The term “synthetic biology” first appeared in 1911 and, at the beginning of the 21st century, officially became an emerging interdisciplinary field of biological research, incorporating the fields of chemistry, engineering, information science and physics. Subsequently, synthetic biology has attracted extensive attention worldwide and has become an emerging scientific field that has quickly established momentum and visibility. From a technical perspective, synthetic biology is more akin to a new engineering discipline, in which new cells or organisms are synthetized according to the design of human cells. Previous reports have described the function of synthetic cells as “like a machine” and some synthetic biologists even refer to their products as “genetically engineered machines”. The findings of synthetic biologists may present many beneficial applications, but also raise potentially serious ethical concerns. Therefore, the development of science and technology must be navigated in accordance with ethical standards. The debate surrounding synthetic biology has raised several issues, such as laboratory biosafety and the exacerbation of injustices and challenges that the discipline may pose to existing systems of intellectual property rights, have long been a point of contention for which there currently is no consensus, with the opinions and comments of most scholars biased towards their own research view-
The rapid development in artificial life and all are just the results of mastering and applying natural laws.

**Defence of synthetic biology:** In addition to numerous scientific and technical challenges, synthetic biology raises questions regarding ethics, biosecurity, biosafety, involvement of stakeholders and intellectual property rights. These implications mainly manifest in the approach, application and distribution of synthetic biological technologies. “Artificial life” means creating new forms or changing the existing forms of life. Some of the great hopes for synthetic biology include the ability to perform transplants, and scientists want to apply the methods used in cloning to produce skin, organs, and other body parts for humans. The approach mainly involves ethical issues of objective, procedural and technical implications on society (i.e., ethical issues in artificial life), application of these concerns on the social impacts of synthetic biological products (i.e., societal issues), and allocation revolving around product use rights and ownership (i.e., benefits, access and justice).

**Ethical issues in artificial life:** The rapid development of life science inevitably impacts society. There is a commonly long-held view that synthetic biology, which aims to design and construct new biological functions and systems not found in nature, will redefine the boundaries between “natural” and “unnatural”. Therefore, this selective perception will no doubt instil public fear and create ethical dilemmas. From a deontological perspective, these arguments are a continuation of longstanding debates, such as “Whether people should play God?”, “If people have the right to intervene with the characteristics of future humans”, “Whether people should interfere with natural development?” and so on. The emergence of artificial life has once again sparked much criticism and the opposition between conservative Catholic and radical Darwinism viewpoints has been particularly intense, in which points of contention revolve around whether that only God (or nature) has the ability to create life, all things in nature evolve after long-term evolution, and only behaviour conforming to natural development is correct. Thus, these groups cannot accept the opposing directions of synthetic biology and nature.

**Playing God:** In fact, the debate on this issue has existed for a long-time, as early as the 1970s, when the transgenic technology was just emerging, and the scientific, bioethics and religious communities began to strongly oppose this new technology. However, the pace of scientific progress has not slowed, but rather has continued at a rapid pace and reached new heights. Regardless, opposing viewpoints between science and traditional ethics has always existed and this controversy and simultaneous progress will likely continue to coexist. Moreover, there is still a long way to go to achieve the goal of manufacturing multicellular organisms (not to mention creatures with conscious), and the impact of synthetic biology to human ethical relations is far less than that of human cloning. Hence, there is no need to terminate the application synthetic biology research in the fields of energy, environmental, material, medical sciences solely because of censure of “Playing God”.

**Replacing nature:** Darwinian Theory holds that unnatural behaviour is not discordant with ethical standards. But mankind's increasing capability to explore and transform nature itself is the inevitable result of natural development. From the manufacture of raw stone tools to complex organisms is just the continuation of human evolution and should not be considered as violation of human evolution. Modern developments in information and medical technologies as well as the creation of hybrid crops have brought about unprecedented material and spiritual wealth to mankind and all are just the results of mastering and applying natural laws.

**Disregarding life:** There exists also the perception that the synthesis of life is contrary to the most basic ethical principles of respecting life. In fact, this is a narrow understanding, as the respect of life does not imply that we are incapable of understanding, controlling, reshaping and transforming life; otherwise, the results of such research, including improvements in animal husbandry, pest control, elimination of pathogenic microorganism and so on, would not be applied. Therefore, an objective judgement from a deontological ethical perspective, synthetic biology technology is just a tool to improve the human condition. As to whether or not new synthetic life forms will affect existing natural organisms life is a consequentialism dilemma that should be discussed in the context of technical experimental rules, security measures, review standards and supervisory regulations.

