Generics Bulletin
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ANDA Litigants Join Forces To Cut Costs And Cope With Competition

13 Feb 2019 | **NEWS**

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Executive Summary

Generics firms challenging patents in the US are seeing benefits through teaming up, according to Kent Walker of Brinks Gilson & Lione.

TEAMING UP LEADS TO BENEFITS FOR ANDA LITIGANTS IN THE US *Source: Shutterstock*

Generics companies engaged in US abbreviated new drug application (ANDA) litigation are increasingly banding together to seek joint representation from a single law firm, according to Kent Walker, counsel at Brinks Gilson & Lione.

In an exclusive interview granted to *Generics Bulletin*, former Actavis and Mylan intellectual-property executive Walker said the trend towards joint representation was particularly prevalent among companies that were filing ANDAs containing Paragraph IV patent challenges on the first possible date – one year before new chemical entity (NCE) exclusivity expires.

Whereas five years ago, this NCE-1 first-filing date might typically have attracted six or seven filers, Walker revealed that he was involved in several cases for which 15 to 20 different companies had submitted ANDAs on the earliest possible date.

In many cases, he continued, several smaller players – including many that were domiciled outside of the US – were among the early paragraph IV filers. "These companies often have budgetary reasons to turn to joint representation and thereby realize economies of scale," he explained.

And with the increased number of NCE-1 filers, the risk of litigation bringing meagre rewards increased, creating a "perfect storm" that was putting pressure on law firms to offer more cost-effective solutions, Walker acknowledged.

Law Firms Actively Researching ANDA Dates

Approaches taken by such law firms had varied, he said, with some actively researching NCE-1 dates, investing in analysis of the originator's patent estate and drawing up positions on particular patents with which to attract clients. Questioned about how many clients could be served by a single patent-law firm, Walker suggested that a "sweet spot" might be two to four generics litigants.

Noting that it was commonplace in patent invalidity cases for Paragraph IV filers to reach joint defense agreements, Walker believed economic factors were a greater driver towards joint representation than the ability to share ideas on intellectual-property strategy. Where ANDA filers felt they had a substantial non-infringement argument, and a potentially unique approach to working around a key patent, joint representation became less attractive, he admitted.

Discussing possible cons to banding together as a co-defendant, Walker identified the potential for some clients to sit back and let others within the joint representation arrangement shoulder the burden, offering little in terms of time and resources. In part, he suggested, this could reflect the varying importance of a given product and patent challenge in each company's pipeline.

While Walker had not observed a similar move towards joint representation in biosimilars litigation, he saw no reason why the trend in the small-molecule ANDA field should not continue. "The number of players challenging patents appears to be increasing," he commented. And with budgets tightening, law firms were having to become more creative in ensuring that clients felt they were receiving value for money.