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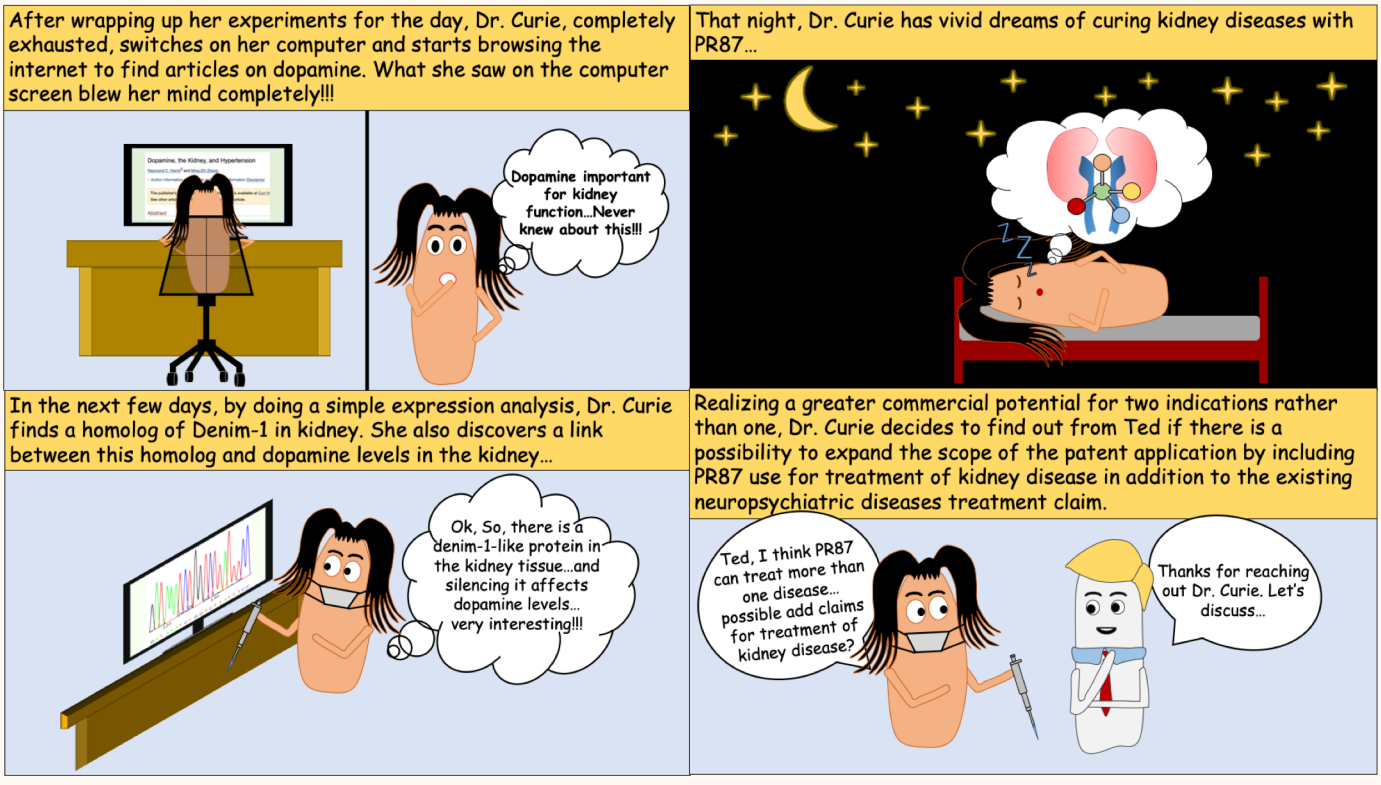
Sufficiency Requirement in a Patent Application

By Parakalan Rangarajan

It's almost been a year since the provisional patent application covering the treatment of neuropsychiatric disorders using PR87 was filed by Ted based on the invention disclosure submitted by Dr. Curie. Dr. Curie has been very busy conducting experiments round-the-clock to generate new data to be included in this application. This data must substantiate the claim that suppressing denim-1 expression and thereby increasing dopamine levels is effective in treating neuropsychiatric diseases, and would fit well with the claim for use of PR87, a suppressor of Denim-1. All the data must be included in the application before the 12-month deadline to successfully convert the provisional patent application into an international patent application.



Dr. Curie: I think we have more than one potential use for PR87. Is there a possibility of writing new claims to cover the use for renal disease treatment in the existing application?

Ted: Ahhh! There are some issues that I need to explain here…First, it is possible to include new claims in the current patent application only if the subject matter content and scope in the filed patent specification is broad enough to cover the new set of claims i.e., we should have mentioned that PR87 can be used potentially for treatment of diseases of other organ systems, in particular in kidney.

Secondly, in case we haven't written a broad specification and you still wish to expand the scope of the claims, it would be preferable to withdraw the existing patent application and file another application with broader specification and claims. This means that we will have to sacrifice the priority date of the first application. The implication is that any other person's public disclosure or patent filing after this sacrificed priority date will be considered as prior art to evaluate the novelty and inventiveness of your new patent application. This is an important reason why it may not be prudent to withdraw the existing application. Could you tell me more about this new hypothesis of yours?

