Biotechnology Journal
www.biotechnology-journal.com
Biotechnol. J. 2015, 10, 236–241
DOI 10.1002/biot.201400604

BTJ-FORUM

Synthetic biology and intellectual property rights: Six recommendations

Report from the IP Expert Meeting at the Danish Agency for Science, Technology & Innovation

On 26th November 2013, the Danish Agency for Science, Technology and Innovation organized an expert meeting on "Synthetic Biology & Intellectual Property Rights" in Copenhagen sponsored by the European Research Area Network in Synthetic Biology (ERASynBio). The meeting brought together ten experts from different countries with a variety of professional backgrounds to discuss emerging challenges and opportunities at the interface of synthetic biology and intellectual property rights. The aim of this article is to provide a summary of the major issues and recommendations discussed during the meeting.

In September 2014 the European Commission's Scientific Committees published a Final Opinion, which defines synthetic biology (SB) as follows: "SynBio is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms" (http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scenihr_consultation_21_en.htm). This operational definition offered by the Scientific Committees is derived from a working understanding of SynBio as a collection of conceptual and technological advances. It is sufficiently broad to include new developments in the field and also addresses the need for a definition that enables risk assessment.

In order to promote an adequate development of SB that will secure innovation and cooperation and prevent fragmentation, it is important to identify and assess new risks and other issues early on and from a broad perspective. Only then scientists, industry, funding agencies and other stakeholders will be enabled to discuss and agree on the best approach to tackle the large variety of challenges associated with this rapidly evolving discipline. SB combines many overlapping disciplines and is based on a culture advocating the free exchange of research results. Thus one of the main challenges can be found in the growing debates over the role of intellectual property rights (IPRs) in stimulating or hindering research and development (R&D) and – ultimately – innovation [1].

On 26th November 2013, the Danish Agency for Science, Technology and Innovation organized an expert meeting on "SB & IPRs" in Copenhagen sponsored by the European Research Area Network (ERA-NET) in SB (ERASynBio). The meeting brought together ten experts from different countries with a variety of professional backgrounds[1]. It consisted of a series of presentations followed by discussions in smaller groups that focused on the following questions: What is the impact of the current IP framework on innovation in SB? Is there any empirical evidence for a negative/positive impact? If there is a negative impact, are there particular solutions or models employed in other sectors that could support the robust development of SB?

The aim of the current publication is to provide an unbiased overview of the major issues and recommendations discussed during the expert meeting. Although SB may involve many different IPRs, the discussions focused in particular on patents and patent-related rights. It should be emphasized, that the authors of the current document do not necessarily share all the views expressed in this publication.

Recommendations

During the workshop, considerable attention was devoted to the particular role and responsibilities of government funding agencies, academic institutions and patent offices. As public organizations their mission goes beyond mere commercial interests and their activities should consider the impact of research activities on global justice, fundamental societal values and social responsibility. By providing funds and setting strategic directions, government funding agen-

Abbreviations: AUTM, Association of University Technology Managers; **EPO**, European Patent Office; **ERA-Net**, European Research Area Network; **ERASynBio**, European Research Area Network in Synthetic Biology; **ESHG**, European Society of Human Genetics; **EU**, European Union; **FTO**, Freedom-to-operate; **ICT**, Information and communications technology; **IPRs**, Intellectual property rights; **NIH**, National Institutes of Health; **OECD**, Organisation for Economic Co-operation and Development; **PCT**, Patent Cooperation Treaty; **R&D**, Research and development; **SMEs**, Small and medium-sized enterprises; **SB** or **SynBio**, Synthetic biology; **TRIPS**, Agreement on Trade-Related Aspects of Intellectual Property Rights; **UPC**, Unified Patent Court; **UPP**, Unitary Patent Protection

[1] In addition to the authors: Calin Guet, Senior Researcher, Institute of Science and Technology, University of Vienna; Henk van Den Belt, Social Scientist Researcher, Genomics, Intellectual Property and Global Justice – Center for Society and the Life Sciences, Nijmegen; Hubert Bernauer, CEO ATG:biosynthetics GmbH; Jakob Wested, PhD fellow, Research project on "IPR and Open innovation in Synthetic biology", University Copenhagen; Martin Skrydstup, Anthropologist, Postdoc fellow, MASCOSPOL project, University Copenhagen; Paula M. da Silva, Patent attorney, PLMJ Lawyers, Lisbon; Philippe Gorry, Associate Professor, Université Montesquieu, Bordeaux.

cies, together with universities, the SB scientific community and patent offices, can take the lead in educating and informing the general public and the stakeholders concerned. Furthermore, they could play a key role in providing more transparency by discussing the "patent landscape", patent quality, freedom-to-operate (FTO) and best practices for licensing.

