

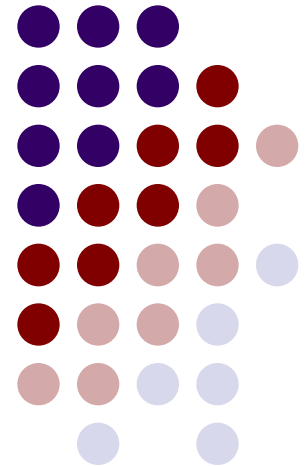


Birch
Stewart
Kolasch
Birch LLP

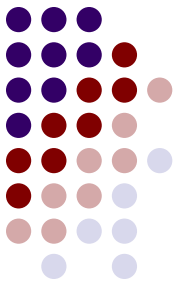
Inconsistent Statements on Claim Scope during Prosecution can Later Invalidate a Patent as being Indefinite

Teva Pharm. USA, Inc. v. Sandoz, Inc.
(Fed. Cir. July 23, 2013)

Shawn Hamidinia
February 12, 2014

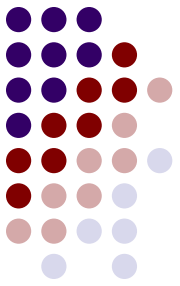


BACKGROUND



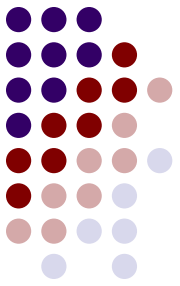
- Sandoz and Mylan filed ANDA for Copaxone®, a drug used in treating multiple sclerosis.
- Teva produces Copaxone® and is the patent owner of the patents-in-suit.
- The patents-in-suit include claims directed to a product called copolymer-1 and claims reciting methods of making copolymer-1.

BACKGROUND



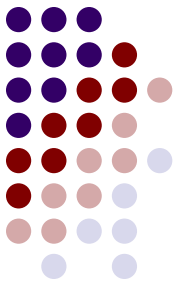
- Copolymer–1 consists of four different amino acids (alanine, glutamic acid, lysine, and tyrosine) combined in a certain ratio to make a polypeptide product.
- There are different ways to describe the resulting distribution of molecular weight values.

BACKGROUND



- Copolymer–1 consists of four different amino acids (alanine, glutamic acid, lysine, and tyrosine) combined in a certain ratio to make a polypeptide product.
- Copolymer-1 consists of a mixture of individual polymer molecules that have varying molecular weights.
- There are different ways to describe the resulting distribution of molecular weight values.

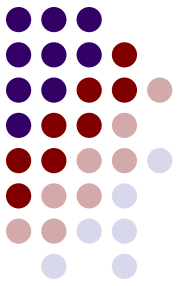
BACKGROUND



First Approach:

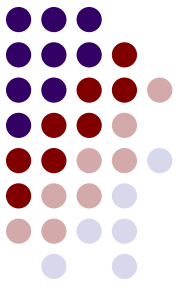
- One uses statistical measures, including the peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w).
- M_p , M_n , and M_w have different values in a typical sample.

BACKGROUND



First Approach:

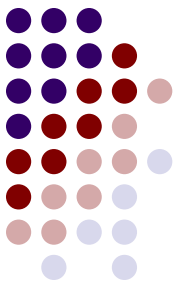
- M_p (peak average molecular weight) is the molecular weight of the most abundant molecule in the sample.
- M_n (average molecular weight) is the arithmetic mean, or the total mass of all the molecules in the sample divided by the total number of molecules.
- M_w (weight average molecular weight) is another average molecular weight measure that is calculated differently from M_p and M_n . M_w takes into account the molecular weight of a chain in determining contributions to the molecular weight average.



I. Definiteness Issue

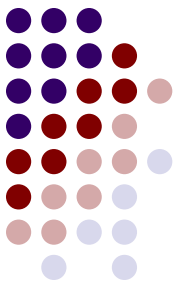
Second Approach:

- Describes how many molecules in a polymer sample have molecular weights that fall within an arbitrarily set range.
- (*e.g.*, 99% of its mole fraction within the molecular weight range of 1kDa to 100 kDa).



