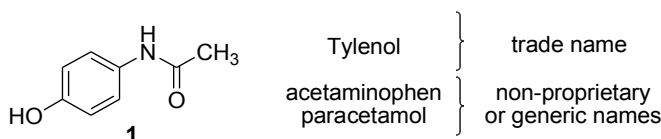


DavidsonX – D001x – Medicinal Chemistry  
Chapter 2 – Drug Discovery: From Concept to Market  
Part 3 – Intellectual Property  
Video Clip – Patents and Branding



Intellectual property is a legal description for certain types of intangible assets. The owner of intellectual property has the exclusive ability to operate within an area defined by those assets. Examples of intellectual property include **patents**, **trademarks**, trade secrets, and registered designs. In medicinal chemistry, patents and trademarks are the most important.

An example of a trademark is the brand name of a drug. Acetaminophen (**1**) is an over-the-counter medication. It is available in its generic form under the names of acetaminophen and paracetamol as well as the brand name Tylenol. Tylenol is a trademark. The owner of the trademark, McNeil Consumer Healthcare, pays to preserve its rights to control the name.



Patents are another type of intellectual property. Patents come in many different types, and the **composition of matter** form is likely most important in the pharmaceutical industry. A composition of matter patent protects a particular chemical substance. Like all patents, a composition of matter patent is valid for 20 years from the date of patent filing. This 20-year window is extremely important and defines the time period during which the drug company will be able to realize the maximum profits from the drug. After the patent expires, generic manufacturers will be able to sell the same drug. Competition will drive down prices, and profitability for the original company will fall.

A full 20 years may seem like a generous amount of time for a drug to recover its development expenses and turn a profit. It is not quite that simple. Drug companies patent interesting leads around the stage of animal studies. Before the lead can be sold as an approved drug, it must progress through all necessary animal studies, the IND application, clinical trials, and the NDA. The time period for each of these steps is *estimated* below, and the total can easily add up to ten years or more.

#### Estimated Time of Development

animal studies	2 years
IND application	1 month
clinical trials	~7 years
NDA	1 year

The actual time for a drug manufacturer to recover its research costs is around ten years. The exact number depends on how smoothly the drug discovery process goes for a specific drug. The finite length of a patent's lifetime places significant pressure on the drug discovery group to work as efficiently as possible to move a lead through the clinical and regulatory steps.

After a composition of matter patent expires, generic manufacturers are free to create their own versions of the same drug and seek approval from the FDA to market their drugs. The

approval process for a generic drug involves **bioequivalence** testing. The generic manufacturer must test its drug in humans and show that blood levels for the generic drug are similar to the branded drug. These trials are fairly short and must be less expensive than traditional clinical trials for new drugs. Therefore, generic manufacturers incur much smaller developmental costs and can charge less for their drugs.

An example of the financial impact of an expired patent can be seen in Pfizer's Lipitor. In 2011 Lipitor had global sales of US\$9.6 billion. At the end of 2011 the composition of matter patent expired and generic drugs entered the market. In 2012 the global sales for Lipitor had dropped to US\$3.9 billion – a drop of around 60%. The 2013 sales numbers will continue to drop. Because so much money is at stake, lawsuits between generic and branded drug manufacturers are very common.

The role of patents in the marketplace is two-fold. First, by granting market exclusivity, patents encourage the introduction of new drugs. Patents reward innovation. Second, with a 20-year lifetime, patents ensure that new drugs eventually become widely available at a lower price. Patents assure that innovations are made available to the public over time.