United States District Court,
E.D. Virginia.

Alexandria Divisio,
Alexandria Division.
SYNTHON IP, INC,
Plaintiff.
v.
PFIZER INC,
Defendant.

Oct. 10, 2006.

Background: Pharmaceutical manufacturer brought action alleging that process used by competitor to make hypertension drug infringed upon its patents. Following preliminary claim construction determinations, 446 F.Supp.2d 497, jury verdict was entered for competitor. Manufacturer moved for reconsideration.

Holding: The District Court, Ellis, J., held that phrase "isolating from a crude reaction mixture" required that intermediary containing permissible amount of impurities be separated from crude reaction mixture.

Motion denied.

6,653,481. Construed.

Jonathan Garwood Graves, Cooley Godward LLP, Reston, VA, for Plaintiff.

John F. Anderson, Troutman Sanders LLP, McLean, VA, for Defendant.

MEMORANDUM OPINION

ELLIS**, District Judge.**

Following extensive briefing and oral argument in this patent infringement case, preliminary claim construction determinations issued pursuant to Markman v. Westview Instruments, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The facts and reasons in support of these determinations were recorded in a Memorandum Opinion dated June 30, 2006. *See* Synthon IP, Inc. v. Pfizer, Inc., 446 F.Supp.2d 497 (E.D.Va.2006) (Synthon I). Predictably, and as anticipated, Synthon sought reconsideration, believing its ox to be gored by one of these determinations. This led to yet another round of briefing and argument. Thereafter, the matter proceeded to trial on the basis of two alternative definitions for the primary claim phrase in dispute, one of which was a derivative of the preliminary definition set forth in Synthon I, while

the second was essentially Synthon's preferred candidate. The seven-day trial that followed culminated in a jury verdict for Pfizer on all remaining infringement and validity issues under both alternative claim phrase definitions. The purpose of this post-verdict Markman opinion is to address several arguments raised by Synthon in the supplemental Markman briefing and argument that followed Synthon I, and to make clear for the record the final claim construction definitions applicable to this case.

I.

The facts of the case, as well as a description of the relevant patents and claims, are fully documented in Synthon I and need not be repeated here. Instead, it suffices here to describe briefly the remaining patent in issue, namely U.S. Patent No. 6,653,481 (the '481 patent), a 24-claim process patent relating to a process for making amlodipine, the active ingredient in Pfizer's well-known hypertension drug Norvasc(R). FN1 In this regard, the '481 patent relates, in part, to a chemical compound referred to in the patent and its file history as "the compound of formula (3)," an organic compound that is integral to the process of producing amlodipine

FN1. By Order dated August 31, 2006, Synthon's claims of infringement related to a derivative compound patent-U.S. Patent No. 6,858,738 (the '738 patent)-were dismissed with prejudice. *See Synthon IP, Inc. v. Pfizer, Inc.,* Civil Action No. 1:05cv1267 (E.D.Va. Aug. 31, 2006) (Order).

As the '481 patent teaches, the compound of formula (3) may be produced by reacting two starting materials-one an ester or ketoester, and the other an aldehyde-in a solvent, such as isopropanol, in the presence of a catalyst, such as piperidine. This chemical reaction creates a "crude reaction mixture" containing the compound of formula (3). The next step in the process is to "isolate" from the crude reaction mixture the compound of formula (3). The '481 patent then requires that "the isolated compound of formula (3)" be reacted with another organic compound-an aminocrotonate-to form the compound of formula (2), otherwise referred to as the phthalimidoamlodipine. The compound of formula (2) is a protected amlodipine compound that is essentially identical to the amlodipine compound itself, except that it also contains a phthalimide protecting group. The '481 patent further teaches that the phthalimide protecting group is ultimately removed from the compound of formula (2) by using a deprotecting agent, thereby resulting in the formation of the final amlodipine compound.

