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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* NICOLAS FAUQUET

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Appeal 2019-005471  
Application 13/884,531  
Technology Center 1700

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Before MICHAEL P. COLAIANNI, GEORGE C. BEST, and  
DEBRA L. DENNETT, *Administrative Patent Judges*.

COLAIANNI, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant<sup>1</sup> appeals under 35 U.S.C. § 134(a) the final rejections of claims 1, 3, 4, 7, 8, 10–13, 16, and 17. Claims 6, 15, 18, and 19 have been canceled; claims 2, 5, 9, and 14 are withdrawn. We have jurisdiction over the appeal pursuant to 35 U.S.C. § 6(b).

We AFFIRM.

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<sup>1</sup> We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Nicolas Fauquet (Appeal Br. 3).

STATEMENT OF THE CASE

Appellant's invention is directed to a method for separating fractions of a mixture by liquid phase chromatography (Spec. 1:11–12). According to the Specification, the claimed method addresses issues inherent in the discontinuous processing of high volumes by liquid phase chromatography (*id.* at 2:1–2). Such high-volume processing is said to be complex in terms of pump and valve connections and entails moving injection points into various columns or changing flow directions (*id.* at 2:5–6). According to the Specification, the claimed method also avoids issues encountered during gradient chromatography, which requires a longer balancing phase between two injections and the use of complex solvent mixtures (*id.* at 2:9–10).

Claim 1 is illustrative (emphasis added):

1. A method comprising:

purifying a mixture by liquid chromatography resulting in separation of fractions of the mixture to be purified, *the fractions consisting of a sole product of interest*, wherein purifying comprises:

*a first set of multiple injections of the mixture*, wherein the first set of multiple injections are made successively into a first liquid contained in a first chromatography column and *wherein the multiple successive injections are each separated in time by a time interval A*,

*a first set of multiple collecting operations*, wherein fractions of the first liquid in the first chromatography column are collected successively and *wherein two successive collections of the fractions are separated in time by the time interval A, generating the fractions comprising the sole product of interest* and wherein a first collecting operation of the first set of multiple collecting operations starts a time after the first injection of

the first set of multiple injections that is at least equal to the retention time of the sole product of interest;

*a second set of multiple injections of the fractions comprising the sole product of interest, wherein the second set of multiple injections of the fractions are carried out successively into the first liquid within the first chromatography column or are carried out successively into a second liquid within a second chromatography column, and wherein two successive injections of the second set of multiple injections of the fractions into the first or second liquid are separated in time by a time interval B, wherein time interval B is not equal to time interval A and where time interval A and B are not integer multiples of one another; and*

*a second set of multiple collecting operations, wherein fractions from the first liquid or from the second liquid in which the fractions comprising the sole product of interest are injected are collected successively, wherein two successive collecting operations from the liquid in which the fractions comprising the sole product of interest were injected into are separated in time by the time interval B not equal to time interval A.*

Appellant appeals the following rejections:

1. Claims 1, 3, 4, 7, 8, 10–13, 16, and 17 are rejected under 35 U.S.C. § 112, ¶ 2 as indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention (Final Act. 2–3).
2. Claims 1, 3, 4, 7, 8, 10–13, 16, and 17 are rejected under 35 U.S.C. § 103(a) as unpatentable over Petro et al. (US 6,730,228 B2; issued May 4, 2004, “Petro”) (Final Act. 3–8).

Appellant offers separate arguments in support of independent claim 1 (*see generally* Appeal Br. 9–13). Appellant argues claims 1, 3, 4, 7, 8, 10–13, 16, and 17 as a group (*id.* at 9, 13). Dependent claims 3, 4, 7, 8, 10–13, 16, and 17 will stand or fall with our analysis of independent claim 1.

#### FINDINGS OF FACT & ANALYSIS

*A. Rejection of claims 1, 3, 4, 7, 8, 10–13, 16, and 17 as indefinite under 35 U.S.C. § 112, ¶ 2*

The Examiner determines that the limitation “the fractions consisting of a sole product of interest” recited in claim 1 is indefinite (Final Act. 2). The Examiner finds that the term “consisting of” renders the claim indefinite because this “transitional phrase . . . excludes any . . . ingredient not specified in the claim” (*id.*). According to the Examiner, claim 1 encompasses a fraction having: (i) a sole product of interest and (ii) other products, which are not products of interest (*id.*). The Examiner finds that claim 1 is unclear as to “how a fraction ‘mixture[,]’ which is ‘consisting of a sole product’ contains ‘a sole product of interest’” (*id.* at 3).

Appellant argues that the claims are definite because “[t]he fraction referred to and claimed is a fraction that *has been purified according to the method* so as to contain only the product of interest, solely the product of interest as the other components have been separated from the sole product of interest” (Appeal Br. 9) (emphasis added).

