Dechert
LLP

2440 W. El Camino Real
Suite 700
Mountain View, CA 94040-1499
+1 650 813 4800 Main
+1 650 813 4848 Fax
www.dechert.com

JONATHAN D LOEB

jonathan.loeb@dechert.com
+1 650 813 4995 Direct
+650 813 4848 Fax

September 21, 2011

Dear Bob:

At your request, I write to provide a progress report concerning our efforts to address the negative effects of Advanced Biological Laboratories' Barry patents on the development of the medical expert systems field. In sum, as a result of your actions as a "third party requester" seeking reexamination of the Barry patents, their scope has been clarified and narrowed by the U.S. Patent Office. The practical result of your efforts is that ABL's ability to successfully assert its patents against medical expert system developers has been significantly limited.

Advanced Biological Laboratories, SA ("ABL") owns the rights to two U.S. Patents, Numbers 6,081,786 and 6,188,988, inventors Barry, *et al.* These patents, first filed in 1998, and issued in 2000 and 2001 respectively, are directed to computer systems for selecting therapeutic treatment regimens for patients with a chronic disease or medical condition. The claims of the two patents are addressed to systems for choosing therapeutic treatment regimens which include three specified knowledge bases: (1) "therapeutic treatment regimens"; (2) "expert rules for evaluating and selecting a therapeutic treatment regimen"; and (3) "advisory information useful for the treatment of a patient with different constituents of said different therapeutic treatment regimens."

Shortly after issuance, ABL initiated a campaign seeking royalties for use of these patents from both private and public organizations. Seemingly, ABL asserted its patents against any expert system used for therapeutic treatment selection irrespective of the structure of its knowledge bases. ABL even filed several patent infringement lawsuits against developers of such expert systems. Based on your conviction that ABL's assertion of the patents was improper and an unfair impediment to important research and the commercialization of vital technology, you engaged me, first at Day Casebeer Madrid & Batchelder LLP, and later at Dechert LLP, to determine whether ABL's patents could be invalidated or otherwise limited.

On your behalf, I initiated a series of legal actions before the U.S. Patent and Trademark Office called reexaminations to challenge the validity of the ABL patents. Given that the European Patent Office had already rejected the Barry patent application as not inventive because the multiple knowledge base configuration was a "common design principle," your belief that the patents would have been obvious in light of the extensive expert system prior art was clearly well-founded. Your position was further confirmed and strengthened when I obtained the sworn declaration of Dr. Ted Shortliffe, President and CEO of the American Medical Informatics Association, and pioneer of medical expert systems, who opined that:

> [T]he claims of the '786 and '988 patents represent no advance over the state of the art as it existed before 1997. I find no feature, functionality, or utility described in the '786 or '988 claims that was not previously developed and described both in my and my colleagues' work on the MYCIN and ONCOCIN expert systems in the 1970s and 80s, and numerous others' work on other expert systems designed to guide physicians in the selection of therapeutic treatment regimens. To the extent that the particular combination of features claimed in the '786 and '988 patents is arguably new, each claim was suggested by the literature.

Patent Reexaminations are proceedings where interested members of the public, known as "third-party requesters," ask the Patent Office to reexamine issued patents in light of newly-identified prior art evidence which demonstrates that the patent was incorrectly granted originally. Your reexamination petitions showed in detail how systems for using knowledge based-expert systems to select therapeutic treatment regimens, and even systems employing multiple knowledge bases, were commonplace before the Barry patent application, and that the ABL patent claims would have therefore been obvious.