**Societal issues:** With the continued developments in the field of synthetic biology, safety and security considerations are being increasingly addressed. Because of the present controversies and potential risks of synthetic biological products, it is necessary to scientifically evaluate all aspects of synthetic biological products before they are marketed. The earliest systemic articles to explore bioethics associated with synthetic biology by De Vriend and the IDEA League
mentioned three types of biological safety risks. Some scholars expressed concern that the diffusion of synthetic biological technologies would automatically create an unprecedented biosafety challenge. From a consequentialist perspective, the potential dangers of synthetic biology are not alarmist, as the risks posed by the application of synthetic biological products to humans are mainly divided into safety and security issues.19

**Safety and security:** Safety issues mainly include unintentional exposure to pathogens, toxins and otherwise harmful or potentially harmful biological materials, or their accidental release. The concern of safety issues associated with biotechnology is indeed worthy of attention. But as long as effective security measures are enforced, for example the use of *Escherichia coli* strains that only survived below 36°C in gene engineering experiments, we can eliminate the possibility of propagation and spread of experimental bacteria to humans. In addition, with the continued improvements in rigorous experimental rules, security measures and new methods of risk assessment to decide whether a new synthetic biology technique or application is sufficiently safe, breaches of biological safety will probability become ever more scarce.

Security issues mainly include misuse through loss, theft, diversion or intentional release of pathogens, toxins and other biological materials. For example, some worry that terrorist attacks and biological warfare with synthetic biological products will become much easier, especially considering that techniques to produce deadly pathogens are relatively very easy to obtain. One should recognize that any new biotechnology will bring similar risks, and synthetic biology is no exception. But, for the moment, at least, the construction of laboratories to conduct synthetic biological experimentation is beyond the range of most terrorist organisations, thereby rendering the use of these products against society unlikely. Furthermore, it must be mentioned that synthetic biology research has the potential to benefit all of humanity, thus we cannot limit the development of synthetic biology because of perceived or hypothetical terrorist attacks. Hence, cautious analysis of events that may occur should be addressed to minimize risks and maximize benefits offered by this technology.

**Governance:** The broader science community has put much effort into the development of guidelines and regulations to address the issues of intellectual property rights and governance, as well as associated ethical, societal and legal implications. Kelle proposed a 5P governance strategy to ensure the security of synthetic biological technologies. Countries should also begin to formulate appropriate regulations and guiding principles for synthetic biological products to prepare for the near future. At the state level, strong enforcement of control regulations will mitigate risks of misuse. For example, in December 2010, the U.S. Presidential Commission report, titled “New Directions: the Ethics of Synthetic Biology and Emerging Technologies”, called for enhanced federal oversight of this emerging technology in the United States and presented an assessment of emerging technologies (including synthetic biology) using a system of five fundamental ethical principles: public beneficence, responsible stewardship, intellectual freedom and responsibility, democratic deliberation, justice and fairness. In 2010, the European Group on Ethics in Science and New Technologies published the report “Ethics of Synthetic Biology” that identified specific ethical issues associated with synthetic biology that mainly focused on biosafety, biosecurity, justice and intellectual property.

**Social impact:** Of greater concern, however, are the moral hazards associated with the application of synthetic biological products; that is, the negative impacts on individuals and ultimately society as a whole. Opponents to this technology have voiced concerns that unnatural products synthesized through chemical methods run the risk of destroying the social pedigree of mankind and disrupting societal and ethical standards and natural order. History has shown that human civilization can successfully deal with the challenges that accompany any human behaviour, new technology or the use of any product presenting certain risks and challenges. Moreover, ethical morality has always changed with the progress of human society and human society remains under constant pressure to continually divide and reconstruct ethical standards.

**Benefits, access and justice:** Synthetic biology presents many beneficial applications, but also raises potentially serious concerns regarding ethics associated with this new knowledge, especially as a discipline with a tremendous impact on human health, nature and society. Analyses of risk factors and costs, as well as use of patent rights are important to ethical considerations and have aroused widespread concern of policymakers, especially the funding of biomedical and social scientists.