There is currently not enough empirical evidence about the effect of intellectual property on SB and most of it seems anecdotal [2, 3, 4]. Still it can certainly be said that the patent landscape in SB is already rather complex and likely to become more complex over time [5]. In that sense it appears better to pro-actively and pre-cautiously address foreseeable problems rather than to wait for them to occur. Academic researchers are generally not accustomed to investigating the patent status of the technologies they select for their work. Empowering the SB scientific community to select unpatented tools for development of foundational technologies could contribute to limiting the complexity and fragmentation of the field.

In view of the important roles that these actors may play in the debate on patenting and licensing practices in SB, the different recommendations are divided into different "perspectives" indicating the potential responsibilities and tasks that these actors could adopt.

RECOMMENDATION 1 – Empirical Evidence and Open Source Software Tools

Develop cheap, easy-to-use open source software tools to map the patent landscape and provide FTO analysis tailored to the particular needs of the SB community in order to properly determine the actual impact of IPRs on SB.[2]

Funding Agencies:

- Provide *financial* support for the development of software tools and for making available patent landscapes and FTO analysis tailored to the particular needs of the SB community.

Figure 1. The ERASynBio consortium consists of 16 governmental funding bodies from 12 EU Member States (Austria, Denmark, Finland, France, Germany, Greece, Latvia, Netherlands, Portugal, Spain, Slovenia, and UK) and two Associated Countries (Norway and Switzerland).

Patent Offices:

- Provide *technical* support for the development of software tools and for making available patent landscapes and FTO analysis tailored to the particular needs of the SB community.

SB Community:

- Identify ontologies to integrate multiple information domains in the patent system (e.g. issued patents, patent file wrapper, court documents) and the scientific literature (e.g. genetically encoded functions);
- Develop software tools for patent landscapes and FTO analysis tailored to the particular needs of the SB community;
- Conduct large-scale empirical studies to investigate the patent landscape and FTO and make the analysis widely available within the SB community.

RECOMMENDATION 2 – Use of Public Domain Tools

Encourage and enable scientists to employ tools unencumbered by IPRs for developing foundational technologies in SB (supported by the tools listed under Recommendation 1).

Funding Agencies:

- Provide *financial* support and create incentives to encourage scientists to employ tools unencumbered by IPRs for developing foundational technologies in SB.

Patent Offices:

- Provide *technical* support to enable scientists to employ tools unencumbered by IPRs for developing foundational technologies in SB.

SB Community:

- Employ tools unencumbered by IPRs for developing foundational technologies in SB.

RECOMMENDATION 3 – Patent Quality and Transparency

Establish collaborations between the SB community, patent offices and other government agencies to improve the quality of issued patents and increase transparency of patent ownership.

Funding Agencies:

- Provide *financial* support and create incentives to encourage scientists to engage in debates about patent quality and transparency and to become more actively involved in the patent system and prior art searches.

Patent Offices:

- Recruit researchers trained in SB to join the patent office as examiners;
- Provide a classification for SB patents consistent with the ontologies developed by the SB community (which can support Recommendations 1 and 2);
- Require applicants to notify the patent office of the current owner-

[2] Such an analysis may go beyond the examination of patents, as in the area of SB not only patents are important, but also copyright and database protection could play a role. In the remainder of the document, we will however focus on the role of patenting and patent licensing.

ship status of granted and pending patents and monitor compliance.[3]
- Explore further possibilities for scientists to become involved in prior art searches and improve the technical and organizational set-up for peer-to-patent and crowd sourcing models [6];
- Conduct surveys and public consultations on prior art searches, such as on the use of crowdsourcing to identify relevant prior art;
- Improve the technical set-up for prior art searches.

SB Community:
- Create educational materials to inform courts and policy makers of the specificity of SB and potential problems with respect to IPRs;
- Employ different mechanisms already available within various patent systems to get involved in prior art searches (i.e. peer-to-patent model adopted or tested in several countries, such as US, Japan) or by submitting evidence as a "third party observation" (e.g. EPO, US, PCT);
- Submit *amicus curiae* briefs to courts in order to inform them about the specificity of SB and potential problems with respect to IPRs.

RECOMMENDATION 4 – Best Licensing Practices

Adopt and promote guidelines and best practices in licensing SB inventions for foundational technologies.

