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Incomplete Hybridization: Lack Of Enablement Found Where Claims Encompass Thousands Of Possibilities

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Finding that the number of possible embodiments that could fit within the limitations of the asserted claims numbered in the "tens of thousands," the US Court of Appeals for the Federal Circuit held that the claims were not enabled because undue experimentation would be required given the high number of possible embodiments and the unpredictability in the art. *Enzo Life Sciences, Inc. v. Roche Molecular Systems, Inc. et al.*, Case Nos. 17-2498, -2499, 2545, -2546 (Fed. Cir. July 5, 2019) (Prost, CJ).

Enzo filed suit against Roche, Becton Dickinson and Abbott Laboratories alleging infringement of patents directed to non-radioactive labeling of polynucleotides where the label is attached at the phosphate position of a nucleotide. Enzo also asserted a patent directed to *in situ* hybridization and liquid phase hybridization against Abbott. The district court granted motions for summary judgment, finding all of the asserted claims of both patents invalid for lack of enablement. Enzo appealed.

The Federal Circuit summarized the current enablement doctrine, noting that to prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without undue experimentation. The Court stated that in analyzing undue experimentation for purposes of determining enablement, it considers factors such as:

- The quantity of experimentation necessary
- The amount of direction or guidance presented
- The presence or absence of working examples
- The nature of the invention
- The state of the prior art
- The relative skill of those in the art
- The predictability or unpredictability of the art

- The breadth of the claims

Although a specification need not disclose what is well known in the art, that rule is not a substitute for a basic enabling disclosure; a patentee cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification.

Turning to the patents-at-issue, the Federal Circuit invalidated the claims related to non-radioactively labeled polynucleotides in nucleic acid hybridization and detection applications, finding that the desired functionality was not sufficiently enabled. The Court found that the specification failed to adequately teach a skilled artisan which variable combinations would produce a polynucleotide that was hybridizable and detectable upon hybridization. The Court explained that merely stating that a labeled polynucleotide would work as a probe was not sufficient to enable a skilled artisan to know that it would function as a probe and be hybridizable and detectable upon hybridization given the broad claims, the degree of unpredictability of art at the time of patent filing, and serious doubts in the art whether labels could be successfully attached to specific positions without disrupting hybridization. The Court also found that because the specification did not enable the narrower claims of the non-radioactive labeling of polynucleotides patent, it also did not enable the broader claims directed to *in situ* hybridization and liquid phase hybridization patent.

Practice Note: In an invention where multiple combinations of variables are possible to achieve a desired functionality, the patent specification must sufficiently guide a skilled artisan of the invention to adequately enable the invention. In combination with the recent *Quake* decision (*IP Update*, Vol. 22, No.8) on written description, an inventor must “mark[] trails by making blaze marks on trees to find one’s way through the woods of a specification such that a skilled artisan would be able to follow that trail and understand what the inventors had invented.” Even though a skilled artisan in the sciences is very knowledgeable, the inventor cannot simply assume that a skilled artisan will be able to “connect the dots” on her own. Sufficiently specific guidance must be explicitly disclosed to show not only possession, but also enablement (reducing undue experimentation).

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