

EXHIBIT 20

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LULLA *et al.*

Appl. No. 10/518,016

Filed: July 6, 2005

For: **Combination Of Azelastine and Steroids**

Confirmation No.: 4912

Art Unit: 1616

Examiner: Nielsen, Thor B.

Atty. Docket: PAC/20632 US (4137-04700)

Declaration of Dr. Sujeet Rajan Under 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

1. I, Dr. Sujeet Rajan (MD, DETRD, DNB), hereby declare and state as follows:
2. I am currently a paid consultant for Cipla. I am not being compensated for the services related to this Declaration. I am not a shareholder of Cipla. I do not have any other financial interest in the allowance or issuance of the above-captioned patent application.
3. I hold the degree of MD, DETRD, DNB. A recent copy of my Curriculum Vitae, accurately listing my scientific credentials and work experience, is attached herewith as Exhibit A.
4. As stated in my Curriculum Vitae, I am a Consultant Chest Physician at **Bombay Hospital Institute of Medical Sciences** (Since August 2000); Honorary Consultant Chest Physician -- **Bhatia Hospital** (Since February 1996), (Asst. Honorary Chest Physician -- 1995-1996); and Honorary Chest Physician & Bronchoscopist -- **Motiben Dalvi Hospital & ICU** (Since March 1997). I am a *Member* of the following Societies-

Indian Chest Society (Life Member); American College of Chest Physicians (ACCP). I am on the *Editorial Advisory Board* of the following journals: Indian Practitioner, and Indian Diet and Nutrition. I am also a reviewer of the *Journal of Association of Physicians of India (JAPI)*. As evidenced in my Curriculum Vitae, I have extensive experience in the treatment of respiratory tract diseases.

5. Based on my education and experience, I am knowledgeable about allergic rhinitis and non-allergic vasomotor rhinitis.

6. It is my understanding that the claims in the above-captioned patent application recite a pharmaceutical composition comprising azelastine or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a pharmaceutically acceptable ester of fluticasone wherein the pharmaceutical formulation is in a dosage form suitable for nasal administration (the "claimed composition").

7. For at least the reasons discussed herein, it is my opinion that the claimed composition represents the fulfillment of a long-felt, but previously unmet, need by patients and healthcare practitioners for management of symptoms of allergic rhinitis and non-allergic vasomotor rhinitis.

8. Duonase[®], a nasal spray product developed by Cipla which contains azelastine hydrochloride and fluticasone propionate, is an embodiment of the claimed composition commercially available in India.

9. Over 50 % of our asthma patients have allergic rhinitis (AR). Prior to Duonase[®] being introduced in India, we have traditionally used nasal corticosteroids alone in treating our patients for both AR and non-allergic vasomotor rhinitis.

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10. Though nasal steroids are an effective medication for AR, their time to onset for action is a bit prolonged, and therefore their use *alone* has been associated with poorer adherence rates in my practice, and subsequently lead to the excess and misuse of over the counter decongestants, which is harmful. The dangers of short-term use of decongestants are well known to the medical community worldwide. Also, use of nasal steroids alone typically required a treatment period of 4 to 8 weeks or longer, which is unpopular with patients and has lead to failure to complete the treatment regimen. Accordingly, long-term problems have existed with use of nasal steroids alone.

11. Another medicine that is typically prescribed for AR is oral anti-histamines. However, the use of *oral* anti-histamine is associated with some common side effects such as sedation, cognition difficulties, dryness of the mouth, and significantly troublesome lower urinary tract symptoms (LUTS) in elderly patients with benign prostatic enlargement. Accordingly, long-term problems have existed with use of oral anti-histamines.

12. Nasal corticosteroids in conjunction with oral antihistamines have also been prescribed for AR, but are characterized by delayed effects with significant potential side effects such as sedation, cognition difficulties, dryness of the mouth, and significantly troublesome lower urinary tract symptoms (LUTS) in elderly patients with benign prostatic enlargement. Accordingly, use of nasal corticosteroids in conjunction with oral antihistamines for treatment of AR is both unremarkable and undesirable.

13. Duonase[®] solves many of these long term problems. Duonase[®] provides superior and almost immediate relief from symptoms of AR, so much so that our patient's compliance and adherence with treatment improves considerably. Improved compliance and adherence ensures that my patients not only get fluticasone with the fast-acting azelastine,

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but continue to take it for periods ranging from 2 weeks to 2 months. Furthermore, I have observed that with the use of Duonase® the side effects which are encountered with oral anti histamine are surmounted. Duonase® has also substantially reduced both our prescription, and the patients' use, of decongestants, and their subsequent rebound congestant effects. Duonase® use has obviated the need for topical decongestants in our practice. Accordingly, in comparison to traditional treatments, the number of medications comes down, the rhinitis is now better controlled, and the patient is maintained on anti-inflammatories more consistently through use of Duonase®.

14. For patients with moderate to severe intermittent rhinitis, Duonase® is the treatment of choice. Duonase® serves as an excellent short-term treatment (lasting 10 to 14 days) to bring all symptoms of AR quickly under control, with minimal side effects, and with an increased efficacy over mono-therapy treatments. Future episodes of moderate to severe symptoms, even in a patient with intermittent AR, when the patient is travelling and especially when primary care physician is not accessible, would tremendously benefit with a short 10-14 days course of nasal corticosteroids and antihistamine combination provided by Duonase®. This could therefore be prescribed as an action plan, just as "prednisolone rescue courses" are in asthma. All in all, Duonase® is an indispensable part of our therapeutic armamentarium in the treatment of both AR and non-allergic vasomotor rhinitis.

15. In summary, it is my opinion that the claimed composition represents the fulfillment of a long-felt, but previously unmet, need by patients and healthcare practitioners for management of symptoms of AR and non-allergic vasomotor rhinitis via its superior efficacy, improved compliance and adherence with treatment, faster response time, and reduced side effects.

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