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Definite Indefiniteness of "Molecular Weight" as a Claim Term for Polymer-Related Patents

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DEFINITE INDEFINITENESS OF "MOLECULAR WEIGHT" AS A CLAIM TERM FOR POLYMER-RELATED PATENTS

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ABSTRACT

The molecular weight of a polymer is not just a number for a single molecule. In fact, molecular-weight measurement is based on a large volume of molecules of the same polymer. Due to the non-uniformity of molecular weights,

there are several methods to measure an "average molecular weight" of a polymer. Unfortunately, the Federal Circuit in Teva Pharms. USA, Inc. v. Sandoz, Inc., 789 F.3d 1335 (Fed. Cir. 2015), held that the term "molecular weight" in several polymer claims were indefinite, because the term could mean either peak average molecular weight, number average molecular weight, or weight average molecular weight. This paper analyzes the claim construction and indefiniteness determination in Teva to illustrate the flaws of the patentee's specification. This paper also proposes practical solutions for patent drafting to avoid indefiniteness issues.

I. INTRODUCTION

A molecule is a compound of atoms that are combined through covalent bonds.[1] "Molecular weight" is defined as a "[s]um of the atomic masses of the atoms (or ions) in a molecular (or formula unit)."[2] The unit of the molecular weight of a molecule is a mu, or *u*, also known as "the molecular mass (or formula mass) of a compound."[3] Amu, or *u*, is replaced by dalton (Da) for the masses of large molecules.[4] That is, 1 *u* is equal to 1 Da.[5] Although molecular weight is a scientifically-defined term, the Federal Circuit in *Teva II*,[6] a 2013 decision, held that the term molecular weight in disputed claims was indefinite.[7]

Teva II involved nine patents.[8] The Federal Circuit interpreted molecular weight as it is associated with a polypeptide copolymer used for treatment of multiple sclerosis.[9] The Federal Circuit divided the claims in dispute into two groups.[10] The representative claim of Group I recited "a molecular weight of

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[1] *See* MARTIN S. SILBERBERG, CHEMISTRY: THE MOLECULAR NATURE OF MATTER AND CHANGE 64 (McGraw-Hill, 2d ed. 2000).

[2] *See id.* at 91 (Table 3.1).

[3] *See id.*

[4] *See* NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY, DEPARTMENT OF COMMERCE, THE INTERNATIONAL SYSTEM OF UNITS (SI) 34 (Barry N. Taylor & Ambler Thompson eds., 2008), www.nist.gov/document-16400 [hereinafter NIST].

[5] *See id.*

[6] Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva II*), 723 F.3d 1363 (Fed. Cir. 2013), *vacated*, 135 S. Ct. 831, *remanded to* 789 F. 3d 1335 (Fed. Cir. 2015).

[7] *See* John C. Gatz, *Decisions in Brief*, 6 LANDSLIDE 55, 57 (2014).

[8] *See Teva II*, 723 F.3d at 1366, 1366 n.1 ("The asserted patents are: U.S. Patent Nos. 5,800,808 ('808 patent), 5,981,589 ('589 patent), 6,048,898 ('898 patent), 6,054,430 ('430 patent), 6,342,476 ('476 patent), 6,362,161 ('161 patent), 6,620,847 ('847 patent), 6,939,539 ('539 patent), and 7,199,098 ('098 patent).").

[9] *See* Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva I*), 876 F. Supp. 2d 295, 305 (S.D.N.Y. 2012); *see also Teva II*, 723 F.3d at 1367.

[10] *See Teva II*, 723 F.3d at 1366, 1366 n.2 ("The six Group II claims are: claims 1 and 2 of the '430 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, and claims 1 and 8 of the '098

about 5 to 9 kilodaltons,"[11] while the representative claim of Group II recited "over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa."[12] However, when construing molecular weight, the Southern District of New York in *Teva I*[13] did not distinguish between Group I claims and Group II claims.[14]

The district court construed molecular weight in light of the issue of indefiniteness[15] and found the disputed claims valid.[16] However, the Federal Circuit disagreed.[17] By interpreting those two claim groups differently,[18] the Federal Circuit finally held that Group I claims were indefinite and that Group II claims were definite.[19]

In 2014, the *Teva II* decision was petitioned to the United States Supreme Court, which granted certiorari on the question of the appellate court's review standard for claim construction.[20] The petition focused only on Group I claims.[21] In 2015, the Supreme Court in *Teva III*[22] vacated and remanded the *Teva II* decision, because the Federal Circuit chose the wrong standard of review for the factual findings of the district court regarding the claim construction of "molecular weight."[23] The correct standard clarified by *Teva III* was the "clear error review,"[24] under which "the Federal Circuit should have accepted the District Court's finding unless it was 'clearly erroneous.'"[25] Eventually, the Federal Circuit in *Teva IV*[26] applied the "clear error review" and reaffirmed the indefiniteness of the disputed term molecular weight in Group I claims.[27] The reason was that the molecular weight could be calculated in three ways.[28]

The *Teva II* decision is the first case where the Federal Circuit actually in-

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patent. The remaining claims are collectively referred to as Group I claims.").

[11] *Teva II*, 723 F.3d at 1367 (1 Da = 1.660 538 86(28) × 10^{-27} kg). *See* NIST, *supra* note 4, at 34.

[12] *Teva II*, 723 F.3d at 1367.

[13] *Teva I*, 876 F. Supp. 2d at 295.

[14] *See Teva II*, 723 F.3d at 1367.

[15] *See Teva I*, 876 F. Supp. 2d at 400.

[16] *See* J. Jonas Anderson & Peter S. Menell, *Restoring the Fact/Law Distinction in Patent Claim Construction*, 109 NW. U. L. REV. ONLINE 187, 199 (2015).

[17] *See Teva II*, 723 F.3d at 1366.

[18] *See id*.

[19] *See id*.

[20] *See* Teva Pharms. USA, Inc. v. Sandoz, Inc., 134 S. Ct. 1761, 1761 (2014); *see also* Patti B. Saris, *The Indefinite Role of the Tr8ial Judge in Patent Litigation*, 18 LEWIS & CLARK L. REV. 751, 759 (2014); Brandi Doyle, *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc. Arguments Scheduled 15 October 2014*, 96 J. PAT. & TRADEMARK OFF. SOC'Y 261 (2014).

[21] Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva IV*), 789 F.3d 1335, 1339 (Fed. Cir. 2015).

[22] Teva Pharms USA, Inc. v. Sandoz, Inc. (*Teva III*), 135 S. Ct. 831 (2015).

[23] *See id.* at 840–43.

[24] *See id*. at 840.

[25] *Id*. at 843.

[26] Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva IV)*, 789 F.3d 1335 (Fed. Cir. 2015).

[27] *See id.* at 1338.

[28] *See id.* at 1344–45.

terpreted molecular weight for polymer patents. In fact, molecular weight is not a strange term to the Federal Circuit. In 2009, the Federal Circuit in *ClearValue, Inc. v. Pearl River Polymers, Inc.*[29] dealt with a claim related to a process for water treatment.[30] The plaintiff's infringement allegation depended on whether the accused process covered the limitation "high molecular weight di-allyl dimethyl ammonium chloride (DADMAC) *having a molecular weight of at least approximately 1,000,000 to approximately 3,000,000*."[31] Although the claim construction of molecular weight was not disputed on appeal,[32] the Federal Circuit experienced the different definitions of molecular weight in the context of polymer chemistry.[33] There, the defendant proposed a broader interpretation as "the sum of the atomic weights of all the atoms in a molecule."[34] Nonetheless, the plaintiff asked for a narrow version as "those in the industry normally calculate molecular weight by measuring a viscosity value and then using a known correlation to achieve the final molecular weight value."[35] The district court adopted the plaintiff's approach and interpreted molecular weight as "the sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods."[36]

The *ClearValue* and *Teva* cases show the complexity of molecular weight for polymers because different measurements create different aspects of molecular weight. Although the standard of review for a district court's factual finding regarding claim construction is the key issue in *Teva III*,[37] it is necessary to explore why molecular weight became an "indefinite" term in *Teva II* and *Teva IV*. In this Article, Part II[38] discusses definitions and measurements of molecular weight in the context of polymer technology. Part III[39] analyzes the claims-in-suit and claim constructions in the *Teva* cases. Part IV[40] explores the nature of indefiniteness of molecular weight as a claim term for polymer patents and discusses what may be sufficient patent drafting.

