SYNTHETIC BIOLOGY: ETHICS, EXCEPTIONALISM AND EXPECTATIONS

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Synthetic biology gives rise to ethical implications. These are already well recognised, with an ever-increasing academic and lay literature and growing attention from policy-makers. What is less clear is whether analysis of ethics in synthetic biology should be 'exceptional'. That is, is there anything about synthetic biology that justifies a distinctive 'ethics of' approach? Likewise, what may or may not be fruitful directions for useful bioethical inquiry in synthetic biology remains under-explored. This paper first synthesises ethical issues arising in synthetic biology. A claim is then advanced that while a purely exceptionalist approach to ethics and synthetic biology is unwarranted, the field nevertheless requires engagement with ethics. Initial suggestions are put forward as to how this might be achieved. The paper then determines several hitherto under-explored lines of enquiry which serve to both further useful discussions of synthetic biology and contribute to the wider project of ethical engagement in emerging technologies.

I INTRODUCTION

Synthetic biology involves the deliberate application of engineering principles to well-defined molecular components to synthesise novel or augment existing biological entities.[1] One aim of this research area is to extend previously limited biological functionalities, or create entirely new ones, in a standardised, defined, and reproducible way. Synthetic biology has become possible due to rapid advances in technologies such as DNA synthesis and engineering.[2] While its practical applications remain putative, its theoretical utility is almost limitless. This combination of research approaches, and its broad array of uses in medicine and the environment, makes synthetic biology a potentially disruptive technology.[3]

This paper will address three interlinked topics. First, the ethical issues that arise, or are likely to arise, in synthetic biology research and its applications are synthesised. As Link has pointed out, these may not be 'debates' as such – discussions regarding ethical issues in the development and application of synthetic biology have been directed more towards

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1 There is no single definition of synthetic biology that is adopted by all who identify as researchers in this field. The description offered in this paragraph is the author's own, based on eight years working in the field. However, a range of definitions of synthetic biology are used in practice. See, eg, News Feature, 'What's in a Name?' (2009) 27 *Nature Biotechnology* 1071, 1071–3; Alexander Kelle, 'Synthetic Biology as a Field of Dual-Use Bioethical Concern' in Brian Rappert and Michael J Selgelid (eds), *On the Dual Uses of Science and Ethics* (Australian National University ePress, 2013) 45, 46–49. Other papers in this special issue of the *Macquarie Law Journal* (*MqLJ*) also define synthetic biology.

2 Jing Liang, Yunzi Luo and Huimin Zhao, 'Synthetic Biology: Putting Synthesis into Biology' (2011) 3 *Wiley Interdisciplinary Reviews: Systems Biology and Medicine* 7, 8–10.

3 James Manyika et al, 'Disruptive Technologies: Advances That Will Transform Life, Business, and the Global Economy' (Report, McKinsey Global Institute, May 2013) 4.

anticipating potential issues.[4] Public attitudes to this technology have generally been positive.[5] However, groups that champion environmental and other interests have also shown an interest in synthetic biology.[6] This scrutiny of the field will no doubt continue.

The paper then examines two interrelated questions: the novelty of ethical issues arising in synthetic biology, and whether its ethical analysis should be regarded as exceptional. Both questions are answered in the negative. However, synthetic biology does give rise to ethical issues and, as such, warrants attention in the discipline of bioethics. Building on this discussion, the third part of the paper then discusses some possible future directions for ethical analysis in synthetic biology.

The paper concludes that there is unlikely to be one straightforward proclamation about the acceptability of synthetic biology. The challenge for bioethics is to develop a reasoned response to synthetic biology that can account for the field's novelty and promise, while at the same time not simply reiterating issues that have been raised in other contexts.

II ETHICS AND SYNTHETIC BIOLOGY

This section will review and synthesise the ethical aspects of synthetic biology and its applications to date. Generally, ethical issues discussed in synthetic biology have not been raised in an attempt to prevent this field of research (unlike in similar fields such as genetic modification). Rather, engagement and bidirectional dialogue between ethicists, researchers and funders have prevailed.[7]

Deliberation over ethical issues has been included in the field of synthetic biology in numerous ways. For example, ethics has been included in programmes for synthetic biology conferences.[8] Research funders providing dedicated resources for synthetic biology research have required researchers to address ethical, legal and social implications.[9] An increasing number of reports are considering the ethical and policy implications of synthetic biology.[10]

The majority of ethics work has evaluated the synthetic biology *as a field*.[11] That is, ethical analysis has tended to examine the implications of synthetic biology research as a whole, as

4 Hans-Jürgen Link, 'Playing God and the Intrinsic Value of Life: Moral Problems for Synthetic Biology?' (2013) 19 *Science and Engineering Ethics* 435, 436.

5 See, eg, Suzanne King and Tara Webster, 'Synthetic Biology: Public Dialogue on Synthetic Biology' (Report, Royal Academy of Engineering (UK), June 2009), 15, 23, 28, 39.

6 See, eg, ETC Group (Canada), 'Extreme Genetic Engineering: An Introduction to Synthetic Biology' (Report, Jan 2007).

7 See, eg, Paul Rabinow, 'Assembling Ethics in an Ecology of Ignorance' (Paper presented at Synthetic Biology 1.0, Massachusetts Institute of Technology, Cambridge MA, 11 June 2004) <http://syntheticbiology.org/Synthetic_Biology_1.0/Speakers.html>.

