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CENTRAL REEXAMINATION UNIT

(For Patent Owner)

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(For Requester)

In re Barry *et alia*
Reexamination Proceeding
Control No. 90/011,056
For: U.S. Patent No. 6,081,786

: DECISION DENYING
: PETITION UNDER
: 37 CFR 1.181 AND
: 37 CFR 1.515(c)

This is a decision on the October 1, 2010 paper entitled "Petition Under 37 C.F.R. §§ 1.515 and 1.181 for the Director to Review the Denial of Reexamination Request No. 90/011,056". No fee is required. The petition is before the Director of the Central Reexamination Unit for decision.

The petition is **DENIED** for the reasons set forth below.

REVIEW OF FACTS

1. U.S. Patent No. 6,081,786 (hereinafter, the '786 patent) issued on June 27, 2000 to Barry *et al.*
2. On June 26, 2006, a first request for *ex parte* reexamination was deposited seeking reexamination of claims 1-66 of the '786 patent. The reexamination filing date was vacated due to the request not providing the requisite pertinency and manner of applying the cited prior art to every claim for which reexamination was requested.
3. On October 10, 2008, a request for *ex parte* reexamination was deposited seeking reexamination of claims 1-66 of the '786 patent. The reexamination was assigned control no. 90/010,313 (hereafter, the '10313 proceeding).
4. On October 14, 2008, a corrected request for *ex parte* reexamination was received and was granted a filing date. The reexamination was assigned control no. 90/009,204 (hereafter, the '9204 proceeding).

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5. On November 29, 2008, reexamination was granted over claims 1-66 in the '9204 proceeding.
6. On January 7, 2009, reexamination was granted over claims 1-66 in the '10313 proceeding.
7. On June 22, 2009, the '9204 proceeding and the '10313 proceeding were merged and claims 1-66 were confirmed as patentable in a notice of intent to issue a reexamination certificate. A reexamination certificate issued for the merged '9204 and '10313 proceedings on September 15, 2009.
8. On July 13, 2009, a request for *ex parte* reexamination was deposited seeking reexamination of claims 1-66 of the '786 patent. The reexamination filing date was vacated due to the request not providing the requisite pertinency and manner of applying the cited prior art to every claim for which reexamination was requested.
9. On July 31, 2009, a corrected request for *ex parte* reexamination was received and was granted a filing date. The reexamination was assigned control no. 90/010,600 (hereafter, the '10600 proceeding).
10. On October 26, 2009, reexamination was granted over claims 1-66 in the '10600 proceeding.
11. On January 19, 2010, claims 1-66 were confirmed as patentable in a notice of intent to issue a reexamination certificate in the '10600 proceedings.
12. On June 21, the instant request for *ex parte* reexamination was received seeking reexamination of claims 1-66 of the '786 patent. The reexamination was assigned control no. 90/011,056 (hereafter, the '11056 proceeding).
13. September 3, 2010, reexamination was denied in the '11056 proceeding.
14. On October 1, 2010, the present petition seeking review of the denial of reexamination was received.
15. On October 22, 2010, Patent Owner submitted a petition in opposition to the third party requestor's petition seeking review of the denial of reexamination.

DECISION

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Third party requester ("Petitioner") in the '11056 *ex parte* reexamination proceeding has petitioned seeking relief from the examiner's September 3, 2010 Order denying *ex parte* reexamination for all requested claims.

I. Standard of Review

37 CFR 1.515(c) and 1.181 provide for the filing of a petition to review an examiner's determination refusing to order *ex parte* reexamination. The CRU Director's review of the reexamination request on petition is *de novo*. Therefore, this review will determine whether the examiner's refusal to order reexamination for claims 1-66 was correct.

The following rules and procedures are applicable to this review:

35 U.S.C. § 303(c) provides:

A determination by the Director pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and nonappealable. Upon such a determination, the Director may refund a portion of the reexamination fee required under section 302 of this title.

37 CFR § 1.515(c) provides:

The requester may seek review by a petition to the Director under 37 CFR § 1.181 within one month of the mailing date of the examiner's determination refusing *ex parte* reexamination. Any such petition must comply with 37 CFR § 1.181(b). If no petition is timely filed or if the decision on petition affirms that no substantial new question of patentability has been raised, the determination shall be final and nonappealable."

MPEP § 2248 provides, in pertinent part:

If a petition seeking review of the examiner's determination refusing reexamination is filed, it is forwarded (together with the reexamination file) to the Office of the CRU Director for decision. Where a petition is filed, the CRU Director will review the examiner's determination that a substantial new question of patentability has not been raised. The Director's review will be *de novo*.