Generally, the use of a biotechnology product is regulated by patent; however, it is also a concern that patent rights may restrict the utilization of important inventions and discoveries, especially in applications of nutrition, energy and medicine. Thus, traditional patenting of biotechnological products has understandably aroused ethical controversies. Synthetic biological products are also facing the same problem. Some think that to grant patents on synthetic biotechnologies or products will directly lead to the formation of monopolies, unfair benefit distribution, lack of fairness and societal freedom, and threaten the
interests of the majority. In addition, there exists the problem of global differentiation, namely, monopolies of synthetic biological products by developed countries and multinational corporations will harm the interests of developing countries and mid- to small-scale companies.\(^{38}\)

These views, that developing countries will be priced out of the field, deepen the health-related nano-divide set by prohibitive royalties and licensing fees that are somewhat superficial. In fact, patents granted to legal synthetic biological products will not only lead to unfair distribution, but also affect measures of the benefits to mankind. A basic principle of the patent system is that a fee is paid to use a patent for profit and anyone using proprietary technology in scientific research does not need to consider the patent rights. Hence, scientific research remains a relatively free activity and developing countries, therefore, do not need to consider whether a developed country holds a patent to conduct scientific research, indicating that developed and developing countries are at the same advantage and have equal opportunities. Meanwhile, patent laws will dissuade large corporations from implementing security systems to protect rights of genetic elements and subsequently avoid repeated research and increase the efficient expenditure of funds for scientific research. Moreover, one can perfect patent inspection processes according to conditions for authorization of patent rights and improve qualities of inspection to improve the threshold of patent rights and regulate the management and marketing of synthetic biological products. From another point of view, strict patent examination and development of an approval system will minimize the risk of misuse of disseminated knowledge.

**DISCUSSION**

Because of a breakthrough on the genome sequencing and DNA synthesis technology, the advances in bioengineering technology are accelerating, finally, brings the synthetic biology appearance. A main goal of synthetic biology is to realize the potential of microbial consortia, to decode and reprogram complex polyketide assembly lines. Science addresses the possibilities of "what can we do?", while ethics considers the dilemma of "what to do?", although both must consider societal values. In fact, various ethical theories and religious beliefs are very difficult to unify and thus it is unlikely that a global consensus will be reached. According to the theory of wide reflective equilibrium, through repeated discussions, we can only reach a basic consensus on moral judgments, regulations and background theory. In terms of synthetic biology, there is no reason to negate all of the achievements of synthetic biology simply because of moral, ethical, and religious controversies. Firstly, consider that debates over religious ethics exist in many disciplines and the aim of synthetic biology research is to benefit mankind, thus it seems to be unnecessary to shackle biologists with excessively harsh moral standards. Secondly, respect for life does not insinuate that it is improper to transform any form of life on Earth. The human centrism doctrine in life science research seems more reasonable, that is, a bottom line of respect for human life while maintaining the highest ethical principles.

Historical experience also shows that ongoing ethical debates will only slightly impede the pace of scientific and technological advancements. The ethical controversies just sound the alarm for the rational use of synthetic biotechnology. Though synthetic biologists face significant challenges,\(^{39}\) the positive effects of synthetic biotechnology in the development of innovative new medicines and vaccines, tissue regeneration, new diagnostic and treatment technologies,\(^{40,41}\) development of clean energy technologies\(^{42}\) and environmental applications,\(^{43-46}\) etc. cannot be ignored. This is not to say that arguments about synbio-ethics are pointless. In fact, such debates provide important avenues to discuss various opinions and suggestions to establish quality management standards, perfect product quality control systems, develop product review and access regulations, arrive at a global consensus, and promote the healthy development of science. Moreover, these types of debates also raise awareness of societal and ethical issues among the scientific community, especially in light of the low level of bio-security awareness among synthetic biologists.\(^{24}\) Through better communication and cooperation between the synthetic biology and biosecurity communities, biosecurity awareness among companies and scientists will be improved. Therefore, further in-depth ethical discussions, even heated debates, are essential.

At present, this discipline has captured the interests of policymakers, bodies of scientific funding, the media and bioethicists. In future ethical debates, we must adhere to the following three principles: the first is to follow the proactionary principle, i.e., if there is not apparent substantial evidence of negative effects, we should consider emerging technology as safe, inherently good, and conforming to economical ideals. The second is to follow the comprehensive objective principle, i.e., to comprehensively and objectively take into consideration all reasonable factors in the evaluation of synthetic biological technology. The third is to adhere to the principle of fair and equitable treatment, i.e., the ethical requirements of managers and those that are being managed should be established on fairness. By improving ethical consciousness and sensitivity to ethical issues, to strengthen abilities of ethical analysis, protect the public rights and interests, maintain ecological balance and diversity, this double-edged sword can work to promote human interests and not work against progress. Perhaps just as Serrano
described: 'In an ideal world, designing living systems for a practical purpose should be like redesigning a car to make it more efficient, or redesigning a computer with a faster processor.'

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