Exhibit 1004

'183 Patent File History ("FH183") Amendment 4/5/2007

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UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Plachetka, et al.

Appl. No.: 10/741,592

Filed: December 22, 2003

For: Multilayer Dosage Forms Containing NSAIDs and Triptans Art Unit: 1615

Examiner: Sharon Kennedy

Atty. Dkt.: 7569/80923

Amendment and Response Under 37 C.F.R. §1.111

Commissioner of Patents U.S. Patent and Trademark Office Customer Service Window, **MS Amendment** Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir:

In response to the Office Action dated December 20, 2006, Applicants respectfully request reconsideration of the above-captioned application in view of the following amendments and remarks.

A Listing of Claims begins on page 2 of the present document.

Remarks/Arguments begin on page 5 of the present document.

Amendments to the Claims

Please amend claims as shown below in the List of Claims.

List of Claims

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- 1. (Currently) A multilayer pharmaceutical tablet comprising naproxen and a triptan and, wherein:
 - a) substantially all of said triptan is in a first layer of said tablet and substantially all of said naproxen is in a second, separate layer; and
 - b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said NSAID <u>naproxen</u> occurs independently of said triptan.
- 2. (Original) The tablet of claim 1, wherein said naproxen is in the form of naproxen sodium at between 200 and 600 mg.
- 3. (Original) The tablet of claim 1, wherein said triptan is selected from the group consisting of: sumatriptan, eletriptan, rizatriptan, frovatriptan, almotriptan, zolmitriptan, and naratriptan.
- 4. (Original) The tablet of claim 1, wherein said triptan is sumatriptan.
- 5. (Original) The tablet of claim 4, wherein said sumatriptan is in the form of sumatriptan succinate at between 25 and 100 mg.
- 6. (Original) The tablet of claim 1, wherein said first layer and said second layer are juxtaposed symmetrically along a single planar surface such that essentially all of said first layer is on one side of said planar surface and essentially all of said second layer is on the other side of said planar surface.

- 7. (Original) The tablet of claim 6, wherein said first layer and said second layer contact one another along said single planar surface.
- 8. (Original) The tablet of claim 6, wherein said first layer and said second layer are separated by at least one additional layer.
- 9. (Original) The tablet of any one of claims 1-8, wherein said tablet is a bilayer dosage form.
- 10. (Original) The tablet of any one of claims 1-8, further comprising a coating layer surrounding both said first layer and said second layer.
- 11. (Original) The tablet of any one of claims 2, 3 or 6-8, wherein said triptan is sumatriptan.
- 12. (Original) The tablet of claim 11, wherein said sumatriptan is in the form of sumatriptan succinate at between 25 and 100 mg.
- 13. (Original) A method of treating a patient for headache, comprising administering to said patient the tablet of any one of claims 1-8, wherein said patient is treated at a dosage effective to alleviate the pain associated with said headache.
- 14. (Original) The method of claim 13, wherein said headache is migraine headache.
- 15. (Original) A method of treating a patient for headache, comprising administering to said patient the tablet of claim 9, wherein said patient is treated at a dosage effective to alleviate the pain associated with said headache.
- 16. (Original) The method of claim 15, wherein said headache is migraine headache.

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- 17. (Original) A method of treating a patient for headache, comprising administering to said patient the tablet of claim 10, wherein said patient is treated at a dosage effective to alleviate the pain associated with said headache.
- 18. (Original) The method of claim 17, wherein said headache is migraine headache.
- 19. (Previously presented) A multilayer pharmaceutical tablet comprising an NSAID and a triptan, wherein
 - a) substantially all of said triptan is in a first layer of said tablet and substantially all of said NSAID is in a second, separate layer; and
 - b) said first layer and said second layer are in a side by side arrangement such that the dissolution of said NSAID occurs independently of said triptan.
- 20. (Previously presented) A method for rapid release of sumatriptan and naproxen from an oral dosage form in a patient, the method comprising administering to said patient the tablet of claim 4 or claim 5, wherein in said patient, dissolution of sumatriptan and naproxen is faster from said tablet as compared to dissolution of sumatriptan and naproxen from a tablet where sumatriptan and naproxen are in a physical admixture.

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