well as micro ‘bugging’

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<sup>133</sup> S Thambisetty, ‘Human Genome Patents and Developing Countries’ (2002) 10 CIPR <[www.iprcommission.org/graphic/documents/study\\_papers.htm](http://www.iprcommission.org/graphic/documents/study_papers.htm)> accessed 28<sup>th</sup> August 2012..

<sup>134</sup> S Baker and C Mezzetti, ‘Disclosure as a Strategy in the Patent Race’ (2005) 48 Journal of Law and Economics 173; G Parchamovsky, ‘Publish or Perish’ (2000) 98 Michigan Law Review 926.

problems. The metaphor of reducing biotechnology to software engineering reveals much, as ‘the experience of most people of software is that it is buggy, unreliable and annoyingly difficult to use, and obsolete almost from the moment you buy it.’<sup>135</sup> Some of the mismatch between contemporary promissory narratives and the actual scientific progress being made is about the natural unpredictability of science; some of it is about inflated claims in synthetic biology that do not work; and yet other aspects appear to indicate a truly unpredictable field.

Experimental uncertainty in emerging technologies can, in Ackoffian terms, be a mixture of messy scientific problems and some merely difficult technological ones.<sup>136</sup> A mess evokes no clear agreement about exactly what the problem is, and is unbounded in terms of the time and resources it can absorb. A difficulty, on the other hand, is characterised by broad agreement on the nature of the problem and by some understanding of what a solution would look like, and is bounded by time and resources required for its resolution. To give an example from synthetic biology, predicting the metabolic network of actual organisms by deleting genes at random, one by one to assess or isolate functional modules, can be a difficult problem. This has been done to 80% accuracy for a relative of E.Coli, *Buchnera Aphidicola*.<sup>137</sup> But a ‘recalcitrant’ living system that actively opposes ‘engineering’ or ‘synthesization’ in its own likeness can present a messy problem. Designing genetic switches, circuits and networks requires predictable molecular components and methods of programming biological behaviours – a problem that seems to fall somewhere between difficult and messy.

Does unpredictability in synthetic biology go over and beyond ‘normal’ risks in experimentation? For example, we are told that few synthetic biologists work with more than ten genes at a time.<sup>138</sup> Keasling’s achievement in making a precursor of artemisinin using a dozen or so genes from multiple species is undercut by the (to some) disproportionate time and expense involved.<sup>139</sup> Another example is the use of Bio-Brick type methods – a process that allows desirable parts or nucleotides to be ‘stitched’ together. But reactions are less successful with longer molecules,

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<sup>135</sup> R Jones, ‘Three Things That Synthetic Biology Should Learn from Nanotechnology Soft Machines: Thoughts on the Future of Nanotechnology from Richard Jones’ (2011) <[www.softmachines.org](http://www.softmachines.org)> accessed 28<sup>th</sup> August 2012.

<sup>136</sup> R L Ackoff, *Redesigning the Future: a Systems Approach to Societal Problems* (John Wiley and Sons 1974).

<sup>137</sup> Royal Society *Scientific Discussion Meeting on Synthetic Biology Summary*, (2008) 8.

<sup>138</sup> Baker, (n 125) 404.

<sup>139</sup> Kwok, ‘Five hard Truths for Synthetic Biology’ (2010) 463 *Nature* 288.

discouraging long assemblies. When it comes to designing new genomes, computational models are not as good as they are at modelling existing genomes. As more genes are brought into the system, uncertainty goes up exponentially, and modelling fails.<sup>140</sup> Synthetic biologists appear to be caught up in a laborious process of trial and error unlike more predictable aspects of modern engineering disciplines.<sup>141</sup>

On an industry-wide level, a major question for synthetic biology is the credibility with which silicon modelling can be transposed to genetic material. Are the bioinformatics tools that define the genetic material more important than the material itself? If not, then with what specificity can we claim to predict biological processes and systems, particularly when they are scaled up? Engineerization is largely about standardization, but biological systems and processes are predictably unpredictable. In such a case, it may be legitimate for patent offices to demand heightened standards of experimental evidence or disclosure in order to develop credibility markers. However such per se rules specific to particular technology sectors are uncommon and controversial in patent law.<sup>142</sup> Human gene therapy patent examination at the USPTO is a case in point where there is a presumption that the field itself is unpredictable.<sup>143</sup>

The EPO has never before considered the morality of inventions on the back of serious risk assessment under Art 53(a). In the oncomouse case the question was raised as to whether genetically modified mice could pose a risk if they escaped into the environment. The EPO was satisfied that the regulation governing the containment of such animals used in experimentation meant that the risk was minimal and not enough to raise the spectre of immoral and unpatentable inventions.

There is also a possibility of risky experimentation, compounded by the intended increase in de-skilling several of these technologies. Patent law is not the right sphere to regulate scientific research; however, the question of unacceptable risk in the case of potential commercialization of an invention through the patent system is likely to be raised in the future. If the EPO adopts its predictable decision-making paradigm described in 3 above, then we can expect it to be disinclined to consider

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<sup>140</sup> Baker, (n 125).

<sup>141</sup> Kwok (n 140).

<sup>142</sup> A Devlin, 'Systemic Bias in Patent Law' (2011) 61 De Paul L Rev

<sup>143</sup> USPTO, Revised Interim Utility Guidelines Training Materials (1999) Example G

risk as a serious ground for exclusion from patentability. An analysis of acceptable levels of risk in the context of exclusion from patentability is a learning need that must be undertaken now in order to facilitate decision-making by patent offices.

