

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Ex Parte* Reexamination of:)
)
Patent No. 6,188,988) Control Number: 90/011,055
)
Inventors: D.W. Barry, C.S. Underwood,) Group Art Unit: 3992
B.J. McCreedy, D.D. Hadden,)
J.L. Lucas) Examiner: Deandra Hughes
)
Issue Date: February 13, 2001) Box: ***Ex Parte* Reexam**
Application No. 09/523,532)
Filing Date: March 10, 2000)
)
For: SYSTEMS, METHODS AND)
COMPUTER PROGRAM PRODUCTS)
FOR GUIDING THE SELECTION OF)
THERAPEUTIC TREATMENT)
REGIMENS)

Mail Stop *Ex Parte* Reexam
Commissioner for Patents
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Sir:

**Petition Under 37 C.F.R. §§ 1.515 and 1.181 for the Director to
Review the Denial of Reexamination Request No. 90/011,055**

I. INTRODUCTION

U.S. Patent 6,188,988 claims software for selecting therapeutic treatments for disease — but the patent was filed more than 20 years *after* such systems were pioneered by Dr. Edward Shortliffe and his colleagues at Stanford University. As explained by Dr. Shortliffe in his attached Declaration, the particular three knowledge base structure purportedly claimed in the ‘988 patent was at most a trivial rearrangement of old elements found in numerous prior art references and did not afford any advantage or improvement over the art. Accordingly, during its examination of the European counterpart to the ‘988 patent, the European Patent Office

finally rejected the analogous claims, finding that organization of knowledge into several knowledge bases was “a common design principle” lying “within the common general knowledge and custom of practice in this field”¹ and therefore was implemented in a predictable manner using well-known techniques.

Subjected to threats by the owners of the ‘988 patent, Stanford Medical Professor Dr. Robert Shafer, the creator of a free database for assisting physicians world-wide in the treatment of HIV-infected patients, has made several attempts to revoke this invalid patent by requesting reexamination by the USPTO. Dr. Shafer’s legitimate requests have been consistently thwarted by a single primary examiner, Deandra Hughes. In confirming the ‘988 patent, Examiner Hughes has made serious technical errors, including misapprehending the content of the cited art, and serious legal errors, such as not considering multiple cited references, misconstruing the claims, and incorrectly applying the obviousness standard. Furthermore, Examiner Hughes dramatically compounded these errors by manipulating USPTO rules to deprive Dr. Shafer of opportunity to apply for review of her determinations. She has done so by repeatedly granting a subset of proposed substantial new questions of patentability (“SNQ”), which precluded petition to the Director, which she followed by immediate confirmation of the claims without issuing any rejections. Dr. Shafer’s current Request for reexamination proposes a single prior art combination, Shortliffe’s *MYCIN* plus *Suan* — of the dozens of invalidating combinations previously proposed — for the express purpose of appealing to the Director to rectify Examiner Hughes’ egregious mishandling of the ‘988 reexamination proceedings.

The Central Reexamination Unit Director’s *de novo* review will reveal that the instant ‘055 Request² establishes that the claims of the ‘988 patent would have been obvious in light of *MYCIN* and *Suan*. Although these references were previously proposed, they raise a substantial new question of patentability because the Examiner failed to consider the *Suan* reference, misapprehended the *MYCIN* reference, and substituted her own inexpert opinion for the evidence presented in Dr. Shortliffe’s Declaration. This incomplete, erroneous, and ineffectual reexamination process calls into question the credibility of the USPTO’s implementation of the

¹ 3/17/06 Decision to Refuse a European Patent Application at ¶ 10.5 (attached as Exh. A).

² Exh. B.

reexamination statutes. Dr. Shafer therefore respectfully requests that the '055 Request be granted and assigned to a new Examiner for thorough reexamination in light of all the cited art as required by M.P.E.P. § 2256.

II. STATEMENT OF FACTS

A. Prosecution of the '988 Patent

In 2001, Barry et al., were issued U.S. Patent 6,188,988, "Systems, Methods, and Computer Program Products for Guiding the Selection of Therapeutic Treatment Regimens," which claims priority to a 1998 provisional application.³ The '988 patent recites claims 1-66, of which claims 1 (method), 23 (system) and 45 (computer program product) are independent. Claims 1, 23, and 45 are otherwise essentially identical. Each claims software for an expert system where patient data is inputted, expert rules are invoked, and treatment recommendations are outputted. The only structure recited in the '988 independent claims is that the software comprises first, second, and third "knowledge bases."