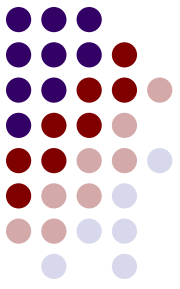
Procedural History

- Patentee (Teva) filed action against competitors (Sandoz and Mylan) alleging infringement of patent.
- Competitors filed counterclaims seeking declaratory judgment of non-infringement, unenforceability, and invalidity.
- The United States District Court for the Southern District of New York, ruled after bench trial that the claims were not invalid for obviousness or lack of enablement, and that the Mylan and Sandoz accused products infringed all of the asserted claims.
- Competitors appealed.



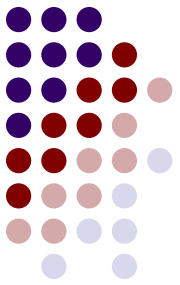
Teva's Patents at Issue

- The patents-in-suit 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)
- 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.



GROUP I CLAIMS

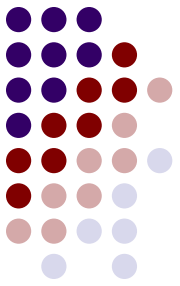
- Use “statistical measures” M_p , M_n , M_w to define molecular weight.
- Claim 1 of the ‘589 patent is representative of Group I claims –
 - “Copolymer-1 having a molecular weight of about 5 to 9 kilodaltons.”



GROUP II CLAIMS

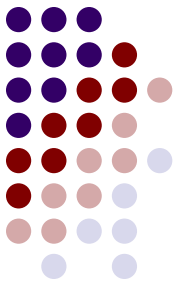
- Describe how many “molecules” in polymer sample fall within range.
- Claim 1 of the ‘430 patent is representative of Group II claims –
 - “Copolymer-1 having over 75% of its molar fraction within MW range from about 2 kDa to about 20 kDa.”

Federal Circuit Holdings



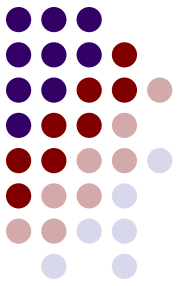
- Affirmed the district court's judgment of infringement and no invalidity with respect to Group II claims. Group II claims have not been proven indefinite.
- Reversed and remanded the district court's judgment of no invalidity with respect to Group I claims. Group I claims are invalid for indefiniteness.

Appellants' Arguments-Group I



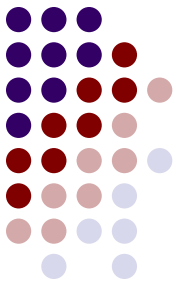
- Sandoz argues that the term “molecular weight” is indefinite because it can refer to different measures, including M_p , M_n , or M_w .
- Sandoz further argues that the scope of the claims varies significantly depending on the measure.

Appellants' Arguments-Group I



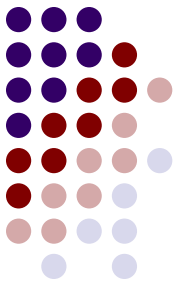
- Sandoz further argues that Teva inconsistently defined “molecular weight” as M_p and M_w during prosecution of two of the familial patents.
- Sandoz contends that the specification does not resolve the intended molecular weight measure.

'539 Patent Prosecution History



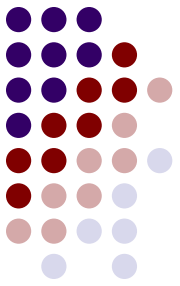
- During prosecution of the '539 patent, the Examiner rejected claims as indefinite because the method of measurement was not specified.
- In response, Teva stated that “[o]ne of ordinary skill in the art, upon reviewing the specification, would understand that ‘average molecular weight’ refers to the molecular weight at the peak of the molecular weight distribution curve shown in Figure 1,” *i.e.*, M_p .
- Based on this response, the application was allowed.

'847 Patent Prosecution History



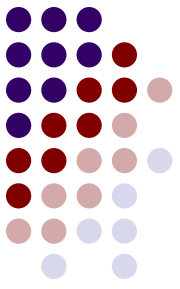
- During prosecution of the '847 patent, the Examiner again rejected claims as indefinite because the term “average molecular weight” is meaningless as a limitation without specifying its basis.
- Teva overcame the rejection by responding that “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight,” *i.e.*, M_w .

Teva's Arguments-Group I



- Teva counters that the prosecution history clarifies that M_p should be used to define “molecular weight” during prosecution of the ‘539 patent.
- Teva argues that the district court correctly determined that during prosecution of the ‘847 patent, “[o]ne of ordinary skill in the art could understand that kilodalton units implies a weight average molecular weight,” was not contradictory.
- Teva further argues that any molecular weight measurement may be expressed in kilodalton units.