But the Patent Office, in each of the ABL patent reexaminations, decided that the ABL claims should be read narrowly, and therefore in their view were not obvious in light of the extensive expert system prior art you had identified. In particular, the Patent Office found that the ABL patent claims were limited to systems comprising three ***distinct*** knowledge bases, even though the term "distinct" is absent from the claims: "the broadest reasonable interpretation of the claims requires three *distinct* knowledge bases."[1] ABL themselves argued to the Patent Office that the claims should be read narrowly to require these three knowledge bases be separate: "one of ordinary skill in the art, reading the independent claims of the '988 Patent in light of the specification, would understand the 'first,' 'second,' and 'third' knowledge bases recited therein to constitute separate elements, not elements inseparably merged into or integrated with each other."[2]

Having found that the claims required that the knowledge bases be distinct, the Patent Office determined that none of the prior art you identified taught the exact three distinct knowledge bases as claimed, and found the claims non-obvious in light of the art we raised. In my view, given the evidence we presented to the Patent Office, the ABL patent claims would have been obvious even

---

[1] Irem Yucel, Director, U.S. Patent Office Central Reexamination Unit, June 14, 2011 Decision in Reexamination 90/011,056 of U.S. Patent 6,081,786. See Attached Chart showing the multiple times various officers of the U.S. PTO made this determination.

[2] ABL's May 3, 2010 Respondent's Brief at 3, Reexamination No. 95/001,088.

under the Office's narrow interpretation, however the Office found otherwise. Nonetheless, the Patent Office's narrow interpretation of the ABL claims has had a significant impact on the threat that they pose to the medical informatics community.

Given the consistent conclusions of the Office concerning the scope of ABL's claims, and particularly because of ABL's own statements clarifying and narrowing their meaning, it is highly probable that they would be interpreted narrowly by the U.S. Federal Courts in a patent infringement case. The Federal Circuit Court of Appeals — the appeals court with jurisdiction over patents — has repeatedly held that a patent's prosecution history — which reexamination records constitute a part — "provides evidence of how the PTO and the inventor understood the patent" and therefore informs the proper interpretation of the claims, especially when the prosecution shows the inventor limited the invention "making the claim scope narrower than it would otherwise be."[3] In other words, given that the U.S. PTO and ABL consistently interpreted the claims to require the three specific knowledge bases, a court in a patent infringement action will very likely interpret the ABL claims in the same way, and only find infringement if an accused system possesses the exact same three specific distinct knowledge bases.[4]

Because, as observed by Dr. Shortliffe in his declaration, there are no advantages or unexpected properties in the particular separation of knowledge bases which the PTO has determined to be a requirement of the ABL claims, they are probably not currently infringed by anyone, and if they were, it would be trivial to design around by making adjustments to the expert system software.

Sincerely,

Jonathan D. Loeb

JDL

---

[3] *Phillips v. AWH*, 415 F.3d 1303, 1317 (Fed. Cir. 2005)(en banc).

[4] Note also that obviousness in light of the references you identified in the reexaminations could still be asserted as a defense if ABL were to bring another infringement action, and that there are additional other potential invalidity defenses available that could not have been raised by reexamination petition.

Representative Statements from the PTO Interpreting the '786 and '988 Patent Claims as Requiring Three "Distinct" Knowledge Bases

PTO Statement	Reexamination Document
90/011,056	
"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 apatient 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." "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."	90/011,056 6/14/11 Decision Denying Petition. Irem Yucel, Director Central Reexamination Unit

PTO Statement	Reexamination Document
"In merged reexaminations 90/009,204 and 90/010,313, Examiner confirmed claims 1-66 as patentable, noting that the prior art of record did not disclose or suggest three distinct knowledge bases in combination with other limitations as recited in claims 1-66." "In view of the prosecution history, a substantial new question of patentability may be raised by the evaluation of a prior art reference (or a combination of prior art references) that teaches a first knowledge base comprising a plurality of different therapeutic treatment regimens for the disease or medical condition; a second knowledge base comprising a plurality of expert rules for evaluating and selecting a therapeutic treatment regimen for the disease or medical condition; and a third knowledge base comprising advisory information useful for the treatment of a patient with different constituents ofthe different therapeutic treatment regimens."	90/011,056 9/3/10 Denial of Reexamination Request. Exr. Leung.
90/011,055	
"This portion of the specifically [sic] certainly 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." "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 ofthe claims sets forth first, second, and third knowledge bases and the specification provides support for the knowledge bases as being separate. Each of the	90/011,055 6/14/11 Decision Denying Petition. Irem Yucel, Director Central Reexamination Unit