8 See, eg, Rabinow, above n 7; *Synthetic Biology 3.0*, (24-26 June 2007) <http://www.syntheticbiology3.ethz.ch/extra/SBProceedings.pdf>; See generally *Synbio.org* (2015) <http://syntheticbiology.org/Conferences.html>, which provides a list of previous conferences in synthetic biology.

9 See, eg, Philip Shapira and Abdullah Gök, 'UK Synthetic Biology Centres Tasked with Addressing Public Concerns', *The Guardian* (online), 30 January 2015 < http://www.theguardian.com/science/political-science/2015/jan/30/uk-synthetic-biology-centres-tasked-with-addressing-public-concerns>.

10 See, eg, Andrew Balmer and Paul Martin, 'Synthetic Biology: Social and Ethical Challenges' (Institute for Science and Society, University of Nottingham, May 2008); Erik Parens, Josephine Johnston and Jacob Moses, 'Ethical Issues in Synthetic Biology: An Overview of the Debates' (Woodrow Wilson International Centre for Scholars, 2009); Presidential Commission for the Study of Bioethical Issues (US), *New Directions: The Ethics of Synthetic Biology and Emerging Technologies* (2010).

11 Patrick Heavey, 'Integrating Ethical Analysis "Into the DNA" of Synthetic Biology' (2015) 18 *Medicine, Healthcare and Philosophy* 121, 121.

opposed to critiquing individual projects or applications within it. There are likely several reasons for this. First, when ethical analysis within synthetic biology commenced, not a great deal was known about particular applications and so it was necessary to take a broad approach. Second, synthetic biology has some novel unifying features. Despite there being no single definition or approach, these 'new' features provide a basis for ethical analysis.[12] Third, while individual projects in synthetic biology are beginning to give rise to novel data and results, such projects are more fundamental (and perhaps aligned with more 'standard' research in disciplines such as chemistry or physics) and may not have any significant ethical relevance beyond questions such as research integrity. Fourth, undertaking implications-based assessments of individual projects may not give much scope for novel ethical inquiry. Finally, there is much about synthetic biology when viewed *as a field* that is ethically relevant and interesting. For example, agenda-setting and reflection on modes of working can and should be subject to ethical inquiry.[13] Analyses are commencing to determine how the field as a whole should move forward. Looking at synthetic biology as a field, the ethical and conceptual issues raised in the literature can be classified as follows: defining and creating life; biosafety and biosecurity; benefit sharing; professional ethics and integrity; and regulation and policy-making. Each of these considerations will now be synthesised.

A *Synthetic Biology and the Definition and Creation of 'Life'*

Synthetic biology has already been used to generate a synthetic genome,[14] and efforts to synthesise minimal cells from simple organisms such as yeast are underway.[15] While not yet possible, future research in synthetic biology could generate novel 'living' entities capable of activities such as self-replication, energy consumption and use. Potential applications of synthetic biology raise numerous philosophical and ethical questions, among them: (i) What properties should an entity possess in order for it to be termed 'alive'? (ii) Is research in synthetic biology that gives rise to new biological entities that are alive warranted? (iii) Should the manner in which an entity came to be alive matter? (iv) If a living entity is created, at what point should that entity have rights normally ascribed to those possessing moral status and thus a right to life? It is beyond the scope of this paper to address these questions in depth, but each will be briefly considered.

With respect to (i) the definition of life, or the properties that an entity should possess to be termed 'alive', there are claims in the literature that a single definition is not possible nor would such a definition be stable.[16]

On question (ii), whether synthetic biology should be used to create new life forms, an absolutist approach is unlikely due to the varying kinds of entities that may be created in different contexts. Nevertheless, the question is a useful guide to the relevant ethical considerations. Those cautious about creating new life forms will point to the fact that as yet,

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12 This point is considered further in the final section of this paper.

13 Thomas Douglas and Julian Savulescu, 'Synthetic Biology and the Ethics of Knowledge' (2010) 36 *Journal of Medical Ethics* 687, 687; Wendy Rogers, 'Ethical Issues in Synthetic Biology: A Commentary' (2015) 15 *Macquarie Law Journal* 39.

14 Daniel G Gibson et al 'Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome' (2010) 329 *Science* 52.

15 Jane Calvert and Emma Frow, 'The Synthetic Yeast Project as a Topic for Social Scientific Investigation' (2015) 15 *Macquarie Law Journal* 27.

16 Balmer and Martin, above n 10, 26–29; Editorial, 'Meanings of "Life": Synthetic Biology Provides a Welcome Antidote to Chronic Vitalism' (2007) 447 *Nature* 1031, 1032. The European Commission has claimed that synthetic biology will give rise to calls for a more sophisticated definition of life. See New and Emerging Science and Technology (NEST) High-Level Expert Group, 'Synthetic Biology: Applying Engineering to Biology' (Project Report No EUR 21796, European Commission, 2005) 19 <ftp://ftp.cordis.europa.eu/pub/nest/docs/syntheticbiology_b5_eur21796_en.pdf>.

very little is known about the possible benefits. Although researchers have established key components of biological knowledge, such as the sequence of the human genome, research to determine the *function* of genes and *regulation* of gene expression in complex organisms is less developed. The risks associated with creating completely new organisms, particularly if they are to be released into the environment, should be carefully considered.[17] There is also a concern that creating life may mechanistically reduce the complexities of life to engineering principles.

