phenomena. In a similar manner, genetically modified organisms, such as microorganisms designed to produce human proteins (e.g., insulin) or an animal that has been genetically modified to establish a disease model (e.g., the SOD1 mouse model of ALS) are patent eligible. The genetic modification required to produce the invention falls outside of the scope of products of nature.

The second requirement for an invention or discovery to be considered patentable subject matter is that it "must be useful or have a utility that is specific, substantial, and credible."[7] In other words, if one were to invent a previously unknown class of compounds, in the absence of a use for the compounds, they are not patentable subject matter. Insubstantial or non-specific uses such as using the new molecules as filler material for a landfill are not enough to qualify a discovery as patentable subject matter. There must be some real world, credible utility for a discovery in order for it to be considered patentable subject matter.

Within the context of the pharmaceuticals industry, utility is often the treatment or prevention of a disease or condition. If, for example, it can be demonstrated that a new class of compounds is capable of lowering blood pressure in patients with hypertension, then the class of compounds may be considered patentable subject matter. They have a specific, real world utility as antihypertensive agents. Of course, generating human data for a single compound requires substantial investment in time, resources, and funding. Requiring human data to demonstrate utility for the purposes of gaining patent protection for potential therapeutic agents would represent a substantial burden.

Fortunately, human data are not required in order for an assertion of utility of a compound or set of related compounds. In fact, the efficacy and safety of potential therapeutic agents in the human population is not a consideration in the determination as to whether or not an invention is considered patentable subject matter. These issues are the purview of other regulatory bodies (e.g., FDA) and the USPTO guidelines explicitly state that "there is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders."[8] *In vivo* animal studies with recognized disease models are also not required, although they certainly could be used to demonstrate utility. A demonstration of utility can be met with an *in vitro* assay that is reasonably correlated with the desired therapeutic utility of a compound, composition, or process.[9] If, for example, a new compound were shown to inhibit HMGCoA reductase, an enzyme known to be important in cholesterol biosynthesis, in an *in vitro* assay, the compound would be considered to have utility as a cholesterol-lowering agent. Additional data such as *in vivo* models or clinical data are not required, as the *in vitro* assay for HMGCoA reductase activity has been shown to correlate with