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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/010,313	10/10/2008	6081786	1911-001	2580

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EXAMINER

ART UNIT PAPER NUMBER

DATE MAILED: 01/07/2009

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CENTRAL REEXAMINATION UNIT

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. 90/010,313.

PATENT NO. 6081786.

ART UNIT 3992.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No. 90/010,313	Patent Under Reexamination 6081786	
	Examiner Deandra M. Hughes	Art Unit 3992	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed 10 October 2008 has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a) PTO-892, b) PTO/SB/08, c) Other: _____

1. The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

- a) by Treasury check or,
- b) by credit to Deposit Account No. _____, or
- c) by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

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cc: Requester (if third party requester)

ORDER GRANTING REQUEST FOR *INTER PARTES* REEXAMINATION

1. A substantial new question of patentability ("SNQ") affecting claims 1-66 of USP 6,081,786 ("Barry") is raised by the *ex parte* reexamination request filed Jan. 10, 2008 ("Request").

Extensions of Time

2. Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extension of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Notification of Other Proceedings

3. The patent owner is reminded of the continuing responsibility under 37 CFR 1.985(a) to apprise the Office of any litigation activity, or other concurrent proceeding, involving **USP 6,081,786** throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §2686 and 2686.04.

References Cited in this Action

4. Shortliffe, E.H., "*Mycin: A Rule-Based Computer Program for Advising Physicians Regarding Antimicrobial Therapy Selection*," (Ph.D. thesis, Stanford University) (on file with Mathematical and Computer Sciences Library, Stanford University), Stanford Artificial Intelligence Laboratory Memo AIM-251, Computer Science Department Report No. STAN-CS-74-465, National Technical

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Information Service (NTIS) Technical Report No. AD-A001 373 (1974);
(hereafter "Shortliffe")

5. Kulikowski, C.A. and Weiss, S.M., "Representation of Expert Knowledge for Consultation: The CASNET and EXPERT Projects," in *Artificial Intelligence in Medicine*, pp. 21-55 (Peter Szolovits ed., Westview Press, Boulder, CO) (1982) **(hereafter "Kulikowski")**
6. Miller, P.L. and Black, H.R., "Medical Plan-Analysis by Computer: Critiquing Pharmacologic Management of Essential Hypertension," *Computers and Biomedical Research* 17:38-54 (1984) **(hereafter "Miller")**
7. Siepman, J.P. and Bachman, J.W., "HTN-APT: Computer Aid in Hypertension Management," *Journal of Family Practice* 24:313-316(1987) **(hereafter "Siepman")**
8. Evans, R.S., *et al.*, "Development of an Automated Antibiotic Consultant," *M.D. Computing: Computers in Medical Practice* 10:17-22 (1993) **(hereafter "Evans 1993")**
9. Pazzani, M., *et al.*, "CTSHIV: A Knowledge-Based System for the Management of HIV-Infected Patients," in *Intelligent Information Systems*, pp. 7-13 (Hojjat Adeli ed., IEEE Computer Society, Los Alamitos, CA) (1997) **(hereafter "Pazzani")**
10. Hickam, D.H., *et al.*, "The Treatment Advice of a Computer-Based Cancer Chemotherapy Protocol Advisor," *Annals of Internal Medicine* 103:928-936 (1985) **(hereafter "Hickam")**
11. Langlotz, C.P., *et al.*, "A Therapy Planning Architecture That Combines Decision Theory and Artificial Intelligence Techniques," *Computers and Biomedical Research* 20:279-303 (1987) **(hereafter "Langlotz")**
12. Evans, R.S., *et al.*, "A Decision Support Tool for Antibiotic Therapy," *1995 Proceedings of the Annual Symposium on Computer Applications in Medical Care*, pp. 651-655 (1995) **(hereafter "Evans 1995")**
13. Degoulet, P., *et al.*, "Computer-assisted Techniques for Evaluation and Treatment of Hypertensive Patients," *American Journal of Hypertension* 3:156-163 (1990) **(hereafter "Degoulet")**
14. Perry, C.A., "Knowledge bases in medicine: a review" *Bulletin of the Medical Library Association* 78:271-282 (1990) **(hereafter "Perry")**
15. Nienow, J.R., Spach, D.H., Hooton, T.M, and Collier, A.C., "Antiretroviral Therapy," in *The HIV Manual: A Guide to Diagnosis and Treatment*, pp. 60-88

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(David H. Spach and Thomas M. Hooton eds., Oxford University Press, New York) (1996) (**hereafter "Nienow"**)

