This interference is between Biogen’s Patent 8,399,514 (the ‘514 patent) and Forward Pharma’s (FP) Application 11/576,871 (the ‘871 application).

Biogen’s patent was also the subject of IPR2015-01993.


Subsequently, on December 3, 2013, FP filed an amendment in its application cancelling all its previously filed claims, adding claims substantially copied from Biogen’s patent and requesting an interference with the patent. Application
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11/576,871, papers filed December 3, 2013. After additional prosecution, an
examiner determined that FP’s copied claims (claims 55 – 70) were allowable but
for the outcome of the interference, and requested that this Board declare an
interference between ’871 application and Biogen’s ’514 patent.

I.
The parties’ substantive motions are before us for consideration. The
following motions are pending:

1. Biogen Motion 1 (Paper 171) for judgment that FP’s involved claims are not
   supported by either an adequate written description or an enabling disclosure.
2. Biogen Motion 3 (Paper 174) attacking the accorded benefit of the filing date
   of FP’s Danish Application PA 2004 01546.
3. Biogen Motion 4 (Papers 556 and 557) for priority of invention.
4. Biogen Motion 7 (Paper 797) to exclude certain of FP’s evidence.
5. FP Motion 3 (Paper 172) to be accorded the benefit of the filing dates of its
   Danish Application PA 2004 01736, Danish Application. PA 2005 00211,
   Danish Application PA 2005 00419, and U.S. Provisional Application
   60/691,513, filed June 16, 2005.
6. FP Motion 7 (Paper 167) for a judgment that Biogen’s involved claims are
   unpatentable over certain prior art.
7. FP Motion 10 (Paper 168) for a judgment that Biogen’s involved claims are
   unpatentable under 35 U.S.C. § 112, ¶ 1, for lack of adequate written
   description support.

II.
The subject matter of this interference relates to the treatment of multiple
sclerosis (MS) by administrating a therapeutically effective dose of about
480 mg/day of certain fumarate compounds. Fumarates are also referred to as
fumaric acid esters. The claims limit the fumarates to dimethyl fumarate (DMF),
monomethyl fumarate (MMF), or their combinations. The therapeutically effective
dose is limited to 480 mg/day (FP’s claims) or “about” 480 mg/day (Biogen’s
claims). FP Clean copy of claims, Paper 7; Biogen Clean copies of claims,
Paper 14.

The parties’ subject matter is represented by Count 1:

A method of treating a human in need of treatment for
multiple sclerosis comprising orally administering to the human
a pharmaceutical composition consisting essentially of
(a) a therapeutically effective amount of dimethyl
fumarate, monomethyl fumarate, or a combination thereof, and
(b) one or more pharmaceutically acceptable excipients,
wherein the therapeutically effective amount of dimethyl
fumarate, monomethyl fumarate, or a combination thereof is
about 480 mg per day.

Declaration, Paper 1, p. 5.

III.

For the reasons detailed below, we grant Biogen’s Motion 1. We are
persuaded that one skilled in the art would not have recognized that the FP’s
inventors had possession of, and described, the specific treatment method claimed.
We think (1) the focus of FP’s specification on controlled release fumarates to
reduce gastrointestinal impact compared to the prior art fumarate compositions and
(2) the general teaching of the applicability of the fumarates to treatment of a
variety of possible diseases or conditions and the teaching of a broad range of
possible dosages would not have conveyed possession or description of the specific
treatment of MS that FP now claims.

Because FP lacks support for its copied claims, FP is not in position to
challenge Biogen’s entitlement to the subject matter claimed in the ’514 patent.
We therefore do not reach FP’s motions. See 37 C.F.R. §41.201 (definition of
threshold issue). Because we hold that FP’s claims are unpatentable, it is
unnecessary to reach Biogen’s other motions or to determine priority. We
terminate this interference with a judgment against FP’s claims in a separate paper.

IV.

A.

Biogen Motion 1 (Biogen Mot. 1) asserts that all of FP’s current claims lack
written descriptive and enabling support as required by 35 U.S.C. § 112, ¶ 1.
Biogen Mot. 1, Paper 171. FP opposed (FP Opp. 1, Paper 739) and Biogen replied
(Biogen Rep. 1, Paper 778).

FP’s ’871 application includes claims 55 - 70. FP Clean copy of claims,
Paper 7. All of FP’s claims require treatment of a patient in need of treatment for
MS with a therapeutically effective amount of 480 mg/day of DMF and/or MMF.
Id. Claims 55, 65 and 69 are independent. Id. In claims 60, 63, 64, and 66-70, the
pharmaceutical composition used for treatment “consists essentially of” DMF. Id.
Claim 61 specifies treating with a pharmaceutical composition “consisting
essentially of” MMF. Id.

We reproduce, as illustrative, FP’s claim 69:

69. A method of treating a subject in need of treatment for
multiple sclerosis comprising
orally administering to the subject a pharmaceutical
composition consisting essentially of
(a) a therapeutically effective amount of
dimethylfumarate and
(b) one or more pharmaceutically acceptable
excipients,
wherein the therapeutically effective amount of
dimethylfumarate is 480 mg per day.

FP Clean copy of claims, Paper 7, 3:20 – 4:2 (paragraphing added).
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B. Because FP substantially copied the claims of Biogen’s patent, to the extent necessary, we construe FP’s claims in light of Biogen’s disclosure. *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1375 (Fed. Cir. 2009).

