the ALJ's summary is brief, such discussion along with the analysis of plaintiff's daily activities and testimony, suffices to support the ALJ's RFC determination.[9]

The ALJ considered all the relevant evidence and adequately discussed the bases for her RFC determination in her findings and evaluation of the evidence. The court concludes that a careful review of the entire record provides substantial evidence, sufficient to support the ALJ's finding that plaintiff could perform a limited range of light work and that jobs existed in significant numbers in the national economy that he could have performed, and that he was not disabled as of May 25, 2010.

## V. CONCLUSION

For the reasons stated, plaintiff's motion for summary judgment will be denied and defendant's motion for summary judgment will be granted. An appropriate order shall issue.

## ORDER

At Wilmington this 22nd day of October, 2014, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. Plaintiff's motion for summary judgment (D.I. 13) is denied.

2. Defendant's motion for summary judgment (D.I. 15) is granted.

3. The Clerk of Court is directed to enter judgment in favor of defendant and against plaintiff.


9. To the extent plaintiff relies on the GAF score to require a finding of disablement, plaintiff's therapist Jake Wayne is considered an "other source" and his report alone can not establish disability. 20 C.F.R. §§ 404.1513(d)(1), 416.913(d)(1); SSR 06–03p ("Information from these "other sources" cannot establish the existence of a medically determinable impairment, [but] . . . may provide insight into the severity of the impairment(s) and how it affects the individual's ability to function").

**PFIZER INC., Pharmacia & Upjohn Company, Pharmacia & Upjohn Company LLC, Sugen, Inc., C.P., Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and PF Prism C.V., Plaintiffs,**

**v.**

**MYLAN PHARMACEUTICALS INC., Defendant.**

**C.A.No. 10–528–GMS**

United States District Court,
D. Delaware.

Signed October 22, 2014

**Background:** Patentees brought action against competitor, alleging infringement of patents related to cancer treatment drugs that operated by blocking angiogenesis. Following bench trial, parties moved and cross-moved for judgment on partial findings with respect to issue of validity.

**Holdings:** The District Court, Gregory M. Sleet, J., held that:

(1) asserted claims were not obvious based on prior patent application disclosing approximately 1,200 drug combinations;

(2) potential "lead compounds" proposed by competitor would not have been selected by one skilled in art;

(3) even if competitor had identified appropriate "lead compound," it failed to establish that modifications to yield claimed compound were obvious; and

(4) even if competitor had established prima facie case of obviousness, second-

ary considerations weighed against finding of obviousness.

Patentees' motion granted.

**1. Patents ⚿681, 683, 701, 709(1), 800**

Obviousness of a patent claim is a question of law that is predicated on several factual inquires; specifically, the trier of fact is directed to assess four considerations, including (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed subject matter and the prior art, and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, acquiescence of others in the industry that the patent is valid, and unexpected results. 35 U.S.C.A. § 103(a).

**2. Patents ⚿794**

Party seeking to challenge the validity of a patent based on obviousness must demonstrate by clear and convincing evidence that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. 35 U.S.C.A. § 103(a).

**3. Patents ⚿720**

When the validity of a patent is challenged based on obviousness, the use of hindsight is not permitted in determining what would have been obvious to one of ordinary skill in the art. 35 U.S.C.A. § 103(a).

**4. Patents ⚿687**

Finding of a patent's obviousness does not require absolute predictability of success, but rather requires a reasonable expectation of success. 35 U.S.C.A. § 103(a).

**5. Patents ⚿687**

Patent's obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art, so long as there was a reasonable probability of success. 35 U.S.C.A. § 103(a).

**6. Patents ⚿768**

Asserted claims of patents related to cancer treatment drugs that operated by blocking angiogenesis, specifically with respect to synthesizing sunitinib malate, were not obvious on basis of prior patent application that disclosed approximately 1,200 drug combinations; process of going from dimethyl sunitinib to sunitinib to sunitinib malate would have required significant guesswork and variation of parameters to achieve end result, and application did not indicate that these steps would yield better angiogenesis inhibition, in absence of data to support taking these steps and in light of sheer volume of possible combinations and additional subsequent chemical alterations necessary to arrive at claimed compound. 35 U.S.C.A. § 103(a).