16. Shafer, R.W. and Merigan, T.C., "Editorial: New Virologic Tools for the Design and Analysis of Clinical Trials," *Journal of Infectious Diseases*, 171:1325-1328 (1995) (**hereafter "Shafer"**)
17. Bartlett, J.G., *Medical Management of HIV Infection* (available as internet pages archived on June 1, 1997):

http://web.archive.org/web/19970601005020/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/jhas_book.html

http://web.archive.org/web/19970601005936/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch01.FM.html

http://web.archive.org/web/19970601005953/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch02.FM.html

http://web.archive.org/web/19970601010004/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch03.FM.html

http://web.archive.org/web/19970601010016/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch04.FM.html

http://web.archive.org/web/19970601010035/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch05.FM.html

http://web.archive.org/web/19970601010059/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch06.FM.html

http://web.archive.org/web/19970601010115/www.hopkins-aids.edu/jhas_htmlcode/jhas_book/D.MedMgt.Ch07.FM.html

Bartlett, J.G., *Medical Management of HIV Infection* (Port City Press, Baltimore) (1997) (**hereafter "Bartlett"**)

Prosecution History

18. On October 6, 1999, a non-final rejection, over the art, of claims 1-10, 13-33, 36-55, and 58-69 was issued. Claims 4, 11-12, 27, 34-35, 50, and 56-57 were objected to as being dependent upon a rejected base claim. The Examiner identified the following reasons for indicating allowable subject matter. (see page 11)

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As per claims 4, 27 and 50, the prior art of record taken either individually or in combination fails to teach or suggest wherein patient information includes viral load information, HIV genotype and phenotype information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic function, and renal function.

As per claims 11-12, 34-35 and 56-57, the prior art of record taken either individually or in combination fails to teach or suggest wherein the therapeutic treatment regimen the drug terfenadine or the drug cisapride.

Following an Examiner interview conducted Dec. 17, 1999, Applicant filed amendments to the independent claims currently numbered 1, 23, and 45 as follows:

Claim 1: (c) generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

Claim 23: (d) means for generating in said computing device advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

Claim 45: (d) computer readable program code means for generating [in said computing device] advisory information for one or more therapeutic treatment regimens in said ranked listing based on said patient information and said expert rules.

19. On January 19, 2000, the Examiner allowed claims 1-5, 7-28, and 30-68 because of the insertion of the word "ranked" as indicated above. (pg. 3 of NOA).

(A) Accordingly, with regard to claim 4, claim 26 (formerly claim 27), and claim 48 (formerly claim 50), a prior art patent or publication must teach or suggest wherein patient information includes viral load information, HIV genotype and phenotype information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic function, and renal function to form the proper basis for an SNQ

(B) With regard to claim 10 (formerly claim 11), claim 32 (formerly claim 34), and claim 54 (formerly claim 56), the prior art patent or publication must teach or suggest a treatment regimen includes terfenadine.

(C) With regard to claim 11 (formerly claim 12), claim 33 (formerly claim 35), and claim 55 (formerly claim 57), the prior art patent or publication must teach or suggest a treatment regimen includes cisapride.

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- (D) With regard to claims 1-3, 5-9, 12-25, 27-31, 34-47, 49-53, and 56-66, prior art patents or publications teaching the "ranked listing" could form the proper basis for a SNQ for the said claims.

20. The requester considers Shortliffe to present a Substantial New Questions of Patentability (**hereafter "SNQs"**)

- (A) Shortliffe presents an SNQ with respect to claims 1-3, 5-8, 12, 14, 17, 20-25, 27-30, 34, 36, 39, 42-47, 49-52, 56, 58, 61, and 64-66.
- (B) Kulikowski presents an SNQ with respect to claims 1, 5, 6, 8, 12, 21, 23, 27, 28, 30, 34, 43, 45, 49, 50, 52, 56, and 65.
- (C) Miller presents an SNQ with respect to claims 1-3, 5, 7, 12, 13, 20-25, 27, 29, 34, 35, 42-47, 49, 51, 56, 57, and 64-66.
- (D) Evans 1993 presents an SNQ with respect to claims 1, 5-8, 12, 14, 17, 20-23, 27-30, 34, 36, 39, 42-45, 49-52, 56, 58, 61, and 64-66.
- (E) Siepman presents an SNQ with respect to claims 1, 5, 6, 8, 12-14, 20-23, 27, 28, 30, 34-36, 42-45, 49, 50, 52, 56-58, and 64-66.
- (F) Pazzani presents an SNQ with respect to claims 1, 12, 19, 20, 23, 34, 41, 42, 45, and 56.
- (G) Hickam in combination with Langlotz presents an SNQ with respect to claims 1, 5-8, 16, 21, 23, 27-30, 38, 43, 45, 49-52, 60, and 65.
- (H) Evans 1993 in combination with Evans 1995 presents an SNQ with respect to claims 1-3, 5, 7, 23-25, 27, 29, 45-47, 49, and 51 .
- (I) Siepman in combination with Degoulet presents an SNQ with respect to claims 1, 5-8, 13, 21, 23, 27-30, 35, 43, 45, 49-52, 57, and 65.
- (J) Shortliffe in combination with Perry presents an SNQ with respect to claims 13-19, 22, 35-41, 44, 57-63, and 66.
- (K) Shortliffe in combination with Nienow presents an SNQ with respect to claims 4, 9-11, 19, 26, 31-33, 41, 48, 53-55, and 63.
- (L) Shortliffe in combination with Nienow and Shafer presents an SNQ with respect to claims 4, 26, and 48.
- (M) Shortliffe in combination with Bartlett presents an SNQ with respect to claims 4, 9-11, 19, 26, 31-33, 41, 48, 53-55, and 63.

