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Editorial

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Litigation on the Increase in Pharma?

Many of you will know that I have acted on quite a few occasions as an expert witness in court on matters to do with process patents, crystallisation and polymorphism issues, salt forms, racemic or enantiomeric drugs, etc., and the number of cases going to court seems to be on the increase. In the period 2000−2010 there were 370 court rulings in the United States alone on pharmaceuticals, with 65 first-to-file lawsuits in 2009, up from 51 the previous year, and 24 in 2005.[1]

Most of these cases involve at least one generic company, and the overall success rate for the generic drug industry is 48% for cases that have gone to trial. However, the success rate increases to 76% when out-of-court settlements are included. Surprisingly, to use a well-known phrase in the patent arena, the results depended on where the trial was held, with some courts never ruling against a generic!

In recent years patent challenges have become the rule rather than the exception for generics, usually occurring when an inventor company's patent is about to expire and the generic company wishes to launch the competitive (usually lower cost) product. In the United States, the first ANDA[2] filer can receive 180 days of market exclusivity during which no other ANDA can be approved for the drug, so there is a large incentive to be the first to file. However, the downside is that they will probably be the first company to be challenged in the courts.

When filing an ANDA, generic companies acknowledge that certain patents exist but claim either that the generic drug (or its process or formulation) does not infringe and/or that the originator's patents are invalid. If the patent holder sues within a certain time period, then a 30-month deferment of FDA approval of the generic version may be granted. Thus, there is a clear incentive for the innovator to go to court as a delaying tactic, but only if they are confident of winning the case, since the 30-month-loss of sales of a generic drug may form part of the court's decision re: costs.

With many blockbuster drugs going off patent (i.e. the discovery or composition of matter patent has expired) in the next few years, innovator companies will be looking to process related patents to hold off the challenge from generics. However, generic companies are generally expert at getting around process patents by discovering modified processes, but whether these "new" processes infringe is matter of debate in court and outside. Expert opinion is usually called on by both sides to discuss the intricacies of different methods of making an API. It makes for fascinating discussions both in and out of court.

Being an expert witness is not everyone's cup of tea, with many of my acquaintances saying after the first appearance in court, "Never again". The pressure and tension when testifying in court is unlike anything else a scientist has to endure. Other scientists like the cut and thrust of the debate with opposing experts or with the lawyers and enjoy the detailed analysis of every facet of the case which is necessary to prepare for the trial. Personally I am in the latter camp.

Nevertheless, one thing is for sure; litigation is likely to be on the increase in the next few years, at least in the U.S.A. and possibly elsewhere.

Trevor Laird, Editor

REFERENCES

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