C. 1. We have reviewed FP’s as-filed specification (Ex. 1001). Our review indicates that a principal focus of FP’s disclosure is the minimization of gastrointestinal side-effects through use of controlled release of fumarates. The title of FP’s as-filed application\(^1\) is “Controlled Release Pharmaceutical Composition Comprising a Fumaric Acid Ester.” Ex. 1001, p. 1. The specification notes that administering fumarates causes certain undesired side-effects:

\[\text{[T]herapy with fumarates . . . frequently gives rise to gastrointestinal side effects such as e.g. fullness, diarrhea, upper abdominal cramps, flatulence and nausea.}\]

Ex. 1001, 2:34-36. The specification identifies these side effects as the problem addressed by the invention:

\[\text{The problem the invention solves is related to the appearance of gastrointestinal side-effects upon oral administration of fumaric acid esters.}\]

Ex. 1001, 9:8-9. The specification describes certain prior art commercial preparations containing fumarates. Ex. 1001, 1:12 – 2:33. The products discussed include

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\(^1\) The title was changed to “Controlled Release Pharmaceutical Composition Comprising a Fumaric Acid Ester (‘480 mg per day dosing’)” by an amendment filed January 21, 2014. Application 11/576,871, “Specification” filed January 21, 2014 (italics shows subject matter added by amendment to the title).
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The specification characterizes the invention as relating to pharmaceutical compositions that include as an active ingredient “one or more fumaric acid esters” which - upon oral administration and in comparison to that obtained after oral administration of Fumaderm® tablets in an equivalent dosage - gives a reduction in GI (gastro-intestinal) related side-effects.

Ex. 1001, 3:25-30 (emphasis added). The section of the specification titled “Field of the invention” describes the invention as follows:

The present invention relates to controlled release pharmaceutical compositions comprising a fumaric acid ester as an active substance. The compositions are suitable for use in the treatment of e.g. psoriasis or other hyperproliferative, inflammatory or autoimmune disorders and are designed to release the fumaric acid ester in a controlled manner so that local high concentrations of the active substance within the gastrointestinal tract upon oral administration can be avoided and, thereby, enabling a reduction in gastro-intestinal related side-effects.

Ex. 1001, 1:4-10. (emphasis added). The written description also notes the benefits of controlled release formulations:

By prolonging and/or delaying the release of the active substance from the composition it is envisaged that the local concentration of the active substance at specific sites of the gastro-intestinal tract is reduced (compared with that of Fumaderm®) which in turn leads to a reduction in gastro-intestinal side-effects. Accordingly, compositions that enable a prolonged and/or a slow release of a fumaric acid ester as defined above are within the scope of the present invention.

Ex. 1001, 9:9-14.
The specification then goes on to express the goals of the invention with respect to administering fumarate preparations: (1) improved efficacy with reduced gastro-intestinal side-effects and (2) a product with fewer fumarates that still has adequate efficacy:

Accordingly, there is a need to develop compositions comprising one or more therapeutically or prophylactically active fumaric acid esters that provide an improved treatment with a reduction in gastro-intestinal related side effects upon oral administration.

Furthermore, the present commercially available products contain a combination of two different esters of which one of the esters (namely the ethylhydrogenfumarate which is the monoethylester of fumaric acid) is present in three different salt forms (i.e. the calcium, magnesium and zinc salt). Although each individual form may have its own therapeutic profile, it would be advantageous to have a much simpler product, if possible, in order to obtain a suitable therapeutic effect.

Ex. 1001, 3: 1-9. The inventors then explain that their response to the perceived need is a treatment regimen using a controlled release preparation that delivers the active substance in a controlled manner that is prolonged or delayed compared to the commercial fumarate products:

The present inventors contemplate that an improved treatment regimen may be obtained [through] administration of a pharmaceutical composition that is designed to deliver the active substance in a controlled manner, i.e. in a manner that is prolonged, slow and/or delayed compared with the commercially available product. Furthermore, it is contemplated that instead of using a combination of different fumaric acid esters, a suitable therapeutic response may be achieved by use of a single fumaric acid ester alone such as dimethylfumaric acid.

Ex. 1001, 3:10-16 (emphasis added). The desired reduction in GI side-effects is compared to those observed with Fumaderm®:
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[A] reduction of GI related side effects is intended to denote a decrease in severity and/or incidence among a given treated patient population, compared to the GI side effects observed after administration of the composition according to the invention compared with that of Fumaderm®.

Ex. 1001, 6:25-28. More specifically, the controlled release compositions provide “fumaric acid ester in a prolonged, slow and/or delayed manner compared to the release of the commercially available product Fumaderm® when tested under comparable conditions . . . .” Ex. 1001, 4:25-28. FP specification says “prolonged” means that the active substance is released during a longer time period than Fumaderm® such as at least during a time period that is at least 1.2 times, such as, e.g., at least 1.5 times, at least 2 times, at least 3 times, at least 4 times or at least 5 times greater than that of Fumaderm®.

Ex. 1001, 6: 7-11. “Delayed,” means release of the chosen fumarate starts later in time than would occur with Fumaderm®:

“[D]elayed” is intended to indicate that the release of the active substance starts at a later point in time compared with that of Fumaderm® (such as at 30 min or more later such as, e.g., 45 min or more later, 1 hour or more later or 1.5 hours or more later, alternatively, that the initial release during the first 2 hours is much less compared with that of Fumaderm® (i.e. less than 80% w/w such as, e.g., less than 70% w/w, less than 60%w/w or less than 50% of that of Fumaderm®).

Ex. 1001, 6:15-20.

