

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

\_\_\_\_\_  
FRESENIUS KABI USA, LLC, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 14-161-RGA  
 )  
WATSON LABORATORIES, INC. and )  
ACTAVIS, INC., )  
 )  
Defendants. )  
 )  
\_\_\_\_\_  
FRESENIUS KABI USA, LLC, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 14-160-RGA  
 )  
DR. REDDY'S LABORATORIES, LTD. and )  
DR. REDDY'S LABORATORIES, INC., )  
 )  
Defendants. )  
 )  
\_\_\_\_\_ )

**PLAINTIFF FRESENIUS KABI USA, LLC'S  
OPENING CLAIM CONSTRUCTION BRIEF**

Bass and Spangenberg  
v.  
Fresenius Kabi USA, LLC  
U.S. Patent No. 8,176,010

*Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1333-34 (Fed. Cir. 2001)  
(reversing claim constructions of district court for importing limitations from specification).

**B. Terms to be Construed**

**1. “From About 0 to About 10% by Weight Solvent for Propofol”  
and/or “From About 0 to About 10% by Weight of the Solvent”  
Should be Construed According to Its/Their Plain and Ordinary  
Meaning**

<b>Claim Term(s)</b>	<b>Plaintiff’s Proposed Construction</b>	<b>Defendants’ Proposed Construction</b>
“from about 0 to about 10% by weight solvent for propofol”  “from about 0 to about 10% by weight of the solvent” <sup>2</sup>	Plain and ordinary meaning.	“less than 10% by weight solvent for propofol, provided that the amount of solvent is also less than any amount of solvent in any prior art Diprivan®”

The use of the term “from about 0 to about 10% by weight” to define the numeric range of the amount of “solvent for propanol” as recited in claims 1-3, 5-15, 17, 20, 24-28, 33-35, 38, 43, 44, 46, 49 and 52-56 has a well-understood, plain and ordinary meaning in the art. *See Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (terms should be given their ordinary and customary meaning unless one of two exceptions is present: “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution”) (citations omitted). Neither the ’010 patent specification nor its prosecution history deviates from that well-understood meaning. *Cf. Marabella Decl., Ex. A* (’010 patent) at 4:9-12 (“The formulation is preferably comprised of an oil in water emulsion with a mean particle size of from

---

<sup>2</sup> The parties have listed separately the two “from about 0 to about 10% by weight” terms because the language following “by weight” differs slightly in the two groups of claims (“solvent for propofol” vs. “of the solvent”). The parties agree that the differences are immaterial. Therefore, the parties have each proposed a single construction for both terms. Every asserted claim includes one of the “from about 0 to about 10% by weight” terms.

about 100 to about 300 nanometers in diameter . . . .”); 4:13-14 (“The composition preferably has a pH in the range of from about pH 5 to about pH 8.”); 6:58-62 (“The mean size of the droplets typically is in the range from about 20 nanometers to about 1000 nanometers, desirably from about 50 nanometers to about 500 nanometers, and more desirably from about 100 to about 300 nanometers.”).

Where, as here, the specification does not set forth a specific definition, courts routinely hold that the term “about” requires no construction. *See, e.g., Ferring BV v. Watson Labs., Inc.*, 764 F.3d 1382, 1389 (Fed. Cir. 2014) (“‘About’ is not defined either explicitly or by implication by the specification. We think that the district court did not err in giving the term ‘about’ its ordinary meaning and in refusing to give it a more specific construction.”); *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005) (holding that the term “about” should be given its ordinary and accepted meaning of “approximately” unless the patentee clearly redefines “about” in the specification).

The issue here is whether compositions with *exactly* 10% by weight of solvent infringe. Defendants’ blatantly results-oriented construction would, in essence, exclude any composition with 10% or more by weight of the solvent from the scope of the asserted claims. But there is no support in the intrinsic record for Defendants’ complicated, multi-pronged construction of the term. Indeed, inserting the limitation “less than 10% by weight” into the construction of “from about 0 to about 10% by weight” plainly flies in the face of the plain meaning of the term(s) as used in the specification. The ’010 patent specification clearly distinguishes the use of the term “about 0% to about 10% by weight” from the term “less than 10% by weight” to describe examples of different amounts of various components that can be present in formulations of the invention. *Compare e.g. Marabella Decl., Ex. A* (’010 patent) at 5:36-38 (“The water miscible



solvent or the water-immiscible solvent is present in an amount that is preferably from 0 to 10% by weight of the composition . . . .”) *with id.* at 25:44-46 (“[A]n inert closure material was essential for formulations containing less than 10% oil.”). Nowhere in the specification is it disclosed that “less than 10% by weight” is *necessary* for the solvent for propofol in the claimed invention. In fact, the specification states that “[t]he . . . the water-immiscible solvent [i.e. solvent for propofol] is present in an amount that is preferably “*from 0 to 10% by weight of the composition*”, which contradicts the “*less than 10% by weight solvent for propofol*” limitation proposed by Defendants.

Additionally, construing “from about 0 to about 10% by weight . . .” as necessitating that the solvent for propofol be present in an amount “less than 10% by weight solvent for propofol” violates the principle of claim differentiation by making claim 1 directly conflict with or be redundant of the language of other claims in the same patent. *See Phillips*, 415 F.3d at 1324-25 (“The inclusion of such a specific limitation on the term ‘baffles’ in claim 2 makes it likely that the patentee did not contemplate that the term ‘baffles’ [as recited in claim 1] already contained that limitation.”). For example, whereas claim 1 does recite compositions comprising “from about 0 to about 10% by weight solvent for propofol”, claim 29 – which depends from claim 1 – recites compositions comprising, *inter alia*, “less than about 0.5% by weight solvent for propofol” *See Marabella Decl., Ex. A* (’010 patent) at 27:55-28:3; 29:55-57. The specific inclusion of the “less than about 0.5% by weight” limitation for the “solvent for propofol” in claim 29 means that the patentee knew how to claim “less than” a desired weight for the “solvent for propofol” where it was applicable, and further, that the patentee did not contemplate that the term “about 0 to 10% by weight” for the “solvent for propofol”, as recited in independent claim 1, should be limited to “less than 10% by weight.” *See Phillips*, 415 F.3d at 1324-25.

Furthermore, during prosecution of the '709 application the patentee expressly amended the term “less than 10% by weight solvent for propofol” to “from about 0 to about 10% by weight solvent for propofol.” *See* Marabella Decl., Ex. B (April 30, 2013 Applicant-Initiated Interview Summary) at WPROP0018388 – WPROP0018402. That change is reflected in an “Examiner’s Amendment” and a Notice of Allowance that allowed claim 1 (and all other pending claims) that issued as the ‘010 patent. Marabella Decl., Ex. C (Notice of Allowance) at WPROP0018403 – WPROP0018410. By proposing a construction that seeks to limit the “from about 0 to about 10%” to mean “less than 10%,” Defendants ignore the express amendment to that term entered by the Examiner and reflected in the Notice for Allowance. Defendants’ construction of this term plainly contradicts the intrinsic evidence in the prosecution history and, thus, the Court should reject it.

Finally, Defendants’ proposal to include the limitation “less than any amount of solvent in any prior art Diprivan®” lacks any support in the intrinsic evidence. The ‘010 patent specification never uses this phrase or even comes close to stating that this criterion is necessary for the solvent for propofol in the claimed invention. Moreover, there is no precision in Defendants’ proposed construction since it is silent as to what amounts are excluded by the “prior art Diprivan®.”

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.