

cholesterol levels. It is worth noting at this point that there is no specific threshold set for biological activity that must be demonstrated in an *in vitro* or *in vivo* assay. A compound that has an IC_{50} of $100\ \mu\text{M}$ in an *in vitro* assay has demonstrated utility, as does a compound that has an IC_{50} of $1.0\ \text{nM}$ in the same assay, provided that there is a correlation between the *in vitro* assay and therapeutic application. In fact, it is not always necessary to have *in vitro* data at all. If it can be demonstrated that a compound is “structurally similar to a compound known to have a particular therapeutic or pharmacological utility,”¹⁰ then an assertion of utility can be made. This presumption of structural similarity is the basis for claiming a wide range of compounds surrounding a smaller set of compounds with demonstrated *in vitro* activity in an assay. Of course, the definition of “structurally similar” is in the eye of the beholder, so great care must be taken in determining the breadth and scope that is appropriate for a particular patent application.

INHERENT PROPERTIES AND PATENTABILITY

It is often the case that there are multiple uses for a single material, some of which may not be recognized when the material becomes available to the public. The discovery of a new use, property, or scientific explanation for the function of a pre-existing material does not, however, make the material itself patentable as a composition of matter.¹¹ Consider, for example, the invention of the first ball. If the first ball was invented by Jim Bounce, he could gain patent protection for the ball, assuming that he could come up with a real world utility for the ball. If his brother, John Bounce were to discover that the ball was red, he would not be able to gain a new patent on the ball based on his determination of the color of the ball. The fact that the ball is red is an inherent property of the ball and does not change the fact that it was already part of the public domain when John Bounce determined its color. In a similar sense, compounds that are publicly available are not patentable as compositions of matter if a new use is identified. Once a compound is available to the public (commercially available, published in the literature, etc.), discovery of an inherent property, such as activity in an *in vitro* assay, does not make the compound itself patentable as a composition of matter.

Continuing the red ball scenario, if Mark and Fred Parker, brothers and contemporaries of Jim Bounce, were to design a toy that incorporated the red ball as a component of the toy, then they could potentially receive a patent on the use of the red ball in the toy. Unlike the discovery of the color of the ball, the use of the red ball in the newly designed toy is not an inherent property of the ball. It is a new use or process that uses the red ball. The red ball itself is still no longer eligible for patenting as John Bounce