Teva's Evidence-Group I



- Teva contends that the specification's reference to the Size Exclusion Chromatography (SEC) method indicates that "molecular weight" means M_p because determining M_w and M_n requires further calculations from SEC data that the specification does not describe.
- Teva further contends that Figure 1 confirms this conclusion because only M_p can be obtained directly from the molecular weight plot in the figure.

Teva's Evidence-Group I

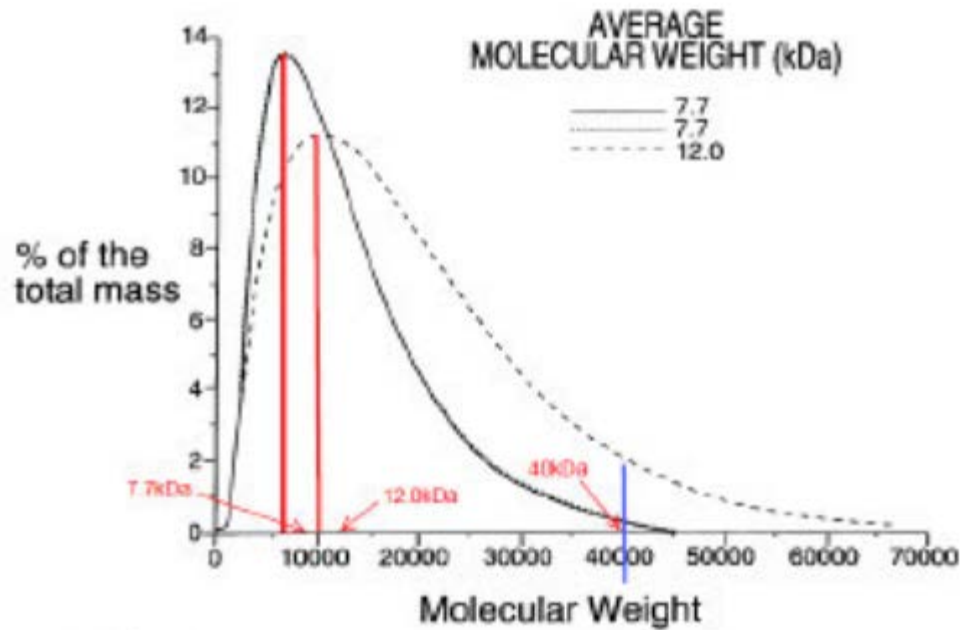
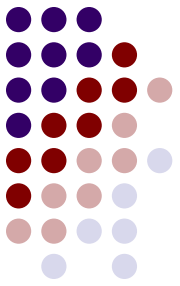
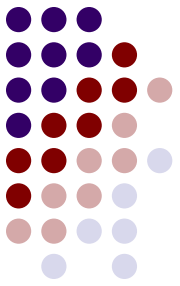
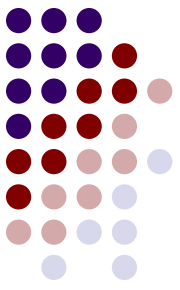


FIG. 1

Teva's Evidence-Group I



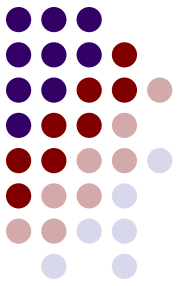
- Expert testified that after examining the curve in Figure 1, and the accompanying legend, a skilled artisan would know that the claim terms “molecular weight” and “average molecular weight” means M_p .
- Expert also testified that only M_p can be read directly from a plot of SEC data.



CAFC Rationale-GROUP I

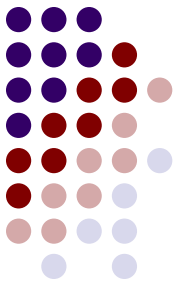
- On *de novo* review, the CAFC ruled that that the evidence does not save the Group I claims.
- They pointed to the testimony of the expert himself, who admitted that SEC does not exclusively provide M_p – both M_n and M_w can also be obtained from the SEC data after calculations.
- They also pointed to the fact that the 7.7 kDa value in Figure 1 is closer to M_w than M_p , which makes it difficult to conclude that M_p is the intended measure.
 - The evidence for this last point is unexplained. CAFC possibly accepted Appellants' expert testimony.