The specification describes, in significant detail, different types of controlled release compositions for different types of dose administration. Ex. 1001, 14:17 – 35:19. The specification notes that those compositions are designed to provide suitable controlled release of the active ingredients:

In the following is given a description of various compositions according to the invention that are designed to obtain a suitable
release of the fumeric acid ester. Based on the description above and handbooks within the field of controlled release of pharmaceutics, a person skilled in the art will know how to choose different formulation principles in order to achieve the required release profile.

Ex. 1001, 14:17-21.

The specification details various controlled release compositions designed for both single and multiple daily administration. The specification refers to “pH controlled release,” “pH independent release,” “release over gradually shifting pH,” and “slow release.” Ex. 100, 14:22 - 35:19. For each category the specification provides exemplary fumarate controlled release profiles. For example, with respect to composition designed for pH controlled release, the specification teaches the following:

In a further aspect of the invention a controlled release pharmaceutical composition for oral use . . . characterized in that it consists of a controlled release dosage form adapted to release . . . over a predetermined time period, according to a[n ] in vitro profile of dissolution when measured according to USP in hydrochloric acid during the first 2 hours and then 0.05 M phosphate buffer at a pH 6.5-6.8, wherein at the most 5 % w/w of the total amount of the fumeric acid ester contained the composition is released within the first 2 hours after start of the test,

wherein from 20% to about 75% w/w of the total amount of the fumeric acid ester contained in the composition is released within the first 3 hours . . .,

wherein from about 50% to about 90% w/w of the total amount of the fumeric acid ester contained in the composition is released within the first 4 hours . . .,

wherein from about 60% to about 90% w/w of the total amount of the fumeric acid ester contained in the composition is released within the first 5 hours . . .,

wherein from about 70% to about 95% w/w of the total amount of the fumeric acid ester contained in the composition is released within the first 6 hours . . .,
wherein from about 75% to about 97% w/w of the total amount of the fumaric acid ester contained in the composition is released within the first 7 hours . . . , and wherein at least 85% w/w of the total amount of the fumaric acid ester contained in the composition is released within the first 8 hours . . . .


The typical composition according to the invention is said to be designed to deliver the active substance “in a prolonged manner.” Ex. 1001, 31:19-22. The written description notes, that while the maximum serum concentration for the active ingredient resulting from the administration of the controlled release composition should be similar to the known values for the previously marketed versions reported in the literature, it is an aim of the invention to prolong the time that the concentration is within the therapeutic window. Ex. 1001, 31:19 – 32:2.

As a result, “the controlled release composition according to the invention may lead to a reduced frequency of dosing and/or a reduced average total daily dose, and/or an increased efficacy at the same total daily dose of the active substance compared to Fumaderm®.” Ex. 1001, 32:8-11.

The specification includes a number of examples describing the preparation of controlled release tablets, granules and microcrystals. Ex. 1001, Examples 1-29, 44:19 – 52:29. While all the examples do not expressly state that the preparations are controlled release, each is described as being enteric coated or includes a component such as ethylcellulose (e.g. Ethocel® NF premium). Id. Enteric coatings and ethylcellulose are conventionally used to impart controlled release properties to pharmaceutical compositions. Examples 30 and 31 describe the tests for determining the controlled release dissolution profiles for capsules and tablets.
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respectively. Ex. 1001, 53:1-32. Examples 32-34 are directed to the controlled
release profiles for the tablets of Example 5 and the capsules of Examples 16 and
17, respectively. The controlled release profiles are graphically shown in
Figures 1-3. The profiles shown in Figure 1 were determined as described in
Example 30. The profiles for Figures 2 and 3 were determined as described in

FP’s original claims are directed to pharmaceutical compositions that give “a
reduction in [gastro-intestinal] side effects” (claim 1), “controlled release
pharmaceutical compositions” (claims 2-43), and the method and use of the
compositions of claims 1-43 composition to treat a listing of diseases (claims 44

2.

With respect to the treatment of specific diseases and conditions, FP’s
specification lists uses of the described fumarate formulations as well as possible
doses. For possible conditions and diseases FP’s written description lists the
following:

The compositions and kits according to the invention are
contemplated to be suitable to use in the treatment of one or
more of the following conditions:

a. Psoriasis
b. Psoriatic arthritis
c. Neurodermatitis
d. Inflammatory bowel disease, such as
   i. Crohn's disease
   ii. Ulcerative colitis
e. autoimmune diseases:
   i. Polyarthritis
   ii. Multiple sclerosis (MS)
   iii. Juvenile-onset diabetes mellitus
   iv. Hashimoto's thyroiditis
   v. Grave's disease
   vi. SLE (systemic lupus erythematosus)
vii. Sjogren's syndrome
viii. Pernicious anemia
ix. Chronic active (lupoid) hepatitis
x. Rheumatoid arthritis (RA)
xi. Optic neuritis

Moreover, the novel composition or kit according to the invention may be used in the treatment of
1. Pain such as radicular pain, pain associated with radiculopathy, neuropathic pain or sciatica/sciatic pain
2. Organ transplantation (prevention of rejection)
3. Sarcoidosis
4. Necrobiosis lipoidica
5. Granuloma annulare

Ex. 1001 37:17 – 38:17 (emphasis added). The same listing of conditions and disease appears in FP’s original claims 44 and 45, referenced above. Treatment of psoriasis and conditions associated with psoriasis are the subject of additional discussion. E.g., Ex. 1001, 1:12-15, 2:23-34, 7:9-17, 38:18-27, 39:21 – 40:7. MS is not identified as of any particular interest compared to the other diseases and conditions listed.