The Examiner responds that: (i) the Specification “does not provide any definition of what the term ‘product of interest’ means” and (ii) the

claim “term ‘fractions comprising’ . . . further renders the claim indefinite” (Ans. 10).

In assessing whether a claim is indefinite, we determine whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). In the present case, the Specification describes a method for separating fractions of a mixture by liquid phase chromatography (Spec. 1:11–12). Contrary to the Examiner’s position (Ans. 10), it would be clear to one of ordinary skill in the art that the claimed “fractions *comprising* the sole product of interest” encompasses fractions which are produced from intermediate steps in the purification method (emphasis added). The Specification, furthermore, provides several examples showing that “[t]he collection of the fractions of interest results in production of the purified product” (Spec. 19:1; *see generally id.* at 15:9–19:10), i.e., the claimed “fractions consisting of a sole product of interest.”<sup>2</sup>

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<sup>2</sup> When used in a claim, the transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520 (CCPA 1931). We note that the Specification describes that the eluted product of interest is isolated within solvent fractions (Spec. 18:5–19:8). In other words, solvent would be excluded from the fractions of the sole product of interest as claim 1 is currently drafted. Claim 1 uses the transitional phrase “comprising” in the context of the method recited and which does not exclude the described solvent. If the described solvent does not materially affect the basic characteristics of the purified product, Appellant has the responsibility to clarify the disputed claim term’s meaning by amending the application to account for the presence of solvent in the fraction “consisting of” a sole product of interest. *See, e.g., In re Janakirama-Rao*, 317 F.2d 951, 954 (CCPA 1963) (“The word ‘essentially’ [in the phrase ‘consisting essentially of’] opens the claims to the inclusion of ingredients which would not materially affect the basic and novel characteristics of appellant’s composition[] as defined in the balance of the

In our view, one of ordinary skill in the art would understand what is claimed when the claim is read in light of the Specification.

We reverse the Examiner's § 112, second paragraph, rejection.

*B. Rejection of claims 1, 3, 4, 7, 8, 10–13, 16, and 17 as unpatentable over Petro*

The Examiner finds that Petro renders obvious each step and limitation of the method for purifying a mixture recited in independent claim 1 (Final Act. 3–6).

The Examiner finds Petro teaches that a first set of multiple mixture injections are made successively into a liquid contained in a first chromatography column (*id.* at 3). The Examiner finds Petro discloses that the first set of multiple mixture injections are made such that two successive injections are separated by a time interval A (*id.* at 3–4).

The Examiner finds Petro discloses a first set of multiple collection operations, in which “the first collecting operation . . . starts a time after the first injection of the multiple injections of the mixture to be purified at least equal to the retention time of the product of interest” (*id.* at 4).

The Examiner finds Petro teaches a second set of multiple fraction injections comprising the sole product of interest, which are generated in the first collecting operation (*id.*). The Examiner finds Petro discloses that the second set of multiple fraction injections are made such that two successive injections of fractions are separated by a time interval B (*id.* at 5).

The Examiner finds “Petro teaches that time intervals A and B are not critical and can include a wide range of time spans,” including 10 minutes

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claim, according to the applicable law.”); *see also In re Zletz*, 893 F.2d 319, 321–22 (Fed. Cir. 1989).

and 180 seconds, respectively (*id.*). The Examiner finds that these specific A and B time intervals are unequal and are not integer multiples of each other, as required by claim 1 (*id.*). The Examiner finds that “Petro teaches that operational conditions, such as separation rate and injection frequency, can be selected to achieve a balance between sample throughput and resolution” (*id.*). The Examiner determines that it would have been obvious for one of ordinary skill in the art at the time of the invention to have “optimized, by routine experimentation, the relationship of” Petro’s time intervals A and B “to obtain the desired balance between chromatography resolution, separation rate, and injection frequency” (*id.*).

Appellant argues that the Examiner has not established a prima facie case of obviousness because Petro’s teachings are deficient (*see* Appeal Br. 10–11). Appellant argues that Petro fails to teach or suggest that time intervals A and B are neither equal nor integer multiples of each other (*id.* at 10). In support of this argument, Appellant directs our attention to the following disclosure in Petro:

In general, the time interval that defines the sampling frequency for sampling the first-dimension mobile phase eluent, and preferably, that also defines the injection frequency of the sampled portion into the second-dimension mobile phase, is not narrowly critical, and can range, for example, from about 10 minutes to about 5 seconds or less. Preferably, the time interval that defines the sampling frequency can range from about 5 minutes to about 10 seconds, and in some embodiments, from about 2 minutes to about 30 seconds. Generally, therefore, a discrete volume of the first-dimension mobile phase is sampled (and preferably, also injected into the second-dimension mobile phase) at least once every 10 minutes, and more preferably at least once every 5 minutes, and most preferably at least once every 2 minutes. In some embodiments, a discrete volume of the first-dimension mobile phase can be sampled (and



preferably, also injected into the second-dimension mobile phase) at least once every 180 seconds, and more preferably at least once every 1 minute, even more preferably at least once every 30 seconds, and in some cases, at least once every 15 seconds, at least once every 10 seconds or at least once every 5 seconds.