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[29] ClearValue, Inc. v. Pearl River Polymers, Inc., 560 F.3d 1291 (Fed. Cir. 2009).

[30] *See id.* at 1295.

[31] *See id.* at 1295–96 (emphasis in original).

[32] *See id.* at 1301–02 ("On appeal, ClearValue, Haase, and Waggett challenge the ruling of the district court that they engaged in sanctionable conduct.").

[33] *See id.* at 1296.

[34] *Id.* (reciting the defendant's construction).

[35] *See ClearValue*, 560 F.3d 1291, 1296 (Fed. Cir. 2009).

[36] *Id.* (quoting Clearvalue, Inc. v. Pearl River Polymers, Inc., No. 6:06–CV–197, 2006 WL 2032313, at *2 (E.D. Tex. July 17, 2006)).

[37] *See* Doyle, *supra* note 20, at 262.

[38] *See infra* Part II.

[39] *See infra* Part III.

[40] *See infra* Part IV.

II. MOLECULAR-WEIGHT DETERMINATION FOR POLYMERS

A. Polymers

A polymer is often referred to as a high-molecular-weight substance.[41] A polymer is composed of repeating units connected by covalent bonds.[42] For example, a polyethylene molecule is composed of a number of the unit –[CH_2–CH_2]–.[43] Making a polymer is referred to as "polymerization."[44] Polymerization involves chemical reactions among monomers by a specific mechanism.[45] For example, ethylene (CH_2=CH_2) molecules are used as monomers to form polyethylene molecules.[46]

Polymerization does not transform monomers into a single polymer molecule or polymer molecules of the same size.[47] Instead, polymerization ends up with a bulk of polymer molecules of different sizes.[48] In addition, polymerization does not always result in high-molecular-weight molecules.[49] Rather, polymerization produces low-molecular-weight substances called "oligomers" that are made of a small number of monomers.[50] Non-uniformity of polymer molecule sizes adds complexity to the concept of molecular weight of a polymer.

A polymer is a mixture of molecules of the same kind, but these molecules may have different molecular weights.[51] Therefore, the molecular weight of a polymer actually means the average molecular weight.[52] The distribution of different molecular weights must be characterized for the calculation of an average molecular weight.[53] The molecular weight of a polymer influences the properties of the polymer.[54] To make a polymer with certain desired properties, it is important to measure the average molecular weight of such polymer.[55]

The *Teva II* court recognized three definitions of "average molecular weight:" "the peak average molecular weight (M_p), number average molecular

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[41] *See* HARRY R. ALLCOCK & FREDERICK W. LAMPE, CONTEMPORARY POLYMER CHEMISTRY (Prentice-Hall ed., 2d ed. 1990).

[42] *See* A. RAVVE, PRINCIPLES OF POLYMER CHEMISTRY (Springer-Verlag New York ed., 3d ed. 2012).

[43] *See id.* at 3.

[44] *See* ALLCOCK & LAMPE, *supra* note 41, at 2.

[45] *See* RAVVE, *supra* note 42, at 2–7.

[46] *See* ALLCOCK & LAMPE, *supra* note 41, at 2.

[47] *See* RAVVE, *supra* note 42, at 51.

[48] *See id.*

[49] *See* ALLCOCK & LAMPE, *supra* note 41, at 2.

[50] *See id.*

[51] *See* GEORGE ODIAN, PRINCIPLES OF POLYMERIZATION (John Wiley & Sons, Inc. ed., 3d ed. 1991).

[52] *See id.* at 20.

[53] *See id.*

[54] *See id*. at 19–20.

[55] *Id*.

weight (M_n); and weight average molecular weight (M_w)."[56] The Federal Circuit further stated:

> M_p is the molecular weight of the most abundant molecule in the sample. M_n is the arithmetic mean, or the total mass of all the molecules in the sample divided by the total number of molecules. M_w is still another average molecular weight measure that is calculated differently from M_p and M_n. In a typical polymer sample, M_p, M_n, and M_w have different values.[57]

However, there are more details regarding "average molecular weight" in terms of definitions and measurements.

M_n is determined by "count[ing] the number of polymer molecules in a sample of the polymer."[58] M_n is defined as the total weight of all the molecules in a polymer sample divided by the total number of moles present.[59] That is, M_n is equal to $(\sum N_x M_x)/\sum N_x$, where the values of x represent all the different sizes of polymer molecules from $x = 1$ to $x = \infty$, and N_x is the number of moles for the polymer molecule whose weight is M_x.[60]

The methods for measuring M_n rely on "the colligative properties of solutions—vapor pressure lowering (vapor pressure osmometry), freezing point depression (cryoscopy), boiling point elevation (ebulliometry), and osmotic pressure (membrane osmometry)."[61] A colligative property is "any property that depends on the lowering of the chemical potential of a solvent by the introduction of a solute."[62] There are some debates about preference. Professor George Odian commented that the most commercially-adopted methods are membrane osmometry and vapor-pressure osmometry.[63] However, Allcock & Lampe criticized that vapor-pressure osmometry is not practical because of the difficulty of measuring the change of vapor pressure when M_n becomes larger.[64]

M_w is defined as $\sum w_x M_x$, where w_x is the weight-fraction of molecules whose weight is M_x.[65] M_w is also defined as $\sum c_x M_x / \sum c_x$, where c_x is the weight concentration for the polymer molecule whose weight is M_x; c is the total weight

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[56] *Teva II*, 723 F.3d at 1367.

[57] *Id.*

[58] ODIAN, *supra* note 51, at 20.

[59] *See id.* at 21. "Mole" is defined as "the amount of substance of a system which contains as many elementary entities as there are atoms in 0.012 kilogram of carbon 12." BUREAU INTERNATIONAL DES POIDS ET MESURES, SI BROCHURE: THE INTERNATIONAL SYSTEM OF UNITS (SI) 115 (Organisation Intergouvernementale de la Convention du Mètre, 8th ed. 2006), http://www.bipm.org/utils/common/pdf/si_brochure_8_en.pdf (last visited June 20, 2017).

[60] *See* ODIAN, *supra* note 51, at 21; *see also* DIETRICH BRAUN ET AL., POLYMER SYNTHESIS: THEORY AND PRACTICE 89 (Springer-Verlag Berlin Heidelberg ed., 4th ed. 2005).

[61] ODIAN, *supra* note 51, at 20.

[62] ALLCOCK & LAMPE, *supra* note 41, at 337.

[63] *See* ODIAN, *supra* note 51, at 21.

[64] *See* ALLCOCK & LAMPE, *supra* note 41, at 339.

