

INTANGIBLE

CTeD's Intellectual Property Digest

Disclosing your Invention to the Technology Transfer Office

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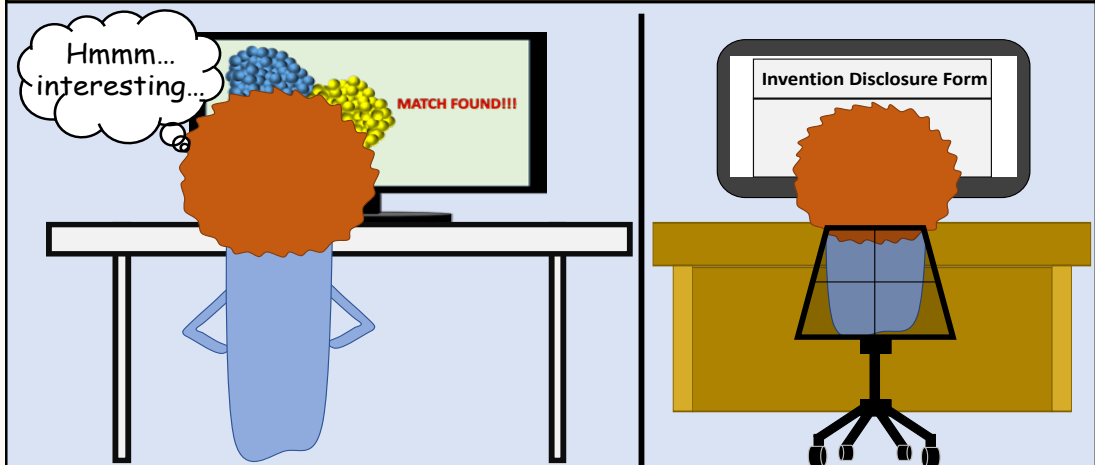
The mission of a university technology transfer office (TTO) is to ensure that the research conducted in the university results in favourable outcomes for the society. For this mission to be optimally achieved, it is essential that inventions are disclosed to the TTO at the right time with the right amount of information. Using the Invention Disclosure Form (IDF), a university employee can effectively record and disclose his/her invention to the TTO. In the current issue, we aim to explain the importance of drafting your IDF as accurately as possible, to allow the TTO to comprehensively assess, and take appropriate decisions on patentability and commercial potential of your invention.

Dr. Curie's lab has grown by leaps and bounds, thanks to her ground-breaking discovery of Denim-1 protein as an effective target for the treatment of neurological disorders. This finding from her lab received a lot of attention from her fellow scientists, clinicians, and pharma companies alike, and has led to Dr. Curie's lab receiving large pots of research funding in the past year.

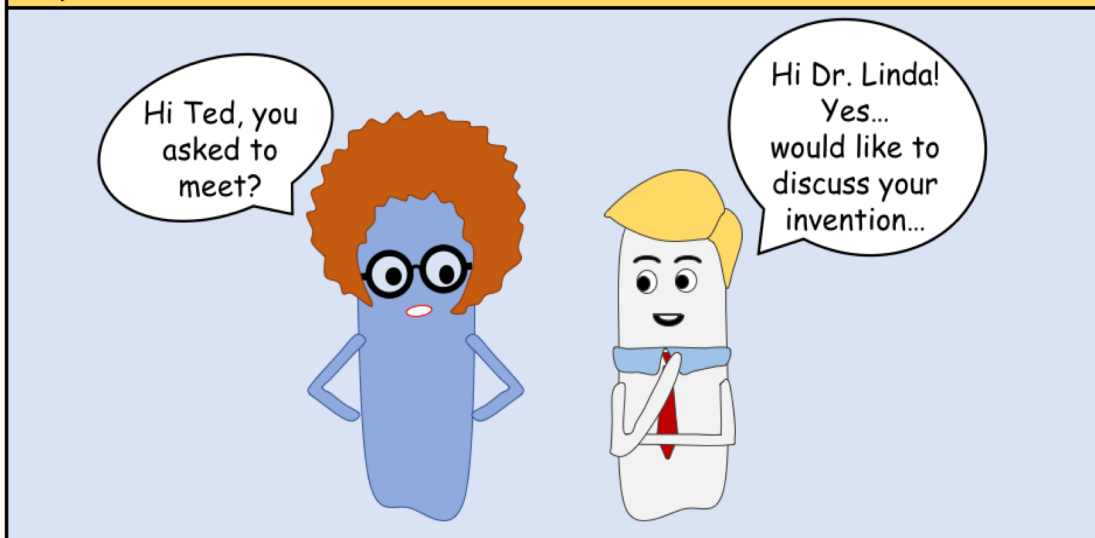
Dr. Curie has recently recruited many new junior scientists. All working very hard, hoping to uncover newer mechanisms regulated by denim-1...



