UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CV THERAPEUTICS, INC.
SECURITIES LITIGATION

DECLARATION OF FRANK J. SASINOWSKI

This Document Relates To: All Actions
I, Frank J. Sasinowski, declare as follows:

1. I am an attorney and Director with Hyman, Phelps & McNamara, P.C. (“HPM”). The facts set forth herein are within my personal knowledge and, if called upon, I could and would testify competently thereto.

2. Beginning in July 2002, HPM provided legal advice to CV Therapeutics, Inc. (“CVT”) regarding the process of seeking Food and Drug Administration (“FDA”) approval of CVT’s drug application for Ranexa. Ranexa is the trade name for the drug ranolazine.

3. While numerous other HPM attorneys have provided legal advice to CVT in connection with its drug application, I have served as CVT’s primary contact at HPM with respect to many FDA-related legal, including regulatory, matters. My legal practice is focused primarily on counseling companies, such as CVT, on the statutory and regulatory requirements for the FDA’s review and approval of drug products.

4. I am aware of the litigation captioned In re CV Therapeutics, Inc. Securities Litigation, Master File No. C-03-3709-SI. I have been informed that the class period in this action is December 30, 2002 to December 5, 2003.

The Regulatory Approval Process For CVT’s Ranexa Drug Application

5. Between 2002 and 2004, CVT was actively engaged in the process of seeking regulatory approval for Ranexa (and more recently in 2005 and 2006, when an amended NDA was submitted to and approved by the FDA). I learned that, in 2002, CVT and the FDA met on multiple occasions to discuss CVT’s New Drug Application for Ranexa (the “NDA”). CVT originally submitted the NDA on December 30, 2002. After CVT announced on March 5, 2003 that the FDA formally filed the NDA, CVT received a July 17, 2003 “discipline review letter” from the FDA.\(^1\) I subsequently learned that the FDA made arrangements with CVT for an anticipated Cardiovascular and Renal Drugs Advisory Committee (the “Committee”) meeting in September 2003 (the “September 2003 Committee Meeting”).

6. The Committee is organized by the FDA. Committee meetings are not chaired

\(^1\) A discipline review letter is a letter used to convey early thoughts on possible deficiencies found by a discipline review team for its portion of the pending application.
by the FDA, though FDA members are present. Instead, meetings are chaired by a Committee Chairperson, who is typically a physician-researcher affiliated with a university medical center. The Committee provides the FDA with independent expert advice that helps the FDA make its decisions regarding whether to approve new drugs. During its deliberations, the Committee often asks for more information in advance of making any recommendations to the FDA. At the end of Committee meetings, Committee members are often asked by the FDA to vote on whether they would recommend that the FDA approve the drug. The FDA generally follows a Committee’s recommendation, but is not bound to do so.

7. On August 1, 2003, CVT announced that CVT and the FDA agreed to cancel the review of Ranexa at the scheduled September 2003 Committee Meeting.

8. On October 23, 2003, CVT announced that a Committee meeting was scheduled to review Ranexa on December 9, 2003.

9. On December 9, 2003, as scheduled, the Committee met to discuss Ranexa (the “December 2003 Committee Meeting”).

10. In January 2006, the FDA approved Ranexa.

Legal Services HPM Provided To CVT

11. Tasks HPM attorneys, including me, have performed in connection with HPM’s legal representation of CVT included, among other things:

   a. advising CVT with respect to its submissions to the FDA, such as proposed drug labeling, amendments to CVT’s NDA, QT interval data, and other information;

   b. editing and/or reviewing documents, such as draft FDA meeting minutes, Committee briefing documents, proposed labeling, and questions for mock Committee meetings;

   c. participating in conferences with FDA officials, all-day mock Committee meetings, and conferences with CVT employees and consultants regarding CVT’s efforts to obtain regulatory approval of its NDA; and

   d. advising CVT on FDA correspondence, drug efficacy studies, drug

2 A “QT interval” is the time it takes the heart to complete one full cycle of ventricular contracting and relaxing.
advertising efforts, examples of drugs that had been recently approved by the FDA’s Division of Cardiovascular and Renal Products, and the timing, substance, and procedures of Committee meetings.

Meetings To Prepare CVT For FDA Advisory Committee Meetings

12. During July 16-17, 2003, I attended a meeting CVT held in Palo Alto, California, to prepare for the scheduled September 2003 Committee Meeting regarding Ranexa (the “July 2003 Meeting”).

13. During December 7-8, 2003, I attended a meeting CVT held in Bethesda, Maryland, to prepare for the December 2003 Committee Meeting regarding Ranexa (the “December 2003 Meeting”).

14. The July 2003 Meeting and December 2003 Meeting (together, the “2003 CVT Meetings”) were important parts of CVT’s efforts to seek approval of the NDA by the FDA. A major purpose of the 2003 CVT Meetings was to provide information to HPM that would enable us to render legal advice to CVT regarding the FDA’s review of the NDA and/or the desired approval of Ranexa.

15. Individuals who attended the 2003 CVT Meetings offered information and opinions on CVT’s NDA and on the approval process generally, with the goal of obtaining the FDA’s approval of the NDA. The primary reason I attended the 2003 CVT Meetings was to provide legal advice to CVT. I used the information I received at the 2003 CVT Meetings to provide legal advice to CVT in connection with the September 2003 Committee Meeting that had been scheduled and then canceled, and the December 2003 Committee Meeting. However, I also used the totality of this information in connection with my legal advice to CVT on the regulatory approval process generally.

16. I understood that with regard to the 2003 CVT Meetings, information obtained during those meetings was to remain confidential.

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I declare under penalty of perjury that the foregoing is true and correct. Executed on July 7, 2006.

/S/
Frank J. Sasinowski

Filer’s Attestation: Pursuant to General Order No. 45, Section X(B) regarding signatures, I attest under penalty of perjury that concurrence in the filing of the document has been obtained from Frank J. Sasinowski.

/S/
Peter T. Snow