

Intellectual Property vs. Open Source

Intellectual Property Strategy for
Synbio Research in Mexico – Stage 1

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Intellectual Property Strategy for Synbio Research in Mexico

Stage 1: Intellectual Property vs. Open Source report

With the objective to provide a wide vision of this topic, we are trying to open a national discussion for the creation and adoption of a strategy for intellectual property and open source for the development of synthetic biology in Mexico.

The first stage consists in define the status of this issue. We're going to introduce some concepts related to open source and intellectual property.

Patents were created as a way to provide financial incentives for inventors to undertake research, by allowing them to exclude competitors from exploiting their invention for a specified period of time. In order to be patentable, an invention must meet the criteria of *novelty*, *industrial applicability* and demonstrate *non-obviousness*. The text of the patent includes patent *claims* that define the subject matter of the invention, as well as all the elements, features and critical aspects of the invention, so that a person trained in the relevant scientific discipline should be able to replicate the invention. Claims define the scope of the patent, or in other words, the size of territory that fits within the protected barrier of the fence (2).

The decision to patent gives the inventor two options to exercise his rights. Use the invention himself and exclude all others from its use or sale or grant others the right to use the invention under agreed-upon terms through a license. While this system can promote innovation by providing a return on investment to early innovators, there is the risk that it could hinder those conducting important research or providing needed services downstream, and can inhibit cumulative innovation (2).

Considerable historical evidence, including evidence from many important industries of the twentieth century, suggests that the transaction costs associated with developing broad patents on foundational research can slow growth in the industry (1). Since synthetic biology is an emerging discipline, that is a big possibility.

The nature of industry interactions may create pressure to use patents as 'anticompetitive weapons' to extend monopolies and block competitors (2). It would be a huge mistake to think that biotech corporations won't attempt to take advantage of synbio advance for economical purposes. There is a real risk that patent thickets will hinder the ability to do research and commercialize applications.

The Biobrick foundation and many synbio leaders support the open source (OS) to ensure the advance of synbio. Nevertheless, there are many questions to solve in order to reach the ideal strategy, especially in iGEM and the Registry of Standard Biological Parts (RSPB)





The idea behind the RSBP is that these parts can, and should, be recombined in different ways to produce many different types of devices and systems (7). Although the Registry currently contains physical DNA, its developers believe that, as DNA synthesis technology becomes capable of generating ever-longer sequences, the Registry will be composed largely of information and specifications that can readily be fabricated in DNA synthesizers. The fabricated, DNA-based functions would then be “executed” in a cell (6).

Proponents hope to use synthetic organisms for economical production of many useful biological materials. Scientists working in this area are sufficiently concerned about the possible impact of intellectual property that they are actively thinking about the applicability of open source-type strategies to parts and devices (8). Synthetic biology illustrates a potentially symbiotic relationship between open and proprietary innovation models (6)

There are many problems in the implementation of open source, to be success, the OS strategy should incorporate a strong intellectual property structure that allow the open access and use to the protected parts, but also avoid any misuse of these parts.

Imagine that a foundational advance biobrick from the registry is not protected by any intellectual property modality; Many researchers have freely used this biobrick for the construction of useful devices; someone even used it for a commercial development and decided to patent the resultant device. One year earlier of this patent application, a giant corporation takes this idea and develops a tool based on it; they decide to patent this tool, what happen if the company decides to assert the researcher? Every aspect of this issue must to be perfectly clear to avoid that kind of problems

Already we are beginning to see problematic foundational patents that could impede the potential of the technology (8). Some synbio leaders propose to use intellectual property rights to create a “commons” in the same way as software developers, by using the copyright and copyleft modalities of IP.

There are many discussions about the applicability of copyright laws to biology. It is clear that genetic instructions can be compared to algorithms in software development, however, there’s another level of complexity that has to be considered. The functionality of biological parts is one aspect that copyright does not cover, it just apply for information and design.

Many times genetic sequences have been compared with songs, and nucleotides with musical notes, but it is not so easy, equilibrium between the patent platform, copyright and sui generis modalities should be reached to have the right strategy for synbio.