With respect to the fumarate content of the formulations, the specification teaches that the active ingredient can be any fumarate:

The active substance in a composition of the invention is any fumaric acid ester. In one embodiment of the invention the fumaric acid ester is preferably selected from the group consisting of dimethylfumarate, diethylfumarate, dipropylfumarate, dibutylfumarate, dipentylfumarate, methyl-ethylfumarate, methyl-propylfumarate, methyl-butylfumarate, methyl-pentylfumarate, monomethylfumarate, monoethylfumarate, monopropylfumarate, monobutylfumarate and monopentylfumarate, including pharmaceutically acceptable salts thereof.

Ex. 1001, 7:31-37 (emphasis added). The specification, however, does separately identify DMF, MMF and their combination for use in treatment formulations.
Ex. 1001, 8:10 – 9:6. Additionally, preparations containing DMF are discussed in many of the examples. E.g., Ex. 1001, Example 17, 49:10-24.

FP’s written description teaches that the daily dosage of fumarate may be in the range of 240 to 1080 mg/day and that the dosage will depend on a number of factors including the specific condition or disease to be treated:

The daily dosage of the controlled release pharmaceutical composition according to the invention that is administered to treat a patient depends on a number of factors among which are included, without limitation, weight and age and the underlying causes of the condition or disease to be treated, and is within the skill of a physician to determine. In one aspect of the invention the daily dosage can be e.g. from 240 to 360 mg active substance given in one to three doses, in another aspect from 360 to 480 mg active substance given in one to three doses, in another aspect 480 to 600 mg active substance given in one to three doses. In another aspect 600 to 720 mg active substance given in one to three doses. In another aspect 720 to 840 mg active substance given in one to three doses, in another aspect 840 to 960 mg active substance given in one to three doses and in yet another aspect 960 to 1080 mg active substance given in one to three doses.

Ex. 1001, 36:13-23 (emphasis added). None of the stated dosages are specifically associated with any particular fumarate (e.g., DMF or MMF). While recognizing that daily dosage will depend on the specific condition or disease to be treated, none of the dosages cited are identified as related to any particular disease or condition. None of the dosages are identified as therapeutically effective.

FP’s written description also discusses dosages that may be provided in the form of a kit for use when the dosage must be increased over time. Ex. 1001, 35:21-24. A table shows a “normal up-scale” schedule for increasing the dosage of DMF for each week over a nine-week period. An “up-scale” dosing is used to limit the side effects that often occur during treatment with fumarates. Ex. 1099A, ¶ 118. The dosage is increased in weekly increments from the initial dose of
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30 mg/day to 720 mg/day in week 9. Ex. 1001, bridging pp. 35 and 36. The table shows using two formulations of DMF containing 30 mg (“Strength A”) and 120 mg (“Strength B), respectively. Ex. 1001, 35:24 – 36:5. The table shows administering an initial dose of Strength A once a day (30 mg/day) for the first week, increasing to 2 doses per day of Strength A (60 mg/day) in the second week, increasing to 2 doses per day of Strength B (240 mg/day) in week 3, progressing to 3 doses of Strength B (360 mg/day) in week 6, 4 doses (480 mg/day) in week 7 and 5 and 6 doses (600 and 720 mg/day) in weeks 8 and 9, respectively. Ex. 1001, 35:24 – 36:5.

The dosage of 480 mg/day, while specified as an intermediate up-scale dose, is not identified as a therapeutically effective dose or of any particular significance within the broad range of possible treatment doses.

V.

A.

Biogen argues that FP’s written description fails to provide written support required by 35 U.S.C. § 112, ¶ 1, for the subject matter of FP’s claims. Biogen presents two main points on this issue: (1) that FP’s written description does not describe the claimed subject matter as an integrated whole and (2) that FP’s written description provides support only for “controlled release compositions.” Biogen Mot. 1, Paper 171, 9:15 - 22:6

Biogen recognizes that each of the three elements required by FP’s claims, i.e., the treatment of MS patients, the administration of the specified fumarates and the use of a dosage of 480 mg/day are individually taught in the specification. However, relying on Novozymes A/S v. DuPont Nutrition Biosciences APS, 723 F.3d 1336 (Fed. Cir. 2013), Biogen argues that the written description does not show possession of the claimed subject matter as an integrated whole and does not provide “blaze marks to guide a reader through the forest of disclosed possibilities.
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toward the claimed [method of treating MS].” Biogen Motion 1, Paper 171, 11:16-23 (bracketed material original). Thus, Biogen argues because certain individual words of the copied claims are mentioned in disparate sections of the ’871 application, Forward Pharma attempts to piece together—through hindsight picking and choosing without any instruction or guidance—Biogen’s claimed method of treating MS.

Biogen Mot. 1, Paper 171, 10:22 – 11:1. In Biogen’s view, FP’s original written description “never integrates these elements to describe such an invention. Nor does it offer any ‘blaze marks to guide a reader through the forest of disclosed possibilities toward the claimed [method of treating MS].’” Biogen Mot. 1, Paper 171, 11:20-22 quoting Novozymes, 723 F.3d at 1346.

Biogen relies on Dr. Buckle’s testimony. Biogen Mot. 1, Paper 171, 13:20-22. Dr. Buckle testifies that he has reviewed FP’s involved application and pending claims. Buckle Test., Ex. 2044A, ¶ 9. Dr. Buckle further testifies that MS is mentioned only in the context of a list of more than twenty diseases and conditions. Buckle Test., Ex. 2044A, ¶ 26. He notes that none of the diseases or conditions on the list, including MS, are associated with any particular dose or any particular active agent. Buckle Test., Ex. 2044A, ¶ 26. He specifically notes the language in the written description that the formulations disclosed therein “are contemplated to be suitable to use in the treatment of one or more” of the conditions listed. Buckle Test., Ex. 2044A, ¶ 26. He then opines that “at best, this language signifies a mere speculation that the disclosed compositions might be suitable to treat ‘one or more,’ i.e., perhaps just one, condition out of the list, highlighting none in particular. Buckle Test., Ex. 2044A, ¶ 26. He goes on to state that in his opinion
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There is no teaching in the ’871 application relating to MS outside the context of the list. The ’871 application does not direct a person of ordinary skill in the art toward a treatment for MS.