Particularly pertinent here is the '481 patent's disclosure in claim 1, the sole independent claim, of "[a] process, which comprises isolating from a crude reaction mixture compound of formula (3)," and then "reacting said isolated compound of formula (3) with an alkyl 3-aminocrotonate of formula B. " '481 Patent, col. 25, ll. 50-51; col. 26, ll. 1-2. This specific claim language is the source of the parties' claim term definition disputes. Specifically, the parties initially disputed the meaning of (i) "crude reaction mixture;" (ii) "isolating;" (iii) "isolating from a crude reaction mixture compound of formula (3);" and (iv) "isolated compound of formula (3)." FN2 As Synthon I reflects, application of the legal principles taught in Markman and its progeny to the intrinsic evidence resulted in the adoption of preliminary definitions for each of the disputed terms and phrases. These preliminary definitions, discussed in detail in Synthon I, were as follows:

FN2. Although the parties also originally disputed a related claim phrase used in the derivative '738 compound patent, that patent has since been dismissed with prejudice from the litigation and thus need not be addressed here. *See supra* n. 1.

(i) "crude reaction mixture" means "a mixture of a chemical reaction, including the compound of formula (3) and any unreacted starting materials or side products or any catalysts or solvent;"
(ii) "isolating" means "separating," generally;

(iii) "isolating from a crude reaction mixture compound of formula (3)" means "separating the compound of formula (3) from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation;" and

(iv) "isolated compound of formula (3)" means "the compound of formula (3) that has been separated from the other components of the crude reaction mixture, except that some amount of impurities, including residual amounts of the other components of the crude reaction mixture, may remain following the act of separation."

See Synthon I, 446 F.Supp.2d at 508, 512.
As noted, the trial proceeded under two alternative definitions for the primary disputed claim phrase, specifically the phrase "isolating from a crude reaction mixture compound of formula (3)." In this regard, the first of these alternative definitions was initially to be the preliminary definition set forth in Synthon I, while the second alternative definition was identified as follows:

"separating the compound of formula (3) from the crude reaction mixture, except that this does not require that the compound of formula (3) be separated from all of the components of the crude reaction mixture or that the compound of formula (3) be completely pure."

See Synthon IP, Inc. v. Pfizer, Inc., 446 F.Supp.2d 497 (E.D.Va.2006) (Order). Thereafter, however, in the course of a final pretrial conference on August 3, 2006, the first alternative definition for the phrase "isolating from a crude reaction mixture compound of formula (3)"-that is, the definition set forth in Synthon I-was clarified and amended in several minor respects to read as follows:

"separating the compound of formula (3) from the other known components of the crude reaction mixture, except that following the act of separation, the resulting compound of formula (3) need not be pure; it may contain known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture."

See Synthon IP, Inc. v. Pfizer, Inc., Civil Action No. 1:05cv1267 (E.D.Va. Aug. 3, 2006) (Order).FN3 One additional minor modification was made to the first alternative definition prior to the jury trial in this matter, FN4 resulting in the following two alternative definitions being presented to the jury for separate consideration on each issue of infringement and validity remaining in the case:

FN3. These modifications were prompted primarily by Synthon's argument that the chemical reactions used in synthesizing compounds typically result in the formation of various unknown side products and unknown impurities and thus, it might prove impossible to determine whether in the course of the isolation step the compound of formula (3) had been separated from *all* of the side products that might be present in the crude reaction mixture.

FN4. Specifically, the phrase "it may contain," appearing after the semi-colon in the first alternative definition, was amended to read "there may be present."

Alternative Definition # 1

"separating the compound of formula (3) from the other known components of the crude reaction mixture, except that following the act of separation, the resulting compound of formula (3) need not be pure; there may be present known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture;" and

Alternative Definition # 2

"separating the compound of formula (3) from the crude reaction mixture, except that this does not require that the compound of formula (3) be separated from all of the components of the crude reaction mixture or that the compound of formula (3) be pure."

