

The Litigator's Toolbox: Winning Oral Arguments Before Trial Courts
and Administrative Agencies – Hypothetical Case

Newpharma v. Pharmalicious

Pharmalicious, an established pharmaceutical company, manufactures Happynol, a “nextgen” anti-depressant, and markets it extensively in the United States and has begun to market it in Europe. Newpharma, a relatively new pharmaceutical company, would like to market its own version of Happynol, called Euphorizem. Pharmalicious holds a U.S. patent on Happynol, but does not produce or market Happynol in South America. Newpharma, however, plans to market Euphorizem in South America, but would also like to market it in Europe. Unlike most pharmaceutical products, it is particularly difficult to manufacture Happynol because it is produced using numerous biological enzymes and chemical reactions, some of which are separately patented by Pharmalicious in the U.S. and in Europe. Because Europe is not the primary focus of Pharmalicious's marketing efforts, it has agreed to license its relevant patents with respect to Happynol and the processes used to produce it to Newpharma, so that Newpharma can market Euphorizem in Europe and South America.

In January 2008, Pharmalicious and Newpharma signed the “Euphorizem Licensing Agreement.” As part of the Licensing Agreement, Pharmalicious agrees to use “reasonable commercial efforts” to “assist” Newpharma in manufacturing and gaining regulatory licenses to market Euphorizem. The Agreement defines “reasonable commercial efforts” as “reasonable, diligent, good faith efforts to assist Newpharma, but not including efforts that would be disproportionately adverse to Pharmalicious's interests or own products.”

The Licensing Agreement further explains that as “assistance,” Pharmalicious shall

(i) promptly provide Newpharma with any necessary Pharmalicious know-how and/or technology required for Newpharma to manufacture Euphorizem;

(ii) promptly provide Newpharma with access to and assistance with Pharmalicious know-how and technology so that Newpharma may properly apply for any necessary regulatory licenses that relate to Newpharma's production or marketing of Euphorizem; and

(iii) promptly provide the relevant regulatory authorities with access to and assistance with Pharmalicious know-how and technology that is reasonably necessary to obtain production and/or marketing authorization with respect to Euphorizem.

The Licensing Agreement also provides that Newpharma shall reimburse Pharmalicious for any “reasonable, documented out-of-pocket costs” incurred in fulfilling its obligations to Newpharma. The Agreement also states that it to be construed in accordance with the laws of the “State of New York.”

Before Pharmalicious and Newpharma began negotiating the Euphorizem Licensing Agreement, they had negotiated a similar agreement with respect to a biological enzyme that Pharmalicious manufactures. In that agreement, which was executed in August 2007, Pharmalicious agreed to provide “all possible efforts” to “assist” Newpharma with marketing the biological enzyme. In October 2007, in the course of negotiations for the Euphorizem Licensing Agreement, Newpharma’s negotiators had urged Pharmalicious to adopt a similar “all possible efforts” clause in the agreement. In November 2007, Pharmalicious’s negotiators responded, suggesting instead a clause requiring Pharmalicious to provide only “commercially prudent efforts that would not in any way adversely affect Pharmalicious’s interest or own products.”

In February 2008, Newpharma discovered that the formulations of Happynol that Pharmalicious had developed for use in the United States were not as effective as had been expected in the warmer and more humid climates in parts of South America. Therefore, Newpharma requested that Pharmalicious undertake research to develop a more effective formulation that Newpharma could market as Euphorizem to South America. In doing so, Newpharma invoked the “commercially reasonable efforts” clause in the Licensing Agreement and offered to pay Pharmalicious’s “out-of-pocket costs.” Taking the position that the “commercially reasonable efforts” clause does not require Pharmalicious to undertake new research or otherwise disrupt its own complex research activities, it refused to comply with Newpharma’s requests, but offered to renegotiate the Licensing Agreement. The parties agree

that Newpharma's request would cause Pharmalicious to incur significant expenses, only some of which would be "out-of-pocket costs," but it is not clear the precise amount of such expenses, not exactly what proportion of those expenses would be "out-of-pocket costs."

Given its steadfast belief that its request was consistent with the parties' Agreement, and the urgency with which a new South America foundation was needed, in early March 2008, Newpharma brought suit in a United States district court seeking to compel Pharmalicious to provide the research assistance that Newpharma had requested. Pharmalicious promptly moved to dismiss the case for failure to state a claim upon which relief could be granted. After somewhat expedited briefing, the motion to dismiss is scheduled for a hearing on April 18, 2008.

This dispute, which is to be resolved under New York law, raises the following issues:

1. Whether the "commercially reasonable efforts" clause and other provisions of the parties' agreement obligate Pharmalicious to undertake new research using its employees, technology, and facilities to assist Newpharma in developing a more effective formulation for its anti-depressant.
2. Whether the drafting and/negotiating history of the parties' agreement supports either party's arguments.