**7. Patents ⚿750**

To establish a prima facie case of patent obviousness based on a "lead compound," i.e., one known in the art that would have served as a logical starting points for further development efforts, the party asserting obviousness must first establish that one skilled in the art would have selected a given "lead compound," and, if one skilled in the art would have chosen the "lead compound," that party must then prove that the modification of the "lead compound" to arrive at the claimed compound would have been obvious to one skilled in the art. 35 U.S.C.A. § 103(a).

See publication Words and Phrases for other judicial constructions and definitions.

**8. Patents ⚿750**

To avoid the possibility of hindsight bias on a claim of patent obviousness based on a "lead compound," i.e., one known in the art that would have served as

a logical starting points for further development efforts, the party asserting obviousness must point to more than mere structural similarity as a reason to select a compound as a lead. 35 U.S.C.A. § 103(a).

See publication Words and Phrases for other judicial constructions and definitions.

**9. Patents ⇦768**

Potential "lead compound" proposed by competitor would not have been selected as such for further development by one skilled in art, precluding any finding of obviousness based on this compound with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; compound was among its developer's second-generation compounds, and, although it represented breakthrough in anti-angiogenesis cancer treatment when it was first disclosed, as of subject patents' priority dates, one skilled in art would have acknowledged its shortcomings and looked to more recent advances in field, which even in developer's publications had taught away from compound. 35 U.S.C.A. § 103(a).

**10. Patents ⇦768**

Potential "lead compound" proposed by competitor would not have been selected as such for further development by one skilled in art, and instead appeared to have resulted largely from hindsight, precluding any finding of obviousness based on this compound with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; compound was among its developer's first-generation compounds, and, although it demonstrated strong potency against vascular endothelial growth factor in vitro, there was no in vivo data available, and this compound, in fact, never made it beyond developer's laboratory. 35 U.S.C.A. § 103(a).

**11. Patents ⇦768**

Potential "lead compound" proposed by competitor, which compound was hypothetical compound listed as one of approximately 1,200 possible combinations in prior patent application, would not have been selected as such for further development by one skilled in art, and instead appeared to have resulted largely from hindsight, precluding any finding of obviousness based on this compound with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; compound was given no name nor chemical structure in that application, had never actually been synthesized, and had no data demonstrating its properties, and application's list of compound's components offered no suggestion that it would yield promising results as lead. 35 U.S.C.A. § 103(a).

**12. Patents ⇦799**

Even if competitor had identified appropriate lead compound in dimethyl sunitinib, it failed to establish by clear and convincing evidence that modifying this compound to yield patented drug, sunitinib malate, would have been obvious to one skilled in art or that one skilled in art would have had reasonable expectation of success, precluding any finding of obviousness based on this compound with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; even though dimethyl sunitinib would have involved single modification to arrive at patented drug, several other structural changes would have been appealing next steps, rather than this modification. 35 U.S.C.A. § 103(a).

**13. Patents ⇦799**

Even if competitor had identified appropriate lead compounds in two compounds created by developer, it failed to

establish by clear and convincing evidence that modifying compounds to yield patented drug, sunitinib malate, would have been obvious to one skilled in art or that one skilled in art would have had reasonable expectation of success, precluding any finding of obviousness based on this compound with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; modifying from developer's second-generation compound to first-generation compound, even if that proposed modification did not result in compound that was already tested and essentially ignored by developer, would have been contrary to developer's teachings, and other proposed modifications to that first-generation compound were unsupported by available data or were contrary to art. 35 U.S.C.A. § 103(a).

**14. Patents ⚿799**

Even if competitor had identified appropriate lead compounds in dimethyl sunitinib or two compounds created by developer, it failed to establish by clear and convincing evidence that modifying this compound by creating malate salt form of sunitinib to yield patented drug, sunitinib malate, would have been obvious to one skilled in art or that one skilled in art would have had reasonable expectation of success, precluding any finding of obviousness based on these compounds with respect to patentees' asserted patents related to cancer treatment drugs that operated by blocking angiogenesis; competitor offered no explanation as to why one skilled in art would have found malate to be obvious choice if motivated to try sunitinib salt, as there was nothing in prior art to suggest that malate was one of limited subset of salts to choose, or even that salt form of sunitinib would be beneficial, and malate did not appear on most current Food and Drug Administration (FDA) list of approved salt forms. 35 U.S.C.A. § 103(a).