Dr. Linda, who is working in Dr. Curie's lab, has discovered new binding partners of Denim-1, and found that altering these binding interactions could lead to newer treatment options... Upon Dr. Curie's instructions, she hastily submits an invention disclosure form to the tech transfer office...



After reviewing Dr. Linda's invention disclosure form, Ted requests to meet her...



Ted: Let's start with the first section. The title of your invention reads as follows: "Uncovering novel mechanisms and protein-protein interactions of Denim-1 in mouse neurons." This title reads more like a title of a grant proposal and not like that of an invention, and let me explain why. The title of the IDF/invention should provide a general idea of the subject matter of the invention, and must not sound like you have discovered or observed something new. Uncovering previously unknown biological mechanisms is not considered to fall within the realm of inventions. One of the key aspects of an invention that differentiates it from a discovery is that it has human involvement that transforms the observation into an invention that is novel, inventive and can be applied commercially. Therefore, the title should be re-written in a manner to concisely capture the nature of the invention, for example, "Targeting Denim-1 interacting partners for treatment of neurological disorders."

Dr. Linda: Very clear explanation, Ted. I will amend my title to reflect my invention.

Discovery vs Invention (case summaries)

The demarcation between discovery and invention was highlighted in the US Supreme Court's ruling on Diamond vs Chakrabarty (1981). Here, the contentious claim was directed to a micro-organism, the naturally occurring Pseudomonas putida, which had been genetically engineered via incorporation of several plasmids to degrade crude oil.

Although the patent examiner and the Board of Appeals were against granting a patent for such an engineered micro-organism, the US Supreme Court disagreed. In its judgement, the Court highlighted the human ingenuity in engineering the microbe and ruled that such modified organisms can be viewed as "manufacture" or "composition of matter" entities, which are eligible for patent protection. Since then, transgenic animals such as the Harvard mouse have been offered patent protection (in the US but not in other jurisdictions).

However, in 2013, the US Supreme Court issued its judgement on the Association for Molecular Pathology et al. vs Myriad Genetics et al. prohibiting the patenting of genes or even mutant forms which occur in nature. Prior to this, Myriad had obtained patents directed to the BRCA1 and BRCA2 genes, their sequence and their precise location. Mutations of these genes were found to be indicators of an increased risk of breast and ovarian cancers, and consequently, Myriad could monopolize the entire diagnostic testing market (using BRCA1 and BRCA2 markers), thereby preventing any company from engaging in providing diagnostic kits. The court ruled that genes occurring in nature upon isolation by man are not patentable. Myriad's research would only amount to a discovery, since they uncovered the location of BRCA1 and BRCA2 genes, which are essentially "products of nature". After the US federal courts' decision on Vanda Pharma vs. West-Ward Pharma, there seems to be

some hope for inventions relying on products of nature or natural correlations (please refer to the case summary provided in Intangible Issue 4). So, the current approach towards determining patent eligibility of such inventions in the US is as follows – (a) whether there are additional elements or steps performed that are not routine or well-understood by skilled persons working in that field, or (b) whether the invention is markedly different from naturally-occurring products such as genetically engineering organisms. If the claims can satisfy one of the above, then it could be deemed as patent-eligible in the US.

Ted: Now, moving on to the next section - “the contributors particulars”. Contributors are: (1) the inventors or actual conceivers of the invention and (2) others who may have contributed to the invention in a non-inventive yet, significant manner. A non-inventive significant contribution, for example, would be providing vital resources such as compounds or lab equipment to reduce the invention to practice. Proper identification of contributors allows the TTO to ascertain who will be eligible to receive a share of the revenue once the invention is licensed. From a patent point of view, however, it is important to note that an inventor is one who has conceived the invention or has devised the inventive idea, and has reduced the idea to practice. This differentiates inventorship from authorship since in research publications, it is normal that even contributions such as statistical data analysis, performing experiments upon