For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in a previous examination

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or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim. MPEP §2242.

II. Summary of the Prosecution and Reexamination History of the '786 Patent

The '786 patent issued on June 27, 2000 to Barry et al. The reason for allowance of the independent claims was detailed by the Examiner as follows:

“As per amended claim 1, the prior art of record taken either individually or in combination fails to teach or suggest a method for guiding the selection of a therapeutic treatment regimen for a patient with a known disease or medical condition including generating in a computing device a ranked listing of available therapeutic treatment regimens and advisory information for one or more therapeutic treatment regimens in the ranked listing based on patient information and expert rules. The specific allowable feature, which distinguishes the present invention over the prior art is the generation of a ranked listing of available therapeutic treatment regimens for the patient. Claims 2-5 and 7-23 are dependent upon claim 1 and thus have all the limitations of claim 1 and are allowable for that reason.” *See Notice of Allowance mailed January 19, 2000.*

The '786 patent has been subjected to three reexamination proceedings prior to the instant proceeding. A first request for reexamination was received on October 10, 2008 and became the '10313 proceeding. Reexamination was granted for claims 1-66 in the '10313 proceeding.

A second request for reexamination was received on October 14, 2008 and became the '9204 proceeding. The '9204 proceeding was later merged with the '10313 proceeding. On September 15, 2009, claims 1-66 were confirmed as patentable in a notice of intent to issue a reexamination certificate in the merged '9204 and '10313 proceedings. The reasons for confirmation stated that the cited references did not teach three distinct knowledge bases as claimed.

A third request for reexamination was received on July 31, 2009 and became the '10600 proceeding. Reexamination was granted as to claims 1-66 in the '10600 proceeding and the claims were later confirmed on January 19, 2010. The reasons for confirmation stated that the cited references did not teach a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of the different therapeutic treatment regimens in combination with the first and second knowledge bases recited in claims 1-66.

The instant request for reexamination was received on June 21, 2010 seeking reexamination of claims 1-66. The instant request cites Mycin and Suan as raising a SNQ over claims 1-66.

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III. Summary of Petitioner's Grounds for Requested Relief

Petitioner requests reconsideration of the June 21, 2010 request for *ex parte* reexamination. Specifically, Petitioner requests the granting of reexamination of claims 1-66 in light of the following grounds:

- (1) The '786 claims would have been obvious in light of the combination of MYCIN and Suan.
- (2) The Examiner erroneously construed the claims to require "distinct" knowledge bases.
- (3) The Examiner unfairly manipulated the rules to deprive Dr. Shafer access to meaningful review.
- (4) The request for reexamination in the '11056 proceeding presented an SNQ.

IV. De Novo Review of the Request for Reexamination

In accordance with the requirements of the reexamination statute and rules, a review of the record as it appeared before the Examiner at the time of the order has been undertaken prior to the preparation of this decision. A *de novo* determination, taking into account the third party requester's position, as presented in the instant petition and the Patent Owner's position presented in the October 22, 2010 opposition petition, has been made as to whether the June 21, 2010 request for *ex parte* reexamination raises at least one substantial new question of patentability (hereinafter "SNQ"). For the reasons set forth below, the request for reexamination of the '786 patent filed in the '11056 reexamination proceeding has been found not to present any SNQ. Therefore, the examiner's decision to deny reexamination is proper.

Petitioner presents four grounds for relief in the present petition for review of the denial of reexamination. First, Petitioner asserts that the '786 claims would have been obvious in light of the combination of MYCIN and Suan. Such an argument is outside the scope of review afforded by a petition to review the denial of reexamination. The question at issue is not whether the MYCIN and Suan render the claims obvious, but is instead whether any of the references cited in the request raise a SNQ over the requested claims. The question of whether either MYCIN or Suan raise a SNQ is addressed below.

Petitioner next argues that the Examiner erroneously construed the claims to require "distinct" knowledge bases. Petitioner asserts that the claimed first, second, and third knowledge bases do not have to be distinct. Instead, Petitioner asserts that the broadest reasonable interpretation of

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the first, second, and third knowledge bases should include the combination of the three knowledge bases into a single unit. As support, Petitioner notes that the specification of the '786 patent states that "the knowledge bases and patient data 21-25 can be combined together" (*see '786 Patent, column 8 lines 16-20 and 38-44*). This portion of the specification sets forth an embodiment wherein the knowledge bases are not entirely distinct; however, for the following reasons, the broadest reasonable interpretation requires three distinct knowledge bases.