Dr. Curie: Certainly! I have based my new hypothesis on existing knowledge that dopamine is involved in renal functioning. We speculate that a denim-like protein (DLP) could regulate dopamine in this kidney context, indicating a new use for PR87 in renal function. However, we do not have any experimental data to support this hypothesis.

Ted: So, this raises another issue that I need to clarify. If I understand correctly, you are saying that **you don't know**: (1) if the underlying molecular mechanism linking DLP to dopamine in the kidney is the same as that in the brain, (2) if PR87 can bind and inhibit DLP, and (3) if PR87 binding would have the same effect on DLP and produce the same downstream effect as it does when it binds with denim-1. Am I correct?

Dr. Curie: You are correct! We do not know if suppressing DLP using PR87 would have beneficial effects on dopamine regulation in the kidney.

Ted: And you said that you have no data to show that PR87 could actually target DLP. So, taking all this information together, I can say with certainty that I don't think we can extrapolate the efficacy and specificity of PR87, and assume that the same will apply for treatment of renal diseases.

The Singapore patent law states that "the patent specification shall disclose the invention in a manner which is clear and complete for the invention to be performed by a skilled person." This concept in patent law is called 'requirement of sufficiency of disclosure' or 'enablement'.

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The 'skilled person' mentioned here is a legal fictional concept that patent examiners and courts often use when examining a patent specification, by construing it through the eyes of this fictional person.

The 'skilled person' or 'person skilled in the art' may be a composite of skills from different real people, and this is a hypothetical concept, is assumed to be of competence at his/her work, knowledgeable about relevant literature in the field, but without being of an imaginative or inventive turn of mind.

The patent specification should provide sufficient information for the skilled person to determine whether or not, by following the teachings of the patent specification, the skilled person has achieved the defined result without undue experimentation and without exercising any inventive ingenuity. A patent may be revoked if the specification fails to do so.

In your case, assuming that a person with skills sufficient to perform routine laboratory experiments were to read your current patent specification, I don't think, from the specification as presently drafted, he/she would be able to assume that it naturally would also apply for treatment of renal diseases.

Dr. Curie: Thanks for clarifying, Ted. I will stick to our earlier schedule and send you the data for converting the provisional to international PCT application.

Ted: As always, happy to help! Look forward to receiving your new data and filing the international application.

A Case on Sufficiency of Claims

Warner Lambert Company vs Generics (UK) Ltd. t/a Mylan and another
By Sachin Seshadri

The operation of patent law may be viewed as a bargain whereby an inventor obtains a monopoly for his/her invention and the public in turn is provided with a sufficient explanation on how to practise the invention, and freedom from the inventor's monopoly after the expiry of the patent. The concept of sufficiency and an extension of it, plausibility, was addressed by the Courts in the following case. Pregabalin is a generic drug used to treat epilepsy and Warner-Lambert applied for a second-medical use patent for pregabalin for the treatment of pain. The following were the claims of the UK patent:

Use of (S)-3-(aminomethyl)-5-methylhexanoic acid or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.

Use according to Claim 1 wherein the pain is inflammatory pain.
Use according to Claim 1 wherein the pain is neuropathic pain.
Mylan and Actavis sought to revoke this patent on the grounds of insufficiency i.e. the applicant is not entitled to such a broad claim of treating all kinds of pain, since the patent only demonstrated treatment of inflammatory pain.

The experimental mice models used in the patent were the rat paw formalin test, the carrageenan test and the post-operative pain model. The rat paw formalin and carrageenan test have been used in the literature solely as models of inflammatory pain while the post-operative pain model is used in modelling nociceptive pain. Nociceptive pain is caused by potentially harmful external stimuli detected by nociceptive receptors. Warner-Lambert argued that empirical data from these models is sufficient to prove that Pregabalin can treat peripheral neuropathic pain too but the Courts did not agree. The Supreme Court opined that there must be a technical rationale in the specification which would elicit a person skilled in this art (for simplicity, let us assume this to be an amateur neurobiologist student) to think that Pregabalin could treat peripheral neuropathic pain too. The rat paw formalin and carrageenan test results were sufficient to demonstrate Pregabalin's effects on inflammatory pain but could not be extrapolated to peripheral neuropathic pain because nothing in the literature suggested that these models could also be used to study neuropathic pain.

There must be a unifying mechanism that links inflammatory pain and peripheral neuropathic pain and if the drug had targeted this unifying mechanism, then a valid argument could have been made in favour of Warner-Lambert's case. Warner-Lambert argued that the concept of central sensitization was a unifying link between the two kinds of pain.

However, the Court ruled that although central sensitization contributed to inflammatory and neuropathic pain, there was no valid hypothesis in the specification suggesting that Pregabalin targets the central sensitization mechanism. Thus, claims 1 and 3 were ruled invalid due to insufficiency while the remaining claims were deemed valid.

In conclusion, it appears that to obtain broader monopolies for drug treatments, the patent specification must contain a technical rationale or a unifying mechanism that connects several conditions of disease that elicits a person skilled in that art to make those small leaps in imagination across those disease conditions. Case summary adapted from: https://www.supremecourt.uk/cases/uksc-2017-0078.html

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