**Fair Use of Genetic Material: An iGEM-Specific Guide**

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ABSTRACT

This paper is meant to provide a general guideline for all International Genetically Engineered Machine (iGEM) teams with a Canadian guideline on submitting third-party modified genetic material to the BioBrick standardized registry of parts. The current practice is to submit open-source material, which can be quite limiting in project scope. By establishing this guideline, we hope Canadian iGEM teams will have better awareness of the legalities of submitting parts from third parties and will hopefully lead to a wider range of part submissions.

The first section of this article will help better understand the legal clauses of the existing agreements: (1) BioBrick Agreement, (2) third party License Agreements, and (3) Material Transfer Agreement. It should be noted that each License Agreement will be unique to the specific company supplying the material, but this guide analyzes the general clauses found in most License Agreements.

The second section of this guideline will simplify the Canadian legal system in relation to patent law. This will include a description of what materials qualify for patenting and how modifications are patented under the Canadian legal system.

Finally, the third section provides Canadian iGEM teams with specific guidelines for using third party genetic material from three distinct sources – patented, naturally occurring, and open source. In general, any modifications made on a sourced part are subject for patenting. However, the situation becomes more complicated when an iGEM team wants to submit the original sourced part in addition to the modifications. In each scenario, a guideline is provided as to how such a part is protected and what rights we have as iGEM teams to submit them.

**Introduction**

Our University of Ottawa iGEM team became interested in creating this guideline when our own lab members wanted to submit a modified version of a part we sourced from a supplier outside our lab, but had difficulty deciphering the multitude of legal documents associated with these materials.

We believe having a clearer understanding of patent regulations over modified parts can save time for future iGEM teams and potentially increase opportunities for more diversified iGEM submissions. Having a clearer understanding of current practices can also lead to more polished policy formulation in the future, and a more systematic way of transferring material between private and public sources.

In the past, other teams have provided general patent guidelines, such as University of Oxford's 2014 *Intellectual Property Report*, which looks at how the current iGEM system can be improved to allow for easier patenting, and even provides students with a guideline on whether a project should be patented or not. Teams such as Valencia and Stanford-Brown have looked at the ethics of patenting genetic material, which has been a highly controversial subject in biotechnology since its start. Although these findings contribute to developing better biotechnology patent law standards, there is currently no guideline which clarifies the legalities of transferring genetic material from supplier to the iGEM registry.

In the following article, we will provide the iGEM teams with a clearer framework of using materials from supplier labs. We will begin by explaining the existing BioBrick and supplier agreements, which will ultimately be the backbone to this guide. Then, we will explain how the current Canadian patent laws apply to iGEM projects. After discussing the current legislation, we will provide a guideline for submitting parts obtained from three possible sources – patented, naturally occurring, and open source. Finally, a recommendation section will hopefully aid as a guideline for future improvements in the policy framework surrounding current iGEM and industry practices.

It should be noted that this work is simply a clarification guideline and was not thoroughly reviewed by a practicing expert in the field. Nonetheless, we hope these guidelines will be useful in expanding participants' project scope and create a platform for further discussion.

## 1. Existing Agreements

The first place to start in understanding how materials can be transferred between suppliers and the iGEM registry is by looking at the existing agreements provided by both parties. The iGEM competition provides a BioBrick Contributor Agreement, which binds the contributor to certain obligations for submitting a part. The suppliers, likewise, provide their own license agreements which bind any user of their material.

### 1.1 BioBrick Contributor Agreement

The BioBrick Foundation was established to create a registry of standardized genetic parts, and as part of this registry a BioBrick Contributor Agreement was created to bind the contributors to specific obligations by the Foundation. A contributor is defined as the 'Person, company, institution, or other entity submitting the Materials...'. This registry is open-source, and therefore requires that any contribution is also made open source.

The agreement claims that anyone contributing a part to the BioBrick registry whose material is protected by any proprietary right agrees not to assert these rights. Therefore, anyone submitting a part that is currently patented can no longer claim monopoly rights over such part once it has been submitted. This should especially be taken into account if the proprietary rights are owned by a third party, such as a supplier. In this case, the contributor must obtain an approval from the third party to void such patents once the part is submitted and clearly disclose to the BioBrick Foundation whether there are any proprietary rights over the material being submitted.

Users of this registry are also bound by this agreement, which states that anyone using materials for distribution or commercialization are required to attribute the BioBrick registry by including the BioBrick Public Agreement logo in its packaging, product inserts, websites, or other public displays. The contributor of the material being used also has the right to request attribution in a similar fashion from the user and can even enter into a separate agreement with the user altogether.

