ENZO LIFE SCIENCES, INC. v. ROCHE MOLECULAR SYSTEMS, INC., Appeal Nos. 2017-2498 -2499, -2545 and -2546 (Fed. Cir. July 5, 2019). Before Prost, Reyna, and Wallach. On appeal from D. Del. (Chief Judge Stark).

Background:

Enzo Life Sciences (Enzo) sued Roche Molecular Systems, Inc. and others (Roche) for infringement of two patents, drawn to hybridizable non-radioactively labeled polynucleotides that are detectable upon hybridization. These materials and earlier radioactively labeled polynucleotides are known as "probes" in the art and are used to detect the presence of nucleic acid sequences of interest. Non-radioactively labeling was just developing at the time of the claimed inventions. The first successful non-radioactively labeled probes were developed in 1981 and a patent portfolio covering this technology was exclusively licensed to Enzo. Enzo soon thereafter filed an initial application in 1982, from which priority was claimed by the applications, filed in 1995, that became the two patents in suit.

The claims in the narrower of the two patents are not directed to any specific polynucleotide, nor do they focus on the chemistry or linker used to attach a label, the number of labels to attach to a polynucleotide, or where within the polynucleotide to attach those labels. Instead, the claims encompass *all* polynucleotides with labels attached to a phosphate,[1] as long as the polynucleotide remains hybridizable and detectable upon hybridization.

A motion for summary judgment by Roche on grounds of patent invalidity for lack of enablement was granted. Enzo appealed to the Federal Circuit.

Issue/Holding:

Did the district court err in granting summary judgment to Roche? No, affirmed.

Discussion:

The Federal Circuit began by discussing the so-called *Wands* factors[2] in order to determine whether the claimed invention could be practiced without undue experimentation. The court concluded that it could not. The court framed the issue as whether the specification enables creation of a labeled probe that is both "hybridizable and detectable upon hybridization," which the court characterized as a "focus on the functionality required by the claims." The court found that *Wyeth and Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380 (Fed. Cir. 2013) controlled the case in that, like in *Wyeth*, the evidence showed that each compound within the terms of the claims would need to be first made and tested to determine if it had the requisite functionality. Indeed, Enzo's expert testified that at the time of the claimed invention, "each labeled polynucleotide would need to be tested to determine whether it is hybridizable and detectable upon hybridization."

Relying on the expert's testimony, the unpredictability of the art, and the breadth of the claims, the court concluded that the claims did not satisfy the enabling disclosure requirement of the statute.

[1] A single nucleotide is made up of a sugar, a phosphate, and a nitrogenous base.
[2] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).