B. The Prior Art

Expert computer systems for guiding the selection of therapeutic treatment regimens have been common in the art since Shortliffe's seminal MYCIN system was first published in 1974.⁴ These systems operate by applying expert rules or "knowledge bases" concerning available treatment regimens, evaluation and diagnosis, and advisory information (such as preferred dosing) to inputted patient information and outputting treatment recommendations and advice.⁵ As early as 1990, the field of medical expert knowledge base systems was "extensive" and subject to "intense activity."⁶

³ Exh. C.

⁴ Edward Shortliffe, "MYCIN: A Rule-Based Computer Program for Advising Physicians Regarding Antimicrobial Therapy Selection," Stanford University; National Technical Information Service (NTIS) Technical Report No. AD-A001 373 (1974) (cited as a reference in the 95/001,088 reexamination).

⁵ 7/7/09 Decl. of Edward H. Shortliffe, M.D., Ph.D. [hereinafter "Shortliffe Decl."] ¶¶ 1, 2, 14.

⁶ Exh. D, C.A. Perry "Knowledge Bases in Medicine: a Review," Bull. of the Medical Library Assoc. 78:271-282 at 271-272 (1990) (cited in Reexamination 95,001,088).

MYCIN is a 1984 book co-edited and co-authored by Dr. Shortliffe, which describes a decade of development of the MYCIN system, as well as the development and structure of numerous other expert systems, such as ONCOCIN and CENTAUR.⁷ *Suan* is a 1990 publication describing an expert system to assist in the diagnosis and treatment selection for malaria.⁸

C. Previous '988 Reexamination Requests

In Smartgene Inc.'s 90/009,213 *ex parte* reexamination, another examiner granted Smartgene's proposed SNQs, including a number that involved *MYCIN*.⁹ Upon transfer to Examiner Hughes, she declined to make any rejections.¹⁰

In Dr. Shafer's 95/001,088 *inter partes* reexamination, Examiner Hughes granted **only one of fourteen** proposed substantial new questions of patentability ("SNQ").¹¹ Dr. Shafer was therefore prohibited from filing a petition to the Director under 37 C.F.R. § 1.927 and M.P.E.P. §§ 2646 and 2648 to dispute the denial of the other thirteen legitimate proposed SNQs. The Examiner then issued a first Action Closing Prosecution without making any rejections, relying on her construction of the claims to require three "distinct" knowledge bases, without explaining what she interprets "knowledge base" to mean, or what it would mean to be "distinct."¹²

Dr. Shafer filed the subsequent 90/010,599 *ex parte* reexamination to educate the Examiner about the legal and factual errors concerning knowledge bases and expert systems she made in the previous reexaminations. Dr. Shafer proposed new SNQs, each involving newly

⁷ *Rule-Based Expert Systems: The MYCIN Experiments of the Stanford Heuristic Programming Project* (Bruce G. Buchanan & Edward H. Shortliffe eds., Addison-Wesley Publishing (1994)); '055 Request at 10-15; Shortliffe Decl. ¶¶ 20-31.

⁸ Ong Lean Suan, *Computer-Aided Diagnosis and Treatment of Malaria: The IMEX System*, *Comp. Biol. Med.* No. 5, 361-72 (1990); '055 Request at 15-18; Shortliffe Decl. ¶¶ 40-43.

⁹ 90/009,213 11/29/08 Order Granting Reexamination. In the '055 Order Denying Reexamination, the Examiner accurately summarizes the previous '988 reexaminations, but errs by implying that Smartgene's '213 Reexamination was filed by Dr. Shafer.

¹⁰ 90/009,213 6/11/09 Action Closing Prosecution.

¹¹ 95/001,088 1/7/09 Order Granting Reexamination.

¹² 95/001,088 6/11/09 Action Closing Prosecution at 7. The Examiner's confirmation of the claims in the '088 *inter partes* reexamination was subject of an appeal to the Board, but through no fault of Dr. Shafer, the appeal was dismissed for untimeliness. 4/15/10 Opposition to Patent Owner's Petition Under 37 C.F.R. § 1.812 Requesting Dismissal of the Appeal.

cited prior art, some of which also involved the previously cited *MYCIN* reference. In addition Dr. Shafer submitted the sworn declaration of Dr. Shortliffe, specifically to educate the Examiner regarding the prior art teachings concerning the division of knowledge bases. Examiner Hughes again granted only a portion of the proposed SNQs, and rejected all SNQs including the *MYCIN* reference, despite its presentation in new art combinations with never cited, non-cumulative art and inclusion of the Shortliffe declaration, which explained new and very different reasons for unpatentability. The Examiner then issued a Notice of Intent to Issue Reexamination Certificate without making any rejections, again relying on her construction of the claims to require three “distinct” knowledge bases.¹³