[65] *See* ODIAN, *supra* note 51, at 21.

concentration of all the polymer molecules; w_x is equal to c_x/c; c_x is equal to N_xM_x; c is equal to $\sum c_x$ and, therefore, equal to $\sum N_xM_x$.[66] For measurement technologies that depend on the size of polymer molecules, M_w is more preferable.[67] M_w may be obtained from light scattering measurements.[68]

M_w is biased toward the higher-molecular-weight fractions of a polymer sample, while M_n is biased toward the lower-molecular-weight fractions.[69] Thus, the ratio of M_w/M_n represents the distribution of different molecular weights and is often used as an index of the polydispersity in a polymer sample.[70]

In addition to M_n and M_w, there are two forms of molecular weight that do not have any descriptive meaning.[71] The first is the z-average molecular weight, M_z.[72] M_z is defined as $\sum c_x(M_x)^2/\sum c_xM_x$.[73] The z-average molecular weight can be determined by measuring sedimentation equilibria in an ultracentrifuge.[74] The second is the viscosity-average molecular weight, M_v.[75] M_v is determined by measuring the viscosity of a solution where the polymer sample is a solute.[76] M_v is defined as $(\sum w_x(M_x)^a)^{1/a}$, where a is a constant.[77] M_v is also equal to $(\sum N_x(M_x)^{a+1}/\sum N_xM_x)^{1/a}$.[78] For most polymers, M_v is less than M_w because a is usually between 0.5 and 0.9.[79] Like M_w, M_v is biased towards larger-sized polymer molecules.[80]

In general, for most polymers, the increasing order for the values of those average molecular weights is M_n, M_v, M_w, and M_z.[81]

Absolute methods and secondary methods are two approaches to measuring polymer molecular weights.[82] Absolute methods provide a direct estimate of the molecular weight.[83] On the other hand, secondary methods (or relative methods[84]) are based on comparisons between a polymer sample and a polymer system that have been studied by absolute methods.[85] These methods are further

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[66] *See id.* at 21; *see also* BRAUN, *supra* note 60, at 89–90.
[67] *See* BRAUN, *supra* note 60, at 89.
[68] *See* ODIAN, *supra* note 51, at 21.
[69] *See id.* at 22.
[70] *See id.* at 23; *see also* BRAUN, *supra* note 60, at 90–91 ("It is called polydispersity index (PDI). The value of PDI can range between approx. 1.01 (for anionically prepared polymers) up to more than 30 (high-pressure polyethylene). In general, it is between 2 and 5.").
[71] *See* BRAUN, *supra* note 60, at 90.
[72] *See id.*
[73] *See id.*
[74] *Id.*
[75] *See id.*
[76] *See* ODIAN, *supra* note 51, at 22.
[77] *See id.* "*a*" is determined by the Mark-Houwink equation. *See infra* Part II.C.1.
[78] *See* ODIAN, *supra* note 51, at 22.
[79] *See id.*; *see also* ALLCOCK & LAMPE, *supra* note 41, at 388–89.
[80] *See* ODIAN, *supra* note 51, at 22.
[81] *See* BRAUN, *supra* note 60, at 90.
[82] *See* ALLCOCK & LAMPE, *supra* note 41, at 335.
[83] *See id.*
[84] *See* BRAUN, *supra* note 60, at 92–93.
[85] *See* ALLCOCK & LAMPE, *supra* note 41, at 335.

described in Sections B and C.

B. Absolute Methods

Absolute methods depend on the dissolution of a polymer sample in a solvent.[86] But, not all solvents are a good solvent for a polymer.[87] A solvent is good for a polymer if the adhesive force between the solvent molecule and polymer molecule is similar to the cohesive force between the solvent molecules or between the polymer molecules.[88] That is, when the polymer is dissolved into the solvent, the dissolution consumes little energy.[89]

1. Osmotic-Pressure Measurement

The osmotic-pressure measurement is based on the osmotic pressure of a solution.[90] This method is used for determining M_n in the range 30,000 to 1,000,000 g/mol.[91] An apparatus for the osmotic-pressure measurement includes a solvent and a solution, while a semipermeable membrane separates the solvent and solution and allows solvent molecules to move to the solution.[92] Because the chemical potential in the solution is lower than that in the solvent, a driving force occurs, causing solvent molecules in the solvent to move to the solution.[93] As a result, the level of the solution rises.[94] The rising stops when the pressure of the solution equals the driving force.[95] The increase of the level is measured for determining M_n.[96]

2. Light-Scattering Measurement

The light-scattering measurement is based on the turbidity of a solution.[97] The turbidity (τ) is defined as I_s'/I_o, where I_s' is the total scattered light intensity and I_o is the incident light intensity.[98] Turbidity represents the degree of scattered light after a light beam traverses a solution.[99] Because heavier molecules influence the turbidity of a polymer solution more than lighter molecules, the

[86] *See id.* at 336.
[87] *See id.*
[88] *See id.*
[89] *See id.*
[90] *See id.* at 339.
[91] *See id.*
[92] *See id.* at 339–40.
[93] *See id.* at 340.
[94] *See id.*
[95] *See id.*
[96] *See id.* at 340–43.
[97] *See id.* at 351.
[98] *See id.* at 350–51.
[99] *See id.* at 350.

light-scattering measurement is used for determining M_w.[100]

The calculation of M_w requires a measurement of the turbidities of the solutions of various polymer concentrations, a measurement of the refractive indexes of these solutions, and a measurement of the refractive index of the pure solvent.[101] But, for a polymer sample where the average size of the largest dimension of the polymer molecules is greater than one-twentieth of the wavelength of the incident light, dissymmetry of scattering should be considered.[102] The dissymmetry will cause a reduction of the total scattered light intensity.[103] The M_w calculation should be modified according to different types of polymer.[104]

3. Ultracentrifugation Measurement

The ultracentrifugation measurement is also used for determining M_w.[105] It depends on a gravitational force created by ultracentrifugation techniques.[106] The gravitational force results in the sedimentation of polymer molecules in a solution.[107] The calculation of M_w under the ultracentrifugation measurement is theoretically different from that under the light-scattering measurement.[108] M_w is determined by the sedimentation coefficient, diffusion coefficient, and partial specific volume of the polymer in a solution.[109] In addition, ultracentrifugation equipment can be designed to measure M_n and M_z.[110]

C. Secondary Methods

There are two secondary measurements.[111] One is based on solution viscosity, and the other uses gel permeation chromatography.[112] While absolute methods are considered difficult to implement, time-consuming, and expensive in terms of equipment cost, secondary methods offer faster and less-costly approaches.[113] However, secondary methods require "a prior determination of empirical relationships that relate the molecular weight to the viscosity of a polymer solution or to the retention volume of a polymer solution being eluted from

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[100] *See id.* at 353.
[101] *See id.* at 351.
[102] *See id.* at 354.
[103] *See id.* at 354–55.
[104] *See id.* at 355–56.
[105] *See id.* at 365.
[106] *See id.* at 365–66.
[107] *See id.* at 366.
[108] *See id.*
[109] *See id.*
[110] *See generally* Peter M. Budd, *The Determination of Number-, Weight-, and Z-Average Molecular Weights by Meniscus-Depletion Sedimentation Equilibrium*, 26 J. OF POLYMER SCI. PART B: POLYMER PHYSICS 1143 (1988).
[111] *See* ALLCOCK & LAMPE, *supra* note 41, at 379.
[112] *See id.*
[113] *See id.*

a gel permeation column."[114] That is, calibration must be completed before secondary methods are carried out.

