Developing a Patent Family Bigger than the Brady Bunch

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New drugs require a huge amount of innovation, time, capital and risk to get to market. Nobody should begrudge a drug company for seeking strong patent protection. Without it, generic drug copies would quickly flood the market, and the original drug manufacturer would lose money and go out of business. Patents help ensure that innovators thrive, so we get more of the R&D that is necessary to develop future drugs. Once the patents on a drug expire, the drug is public domain and any generic company is free to make its own version (subject to regulatory exclusivities, which will not be discussed here).

There is rarely a single patent on a new blockbuster drug. The initial patent will often focus on the drug compound itself, methods of manufacture and the known medical uses. Improvements are then captured, such as formulations that may provide greater stability or desired drug delivery properties. Combinations with other drugs may be made that provide better clinical outcomes. Chemical variants of the drug may be made by modifying the drug's side groups or attaching totally new functional groups. For example, some biologic drugs were the subject of another patent after they were PEGylated, which improved their stability against degradation in the body. Small chemical molecules may be developed into a new polymorphs or crystal. A new dosage form may be developed. A new isomer may be isolated with increased efficacy and lower toxicity. Improved methods of manufacture may be developed, including the development of new chemical intermediates for synthesis. New medical uses or highly effective dosages may be identified. Each of these could be the subject of a new patent.

The patents sharing common priority (ie. first filing date) are called a patent "family". Some patent families are small, while patent families on blockbuster drugs would typically put the Brady Bunch to shame! The entirety of the patents around a drug make up the patent portfolio. The continued filing of new patents is intended to prolong the patent protection around a drug. The drug's manufacturer can then enjoy a longer monopoly on the drug and increased profit margins. Generic drugs cannot launch competing, low-cost drugs while there is meaningful patent protection on a drug. The delay in generic market entry caused by improvement patents has been a source of consternation with some consumer groups and generic drug companies. Prolonging the patent protection through improvement inventions is reasonable if the drug manufacturer is making legitimate inventions that are new, inventive and useful. Patent Offices in key jurisdictions, such as the U.S., Europe and Canada examine patent applications to make sure these criteria are met. If these criteria are met, the drug manufacturer deserves its patent. If they are not, the Patent Office is right to refuse to grant a patent, or the patent should be invalidated in litigation. It is important for innovators work with their patent agents to be proactive in planning future R&D. Identify and capture the patentable intellectual property that it generates if there is a cost-benefit advantage. This will keep your drug patent portfolio on track for a long and productive life cycle.

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