In the pending 90/011,055 *ex parte* reexamination request, Dr. Shafer proposed a single SNQ, the combination of *MYCIN* and *Suan*. Dr. Shafer duplicated a proposed SNQ previously submitted and improperly denied in the ‘599 Request because it was the only way to ensure the right to petition to the Director. If he had proposed a new SNQ, the Examiner could have granted the SNQ then issued a NIRC, again depriving Dr. Shafer of any review by the Central Reexamination Unit Director. Likewise, if Dr. Shafer had proposed multiple SNQs, Examiner Hughes could have granted a portion, and thereby again prevented review. In response, Examiner Hughes denied the ‘055 Request without addressing the substance of Requester’s evidence and arguments, rather again relying on her construction of the claims to require three “distinct” knowledge bases.¹⁴

D. Dr. Shortliffe’s Declaration

Accompanying the ‘055 Request, Dr. Shafer also submitted a 23-page supporting expert declaration from Dr. Edward Shortliffe, a pioneer and leader in the field, who explains the content of the cited art and its significance to the ‘988 claims.¹⁵ Dr. Shortliffe is the author of the original *MYCIN* program, editor of the *MYCIN* book cited in the instant Request, a distinguished professor of medical informatics, and the current President and CEO of the American Medical Informatics Association.¹⁶ Dr. Shortliffe volunteered to prepare his declaration without

¹³ 90/010,599 12/22/09 NIRC at 4.

¹⁴ Order Denying ‘055 Request at 5.

¹⁵ Exh. E.

¹⁶ Shortliffe Decl. ¶¶ 5-9.

compensation because he was “appalled” by the patent owner’s attempts at enforcement of patent claims he believes “had long been in the public domain.”¹⁷

III. ARGUMENT

A. The ‘988 Claims Would Have Been Obvious in Light of *MYCIN* in Combination With *Suan*.

1. The Examiner Erroneously Construed the Claims to Require “*Distinct*” Knowledge Bases.

Both the original Examiner and the Reexamination Examiner found the ‘988 claims patentable over the art *solely* because — in their view — the three knowledge bases must be “distinct” from each other.¹⁸ In her Order Denying Reexamination, the Examiner simply declines to address Dr. Shafer’s detailed claim construction arguments, which were set forth in detail in the ‘055 Request.¹⁹ Instead, the Examiner merely restated her longstanding position: “Consequently, the Examiner considers a teaching as to these claimed three *distinct* knowledge bases to form the proper basis of an SNQ as to the ‘988 patent.”²⁰

Examiner Hughes failed to apply the “broadest reasonable construction consistent with the specification.”²¹ When so construed, the claims are *not limited to “distinct” knowledge bases*. The plain language of the claims has no such “distinct” requirement, and the inventors never so distinguished their claims, either in the specification or during prosecution.²² Nowhere in the specification are the recited knowledge bases described as “distinct.” In other words, the Examiner imported a limitation into the claims that has no basis in the claim language or the

¹⁷ *Id.* ¶ 1.

¹⁸ 90/011,055 Order Denying Request For *Ex Parte* Reexamination at 5 (emphasis added); Application No. 09/523,532, Paper No. 8, 9/11/00 Notice of Allowability at 2.

¹⁹ ‘055 Request at 19-24.

²⁰ 90/011,055 Order Denying Request For *Ex Parte* Reexamination at 5; 95/001,088 RAN at 7 (emphasis added); 90/010,599 NIRC at 4.

²¹ *In re Icon Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007); M.P.E.P. § 2111.

²² *See Linear Tech. Corp. v. ITC*, 566 F.3d 1049, 1054-55 (Fed. Cir. 2009) (holding claim recitation of “second circuit” and “third circuit” does not require “entirely separate and distinct circuits” where “there is nothing in the claim language or the specification that supports narrowly construing the terms to require a specific structural requirement or entirely distinct ‘second’ and ‘third’ circuits.”).

specification. To the contrary, the specification expressly states that the knowledge bases “*can* be combined together:”

Note also that, while the knowledge bases and patient data 21-25 are shown as separate blocks, *the knowledge bases and patient data 21-25 can be combined together (e.g., the expert rules and the advisory information can be combined in a single database).*²³

“[T]he inventor’s intention, as expressed in the specification, is regarded as dispositive.”²⁴

Where the inventor intended that the knowledge bases *could be combined together*, the broadest reasonable interpretation cannot be that they must be “distinct.” Thus the claims are properly construed to encompass any system comprising the subject matter of the three knowledge bases, however they are organized.