In reply, it may be claimed that the benefits of creating new life forms should not be discounted before research is undertaken. Some synthetic biology researchers are working towards developing new life forms, but only on a small scale, and with careful design and oversight. Creating new life forms will also give rise to intrinsic biological knowledge, valuable in its own right. It may inspire awe in life's complexity as opposed to viewing life mechanistically. While risk will be inherent when creating life, this on its own may not be enough to condemn the creation of new life forms, so long as there is accountability and risks are well assessed.

Related to these questions is (iii), whether the manner in which an entity came to be alive should matter. It could be claimed that the properties of an entity denoting it as 'living' are all that are needed. Others, perhaps those who value the 'natural' or 'naturalistic' concepts of life, may argue that the mode of creation of a life and the intent in such creation are also important. However, a consensus seems to be emerging that the former of these positions is more relevant to ethical deliberation. Namely, we should look at the properties of an entity to determine its moral status, not how that entity was made. To this end, demarcating between 'natural' and 'artificial' means of creating life is likely to be unhelpful and unnecessary.[18]

The final question (iv) asks at what point a new life form created by synthetic biology attains moral status. This question is motivated by a concern that if synthetic biology can create new (and potentially complex) entities, then we need to know how to treat them. It may be ethically inappropriate to create new entities that have moral status, but then treat those entities poorly. If the answer to (iii) is that it is justifiable to separate 'natural' and 'artificial' life forms, and to treat them differently depending on their origins, then this final question may be moot. However, consensus is emerging that the rights of artificially created living entities should not depend on their mode of creation.[19] If correct, this means it would be inappropriate to apportion different ethical significance to entities created in different ways. If mode of creation is irrelevant to moral status, then the focus shifts to a more classic investigation as to the properties of a living entity that afford it moral status, and accordingly, certain rights. These properties remain contested, but may include sentience, the ability to feel pain, and the ability to conceive of oneself as a being with a past and a future.[20] Mere biological life is not enough. It is therefore reasonable to suggest that not all living entities created through synthetic biology will have a status deserving of moral respect.

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[17] This point is considered further in the discussion of ethical issues and policy and regulation in synthetic biology.

[18] David Heyd, 'Is There Anything Unique in the Ethics of Synthetic Biology?' (2012) 55 *Perspectives in Biology and Medicine* 581, 583–584, 586; Simon Heuksen, 'Artificial Life and Ethics' (2014) 8 *Nanoethics* 111, 112–114; Thomas Douglas, Russell Powell and Julian Savulescu, 'Is the Creation of Life Morally Significant?' (2013) 44 *Studies in History and Philosophy of Biological and Biomedical Sciences* 688, 696.

[19] Bernard Baertschi, 'The Moral Status of Artificial Life' (2012) 21 *Environmental Values* 5, 16–17; Link, above n 4, 437; Douglas et al, above n 18, 696.

[20] Ainsley Newson, 'Personhood and Moral Status' in Richard Ashcroft et al (eds), *Principles of Health Care Ethics* (John Wiley, 2nd ed, 2007) 277, 281–282.

B *Biosafety and Biosecurity in Synthetic Biology*

Concerns around biosafety and biosecurity are prevalent in the synthetic biology literature.[21] Other papers in this edition have addressed current regulations pertaining to biosafety in an Australian context.[22] From an *ethical* perspective, questions of biosafety and biosecurity can be framed as follows: What measures of safety are ethically appropriate for use in synthetic biology? How should nefarious and worthy applications of synthetic biology technologies be weighed and compared?

Biosafety refers to containment and other measures put in place to ensure safe working with, and use of, potentially hazardous biological agents. Regarding biosafety measures, a key ethical rationale is protection from harm. It is important to ensure the products of synthetic biology do not leave populations or environments worse off. However, it is also important to note that not everything produced in synthetic biology research will have biosafety implications. Some products may be benign or not capable of infection.

Ethical considerations will arise when a balance needs to be struck between regulating scientific conduct on biosafety grounds, which may impinge on scientific freedom, and facilitating open-ended research to encourage beneficial outputs. So-called 'garage biology' is one area where this balancing is relevant. The 'component' approach used in some domains of synthetic biology research lends itself to use by individuals who may not be working within a traditional sphere of scientific research, such as a university or research institute. Questions have been raised as to how the conduct and products of those undertaking garage biology should be monitored and controlled.[23] Another cause for concern builds on the above issue of creating new life forms which may be capable of evolving and changing if and when they are released into the environment. Ethical deliberation may assist in determining the appropriate risk trade-offs and standards of conduct.

Biosecurity can mean both the kinds of protections put in place to ensure biosafety, and the prevention and management of nefarious uses of synthetic biology. For example, with inexpensive DNA synthesis and publicly available virus sequences, it has been possible to construct virulent viruses using mail-order DNA fragments.[24]

Ethical questions relevant to biosecurity include consideration of how to trade off beneficial and potentially harmful uses of the same technology. This is termed the 'dual use' problem. It applies in contexts where the same research can be used for 'both good and bad purposes', specifically 'research that can be used for especially harmful purposes... where the consequences... would be potentially catastrophic.'[25] Dual use problems are not unique to synthetic biology. However, synthetic biology offers a good prototype for their

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21 See, eg, Alexander Kelle, 'Synthetic Biology and Biosecurity: From Low Levels of Awareness to a Comprehensive Strategy' (2009) 10 *EMBO Reports* S23; Markus Schmidt et al, 'A Priority Paper for the Social and Ethical Aspects of Synthetic Biology' (2009) 3 *Systems and Synthetic Biology* 3, 4–5; Jonathan B Tucker and Raymond A Zilinskas, 'The Promise and Perils of Synthetic Biology' [2006] *The New Atlantis* 25 (Spring) 32–34, 37–42; Presidential Commission for the Study of Bioethical Issues (US), above n 10, 71–74, 129–131.

