

INTANGIBLE

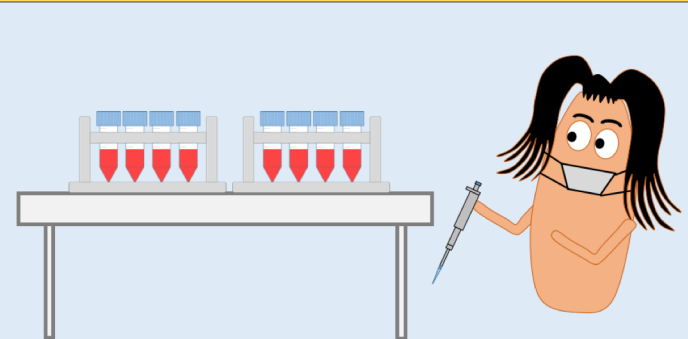
CTeD's Intellectual Property Digest

Patent Ineligible Subject Matter

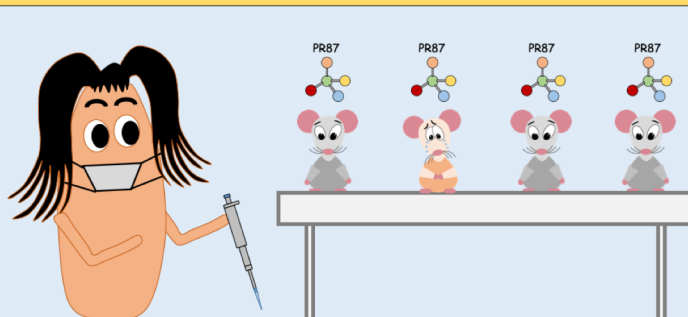
By Parakalan Rangarajan

Dr. Curie recently conducted a DNA sequencing analysis of samples derived from patients suffering from dopamine-related neurological disorders. Surprisingly, she found point mutations in Denim-1, which seem to affect dopamine levels, and could have an effect on PR87 treatment efficacy.

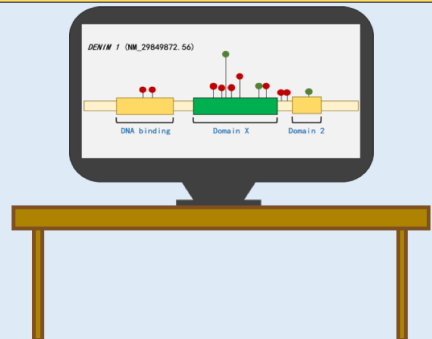
Dr Curie performs DNA sequencing of samples derived from patients suffering from dopamine-related brain disorders...



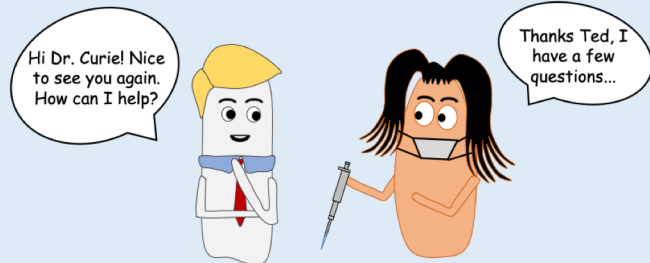
To test the functionality of these point mutations, Dr. Curie creates mutant mice. She discovers that only one particular point mutation of DENIM-1 causes PR87 treatment to be ineffective...



Dr Curie identifies that the active domain of Denim-1 (involved in regulation of dopamine) is a hotspot for genomic point mutations...



Dr Curie sets up a meeting with Ted to discuss if she can file a patent claiming the novel point mutants of DENIM-1...



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Dr. Curie: Hey Ted, it is nice to meet you again. I got some exciting results from my recent study. I found some novel mutant forms of Denim-1 which I believe can predict which patients will and which won't benefit from PR87 treatment.

Ted: Wow! That is some exciting new information, indeed!

Dr. Curie: Which is why I have come to you to ask if we could file a patent application claiming this?

Ted: Ah! Let me see if I am understanding this correctly. So, you are saying that you have discovered different forms of the Denim-1 protein, and one of which is resistant to PR87 treatment. So, you would like to know if you can protect these previously unknown forms of a known protein, denim-1.

Dr. Curie: That's exactly what I want to know.

Ted: While I certainly think there is patentability potential in your recent findings, I must however, inform you that the discovery of the mutant form of denim-1 is not patent eligible subject matter.

Dr. Curie: I don't quite understand. Just to re-iterate, these are previously unknown mutants of denim-1, and this knowledge that I have acquired has the potential to provide breakthrough in treatment of neuropsychiatric diseases.