No Examiner has asserted that the subject matter of the three recited knowledge bases were absent from the art. In fact, all the elements of the independent claims were taught by *MYCIN* and *Suan*.²⁵ The Examiner actually expressly recognized that the *MYCIN* system comprised the subject matter of each of Barry’s three knowledge bases.²⁶ The ‘988 claims thus provide nothing new or non-obvious over *MYCIN* and *Suan*. Since the knowledge bases need not be distinct, and since the claims cannot otherwise be distinguished from the art, the ‘988 claims would have been obvious.

2. Even Under the Erroneous “Distinct” Construction, *MYCIN* and *Suan* Would Have Rendered the ‘988 Claims Obvious.

Even if one assumes for argument’s sake that the recited knowledge bases need be “distinct,” such a difference would have been trivial, non-inventive, and unpatentable under *KSR Int’l v. Teleflex Inc.*²⁷ Dr. Shortliffe, the inventor of *MYCIN*, states in his declaration that “[I]t was a common design principle to organize expert knowledge into distinct knowledge structures (or ‘knowledge bases’ if you like) to implement expert decision-making systems. Indeed, numerous prior art therapy-selection systems *explicitly* divided system knowledge into multiple

²³ ‘988 patent col. 8:11-26 (emphasis added); see also *id.* col. 8:47-50.

²⁴ *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

²⁵ See ‘055 Request at 11, 16-17, 24-25; ‘055 Claim Chart (Exh. F) at 1-10.

²⁶ ‘055 Request at 11.

²⁷ 550 U.S. 398 (2007).

‘knowledge bases’ along the same lines of demarcation as Barry.”²⁸ These include the *MYCIN* and *Suan* systems raised here, which taught separation of system knowledge into discrete subunits, thereby suggesting the three “distinct” knowledge bases.²⁹ For example, *MYCIN* states: “limited experience with CENTAUR, WHEEZE, NEOMYCIN, and QN leads us to believe that ***the tasks of building, maintaining, and understanding the knowledge base will be easier if the types of knowledge are separated.***”³⁰

Accordingly, during its examination of the European counterpart to the ‘988 patent, the European Patent Office ***finally rejected*** Barry’s analogous claims, finding that organization of knowledge into discrete units was “a common design principle” lying “within the common general knowledge and custom of practice in this field”³¹ and therefore was implemented in a predictable manner using well-known techniques. Moreover, the specification does not identify “distinct” knowledge bases as an improvement over the art, does not identify a problem with the art solved by this particular arrangement, and does not identify any unexpected result or advantage therefrom. Nor could it, since the prior art taught numerous systems where precisely the same knowledge is used to act upon precisely the same inputs to deliver precisely the same output.³² Indeed, there is ***nothing*** in the Barry specification showing ***any significance*** for implementation of a system with “distinct” knowledge bases for treatment regimen information, expert rules for selecting a therapy, and advisory information, as compared to a system comprising the exact same knowledge with some other organization.³³ Thus Barry’s purported invention was at most a routine design choice, trivially rearranging old elements of software

²⁸ Shortliffe Decl. ¶ 19. See also *id.* ¶ 3 (“This is a trivial distinction without a practical difference since multiple knowledge bases could be merged into a single entity and have long been separated into multiple representations largely for computational convenience and clarity.”)

²⁹ ‘055 Request at 10-18; Shortliffe Decl. ¶¶ 3, 4, 19, 21-23, 25, 28, 31, 40-43, 49.

³⁰ *MYCIN* at 676 (emphasis added).

³¹ 3/17/06 Decision to Refuse a European Patent Application at ¶ 10.5.

³² *Id.* at ¶ 10.8; Shortliffe Decl. ¶¶ 1, 2, 14.

³³ *Id.* ¶ 18.

architecture, a mature, predictable technology as of the 1998 filing.³⁴ Under *KSR*, the claims therefore would have been obvious in light of the prior art.

3. The Examiner Ignored or Misapprehended the Evidence.

In denying the ‘055 Request, the Examiner did not perform a detailed analysis of the proposed SNQ.³⁵ Instead, she relied on her decisions in the previous ‘988 reexaminations requested by Dr. Shafer and others. But with respect to the *MYCIN* and *Suan* references, those previous decisions were both incomplete and erroneous.