22 Sonia Allan, 'Macquarie University Workshop on Ethical, Legal and Social Issues Raised by Synthetic Biology', (2015) 15 *Macquarie Law Journal* 5; Lisa Eckstein, 'Regulatory Challenges of Synthetic Biology Trials and Other Highly Innovative Investigational Products', (2015) 15 *Macquarie Law Journal* 65.

23 Balmer and Martin, above n 10, 19–20.

24 Jeronimo Cello, Aniko V Paul and Eckard Wimmer, 'Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template' 297 (2002) *Science* 1016.

25 Michael J Selgelid, 'Ethics and Dual-Use Research' in Michael J Selgelid and Seamus Miller (eds), *On the Dual Uses of Science and Ethics: Principles, Practices, and Prospects* (Australian National University ePress, 2013) 3, 4.

consideration.[26] Douglas and Savulescu reflect on the deliberate misuse of synthetic biology and evaluate this dual use dilemma. They coin the term an 'ethics of knowledge' which asks 'whether to pursue and disseminate certain kinds of [potentially very harmful] knowledge' even though benefits would also arise.[27] They claim that this question has so far been overlooked in synthetic biology, as it has been also for other emerging technologies. This approach would complement retrospective ethical analyses of the production of scientific knowledge, as well as prospectively help to resolve dual use problems.

An ethics of knowledge for synthetic biology has not been universally endorsed. Pierce has critiqued this approach, pointing to a lack of consensus as to who should determine the ethics of knowledge.[28] She also rejects Douglas and Savulescu's claim that this is a job (purely?) for ethicists.[29] Pierce further points out the lack of clarity regarding whose interests such a consensus should serve,[30] and concludes by pointing to the complex deliberative processes that would be required to develop a truly representative ethics of knowledge. Would determining acceptable and unacceptable knowledge actually achieve the objective of preventing deliberate harm, or would it merely give that illusion?[31] As an alternative, Pierce suggests an 'ethics of knowledge priorities' to ask 'about which resources we should generate and which should be our priorities, and under what conditions.'[32] This approach is not solely guided by misuse, but by a range of considerations including resource allocation.

C *Benefit Sharing*

Ethical aspects pursuant to benefit sharing in synthetic biology include questions such as whether patenting an artificially synthesised genome is appropriate. For example, the J Craig Venter Institute, which produced the first minimal synthetic genome, patented the sequence of the minimal genome in 2007.[33] Taking a very different approach, the BioBricks Foundation has adopted an open-source model in which anyone can upload or download biological components.[34] Questions also arise about the role of patents and other intellectual property in influencing pricing and availability of products of synthetic biology. For example, the medical and bioremediation applications of synthetic biology could have a significant impact in developing countries, especially where resources are low and needs are great.

Another question, though one not unique to synthetic biology, is how benefits should be justly distributed. For example, concerns have been expressed that synthetic biology could, in the short term, undermine the livelihoods of communities producing natural products that synthetic biology could replace. The paradigmatic example here has been that of anti-malarial drug artemisinin which is produced from a rare natural product by communities with minimal resources. Large-scale synthetic production of artemisinin is now all but a reality. While this could ease the global shortage of this much-needed drug, concerns have been expressed that synthetic artemisinin will be expensive and that the communities which currently produce the natural precursor will be worse off.[35]

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[26] Kelle, above n 1, 62.
[27] Douglas and Savulescu, above n 13, 687, 692.
[28] Robin L Pierce, 'Whose Ethics of Knowledge? Taking the Next Step in Evaluating Knowledge in Synthetic Biology: A Response to Douglas and Savulescu' (2014) 38 *Journal of Medical Ethics* 636, 636–637.
[29] Ibid.
[30] Ibid 637.
[31] Ibid 637–638.
[32] Ibid 638.
[33] Minimal Bacterial Genome, US 20070122826 A1 <http://www.google.com/patents/US20070122826>.
[34] iGEM, *Registry of Standard Biological Parts DNA Submission* (2015) <http://parts.igem.org/DNA_Submission>.
[35] Balmer and Martin, above n 10, 25–26.

