only to reproduce the invention, which they cannot do through the course of the patent term and any extensions granted by the FDA. So, while there may be other molecules, perhaps better ones, available, imitators are unlikely to invest in their development, as they are unprotected and there is no guarantee that the FDA will approve them. So, in the field of a new drug development, a single chemical entity does have substantial value. Such is not the case in other industries where regulatory costs are not involved, such as in the chemical industry.

Once a decision is made about what is invented, how much to claim, and what specifically to claim, the process of drafting the specification begins. One method is to draft the main claim, defining the scope of the invention in the form of the statement of invention, which is the heart of the patent specification, and then, the rest of the specification and claims will be drafted.

Specification begins with a title. Newcomers to the field of patenting would be amazed or perhaps amused at the choice of patent titles and even the language used to describe an invention. Historically, inventors kept the titles vague to keep the searchers (who then did manual searches) from finding out about their inventions. Today, as most patent offices have gone electronic, this is no long an issue; nevertheless, the practice continues.

Patent applications have fixed formats that often vary between patent offices but nevertheless require a similar information submission: a background, summary, details of invention, and so on. The patent application must be comprehensive to demonstrate novelty and the inventive step in light of prior art. It should be understood that the purpose is not to fool the patent examiner into allowance but to protect the invention from the competitors who will challenge it, should it be worth anything. A full disclosure is required to keep the infringers out, to decrease the chance of their success in knocking out a patent. Additional statements are included, defining the features of the invention for use as a basis for specific claims, for example, stating "In one aspect the invention provides...." "In another aspect the invention provides...." The described widgets are new and form part of the invention. Attorneys have their word preferences, and standard statements to fill the specification are written quickly.

After the statements of invention, there is a description to indicate the preferred parts of the scope, and one or more formulae may be given, defining narrower subgeneric scopes. This section fulfills the requirement of the adequacy of description. The specification must also describe how the invention is to be carried out, an essential part of a patent application. This is a critical stage in deciding how and what to disclose. As discussed earlier, often at this stage, a decision may be made not to file a patent application, for the disclosure will inevitably cause the invention to escape from the hands of inventors, and if there were no certain ways to determine infringement, this would make patenting useless. It is also not a smart move to be deceptive when it comes to describing how the invention works; many a patent application has been declared invalid after the companies have made significant investments in marketing the invention, because a competitor was able to demonstrate that the inventors hid certain critical facts. It must be understood that the disclosures need not be for a commercial model of the invention and thus need not include many fine details generally required for a large-scale production of the invention, such as in-process specifications, certain handling conditions, the grade of excipients used, and so on, which may be material to produce a product fit for a particular purpose, such as human consumption. As long as the competitor can manufacture the article, not necessarily for the commercial