First, the Examiner never properly considered *Suan*’s teachings. No analysis of *Suan*’s teachings appears anywhere in the ‘055 Order denying reexamination or the previous ‘599 reexamination where it was also cited. The only mention of *Suan* in the ‘055 Order Denying Reexamination is a red herring — the Examiner incorrectly states that Dr. Shafer changed his position concerning *Suan*’s teachings. Comparison of the ‘599 and ‘055 Requests shows no inconsistency. In both cases, Dr. Shafer made clear that *Suan* explicitly teaches the second and third knowledge bases and “clearly utilizes knowledge of ‘therapeutic treatment regimens’” (the first knowledge base).³⁶

This absence of analysis is egregious because of the care with which Dr. Shafer explained why *Suan* provided what the Examiner had previously purported to be the missing element of *MYCIN*: distinct knowledge bases. Because the Examiner did not consider *Suan* in the ‘599 or ‘055 reexaminations, this reexamination request is proper under 35 U.S.C. § 303(a) and *In re Swanson*.³⁷

Second, while there is no analysis of *MYCIN* in the Order Denying the ‘055 Request, in previous decisions, the Examiner misapprehended *MYCIN*’s teachings in at least two ways. In the ‘599 Order Denying Reexamination in light of *MYCIN* in various combinations, the Examiner asserted that:

³⁴ *Id.* ¶¶ 2, 4, 19, 49.

³⁵ M.P.E.P. § 2247 (“The examiner should also, in the decision respond to the substance of each argument raised by the requester which is based on patents or printed publications.”).

³⁶ Compare the ‘599 Request at 145 to the passage quoted by the Examiner in the ‘055 Order Denying Reexamination at 6 to ‘055 Request at 15-17 and ‘055 Claim Chart at 4 (Exh. F).

³⁷ 540 F.3d 1368, 1380 (Fed. Cir. 2008).

“MYCIN expressly warns against destroying the modularity of the *knowledge base* in order to keep the *knowledge base* manipulable. (pg. 85: 1st ¶). Consequently, MYCIN teaches against such a modification.” (Emphasis added.) In other words, MYCIN teaches against modifying the CONSULTATION PROGRAM to incorporate the decision rules of MYCIN’s *knowledge base* to become the claimed ‘third’ *knowledge base*.³⁸

As explained in detail in the ‘055 Request, *MYCIN*’s stated desire for modular system knowledge is in no way inconsistent with rearranging MYCIN into the three “distinct” knowledge bases.³⁹ Moreover, the Examiner’s conclusion that “the CONSULTATION PROGRAM” “has to be modified to incorporate the decision rules of the MYCIN’s knowledge base to become the claimed ‘third’ knowledge base”⁴⁰ reveals a misunderstanding of the *MYCIN* system. MYCIN’s CONSULTATION SYSTEM is an “inference engine” as the term is used by Barry, not a knowledge structure.⁴¹ Thus it is nonsensical to ask whether the art suggests modifying the CONSULTATION SYSTEM. Rather, assuming for the sake of argument that the recited knowledge bases must be “distinct,” the appropriate question is merely whether separating *MYCIN*’s system knowledge (“Static Factual and Judgmental Knowledge”) into three “distinct” units would have been suggested by the prior art. As explained in Dr. Shortliffe’s declaration, because system knowledge in MYCIN was already divided into separate knowledge structures, *MYCIN* does not teach away from, but in fact suggests modification of the system knowledge into distinct knowledge bases.⁴²

Moreover, the Examiner has never addressed the additional citations to different portions of *MYCIN* that had not been previously raised. In its ‘213 Request, Smartgene did not point some of the most telling portions of the *MYCIN* reference, including the section quoted above suggesting the advantages of separating knowledge, and the Section describing the CENTAUR system.⁴³ The Examiner’s oversight is clear from her statement: “The MYCIN reference is a

³⁸ 90/010,599 Order Denying Reexamination at 8-9 quoting 95/001,088 RAN at 11-12.

³⁹ ‘055 Request at 35-36; Shortliffe Decl. ¶ 26.

⁴⁰ 90/010,599 Order Granting/Denying Reexamination at 8. *See also* 95/001,088 ACP at 11 n.1.

⁴¹ *Compare MYCIN* Figure 4-1 (p. 68) to ‘988 Figure 2 and col. 8:27-31.

⁴² Shortliffe Decl. ¶¶ 21-29.

⁴³ The Smartgene 90/009,213 Reexamination Request lacks citations to *MYCIN* Chapter 23 concerning CENTAUR, and page 676, suggesting knowledge separation.

book written about the MYCIN system of Shortliffe's Ph.D. thesis ('Shortliffe')."⁴⁴ In fact, as discussed in the '055 Request, the *MYCIN* book addresses many different systems in great depth.