Petro 12:43–64.

Appellant contends that this disclosure describes executing the second successive injections at the same time interval frequency as the first successive injections (Appeal Br. 10). Appellant distinguishes the claimed subject matter from Petro’s method because the latter teaches “a common frequency of first collection column and injection in the second column” (*id.*). Appellant argues that Petro teaches away from the claimed method because the prior art method does not vary the sample frequency within a run (*id.* at 11).

Appellant’s arguments are not persuasive.

Teaching away requires that a reference “criticize, discredit, or otherwise discourage the solution claimed” by Appellant. *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Here, we find that Petro does not teach away from the claimed subject matter because Appellant has not identified any disclosure that disparages varying the sample frequency within a run. Rather, Petro explicitly discloses that “the time interval that defines the sampling frequency” of a first set of multiple collection operations, “and preferably, that also defines the injection frequency of the sampled portion into the” second set of multiple fraction injections, “is not narrowly critical.” Petro 12:43–47 (emphasis added); *see also In re Fritch*, 972 F.2d 1260, 1264 (Fed. Cir. 1992) (explaining that “[i]t is well settled that a prior art

reference is relevant for all that it teaches to those of ordinary skill in the art”).

Furthermore, all disclosures of a reference including non-preferred embodiments must be considered in the obviousness analysis. *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976). In our view, Petro’s non-preferred embodiments would have reasonably suggested varying the sample frequency within a run such that: (i) the sampling frequency time interval of a first set of multiple collection operations is 10 minutes and (ii) the injection frequency of the sampled portion into the second set of multiple fraction injections is 180 seconds. *See* Petro 12:43–64.

In view of the prior art’s teachings, Appellant has not identified reversible error in the Examiner’s findings that Petro renders obvious each step and limitation of the method recited in claim 1 (Final Act. 3–6).

When the Examiner establishes a prima facie case of obviousness, “[t]he burden then shifts to the applicant, who then can present arguments and/or data to show that what appears to be obvious, is not in fact that, when the invention is looked at as a whole.” *In re Dillon*, 919 F.2d 688, 696 (Fed. Cir. 1990) (en banc). Thus, “the burden of showing unexpected results rests on [the party] . . . who asserts them.” *In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). For the reasons set forth below, Appellant has not met his burden of showing unexpected results.

Appellant argues that the Affidavit of Prof. Anna Maria Papini and Dr. Olivier Monasson (“Exhibit A”) demonstrates the unexpected results of not only improving “productivity by a factor of two . . . [,] but also reduc[ing] the amount of consumables” (Exhibit A; *see also* Appeal Br. 12). In particular, Appellant argues that the Examiner reversibly erred “in

discounting the unexpected results previously provided in” Exhibit A (Appeal Br. 12).

We, however, agree with the Examiner that these results are not probative evidence of unexpected results (Ans. 16–17). As a preliminary matter, we note that there is no indication that the statements made by Prof. Papini or Dr. Monasson in Exhibit A have been sworn to before a notary. *See* MPEP § 715.04 II. Even assuming that Appellant submitted competent evidence in the form of a notarized affidavit or a sworn declaration,<sup>3</sup> the provided statements lack factual corroboration and, thus, are entitled to little weight. *See In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) (“It is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements . . . does not suffice.”).

We, moreover, agree with the Examiner that Exhibit A’s showing of unexpected results is not commensurate in scope with the degree of protection sought because claim 1 is not directed to, *inter alia*, improved productivity by a factor of two or consumables reduction (*see* Ans. 16). Therefore, Appellant’s results do not rebut the Examiner’s established prima facie case of obviousness.

Thus, based on this record, we sustain the Examiner’s § 103(a) rejection.

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<sup>3</sup> We further note that there is also no acknowledgment by either Prof. Papini or Dr. Monasson that any willful false statements contained therein: (i) are punishable by fine and/or imprisonment and (ii) may jeopardize the validity of the application or any patent issuing thereon. *See* MPEP § 715.04 II. Exhibit A, furthermore, contains no declaration that all statements made of Prof. Papini’s or Dr. Monasson’s own: (i) knowledge are true and (ii) information and belief are believed to be true. *Id.*

CONCLUSION

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
1, 3, 4, 7, 8, 10–13, 16, 17	112, second paragraph	Indefiniteness		1, 3, 4, 7, 8, 10–13, 16, 17
1, 3, 4, 7, 8, 10–13, 16, 17	103(a)	Petro	1, 3, 4, 7, 8, 10–13, 16, 17	
<b>Overall Outcome</b>			1, 3, 4, 7, 8, 10–13, 16, 17	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED