

The interplay of drug design and patents

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13 Nov 2020

The development of novel or blockbuster drug compounds invariably requires an initial search to determine whether target compounds have already been synthesised and are protected by a patent.



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Several companies have developed interesting computational software suites that allow these searches to be performed in a matter of seconds, while other suites even provide synthetic alternative pathways that are not protected by a patent. While the results are easily attainable, some problems arise where some patents disclose a myriad of compounds through what is known as a Markush structure. Simply put, a Markush structure is used to represent a large set of related chemical compounds that can often be described over tens, if not hundreds, of pages in a patent document. It is important for each formulation, medicinal or synthetic chemist to discern the Markush structure from those structures or compounds that are exemplified in each patent document.

Typically, some patent documents disclose one or more Markush structures, but only a handful of the compounds are fully exemplified by providing the necessary experimental and analytical data that is required to synthesise the compounds. Each inventor will rightfully be devastated when they find out that their newly synthesised compound is in one line of text in a 500-page patent document, as this would constitute a disclosure which renders their invention unpatentable. However, it would appear that this is not necessarily the case.

Court decision

Our courts dealt with this issue in the case of *Merck Sharpe and Dohme Group & Merial LLC v Cipla Agrimed (Pty) Ltd.*^[1] In this case, the court had to determine with whether a throw-away reference to a compound would constitute disclosure of that compound. The court held that merely mentioning a compound is not sufficient for purposes of disclosure, as the compound would have to be exemplified in full by no further experimentation being required. As a result an enabling disclosure would be one where no further experimentation is required.

Inventors need to realise that the mere mentioning of a compound in a patent document does not necessarily mean that a separate patent cannot be obtained for such a compound.

It is important to establish whether the compound was properly exemplified, as a particular method of synthesising such a compound could very well be novel and inventive, and therefore patentable. If you are uncertain about whether your compound is patentable, it is strongly advised to contact a patent attorney in order to assess the patentable merit thereof.

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