Appellants' Arguments-GROUP II



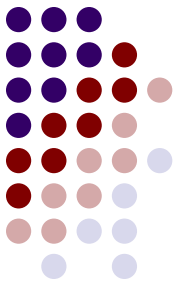
- Sandoz argues that indefiniteness arguments apply equally to Group I and Group II claims.

Teva's Arguments-GROUP II



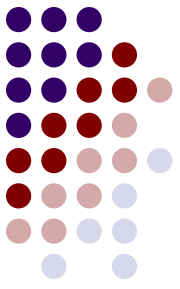
- Teva argues that Group II claims refer to **exact molecular weight values** and are therefore not ambiguous.
- Teva further argues that Group II claims recite percentages of molecules in a copolymer-1 sample that fall within a specified molecular weight range, **not average values**.

CAFC Holding-GROUP II



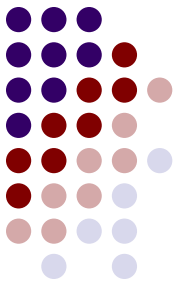
- Agreed with Teva.
- Claims are “not indefinite”.
- Claims refer to precise points on the “molecular weight” axis, rather than to statistical properties of the molecular weight curves.

CAFC Holding-GROUP II

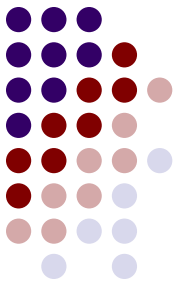


- Claims recite % of copolymer-1 molecules in a sample falling within arbitrary set MW range.
 - Claims regarding copolymer-1 having over 75% of its mole fraction within molecular weight range from about 2 kilodaltons (kDa) to about 20 kDa;
 - numbers that set boundaries of that range referred to precise points on “Molecular Weight” axis, rather than to statistical properties of polymer molecular weight curves.

II. Enablement

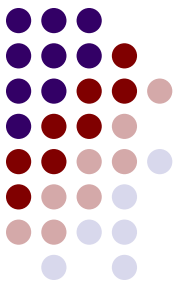


- Claims not invalid for lack of enablement
 - two methods, self standards and universal calibration, were available to make drug's active ingredient with claimed molecular weights, and
 - amount of experimentation necessary to accurately determine average molecular weight or molecular weight distribution of sample of ingredient was not undue.



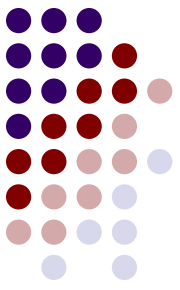
III. Obviousness

- Not invalid for obviousness
 - prior art expressed preference for higher molecular weight copolymer-1, and therefore taught away from claimed invention, and
 - secondary considerations further supported conclusion of nonobviousness



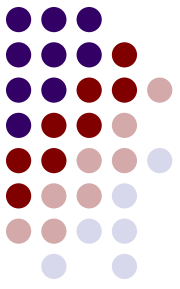
IV. INFRINGEMENT

- The district court construed “copolymer-1” to mean “a mixture of polypeptides composed of alanine, glutamic acid, lysine, and tyrosine in a molar ratio of approximately 6:2:5:1.”
- This construction was not in dispute.
- The court converted this ratio into percentages to facilitate comparison with the accused products (42.9% Ala, 14.3% Glu, 35.7% Lys, and 7.1% Tyr” (total 100%).



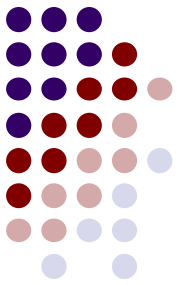
IV. INFRINGEMENT

- Court interpreted “copolymer-1” to mean “approx. 6:2:5:1 Ala, Glu, Lys, Tyr” or “approx. 42.9% Ala, 14.3% Glu, 35.7% Lys, and 7.1% Tyr” (total 100%).
- Court determined that “approximately” means $\pm 12\%$ aggregate amount of percent variation (from intrinsic record and expert testimony).
- Court held literal infringement of Mylan and Sandoz because accused products differ by aggregate of only 4.4% and 4.5%, respectively.

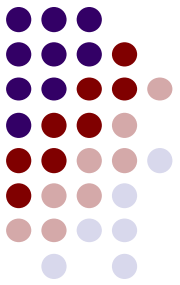


PRACTICE TIPS

- Define all terms and measurements in the specification that might eventually be recited in claims.
- When multiple measurements can be used, recite in claim which one is contemplated.
- Be consistent in responding to indefiniteness issues, even between patent applications in the same family.



Questions?



Thank you.