During reexamination, claims are given the broadest reasonable interpretation consistent with the specification and limitations in the specification are not read into the claims (*In re Yamamoto, 740 F.2d 1569, 222 USPQ 934 (Fed. Cir. 1984)*). In applying this standard to the claims at issue, the broadest reasonable interpretation of the claims requires that the claimed knowledge bases be distinct because the plain language of the claims sets forth first, second, and third knowledge bases and the specification provides support for the knowledge bases as being separate. Each of the first, second, and third knowledge bases is claimed as containing a specific set of data as follows:

- a first knowledge base comprising a plurality of different therapeutic treatment regimens for said disease or medical condition;
- a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for said disease or medical condition;
- a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens;

Hence, the claims specifically define a first, second, and third knowledge bases with each knowledge base containing a different type of data. The specification similarly discloses the separation of the knowledge bases in Figure 2 with each separate knowledge base including its own input and its own output into the inference engine. The portions of the '786 patent discussing the combining of the knowledge bases amounts to an alternative embodiment that is different from what is specifically and positively set forth in the claims. Thus, Petitioner's position is essentially an argument to read a portion of the specification into the claims. Given the clear positive recitation of first, second, and third knowledge bases coupled with specification support for the separation of the knowledge bases, the broadest reasonable interpretation of the claims requires three distinct knowledge bases.

Petitioner next asserts that the Examiner unfairly manipulated the rules to deprive Dr. Shafer access to meaningful review. It is noted that this review is *de novo* and will focus upon whether the June 21, 2010 request for *ex parte* reexamination raises a SNQ over the requested claims. The particular actions of the Examiner will not be addressed.

Finally, Petitioner asserts that the June 21, 2010 request for *ex parte* reexamination raises a SNQ over claims 1-66. The Request argues that MYCIN and Suan raise a SNQ by stating:

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“A substantial new question of patentability as to claims 1-66 is raised by the combination of MYCIN and Suan. Claims 1-66 of the '786 patent would have been obvious in light of the combination of MYCIN and Suan. These references teach each limitation of the indicated claims. Ordinarily skilled artisans would have been motivated to combine the old elements found in these references in a predictable manner to achieve the claimed subject matter. The Suan reference provides a new, non-cumulative technical teaching that was absent from the original prosecution and the '204 and '313 reexaminations. Moreover, in the '600 reexamination, the Examiner failed to analyze -- or even acknowledge - Suan's teachings. Thus the specific combination proposed has never been applied or discussed on the record. Suan is not cumulative of any reference of record because it describes a different expert system with a different architecture where its system knowledge was explicitly divided into multiple distinct knowledge bases. This technical teaching is highly relevant because the Reexamination Examiner previously found the '786 claims patentable solely because in her view the art then of record lacked multiple distinct knowledge bases. Although the MYCIN reference was not of record during prosecution of the '786 patent, it was addressed in the previous '786 reexaminations. Here, however, this proposed SNQ involving MYCIN in combination with Suan is different from, and for a substantially different purpose than, the SNQ previously raised by Smartgene in the pending '786 reexamination. The combination with Suan obviates the Examiner's previous reasons for patentability over MYCIN. Moreover, the present request shows how the Examiner previously misconstrued MYCIN's teachings. Specifically, Requester identifies passages from MYCIN that both suggest separation of different knowledge types and expressly teach division of knowledge into multiple distinct data structures that the Examiner never previously discussed or considered. Because MYCIN and Suan in combination provide a new basis for rejection of '786 claims 1-66 under § 103, Requester contends that a reasonable examiner would consider their teachings important in determining whether these claims are patentable.”
See Request for Reexamination at Pages 1-2.

Turning first to MYCIN, the MYCIN reference has been previously considered in the '10600 proceeding and '9204 proceeding where the reference was cited for its teachings regarding the MYCIN and ONCOCIN systems. The specific proposed combination of MYCIN and Suan was previously proposed in the '10600 proceeding and found to not raise a SNQ. In the instant Request, additional portions of MYCIN such as discussions of the CENTAUR system are cited in addition to the previously considered MYCIN, and ONCOCIN systems. In the case of the discussions of MYCIN and ONCOCIN, MYCIN does not raise a SNQ because the teachings are not new and non-cumulative with respect to the teachings previously considered. Further, with respect to the teachings of CENTAUR, MYCIN does not raise a SNQ because CENTAUR's teachings are not on point as to the distinguishing features of the claims. For the reasons discussed below, MYCIN does not raise a SNQ over claims 1-66.