As noted, the ensuing seven-day jury trial culminated in a jury verdict for Pfizer on all remaining infringement and validity issues under *both* of the alternative definitions for the disputed claim phrase "isolating from a crude reaction mixture compound of formula (3)." FN5 This post-verdict Markman opinion now addresses several arguments raised by Synthon in a supplemental claim construction brief filed following issuance of Synthon I, but before commencement of the jury trial, and makes clear for the record the final claim construction definitions applicable to this case.

FN5. The 17-page special verdict form was divided into four separate sections, namely (i) infringement under Alternative Definition # 1, (ii) infringement under Alternative Definition # 2, (iii) validity under Alternative Definition # 1, and (iv) validity under Alternative Definition # 2. Only literal infringement was in issue.

II.

Because the parties do not dispute the legal principles cited and relied on in Synthon I, it is unnecessary to do more here than to adopt and incorporate those principles by reference. *See* Synthon I, 446 F.Supp.2d at 502-507. The essential dispute between the parties continues to focus on the meaning of the claim phrase "isolating from a crude reaction mixture compound of formula (3)." In this regard, Synthon continues to oppose, as it has from the outset, the argument offered by Pfizer and adopted in Synthon I that isolating the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other known components of the crude reaction mixture, as required by Alternative Definition # 1. Instead, Synthon contends that subjecting the crude reaction mixture to a "phase separation where two layers emerge" and then pouring off or decanting "the upper isopropanolic layer," leaving behind an oily layer containing the compound of formula (3) is sufficient to meet the isolation requirement of the patent claims in issue. Yet, as in the initial round of briefing and argument, Synthon is clearly mistaken in this regard, for the intrinsic evidence points persuasively to the claim construction set forth in Alternative Definition # 1. In other words, a careful review of the claims, the specification and the prosecution history teaches that isolating the compound of formula (3) from the crude reaction mixture necessarily involves separating the compound of formula (3) from the other known components of the crude reaction mixture, with some impurities, unknown side products and residual amounts of the other known components of the crude reaction mixture permitted to remain following the act of isolation. Thus, removal of only one of the other known components of the crude reaction mixture, i.e. the solvent, is not sufficient to *isolate* the

compound of formula (3) from the crude reaction mixture.

Indeed, as explained in Synthon I, Alternative Definition # 1 derives first from the plain language of the claims themselves. To begin, claim 1 of the '481 patent describes a process that begins with "isolating from a crude reaction mixture compound of formula (3)." This statement, standing on its own, plainly refers to separating the compound of formula (3) from the crude reaction mixture. Significantly, the claim language teaches that it is the compound of formula (3) that is to be *separated from* the crude reaction mixture; the claim language does not teach separating the solvent or any component other than the compound of formula (3) from the crude reaction mixture. Nor does the claim language refer to separating the compound of formula (3) from only a single component of the crude reaction mixture, such as the solvent. Instead, the plain language of the patent requires that the compound of formula (3) itself be separated from the crude reaction mixture, namely from the other components of the crude reaction mixture. In other words, were the compound of formula (3) left in a mixture with the other components of the crude reaction mixture-with the exception of any permissible amounts of impurities-it would not be *isolated from* the crude reaction mixture as required by claim 1 of the '481 patent.

The specification also makes clear that the isolating step must involve more than removing the solvent from the crude reaction mixture, as it expressly states that "[t]he solvent should be one in which the compound (3) product is only sparingly soluble, so that it may be *separated from the rest of the unreacted starting materials and also from any potential side products*. " '481 Patent Specification, col. 6, ll. 22-25 (emphasis added). The specification further provides that

[p]referably the compound (3) oil is recovered and used directly without further purification to form phthalimidoamlodipine as such oil contained only minor amounts of impurities and *the remaining starting materials can be easily removed*. Recovery can be by any known technique and is typically accomplished by a liquid-liquid phase separation optionally with washing of the oil product. It should be understood that such washing is not intended to be considered a 'purification step,' but rather merely part of the recovery.

