

Attachment A

DECLARATION OF DR TIPPASANDRA GOWRIPATHI CHANDRASHEKHAR

I, Tippasandra Gowripathi Chandrashekhar, do hereby declare as follows:

1. I hold the position of Director and Head, Analytical Research for Ranbaxy Laboratories Limited.

2. I joined Ranbaxy Laboratories Limited in 1995 and have held the following positions:

From July 1995 to April 1997 Group Leader – Analytical Research

From April 1997 to March 2000 Assistant Director – Analytical Research

From April 2000 to March 2002 Associate Director – Analytical Research

From April 2002 to till date Director and Head – Analytical Research.

3. From 1990 to 1995 I was Head Analytical Research at Torrent Pharmaceuticals Limited.

4. From 1987 to 1990 I was a Trainee Quality Control and later promoted to Manager Quality Control/Quality Assurance at Cipla Limited.

5. I obtained a B.Sc. degree in Chemistry in 1982 from Bombay University in Maharashtra, India; an M.Sc. in Analytical Chemistry in 1984 from Bombay University in Maharashtra, India; and a Ph.D in Analytical Chemistry with specialization in Pharmaceutical Analysis in 1987 from Bombay University in Maharashtra, India.

6. In my position as Director and Head, Analytical Research for Ranbaxy Laboratories Limited, I am ultimately responsible for all research and



of a certain mass to continue through the process. The precursor ions that pass through the first mass filter enter into a collision chamber where neutral gas molecules break apart the precursor ion into smaller fragment ions. These fragment ions are then analyzed by a second mass filter. This technique allows one to discover the mass of both the precursor ion and the fragment ions. By discovering the masses of the ions, one can deduce which chemical components are found in the precursor and fragment ions.

10. A substance subject to analysis by this technique is identified by its characteristic retention time in the liquid chromatograph, the mass of its precursor ion, and the masses of any fragment ions it is observed to produce. Information as to the quantity of a substance may be obtained from the intensity of the ions produced in the mass spectrometer.

11. I was requested to perform analytical testing of Merck's Zocor® tablets to determine if any of the compounds claimed in U.S. Patent Nos. RE36,520 ("the '520 patent") and RE36,481 ("the '481 patent") are present in the tablets. I have read the '520 and the '481 patents and understand the compounds claimed in these patents. I have determined the molecular weights of the compounds claimed by name in the '481 and '520 patents.

12. I have conducted LC-MS/MS testing of Merck's Zocor® tablets (80 mg) and have determined that at least eight of the compounds claimed in the '481 patent and at least one of the compounds claimed in the '520 patent are present in Merck's Zocor® tablets. In performing LC-MS/MS testing on the Zocor® tablets, I used mass spectrometry to determine the molecular weights of the compounds partitioned by liquid chromatography. Specifically, my testing demonstrates that at least nine



development analytical testing for Ranbaxy's pharmaceutical business in the United States and in the rest of the world.

7. Liquid chromatography/tandem mass spectrometry ("LC-MS/MS") is a technique commonly used to determine the exact composition of a compound and the quantity of each element within a compound. This technique is widely accepted within the industry as a means of identifying unknown chemical substances. I am familiar with and have used LS-MS/MS extensively for the last eight years for identifications of unknown compounds in different active pharmaceutical ingredients (API's) and Drug Products and for other applications, such as dissolution profiling of different drug products. The instruments currently in use are products of Applied Biosystems MDS SCIEX and the Model numbers are API 2000 and Q TRAP.

8. LC-MS/MS uses both the techniques of liquid chromatography ("LC") and mass spectrometry ("MS") to gain enough information about a substance to identify its composition. The compound is first subjected to LC. During this process, the compound is dissolved in a liquid and then forced through the "solid phase" (i.e., a compacted solid absorbent substance). This technique segregates the various components within a compound based on how quickly each component can move through the solid phase. In addition, the retention time of each component (i.e., how quickly it moves through the solid phase) indicates certain aspects of the substance that help to identify it.

9. After the compound has been separated into its various components by LC, those components are subjected to tandem mass spectrometry ("MS/MS"). In this process, a component is ionized creating what is called the precursor ion. The precursor ions are then subjected to a mass filter that allows only precursor ions



compounds present in Merck's Zocor® had molecular weights that are the same as those of the compounds claimed by name in the claims of the '481 patent and/or the '520 patent. The fragmentation patterns of the fragment ions were used to eliminate from consideration those compounds from a larger set of compounds having the same molecular weight but predicted to have a different fragmentation pattern. This application of the fragmentation pattern increased the certainty of my results.

13. In conclusion, I have determined through LC-MS/MS testing that at least eight compounds claimed in the '481 patent and one compound claimed in the '520 patent are present in Merck's Zocor®.

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I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10 day of May 2005 in Gurgaon, India.



T.G. Chandrashekhar