instruction, writing the manuscript or completing the final experiment are sufficient to warrant authorship. While author lists on publications are not governed by laws, inventorship is a legal issue and the laws and judicial decisions can vary from country to country. Therefore, not all contributors who have been named in the IDF will be named as inventors on a patent application. This section also helps in identifying the rightful owners of a particular invention. Patent laws in most countries state that ownership follows inventorship, meaning one who invents inevitably becomes the owner of that invention. There is however a caveat to this general rule: as an employee of the university, the inventor agrees to assign all his/her rights, title and interests in the invention to the university, allowing the university to handle patent filing and commercialization efforts. This transfer of ownership is executed in the form of an assignment agreement between the employee and the university. The erroneous naming of inventors would not only risk a patent being revoked, but might also establish the patent owners incorrectly (through the incorrect naming of the inventors) which could result in patent litigations. Therefore, before you fill out this section, you should ascertain which one of your collaborators contributed intellectually and significantly to this invention, rather than merely suggesting or performing routine scientific experiments. The answer to this question will help you identify the actual contributors, and also distinguish inventors from non-inventors.

Inventorship vs Ownership

In a previous issue of Intangible, we highlighted how inventorship and ownership of a patent are determined. In Singapore, rights in an employee-generated invention belongs to the employer. Hence, the rights in any invention made by a Duke-NUS employee during the course of his normal duties shall belong to the Institution. However, this does not preclude the operation of a contract or any other agreement in establishing ownership. This is commonly observed in company-sponsored research, where, by way of contract (such as a collaboration/IP agreement), it is agreed by the parties that the company is the owner of the patent. Thus, the natural inventor-owner chain can be superseded by contract law.

Dr. Linda: Okay, Ted. Now, there are some other 'required' fields but I am not sure why you guys need them; such as – citizenship, home address, etc. What's the use of all this personal data?

Ted: Sure, contributors' citizenship is important for determining what important measures are to be taken before filing the patent application in a national office.

Inventors' Nationality

In Singapore (and other jurisdictions), the nationality/residential status of the patent applicant is important since the Patents Act forbids a Singaporean (including foreign residents) applicant or inventor from filing a first patent for the invention with a foreign patent office without obtaining a foreign filing licence from the Singapore registry.

Since patents disclose the working of an invention, filing a patent abroad could be prejudicial to the national security of Singapore, necessitating a National Security Clearance. Another reason for the importance of nationality is its implication on the PCT patent filing process. Briefly, the PCT allows members of the Patent Cooperation Treaty (PCT) to have a unified protocol to file a patent in all of its Contracting States (>150 countries) without having to file the patent individually in different offices. The PCT regulations state that a PCT patent can only be received by a certain patent office if at least one applicant (or inventor) on the patent is of the same nationality as the receiving office. For instance, a PCT can only be filed with Singapore as the receiving office if the patent has an inventor that is a Singapore resident or National.

Ted: As for the residential address, this is to ensure that in the event that a contributor/inventor leaves the institution, he/she will still be reachable by the TTO in order to convey patent-related notifications (to inventors) or to disburse revenues earned from licensing deals (to inventors/contributors).

Dr. Linda: What if I am unable to or erroneously distinguish between inventors and other contributors? Is there a more fool-proof way to find out who should be named as inventors in the patent application?

Ted: Yes, there is. We can request the drafting attorney to conduct an

inventorship determination whereby he/she will interview each individual named in the IDF to determine their respective contributions. This helps the attorney to then apply the law to identify the inventors.

Dr. Linda: Okay, understood. The next two sections in the IDF are on grants and contracts. I thought this information was only useful for the department that manages grants and does legal stuff.

Ted: Providing us with details on the funding support that you and your co-inventors received for conducting your research and making this invention informs us that there might be obligations to the research sponsor(s) that will have to be met if the patent is filed and/or licensed. For example, when a patent application is filed/granted for an invention made using a research grant received from a government body, the government body might require the university to report the number of patent applications filed/granted. This information may be used by the government to determine how productively the tax-payer's money is being spent for R&D in the country's research sector. In addition, contracts such as material transfer agreements (MTA) and research collaboration agreements (RCA) between the university and external parties may contain clauses which will determine how exactly new foreground IP resulting from the use of a third party's material or funds will be dealt with, vis-à-vis the ownership of the new IP.

Dr. Linda: I see, thanks.

Ted: The date and evidence of conception is very important information, as it might establish that you and your team of inventors conceived the invention before everyone else. Providing us with relevant keywords assists us in conducting prior art searches as accurately as possible to ensure that no information is available in the public domain that can adversely affect the novelty and inventiveness of your invention.