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- (N) Miller in combination with Nienow presents an SNQ with respect to claims 4, 9-11, 19, 26, 31-33, 41, 48, 53-55, and 63.

Decision

SNQs (A), (J), (K), (L), and (M): The Shortliffe Reference

21. It is agreed that the consideration of Shortliffe raises a SNQ as to claims 1-3, 5-9, 12, 13-25, 27-31, 34-47, 49-53, and 56-66 because Shortliffe discloses a **ranked listing** of possible therapeutic treatment regimens on page 184. Shortliffe was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1-3, 5-8, 12, 14, 17, 20-25, 27-30, 34, 36, 39, 42-47, 49-52, 56, 58, 61, and 64-66 are patentable.

With regard to claims 10-11, 32-33, and 54-55, it is agreed that the consideration of Shortliffe in combination with Nienow presents an SNQ because Shortliffe in combination with Nienow disclose therapeutic treatment regimens which include the drug terfenadine and the drug cisapride. (See Request, pg. 149). Nienow was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 10-11, 32-33, and 54-55 are patentable.

With regard to claims 4, 26, and 48, it is agreed that the consideration of Shortliffe in combination with Nienow and Shafer presents an SNQ because Shortliffe in combination with Nienow and Shafer collectively disclose patient information including viral load information, HIV genotype and phenotype information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic

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function, and renal function. (See Request, pgs. 153-156). Shafer was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 4, 26, and 28 are patentable.

Accordingly, Shortliffe, Shortliffe in combination with Nienow, and Shortliffe in combination with Nienow and Shafter, raise SNQs as to claims 1-66, which question has not been decided in a previous examination of the Barry patent.

SNQ (B): Kulikowski

22. It is agreed that the consideration of Kulikowski raises a SNQ as to claims 1, 5, 6, 8, 12, 21, 23, 27, 28, 30, 34, 43, 45, 49, 50, 52, 56, and 65 because Kulikowski discloses a **ranked listing** of possible therapeutic treatment regimens on page 34. Kulikowski was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1, 5, 6, 8, 12, 21, 23, 27, 28, 30, 34, 43, 45, 49, 50, 52, 56, and 65 are patentable. Accordingly, Kulikowski raises a SNQ as to claims 1, 5, 6, 8, 12, 21, 23, 27, 28, 30, 34, 43, 45, 49, 50, 52, 56, and 65, which question has not been decided in a previous examination of the Barry patent.

SNQs (C) and (N): Miller

23. It is **not** agreed that the consideration of Miller raises a SNQ as to claims 1-3, 5, 7, 12, 13, 20-25, 27, 29, 34, 35, 42-47, 49, 51, 56, 57, and 64-66 of the Barry patent. Miller does not disclose a "ranked listing" of therapeutic regimens. Rather, Miller

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discloses an *alternative* to a therapeutic regimen (see pg. 64 of the Request). The Examiner does not consider an "alternative" to be "listing". Further, 3PR's cited portions of Nienow do not teach the ranked listing (see Request, pgs. 175-180). Accordingly, Miller nor Miller in view of Nienow do not raise a SNQ as to claims 1-3, 5, 7, 12-13, 20-25, 27, 29, 34-35, 42-47, 49, 51, 56-57, and 64-66.

With regard to claims 10-11, 32-33, and 54-55, it is agreed that the consideration of Miller in combination with Nienow presents an SNQ because Miller in combination with Nienow disclose therapeutic treatment regimens which include the drug terfenadine and the drug cisapride. (See Request, pg. 179). Nienow was not present in the prosecution of the application which became the Barry patent . Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 10-11, 32-33, and 54-55 are patentable.

With regard to claims 4, 26, and 48, it is agreed that the consideration of Miller in combination with Nienow and Shafer presents an SNQ because Miller in combination with Nienow and Shafer collectively disclose patient information including viral load information, HIV genotype and phenotype information, hemoglobin information, neuropathy information, neutrophil information, pancreatitis, hepatic function, and renal function. (See Request, pgs. 153-156). Shafer was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 4, 26, and 28 are patentable.