PTO Statement	Reexamination Document
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." "Given the clear positive recitation of first, second, and third knowledge bases coupled with specification support for the separation ofthe knowledge bases, the broadest reasonable interpretation of the claims requires three distinct knowledge bases." 'While Suan does teach several distinct knowledge bases, Suan does not teach three distinct knowledge bases as claimed.'	
"The reasons for confirming the claims as patentable through the reexamination proceedings have consistently been that the prior art of record did not reach or make obvious: - 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	90/011,055 8/21/10 Denial of Reexamination Request. Exr. Hughes.

PTO Statement	Reexamination Document
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. 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."	
90/010,600	
"Lau does not disclose or suggest, inter alia, at least three distinct knowledge bases wherein the third knowledge base comprises advisory information useful for the treatment of a patient with different constituents of the claimed different therapeutic treatment regimens in combination with the other features set forth in the claims." "As such, a teaching or suggestion as to three distinct knowledge bases or partitioning knowledge bases into three separate knowledge bases would form the proper basis of an SNQ." "A disclosure suggesting three distinct knowledge bases would form the proper basis of an SNQ as to the Barry patent. Lau teaches 'selected knowledge bases', which suggests multiple knowledge bases. A reasonable examiner would consider a teaching suggesting multiple knowledge bases in a decision support system to form the proper basis of an SNQ as to the claims of the Barry patent."	90/010,600 1/19/10 Notice of Intent to Issue Ex Parte Reexamination Certificate. Exr. Hughes
90/010,599	
"Lau does not disclose or suggest, inter alia, at least three distinct knowledge bases wherein the third knowledge base comprises advisory information useful for the	90/010,599 12/22/09 Notice of Intent to Issue Ex Parte Reexamination Certificate.

PTO Statement	Reexamination Document
treatment of a patient with different constituents of the claimed different therapeutic treatment regimens in combination with the other features set forth in the claims."	Exr. Hughes
95/001,088	
"The Examiner considers a 'first' knowledge base, a 'second' knowledge base, and a 'third' knowledge base to be inherently distinct because the alternative would be for the knowledge bases to be indistinct thereby rendering the positive recitation of the terms 'first', 'second', and 'third' meaningless." "The Examiner considers the 'first', 'second', and 'third' knowledge bases to be distinct." "Siepman does not disclose three distinct knowledge bases. The knowledge databases cited by IP-3PR (see Request P9s. 79-80) are not disclosed as distinct databases.	95/001,088 6/11/09 Action Closing Prosecution. Exr. Hughes
"The Examiner considers a 'first' knowledge base, a 'second' knowledge base, and a 'third' knowledge base to be inherently distinct because the alternative would be for the knowledge bases to be indistinct thereby rendering the positive recitation of the terms 'first', 'second', and 'third' meaningless."	95/001,088 12/22/09 Right of Appeal Notice Exr. Hughes
90/009,213	
"The Examiner considers a 'first' knowledge base, a 'second' knowledge base, and a 'third' knowledge base to be inherently distinct because the alternative would be for the knowledge bases to be indistinct thereby rendering the positive recitation of the	90/009,213 6/11/09 Action Closing Prosecution. Exr. Hughes

PTO Statement	Reexamination Document
terms 'first', 'second', and 'third' meaningless." "Nonetheless, the Examiner thoroughly considered whether one of ordinary skill in the art (e.g. a database engineer), at the time the invention was made, would have modified the single knowledge base of Shortliffe's MYCIN system to become the three distinct knowledge bases, which Barry claims as elements of his invention." "The Examiner considers the 'first', 'second', and 'third' knowledge bases to be distinct."	