1. Solution Viscosity

M_v is measured by the solution viscosity method based on a phenomenon whereby "the presence of the polymeric solute always increases the viscosity [of the polymer solution]."[115] M_v can be calculated by the Mark-Houwink equation, $[\eta] = K(M_v)^a$, where $[\eta]$ stands for intrinsic viscosity[116] and K and a are constants determined by the calibration using carefully-fractionated samples specifically for a given polymer-solvent system at a given temperature.[117] $[\eta]$ is defined as the limit of the reduced specific viscosity as the concentration (c) of a polymer simple in the solution approaches zero.[118] "Reduced specific viscosity" (or "reduced viscosity") is defined as η_{sp}/c, where η_{sp}, "specific viscosity," is defined as $(\eta - \eta_0)/\eta_0$, where η and η_0 represent the viscosities of the polymer solution and pure solvent respectively.[119] To obtain $[\eta]$, first draw a plot of η_{sp}/c for the Y-axis verse c for the X-axis.[120] Then, use linear regression to create an equation, $\eta_{sp}/c = a_1 + a_2(c)$, where a_1 and a_2 are constants.[121] $[\eta]$ is equal to a_1.[122]

2. Gel Permeation Chromatography

The gel permeation chromatography (GPC) method is based on a process for separating different polymer molecules by their size.[123] Because the GPC method is the fractionation of polymer molecules by their size or molecular weight, it is also called "size exclusion chromatography" (SEC).[124]

The GPC method is carried out through a column that is packed with finely-divided solid particles. Each particle has pores or tunnels inside.[125] When a polymer solution passes through the column, the small-sized polymer molecules enter into the pores or tunnels and spend more time in the column, but the large-sized molecules ignore the pores or tunnels and leave the column earlier than the

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[114] *Id.*
[115] *Id.* at 384.
[116] *See id.*
[117] *See id.* at 387–88.
[118] *See id.* at 384.
[119] *See id.*
[120] *See id.*
[121] *See id.*
[122] *See id.*
[123] *See id.* at 394.
[124] *See id.* at 395; *see also* DENNIS B. MALPASS & ELLIOT I. BAND, INTRODUCTION TO INDUSTRIAL POLYPROPYLENE: PROPERTIES, CATALYSTS PROCESSES 38 (Scrivener Publishing LLC 2012), http://onlinelibrary.wiley.com/book/10.1002/9781118463215.
[125] *See* ALLCOCK & LAMPE, *supra* note 41, at 394.

small-sized molecules.[126] As a result, the large-sized molecules can be separated from the small-sized molecules.[127] To enhance the effectiveness of the process, several columns are used and the pore size of particles of one column is different from that of another column.[128]

The measurement by the GPC method relies on forming a distribution curve in a Y-X plot, where the Y-axis of the plot represents weight fractions that can be derived from measuring the refractive index differences between the solvent and the polymer solution for each volume that elute from the GPC column, and the X-axis represents different elution volumes.[129] Before measuring a polymer sample, calibration must be completed by using standard samples of different molecular weight ranges. The calibration produces a chart showing the relationship between molecular weight ranges and elution volumes.[130] With such calibration chart, M_n, M_w, and M_v can be calculated from the Y-X plot.[131]

III. CLAIM CONSTRUCTION AND INDEFINITENESS OF MOLECULAR WEIGHT IN *TEVA*

A. Legal Standards

In the series of *Teva* cases, the major invalidity issue was indefiniteness.[132] Before *Teva II*, the standard of indefiniteness was that "[a] claim is indefinite only when it is not amenable to construction or insolubly ambiguous."[133] But, in 2014, the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*[134] changed the indefiniteness standard.[135] The current standard applied by *Teva IV* requires "that a patent's claims, viewed in light of the specification and prosecution his-

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[126] *See* ALLCOCK & LAMPE, *supra* note 41, at 394; *see also* MALPASS & BAND, *supra* note 124, at 37; Gaylon Ross & Lois Frolen, *The Characterization of Linear Polyethylene SRM 1475. X. Gel Permeation Chromatography*, J. OF RES. OF THE NAT'L BUREAU OF STANDARDS, 76A2, 163–64 (1972), http://nvlpubs.nist.gov/nistpubs/jres/76A/jresv76An2p163_A1b.pdf (last visited Oct. 16, 2017).

[127] *See* ALLCOCK & LAMPE, *supra* note 41, at 394–95.

[128] *See id.*

[129] *See* Malpass & Band, *supra* note 124, at 38; *see also* Ross & Frolen, *supra* note 126, at 164; Jian Xu, Guanying Wu, Yufeng Sun, & Yibing Shen, *A New Theoretical Formula for the Determination of the Copolymer Composition Distribution Measured by Gel Permeation Chromatography*, 18 MACROMOLECULAR RAPID COMMUNICATIONS 601, 605 (1997).

[130] *See* Ravve, *supra* note 42, at 57–58.

[131] *Id.* at 59–60.

[132] *See Teva IV*, 789 F.3d at 1338–40.

[133] *Teva II*, 723 F.3d at 1368 (quoting Biosig Instruments, Inc. v. Nautilus, Inc., 715 F.3d 891, 898 (Fed. Cir. 2013)).

[134] Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014).

[135] *See* David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2184 (2017); *see also* Christopher M. Holman, *The Supreme Court's Devaluation of U.S. Patents*, 36 BIOTECH. L. REP. 151, 153 (2017) (criticizing that *Nautilus* has made it difficult to claim an invention in a full scope).

tory, inform those skilled in the art about the scope of the invention with reasonable certainty."[136]

Before determining any issues of invalidity, courts must construe claim terms.[137] The Federal Circuit in *Phillips v. AWH Corp.*[138] established the contemporary principle of claim construction.[139] To perform claim construction, courts rely on two categories of information: intrinsic evidence and extrinsic evidence.[140] Intrinsic evidence includes claims, the specification, and prosecution history,[141] while extrinsic evidence covers "expert and inventor testimony, dictionaries, and learned treatises."[142]

Under *Phillips*, claim construction starts with giving a claim term its ordinary and customary meaning in view of a person of ordinary skill in the art.[143] Both disputed claims and unasserted claims are considered.[144] Additionally, courts consult the specification because it is part of the entire patent and the inventor's description is helpful.[145] Particularly, the specification may give a claim term a special meaning that is different from the ordinary and customary meaning.[146] The specification may also limit the scope of the ordinary and customary meaning.[147] Furthermore, courts may look at the prosecution history to determine how the applicant and patent agency understood the invention.[148] The prosecution history may also help find "whether the inventor limited the invention in the course of prosecution."[149] However, the prosecution history may merely represent "an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation."[150] That makes the prosecution history less useful than the specification.[151]

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[136] *Nautilus, Inc.*, 134 S. Ct. at 2129. The Federal Circuit adopted the *Nautilus* standard. *See* Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1369–70 (Fed. Cir. 2014).

[137] *See* Leora Ben-Ami & Corinne Stone, *A Race to the Federal Circuit: How the Differing Claim Construction Standards and Standards of Review Influence Patent Invalidation*, 44 AIPLA Q.J. 639, 643 (2016) (discussing the applications of claim construction in the United States Patent and Trademark Office and federal courts).

[138] *See* Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

[139] *See* Ben-Ami & Stone, *supra* note 137, at 643–52.

[140] *See id.* at 645.

[141] *See Phillips*, 415 F.3d at 1303.

[142] *Id.* at 1317.

[143] *See id.* at 1312–13.

[144] *See id.* at 1314.

[145] *See id.* at 1315–16.

[146] *See id.* at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess."). *Id.*

[147] *See id.* ("[T]he specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor."). *Id.*

[148] *See id.* at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent."). *Id.*

[149] *Id.*

[150] *Id.*

[151] *See id.*

Phillips considers extrinsic evidence as useful in claim construction,[152] but "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'"[153] Particularly, *Phillips* cautions that "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court."[154] *Phillips* also requires courts to discount any expert testimony that is contrary to the intrinsic evidence.[155] Thus, while permitting courts to exercise discretion to admit and use extrinsic evidence, *Phillips* urges the courts to carefully examine the flaws of such evidence.[156]

Last, claim construction is a question of law.[157] The Federal Circuit had reviewed the district court's claim construction in all aspects by a *de novo* standard.[158] However, the Supreme Court in *Teva III* has required the Federal Circuit to "apply clear error review when reviewing subsidiary factfinding in patent claim construction."[159] In *Teva II* and *Teva IV*, the Federal Circuit interpreted molecular weight in light of claim language, specification, and prosecution history.[160] The Federal Circuit also considered the district court's evidentiary ruling on the patent's expert witness, Dr. Gregory Grant.[161]

B. The Claims in Dispute

The claims in dispute were categorized by the Federal Circuit in *Teva II* as two separate groups.[162] In Group I, claim 1 of U.S Patent No. 5,981,589 ('589

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[152] *See id.*

[153] *Id.* (quoting C.R. Bard Inc. v. U.S. Surgical Corp., 388 F.3d 858, 862 (Fed. Cir. 2014)).