Hunter has explicitly considered the role of claims that rely on the concept of justice in debates over emerging technologies, using synthetic biology as an example.[36] He claims that contrary to how they are often used, only rarely can justice considerations block the ingress of new technologies.[37] Hunter argues that while justice should certainly guide *how* a new technology is introduced, it is often problematic in that those supporting them tend to take a short-term view.[38] Instead, justice considerations regarding emerging technologies should be based on a long-term view, although he also claims that even justice concerns that take a longer-term view are not of concern for synthetic biology.[39]

A potential solution to concerns of justice in synthetic biology is to build mechanisms of benefit sharing into the technology's translation. In a different context, Schroeder has offered the following definition of benefit sharing for non-human resources:

> Benefit sharing is the action of giving a portion of advantages/profits derived from the use of non-human genetic resources or traditional knowledge to the resource providers, in order to achieve justice in exchange.[40]

She then offers a separate definition of benefit sharing regarding human genetic resources:

> Benefit sharing is the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers to achieve justice in exchange, *with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services.*[41]

Schroeder justifies a two-definition approach on the basis that human genetic information is the common inheritance of humanity, whereas other resources are part of the sovereign rights of states. However, synthetic biology may challenge this dichotomous approach, or at least extend the application of the definition of human genetic resources to encompass chimeric resources. Synthetic biology may well see biological components or other artefacts being made that *combine* both human and non-human DNA.

It does not seem unreasonable to suggest that a laudable goal for synthetic biology is to reach end points at which benefit sharing is achieved and that this is done in line with a reasonable consensus definition of what it means to justly share those benefits. Where synthetic biology is used to negate the need for a natural resource (such as with the artemisinin example above), perhaps benefit sharing approaches could include assistance for those whose livelihoods in producing natural precursors have been affected.

D *Professional Ethics and Integrity in Synthetic Biology*

Given the open-endedness of research in synthetic biology and its applications, including possibly nefarious ones, engendering researcher responsibility and accountability is paramount. However, such a claim is not straightforward given the diverse methodologies and disciplines involved in synthetic biology, and the various cultural and other factors they incorporate. Engineering, for example, has historically been a discipline that has more overtly taught and addressed aspects of professional ethics, perhaps because many

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36 David Hunter, 'How to Object to Radically New Technologies on the Basis of Justice: The Case of Synthetic Biology' (2013) 27 *Bioethics* 426.
37 Ibid 428, 430.
38 Ibid 433.
39 Ibid 434.
40 Doris Schroeder, 'Benefit Sharing: It's Time for a Definition' (2007) 33 *Journal of Medical Ethics* 205, 207.
41 Ibid 207, 208 (emphasis added).

engineering graduates end up working in the profession. This is not to say that those working in the pure sciences have acted unethically, but perhaps these kinds of considerations have been more implicit. It may be that synthetic biology cannot (and perhaps should not) have *one* professional ethics. Determining researcher responsibility may also lead to similar 'ethics of knowledge' questions as those discussed above.

Synthetic biology could give rise to biological components that self-assemble, self-replicate or display other properties usually associated with living entities. If these components are considered for use outside the laboratory, stakeholders need to feel confident that they have been produced by researchers who have the necessary expertise, who have made a commitment to act with integrity and who appreciate any sensitivities in their chosen field. It has been a very positive occurrence in synthetic biology that so many researchers have been prepared to engage with experts in social sciences, ethics and law to deliberate on the implications of their work.

Beyond the initial question of acting ethically in scientific research, some are questioning whether professionalisation of the field of synthetic biology should be employed as a governance strategy.[42] Professionalisation would involve a central body setting standards for elements of practice such as training and conduct. The body would likely comprise peer-selected experts, thus promoting responsiveness to the community of researchers it will serve. Researchers seeking professional recognition would then be required to demonstrate adherence to these standards. The benefit of professionalisation is that it represents a compromise between internal and external regulation of conduct. That is, researchers would not be left to entirely self-regulate on an individual basis. Neither would researchers be subject to standards or limits that have been imposed from outside the discipline. The interests of broader stakeholders, such as community members and the state, could be incorporated into the standards that are set. Professionalisation would not be the only mechanism of governance, but would form part of a 'web of prevention' of improper conduct.[43]

While attractive, professionalisation is a new concept for science. Questions will arise as to how to agree on standards and training requirements. This would be a big task, one likely to be resource intensive, considering the number of disciplinary approaches and techniques used in synthetic biology research.

E *How Should Synthetic Biology be Regulated?*

Potential regulatory or policy approaches, and possible gaps, regarding synthetic biology in an Australian context are discussed elsewhere in this issue.[44] However, there are also ethical aspects to questions of regulation of synthetic biology as an emerging technology. One such question is whether synthetic biology should be regulated at all. An in-depth answer to this question is beyond the scope of this paper, so for the purposes of this discussion it will be assumed that synthetic biology, like many other fields of inquiry, is already subject to regulation and that a degree of external oversight is warranted.

If it is correct to assume that synthetic biology does need regulatory oversight, a further question arises as to whether synthetic biology requires specific regulation. The answer to

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[42] Lorna Weir and Michael J Selgelid, 'Professionalization as a Governance Strategy for Synthetic Biology' (2009) 3 *Systems and Synthetic Biology* 91, 94–96. Governance options for synthetic biology are briefly surveyed in the next section.

[43] Ibid 95–96.

[44] Allan, above n 22; Eckstein, above n 22.

this question is more complex. On the one hand, as Allan and Eckstein have shown, there is already a range of oversight relevant to synthetic biology in Australia. It is also prudent not to over-regulate or exceptionalise an emerging technology to the detriment of what that technology might achieve. The broad range of disciplines, methodologies and potential applications of synthetic biology (such as in health or environmental remediation) mean that specific laws or regulations may be insufficient to effectively monitor the entire field. On the other hand, it seems clear that synthetic biology could have detrimental outcomes if misapplied or if control is lost. Potentially problematic outcomes may be mitigated, and stakeholder confidence optimised, if there is specific oversight of synthetic biology.