Buckle Test., Ex. 2044A, ¶ 27. He further opines that the ’871 application does not reasonably convey to a person of ordinary skill in the art at the time the application was filed that Forward Pharma had possession of a method of treating a subject in need of treatment for MS by orally administering 480 mg per day of DMF, MMF or a combination thereof.

Ex. 2044A, ¶ 29. Dr. Buckle testifies that in order to arrive at FP’s claimed subject matter a person of ordinary skill in the art, without being provided any guidance, would need to (1) select MS from a list of more than twenty diseases and conditions, which would require (a) selecting autoimmune diseases out of the several listed disease classes and (b) selecting MS out of the sub-list of 11 autoimmune diseases; (2) select DMF, MMF or a combination thereof from the disclosed fumarate esters; and (3) select 480 mg per day from the ladder of indiscriminate possible doses, despite the application’s direction to up-titrate to a 720 mg per day dose for, at best, treating psoriasis, and then conclude that the selected agent in the selected amount would be therapeutically effective for treating the selected condition (i.e., MS). All the while, one would need to ignore, without any reason to do so, the application’s explicit focus on providing controlled release compositions for allegedly reducing the side effects associated with a known psoriasis treatment.

Buckle Test., Ex. 2044A, ¶ 37.

FP responds that its written description describes and shows possession of its claimed subject matter. FP Opp. 1, Paper 739, 8:6 – 24:14. FP refers to its involved application as “FP7.” FP argues: “FP7 describes the use of oral pharmaceutical compositions of fumaric acid esters, and in particular, DMF and/or
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MMF, for treating psoriasis or other hyperproliferative, inflammatory or autoimmune disorders, including MS.” FP Opp. 1, 8:16-18. FP notes that its written description “highlights the use of DMF and/or MMF as the preferred fumaric acid esters of the pharmaceutical compositions for use in the claimed methods of treatment . . .” FP Opp. 1, Paper 739, 9:14-16.

For support of treating patients in need of treatment for MS, FP directs us to its listing of diseases and conditions that includes MS. FP Opp. 1, Paper 739, 8:16-18. FP further argues that one skilled in the art would have recognized that the up-scale table applies to MS because it was well known that fumarates, including DMF, were useful for treating MS. FP Opp., Paper 739, 11:13-14.

FP also relies on *Falkner v. Inglis*, 448 F.3d 1357, 1366-68 (Fed. Cir. 2006); *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285-87 (Fed. Cir. 2012) as permitting an applicant to rely on what was well known in the art to satisfy the written description requirement. FP Opp. 1, Paper 739, 4:16-21. FP directs us to the testimony of Dr. Jeffrey V. Ravetch (Ex. 1099A). *Id.* at 4:22 – 5:11. His testimony summarizes the substance of the reports and patents that are said to show that the administration of Fumaderm® and DMF was known to have had positive results on MS patients. Ex. 1099A, ¶¶ 40-90.

With respect to the treatment dose of 480 mg/day, FP directs us to the portion of its disclosure describing the up-scale table. FP Opp. 1, Paper 739, 9:22 – 11:18. FP notes that the specified dosage for week 7 is 480 mg/day. FP Opp. 1, Paper 739, 10:14-17. Relying on Dr Ravetch’s testimony, FP argues that one skilled in the art would recognize that the up-scale table is suitable for treating all of the twenty-four conditions listed in the specification and would apply to the treatment of MS. FP Opp. 1, Paper 739, 11:3-10. On this point FP relies on *Snitzer v. Etzel*, 465 F.2d 899, 902-903 (C.C.P.A. 1972) for the proposition that a listing in the written description provides literal written descriptive support for a
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1 claim limited to any of the listed members. FP Opp. 1, Paper 739, 11:10-12.
2 FP also directs us to its originally filed claims as supporting its currently
4 identifies the subject matter of claim 44, combined with the subject matter of
5 claims 27, 28, 33, 32 and 37. FP Opp. 1, Paper 739, 11:24 – 12:23. Claim 44 is
6 directed to a method of treating any of the twenty-four conditions and diseases
7 identified for treatment in the specification with a pharmaceutically effective
8 dosage of a composition set forth in any of the forty-three preceding claims.
9 Ex. 1001, 60:5-14. Claim 33 is directed to a controlled release pharmaceutical
10 composition containing an “amount of one or more fumaric acid esters selected
11 from di-(C1-C5)alkylesters of fumaric acid and mono-(C1-C5)alkylesters of
12 fumaric acid or a pharmaceutically acceptable salt thereof, in a dosage form having
13 90 mg to 360 mg of active substance.” Ex. 1001, 59:5-9. Claim 37 is relied on for
14 the recitation of a dosage form having 240 mg of active substance. Claims 27 and
15 28 specify a controlled release pharmaceuticals composition comprising DMF and
16 MMF, respectively. Claims 31 and 32 require the use of once or twice daily
17 administration of a controlled release composition, respectively. Ex. 1001, 59:3-4.
18 Claims 35-38 are directed to a controlled release pharmaceutical composition
19 where the amount of active ingredient present in the composition, i.e., the tablet or
20 capsule, is 120, 180, 240 or 360 mg, respectively. Ex. 1001, 59:12-19. According
21 to FP, the combined disclosures of the identified claims “[t]aken together and
22 eliminating redundancies, a POSA would have been guided towards only six
23 preferred daily dose amounts for the treatment of MS: 120 mg/day, 180 mg/day,
24 240 mg/day, 360 mg/day, 480 mg/day and 720 mg/day.” FP Opp., Paper 739,
Biogen replies that, FP’s explanations attempt to piece together the three specific elements through hindsight picking and choosing without providing “blaze marks to guide a reader through the forest of disclosed possibilities toward the claimed [method of treating MS]” Biogen Motion 1, Paper 171, 11:16-23 (bracketed material original) (citation omitted). In Biogen’s view, FP’s original written description “never integrates these elements to describe such an invention.” Biogen Motion 1, Paper 171, 11:19-21.