Funding Agencies:
- Provide *financial* support for the adoption and promotion of guidelines and best practices in licensing SB inventions for foundational technologies;
- Use guidelines and best practice documents in 'other' fields of (biological) research (i.e. research tools, genomic inventions) as a source of inspiration (e.g. NIH, AUTM, ESHG, OECD);
- Make the guidelines and best practices easily available within the SB community;
- Create incentives or impose an obligation to make public research funding conditional upon the employment of less restrictive licensing conditions (e.g. inventions must be either placed in the public domain or made available on reasonable and nondiscriminatory terms to all interested parties, no exclusive licensing for foundational technologies, or only exclusive licensing for a very specific field of use).

Patent Offices:
- Engage in the debate on post-grant issues, such as patent licensing and the potential implications of the utilization of particular licensing practices in SB.

SB Community:
- Commit to the utilization of public domain tools and/or less restrictive licensing conditions for foundational technologies in SB.

RECOMMENDATION 5 – Private Ordering Mechanisms

Explore opportunities for private ordering mechanisms to improve transparency of ownership and facilitate licensing (e.g. open source SB, patent pools and clearinghouses [7]).

Funding Agencies:
- Provide *financial* support to examine the pros and cons of open source SB, patent pools and clearinghouses in SB;
- If the examination of the pros and cons turns out in favor of promoting such private ordering mechanisms, provide *financial* support for initiating such mechanisms, which could then be taken forward by a national or international organization, the scientific community and/or an independent (public or private) licensing entity.

Patent Offices:
- Engage in the debate on post-grant issues, such as the pros and cons of open source SB, patent pools and clearinghouses in SB.

SB Community:
- Examine and actively engage in the debate about the pros and cons of open source SB, patent pools and clearinghouses in SB;
- Encourage their organizations to adopt an open source approach towards foundational technologies in SB and collaborate with initiatives for the establishment of patent pools or clearinghouses to facilitate access to and use of technologies encumbered by IPRs.

RECOMMENDATION 6 – Legislative and Regulatory Changes

Explore the need/options for further legislative and regulatory changes in order to facilitate R&D and innovation in SB, while at the same time protecting the enforceability of well-defined patent claims on the use of genetically encoded functions and concrete applications in industry, health care and agriculture.[4]

Legislator and Regulator:
- **Consider to adopt a new or optimized regime for utility model protection that would be applicable to SB related technology.**

  This particular form of protection is considered particularly suited for small and medium-sized enterprises (SMEs) that make "minor" improvements to, and adaptations of existing products. Originally developed for mechanical inventions it can be described as: "an exclusive right granted for an invention, which allows the right holder to prevent others from commercially using the protected invention, without his authorization, for a limited period of time." (http://www.wipo.int/sme/en/ip_business/utility_models/utility_mod-

[3] In Europe, after grant, this is regulated by national law. In the future, this notification requirement could also be included in the regulatory framework for unitary patent protection.

[4] In considering the need for regulatory changes it is important to examine to what extent any pursued regulatory changes should be of a general nature or more technology-specific.

els.htm). The main differences between utility models and patents are the following: (1) the requirements for acquiring a utility model are generally less stringent than for patents; (2) the term of protection for utility models is shorter than for patents (between 7 and 10 years); (3) the registration process is often significantly simpler and faster; (4) utility models are much cheaper to obtain and to maintain; and (5) in some countries, utility model protection can only be obtained for certain fields of technology and only for products but not for processes. Herein lies the challenge: in Germany, for example, § 1 (2) and § 2 (3) of the German Utility Model Act, (http://www.wipo.int/wipolex/en/text.jsp?file_id=229677) provide that biotechnological inventions and processes in general are excluded from utility model protection. The explicit exclusion of such inventions from protection stems from the assumption that biotechnological inventions are too complex to be protected by utility models. In particular the fact that no substantial examination is conducted during the registration procedure provided the basis for the legislator's decision that the protection conferred by utility models would be inappropriate for biotechnological inventions [9].

SB applies the principles of engineering – abstraction, decoupling and standardization – to biological studies and recent advances indicate that many products and techniques developed and used within SB are likely to be high volume and relatively predictable low-tech tools. The question is then, if this provides enough reason to re-evaluate restrictive approaches with regard to utility model protection. Evaluating the suitability of utility model protection for SB related inventions would therefore require further studies. Moreover, such studies would need to address the risk that an increase of utility model rights in the field of SB could also result in utility model thickets and increased litigation. Last but not least, while some European countries already provide for utility model protection, such as Denmark and Germany, most do not. Thus it is important to further discuss the need for an EU Regulation or Directive on this type of protection.