Assuming that some means of regulation will be put in place, even if just for the initial stages of the field's emergence in Australia, a third question that will arise is which regulatory approach to adopt. A brief sketch of some of the predominant regulatory approaches and concepts follows.

Three approaches to governance are anticipatory governance, adaptive governance and responsible research and innovation (RRI). All involve some kind of deliberative engagement with stakeholders. Anticipatory governance describes a set of procedural principles for how to collectively imagine, deliberate, design and influence emerging technologies.[45] Adaptive governance involves analysis of different aspects (such as social and economic) that contribute to multi-level governance, and how these help build resilience in a particular society. It is an integrated and holistic theory. RRI encourages *responsible* practice in research and innovation, undertaking a transparent and interactive process.[46] It involves collective stewardship now to protect the future. RRI has become a predominant framework in which to discuss regulation of emerging technologies, particularly in Europe, where a number of funders have built RRI considerations into funding documentation.[47]

An alternative approach to these kinds of governance strategies is to have more informal oversight, or partnership between researchers and other stakeholders. In the United States, the Presidential Commission for the Study of Bioethical Issues suggested such a strategy when it recommended 'prudent vigilance' to oversee synthetic biology.[48] This is a 'middle way' between having a moratorium, which was proposed and then rejected at the outset of synthetic biology research, and unfettered freedom of self-regulation. Self-regulation overlaps with the above discussion of professionalisation and 'ethics of knowledge'. At the outset of a field that has the potential for controversy, complete self-regulation may not appease all stakeholders.

Within the above governance approaches, questions will also arise as to how possible risks should be managed. Two broad principles relevant to synthetic biology are the precautionary and proactionary principles.[49] The proactionary principle commences with a 'pro' perspective on research, encouraging freedom to innovate on a strong evidence base. Proponents of this perspective aim to protect innovation and avoid costs arising from restrictions on research.

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45 David H Guston, 'Understanding "Anticipatory Governance"' (2014) 44 *Social Studies of Science* 218, 219.

46 René von Schomberg, 'Prospects for Technology Assessment in a Framework of Responsible Research and Innovation' in Marc Dusseldorp and Richard Beecroft (eds), *Technikfolgen Abschätzen Lehren: Bildungspotenziale Transdisziplinärer Methoden* (Springer, 2012) 39, quoted in Richard Owen, Phil Macnaghten and Jack Stilgoe, 'Responsible Research and Innovation: From Science in Society to Science for Society, with Society' (2012) 39 *Science and Public Policy* 751, 753.

47 See, eg, Engineering and Physical Sciences Research Council, *Anticipate, Reflect, Engage and Act (AREA)* (2015) <http://www.epsrc.ac.uk/research/framework/area/>.

48 Presidential Commission for the Study of Bioethical Issues (US), above n 10, 25–27, 123–140.

49 Christopher Wareham and Cecilia Nardini, 'Policy on Synthetic Biology: Deliberation, Probability, and the Precautionary Paradox' (2015) 29(2) *Bioethics* 118; Parens et al, above n 10, 18–22.

The precautionary principle (PP) is widely applied in policy-making. In contrast to approaches more overtly favouring innovation, adopting the PP means that a technology or other innovation should not be widely applied until there is good evidence that it will be safe, or that the risks of its use will not outweigh its benefits. The PP is controversial in bioethics. Critiques of the principle include that it prioritises the current status quo, and that is stymies innovation due to inaction arising from any risk calculation that is inherent to applying the PP. In response, Wareham and Nardini present a modified PP49F that may mitigate these concerns.[50] They describe a deliberative method for collectively arriving at a measure of probability of a harmful event, with a risk being able to be discarded if it falls below that level. They also describe a particular method of determining those risks.[51]

Whatever approach to risk is taken in synthetic biology, there needs to be consideration of cooperative risk management to ensure the beneficial uses of synthetic biology will outweigh its possible misuse.

III Does Synthetic Biology Give Rise to New Ethical Issues, Warranting an Exceptionalist Approach to Ethical Analysis?

Having described and briefly analysed some of the ethical and regulatory issues that have arisen, or will likely arise, in synthetic biology research, this paper will now examine and critique approaches to the analysis of synthetic biology within bioethics generally. Two interrelated questions arise: (i) Does synthetic biology raise new ethical issues? (ii) Can and should there be a distinctive 'ethics of' synthetic biology?[52]

The emergence of a new technology or disciplinary area in bioscience, medicine or health often brings with it a distinct ethical discussion and a slew of dedicated papers. For example, the literature is dotted with papers incorporating terms such as nanoethics, neuroethics and genethics. This kind of practice is subject to critique.[53] It may lead to a repetition of previous debates, it could stymie creative reflection on emerging technologies, and it could fragment bioethics as a field of inquiry.

This section is premised on a claim that there *is* a role for bioethics in discussions about synthetic biology. While this presumption is not uniformly accepted by all scientists working in synthetic biology,[54] the over-arching consensus in the field is that the approaches and applications of synthetic biology have, and will continue to give rise to, ethical implications.[55] What will be apparent from the synthesis of ethical issues in synthetic biology presented above is that the types of issues, questions and approaches to which synthetic biology gives rise are already familiar to scholars in bioethics.