'481 Patent Specification, col. 6, ll. 34-43 (emphasis added). Moreover, the specification summarizes the claimed process by recognizing that "the use of the compound (3) of our invention...allows for a reduction in side products by producing a stable intermediate that is *easily separable from the rest of the reactive starting materials,* thereby reducing the chance of side effects in subsequent reaction steps." '481 Patent Specification, col. 8, ll. 53-61 (emphasis added). Given these statements in the specification acknowledging removal of the starting materials and other side products, it is clear that merely pouring off from the crude reaction mixture a single layer of solvent, which Synthon contends is sufficient to meet the requirement of isolating, does not serve to separate the compound of formula (3) from the other components of the crude reaction mixture; rather, as illustrated above, this suggested step only serves to separate or isolate most of the solvent-typically isopropanol-from the crude reaction mixture, which mixture still contains the compound of formula (3).

Alternative Definition # 1 is also consistent with the patent's prosecution history. Thus, the '481 file wrapper reflects that the original process claims of the '481 patent did not include the phrases "isolating from a crude reaction mixture" or "isolated compound of formula (3)." In fact, in February 2003, the patent examiner rejected Synthon's asserted claim 18-which ultimately matured into claim 1 of the '481 patent-as being anticipated by the prior art on the basis that the compound of formula (3) would be formed during the reaction steps of a prior art reference, namely U.S. Patent No. 4,572,909, a twenty-year old patent owned by Pfizer relating to the pharmaceutical compound amlodipine. To overcome this rejection, Synthon amended

its application claim 18 to include the step of "isolating from a crude reaction mixture compound of formula (3)." FN6 Significantly, this amendment served to distinguishthe claimed process from the prior art by making clear that the compound of formula (3) is required to be separated from the other components of the crude reaction mixture prior to the next step of the claimed process.

FN6. In this regard, Synthon's original application claim 18-prior to the addition of the "isolating" requirement-simply claimed "[a] process, which comprises reacting a compound of formula (3)...with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." Significantly, this form of application claim 18 was rejected by the patent examiner as being anticipated by the prior art, in that the compound of formula (3) referenced in application claim 18 would be formed during the reaction steps of Pfizer's '909 patent. Synthon thereafter amended its application claim 18 to cover "[a] process, which comprises *isolating from a crude reaction mixture* a compound of formula (3)... *and reacting said isolated compound of formula (3)* with an alkyl 3-aminocrotonate of formula B...to form a compound of formula (2)." (Emphasis added). And, in its supporting amendment papers, Synthon noted, *inter alia,* that "[s]uch an isolation step is not taught or suggested in...[the] '909 [patent]."

Likewise, in the course of the prosecution of the derivative '738 patent, the patent examiner rejected application claim 2 for indefiniteness, noting that it was a "substantial duplicate" of claim 1 in that it did not "limit the compounds" of claim 1. In this regard, while application claim 1 covered "a compound having the formula (3)," application claim 2 covered the compound of claim 1 in "isolated form." In response to this preliminary indefiniteness rejection, the applicants stated the following:

Claim 1 [of the '738 patent'] is directed to a compound *per se*. Accordingly it reads on the isolated, purified compound itself as well as the compound in compositions/mixtures with other ingredients. That is, claim 1 is not avoided simply because the compound of formula (3) is contained in a mixture with other compounds. Certainly any composition that contained the compound of formula (3) falls within the scope of claim 1. In contrast, claim 2 requires the compound of formula (3) to be in isolated form. A composition that contains a compound of formula (3) and, e.g., phthalimidoamlodipine of formula (2) would avoid claim 2, but not claim 1. Claim 2 is not a substantial duplicate of claim 1. Indeed, there is no reason to read claim 1 as requiring the compound of formula (3) to be in isolated form. Therefore, claim 2 is a proper dependent claim of clear and definite scope.

In other words, and of particular significance here, Synthon explained to the patent examiner that the "isolated form" asserted in application claim 2 of the '738 patent would not cover the compound of formula (3) if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." FN7 This statement essentially amounts to an admission by Synthon that the compound of formula (3) is not "isolated" within the meaning of the relevant patent claims if it is still contained in a mixture with other ingredients or compounds. In other words, this admission made in the course of the patent's prosecution is wholly inconsistent with Synthon's proposed construction of the disputed claim phrase and fully consistent with the definition set forth in Synthon I, later modified to form Alternative Definition # 1.