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Accordingly, Miller in view of Nienow raises a SNQ as to claims 4, 10-11, 26, 32-33, 48, and 54-55, which question has not been decided in a previous examination of the Barry patent.

SNQ (D) and (I): Siepman

24. It is agreed that the consideration of Siepman raises a SNQ as to Siepman presents an SNQ with respect to claims 1, 5, 6, 8, 12-14, 20-23, 27, 28, 30, 34-36, 42-45, 49, 50, 52, 56-58, and 64-66 because Siepman discloses a **ranked listing** of possible therapeutic treatment regimens on page 313. Siepman was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1, 5, 6, 8, 12-14, 20-23, 27, 28, 30, 34-36, 42-45, 49, 50, 52, 56-58, and 64-66 are patentable. Accordingly, Siepman raises a SNQ as to claims 1, 5, 6, 8, 12-14, 20-23, 27, 28, 30, 34-36, 42-45, 49, 50, 52, 56-58, and 64-66, which question has not been decided in a previous examination of the Barry patent.

SNQ (E) and (H): Evans 1993

25. It is agreed that the consideration of Evans raises a SNQ as to Evans presents an SNQ with respect to claims 1, 5-8, 12, 14, 17, 20-23, 27-30, 34, 36, 39, 42-45, 49-52, 56, 58, 61, and 64-66 because Evans discloses a **ranked listing** of possible therapeutic treatment regimens on page 20. Evans was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1, 5-8, 12, 14, 17, 20-23, 27-30, 34, 36, 39, 42-45, 49-52, 56, 58, 61, and

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64-66 are patentable. Accordingly, Evans raises a SNQ as to claims 1, 5-8, 12, 14, 17, 20-23, 27-30, 34, 36, 39, 42-45, 49-52, 56, 58, 61, and 64-66, which question has not been decided in a previous examination of the Barry patent.

SNQ (F): Pazzani

26. It is agreed that Pazzani presents an SNQ with respect to claims 1, 12, 19, 20, 23, 34, 41, 42, 45, and 56 because Pazzani discloses a **ranked listing** of possible therapeutic treatment regimens on page 7. Pazzani was not present in the prosecution of the application which became the Barry patent. Further, there is a substantial likelihood that a reasonable examiner would consider this teaching important in deciding whether or not claims 1, 12, 19, 20, 23, 34, 41, 42, 45, and 56 are patentable.

Accordingly, Pazzani raises a SNQ as to claims 1, 12, 19, 20, 23, 34, 41, 42, 45, and 56, which question has not been decided in a previous examination of the Barry patent.

SNQ (G): Hickman in Combination with Langlotz

27. It is **not** agreed that the consideration of Hickman in combination with Langlotz raises a SNQ as to claims 1, 5-8, 16, 21, 23, 27-30, 38, 43, 45, 49-52, 60, and 65 of the Barry patent. Neither Hickman nor Langlotz discloses a ranked listing of therapeutic regimens. 3PR cites figure 11 of Langlotz and pages 928-929 of Hickman as teaching a ranked listing. However, the said cited portions do not teach or suggest a ranked listing. Accordingly, Hickman in combination with Langlotz does **not** raise a SNQ as to claims 1, 5-8, 16, 21, 23, 27-30, 38, 43, 45, 49-52, 60, and 65.

Conclusion

28. For the reasons above, claims 1-66 of the Barry patent will be reexamined.

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29. All correspondence relating to this *inter partes* reexamination proceeding should be directed:

By Mail to: Mail Stop Ex Parte Reexam
Attn: Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand: Customer Service Window
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30. Registered users of EFS-Web may alternatively submit such correspondence via the electronic filing system EFS-Web, at:

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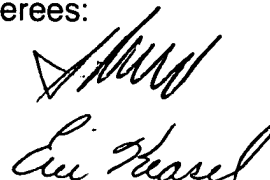
EFS-Web offers the benefit of quick submission to the particular area of the Office that needs to act on the correspondence. Also, EFS-Web submissions are "soft scanned" (i.e., electronically uploaded) directly into the official file for the reexamination proceeding, which offers parties the opportunity to review the content of their submissions after the "soft scanning" process is complete.

31. Any inquiry concerning this communication or earlier communications from the examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

Signed:

/Deandra M. Hughes/

Conferees:



The image shows two handwritten signatures in black ink. The top signature is a stylized, cursive signature that appears to be 'M. Hughes'. The bottom signature is also cursive and appears to be 'E. Haseel'.

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Deandra M. Hughes
Primary Examiner
Central Reexamination Unit 3992
(571) 272-6982