**15. Patents ⚿708**

Patented compounds, including sunitinib, possessed unexpected properties, thus weighing in favor of non-obviousness finding with respect to patents related to cancer treatment drugs that operated by blocking angiogenesis; activity of sunitinib, when compared with previous clinical candidates, was much more potent against target receptor tyrosine kinases (RTKs) in vitro, even though it was synthesized with entirely different goals in mind, and claimed malate salt form of sunitinib solved several manufacturing problems that posed major barrier to bringing sunitinib to market and had superior properties when compared to other salts, though this form was not among initial screen of salts and was chosen "just for kicks." 35 U.S.C.A. § 103(a).

**16. Patents ⚿704**

Patented compound, sunitinib malate, satisfied long-felt need in market for treatments for renal cell carcinoma and pancreatic neuroendocrine tumors, thus weighing in favor of non-obviousness finding with respect to patents related to cancer treatment drugs that operated by blocking angiogenesis; this need was caused largely by frequent failures of others to develop effective treatment for these cancers, despite efforts to address question of anti-angiogenesis, and evidence demonstrated that sunitinib malate provided greatly improved clinical outcomes for treating these cancers. 35 U.S.C.A. § 103(a).

**17. Patents ⚿768**

Patented compound, sunitinib malate, was commercial success, thus weighing in favor of non-obviousness finding with respect to patents related to cancer treatment drugs that operated by blocking angiogenesis; drug remained dominant drug

for treating renal cell carcinoma, maintaining nearly 50% of market six years after its launch and with almost twice as much market share as its nearest competitor, drug was patentees' largest revenue generator among its oncology drugs, revenues had exceeded expenses each year drug had been on market, and, although drugs in industry, on average, tended to take 15 or 16 years to break even and recoup investment, drug was on pace to break even within 10 years. 35 U.S.C.A. § 103(a).

**18. Patents ⇐705, 707**

Evidence of both initial skepticism and subsequent acceptance of patented compound, sunitinib malate, weighed in favor of non-obviousness finding with respect to patents related to cancer treatment drugs that operated by blocking angiogenesis; several prior failed attempts at creating effective anti-angiogenesis drug created general sense of skepticism as to whether concept could work in practice, and patentees' drug constituted breakthrough in industry, widely praised by researchers and doctors. 35 U.S.C.A. § 103(a).

**Patents ⇐2091**

6,573,293, 7,125,905. Valid.

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Joshua A. Mack, Pro Hac Vice, Katherine Hasper, Pro Hac Vice, Katherine Van Gunst, Pro Hac Vice, Kirin K. Gill, Pro Hac Vice, Robert A. Delafield, II, Pro Hac Vice, Tung–On Kong, Pro Hac Vice, for Defendant.

***MEMORANDUM***

GREGORY M. SLEET, UNITED STATES DISTRICT JUDGE

## I. INTRODUCTION

In this patent infringement action, plaintiffs Pfizer Inc., Pharmacia & Upjohn Company, Pharmacia & Upjohn Company LLC, Sugen, Inc., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and PF Prism C.V. (collectively, "Pfizer") allege that pharmaceutical products proposed by defendant Mylan Pharmaceuticals Inc. ("Mylan") infringe the asserted claims of the patents-in-suit. (D.I.1.) The court held a four-day bench trial in this matter on November 26 through November 29, 2012. (D.I.148–151.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit, specifically whether the asserted claims are invalid as obvious under 35 U.S.C. § 103. (D.I.152, 153.)

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (1) all asserted claims of the patents-in-suit are not invalid due to obviousness; and (2) Pfizer's Rule 52(c) motion is granted, and Mylan's Rule 52(c) motion is denied. These findings of fact and conclusions of law are set forth in further detail below.

## II. FINDINGS OF FACT [1]

### A. The Parties

1. Plaintiff Pfizer Inc. is a corporation organized and existing under the

1. Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I.138, Ex. 1.) The court takes most of its findings of fact from the parties' uncontested facts. The court has also reordered and renumbered some paragraphs, corrected some formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe

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