In essence, the BioBrick Foundation establishes a community of open-sourced parts that discourages contributors and users from obtaining proprietary rights. Although this is beneficial for the research community, it hinders project creativity and often puts students in a conflicting position to choose between profiting off their invention or submitting it for the public good. To bypass such a problem, the University of Oxford iGEM team has in the past to introduce a reach-through license agreement, which binds the user of the agreement to give a cut of the profit to the contributor if his part is used in a marketable final product. Indeed, enforcing such a law would also allow other iGEM teams to negotiate with third-party genetic material suppliers in submitting their parts to such a registry. It would provide the team and the supplier with adequate incentive to submit parts that are not necessarily open sourced, and would result in a diversified and expanded scope of parts submitted to the registry. Although such an agreement

would discourage many from submitting any open-sourced parts at all, the incentive to create more innovative constructs would outweigh the negatives of a conversion to a semi-proprietary registry of parts.

### 1.2 Non-commercial License Agreements

Non-commercial license agreements are legal documents sent by a supplier of genetic material, which enforces the licensee to use genetic material according to a set of particular rules. The supplier of genetic material could either be a company or another academic institution.

When receiving materials from a company, a stringent non-commercial license agreement is sent with the materials. The particular clauses vary from company to company, and as such each should be analyzed before making assumptions about how the genetic material may be used. Some common conditions set by the company are that (1) the material is to be used for research purposes only, (2) all modifications are to be disclosed to the company, and (3) the lab cannot transfer materials to another third party. These basic guidelines essentially restrict the user of the material from modifying or submitting the material to the BioBrick registry.

If an iGEM team creates a construct using a modified version of such a part, the current clauses suggest that such a part would not belong to the iGEM team itself and would not qualify for submission to the BioBrick registry, discouraging teams from making such constructs in the future. However, teams should be aware that they have a right to negotiate with the supplier lab an adequate contract that would allow for submission to an open registry of parts. In establishing such a contract, the team and the supplier would both be forced into giving up any proprietary rights over this construct. It should be noted that such a contract would only be reasonable if the modifications made by the iGEM team have made the part distinct enough that it no longer threatens to nullify the original patent held by the supplier. To verify whether it is distinct enough, the team must read into the original patent as well as the section defining modifications in the original Non-commercial License Agreement.

### 1.3 MTA

The Material Transfer Agreement (MTA) is a document that outlines the access rights granted to a user of materials such as molecules, pharmaceuticals, proteins, etc. This agreement is constructed by the party supplying the material, and unlike the non-commercial license agreement, can be used by individuals to transfer research material between labs.

The agreement will again begin with formal definitions, which often makes a clear distinction between the original material and the modifications. The document will state that the original material is to be used for research purposes only, is to be used by the recipient laboratory only, and limits the distribution of any modifications of the material. The specific MTA depends on the particular situation, but in most cases the modifications made on the original material will

belong to the provider of the material. However, if the recipient created modifications using the original material in collaboration with the provider, then joint ownership may be negotiated.

Therefore, although the recipient cannot claim proprietary rights on the material or its modifications, there is still opportunity to claim proprietary rights over such material. These proprietary rights would be beneficial to iGEM teams wanting to market their product, but would still pose a problem in submitting such a part to an open registry. As a result, the only solutions to this problem would be to either change the BioBrick Agreement to include a reach-through agreement discussed earlier, or to negotiate with the provider of the material to make a modified version of his part open-sourced.

## 2. Canadian Patent Law

### 2.1 What is Patentable?

A patent provides the inventor with exclusive rights to make, use or sell an invention for 20 years in Canada. Since patents are expensive and time-consuming, it is important to understand what the Canadian law will allow for patenting and what it will not. This understanding not only will help an iGEM member understand whether a third party may actually own a patent on particular genetic material, but also whether the modifications derived from this supplied part are patentable.

First of all, the Canadian patent legislature excludes all higher life forms from patenting. Therefore, iGEM teams are only able to patent innovative single-cell organisms such as yeast, bacteria, and GM crops. In addition, the legislature does not exclude methods of diagnosing a disease, such as the highly controversial diagnostic test for long QT syndrome in Canada.

The Canadian patent legislature requires that an invention must show novelty, utility, and inventiveness.

(1) Novelty means that the invention has not been anticipated by the general public, although there is a grace period of one year from the date of public disclosure to file for a patent. Therefore, any iGEM team interested in patenting their invention must do so within a year of disclosing their project, whether it is at the World Championship or prior to that.
(2) Utility requires that the invention is operative and has commercial value. Therefore, if the iGEM project or invention does not have any useful functionality, then such an invention is not patentable.
(3) Inventiveness is often also referred to as non-obviousness. This means that the invention must not be obvious to a person skilled in the art. To test this criteria, the iGEM team must show that the invention would have required some sort of ingenuity from the person skilled in the art to arrive at it.

Understanding these patent rights can help an iGEM team to understand whether their project is subject to patent or whether others have a legal right to hold a patent over their invention. This is important because such knowledge can empower iGEM teams to stand up against potentially unfair business practices that can limit iGEM project scope.