FN7. Following the applicant's clarification in this regard, the patent examiner withdrew the earlier indefiniteness rejection and allowed application claim 2 of the '738 patent.

Now, in its motion for reconsideration, Synthon reasserts several arguments that were already addressed and rejected in Synthon I, the primary one being that none of the examples set forth in the '481 patent specification support Alternative Definition # 1. This fact, however, was already acknowledged in Synthon I, where it was noted that "none of the examples set forth in the specification specifically mention the isolating step or the isolation process." *See* Synthon I, 446 F.Supp.2d at 514. It was also noted in Synthon I that "only 3 of the 13 examples set forth in the specification even arguably pertain to isolating the compound of formula (3) from the crude reaction mixture, despite the centrality of this particular step in the claimed inventions." *See* id. at 514.FN8 And significantly, all of these examples refer only to "the organic layer *containing* the desired product," rather than to the "isolated form" of the compound of formula (3), *i.e.*, the "desired product" itself.

FN8. Consistent with the parties' initial assertions, Synthon I noted that only 3 of the 13 examples set forth in the '481 patent specification specifically relate to the formation and alleged isolation of the compound of formula (3), namely examples 1, 1A and 4. Although example 12 also addresses the compound of formula (3) to a limited extent, that example is explicitly directed to the compound of formula (2) and contains no additional information or explanation material to the result reached here.

As previously explained in Synthon I, this absence in the applicable examples of any specific treatment or discussion of isolation of the compound of formula (3) is not surprising in the circumstances given (i) that the "isolating" requirement was added to the claims in issue in the course of the patent's prosecution, *see supra,* and (ii) that the original specification and examples submitted to the Patent and Trademark Office (PTO) in Synthon's initial application were not changed, modified or updated in any respect following the "isolating" amendments, presumably to protect the applicant's priority date. For all of these reasons, it remains clear, as noted in Synthon I, that the relevant examples set forth in the patent's specification are not particularly instructive or illuminating as to the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)" given that Synthon's original application claims did not require the compound of formula (3) to be isolated from the crude reaction mixture.

Yet now, in an attempt to avoid the result in Synthon I, and hence application of Alternative Definition # 1, Synthon raises several new arguments in its motion for reconsideration that were not previously addressed in Synthon I. In this regard, Synthon first argues that the inventors contemplated from the outset-at the time the original patent application was filed-that the compound of formula (3) would be isolated from the crude reaction mixture and thus that the examples set forth in the original specification must be read as addressing the meaning of the phrase "isolating from a crude reaction mixture compound of formula (3)." In support of this new argument, Synthon claims that the word "isolated" was present in an originally-filed claim directed at the compound of formula (3) itself. Yet, a review of the prosecution history discloses that Synthon is clearly mistaken in this regard.

To be sure, Synthon correctly notes that the original patent application-Application No. 09/809,351 (the '351 application)-was filed with the Patent and Trademark Office (PTO) on March 16, 2001. This application contained not only process claims, but also additional claims directed to the compound of formula (3) itself. In the course of the prosecution history, however, the patent examiner, issued a restriction requirement requiring the applicants to split the originally-filed claims into multiple applications, all with a common specification. Thus, original application claims 18-34 of the '351 application were pursued first, ultimately maturing into the '481 process patent. Original application claims 1-17, in turn, were prosecuted at a later date and ultimately matured into the '738 derivative compound patent. Given their provenance, both patents

share the identical specification.