[154] *Id.* at 1318.

[155] *See id.* ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" (quoting *Keys Pharms*., 161 F.3d at 716)).

[156] *See id.* at 1319 ("[I]t is permissible for the district court in its sound discretion to admit and use such evidence. In exercising that discretion, and in weighing all the evidence bearing on claim construction, the court should keep in mind the flaws inherent in each type of evidence and assess that evidence accordingly.").

[157] *See* Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva III*), 135 S. Ct. 831, 835 (2015).

[158] *Id.* at *833.*

[159] *Id*. at 840.

[160] *See, e.g.*, Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva II*), 723 F.3d 1363, 1368-70 (Fed. Cir.) *vacated*, 135 S. Ct. 831 (2015); Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva IV*), 789 F.3d 1335,1339–45 (Fed. Cir. 2015).

[161] *See, e.g.*, *Teva II*, 723 F.3d at 1368-70; *Teva IV*, 789 F.3d at 1339–45. Dr. Grant was a Professor of Biochemistry in Medicine and Developmental Biology at the School of Medicine at Washington University School of Medicine and an expert in the characterization of proteins and polypeptides using size exclusion chromatography. Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva I*), 876 F. Supp. 2d 295, 310–11 (S.D.N.Y. 2012), *aff'd in part, rev'd in part*, 723 F.3d 1363 (Fed. Cir. 2013), *vacated*, 135 S. Ct. 831 (2015).

[162] *See Teva II*, 723 F.3d at 1366 n.2 ("The six Group II claims are: claims 1 and 2 of the '430 patent, claim 1 of the '476 patent, claim 1 of the '161 patent, and claims 1 and 8 of the '098 patent. The remaining claims are collectively referred to as Group I claims.").

Patent) was selected as the representative claim reciting "a molecular weight of about 5 to 9 kilodaltons."[163] The district court referred to the Group I recitation as the "average molecular weight" limitation.[164] The representative claim in Group II, claim 1 of U.S. Patent No. 6,054,430 ('430 Patent) recited, "over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa."[165] The district court referred to the Group II recitation as the "mole fraction" limitation.[166]

C. District Court's Decision

The district court construed average molecular weight as "peak molecular weight detected using an appropriately calibrated suitable gel filtration column."[167] "Gel filtration" was known as "size exclusion chromatography" (SEC), which "is a separation and analytical technique that separates molecules based upon their size in solution."[168]

Applying the district court's interpretation, the defendants argued that average molecular weight was indefinite, "because there were different ways to 'appropriately' calibrate an SEC column, and because the different calibrations would not yield the same molecular weight values."[169] But, the district court disagreed.[170] While recognizing that "there were at least two ways to accurately measure the molecular weight of copolymer–1 using SEC,"[171] the district court found that "a person of skill in the art [back then] would have known how to appropriately calibrate an SEC column to obtain accurate molecular weight values for copolymer–1."[172]

D. Federal Circuit's Decision in Teva II

The *Teva II* court identified two approaches to describe molecular weight.[173] The first approach was statistical measures, including M_p, M_n, and

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[163] *Id.* at 1367.

[164] *See Teva I*, 876 F. Supp. 2d at 313 ("The asserted claims containing 'average molecular weight' limitations require copolymer–1 having an average molecular weight of 'about 5 to 9 kilodaltons.'").

[165] *Teva II*, 723 F.3d at 1367.

[166] *See Teva I*, 876 F. Supp. 2d at 314 ("The copolymer–1 'molar fraction' limitations include 'over 75% of its molar fraction within the molecular weight range from about 2 kDa to about 20 kDa.'").

[167] *Id.* at 347.

[168] *Id.* at 323.

[169] *Id.* at 400.

[170] *See id.* at 401.

[171] *Id.* at 400.

[172] *Id.* at 401.

[173] *See* Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva II)*, 723 F.3d 1363, 1367 (Fed. Cir. 2013), *vacated*, 135 S. Ct. 831 (2015).

M_w.[174] The Federal Circuit found that Group I claims adopted the first approach.[175] The second approach "describe[d] how many molecules in a polymer sample have molecular weights that fall within an arbitrarily set range."[176] The Federal Circuit found that Group II claims used the second approach.[177]

Group I claims were held indefinite.[178] The Federal Circuit found that "Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended."[179] In addition, the prosecution history of one Group I patent, U.S. Patent No. 6,939,539 ('539 Patent), showed that molecular weight should be M_p, while the prosecution history of another Group I patent, U.S. Patent No. 6,620,847 ('847 Patent), suggested that molecular weight should be M_w.[180] The claims of both patents were initially rejected.[181] The examiner for the '539 Patent considered the average molecular weight indefinite, while the applicant responded that the term should be M_p.[182] Moreover, the examiner for the '847 Patent rejected the term average molecular weight, because the term was "meaningless as a limitation without specifying its basis . . . ."[183] The applicant responded that the term meant M_w.[184] Because M_p and M_w have different values in a typical polymer sample,[185] the Federal Circuit held that the prosecution history "render[s] the ambiguity insoluble."[186]

The patentee relied on Dr. Grant's expert testimony to argue that the specification can resolve the issue of indefiniteness.[187] The patentee specifically pointed out one figure showing the molecular-weight data measured by the SEC method.[188] In the figure, there were two curves representing two different values of average molecular weight, 7.7 kDa and 12.0 kDa.[189] The peak of each curve corresponded to M_p of that curve.[190] Dr. Grant testified that the curves in the figure demonstrate that the claim term molecular weight means M_p.[191]

But, the Federal Circuit disagreed.[192] First, Dr. Grant also opined that M_n

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[174] *See id.*
[175] *See id.*
[176] *Id.*
[177] *See id.*
[178] *See id.* at 1369.
[179] *Id.*
[180] *See id.*
[181] *See id.*
[182] *See id.*
[183] *Id.*
[184] *See id.*
[185] *See id.* at 1367.
[186] *Id.* at 1369.
[187] *See id.* at 1368. Dr. Grant was the patentee's expert witness. *See Teva IV*, 789 F.3d 1335 at 1341 (Fed Cir. 2015).
[188] *See Teva II*, 723 F.3d at 1369.
[189] *See id.* at 1370.
[190] *See id.*
[191] *See id.* at 1368–69.
[192] *See id.* at 1369.

and M_w can be calculated through the data in the figure.[193] Second, the peak of each curve did not match the corresponding value of average molecular weight.[194] For example, in the 7.7 kDa curve, the peak corresponded to a value of molecular weight less than 7.7 kDa.[195] That is, M_p was actually not 7.7 kDa.[196] Third, M_w of the 7.7 kDa curve was closer to 7.7 kDa.[197] Therefore, the Federal Circuit held that average molecular weights in the figure could not represent M_p.[198] The ambiguity was not overcome.[199]

On the other hand, Group II claims were held definite.[200] The Federal Circuit found that "[t]he numbers that set the boundaries of [the molecular weight range from about 2 kDa to about 20 kDa] refer to precise points on the 'Molecular Weight' axis, rather than to statistical properties of the polymer molecular weight curves."[201] Therefore, the Federal Circuit concluded that "[t]he scope of Group II claims is thus readily ascertainable."[202]