The Request asserts that the Examiner misconstrued the teachings of MYCIN and “identifies passages from MYCIN that both suggest separation of different knowledge types and expressly teach division of knowledge into multiple distinct data structures that the Examiner never

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previously discussed or considered.” The passages discussed in the Request deal with the MYCIN, CENTAUR, AND ONCOCIN systems. The passages related to the MYCIN and ONCOCIN systems have been previously considered in the prior reexaminations and found to not teach the three distinct knowledge bases as claimed. Accordingly, the cited passages do not present any new teachings that a reasonable Examiner would consider important in determining the patentability of the claims nor do they present a new and materially different interpretation of MYCIN. Instead, they revisit the same questions of patentability that were previously decided in the prior reexaminations.

For example, in discussing the division of knowledge into multiple distinct data structures, the Request cites to page 676 of MYCIN that states “the tasks of building, maintaining, and understanding the knowledge base will be easier if the types of knowledge are separated.” This portion of MYCIN was previously presented (*see '10600 proceeding, Request for Reexamination, Page 42*). The Request further discusses Figure 18.1 of MYCIN which has been previously considered in the prior reexaminations.

The Request further discusses the CENTAUR system. The CENTAUR system as disclosed in MYCIN was not previously considered in the prior reexaminations. However, the teachings of the CENTAUR system would not have been important to a reasonable Examiner in determining the patentability of the claims because its teachings are not on point as to the distinguishing features of the claims.

The Request cites MYCIN discussing CENTAUR that states:

“The principal hypothesis being explored in this chapter is that there are many advantages to a system that uses both framelike structures and rules to solve problems in knowledge-intensive domains In order to test this hypothesis, a knowledge representation was designed that uses a combination of frames and rules in a data structure called a prototype. The domain chosen was that of pulmonary physiology.” *See MYCIN at 431.*

The Request goes on to state:

“Moreover, CENTAUR's rules were also divided into distinct groups: “The CENTAUR knowledge base also includes rules, which are grouped into four sets according to their functions.”⁵⁴ Therefore, this portion of MYCIN also expressly suggests creation of a system for guiding selection of therapeutic treatment regimens using multiple “distinct” knowledge bases.” *See Request for Reexamination at Page 14.*

However, these portions of MYCIN and the discussion set forth in the Request do not establish that MYCIN teaches the distinguishing feature of the three distinct knowledge bases as claimed. The cited portions of MYCIN discussing CENTAUR discuss four sets of knowledge, but the four sets of knowledge are not on point as to the three sets as claimed including a plurality of different therapeutic treatment regimens for said disease, a plurality of expert rules for evaluating

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and selecting a therapeutic treatment regimen for said disease, or advisory information useful for treatment of a patient with different constituents of said different therapeutic treatment regimens. Thus, CENTAUR as discussed in MYCIN does not raise a SNQ because its teachings are not on point as to the distinguishing features of the claims. Thus, for this additional reason, MYCIN fails to raise a SNQ over claims 1-66.

Turning to Suan, the request does not raise a SNQ with respect to Suan because the request fails to establish that Suan teaches the features that distinguished the '786 patent over the prior art. The Request states:

"The IMEX system explicitly teaches the use of separate, distinct knowledge bases in an expert system for medical decision-making: "The IMEX system is implemented as four modules, namely the initialization module, the diagnosis module, the treatment module, and the drug information module" where "[e]ach module has its own knowledge base which is organized as a hierarchy of rules, and passes intermediate conclusions to the other modules." *See Request for Reexamination at Page 16.*

The Request goes on to assert that the treatment module corresponds to the claimed first and second knowledge bases and the drug information module corresponds to the claimed third knowledge base. *See Request for Reexamination at Pages 15-18 and Claim Charts at Pages 5-7.* Hence, the Request does not establish that Suan teaches the three distinct knowledge bases as claimed because Suan teaches a single knowledge base that corresponds to the claimed first and second knowledge bases. While Suan does teach several distinct knowledge bases, Suan does not teach three distinct knowledge bases as claimed. Accordingly, the request fails to establish that Suan discloses the distinguishing features of the '786 patent and thus Suan would not have been important to a reasonable examiner in determining the patentability of one or more claims in the '786 patent.

Accordingly, the petition is **denied**.

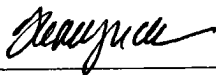
SUMMARY AND CONCLUSION

1. The petition is **DENIED**. This decision is without prejudice to the right of the requester to file a new request for reexamination. The new request must set forth a substantial new question of patentability that is different from the substantial new question of patentability set forth in the prior examinations.
2. The decision is final and nonappealable. See 35 USC 303(c) and 37 CFR 1.515(c). No further communication on this matter will be acknowledged or considered.

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Irem Yucel, Director
Central Reexamination Unit