Also, again even assuming that the Examiner's erroneous "distinct knowledge bases" construction is correct, the Examiner did not correctly apply the obviousness standard to the facts. In stating "the Examiner considers a teaching as to these claimed knowledge bases to form the proper basis of an SNQ as to the '988 Patent,"⁴⁵ the Examiner is not properly applying the obviousness standard as set forth in *KSR*. In essence, the Examiner is saying that the prior art would have to teach the exact three knowledge base structure to even raise an SNQ. But, a novel structure made by rearranging old elements can be obvious. As the Supreme Court held in *KSR*, "when a patent 'simply arranges old elements each performing the same function it had been known to perform' and yields no more than one would expect from such arrangement, the combination is obvious."⁴⁶ In other words, when considering the obviousness of a rearrangement of known elements, the operative question is: "whether the improvement is more than the predictable use of prior art elements according to their established functions."⁴⁷ A combination of old elements is obvious when it creates no synergy, *i.e.*, when the two technologies "in combination [do] no more than they would in separate, sequential operation."⁴⁸ The '988 independent claims would have been obvious because they are nothing more than a predictable new arrangement of the old elements of *Suan*'s IMEX system and the MYCIN, CENTAUR, and ONCOCIN systems as described in the *MYCIN* book. Because all of the claimed elements are old and patentee cannot show any unpredictable or unexpected synergy between these old elements due to their rearrangement, the claims would have been obvious.

Rather, the '988 claims are at most a trivial, routine modification of *Suan*, which teaches two of the three distinct knowledge bases explicitly and includes the subject matter of the other, and *MYCIN*, which includes the subject matter of all three knowledge bases distributed across

⁴⁴ 90/010,599 10/09/09 Order Granting/Denying Request at 7.

⁴⁵ Order Denying '055 Request at 5 (emphasis original).

⁴⁶ *KSR* at 417 (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976)).

⁴⁷ *Id.*; see also *id.* at 416 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); M.P.E.P. § 2141.

⁴⁸ *Id.*

multiple knowledge structures and suggests the separation of system knowledge into different types.

Moreover, ordinarily skilled artisans would have been motivated to combine *MYCIN* with *Suan* because *Suan* expressly cites to *MYCIN* as “the most well-known medical system,”⁴⁹ thereby suggesting their combination. *Suan*’s discussion of *MYCIN* illustrates that ordinarily skilled artisans would have considered both *Suan* and *MYCIN* when designing a medical-decision making expert system that guided the selection of a therapeutic treatment regimen for chronic known diseases.

Lastly, the Examiner improperly substituted her own unqualified opinion for the declaration testimony of an acknowledged leader in the pertinent field who was also the inventor of key prior art. In the ‘055 Order, the Examiner discounted Dr. Shortliffe’s analysis of *MYCIN* because in her view, Shortliffe’s analysis only found that the art taught separating knowledge structures, not the claimed knowledge bases: “a declaration of Edward H. Shortliffe filed with the request was unpersuasive because the **Shortliffe Declaration** addressed knowledge structures and not the claimed knowledge bases.”⁵⁰ First, it is clear from the declaration that Dr. Shortliffe did not differentiate between knowledge “bases” and knowledge “structures”: “In fact, it was a common design principle to organize expert knowledge into distinct knowledge structures (*or “knowledge bases” if you like*) to implement expert decision-making systems.”⁵¹ Second, the Examiner completely disregarded Dr. Shortliffe’s further observations that many prior expert systems, including *Suan*, explicitly divided knowledge into multiple knowledge bases: “Indeed, numerous prior art therapy-selection systems *explicitly* divided system knowledge into multiple ‘knowledge bases’ along the same lines of demarcation as Barry.”⁵²

Dr. Shortliffe is eminently qualified to explain the state of the art at the time of Barry’s application. He is both a pioneer and a current leader in the field of medical decision-making expert systems.⁵³ And, he is the co-editor and co-author of *MYCIN*, one of the cited references.

⁴⁹ *Suan* at 341; *see also* ‘055 Request at 25.

⁵⁰ Order Denying ‘055 Request at 4 (emphasis original).

⁵¹ Shortliffe Decl. ¶ 19. *See also id.* ¶ 24.

⁵² *Id.* ¶ 19. *See also id.* at ¶¶ 35-48.

⁵³ *Id.* ¶¶ 5-9.