E. Federal Circuit's Decision in Teva IV

In light of the Supreme Court's two decisions, *Teva III* and *Nautilus*, the *Teva IV* court revisited its decision concerning Group I claims and upheld its indefiniteness decision.[203] However, instead of interpreting the representative claim of the '589 Patent, the Federal Circuit focused on the sole unexpired Group I patent, U.S. Patent No. 5,800,808 ('808 Patent).[204] Then, the representative claim in *Teva IV* became claim one of the '808 Patent, which recites "a molecular weight of about 5 to 9 kilodaltons."[205]

The Federal Circuit started with the claim language and held that the representative claim "recites 'molecular weight' without specifying the meaning of that term."[206] The Federal Circuit also confirmed that both parties agreed that the

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[193] *See id.*
[194] *See id.*
[195] *See id.*
[196] *See id.*
[197] *See id.*
[198] *See id.*
[199] *See id.*
[200] *Id.* at 1370.
[201] *Id.*
[202] *Id.*
[203] *See* Teva Pharm. USA, Inc. v. Sandoz, Inc. (*Teva IV*), 789 F.3d 1335, 1338 (Fed. Cir. 2015).
[204] *See Teva IV*, 789 F.3d at 1338 n.3 ("While the case was pending at the Supreme Court, all of the patents-in-suit expired, with the exception of U.S. Patent No. 5,800,808. Thus, claim 1 of the '808 patent is the sole unexpired Group I claim. Our analysis will therefore focus on that claim, but to the extent that issues relating to the expired Group I claims remain unresolved, this analysis should be understood to apply equally to the other Group I claims."). The '589 Patent was actually a division application of the '808 Patent. *See* U.S Patent No. 5,981,589 (Related U.S. Application Data).
[205] *See Teva IV*, 789 F.3d at 1338.
[206] *Id.* at 1341.

disputed term, molecular weight, could mean M_p, M_n, or M_w, each of which "is calculated in a different way and would typically yield a different result for a given polymer sample."[207] Therefore, Group I claims gave no clue of the meaning of molecular weight.[208]

Second, the Federal Circuit found again that the specification failed to define molecular weight because it did not use the terms M_p, M_n, or M_w.[209] The patentee argued that to a person having ordinary skill in the art, average molecular weight has a presumed meaning in the context of the specification and prosecution history.[210] The patentee also asserted that the district court agreed with their position.[211] However, the Federal Circuit found that the district court did not conclude any presumed meaning of molecular weight.[212]

Third, the Federal Circuit responded to the Supreme Court's request of reconsidering Dr. Grant's testimony[213] and found that the district court did not err in adopting Dr. Grant's testimony.[214] However, the Federal Circuit concluded that accepting Dr. Grant's testimony does not "mean that there now exists a *presumption* regarding the meaning of the claim term [molecular weight] in the art in general or in the context of this patent."[215]

The Federal Circuit emphasized that "[t]he internal coherence and context assessment of the patent, and whether it conveys claim meaning with reasonable certainty, are questions of law."[216] Because claim construction is a question of law, the Federal Circuit criticized that "[t]he district court should not defer to Dr. Grant's ultimate conclusion about claim meaning in the context of this patent nor do we defer to the district court on this legal question."[217] The Federal Circuit then looked to the prosecution history because "[s]tatements made during prosecution history are relevant to claim construction."[218]

To devalue Dr. Grant's testimony, the Federal Circuit further discussed the prosecution history of the '847 Patent and '539 Patent.[219] The '808 Patent was a parent patent of both the '847 Patent and '539 Patent.[220] By holding that "[a] statement made during prosecution of related patents may be properly considered in construing a term common to those patents, regardless of whether the

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[207] *Id.*
[208] *See id.*
[209] *See id.*
[210] *See id.*
[211] *See id.*
[212] *See id.*
[213] *See id.* at 1341; *see also* Teva Pharms. USA, Inc. v. Sandoz, Inc. (*Teva III*), 135 S. Ct. 831, 843 (2015).
[214] *See Teva IV*, 789 F.3d at 1341–42.
[215] *Id.* at 1342.
[216] *Id.*
[217] *Id.*
[218] *Id.* at 1342–43.
[219] *See id.* at 1343–45.
[220] *See id.* at 1343.

statement pre- or post-dates the issuance of the particular patent at issue,"[221] the Federal Circuit considered the statements made during the prosecution of the '847 Patent and '539 Patent as "legally relevant to the meaning one of skill in the art would attribute to the identical term in the '808 [P]atent."[222] Eventually, the Federal Circuit reaffirmed its previous legal conclusion that the prosecution history of the '847 Patent and '539 Patent has shown different meanings of "molecular weight."[223]

Unlike *Teva II*, the Federal Circuit in *Teva IV* gave more comprehensive reasoning when it addressed the prosecution history of the '847 Patent.[224] First, the Federal Circuit emphasized that the rejection was overcome merely because the applicant defined molecular weight as M_w.[225] Second, while recognizing that the district court did not err in finding that the applicant's statement regarding M_w was a scientific error,[226] the Federal Circuit held that the meaning of molecular weight was still confusing.[227] The main concern was "[t]he public notice function of a patent and its prosecution history [which] requires that a patentee be held to what he declares during the prosecution of his patent."[228] As the Federal Circuit held, "[t]he fact that their explanation contained further elaboration which itself included a scientific error does not undermine the statement's legal import."[229] Therefore, the Federal Circuit concluded that "[r]egardless of the scientific accuracy of the statement, a person of ordinary skill in the art would have understood that the applicants defined the term 'molecular weight' as M_w to gain allowance of the claims."[230]

Finally, the Federal Circuit held that "in light of the specification and the prosecution history, the patentee has failed to inform with *reasonable certainty* those skilled in the art about the scope of the invention."[231] Thus, Group I claims were found indefinite again.[232]

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[221] *Id.*
[222] *Id.*
[223] *See id.* at 1343–44.
[224] *See id.*
[225] *See id.* at 1343.
[226] *See id.* at 1343–44. During the prosecution, the applicant stated that "[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight." *Id.* at 1343. But, the district court found that each of M_p, M_n, and M_w can be expressed in kilodaltons. *See id.* at 1343–44.
[227] *See id.* at 1344.
[228] *Id.* (quoting Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003)).
[229] *Id.*
[230] *Id.*
[231] *Id.* at 1345.
[232] *See id.*

IV. MOLECULAR WEIGHT AS A CLAIM TERM FOR POLYMER-RELATED PATENTS

A. Nature of Indefiniteness

Teva IV affirmed that molecular weight is an indefinite term for polymer-related patents if the specification does not state the definition of molecular weight.[233] Molecular weight associated with polymers may have different definitions, which makes the scope of the invention fall outside reasonable certainty.[234] *Teva IV* is consistent with polymer science as described in Part II. In addition to three definitions (e.g., peak-average molecular weight, number-average molecular weight, and weight-average molecular weight) recognized by *Teva II* and *Teva IV*, there are two more definitions, viscosity-average molecular weight and z-average molecular weight.[235] These five average molecular weights are based on different theories of physical chemistry and expressed as different mathematic formulas.[236]

Teva IV creates an invalidity concern for claims reciting molecular weight as a polymer-related limitation. For example, claim 1 of U.S. Patent No. 8,318,844 recites "[a]n oil-dispersible composite of metallic nanoparticles, the composite having . . . and polyurethane (PU); wherein . . . and the polyurethane (PU) has . . . a molecular weight ranging from 2,000 to 200,000 g/mol."[237] But, the specification does not define "molecular weight." Another example is claim 4 of U.S. Patent No. 8,048,342 reciting the "[sol-gel composition for fabricating conductive fibers in an electrospinning process] of claim 1, wherein the polyethylene oxide has a molecular weight [(Mw)] of greater than 100,000."[238] The claim uses the symbol "Mw," as does the specification.[239] But, "Mw" seems to be the abbreviation of "molecular weight."[240] Under *Teva IV*, these two claims will be found invalid for indefiniteness.