All of FP’s claims require the following elements: (1) a method of treating a patient in need of treatment for MS, (2) by orally administering a therapeutically effective amount of specified fumarates and (3) that the therapeutically effective amount is 480 mg/day. We understand Biogen’s argument to be that while each of these elements may be separately taught as possibilities, FP’s written description requires picking and choosing from separate parts of the written description and does not describe these elements as an integrated or unified invention or provide adequate blaze marks that would act to guide one skilled in the art to the currently claimed invention. Biogen, Mot. 1, Paper 171, 11:16-23.

Our review of FP’s written description does not reveal an express description of a method that includes the specific elements now claimed connected as required by the claims, i.e., (1) treating a patient in need of treatment for MS (2) by orally administering a therapeutically effective amount of DMF and/or MMF and (3) where the therapeutically effective amount is 480 mg/day. In response to Biogen’s motion, FP has not directed us to such an express disclosure. However, the exact language need not be used “in haec verba.” Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010); In re Hayes
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Microcomputer Prods., Inc., 982 F.2d 1527, 1533 (Fed. Cir. 1992) ("[the applicant] does not have to describe exactly the subject matter claimed").

B.

The issue before us is, notwithstanding the absence of an express description of the specific treatment method claimed, whether FP’s specification provides sufficient blaze marks that would lead one of ordinary skill to the specific subject matter FP now claims. Stated in terms of “possession,” the issue is whether FP’s written description conveys to the person skilled in the art that the inventors had possession of FP’s specifically claimed treatment method.

C.

The first paragraph of 35 U.S.C. § 112 (1975), requires that an applicant’s “specification shall contain a written description of the invention . . . .” “The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1564 (Fed. Cir. 1991). “[T]he hallmark of written description is disclosure.” Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (in banc). The standard for satisfying the written description requirement is whether the disclosure “allow[s] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.” Enzo Biochem, Inc. v. Gen–Probe Inc., 323 F.3d 956, 968 (Fed.Cir.2002). There is no requirement that the disclosure contain “either examples or an actual reduction to practice;” rather, the critical inquiry is whether the specification has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing. Ariad, 598 F.3d at 1350, 1352; Koito Mfg. Co. v. Turn–Key–Tech, LLC, 381 F.3d 1142, 1154 (Fed.Cir.2004). That assessment “requires an objective inquiry into the four corners of the specification.” Ariad, 598 F.3d at 1351. In considering sufficient
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written description each claim must be considered "as an integrated whole rather than as a collection of independent limitations." *Novozymes*, 723 F.3d at 1349. However, the exact terms need not be used "*in haec verba.*" *Ariad*, 598 F.3d at 1352; *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533 (Fed. Cir. 1992) ("[the applicant] does not have to describe exactly the subject matter claimed"). The evaluation of written description is forward-looking, i.e., the evaluation is made from the perspective of a person skilled in the art with no foreknowledge of the later-claimed invention. *See Novozymes*, 723 F.3d at 1349 ("viewing the matter from the proper vantage point 'of one with no foreknowledge of the specific compound . . . '"). Where a generic invention is disclosed the written description must "provide sufficient 'blaze marks' to guide a reader through the forest of disclosed possibilities toward the claimed [method], which resided among the myriad others that also could have been made." *Novozymes*, 723 F.3d at 1349 (citation omitted). The written description requirement is met by describing the invention, with all its claimed limitations, not that which makes it obvious. *Regents of Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997).

D.

The clear focus and fundamental concern of the inventors as expressed in their written description is ameliorating the gastro-intestinal side effects due to the administration of fumarates by using controlled release preparations. As FP's written description states:

The present invention relates to *controlled release pharmaceutical compositions* comprising a fumaric acid ester as an active substance. The compositions are suitable for use in the treatment of e.g. psoriasis or other hyperproliferative, inflammatory or autoimmune disorders and *are designed to*
release the fumaric acid ester in a controlled manner so that
local high concentrations of the active substance within the
gastrointestinal tract upon oral administration can be avoided
and, thereby, enabling a reduction in gastro-intestinal related
side-effects.

Ex. 1001, 1:4-10 (emphasis added).

Looking at the entirety of FP’s disclosure, we note that DMF, MMF and
their mixtures are discussed in significant detail. Thus, the specification
demonstrates that one skilled in the art would have recognized that the inventor’s
had considered those fumarates to be significant in treatment of the listed
conditions and diseases.

