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Patent Validity Could Come Down to Clarity

A patent is intended to expand the public's knowledge in a particular area of technology, and it must clearly convey exactly what the patent covers and what it does not. An individual learns that information by reading the patent's claims, a relatively simple task unless a claim term is unclear, or, to use the legal term, indefinite. If an indefinite term is clarified in the body of the patent or in the patent's record on file at the U.S. Patent and Trademark Office (USPTO), the term will not invalidate the patent. If it is not, however, the claim, and often the entire patent, can be deemed invalid. The standard, recently articulated by the U.S. Supreme Court, is that a patent is invalid for indefiniteness if its claims, read in light of the body of the patent and the patent's record on file at the USPTO, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Two recent cases demonstrate how a failure to meet this standard can defeat a patent.

One case focused on the term average molecular weight used to characterize a polydisperse polymer. Teva Pharmaceuticals' Patent No. 5,800,808 describes a method for making copaxone, a drug used to treat multiple sclerosis. Copaxone is a synthetic polypeptide analog of myelin basic protein known as copolymer-1. Copaxone is polydisperse but has a narrowly defined average molecular weight range of 5–9 kilodaltons; copolymer-1, as obtained directly from synthesis, typically has a higher average molecular weight. In the method claimed in Teva's patent, a chemically protected form of copolymer-1 as obtained from synthesis is converted to its trifluoroacetyl derivative and deprotected to produce a synthetic copolymer-1 with an average molecular weight within the desired range.

When Teva sued Sandoz and Mylan, both developers of generic forms of copaxone, for patent infringement, the defendants challenged the claim for indefiniteness. They argued that the expression *average molecular weight* as applied to a polydisperse polymer could refer to a weight average, a number average, or a peak average (the value at the peak apex in a size-exclusion chromatogram), each of which could have a different value. Sandoz and Mylan contended that by not indicating which average the patent was referring to, the patent failed to inform the reader as to what the claim covered. Neither the patent nor the official record of the patent in the Patent Office included any statements identifying the type of average molecular weight of interest, or acknowledgment of three such averages.

A pair of later but related patents, filed as continuations of Patent No. 5,800,808, were also brought into evidence, since both contained claims that included the same reference to average molecular weight. In those patents, however, the

USPTO questioned the meaning of the expression and, interestingly, the patent attorney responded with a different explanation for each patent. The attorney said that the expression referred to weight average for one of the patents, and peak average for the other. This difference added to the indefiniteness of the patent claim, which was accordingly held invalid.

The second case involved Dow Chemical Co.'s Patents No. 5,847,053 and No. 6,111,023. This case concerned the methods used to determine the slope of a curve. The invention in both patents was essentially the same: composition of a polymer mixture consisting of a pair of ethylene polymers that is used to make thin films with high tensile strength and high impact strength. The patents define each ethylene polymer by a combination of parameters, one of which is the strain-hardening coefficient (SHC). Dow conceived of the SHC and defined it as the product of the slope of a stress/strain curve in the hardening region of the curve and $I_2^{0.25}$, where I_2 is the melt index in g/10 min; both patents specified an SHC greater than or equal to 1.3. The strain-hardening region is near the end of the stress/strain curve just before the sample breaks.

When Dow sued Nova Chemicals for patent infringement, Nova challenged the claims for indefiniteness. Nova argued that the strain-hardening region of the stress/strain curve was itself a curve, with a varying, rather than a single, slope. An explanation was provided in the body of each patent instructing the reader to use the slope of a line parallel to the curve in the strain-hardening region. Since a line and a curve cannot be completely parallel, however, and neither of the patents included a figure showing the stress/strain curve, the explanation was inadequate. To address this problem, Dow presented an expert at trial who testified that a person of ordinary skill in the art would know to measure the slope at its maximum value on the curve, since this value would reflect the best tensile performance of the material. Nova responded that the maximum value itself could be measured in different ways, each potentially producing a different result.

Polymer chemists use three methods to determine the relevant slope of this curve. The *10% secant tangent method* measures the slope of a straight line drawn between the failure point and a point 10% back from the failure point; the *final slope method* measures the slope of the curve just prior to the break; and the *most linear method* measures the slope of the line between two manually selected points in the most linear portion of the curve. For a given polymer, each method would produce a different result, and yet neither the patents nor their official record specified which one was to be used in interpreting the claim. These patents were, therefore, declared invalid as well.

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