On the other hand, there is no indication that Examiner Hughes has any experience or expertise in medical expert systems or any related field. A search of the PTO issued patent database reveals that the Examiner has only examined patents in optics and acoustics, specifically classes 359 (Optical: Systems And Elements), 367 (Communications, Electrical: Acoustic Wave Systems And Devices) and 372 (Coherent Light Generators) — a far leap from the classes identified for the '988 patent: 705 (Data Processing: Financial, Business Practice, Management, Or Cost/Price Determination) and 706 (Processing: Artificial Intelligence). An examiner with no technical expertise or experience in the pertinent field should not substitute her interpretation of the prior art for that of a foremost expert in the field of the invention.

B. The Examiner Unfairly Manipulated the Rules to Deprive Dr. Shafer Access to Meaningful Review.

Via three requests for reexamination, Dr. Shafer has presented an enormous amount of prior art, expert evidence, and argument which demonstrate that the '988 patent was issued in error. Notwithstanding, Dr. Shafer has been rebuffed by Primary Examiner Hughes at every turn. The Examiner's actions in each case have consistently prevented or narrowed Dr. Shafer's ability to seek review of her decisions. In Dr. Shafer's '088 *inter partes* reexamination, based on her flawed claim construction, Examiner Hughes granted ***only the single most narrow of fourteen*** SNQs, which did not even include the independent claims.⁵⁴ Dr. Shafer was therefore prohibited from filing a petition to the Director under 37 C.F.R. § 1.927 and M.P.E.P. §§ 2646 and 2648 to dispute the denial of the other thirteen legitimate proposed SNQs. The Examiner then made no rejections and issued an Action Closing Prosecution. By not making any rejections the Examiner prevented the Requester from making any record, including submitting expert evidence or any further argument. And, by granting only the single most limited of 14 SNQs, the Examiner also prevented meaningful review by the Board on Appeal since only granted SNQs can be appealed.

In the '599 reexamination, the Examiner refused to grant reexamination of any proposed SNQ involving *MYCIN* for the erroneous reasons discussed above, but granted others. Again, Dr. Shafer was prohibited by 37 C.F.R. § 1.515 and M.P.E.P. § 2248 from petitioning the Director for review of the denial of this proposed SNQ since limited reexamination was granted.

⁵⁴ 95/001,088 1/7/09 Order Granting Reexamination.

The Examiner summarily issued a Reexamination Certificate without ever making any rejections under the SNQs she did grant in the reexamination. Given the Examiner's familiarity with the patent and the cited art by this point, she must have known when she partially granted the '599 Request that she would not issue any rejections, but did so anyway — shielding herself from any possibility of review by petition.

But for the presence of the unrelated SNQs that the Examiner granted, Dr. Shafer could have shown by petition in the '599 reexamination that *MYCIN* plus *Suan* met the requirements of an SNQ. In that case, the Examiner had (1) failed to consider *Suan*; (2) misconstrued the claims; (3) misapprehended *MYCIN*'s teachings; (4) did not consider the additional citations to different portions of *MYCIN* that had not been previously raised; and (5) failed to give the Shortliffe Declaration proper weight.

C. The Director Should Find that the '055 Request Presented a SNQ and Reinstatement the Reexamination.

The net effect of the Examiner's actions has been to create a situation where her erroneous judgment regarding the *MYCIN* reference has been thus far unreviewable by the CRU Director or the courts.⁵⁵ The Patent Owner might nonetheless oppose this Petition by arguing there cannot be an SNQ because *MYCIN* plus *Suan* was presented and denied in the '599 Request. Even though the combination was previously proposed, this reexamination request is proper under 35 U.S.C. § 303(a) and *In re Swanson*, which requires consideration of the "context" and "scope" of the previous consideration.⁵⁶ First, as explained above, the *Suan* reference at issue was *never* truly considered.⁵⁷ The statute and *Swanson* both assume a reference has been previously considered for some purpose. Where a reference has *never* been properly considered, it stands to reason that it can be the basis of a substantially new question of patentability. Second, the legislative history of § 303(a) indicates that where the Examiner

⁵⁵ *MYCIN* was not cited in the 95/001,088 *inter partes* request because it was already the subject of Smartgene's 90/009,213 *ex parte* request.

⁵⁶ *In re Swanson*, 540 F.3d 1368, 1380 (Fed. Cir. 2008). 35 U.S.C. § 303(a) ("The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.").

