

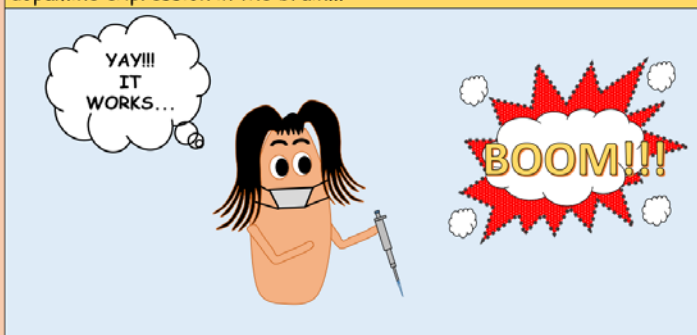
INTANGIBLE

CTeD's Intellectual Property Digest

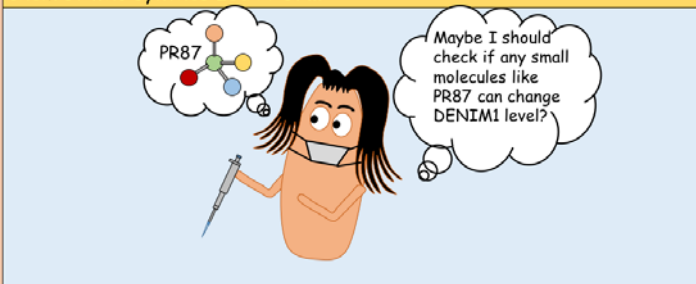
A Dialogue on Inventorship

by Parakalan Rangarajan

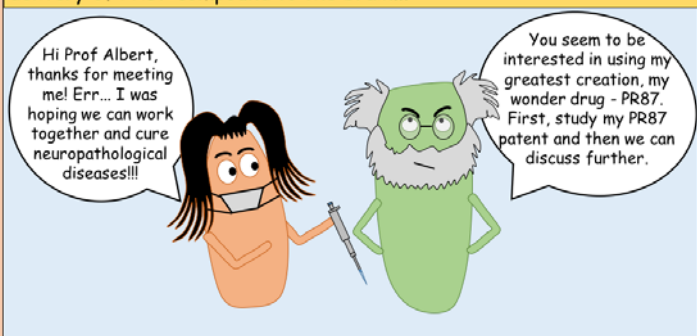
Dr Curie has just discovered that a protein *DENIM1* decreases dopamine expression in the brain...



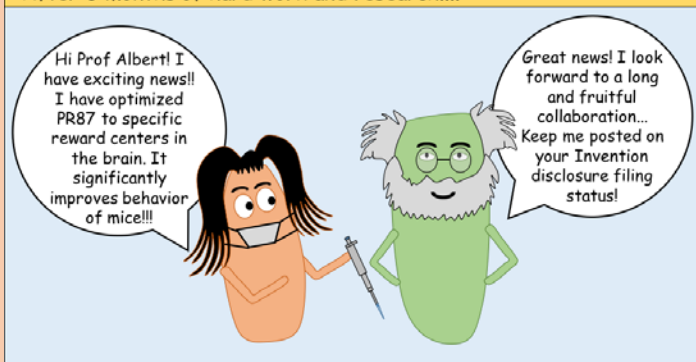
Dr Curie identifies that PR87, a compound used in cancer research to kill cancer cells increases dopamine levels by suppressing *DENIM1* expression!! Excited about this she rushes to meet Prof Albert, the chemist who synthesized PR87...



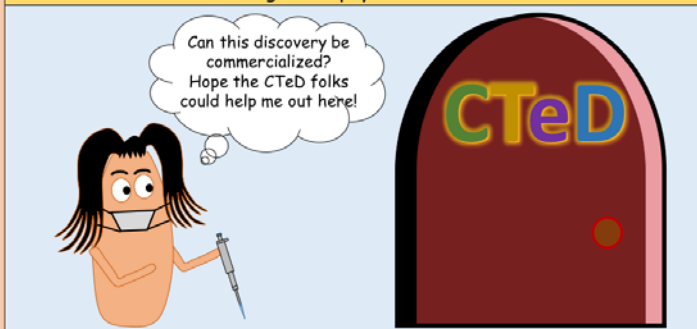
Dr Curie explains her finding to Prof Albert and asks for his help in delivery of PR87 compound to the brain...



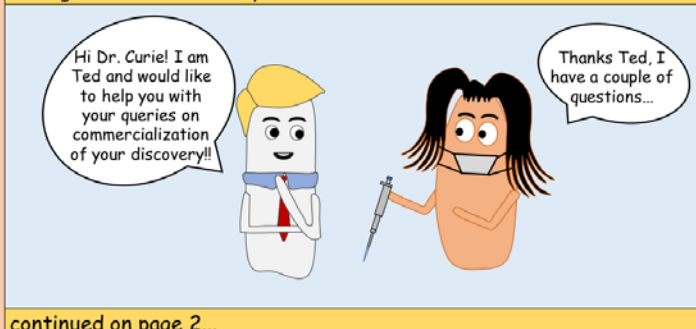
After 6 months of hard work and research...



Dr Curie realizes that there might be a future commercial value to this use of PR87 in treating neuropsychiatric disorders.



Dr Curie sets up a meeting with Ted, a Technology Development Manager at the university...



continued on page 2...

Dr. Curie: I would like to know if we have included enough information in the invention disclosure form to proceed to file for a patent.

Ted: I read your invention disclosure and found your study to be very interesting. I have also performed a preliminary prior art search and I am happy to inform you that your invention seems to have crossed all barriers of patentability.

Dr. Curie: Thanks, I was expecting that. So, we shouldn't waste any more time and proceed with filing this patent application since I want to submit this study for publication.

