Medicinal Chemistry & Drug Discovery
Section 1.5.1 – Patents & Generics

Learning goals

- differentiate types of intellectual property
- distinguish branded and generic drugs

Vocabulary

- patent
- intellectual property
- composition of matter patent
- generic
- abbreviated new drug application
- Bioequivalence
- international non-proprietary name
- brand name
- trademark
- active pharmaceutical ingredient

What are **patents**?

- a form of **intellectual property** which are rights to a creative work
- give an inventor the ability to keep others from using an invention during the term of the patent
- have a life of 20 years from date of filing in most parts of the world
- most important for oral drugs is the **composition of matter patent** which covers a molecule's structure and its therapeutic use

Patents on a molecule are often filed late in the lead optimization stage as animal studies begin. The time to bring the lead through preclinical testing and clinical trials can easily be 10 to 12 years. If development requires 12 years, then the company (the patent holder) will only have 8 years of exclusive rights to the molecule. Therefore, the exclusive time window for any drug is effectively much shorter than the 20-year patent term would imply. What happens when the patent expires? **Generic** drug makers can begin marketing their own versions, their own drug formulations, of the same molecule.

What is a generic drug?

- approved by the FDA through an **abbreviated new drug application** (**ANDA**)
- ANDA for a generic drug requires **bioequivalence** testing to show the generic and original forms behave similarly
- same **active pharmaceutical ingredient** (**API**) as the branded drug

Generic drugs are sold under a different name than the original drug. The original drug actually has two names. One is the **brand name**. The brand name will be protected as a **trademark**, another form of intellectual property. The other name for the original drug is its **international non-proprietary name** or

INN. The INN is assigned to the molecule during clinical trials. Generic forms of a drug are sold under the INN while the original company will continue to sell its form of the drug under the brand name. Both the generic and branded forms are considered equally safe and effective by the FDA.