

PATENT
Attorney Docket No.: 0134.0015
Customer No.: 39878

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Beth A. Burnside et al. Confirmation No.: 7066
Application Number : 10/940,265
Filed : 14 September 2004
Title : ANTIBIOTIC PRODUCT, USE AND FORMULATION THEREOF
TC/Art Unit : 1628
Examiner: : Paul E. Zarek

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APPEAL BRIEF UNDER BOARD RULE 37 C.F.R. § 41.37

In support of the Notice of Appeal filed 19 October 2012, and pursuant to Board Rule 41.37, Appellant presents this brief and pays the small entity fee of \$315.00 required under 37 C.F.R. § 41.20(b)(2). This Appeal Brief is due by 19 December 2012 and is timely filed.

This Appeal responds to the final rejection of claims 1-5, 7-37, 39, and 40 set forth in the Final Office Action mailed 19 July 2012.

If any additional fees are required or if the submitted payment is insufficient, Appellant requests that the required fees be charged to Deposit Account No. 50-2961.

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V. Summary of the Claimed Subject Matter

The claimed subject matter under examination is directed generally to antibiotic products. Claims 1, 37, and 39 are the only independent claims.

Claim 1 is directed to a once-a-day, oral antibiotic product comprising three dosage forms, where the first and second dosage forms are delayed release dosage forms and the third dosage form is a delayed sustained release dosage form (i.e., a DR-DR-DSR release profile) and where the antibiotic product does not contain any immediate release dosage forms. Each of the dosage forms comprises at least one antibiotic having a half life of 2-10 hours and a pharmaceutically acceptable carrier. The third dosage form initiates release of antibiotic after the second dosage form initiates release of antibiotic, and the second dosage form initiates release of antibiotic after the first dosage form initiates release of antibiotic. C_{max} of the total antibiotic release from the antibiotic product is achieved in less than 12 hours from initial release of antibiotic and the once-a-day antibiotic product contains the total dosage of antibiotic for a twenty-four hour period. Support for claim 1 can be found throughout the specification, including, for example, at paragraphs [0013], [0015], [0021], [0022], [0032], [0033], and [0064] and in original claims 1, 3, and 6.

Claim 37 is similar to claim 1 except the antibiotic is amoxicillin. Thus, claim 37 is directed to a once-a-day, oral amoxicillin product comprising three dosage forms, where the first and second dosage forms are delayed release dosage forms and the third dosage form is a delayed sustained release dosage form (i.e., a DR-DR-DSR release profile) and where the antibiotic product does not contain any immediate release dosage forms. Each of the dosage forms comprises amoxicillin and a pharmaceutically acceptable carrier. The third dosage form initiates release of amoxicillin after the second dosage form initiates release of amoxicillin, and the second dosage form initiates release of amoxicillin after the first dosage form initiates release

of amoxicillin. C_{max} of the total amoxicillin release from the antibiotic product is achieved in less than 12 hours from initial release of amoxicillin and the once-a-day amoxicillin product contains the total dosage of amoxicillin for a twenty-four hour period. Support for claim 37 can be found throughout the specification, including, for example, at paragraphs [0013], [0015], [0021], [0022], [0032], [0033], and [0064] and in original claims 1, 3, and 6.

Claim 39 is similar to claim 1 except the antibiotic is azithromycin. Thus, claim 39 is directed to a once-a-day, oral azithromycin product comprising three dosage forms, where the first and second dosage forms are delayed release dosage forms and the third dosage form is a delayed sustained release dosage form (i.e., a DR-DR-DSR release profile) and where the antibiotic product does not contain any immediate release dosage forms. Each of the dosage forms comprises azithromycin and a pharmaceutically acceptable carrier. The third dosage form initiates release of azithromycin after the second dosage form initiates release of azithromycin, and the second dosage form initiates release of azithromycin after the first dosage form initiates release of azithromycin. C_{max} of the total azithromycin release from the antibiotic product is achieved in less than 12 hours from initial release of azithromycin and the once-a-day amoxicillin product contains the total dosage of azithromycin for a twenty-four hour period. Support for claim 39 can be found throughout the specification, including, for example, at paragraphs [0013], [0015], [0021], [0022], [0032], [0033], and [0064] and in original claims 1, 3, and 6.

The remaining claims under rejection depend directly or indirectly from claim 1.