⁵⁷ *In re Swanson* at 1377 ("[T]he test for a substantial new question of patentability should focus on what 'the examiner' considered.").

previously did not understand a reference, or did not consider a portion of the reference, a SNQ should be found.⁵⁸ Surely here there is substantial evidence that Examiner did not understand the *MYCIN* reference and did not consider important portions thereof. Third, where an Examiner blatantly substitutes her view of the prior art for that of an undeniable expert, as Examiner Hughes has done with Dr. Shortliffe's Declaration, an SNQ can be found based on the disregarded expert evidence. Lastly, should the Patent Owner complain that it is being harassed by Dr. Shafer's Reexamination Requests, the Office should recognize that these Requests cannot possibly be considered abusive of the patentee, because over the course of four reexaminations the Examiner has never required the patentee to file any response to any paper.

Examiner Hughes has repeatedly erred in refusing to reject the '988 claims in light of overwhelming prior art and expert testimony. It has been unfair for her to use the Rules prohibiting petition of a partial grant of reexamination and the difference in standards between SNQs and rejections to become the judge, jury, and executioner over a member of the public's earnest attempts to revoke a wrongly granted patent. Because the proposed combination of *Suan* and *MYCIN* presents a SNQ, the proper action here is for the Office to grant reexamination and to assign the case to a new examiner to thoroughly reexamine the claims in light of all the cited prior art.

* * *

No fees are believed to be due in connection with this Petition under 37 C.F.R. §§ 1.181 and 1.515. However, the Director is authorized to charge any fees that may be required, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 (Order No. 383003-088RX (106555)).

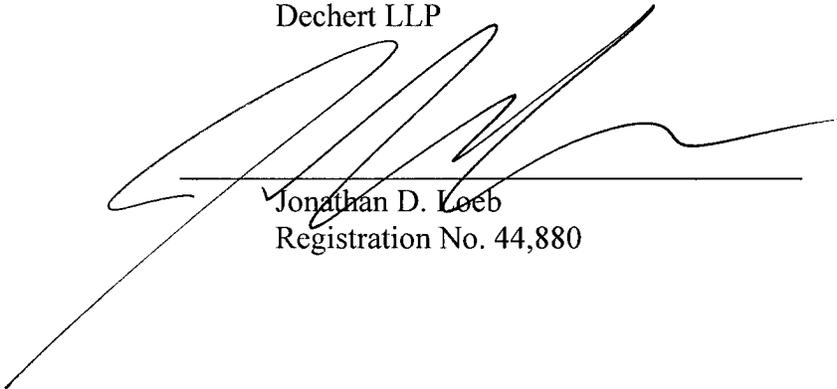
⁵⁸ *Id.* at 1381 (“also H.R. Rep. No. 107-120, at 3 (stating that there should be ‘substantial evidence’ that the examiner ‘did not properly understand the reference, or did not consider a portion of the reference in making his decision.’”)).

Please direct any inquiries in connection with the above referenced patent reexamination to the undersigned at 650.813.4800.

Dated: September 20, 2010

Respectfully Submitted,

Dechert LLP

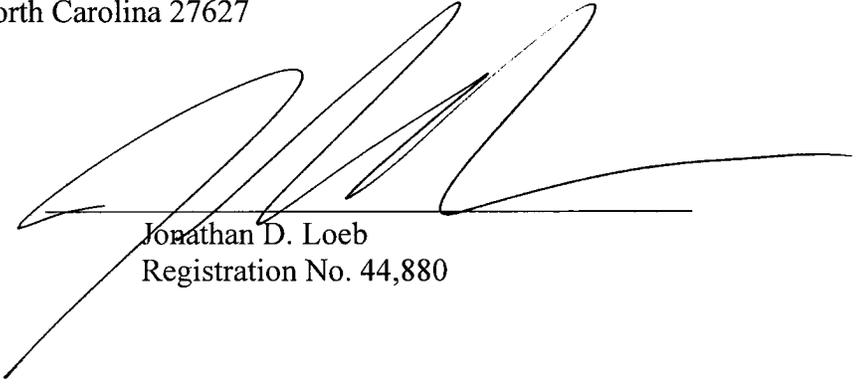


Jonathan D. Leeb
Registration No. 44,880

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 20th day of September, 2010, a copy of the foregoing **Petition Under 37 C.F.R. §§ 1.515 and 1.181 for the Director to Review the Denial of Reexamination Request No. 90/011,055**, including all accompanying papers, has been served in its entirety on the patent owner by transmitting the same via First Class Mail, postage pre-paid, to the patent owner's attorney of record at the following address:

KENNETH SIBLEY, ESQ.
Myers Bigel Sibley & Sajovec
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