In addition, the disputed claim in *ClearValue, Inc.* may be challenged now because of indefiniteness. The disputed claim recites molecular weight interpreted as "the sum of the atomic weights of all the atoms in a molecule as measured by viscosity, osmotic pressure, light scattering, gel permeation, chromatography, ultracentrifugation, and/or similar accepted methods."[241] The interpretation indicates that molecular weight can be measured by different methods. Because dif-

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[233] *See id.*

[234] *See id.*

[235] *See generally* RAVVE, *supra* note 42, at 51–60.

[236] *See id.*

[237] U.S. Patent No. 8,318,844 claim 1.

[238] U.S. Patent No. 8,048,342 claim 4.

[239] *See* U.S. Patent No. 8,048,342 col. 2 ll. 49–52 ("In one embodiment, PEO has a molecular weight (Mw) of greater than 400,000."). *Id.*

[240] *Id.*

[241] *ClearValue*, 560 F.3d at 1296 (quoting *Clearvalue, Inc. v. Pearl River Polymers, Inc.*, No. 6:06–CV–197, 2006 WL 2032313, at *2 (E.D. Tex. July 17, 2006)).

ferent measurements may result in different average molecular weights, the term molecular weight will be held indefinite under *Teva IV*.

Teva IV may cause many polymer-related claims reciting molecular weight to be determined indefinite. But, the question is whether those claims can be saved by prosecution history or expert testimony.

Teva IV implies that prosecution history may save those claims from being held indefinite.[242] However, expert witness testimony cannot outweigh prosecution history.[243] Although the Federal Circuit found no clear error in the district court's acceptance of the expert testimony that the statement regarding M_w during the prosecution was scientifically erroneous,[244] it held that "[r]egardless of the scientific accuracy of the statement, a person of ordinary skill in the art would have understood that the applicants defined the term 'molecular weight' as M_w to gain allowance of the claims."[245]

In addition, the Federal Circuit in *Teva IV* almost found that the specification contrasts with the patentee's expert testimony.[246] The expert relied on one figure of SEC data to testify that molecular weight means M_p.[247] The figure included a list of average molecular weights, each of which corresponded to one curve, while each curve had a peak that corresponded to a value of molecular weight.[248] As the *Teva II* court pointed out, the peaks of the curves did not match their corresponding average molecular weights in the list.[249] However, the expert explained that the variations fall within a margin of error.[250] While holding that the district court did not clearly err in accepting this explanation, the Federal Circuit criticized the lower court by noting that the explanation was "relatively cursory and unexplained."[251] As *Phillips* has warned,

> conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent."[252]

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[242] *See Teva IV*, 789 F.3d at 1341–42.

[243] *See Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'").

[244] *See Teva IV*, 789 F.3d at 1343–44.

[245] *Id.* at 1344.

[246] *Id*. at 1341.

[247] *See id.* at 1341–42.

[248] *See Teva II*, 723 F.3d at 1369.

[249] *See id.*

[250] *See Teva IV*, 789 F.3d at 1342.

[251] *Id.*

[252] *Phillips*, 415 F.3d at 1318.

Therefore, the Federal Circuit may conclude that it was clearly erroneous to accept the "margin of error" explanation, but it might choose not to do so because the prosecution history was enough for supporting its legal conclusion.[253]

B. Post-Teva IV District Court Decisions

As Part II described, there are several ways to measure or express the molecular weight of a polymer.[254] To avoid the issue of indefiniteness, it is important to describe a precise measurement for polymers used in the invention.[255] Since *Teva IV*, there have been two cases indicating what kind of patent may survive the indefiniteness challenge.

1. Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.

In *Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.*,[256] one of the patents-in-suit regarding claim construction of molecular weight was U.S. Patent No. 8,017,150 where the representative claims were related to a mucosally-adhesive water-soluble film product.[257] The relevant limitation recited that

> the polyethylene oxide [(PEO)] comprises one or more low *molecular weight* polyethylene oxides and one or more higher *molecular weight* polyethylene oxides, the *molecular weight* of the low *molecular weight* polyethylene oxide being in the range 100,000 to 300,000 and the *molecular weight* of the higher *molecular weight* polyethylene oxide being in the range 600,000 to 900,000.[258]

The defendant argued that the term molecular weight was indefinite because the patent lacked the appropriate measure for determining "molecular weight."[259] But, the patentee contended that a person of skill in the art would measure viscosity average molecular weight by the GPC method.[260] However, the district court was aware of "numerous methods to characterize the molecular weight of PEOs, including number average molecular weight, weight average molecular weight, Z-average molecular weight, and viscosity average molecular

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[253] *Id.*
[254] *See supra* Part II.A.
[255] *See Teva IV*, 789 F.3d at 1341.
[256] Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc., 2016 U.S. Dist. LEXIS 72391, 2016 WL 3186659 (D. Del. June 3, 2016).
[257] *See id.* at *1, *3.
[258] *Id.* at *9 (emphasis added).
[259] *See id.* at *79.
[260] *See id.* at *80.

weight"[261] and "two different experimental methods for obtaining the average molecular weight of PEOs: rheological measurements and [GPC] analysis."[262] Eventually, the district court held that the term molecular weight was reasonably certain and not indefinite, because a person of ordinary "skill in the art would understand that the patent relies on the molecular weight of Polyox N80 reported by Dow as the measure of 'molecular weight.'"[263]

The decision on definiteness was primarily based on the product information of PEOs used by the patented invention and accused product.[264] First, the district court found that the accused product used PEO Polyox N80 as an ingredient.[265] The PEO Polyox N80 was a PEO product manufactured by the Dow Chemical Company that "assigns an approximate viscosity average molecular weight to a [PEO] sample based on measurements conducted using a viscometer."[266] Second, the district court found that the specification disclosed the Dow Chemical Company as the source of PEOs.[267] Third, partially relying on the defendant's expert testimony, the district court found that Table 22 in the specification further showed a list of approximate viscosity average molecular weights assigned to different PEO grades provided by the Dow Chemical Company.[268] The third fact-finding was based on both intrinsic evidence and extrinsic evidence.[269]

In addition, the district court was aware of "the absence of a specified method to measure molecular weight,"[270] but held that "[t]he claims are not indefinite merely because multiple methods of measuring molecular weight exist."[271] Therefore, the district court concluded that "[a] person of ordinary skill in the art would understand [that] the term 'molecular weight' in the patent [refers] to viscosity average molecular weight as reported by the manufacturers of commercial PEOs."[272]

2. Purdue Pharmaceuticals L.P. v. Amneal Pharmaceuticals, LLC

In *Purdue Pharmaceuticals L.P. v. Amneal Pharmaceuticals, LLC*,[273] the patents-in-suit claimed pharmaceutical compounds with oxycodone, processes

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[261] *Id.* at *79–*80.
[262] *Id.* at *80.
[263] *Id.* at *82.
[264] *See id.*
[265] *See id.* at *87.
[266] *Id.* at *80.
[267] *See id.*; *see also* U.S. Patent No. 8,017,150 – col.48 (Table 21).
[268] *See* Reckitt Benckiser Pharm. Inc., 2016 WL 3186659, at *81–82; *see also* U.S. Patent No. 8,017,150 col.50 (Table 22).
[269] *Id.*
[270] Reckitt Benckiser Pharm. Inc., 2016 WL 3186659, at *82.
[271] *Id.*
[272] *Id.*
[273] 2017 WL 634939 (D. Del. Feb. 16, 2017).