- **Clarify and amend the European statutory regimes for research exemptions, in particular in areas that are specifically (but not only) relevant to SB.**
  This could encompass clarifications with regard to patent-protected research tools in the pursuit of research or education or additional stipulations on the applicability of these exemptions vis-à-vis third parties. Although national patent legislations in Europe generally provide for research exemptions and clinical-trials specific (Bolar-type) exemptions from patent infringement, there is considerable uncertainty about the scope and correct interpretation of these exemptions[5].
- **Devise rules that would support Recommendation 5 by specifically exempting intermediaries, which meet certain conditions, from liability for patent infringement of claims on SB tools and genetically encoded functions.**
  Such an exemption could encompass different types of intermediaries, including (1) foundries providing services by producing functional devises with genetic material and following the instructions of third parties; or (2) patent pools or clearinghouses offering for sale, selling or licensing tangible SB tools and material provided by third parties.
- **Exempt users who purchase or receive SB tools from private ordering mechanisms from IP liability provided certain conditions are fulfilled.**
  To support Recommendation 5 it could be desirable to provide a "safe harbor" from IP infringement for users that are encouraged to utilize private ordering mechanisms, such as patent pools or clearinghouses. However, the panel agreed that it would be important to explore the adoption of certain conditions, for instance that a "safe harbor" provision should only apply if the users have studied the database of IP ownership information provided by intermediaries and if they – based on the search – could not detect any IP rights directed to a relevant tool. The "safe harbor" provision should, hence, not apply if the respective user acted irresponsibly, if he did not search the database made available by the intermediary at all or if he searched it without due diligence. A willful infringement of claims included in the database with the knowledge of the user, should result in severe damages for patent infringement.

Funding Agencies, Patent Offices & SB Community:

- Many of the above recommendations remain exploratory and/or controversial and have been debated vigorously during the workshop. Thus they do not necessarily reflect in every detail the interests of all the stakeholders neither do they reveal the opinion of the authors or of all panel members. The public pressure towards reforming the current IP-based innovation system, however, is considerable. The implications of any new legislation could be more far-reaching than it would seem at first sight. It is therefore utterly important for stakeholders in SB, including funding agencies, patent offices and the SB community, to get involved in the process and to make their voices heard in order to

[5] It remains to be seen how Art. 27 UPC agreement ("Limitations of the effects of a patent") will impact on the harmonisation of these issues in Europe.

Glossary

Amicus curiae:
Literally a "friend of the court" is someone who is not a party to the case concerned but still offers information that bears on the case in order to assist the judges. It is a way to introduce correct scientific information or important concerns to ensure that the possibly broad legal effects of a court decision will not depend solely on information provided by the parties directly involved in the case. The decision on whether to admit the information by the amicus curiae is at the discretion of the court.

ERASynBio:
The European Research Area Network (ERA-NET) in SB (ERASynBio) brings together 16 funding and policy agencies from 12 EU Member States and two associated countries (Austria, Denmark, Finland, France, Germany, Greece, Latvia, The Netherlands, Norway, Portugal, Slovenia, Spain, Switzerland and the UK) with the key objective to promote the robust development of SB by structuring and coordinating national initiatives and investments. An important aim of ERASynBio is to address ethical, legal, economic and societal issues raised by the particular nature of SB.

European patent:
After grant by the European Patent Office under the European Patent Convention the European patent turns into a "bundle" of national patents. Depending on which member states of the European Patent Convention (currently 38) have been chosen for validation, the patent will be transformed into the respective national patent rights subject to national patent law which may require translations and the payment of fees. National law also regulates post-grant issues such as licensing or infringement.

Freedom-to-operate (FTO):
An FTO analysis is an analysis performed by patent professionals (e.g. patent attorney, paralegal) of issued patents and/or pending patent applications to determine whether a product or process infringes upon the claims of the issued patents or pending patent applications. The analysis may also include a search for expired patents in the public domain that may act as a 'safe harbor'. The analysis may consist of different components, including an opinion regarding the risk of infringement, the validity of the patents concerned, their enforceability and potentially also the availability of licenses.

Licensing guidelines:
In some research fields particular national funding organizations, national interest groups, European scientific associations and international organizations have issued guidelines and/or listed best practices regarding patenting and licensing (see e.g. http://www.autm.net/AM/Template.cfm?Section=Nine_Points_to_Consider, http://www.oecd.org/dataoecd/39/38/36198812.pdf [9, 10, 11, 12, 13]).