### 2.2 Patenting a Modification

Any improvements on a currently patented invention are subject to patent, but the inventor cannot use the original invention for commercial purposes. Therefore, any iGEM team who improves on an existing patent, cannot use the original material supplied by another lab, but has the right to obtain a patent on the improvement. It is, in fact, common in the patent landscape

that a patent is acquired on an improvement of a previous invention, which should be taken as an opportunity by iGEM teams to improve their own projects and project scope.

It should be noted by iGEM teams that agreements restricting the licensee from claiming ownership of the modifications may be deemed unfair business practice. However, it would not pose any problems provided that the agreement allows the licensor to earn fees contingent on success, which would be beneficial to both parties*.

* The Role of Intellectual Property Rights in Biotechnology Innovation By David Castle (Page 81)

## 3. Guidelines

### 3.1 Patented Source

If the part being sourced is from a supplier who currently owns a patent or some form of intellectual property rights on the material being supplied, then the user must take care not to infringe on such rights. Infringement would occur if the user distributes the original material for commercial purposes or submits such a part to an open source registry, such as the BioBrick Foundation, which requires the user not to assert any intellectual property rights.

To avoid such a problem, teams are encouraged to only attempt to submit a sufficiently modified version of the patented part by negotiating a new agreement with the original supplier. Of particular concern is whether such a modified version or modifications derived from the original material can be submitted to an open registry. The two cases should be treated separately, and it should be noted that any such modifications would have to be first disclosed to the original provider of the material.

In the first case, a modified version would consist of the original part plus any modifications. If the modification is drastic enough, then a distribution license may be negotiated between the two parties for submission. However, if the modification is not, then submitting such a part to an open registry would require the user to agree not to assert any proprietary rights on the original part. This would in effect void the intellectual property rights of the supplier, to which the supplier would have to agree beforehand.

In the second case, modifications derived from the original part are assumed to have benefit of their own without including the supplier's original part. Such modification could be either subject to an improvement patent or a joint ownership. In this case, it is important to read the original clauses outlined by the patent holder and search the patent registry for any similar patents. If the modifications are innovative and have not been patented by any other party yet, then no permission is required from the original patent holder. However, if the modifications violate any clauses of the original patent, then the iGEM team should negotiate a new contract with the supplier for such modifications to either allow for patenting or submission to an open registry.

### 3.2 Naturally Occuring

Material that occurs in nature is not subject for patentability because it does not satisfy the 'novelty' criteria. Therefore, any such product is automatically part of the open registry. The primary dilemma in this scenario concerns those who perform the purification. If the material has been purified by another institution, then such institution deserves due credit for the work if it is to be submitted to the BioBrick registry. Otherwise, if the material is purified by the same lab as the one submitting to the iGEM BioBrick registry, then the lab can submit such parts without any other consultation.

### 3.3 Open Source

A company may also choose to submit open source material not typically found in nature. In this case, submitting such material to another open-source registry, such as the BioBrick Foundation, would not pose any problems. If the team desires to acquire a patent on this part, however, then care must be taken to first make sure that the part is eligible for patenting and then to get permission from the source for either sole-ownership or join-ownership in the modified product.

**Recommendations**

In providing other teams with clarity on Canadian patent law and license agreements, we hope to empower other iGEM teams to increase the scope of their projects and to establish a platform for improved contract negotiations between iGEM teams and suppliers. To accomplish this, improvements should be made on behalf of iGEM, the industry, and the Canadian legislature.

To make the iGEM BioBrick registry more diverse and to establish adequate incentive for other teams, it is necessary to include a reach-through agreement as proposed by the University of Oxford iGEM team. This alteration can lead to a more diverse and higher quality scope of projects from iGEM teams, which would prove to be invaluable in the long-term for research purposes and industry commercialization alike.

The industry can further be improved by having a more open approach to modifications of its genetic material. To facilitate this, all iGEM members should be aware of their rights to negotiate joint contracts with industry on parts that are significantly distinct from original patents. This could lead to increased collaborative work between iGEM and industry, which would open the doors for more innovative projects and lead to quicker integration by the industry and general public.

It is likewise important for iGEM teams to recognize the necessity of understanding Canadian legislature to prevent its misuse by others and to help the teams themselves adequately protect or choose to give their projects to the public domain. A common problem with incomplete understanding of your team's property rights is that teams are often limited by the property rights of industry leaders. However, many patents arise as improvements on past inventions, which enrich the iGEM teams with increased scope of projects.

Until the legal framework on genetic material is perfected in Canada, iGEM teams should take all opportunities to learn about their fundamental legal rights. We hope this paper will help navigate such framework and that the guidelines will help promote an increase in iGEM project scope in the future.