for making such compounds, and treatments by using such compounds.[274] The claim language relevant to the claim construction of molecular weight was "at least one polyethylene oxide having, based on *rheological measurements*, an approximate molecular weight of 4,000,000."[275] The defendant asserted that the disputed claims were indefinite because the intrinsic evidence did not show "which measure of molecular weight (e.g., M_n, M_v, M_w, M_z) is required by the asserted claims."[276] The defendant also challenged the test data regarding molecular weights in the specification.[277] However, the district court disagreed.[278]

The district court did not decide the indefiniteness issue directly.[279] Rather, the decision focused on claim construction and held that "a person of ordinary skill in the art would understand the scope of the invention."[280] The district court examined U.S. Patent No. 8,808,741 ('741 Patent) and found that "[t]he specification defines polyethylene oxide as having a molecular weight of 4,000,000 by reference to a specific test performed on a specific instrument."[281] The most relevant description in the specification was: "Polyethylene oxide is considered to have an approximate molecular weight of 4,000,000 when a 1% (by wt) aqueous solution of said polyethylene oxide using a Brookfield viscometer Model RVF, spindle No. 2, at 2 rpm, at 25 °C. shows a viscosity range of 1650 to 5500 mPa s (cP)."[282] The district court considered such description as "an express definition of what the inventor considered to be a PEO having an approximate molecular weight of 4,000,000."[283]

The specification of the '741 Patent discloses that the invention uses a commercial product of polyethylene oxide called Polyox™.[284] Polyox™ represents a product line of Dow Chemical Company.[285] Dow has a Polyox™ document, listing several conditions of rheological measurements.[286] The specification of the '741 Patent simply replicates those conditions.[287]

The *Amneal Pharmaceuticals* decision indicates that a specification is a

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[274] *See id.* at *1.
[275] *Id.* at *2–*4 (emphasis added).
[276] *Id.* at *5.
[277] *See id.*
[278] *See id.*
[279] *See id.*
[280] *Id.*
[281] *Id.* (citing U.S. Patent No. 8,808,741 col.7 l.64 – col.8 l.1).
[282] U.S. Patent No. 8,808,741 col.7 l.64 – col.8 l.1
[283] Purdue Pharm. L.P., 2017 WL 634939, at *5.
[284] *See* U.S. Patent No. 8,808,741 col.44 ll.10–30.
[285] *See* DOW CHEMICAL COMPANY, POLYOX™, http://www.dow.com/dowwolff/en/industrial_solutions/product/polyox.htm (last visited Sept. 8, 2017).
[286] *See* DOW CHEMICAL COMPANY, POLYOX WATER-SOLUBLE RESINS pg. 17 (2002), http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_094e/0901b8038094e22f.pdf?filepath=/pdfs/noreg/326-00001.pdf&fromPage=GetDoc.
[287] *See* U.S. Patent No. 8,808,741 col.7 l.64 – col.8 l.1; *see also* DOW CHEMICAL COMPANY, POLYOX WATER-SOLUBLE RESINS, *supra* note 286, at 17.

dispositive factor for determining the scope of "molecular weight."[288] The rationale follows a principle that "if the specification reveals a special definition given to a claim term by the inventor, then the inventor's lexicography governs, even if it differs from the term's ordinary meaning."[289] However, the district court construed molecular weight so narrowly that a Brookfield viscometer is the only equipment for molecular weight measurements.[290]

In fact, the specification of the '741 Patent refers to "Brookfield viscometer."[291] That alone indicates that "viscosity-average molecular weight" was intended.[292] The term "rheological measurements" used in the disputed claims also sufficiently indicates that the term molecular weight in the claims should mean "viscosity-average molecular weight." As described in Part II.C.1, M_v is measured by the solution viscosity method.[293] Viscosity is a rheological property of a polymer solution.[294] Thus, stating "rheological measurements" is equal to stating "viscosity-average molecular weight."

It should be noted that had the term molecular weight been possibly construed as "viscosity-average molecular weight," the issue of indefiniteness would have been reviewed. The district court did find that "the intrinsic evidence indicates that the inventors were referring to weight average molecular weight."[295] Thus, whether molecular weight means "weight-average molecular weight," "viscosity-average molecular weight," or both should have been adjudicated in light of *Teva IV*.

C. Good Patent Drafting

Reckitt indicates that if the specification discloses the source of the claimed polymer, the scope of molecular weight may be reasonably certain.[296] But, whether the term molecular weight is not indefinite may depend on extrinsic evidence that suggests a specific average molecular weight adopted by the source.

Amneal Pharmaceuticals may be a better approach than *Reckitt*. Under *Am-*

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[288] 2017 WL 634939 (D. Del. Feb. 16, 2017), at *1

[289] *David Netzer Consulting Eng'r LLC v. Shell Oil Co.*, 824 F.3d 989, 994 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 695 (Cal. 2017).

[290] The same district court also took a similar approach in *Purdue Pharm. L.P. v. AL Vogen Pine Brook, LLC*, 2017 WL 1943957, at *2 n.18 (D. Del. May 10, 2017).

[291] *See* U.S. Patent No. 8,808,741 col.7 l.54 – col.8 l.26.

[292] *See* BARRY A. MORRIS, THE SCIENCE AND TECHNOLOGY OF FLEXIBLE PACKAGING 132 (William Andrew 2017) (noting that a Brookfield viscometer is a tool for the solution viscosity method).

[293] *See supra* Part II.C.1.

[294] *See generally* Chiara F. Ferraris, *Measurement of the Rheological Properties of High Performance Concrete: State of the Art Report*, 104(5) J. OF RES. OF THE NAT'L INST. OF STANDARDS AND TECH. 461 (1999), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4878862/pdf/j45fer.pdf (last visited Sept. 8, 2017).

[295] *Purdue Pharma L.P.*, 2017 WL 634939, at *5.

[296] *See generally Reckitt*, 2016 WL 3186659 (D. Del. June 3, 2016).

neal Pharmaceuticals, if the specification defines the measurement of molecular weight, the term molecular weight is deemed to be definite. But, the disadvantage is that courts may limit the term molecular weight to a molecular weight measured by a particular method or equipment. That may cause a potentially infringing product to fall outside the scope of a patent. Let us assume that a claim limitation "having a molecular weight of a certain range" is construed as "having a molecular weight of a certain range, where the molecular weight is measured by Method A" and the infringer uses Method B to measure the molecular weight of the polymer ingredient of the infringing product. It is possible that the measurement based on Method B for the infringing product will make the molecular weight value fall within the claimed range, but when Method A is applied to the same sample, the measured value of molecular weight will fall outside the claimed range.

In light of *Teva IV*, to avoid the unnecessary restriction on the scope of molecular weight, the best practice may be to use a specific average molecular weight in a claim and to describe how to measure such average molecular weight in the specification. The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."[297] Therefore, the particular measurement described in the specification will not limit the scope of the specific average molecular weight recited in the claims.

V. CONCLUSION

The term molecular weight for describing polymers could mean "number-average molecular weight," "weight-average molecular weight," "peak-average molecular weight," "viscosity-average molecular weight," and "z-average molecular weight." Under *Teva IV*, using molecular weight as a claim term in polymer-related patents without defining molecular weight in the specification will create reasonable uncertainty of the scope of molecular weight. Eventually, those claims with molecular weight will be held as indefinite. However, two types of molecular weight will survive the indefiniteness challenge. This first type is a patent disclosing the source of the claimed polymer while the second type is a patent describing the measurement of polymer molecular weight. But, it is better to recite a specific average molecular weight in a claim and describe the measurement of that average molecular weight in the specification.

[297] *Phillips*, 415 F.3d at 1323.