

Filed on behalf of Accord Healthcare, Inc., USA

By: Chid S. Iyer  
Chandran B. Iyer  
SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, NW  
Washington, DC 20037  
Tel.: (202) 293-7060  
Fax: (202) 293-7068  
[Email: AccordIPR@Sughrue.com](mailto:AccordIPR@Sughrue.com)

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

ACCORD HEALTHCARE, INC., USA,  
Petitioners

v.

Patent Owner of  
U.S. Patent 7,772,209 to Niyikiza  
Appl. No. 11/776,329 filed June 11, 2007  
Issued Aug. 10, 2010

---

IPR Trial No.     TBD    

---

**DECLARATION FOR PETER COLE, M.D. IN SUPPORT OF PETITION  
FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,772,209  
PURSUANT TO 35 U.S.C. § 312 AND 37 C.F.R. § 42.108**

1. I, Peter D. Cole, resident at Montclair, New Jersey, hereby declare as follows:

2. I have been retained by Sughrue Mion, PLLC to provide my opinion concerning the validity of U.S. Patent No. 7,772,209 ("209 Patent"). I am being compensated for my time at the rate of \$ 400 per hour. My opinion is not influenced in any way by the compensation that I receive and my compensation will not be affected by the outcome of this matter.

### **QUALIFICATIONS**

3. I am an Associate Professor at Albert Einstein College of Medicine of Yeshiva University. I received an M.D. from Cornell University Medical College in 1993 and a Bachelor of Science with distinction from Cornell University in Neurobiology in 1989. I completed training in general pediatrics at the Mount Sinai Medical Center in 1996. I completed training in pediatric hematology and oncology at The New York Hospital and Memorial Sloan-Kettering Cancer Center in 1999. While at Memorial Sloan-Kettering Center, I spent 2 years in the laboratory of Joseph R Bertino M.D. studying molecular pharmacology related to antifolate therapy.

4. I have authored 30 papers and 4 book chapters and have been a speaker at various venues all over the world. I am an active member of the

American Association of Cancer Research, American Society of Clinical Oncology, American Society of Hematology, American Society of Pediatric Hematology and Oncology, American Society for Pharmacology and Experimental Therapeutics, and the Society of Pediatric Research and serve on Journal and Grant Review Boards for Pediatric Hematology-Oncology, St. Baldrick's Foundation, Damon Runyon Cancer Research Foundation, and the Beez Foundation, Medical Board.

5. In 2012 I was honored as Clinical Research Training Program Mentor of the Year, in 2009 I received the Henry L. Moses Award for Best Clinical Paper, between 1997 to 1998 I served as the Neal Perkell Fellow in Pediatric Oncology, in 1996 I received the Kurt Hirschorn MD Award for Academic Excellence, in 1993 I received the Clarence C. Coryell Prize in Medicine, and in 1993 I was admitted to Alpha Omega Alpha Honor Medical Society.

6. My clinical research focuses on improving treatment for children, adolescents and young adults with acute lymphoblastic leukemia or Hodgkin's lymphoma, with the goals of both increasing cure rates and decreasing toxicity. To this end, I have designed, conducted, and analyzed clinical trials testing different antifolates for patients with cancer.

7. My laboratory background is in the molecular pharmacology of antifolates, such as methotrexate - drugs that exert their antineoplastic effects by interfering with cellular processes dependent on the vitamin folic acid. My current laboratory research centers on reducing the toxicity of anticancer therapy, including that caused by antifolates.

8. I have worked as an expert in various cases and have provided opinions on medical standards of care and medical practices. Of these cases, I have served as a testifying expert twice.

9. A copy of the latest version of my CV is attached as Exhibit 1012.

### **LEGAL STANDARD**

10. I understand that a claim is invalid if it is obvious.

11. I further understand that obviousness of a claim requires that the claim be obvious from the perspective of a person of ordinary skill in the relevant art, at the time the invention was made. In analyzing obviousness, I understand that it is important to understand the scope of the claims, the level of skill in the relevant art, the scope and content of the prior art, the differences between the prior art and the claims, and any secondary considerations.

12. I understand that the United States Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), noted that “[g]ranting patent protection to

advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.” *Id.* I understand that the Supreme Court stressed the need for “caution” before validating patents that are merely combinations of elements found in the prior art. *Id.* at 1741. In view of this caution, the Supreme Court explained that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 1731.

13. I further understand that the Court pointed to other factors which may show obviousness. For example, the Supreme Court observed, “[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill in the art can implement a predictable variation,” it is obvious. *Id.* And “[i]f a technique had been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious, unless its actual application is beyond his or her skill.” *Id.* Further, “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.