Limitations of the effects of a patent:
The protection conferred by a patent can be limited by research exemptions, clinical trials exemptions (also "Bolar-exemption") or breeders' exemptions. Further limitation is brought about by compulsory licenses (e.g. on research tools). These exemptions are dealt with by national law within the boundaries of international (e.g. TRIPS) and EU (e.g. Enforcement Directive, Biopatent Directive) legal provisions. In the future, the Unitary Patent Protection (UPP) and the Unified Patent Court (UPC) could provide a framework for a harmonized European approach on exemptions.

Open source:
Developed with respect to software, but gradually extended to other fields. With respect to software it means that an open development process has been used and that it is available for modification and enhancement by anyone. The BioBricks Foundation borrowed elements from the open-source software movement to develop a public agreement for designers of synthetic-biology parts (https://biobricks.org/bpa/).

Patent mapping (also patent landscaping):
Provides a graphical overview of granted patents/patent applications in a particular technological field. These activities enable companies and other actors to identify relevant patents and the relationship between them, to verify the strength and value of these patents and to explore the risks of patent infringement.

Patent quality:
No uniform definition of patent quality exists: economists use a variety of indicators to measure patent quality, including patent family size, number of claims, generality, breakthrough nature invention, grant lag, forward citations, and backward citations. Ultimately the validity of a patent can only be tested in court.

Patent pools and clearinghouses:
One-stop-licensing mechanisms that facilitate access and use of technologies encumbered by IPRs. Whereas in a patent pool model the patent owners agree on the licensing conditions for licensees, the clearinghouse model can be compared to a supermarket model. Although patent pools and clearinghouses have typically been employed in other sectors, such as ICT, consumer electronics, and copyright collective licensing management, the application of these models are increasingly considered in the biomedical sector, including SB [7].

Research exemption:
Limited exception to the rights conferred by a patent allowing third parties to perform purely research-based activities with no commercial implications with regard to the subject matter of a patented invention. In some European countries, such as Belgium, the research exemption has a broader scope than in other countries [14].

Unified Patent Court (UPC):
A specialised patent court with exclusive jurisdiction for litigation relating to 'classical' European patents and European patents with unitary effect (unitary patents). The Agreement on the UPC was signed by 25 EU Member States on 19 February 2013. It will need to be ratified by at least 13 states, including France, Germany and the United Kingdom to enter into force (http://www.unified-patent-court.org).

Unitary Patent Protection (UPP):
An arrangement between 25 EU member states to establish a patent with unitary effect for their respective territories. It will enter into force once the agreement on the Unified Patent Court which is created in parallel is ratified by a sufficient number of member states. A unitary patent will be a European patent granted by the EPO under the provisions of the European Patent Convention to which unitary effect for the territory of the 25 participating states is given after grant, at the patentee's request (http://www.epo.org/law-practice/unitary/unitary-patent.html).

influence the outcome and – ideally – to avoid unintended adverse effects. It will therefore be crucial to constantly monitor all legislative activities and to take an active part in commenting on any legislative proposals and preparatory works. Moreover, it appears highly likely that some substantial changes will occur in the wake of the current debates on open innovation models in general, and SB in particular.

Concluding remarks

In the above we have summarized in a simplified form the most relevant recommendations discussed during the workshop. It should be noted that the actual discussion addressed further controversial issues, such as the adoption of an exemption from liability for infringement of patent claims on DNA sequences that are used, made or sold as carriers of information rather than as a tangible product for specific uses. However, a large fraction of the panel regarded the lines between the use of the informational and tangible value of DNA as being too blurred and thus not appropriate to be used in legislation due to a high risk for legal uncertainty and subsequent litigation. We therefore decided not to include such controversial topics in the recommendations.

Moreover, the panel has recognized that an optimization of the current patent system and a better governance of granted patent rights are necessary to unleash the full potential of SB. Although in theory patenting research results does not limit access to the actual information (i.e. disclosure is actually an important requirement of patent law), solutions that could facilitate transparency, access and use of the patented technology could contribute to stimulating R&D and innovation in SB. In proposing creative and innovative solutions, the interests of the different stakeholders involved in SB should be taken into consideration. While patents will remain a crucial aspect of SB, policymakers, legislators and the SB community should also re-consider the governance and legal framework for other IPRs that will become increasingly significant for SB, such as trademarks, copyrights and trade secrets. Moreover, it is important to recognize that the wide array of potential developments and applications of SB also poses enormous challenges to other areas of law, such as for control and safety regulations or ethical frameworks. There is perhaps an even more pressing need to develop recommendations and best-practice guidelines for these aspects of SB.