Synthon's recitation of the prosecution history is correct in these preliminary respects, but then goes awry in contending that application claim 2, as originally filed in the '351 application, included the term "isolated" in connection with the compound of formula (3). Specifically, Synthon claims that original application claim 2 described "[t]he compound according to claim 1, wherein said compound is in isolatedform." The record flatly refutes this contention; application claim 2, at the time the '351 application was *originally* filed, claimed something entirely different, namely "[t]he compound according to claim 1 in the form of an oil." And significantly, not a single claim in the entire original application was directed to the isolated form of the compound of formula (3). Indeed, it was not until August 27, 2001, when Synthon submitted a continuing-in-part application, that the claim that ultimately matured into claim 2 of the '738 derivative compound patent was added to the application, specifically "[t]he compound according to claim 1, wherein said compound is in isolated form." Indeed, the record reflects that prior to that amended application in August 2001, the isolation requirement for the compound of formula (3) appeared nowhere in the asserted claims.FN9 This notable absence therefore casts significant doubt on Synthon's current position that the examples in the specification should be read as addressing the isolating step because the inventors contemplated isolating the compound of formula (3) from the crude reaction mixture from the outset, at the time the original patent application was filed.

FN9. The only claims of the original '351 application that used the term "isolating" were directed at "isolating" the compound of formula (2)-the phthalimidoamlodipine-as opposed to the compound of formula (3).

In its motion for reconsideration, Synthon also argues that the "oily layer" referenced in the relevant specification examples FN10 is, in fact, "the compound of formula (3) in isolated form." In other words, Synthon now contends that subjecting the crude reaction mixture to a "phase separation where two layers emerge" and then pouring off or decanting "the upper isopropanolic layer," leaving behind an oily layer containing the compound of formula (3) is equivalent to isolating the compound of formula (3) from the crude reaction mixture, as required by the claims in issue. The problem with this proposed construction, however, is that it would essentially deprive the "isolating" requirement of any significant meaning, as the oily layer undeniably contains all of the known components of the original crude reaction mixture with the exception of most of the solvent or isopropanol. Such a construction is thus contrary to the specification and the prosecution history, both of which teach that the compound of formula (3) is separated from the starting materials and side products during the isolation process and cannot remain in a mixture with other compounds or ingredients following the act of isolation, with the exception of various "known and unknown impurities, unknown side products, as well as residual amounts of the other known components of the crude reaction mixture." *See supra,* Alternative Definition # 1.

FN10. None of the examples actually use the precise term "oily layer," as argued by Synthon; rather, Examples 1 and 4 reference an "organic layer, containing the desired product," Example 1A refers to "an oil" or "gum like solid," and Example 12 simply references "an oil."

In support of its argument that the oily layer containing the compound of formula (3) described in the relevant examples of the patent specification constitutes the "isolated compound of formula (3)," Synthon relies, in part, on a declaration submitted by the named inventors in the course of the prosecution history.

Specifically, in September 2002, the patent examiner rejected Synthon's asserted application claim 18 as being anticipated by a Russian prior art reference, namely the RU 21611156 patent. To overcome that anticipation rejection, Synthon submitted a "Rule 131 declaration" from the named inventors in order to establish an earlier invention date and thus "swear behind" the publication date of RU 21611156.FN11 As required by the applicable federal regulations, the inventors' Rule 131 declaration referred only to rejected application claim 18. And significantly, the Rule 131 declaration was signed by the inventors *before* application claim 18 was officially amended to add the "isolating" requirement. Indeed, the Rule 131 declaration was signed by the inventors between February 4 and 6, 2003, while Synthon did not file the amendment papers adding the "isolating" requirement to the claims in issue until February 10, 2003. For this reason, it is not surprising that the Rule 131 declaration nowhere explicitly refers to isolating the compound of formula (3); instead, similar to the original application claims, the declaration refers only to isolating the compound of *formula (2)*.

FN11. Title 37 C.F.R. 1.131 provides that "[w]hen any claim of an application...is rejected, the inventor of the subject matter of the rejected claim...may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference."