With respect to the treatment of MS with a dose of 480 mg/day, the written
description does not indicate 480 mg/day is a therapeutically effective dose with
respect to any condition or disease or is otherwise of any particular significance
with respect to treatment of MS or any other disease or condition. We recognize
that 480 mg/day is expressly mentioned three times in the disclosure, i.e. as both
the low and high end of ranges within the broader range of 240 to 1080 mg/day
(Ex. 1001, 36:13-23) and as an interim dose in the up-scale table (id. 35:21 – 36:5).
However, as noted elsewhere in the written description:

The daily dosage of the controlled release pharmaceutical
composition according to the invention that is administered to
treat a patient depends on a number of factors among which are
included, without limitation, weight and age and the underlying
causes of the condition or disease to be treated and is within
the skill of a physician to determine. . . .

Ex. 1001, 36:13-23 (emphasis added). There is no discussion that would guide one
skilled in the art to treat MS with a therapeutically effective dose of 480 mg/day, or
any other therapeutically effective doses within the ranges disclosed. None of the
disclosed doses are identified as of any greater or lesser significance compared to
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any other treatment dose. The section of the specification relating to doses does not associate any dose with any particular fumarate, disease or condition. Even if it is assumed that the doses would be associated with the administration of DMF and/or MMF, there is no description that would guide one skilled in the art to choose treatment of MS from the listing of conditions and diseases and to choose 480 mg/day as a therapeutically effective dosage from the dosing range of 240 to 1080 mg/day.

The up-scale table, while reasonably read as directed to DMF, does not associate the protocol with MS or any other specific condition or disease. None of the identified doses are identified as a therapeutically effective dose. In light of the strong emphasis in the specification on using controlled release formulations to limit gastro-intestinal side effects, the dosages in the up-scale table simply provide guidance on dosing to allow the patient to acclimate or adapt to the fumarate to limit side effects. An "up-scale" dosing is used to limit the side effects that often occur during treatment with fumarates. Ex. 1099A, ¶ 118.

Certainly, beginning with FP’s claimed subject matter, one can pick out support for each of the individual required elements. One skilled in the art could likely choose each of the claimed elements from the disclosed listings of conditions, diseases, fumarates and the dosages. However, we must look for support for the claimed subject matter without foreknowledge of the invention. Novozymes, 723 F.3d at 1349. The picking and choosing from FP’s specification required to arrive at the claimed subject matter are indicative of obviousness, rather than description. As noted in In re Arkley, 455 F.2d 586 (C.C.P.A. 1972), with respect to description in the context of anticipation of a compound:

"[T]he reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other
by the teachings of the cited reference. Such picking and
choosing may be entirely proper in the making of a 103
obviousness rejection . . . .

Arkley, 455 F.2d at 587. Like description under 35 U.S.C. § 102, the written
description requirement is met by describing the invention, with all its claimed
limitations, not by merely describing that which would make the invention
obvious. Regents of Univ. of Calif. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir.
The picking and choosing necessary for one skilled in the art from FP’s generically
described subject matter to arrive at the invention would, at best, render the
claimed subject matter obvious. It does not show possession of the specific
treatment claimed.

E.

FP argues that the subject matter of its original claim 44, combined with the
subject matter of original claims 27, 28, 33, 32 and 37 “[t]aken together and
eliminating redundancies, a POSA would have been guided towards only six
preferred daily dose amounts for the treatment of MS . . . .” FP Opp. 1, Paper 739,

In order to arrive at the specifically claimed subject matter, a person skilled
in the art would need to pick and choose from the certain of FP’s claims without
guidance from the written description. Combining the subject matter of selected
claims to arrive at the invention is, in our view, indicative of obviousness, and does
not provide a basis for a written description of the claimed subject matter.

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2 To anticipate, a reference must describe each claimed element arranged as in the
2001).
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FP argues that *Snitzer v. Etzel*, 465 F.2d at 902-903 controls the outcome here. FP characterizes *Snitzer* as holding that

- claims to a particular, clear glass laser using a specific laseractive ytterbium ion were adequately described in an application that (i) disclosed numerous different glass and glass-type lasers, and (ii) named the specific ytterbium ion among a group of fourteen individually enumerated ions that were described as useful separately or in various combinations.


We think FP overstates *Snitzer*’s holding. *Snitzer* was an appeal from a decision of the former Board of Patent Interferences holding that Snitzer had no right to make the counts of the interference. The subject matter involved was directed to a glass laser activated with trivalent ytterbium ions. *Snitzer*, 465 F.2d at 900. Snitzer had copied the claims from Etzel’s patent. *Snitzer*, 465 F.2d 900.

Snitzer’s specification is said to have disclosed specific details of a glass laser activated with neodymium ions. *Snitzer*, 465 F.2d at 901. That specification was also said to list fourteen materials, including trivalent ytterbium, as active laser ingredients. *Snitzer*, 465 F.2d at 901. Some of the materials on the list had not been shown to operate successfully in a laser. *Snitzer*, 465 F.2d at 902. The Board found that the use of materials other than neodymium was merely speculation and held it insufficient to support the copied claims that were limited to the use of trivalent ytterbium ions. *Snitzer*, 465 F.2d at 902. The Court described the Board’s conclusion:

In view of the complexity and unpredictability of the involved art, the fact that some of the ions disclosed by Snitzer have not been made to operate successfully, and the fact that trivalent ytterbium is mentioned but not stressed in the Snitzer specification, the board apparently concluded that one of ordinary skill in the art would not be led to select trivalent ytterbium and appellant may therefore not claim it.
Snitzer, 465 F.2d at 902. The Court reversed because “the use of trivalent ytterbium is clearly described in [Snitzer’s] specification.” Snitzer, 465 F.2d at 902. The Court noted that
to approach this case realistically, the specification must be viewed as emphasizing the fourteen named ions. It may be that were boundless speculation evident, a different result would be reached. We find no such situation here, and under these circumstances, we see no reason to hold that which is plainly described not to be described.