### **Synthetic Biology as an Emerging Biotechnology: Guidelines to Address Learning Needs and Constraints in the Patent System**

1. A systematic mapping of unconventional locations and formats of prior art must be undertaken either by the UKIPO or another Government body aided by contemporary experts in the field.
2. Contemporary scientists and peer-reviewed journals must be incentivised to develop a reflexive archival function about research processes and decisions with a view to informing the person or team skilled in the art and inventive step standard in future years.
3. Anticipatory legal analysis of patentability of bioinformatics tools and the scope of the exclusion of computer-implemented inventions would be worthwhile, given patent office learning constraints.
4. Unpredictability and risk assessments in synthetic biology are relevant for standards of inventiveness and the exclusion of inventions the commercialization or exploitation of which may be unethical, respectively. The scope of the Biotech Directive in this context must be explored. Patent office learning needs could be met in consultation with contemporaneous scientists in the field.
5. Open source biology is not driven by the same research and development ethic as open source software and is much more subject to the possibility of exclusivity of data and restricted access due to patents. Public funding in early years for shared innovation platforms will directly contribute to the infrastructure in synthetic biology.
6. Alternate reputational incentives for the development of technical standards and integration technologies through research council funding guidelines, tenure processes and universities would yield valuable

results. Such incentives will directly encourage norms of sharing and help supplant patents in the early years.

7. Greater clarity and information on the research use exception will help curb the real and imagined chilling effect of patents. Flagging up key patents will help publicly funded and commercial scientists in this respect.

8. Certainty about the ownership of inventions and unpatentable information developed during employment would be valuable. Open access and open source may be valuable strategies to escape employer control over innovations.

9. Synthetic biology appears to be post open-source, given the level of juxtaposition of exclusive and non-exclusive information. It would be beneficial to consider principles on which access to exclusive information may be negotiated when key patents with potential blocking effects arise.

10. Emerging technologies present narrow windows of opportunity to set strategic policy and legal agendas. Policy-makers must not be discouraged by the structural characteristics of the patent system nor by the epistemic nature of the patent community. Inflection points for policy intervention in synthetic biology could be actively explored in consultation with contemporary scientists.

**Table 1: Patents in Synthetic Biology**

The following table profiles a handful of patents in synthetic biology that appear to incorporate key technologies. Information included here demonstrates the science linkage of these patents by noting the immediacy of most of the references – a sign of emergence in a technology. The number of non-patent references compared to patent references and origin of inventors/applicants are also relevant. A large number of claims can indicate breadth and potential future impact on technical advances.

Patent no:	Inventor	Year	NPR	PR	Claims	What is claimed?	Potential Impact?
US7604805 Protein Logic Gates	Wendell, Dauber, Yeh University of California	2009	7	0	3	A major goal in bioengineering is to create designer cells with novel input/output properties. Such rewired cells would have many practical applications, such as inexpensive but sophisticated biosensors as well as therapeutic applications including the repair or reconstruction of defective biological function. Here we describe a new, biologically inspired strategy that can be used to link protein input and output functions that are normally not related. This strategy provides protein signaling switches analogous to logic gates with diverse and novel input/output properties.	This patent presents a very important emerging strategy in credible but hypothetical terms. It appears to have immense blocking potential.
US2010009871 Devices and Systems for the Creation of DNA Cluster Arrays	Mark Reed (Menlo Park) Andrea Sabot	2010	0	0	12	The present invention comprises systems and devices for isothermal amplification of polynucleotide sequences to produce DNA cluster arrays.	Nucleic acid amplification is core technology – the patent claims are very broad. The lack of NPR or PR is striking (and puzzling)
EP1848815B1 Esterases for Monitoring Protein Biosynthesis in vitro	University of Bayreuth	2010	11	2	42	A cell-free translation system comprising a nonsense-codon suppressing agent and an anti-release factor antibody which precipitates and/or crosslinks a release factor in said cell-free translation system. Also, this application relates to the use of such a cell-free translation system for the production of an alloprotein.	Cell free protein synthesis - A rapid and high throughput technology for obtaining proteins from their genes.
US2011009772 In vivo gene sensors	James Collins University of Boston	2011	101	5	49	Methods and compositions for the detection of target genes. The inventors have developed a synthetic nucleic acid sensor-effector gene circuit through	Potentially of great therapeutic value. More than 95 of the references date from 2000 or are more recent. Many of the claims

						which cells expressing a target gene can be selectively targeted for treatment or elimination. The invention permits the selective expression of an agent such as a therapeutic gene product, in a specifically targeted population of cells in an organism.	applying the methods to oncogenes or tumor associated genes, drug resistance or virulence gene appear speculative.
WO201115337 Methods and systems for simulations of complex biological networks using gene expression indexing in computational models	Phelix Clyde, Univ of Texas	2011	0	0	27	This approach allows a model to be generated for any individual organism at any state of life, health condition, or disease/traumatic process. The model can include any or all biological reactions and processes, based on an exact kinetic value. Model systems without and with regulatory steps and mechanisms can be used to assess the present state of the specimen or sample and an acute response to an intervention within the system for the former and to predict some future state or status of treatment by testing single or multiple interventions within the regulated, dynamically responsive system for the latter; providing a prognostic value.	The invention is a method that uses a data set in a modelling system, is broadly conceptualised and appears to cover an infinite number of possibilities for prediction. An interesting example of mathematical modelling, but appears mainly speculative.