The Biobrick foundation has partially solved the Intellectual Property issue by implementing its Biobrick Public Agreement, which is a new legal instrument for sharing synthetic biological parts. Open source products (such as Linux software) have traditionally been favored by developing world governments and companies, as they provide access to new technology at low cost. The Biobrick Foundation hopes that the BPA will enable open platform-based synthetic biological tools





to be used, transformed, and strengthened through the efforts of researchers around the world, including those in developing countries (3).

The BPA imposes very few restrictions on what users can—or cannot—do with the materials they receive. Instead, the agreements are structured not as licenses to use existing intellectual property, but as contracts between two parties (the “user” of the materials and “contributor” of the materials”) with a promise by the contributor not to assert any intellectual property rights, including patents, against the user (9)

The simplicity of the BPA should help the synbio community grow without the cost or complexity of navigating the patent system. Those who wish to continue to use the patent system and other intellectual property frameworks (outside of the sharing system established via the BPA) are free to do so (9)

Open source could represent a great opportunity in developing economies, conditions for synbio researches in Mexico are very different for those who exist in industrialized countries, and research budgets are not as big in Mexico as in USA. This is not a limitation for creativity and innovation, but it is for equipment acquirement. Some labs in Mexico just cannot afford some useful technologies.

The RBSP is based in giving and receiving; all the users should contribute new parts to the registry, it is similar to a copyleft in software. When something is protected by a copyleft, everyone could freely use it, but it also requires that any improvement to this have to be available in the same terms. The BPA have some differences with copyleft, since it is possible to patent any improvement of BPA protected parts by reaching an agreement with the IP holder.

This is important for developing countries, since R&D resources are extremely limited, it is important for a developing country to choose its research programs very carefully to be able to become competitive in that area (5). If Mexico wants to be competitive as a country it is essential to adopt a knowledge based economy, this would be possible with the creation of biotech and synbio based industries.

The Mexican Association for Synthetic Biology asked many experts for some recommendations for the development of synbio industries, participants recommended to use the parts of the Registry, and to add new parts. In addition, it is recommended for developing countries to keep some of the parts in order to create sustainable competitive advantages. Nevertheless, universities should not keep the developed parts, but should share new parts as a way to enable the advancement of science and technology. It is not recommended that developing countries only use the freely available parts of the registry without developing new ones. An open collaboration is necessary in order to promote field’s development (5).

This generates a new question, what parts should be patented? Synbio based invents must be categorized as the European group on ethics in science and new technologies to the European commission suggest (3):





- a. That which is common to all humankind, and should not be patentable or directly exploited for commercial gain, this include the human genome and the hap-map project.
- b. That which, for a variety of reasons, should be placed in the public domain for all to use and exploit, such as many foundational advances. It may be that the process or product is so expensive to produce, or that the placing of the information in the public domain enables open standards that allow for the effective commercialization and use of a number of products that use the technology or product.
- c. That which may, at the inventor's discretion, be protected through an intellectual property rights system to encourage innovation.

That categorization could apply for synbio industries and universities, but does it apply to iGEM teams? iGEM's open system makes parts freely accessible and exchangeable. What would happen to this contest if parts became patentable, or were patented? If an iGEM team makes something with commercial or industrial applications, it can be patented under the same proposal.

Synthetic biology is trying to make biology easier to engineer, by introducing some ideas of many areas of engineering to life sciences, the core proposal is the standardization of biological parts. Our proposal is to incorporate standardization to synbio IP issues.

Sometimes is better to patent a synbio invention, sometimes is better to give invention to the world for its free use, in other cases special strategies should be adopted. Application of BPA must be complemented by other standard procedures for each case. It is necessary to define what should be patented according to this. An interdisciplinary committee must be integrated to discuss this categorization and those standard procedures.

Mexico should establish a strong strategy for synbio development and synbio industries creation, that should take into consideration all those IP and OS aspects.

As we said, this report was the first stage of an effort to collaborate with synbio development in Mexico.

The next stage is to ask for opinion to synbio and biotech leaders in Mexico and IP experts, and identify the needs and critical issues in Mexico. Then we'll be able to create the mentioned committee with iGEM teams and experts and elaborate a list of recommendations directed to decision makers in order to reach a national strategy.

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