



Biochemical Analysis

→ Challenge

PharmaForensics Laboratories was contacted by a large East Coast law firm representing a major pharmaceutical brand. Their client needed help in an infringement case involving an FDA-approved drug comprised of an antibody. The lead attorney asked us to independently perform a comparative biochemical analysis between their client's drug and their competitor's, following assay methods described in the patent in suit. Each assay evaluated the ability of the antibody drugs to neutralize the effects of their specific antigen in mammalian cell-based assays.

↳ Solution

We performed biochemical analyses of the two antibodies in three phases. In Phase 1, we procured the required cell strains and established appropriate culture conditions. In Phase 2, we established the repeatability and robustness of the biochemical assays using a known, commercially available antibody that acted on the same antigen. In Phase 3, we evaluated the client and competitor's pharmaceutical compositions to neutralize the effect of the antigen. Our independent results were consistent with the client's internal analyses.

↗ Results

We compiled and summarized the results and submitted a detailed report to the lead attorney. This report was subsequently converted into an "expert" report that was submitted to the opposing legal counsel as part of the litigation process. During deposition, Dr. Kittendorf of PharmaForensics Laboratories was called on to testify about our methods and data analyses. •

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Email us at info@pharmaforensicslabs.com or call **734-996-7343** to learn how we can assist with your infringement matter.