This is not to say that there are no ethical issues arising from synthetic biology, or that the issues are settled. Synthetic biology will clearly have ethical implications in a number of domains. In one of the first reports written on the social and ethical implications of synthetic biology, Balmer and Martin recognised some of the novel aspects of the field of synthetic biology, stating that something 'new and important' is happening.[56] Heyd claims that

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[50] Wareham and Nardini, above n 49, 121–123.
[51] Ibid, 123.
[52] Erik Parens, Josephine Johnston and Jacob Moses, 'Do We Need "Synthetic Bioethics"?' (2009) 321 *Science* 1449.
[53] See, eg, Benjamin Wilfond and Vardit Ravitsky, 'On the Proliferation of Bioethics Sub-Disciplines: Do We Really Need "Genethics" and "Neuroethics"?' (2005) 5 *American Journal of Bioethics* 20, 20.
[54] Personal experience of author.
[55] Link, above n 4.
[56] Balmer and Martin, above n 10, 4, 29.

'synthetic biology does not create any ethical dilemmas that have not already been raised' but that 'the issue is, nevertheless, ethically serious.'[57] Likewise, Brassington has claimed that it 'seems plain that synthetic biology is something that ought to be taken seriously by policymakers.'[58]

However, Brassington also claims 'that there is nothing lacking from the philosophers' toolkit that would be required to address [synthetic biology].'[59] Synthetic biology is unlikely to give rise to *novel* ethical theory. That said, there is nothing wrong with applying known ethical concepts to new research domains, so long as scholars then also 'dig deeper',[60] testing claims that have been made in previous debates (such as in relation to nanotechnology) and any consensus that has arisen, and assessing validity in the new field. There are also opportunities for methodological innovation in bioethics, including novel work on the role of visions and speculation when applied to emerging technologies.[61]

It seems clear that synthetic biology does not present any completely new ethical issues, and that ethical analysis within synthetic biology should not be described as a discrete field of inquiry within bioethics. However, ethical questions, such as the best governance strategy or the appropriateness of an 'ethics of knowledge', have not yet been settled for synthetic biology, or indeed for other emergent and emerging technologies. There are several ethical issues and concepts relevant for synthetic biology, whether or not they have been initially raised elsewhere. There is much scope for rich analysis, and the open-endedness and capacity for creativity within synthetic biology offers opportunities for novelty. As Rogers writes, there is scope for reflecting on aspects of synthetic biology such as agenda setting, the partnership between ethics and science, and the attributes of researchers that ought to be encouraged.[62] This will be a multi-dimensional process. Synthetic biology can draw on, and in turn influence, wider ethical and socio-political analyses of the place of technology in society.

IV MOVING FORWARD: HOW MIGHT ETHICAL ANALYSIS IN SYNTHETIC BIOLOGY BE EXTENDED?

A concern with ethical analysis of emerging technologies like synthetic biology is that analyses often become superficial lists of general issues that might arise. Indeed, this paper is liable to such a charge, although the intention here is not to examine a particular issue in depth but to scope out the current debate and indicate how it might progress. The problem is how to best analyse an emerging technology when its application remains more speculative than tangible. In the prior section it was suggested that synthetic biology does not give rise to novel ethical issues, nor should it be treated as a discrete field of academic inquiry. Nevertheless, synthetic biology offers plenty of opportunities for ethical analysis. In this final section, some suggestions are made as to how ethical analysis in synthetic biology could be extended. Three domains for analysis are briefly outlined: the use of imagination, questions of scope, and fine-grained integration of ethical analysis into synthetic biology research.

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57 Heyd, above n 18, 581.
58 Iain Brassington, 'Synthetic Biology and Public Health: Problems, Politics and Policy' (2011) 1 *Theoretical and Applied Ethics* 34, 34.
59 Ibid 39.
60 Parens, Johnston and Moses, above n 52.
61 This is addressed in the final section of this paper.
62 Wendy Rogers, 'Ethical Issues in Synthetic Biology: A Commentary' (2015) 15 Macquarie Law Journal 42.

A *The Use of Imagination, Vision and Speculation*

A criticism of bioethics scholarship on emerging topics is that when a new area of interest is identified, there is a flurry of activity to identify issues and publish papers before the next topic arises. Scholarship then moves on, yet 'bioethics remains, disappointingly, familiar'.[63] One way this might be addressed is through augmenting how bioethics scholarship is approached, using imagination, vision or speculation to generate detailed ideas about the future of emerging technologies.[64] This is not to say that imagined scenarios are going to be accurate, and there is controversy over how visions and speculation should be used in bioethics debates.[65] However, even if an imagined scenario is incorrect it may still be of use. For example, while the swine flu pandemic was curtailed, the ethical deliberation over aspects of care such as resource allocation and risk-taking by healthcare staff provided valuable ethical insights and contributed to policy development.

The rationale for using vision or speculation to critically reflect on synthetic biology is threefold. First, it may help prevent criticisms that bioethics is repetitive or constantly fragmenting.[66] Second, it may encourage ethical debate in synthetic biology unconstrained by the current practical limitations and relative lack of real-world applications. Third, it reflects the fact that imagination and speculation are inherent to bioethics research. Delineating interesting ideas about the potential of synthetic biology in the future may assist in assessing relevant moral questions and concepts.

