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Statement of Invention or “Hunting Expedition”?: Written Description for Claimed Ranges

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“A written description . . . requires a statement of an invention, not an invitation to go on a hunting expedition to patch together after the fact a synthetic definition of an invention.”¹ For claims reciting ranges, satisfying the written description requires an applicant to explicitly describe the claimed ranges or the end values of the ranges **as of the filing date**. Written description cannot solely rely on cobbling together the numbers of the range after the fact. *Id.* at 1329. A failure to meet the written description requirement due to the lack of such a statement cannot be cured by disclosing representative working examples within the claimed range.

In *Indivior UK Ltd. v. Dr. Reddy’s Laboratories S.A.*, the Federal Circuit, when deciding on an appeal from an IPR decision, agreed with the Patent Trial and Appeal Board that claims² in U.S. Pat. No. 9,687,454 (the “454 Patent”) reciting ranges of polymer percentages are not supported by the purported priority application, U.S. Patent Application Serial No. 12/537,571 (the “571 Application”). The Federal Circuit held that these claims (owned by Indivior UK Ltd.) are not entitled to priority of the filing date of the ‘571 Application and thus are anticipated by the publication of the ‘571 Application (“Myers”). The court’s analysis of claims 1, 7, and 8 are discussed below.

Claim 1 of the ‘454 Patent relates to an oral, self-supporting, mucoadhesive film having a range about 40 wt % to about 60 wt % of a water-soluble polymeric matrix. ‘454 Patent col. 24 ll. 25-46. Claim 7 depends on claim 1 and recites a narrower claim range of about 48.2 wt % to about 58.6 wt %. *Id.* col. 24 ll. 57-59. Claim 8 refers to the specific percentage value of about 48.2 wt %. *Id.* col. 24 ll. 60-61.

The court held claims 1 and 7 are not supported by the ‘571 Application because the application does not explicitly disclose the range of 40 wt % to 60 wt %, or the range of about 48.2 wt % to about 58.6 wt %; neither does the ‘571 Application disclose any of the end values of said ranges (i.e., 40 wt %, 48.2 wt %, 58.6 wt %, or 60 wt %). Notably, the ‘571 Application discloses many exemplary films (working examples): four (4) in Table 1 and six (6) in Table 5, each comprising four types of polymers, and the aggregate polymer percentage of which fall within the claimed ranges. However, the court stated that the tables do not disclose the claimed ranges; instead, one must sum up individual values of four types of polymers and then divide the sum by the total weight of each film to determine the aggregate percentages to create an otherwise unstated range. Thus, the court considers the disclosure does not provide “a statement of an invention,” but requires “cobbling together numbers after the

fact,” and “patch[ing] together after the fact a synthetic definition” of the claimed invention, thus failing to provide the required written description support. *Indivior*, 18 F.4th at 1329.

Contrary to its disposition of claims 1 and 7, the court held that claim 8, which recites a film comprising about 48.2 wt % of polymer, has support from the ‘571 Application. *Id.* at 1330. The court reached this conclusion even though the ‘571 Application also failed to explicitly disclose the value of 48.2 wt % and said value would also need to be generated by summing all four types of polymers in the data tables in the ‘571 Application. *Id.* at 1329-30. It appears that the court applies the requirement of “a statement of an invention” only to claims reciting **ranges**. *Id.* For claims reciting discrete values (e.g., 48.2 wt.%), the court does allow the “selection and addition of the amounts of selected, but identified, components” to provide support to the claimed value and does not require literal disclosure of said value. *Id.* at 1330. Finally, the court found the disclosure in the ‘571 Application of the open-ended ranges, i.e., “at least 25% by weight” or “at least 50%,” and the statement “[t]he film may contain any desired level of self-supporting film forming polymer” contradict the claimed closed ranges in the ‘454 Patent, which reinforced the court’s position that the ‘571 Application does not support the claims. *Id.* at 1326, 1327, 1329 (alteration in original).

In a vigorous dissent, Judge Linn stated that the disclosures of *at least 25%* and *at least 50%* are no different than if restated as closed ranges of 25%-100% and 50%-100% and they do not contradict the claimed range of 40% to 60%. *Indivior*, 18 F.4th at 1331. Judge Linn also stated that the majority took the language “the film may contain any desired level of self-supporting film forming polymer” out of context. *Id.* In Judge Linn’s view, this language does not suggest that any polymer percentage is acceptable; to the contrary, the paragraph identifies the essential desired characteristics possessed by the claimed films, *i.e.*, mucoadhesion and the rate of dissolution shared by the films and polymer levels needed to impart those characteristics. *Id.* at 1331.

Takeaways

The problem in *Indivior* is not claiming ranges; it is making it clear that there is explicit disclosure in the application for the claimed ranges. There is no rule “applicable to all description requirement cases involving ranges” and “[b]roadly articulated rules are particularly inappropriate in this area,” *Id.* at 1329-30 (alteration in original) (quoting *Wertheim*, 541 F.2d at 263, 264-65); however, this case and the court’s precedents³ show that it is important to expressly state the claimed ranges or the end values in the specification (notably, in addition to acknowledging the importance of those precedents, the majority argued that written description is a fact-intensive issue). While disclosure of representative working examples within the claimed range is helpful and may be required, it cannot replace an express statement. Applicants need to extract the information from these working examples and perform the necessary calculations to show how they support the claimed ranges in the as-filed application; they cannot put together the ranges or end values *after* filing the application. Finally,

applicants need to be wary about the pitfalls associated with all-encompassing statements such as used in *Indivior*, “[t]he film may contain any desired level of self-supporting film forming polymer.” *Indivior*, 18 F.4th at 1326. Applicants should consider limiting such statements with the properties that are expected to the “desired level.” *Id.*

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Footnotes

¹ *Indivior UK Ltd. v. Dr. Reddy's Lab's S.A.*, 18 F.4th 1323, 1329 (Fed. Cir. 2021).

² Claim 1 of the '454 Patent states:

An oral, self-supporting, A mucoadhesive film comprising:

- (a) about 40 wt % to about 60 wt % of a water-soluble polymeric matrix;
- (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;
- (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and
- (d) an acidic buffer;

wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;

wherein the weight ratio of (b):(c) is about 4:1;

wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and

wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption between buprenorphine and naloxone, with a buprenorphine C_{max} from about 0.624 ng/ml to about 5.638 ng/ml and a buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml; and a naloxone C_{max} from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml.

'454 Patent col. 24 ll. 25-46.

³ *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976)); *Nalpropion Pharms., Inc. v. Actavis Lab's FL, Inc.*, 934 F.3d 1344 (Fed. Cir. 2019), *cert. denied*, 140 S. Ct. 2804 (2020).