

Innovating with Yesterday's Inventions: Repurposing Drugs for New Indications

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Pharmaceutical research and development (R&D) has skyrocketed in recent years and is projected to reach even greater levels in the [future](#). The total R&D spending has increased by 33 billion USD from 2005 to 2015 and is projected to rise by an additional 19 billion USD by 2020. Is there a way to cut these costs and still be as productive?

Instead of creating new compounds, drug developers can undergo [drug repurposing](#): finding new uses/indications for already known drugs. Potential [candidates](#) for repurposing include drugs that have long been on the market or that were shelved by inventors for reasons other than not meeting safety standards.

Repurposing drugs for new indications can save on time and money in R&D. Repurposed drugs are approved 3-12 years sooner and at a 50-60% lower cost than drugs created *de novo* (i.e. from scratch). These savings stem from the [data](#) that already exists on the drug, such as its safety information, prescribed dosage, and tolerability. This data allows one to bypass the early clinical trial phases that would have been used to gather this information in drugs developed *de novo*. Consequently, bypassing those phases will save developers the investment that would have been funnelled into those stages. An example of the benefits of drug repurposing can be seen in the emergency contraceptive, [mifepristone](#). This drug was repurposed for Cushing's syndrome. Repurposing required a clinical trial with only 30 patients to test the drug's efficacy. This trial was 1/3 the size of the trials used for newly developed drugs on Cushing's syndrome. By being 1/3 the size of the test for *de novo* drugs, the developers were able to save on resources that would have had to be funnelled into a larger test. Through repurposing, the developers produced a drug to treat Cushing's syndrome at a fraction of the cost. Given its benefits, repurposing drugs for new indications is a potential goldmine for the pharmaceutical industry.

So, why aren't more pharmaceutical companies repurposing drugs?

One of the major barriers to drug repurposing is its associated intellectual property (IP) drawback. It is cheaper to repurpose these drugs because they have existed for a long time and are thoroughly researched. However, because the drugs have existed for so long, most of the associated patent protection for their chemical composition would be nearing expiration or have already expired. The loss of patent rights for the drugs themselves reduces the ability of companies to recoup a healthy return on their R&D investment. Furthermore, despite the repurposed drugs being cheaper to develop, the R&D tests can still be very [costly](#), ranging between US\$40 – 300 million. Some drug developers may not want to risk investing into repurposing an old product with limited IP rights when they can funnel that money into creating something completely new.

However, this issue may not be as problematic as it first appears. Repurposing drugs opens the door to new IP rights. Once a new indication has been found for a drug, the developer could file a patent for the drug's use in the new [indication](#). This [type of patent](#) looks beyond the drug itself and focuses on the relationship between the drug and the new indication, providing the developer protection for the newly found use of the drug in treating the respective illness. Issuing patents for new uses of old inventions was first seen in *Shell Oil Co. v. Commissioner of Patents*. In *Shell Oil Co.*, the appellant discovered a new use for commonly known chemical compounds as plant growth regulators. Despite the lack of novelty in the compounds themselves, the appellant was able to obtain a patent on the new use of the compounds, with the application in plant growth regulation considered a "new and useful art" under s. 2 of the [Patent Act](#). Like the outcome of that case, repurposing drugs for new indications could be seen as a "new and useful art" under the Patent Act. Consequently, patent protection may be obtainable for drug developers and drug repurposing may still have IP potential.

It seems that repurposing drugs for new indications is just like the drugs at the center of the process – worthy of taking a second look.

Imtiaz Karamat is a Contributing Editor with the IPilogue. He holds a MSc from the Medical Sciences Graduate Program at McMaster University and is a JD candidate at Osgoode Hall Law School.

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