Ted: I appreciate your drive in pursuing this. But before we proceed to file, we need to discuss the crucial issue of inventorship. I see that apart from yourself, you have named Prof. Albert as an inventor. Could you tell me more about his role in this particular invention?

Dr. Curie: Prof. Albert is a very senior and experienced chemist who has invented many important classes of compounds, of which, some are already in the market for the treatment of various cancers. He graciously agreed to meet me despite his busy schedule and asked me to refer to his patents on PR87, which did contain some useful information on delivering this compound across the blood-brain-barrier.

Ted: Did those patents tell you if the compound reaches the exact part of the brain that you intend it to reach?

“While author lists on publications are not governed by laws, inventorship is a legal issue....In fact, patents can be invalidated based on an erroneous list of inventors”

Dr. Curie: No. While I did follow the teachings provided in the patent, I had to make some adjustments to the drug delivery process so that it is specifically targeted to the part of the brain we want it to reach. Having said this, Prof Albert and I have only recently started the collaboration and will need at least one year to make an effective working prototype of this drug formulation. However, we do not want to wait any longer on filing a patent application claiming the new use for this compound since that would hinder our publication and conference presentations by more than a year or so.

Ted: So, from what you say, it seems like Prof. Albert hasn't had any role in this particular invention so far – the new use for PR87 of not just decreasing levels of denim-1 in the brain but also showing a drastic increase in dopamine levels.

Dr. Curie: But you must understand that Prof. Albert made the compound and has offered me guidance on how to deliver it to the brain.

Ted: I do understand, Dr. Curie, and before we arrive at a conclusion, let me explain to you who an 'inventor' on a patent is: Any person who has conceived the invention or has devised the inventive idea and has reduced the idea to practice can be considered as an inventor on a patent application.

Performing routine experiments which exist in the art and statistical analysis of data do not qualify one to earn the inventor status since neither of these has to do with conceiving the invention. It is the ideation that is critical to determining the inventor(s). This differentiates inventorship on a patent from authorship on a publication since on 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. In fact, patents can be invalidated based on an erroneous list of inventors. Hence, “courteous granting” of inventorship may have serious consequences.

So, Dr. Curie, do you think Prof. Albert has had any inventive contribution so far in this study? I mean, looking at the data you have shown in the disclosure, did Prof. Albert have any contribution in decreasing levels of denim-1 for treatment of neuropsychiatric disorders or the idea of delivering PR87 to the reward centers of the brain to decrease levels of denim-1?

Dr. Curie: No, he has had no role. But...

Ted: I know what you want to ask, “but didn’t he enlighten me on how to deliver PR87 to the brain?” He might have, but we are not going to claim the compound or the methods to deliver it across the blood-brain-barrier because that is a subject matter of his earlier patents.

All we plan to do is to file a patent application claiming the new use for PR87 in the treatment of neuropsychiatric disorders since that invention stems from your research alone, and Prof. Albert has clearly had no role in this. Further, it was you who figured out how to target the drug to the specific part of the brain since Prof. Albert’s patents don’t disclose that.

Dr. Curie: Thanks for that very clear explanation. I plan to collaborate with Prof. Albert to take this study to clinical trials. I anticipate his role in this project might get bigger as we move from small animals to large animals and then to man. Do you think we will be able to add his name as an inventor if he provides an inventive idea during later stages of this project?

Ted: Most certainly! In fact, we must add his name in the patent application before it is granted provided, as you rightly said, he provides inventive input. We assess individual contributions periodically and come to relevant conclusions about inventorship as and when new developments occur.

A Case on Inventorship in Biotech

by Sachin Seshadri

As we have seen in the accompanying article, inventorship and authorship are hardly synonymous and phrases such as “inventive contribution” and “actual deviser of the invention” are frequently used in tech transfer offices and court rulings on this issue. But what do these phrases mean in patent law in a biotech context? The following case (not concluded) in the US outlines what kind of activities bestow an “inventor” status and more importantly, why it is imperative that this issue is addressed head-on and early.

Arefolov was a post-doctoral fellow in Matthew Shair's chemistry lab at Harvard. He joined the lab in 2011 to work on developing a promising new approach to treat acute myeloid leukemia, an area of research that's certain to find utility in the pharma industry. Fast-forward five years and Harvard had licensed the new compounds from Shair's lab to Merck in a deal that saw Harvard earn \$20 million as an upfront fee plus additional payments as the drugs entered clinical trials and royalties when the drugs entered the market. Harvard, like most universities, has the policy to reward the inventors on a patent (30% of royalty payments, in this case) and Arefolov was looking forward to cashing those royalty cheques.

Unfortunately for him, Shair had not named him as an inventor on the patent when it was filed. Arefolov sued Shair and Harvard. Whilst the case is not concluded, there are several arguments in Arefolov's complaint that outline aspects of inventorship. Arefolov alleged that he was always part of a creative team that conceived the idea of a broad category of Cortistatin A analogs in theory and in practice. He also argued the 3 new compounds in the patent (whose rights were licensed to Merck) were suggested by him to Shair and in fact, he devised a method to synthesize and synthesized one of these 3 compounds. Arefolov had evidence for these arguments courtesy of his laboratory notebook and e-mails!

Considering that the Harvard patent claimed new compounds, it is clear to see why Arefolov, a creator/deviser of those compounds, is aggrieved. Inventors are not merely "a pair of hands" who take instructions from a Professor, they actually conceptualize and bring ideas to life using not-so-routine experiments. In the same vein, following a routine PCR protocol wouldn't warrant an inventor status. This is a pending litigation, we'll keep you posted on the outcome.

Case summary adapted from:

<http://www.sciencemag.org/careers/2017/08/who-counts-inventor-answer-could-be-worth-millions>

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cted@duke-nus.edu.sg

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