Ted: I agree that your results are very promising. However, patent offices deny granting patents in which the claims are directed to abstract ideas, laws of nature and natural phenomena (including products of nature). Your discovery of the existence of previously unknown forms of a particular protein falls within this category of judicially recognized exceptions to patent eligibility.

Dr. Curie: Okay, now I understand. Patent laws are designed in this manner so that people do not claim monopoly to, and exclude others from utilizing and reaping benefits from things that already exist in nature. So, can you think of anything else in my recent findings that could be protected so that I have an incentive to work on this further and bring it to market?

Ted: Well, as I mentioned before, I do think you have some surprising findings which have potential for patentability.

For instance, a method of stratifying patients based on these point mutations to decide on whether or not they should receive PR87 could be patent eligible.

Another alternative approach would be to elucidate a novel gene signature that is potentially regulated by the PR87-treatment resistant mutant Denim-1, and use this information to identify new drugs targeting one or more key downstream molecular players, which could then be used in combination with PR87 to make it more efficacious and safe for treating neuropsychiatric disorders.

In other words, novel drug combinations/pharmaceutical formulations designed using new knowledge of naturally occurring molecules and signaling pathways is likely to be considered as patent eligible subject matter.

Dr. Curie: Oh cool! These are some great suggestions, and I am glad to inform you that I am already looking at some of the downstream targets of this treatment resistant mutant Denim-1. I shall get back to you in roughly 6 months' time with hopefully, some new leads. As always, it was great talking to you, Ted.

Case Summaries on Patent Ineligible Subject Matter

By Sachin Seshadri

The accompanying sketch tells us that IP practitioners can often be faced with the conundrum of whether a particular invention is indeed eligible for patent protection. We shall now look at a few cases where the law addresses the issue of patent eligibility with respect to diagnostics and method of surgeries. Section 101 of the US patent law defines subject-matter eligibility as follows: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".

"Because abstract ideas, laws of nature, and natural phenomenon are the basic tools of scientific and technological work, the U.S. Supreme Court has expressed concern that monopolizing these tools by granting patent rights may impede innovation rather than promote it. Accordingly, the Court has said that applications of abstract ideas, laws of nature or natural phenomena to devise a novel product or process may be eligible for patent protection"

- adapted from the USPTO webpage on Patent Subject Matter Eligibility

Often in diagnostic patents, the potential invention is directed to the existence of an aberration in the body (such as a mutation in a specific gene), and since this aberration is naturally occurring, it fails to qualify as a process, machine, manufacture or composition of matter, rendering it a "discovery" and not a "patent-eligible invention".

In *Association for Molecular Pathology vs Myriad Genetics*, claims were directed to BRCA1 and BRCA2 genes (and their mutations) for the diagnosis of breast cancer and these were ruled to be patent-ineligible. The US Courts designed a 2-step test to determine the eligibility of diagnostic patents: (1) determine if the invention is directed to patent-ineligible subject matter (2) If yes, determine if there is some inventive concept about the elements of the claim that transforms the invention into something more than an ineligible subject matter.

Applying this test in *Ariosa Diagnostics vs Sequenom*, claims directed to methods of isolating cell-free fetal DNA (cffDNA) from maternal blood and determining characteristics (such as the sex of the foetus) from the paternal DNA fraction were deemed invalid.

The claims were directed to the presence of cffDNA in maternal blood, a natural phenomenon devoid of human engineering. Steps such as isolating, amplifying and sequencing paternal cffDNA are routine and do not lend the necessary novelty or inventiveness either.

However, there is hope for patentees after *Vanda Pharma vs. West-Ward Pharma*. Here, the claims were directed to the application of a specific drug for a specific condition at a specific dosage based on the natural interplay between a gene, CYP2D6 and metabolism of the drug, iloperidone. The claim was ruled valid because there is a human-engineered application of this natural interplay to a method of treating schizophrenia patients at specific doses. Thus, it appears that the USPTO may look favourably at diagnostic claims which are worded as method of treatment claims.

In Singapore, to prevent monopolies on medical services, methods of treatment, diagnosis and surgery practised on a human and animal body cannot be considered for patent protection.

For surgical inventions, purely cosmetic procedures which are non-invasive and which do not have a therapeutic consequence may fall outside the above exception. For instance, cosmetic treatments such as removal of under-eye wrinkles by phototherapy or removal of body hair are concerned with aesthetics and have no therapeutic effects and hence these falls within the boundaries of patent-eligible subject matter. However, when surgical procedures have a therapeutic effect (irrespective of whether cosmetic benefits can be reaped too), the exception to patent-eligibility applies. For example, although removal of dental caries can also have a cosmetic teeth-whitening benefits, it is performed primarily to arrest tooth decay caused by bacteria. Such therapies cannot be offered patent-protection and the same applies to treatments/surgeries for other diseases.

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