The complete report of the workshop can be found at

https://www.erasynbio.eu/

We thank ERASynBio (see Fig. 1) for the organizational support and the workshop participants for their valuable contributions and feedback to this report.

The authors declare no financial or commercial conflict of interest.

The present article does not necessarily reflect the personal opinion of the authors or the official position of the European Patent Office on the subject.

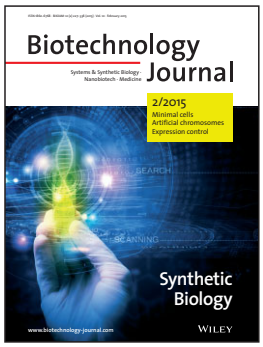
Timo Minssen
University of Copenhagen, Centre for Information & Innovation Law (CIIR), Copenhagen, Denmark
E-mail: Timo.Minssen@jur.ku.dk

Berthold Rutz
European Patent Office, Dir. 1.406 Biotechnology, Munich, Germany
E-mail: brutz@epo.org

Esther van Zimmeren
University of Antwerp, Research Group Government & Law, Antwerp, Belgium
E-mail: Esther.vanZimmeren@uantwerpen.be

References

[1] Rai, A., Boyle, J., Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons. *PLoS Biol.* 2007, *5*, e58.
[2] Heller, M. A., Eisenberg, R. S., Can patents deter innovation? The anticommons in biomedical research. *Science* 1998, *280*, 668-701.
[3] Kahl, L., Endy, D., A survey of enabling technologies in synthetic biology. *J. Biol. Eng.* 2013, *7*, 13.
[4] Minssen T., *Assessing the Inventiveness of Bio-Pharmaceuticals under European & US Patent Law*, Ineko AB/Lund University 2012, 30 ff.
[5] Minssen, T., Wested, J., *Standardization, IPRs and open innovation in synthetic biology. Contribution* to article compilation "Innovation, Competition, Collaboration" based on 2013 conference at Bucerius Law School, Hamburg, Germany. 2014, DOI:10.2139/ssrn.2153957.
[6] Rutz, B., Synthetic biology and patents. A European perspective. *EMBO Rep.* 2009, *10(Suppl 1)*, S14–S17.
[7] Van Zimmeren, E., Vanneste, S., Matthijs, G., Vanhaverbeke, W., Van Overwalle, G., Patent pools and clearinghouses in the life sciences. *Trends in Biotechnol.*, 2011, *29*, 569–576.
[8] Grund, M., Richly, E., Farmer, St. J., Is german utility model protection available for biotechnology inventions? *Bio-Science Law Review* 2006, *8*, 123–125.
[9] United States (US) National Institutes of Health (NIH) Office of Technology Transfer, Research Tools Guidelines, *Federal Register* 1999, *64*, 72090.
[10] US NIH Office of Technology Transfer, Best Practices for the Licensing of Genomic Inventions, *Federal Register* 2005, *70*, 18410–18415.
[11] Association of University Technology Managers (AUTM), In the Public Interest: Nine Points to Consider in Licensing University Technology, 2007.
[12] European Society for Human Genetics (ESHG), Patenting and licensing in genetic testing, *Eur. J. Hum. Genet.* 2008, *16*, 405–411.
[13] Organization for Economic Co-operation and Development (OECD), Guidelines for the Licensing of Genetic Inventions, 2006.
[14] Van Overwalle, G., van Zimmeren, E., Reshaping belgian patent law: the revision of the research exemption and the introduction of a compulsory license for public health, in Jayanthi Reddy, P.L. (ed.), *Compulsory Licensing – Developing Countries*, Amicus Books/Icfai University Press, 2008, 168–181.



Special issue: Synthetic Biology.
Synthetic biology has become more application oriented, by designing and implementing synthetic pathways in industrial biotechnology. This Special issue, edited by Roland Eils (German Cancer Research Center, DKFZ, and University of Heidelberg), Julia Ritzerfeld (German Cancer Research Center, Heidelberg) and Wolfgang Wiechert (IBG-1: Biotechnology, Forschungszentrum Jülich), includes contributions from the Helmholtz Initiative on Synthetic Biology and focusses on applications of synthetic biology in biotechnology.
Image: © Sergey Nivens Fotolia.com

Biotechnology Journal – list of articles published in the February 2015 issue.