To be sure, the Rule 131 declaration provides that an experiment was performed by the named inventors of the '481 patent in the Czech Republic prior to the critical date applicable to RU 21611156. That experiment, according to the inventors, involved a "two-step reaction scheme," whereby in the first step, two starting materials are reacted to form an intermediate compound-the compound of formula (3)-and in the second step, "the formed intermediate...is reacted with methyl-3-aminocrotonate" to form an additional compound-the compound of formula (2)-elsewhere referred to as the phthalodipine or phthalimidoamlodipine. Nowhere in the Rule 131 declaration do the named inventors acknowledge that the intermediate compound of formula (3) is "isolated" prior to its reaction with the aminocrotonate. And this absence of any reference to isolating the compound of formula (3) does not appear to be inadvertent or insignificant, for the Rule 131 declaration *does* expressly mention isolating with respect to the compound of *formula (2)*.FN12 It follows, therefore, that if isolation of the compound of formula (3) was intended to be part of the claimed process from the outset, as Synthon unpersuasively argues in its motion for reconsideration, then such an isolation step would likewise have been expressly mentioned in the Rule 131 declaration. It was not.

FN12. Specifically, the Rule 131 declaration provides, in pertinent part, that "the yield of phthalodipine, *after isolation of the product as crystals,* is reported as 12.27 g. (47.2% of theoretical yield)." (Emphasis added).

[1] But this does not end the analysis, for Synthon offers one final argument in support of its assertion that the isolated form of the compound of formula (3) required by the claims in issue is the "oily layer" left behind following removal of the solvent from the crude reaction mixture. Specifically, Synthon points to a statement made by its prosecuting attorney in certain submissions filed with the patent examiner contemporaneously with the Rule 131 declaration that "[t]he invention, including the isolation of a compound of formula (3) (as an oil layer) and reacting it with an alkyl 3-aminocrotonate to successfully form a compound of formula (2), was performed in the Czech Republic" by the named inventors before the publication date of RU 21611156. While this single statement made by the prosecuting attorney arguably supports Synthon's assertion that the "oily layer" containing the compound of formula (3) constitutes the "isolated form" of the compound of formula (3), this does not alter the critical fact that there is no reference

whatsoever to isolating the compound of formula (3) in the Rule 131 declaration itself, either as an oily layer or otherwise. Moreover, it is clear that a prosecuting lawyer's statement made in the course of the prosecution history cannot broaden the requirements of the actual patent claims themselves. *See* Biogen v. Berlex, 318 F.3d 1132, 1140 (Fed.Cir.2003) (recognizing that "[r]epresentations during prosecution cannot enlarge the content of the specification"). Put differently, this single statement made by the prosecuting attorney cannot serve to make the "oily layer" containing the compound of formula (3)-which layer is without question still a mixture of all of the known components of the crude reaction mixture with the exception of the majority of the solvent-the "isolated form" of the compound of formula (3) required by claim 1 of the '481 patent. Indeed, it was the very same prosecuting attorney who later told the patent examiner, in order to overcome a preliminary indefiniteness rejection, that the compound of formula (3) would *not* be isolated within the meaning of the asserted claims if it was "contained in a mixture with other compounds" or "in compositions/mixtures with other ingredients." *See* supra, pp. 8-10.

III.

[2] In the end, all of Synthon's arguments against application of Alternative Definition # 1, including those asserted both before and after issuance of Synthon I, are unpersuasive. Rather, a careful review of the intrinsic evidence compels the conclusion that Alternative Definition # 1 is the appropriate and final definition applicable to the disputed claim phrase "isolating from a crude reaction mixture compound of formula (3)." This final definition requires that the compound of formula (3) be separated from the other known components of the crude reaction mixture, with the understanding that following the act of separation, the resulting compound of formula (3) need not be pure, as there may be present (i) known and unknown impurities, (ii) unknown side products, as well as (iii) residual amounts of the other known components of the crude reaction mixture. Corresponding definitions for the related disputed claims terms and phrases naturally flow from this final definition.

An appropriate order will issue setting forth the final definitions applicable to the disputed claim phrases in issue, including the definition provided to the jury as Alternative Definition # 1.

E.D.Va.,2006.
Synthon IP, Inc. v. Pfizer, Inc.

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