Record Keeping and Prior Art

Maintenance of lab notebooks is crucial for a number of reasons. One of the ways in which a patent can be revoked or invalidated is upon proving that the patent was granted to the wrong inventor. In such cases, the inventor may be called to court years after he/she made the invention and a well-maintained lab notebook that contains the complete conception of the invention can offer convincing evidence in litigation.

"State of the art" (or prior art) may be defined as any information that is made available to the public by any form of communication anywhere in the world at any time before a patent application has been filed. Although granted patents offer national protection for inventions, their novelties are judged on a worldwide basis during examination. "Made available to the public" is viewed in a strict sense by the law and even ephemeral disclosures such as oral lectures at conferences may be considered as being made public if two listeners were found to have written notes

of the invention (Genentech / Immunoglobulin preparations, Technical Board of Appeal of EPO, 2001). Even more convincing forms of public disclosure are written forms such as handouts of slides and publication of scripts. Hence, inventors are well-advised not to disclose the invention in any form before a patent application has been filed, including forms such as posters, publishing of abstracts in conference books, etc.

Dr. Linda: The detailed description section is essentially same as the manuscript or a grant proposal write-up, isn't it?

Ted: Not quite. The detailed description of the invention section is aimed at providing as much information and data as possible (including background information) to enable a skilled person to perform/reproduce the invention. This also includes the description of all the possible ways certain steps can be achieved.

This key requirement for patentability is also known as sufficiency of disclosure or enablement. Patents can be invalidated for lack of sufficiency. In the US, sufficiency is determined as of the patent filing date, and therefore any critical information obtained after filing may not be used to supplement an insufficient patent application.

Dr. Linda: And what is the meaning of reduction to practice?

Ted: Reduction to practice, which is another key element of patentability, refers to the fact that the invention claimed in a patent application is not just a mere concept or an idea but has actually been shown to work with experimental evidence, prototypes, pre-clinical data, clinical data, etc.

There might be different aspects of an invention that an inventor might conceptualize, and it is important to reduce the invention to practice for all of those aspects. For example, your invention may have different aspects such as – protein A's interaction with Denim-1 indicates a certain diagnostic outcome while protein B's interaction with Denim-1 indicates a different diagnostic outcome. Another aspect could be repurposing a known drug to disrupt an unfavorable protein's interaction with Denim-1 as a treatment option for neurological diseases. Now for each of these aspects of your invention, you will have to show experimental evidence. In case you don't have these data yet, the TTO needs to know the project status and a clear timeline to strategize the timing of the patent filing and commercialization activities.

Immaterial Variants

Sometimes, inventors may disclose inventions which are merely immaterial variants of certain competing technologies. In such cases, the TTO would look at patents of these competing technologies and assess whether the disclosed invention may fall under the ambit of a competitor's patent claims and

hence, result in an infringement. For instance, a 4-legged chair may be considered an immaterial variant of a competitor's 3-legged chair if it can be shown that the absolutely essential features of a chair do not depend on the existence of a 4th leg. If this is the case, the 4th leg is redundant and hence a 4-legged chair would infringe a broad claim to a chair with legs.

Ted: Now, coming to the last few sections about commercialization. As mentioned previously, the purpose of seeking patent protection is to be able to commercialize the invention for the benefit of the society. Many blockbuster drugs were once inventions made in university labs that have gradually made their way to the market through multiple developmental stages carried out in start-ups, medium-sized and large pharma/biotech companies. Many of these drugs available on the market today are university assets licensed to pharma companies. Universities and pharma/biotech companies often collaborate and co-develop inventions/technologies to bring the finished drug product to the market. Knowing which companies might be interested in your invention can help the TTO in developing suitable patent filing and commercialization strategies.

Early interactions with potential commercial partners also aids in assessing the market need for your invention, and justifies the expenses the university will have to bear to file patent applications and conduct other business development activities (these expenses

are known as “out-of-pocket expenses”), and may improve the chances of finding a commercial partner and recouping these expenses in future.

Singapore is one of the most innovative countries in the world. Research institutes and universities in Singapore encourage and support scientists in creating new and more effective solutions through their scientific endeavors. These efforts are redoubled if scientists and inventors are willing to participate in translating lab-based research into scalable businesses by founding start-up companies. This transforms scientists into innovators and entrepreneurs, and strengthens the innovation ecosystem of Singapore.

Got any feedback?

We'd love to hear what you think about this IP digest and what topics you'd like us to cover in the upcoming issues.

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