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No Enablement of a "Make and Screen" Invention Where Working Examples Do Not Represent Diversity of the Claimed Genus

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Claim 1 of the asserted patent in this case was directed to a genus of antibodies defined by two requirements—an isolated antibody or antibody fragment (1) "binds Factor IX or Factor IXa" and (2) "increases the procoagulant activity of Factor IXa."

In reaching its decision, the court first walked through the *Wands* factors and found the number of potential candidate antibodies that could fall within the scope of the claim was potentially in the millions, and that screening was required at every "critical step" to determine whether antibodies fall within the claims. The court further found that there were few working examples in the specification and little guidance for how to identify which candidates satisfy the claim. The court deemed the field of antibodies unpredictable, and found the lack of guidance compounded the unpredictability.

Based on its review of the *Wands* factors, the court dubbed the technology a "make and screen invention," where suitable antibodies could only be discovered through trial and error. The court discounted the patentee's argument that the claimed genus contains few antibodies, finding the disparity between the number of possible candidates and the number of claimed antibodies weighed in favor of no enablement. The court reasoned "[t]hat there are fewer needles in the haystack makes the search harder, not easier."

The court also gave little credit to the patent's teachings regarding how screening should be performed to identify suitable antibodies, finding that even if such screening had become routine, the teachings still required someone to repeat the same process the inventors used in the first place.

Next, the court noted that although the claims covered antibodies having a wide range of efficacies, there was no indication that antibodies were made or could have been made that achieved the highest levels of efficacy. The court appeared particularly persuaded by two facts. First, the accused infringer took almost 10 years to develop the accused product, which achieved better activity than any antibody disclosed in the patent, but was still far lower than normal levels. Second, the patentee never brought a product to market that embodied the claimed invention. In fact, one of its experts eventually conceded that the patent's description of therapeutic utility was aspirational, and that it would be difficult or impossible to create an antibody that increased activity back to normal levels.

Finally, the court noted that the working examples in the patent were limited to mouse monospecific IgG or IgM antibodies, which made up only a small subset of the broad antibody structures the claim covered. The court noted that the specification "does not remotely enable the accused antibody," a bispecific antibody that plaintiff alleges falls within the claims. The dependent claims fared no better—some of them limited the genus to specific structural features for which there were zero examples.

The court concluded that the patent owner merely provided a starting point for further research, but was attempting to claim someone else's solution.

Practice Tip: Patent Owners should pursue a range of genus claims, some tailored specifically to the working examples in the patent and, in response to an enablement challenge, should highlight any teaching in the patent that provides a shortcut in development, whether it be structural features of relevant compounds or manufacturing techniques that can be used with some expectation of success. For patent challengers, this case reinforces that it can be important to establish the breadth of claims and the degree of trial and error required to identify candidates that fall within a genus.

Baxalta, Inc. v. Genentech, Inc., 1:17-cv-00509 (D. Del. Jan. 13, 2022)

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