B *Analysing Questions of Scope in Synthetic Biology*

Related to considerations involving imagination, the open-ended potential of synthetic biology also has an ethical dimension. Synthetic biology offers unprecedented scope for innovation and application in a number of spheres ranging from health to the environment. This is both exciting and challenging. For example, synthetic biology may remove current limits on what life forms exist. This expansion in scope, as with other emerging technologies such as genome editing (a technology that has some overlap with synthetic biology), may provide a tipping point that requires us to critically reflect on the ethical implications, as well as considering whether current ethical and governance responses are satisfactory.[67]

C *A Finer-Grained Ethical Integration?*

Ethical analysis within synthetic biology has been characterised by scientific engagement with implications of this research right from the field's inception. However, as might be expected, most analysis of ethical and social issues has been undertaken by those who work in these disciplines and not by synthetic biology scientists. There have been some exceptions,

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[63] Angus Dawson, 'The Future of Bioethics: Three Dogmas and a Cup of Hemlock' (2010) 24 *Bioethics* 218, 218.

[64] This section is adapted from research undertaken for the SYBHEL project. See Sybhel, *Synthetic Biology for Human Health: the Ethical and Legal Issues* (2010) <http://sybhel.org/>. The author obtained funding for this project from the European Union (SiS-2008-1.1.2.1-230401). Research on the role of imagination in bioethics was carried out by Research Associate A M Calladine.

[65] See, eg, Gareth Jones, Maja Whitaker and Michael King, 'Speculative Ethics: Valid Enterprise or Tragic Cul-de-Sac?' in Abraham Rudnick (ed), *Bioethics in the 21st Century* (InTech, 2011), 139, 147–154.

[66] This point has been discussed in Part III above.

[67] Ainsley Newson and Anthony Wrigley, 'Identifying Key Developments, Issues and Questions Relating to Techniques of Genome Editing with Engineered Nucleases' (Background Paper, Nuffield Council on Bioethics, 2015), 7, 19 <http://nuffieldbioethics.org/wp-content/uploads/Genome-Editing-Briefing-Paper-Newson-Wrigley.pdf>.

such as 'sandpit' funding initiatives, which have led to inter-disciplinary collaborations.[68] In line with critiques of the 'overview' approaches to ethics and synthetic biology already discussed, some have claimed that integration of ethics into synthetic biology can go even further. Heavey, for example, suggests that each domain of synthetic biology needs in-depth ethical analysis to better account for the 'everyday research' occurring in synthetic biology.[69] This could comprise activities such as encouraging researchers to train in both the scientific and ethical aspects of their field.[70] These individuals could then take a leading role in assessing the implications of discrete projects in synthetic biology, ensuring that analysis of ethical implications is aligned with project expectations. Heavey additionally suggests that each research paper published in synthetic biology could contain a brief ethics statement, similar to existing requirements for papers reporting research with human participants.[71]

While improving the integration of science and ethics in synthetic biology research is laudable, the strategies require further consideration. For example, is the claim for integration of ethics and science in synthetic biology unreasonably exceptionalising synthetic biology? Should this kind of approach be introduced to *all* science? Would requiring a 'brief ethical evaluation' on every synthetic biology manuscript (assuming what constitutes a synthetic biology manuscript can be determined) reduce ethical consideration to a box-ticking exercise?[72] The objective and potential for integration show promise, but need development.

V CONCLUSION

This paper has surveyed ethical issues arising in synthetic biology, before considering the mode and methodology for engagement with these ethical issues. It has claimed that synthetic biology neither raises entirely new ethical issues, nor represents a discrete sub-field of bioethical inquiry. However, the field does give rise to issues that are of ethical interest and will offer opportunities for analysis on aspects not yet fully explored. Some suggested avenues for further investigation were then put forward. These suggestions have been made in response to some ethically interesting hallmarks of synthetic biology, including its potentially limitless scope and the creativity that may be harnessed by researchers. The field may benefit from an approach to ethical analysis that is capable of both thinking about the broad possible future scenarios of synthetic biology, and also focusing in on some of the more specific implications that are probable or actual. Ongoing critical reflection on bioethics methodology in synthetic biology will also in turn allow critical reflection on methodology in bioethics more generally. It may also give rise to some novel observations, particularly given the inter-disciplinary nature of this field. Issues familiar to academic ethicists may play out in unexpected ways in different fields of research.71F[73] Focus on the details of particular applications of research in synthetic biology will allow the development of a suite of thought experiments to guide further ethical analysis.

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68 CollectiveIP, *'Sandpit' to Address Grand Challenges in Synthetic Biology* (2015) <https://www.collectiveip.com/grants/NSF:0935932>. Sandpit events are used to bring together researchers from a range of backgrounds to build collaborations and develop projects. The idea is to 'play' in the sandpit with new colleagues and see what arises. A discrete amount of funding is then allocated to selected projects following a competitive grant submission process.

69 Heavey, above n 11, 122–124.

70 It is worth noting that this is not necessarily new. There are many working in science or bioethics who have qualifications in more than one discipline.

71 Heavey, above n 11, 122, 125.

72 Ibid 125.

73 Thanks to Dr Jane Calvert for this point.

Synthetic biology research is inherently inter-disciplinary. The range and scope of its potential applications, and the varied methodological approaches of those assessing it, mean that a single ethical determination of the field's acceptability is unlikely. However, ethical analysis will contribute to discussions on the research agenda and underlying values. Ethical analysis will also add a further lens with which to evaluate the implications of this research field and its applications.

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