



Aptalis Pharma US, Inc.
100 Somerset Corporate Boulevard
Bridgewater, NJ 08807
United States

Tel: (908) 927-9600
1-877-275-1925
Fax: (908) 927-9648

www.aptaispharma.com

August 15, 2013

Dear Pharmacist:

I am the Assistant General Counsel, Vice President, Patents for Aptalis Pharma US, Inc. ("Aptalis") and I am following up regarding Dr. David Ellis' correspondence to you dated August 15, 2013, informing you of the recent launch of RECTIV[®] Ointment 0.4%, the first and only FDA-approved medication for the treatment of moderate to severe pain associated with chronic anal fissure.

As you are now aware from Dr. Ellis' letter, Aptalis has expended considerable resources in obtaining FDA approval for RECTIV[®] Ointment, including the support of clinical studies. Aptalis has also incurred considerable expense obtaining exclusive rights to U.S. Patent No. 7,189,761 titled *Nitric Oxide Donor Composition and Method for Treatment of Anal Disorders* ("the '761 patent"), which covers the use of RECTIV[®] Ointment and is listed in the FDA's Orange Book. As the result of Aptalis' exclusive license under the '761 patent, it has the right to exclude others from preparing a nitric oxide donor composition for administration to a patient for the treatment of pain associated with anal disorders. Furthermore, our patent rights covers the use of the compositions wherein the concentration of nitric oxide donor is in the range of 0.01 % to 10%. The '761 patent also covers the use of compounded compositions that also comprise carriers, are formulated in different forms, and/or that further comprise other therapeutics.

In view of the expenses incurred to secure our exclusive market position, we want to emphasize that Pharmacy has not been granted any rights under the '761 patent to market, promote, distribute or sell compounded compositions comprising an organic nitric oxide donor (e.g., nitroglycerine) for use in ameliorating a patient's pain associated with an anal disorder, such as an anal fissure in contravention of our patent. As mentioned in Dr. Ellis' letter, there are multiple sources where you can purchase directly the FDA-approved RECTIV[®] Ointment to fill prescriptions. To reiterate, RECTIV[®] Ointment, including the following drug wholesalers:

Wholesaler	Order Number
AmerisourceBergen	195-404/10109463
Cardinal Health	4768198
H.D. Smith	355-7063
Kinray	849-851
McKesson	2008977

Rectiv NDC#:58914-301-80

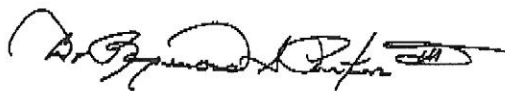
Aptalis recognizes that there may be circumstances, pursuant to FDA's Guidelines, where a need arises to compound a composition comprising an organic nitric oxide donor for use in ameliorating a patient's pain associated with an anal disorder. In such limited cases, Aptalis is willing to consider possible business arrangements with Pharmacy regarding Aptalis' patented technology to allow you to meet your customers' needs.

Such an arrangement could include, for example, Aptalis potentially providing a license on commercially reasonable terms that would enable [redacted] Pharmacy to make, use and sell Aptalis' patented technology. If you are interested in exploring the possibility of a cooperative arrangement with Aptalis, I would welcome your call or inquiry. I can be reached at (908) 927-9600, ext. 4096.

I would appreciate a written response to this letter within 30 days, (1) confirming that [redacted] Pharmacy is not involved in or will discontinue any unauthorized marketing, promotion or sale of compounded nitroglycerin compositions for administration to a patient for the treatment of pain associated with anal disorders and instead order RECTIV[®] Ointment directly through a drug wholesaler to fill its prescriptions for such compositions; and (2) providing notice whether [redacted] Pharmacy is interested in pursuing a cooperative arrangement for those circumstances where the FDA guidelines provides for a compounded composition deemed appropriate by a doctor that is slightly different than commercially available with RECTIV[®] Ointment.

Thank you in advance for your consideration of this matter.

Regards,



Raymond S. Parker, III, PhD
Assistant General Counsel, Vice President, Patents
Aptalis Pharma US, Inc.