Snitzer, 465 F.2d at 903.

We think FP’s specification presents a different description situation than that present in Snitzer. Snitzer’s specification apparently emphasized a single listing of fourteen ions, including ytterbium, for use in lasers. Notwithstanding that it may have been speculative whether all fourteen would be operative, the Court found the list expressly described each of the fourteen. In other words the reasonably short list conveyed possession of the use of each of the described ions, including ytterbium, as part of Snitzer’s invention. We think the principal involved in Snitzer is analogous to that involved in anticipation by a “small genus.” A small genus may describe, and thus anticipate, each of its members. “[W]hen the class of compounds that falls within the genus is so limited that a person of ordinary skill in the art can ‘at once envisage each member of this limited class,’ … a reference describing the genus anticipates every species within the genus.” In re Gleave, 560 F.3d 1331, 1337-38 (Fed. Cir. 2009) (citation omitted); see also Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1377 (Fed. Cir. 2005). FP’s specification, on the other hand, requires selection from more than a single limited list. In order to arrive at the subject matter it now claims, MS must be selected from the listing of 24 diseases. Ex. 1001, 37:17 – 38:17. Then the appropriate therapeutically effective dose must be determined and selected from the range of
240 mg/day to 1080 mg/day identified in the specification. Ex. 1001, 36:13-23. In our view, such necessary picking and choosing to arrive at the claimed invention may indicate obviousness of the now claimed subject matter but does not indicate it was described.

FP relies on *Falkner v. Inglis*, 448 F.3d 1357, 1366-68 (Fed. Cir. 2006), and *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285-87 (Fed. Cir. 2012), for the proposition that it is permissible to rely on well-known prior art to satisfy the written description requirement. FP Opp. 1, Paper 739, 4:15 – 6:1. FP argues that by October 7, 2005, it was well known that positive results in Phase 2 MS trials had had been reported for Fumaderm®. FP points to certain published abstracts, patents and publications to establish that treatment of MS with fumarates was well known. FP Opp. 1, Paper 739, 4:22 – 5:7. In particular, FP relies on the prior art to support the argument “that a person of ordinary skill would recognize the up-scale table ties the dose (about 480 mg/day), active ingredient (DMF), and condition (MS) together as an integrated whole.” FP Opp. 1, Paper 739, 11:3-18.

We think FP’s use of the prior art teachings is different in kind than the use in *Falkner* and *Streck*. In both cases, the prior art was used to support the recitation of generically claimed subject matter. The Falkner invention related to a vaccine that included a mutated poxvirus having a deactivated “essential gene.” The essential gene was necessary to the production of infectious poxvirus. The alleged undescribed claim element was the DNA sequenced of the essential genes of poxvirus that were to be deactivated. The court held that the specification made general reference to the poxvirus, the record established that the sequences of the essential genes were well known in the art, and one skilled in the art would have been readily able to choose an essential gene. *Falkner*, 448 F.3d at 1366. In *Streck* the invention related to hematology controls used to standardize hematology analyzers. *Streck*, 665 F.3d at 1274. The claims required a “stabilized reticulocyte
component.” *Id.* at 1275. It was argued that the specification described only analog reticulocytes and did not describe naturally occurring or true reticulocytes that were also encompassed by “stabilized reticulocyte component” language in the claim. *Streck*, 665 F.3d at 1275. The court held that the specification expressly described the use of “true mammalian reticulocytes” and also identified several species of true reticulocytes. *Id* at 1286-87. Additionally, the court noted that use of true reticulocytes in standalone standards was well known in the art. *Id.* at 1287.

In both cases the issue was whether the written description supported the scope of the claimed subject matter. The well-known prior art established that those working in the art were aware of examples within the generic claim element, *i.e.*, species of the “essential genes” and species of naturally occurring “stabilized reticulocytes.” Here, FP is attempting to use the prior art, not to show that a generic claim element is well known by those working in the field, but to provide the blaze marks necessary to guide one skilled in the art from a generic disclosure of twenty-four diseases and a broad range of possible, but undetermined, therapeutic doses, to a single specific treatment—treatment of MS with a therapeutically effect dose of 480 mg/day of the specific fumarates. It is the content of FP’s written description which must include the blaze marks that guide one skilled in the art to the specific treatment method, not the prior art. The specification itself must show possession. *Ariad*, 598 F.3d at 1352. Possession is shown by disclosure, *i.e.* by what the written description tells one skilled in the art, not by what might have been obvious. Using the prior art in the way urged by FP may show that the claimed subject matter, when considered with the prior art, might have been obvious to one skilled in the art, but in our view, it fails to show that one skilled in the art would have thought that FP’s inventors had possessed and described the specific treatment method they now claim.
CONCLUSION

In light of the emphasis in FP’s written description on controlled release compositions, as well as the picking and choosing from the listing of possible diseases and conditions and the determination of the appropriate therapeutically treatment dosage necessary to arrive at the claimed invention, we are persuaded that FP’s written description would not have conveyed to a person skilled in the art that Biogen’s inventors were in possession of the specific treatment now claimed. We find that FP’s written description does not provide sufficient blaze marks to guide one skilled in the art to the subject matter of its claims 55-70. The subject matter of FP’s claims 55-70 is not described by its written description as require by 35 U.S.C. § 112, ¶ 1. We therefore grant Biogen’s Motion 1.
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