

Exhibit D

PATENT CLAIM COVERAGE OF APPROVED PRODUCT

Applicable Claims of U.S. Patent No. 5,817,338	Manner in Which Each Claim Reads on Approved Product (Prilosec OTC), Method of Using or Method of Manufacturing the Approved Product
1. A pharmaceutical multiple unit tablet composition for oral treatment of gastrointestinal disorder comprising: at least one tablet excipient; and a multiple of a pellet or granule, the pellet or granule ranging between 0.1 mm and 2 mm in size and comprising an active ingredient selected from the group consisting of omeprazole, a single enantiomer of omeprazole, an alkaline salt of omeprazole; and an alkaline salt of a single enantiomer of omeprazole; and the pellet or granule being covered with at least one enteric coating layer comprising a plasticizing compound in the amount of more than about 20% to less than about 50% by weight of the enteric coating layer polymer so as to minimize the reduction of acid resistance of the enteric coating layered units upon compression into the tablet form.	A Prilosec OTC™ (omeprazole magnesium delayed-release, 20 mg) (“Prilosec OTC”) tablet is a pharmaceutical multiple unit composition approved for the oral treatment of frequent heartburn for consumers aged 18 and older. The Prilosec OTC tablet comprises at least one tablet excipient and several hundred pellets. The pellet ranges between 0.1 mm and 2 mm in size, comprises the magnesium salt of omeprazole as the active ingredient, and is covered with at least one enteric coating layer. The enteric coating layer comprises a plasticizing compound in the amount of more than about 20% to less than about 50% by weight of the enteric coating layer polymer so as to minimize the reduction in acid resistance of the enteric-coated pellets upon compression into the tablet form. Prilosec OTC tablets are therefore within the scope of claim 1.
2. The composition according to claim 1, wherein the acid resistance of the individually enteric coating layered units is in coherence with the requirements on enteric coated articles defined in the United States Pharmacopeia.	The Prilosec OTC tablet comprises multiple enteric-coated pellets, which have a resistance to acid that is in accordance with the requirements for enteric-coated articles defined in the United States Pharmacopeia. Prilosec OTC tablets are therefore within the scope of claim 2.
3. The composition according to claim 1, wherein the acid resistance of the individually enteric coating layered units does not decrease more than 10% during the compression of the individual units into the multiple unit tableted dosage form.	The acid resistance of the enteric-coated pellets does not decrease more than 10% during the compression of the individual pellets into Prilosec OTC tablets. Prilosec OTC tablets are therefore within the scope of claim 3.
4. The tablet composition according to claim 1 wherein the enteric coating layer or a multiple thereof comprises a thickness of at least 10 µm.	The Prilosec OTC tablet comprises multiple pellets, which comprise an enteric coating layer comprising a thickness of at least 10 µm. Prilosec OTC tablets are therefore within the scope of claim 4.
5. The tablet composition according to claim 1 wherein each enteric coating layered unit is covered with an over-	The Prilosec OTC tablet comprises multiple pellets, which are covered with an over-coating layer comprising a pharmaceutically acceptable excipient.

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coating layer comprising a pharmaceutically acceptable excipient.	Prilosec OTC tablets are therefore within the scope of claim 5.
6. The tablet composition according to claim 1, wherein the pellet or granule further comprises at least one alkaline compound.	The Prilosec OTC tablet comprises multiple pellets, which further comprise at least one alkaline compound. Prilosec OTC tablets are therefore within the scope of claim 6.
7. The composition according to claim 1, wherein the active ingredient is a magnesium salt of omeprazole having a degree of crystallinity which is higher than 70% as determined by X-ray powder diffraction.	The Prilosec OTC tablet comprises multiple pellets, which comprise, as the active ingredient, the magnesium salt of omeprazole having a crystallinity higher than 70% as determined by X-ray powder diffraction. Prilosec OTC tablets are therefore within the scope of claim 7.
9. The composition according to claim 1, wherein the multiple unit form is divisible.	The Prilosec OTC tablet comprises several hundred individual enteric-coated pellets and is divisible. Prilosec OTC tablets are therefore within the scope of claim 9.
10. The composition according to claim 1, wherein the multiple unit form is dispersible to a suspension of individually enteric coating layered units in an aqueous liquid.	The Prilosec OTC tablet is formulated to disintegrate shortly after ingestion, thereby dispersing the enteric-coated pellets in the stomach. If a tablet is placed into an aqueous liquid, the same disintegration event will take place to yield a suspension of, inter alia, the individual enteric-coated pellets. Prilosec OTC tablets are therefore within the scope of claim 10.
<p>11. A process for the manufacture of the oral pharmaceutical composition according to claim 1 comprising the following steps:</p> <p>(a) Shaping a multiple of a pellet or granule comprising an active ingredient selected from the group consisting of omeprazole, a single enantiomer of omeprazole, an alkaline salt of omeprazole, and an alkaline salt of a single enantiomer of omeprazole;</p> <p>(b) covering the pellet or granule of step (a) with at least one enteric coating layer having advantageous mechanical properties;</p> <p>(c) mixing a multiple of the enteric coating layered pellet or granule of step (b) with at least one tablet excipient; and</p> <p>(d) compressing the mixture into, tablet</p>	<p>The process of manufacturing Prilosec OTC tablets comprises the following steps:</p> <p>(a) Shaping a multiple of a pellet comprising a sugar sphere (seed) layered with the magnesium salt of omeprazole;</p> <p>(b) Covering the pellet of step (a) with a separating layer, further covering with at least one enteric coating layer, and further covering with an over-coating layer;</p> <p>(c) Mixing a multiple of the pellet of step (b) with at least one tablet excipient; and</p> <p>(d) Compressing the mixture into tablet form without</p>

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form without significantly affecting the acid resistance of the enteric coating layered units due to the advantageous mechanical properties of the enteric coating.	significantly affecting the acid resistance of the enteric-coated pellets due to the advantageous mechanical properties of the enteric coating, and coating and drying of the tablets. The process of manufacturing Prilosec OTC tablets is therefore within the scope of claim 11.
12. The composition according to claim 1, wherein the pellet or granule comprises a seed layered with the active ingredient.	The Prilosec OTC tablet comprises multiple pellets, which comprise a sugar sphere (seed) layered with the magnesium salt of omeprazole. Prilosec OTC tablets are therefore within the scope of claim 12.
13. The composition according to claim 12, wherein the seeds have a size of 0.1-2mm.	The sugar spheres (seeds) within the pellets in Prilosec OTC tablets have a size of 0.1-2mm. Prilosec OTC tablets are therefore within the scope of claim 13.
14. A process according to claim 11, wherein the individually enteric coating layered units are further coated with an over-coating layer.	In manufacturing Prilosec OTC tablets, the enteric-coated pellets are further coated with an over-coating layer. The process of manufacturing Prilosec OTC tablets is therefore within the scope of claim 14.
15. A method for inhibiting gastric acid secretion in mammals and man comprising administering to a host in a need thereof a therapeutically effective dose of the composition according claim 1.	The magnesium salt of omeprazole is useful for inhibiting gastric acid secretion in humans. Prilosec OTC tablets have been approved for treatment of frequent heartburn in consumers 18 years and older. The method of treatment of frequent heartburn by administration of Prilosec OTC tablets is therefore within the scope of claim 15.
17. A press-through blister package comprising at least one press-through blister; comprising a pharmaceutical multiple unit tablet of the composition according to claim 1.	Prilosec OTC tablets are approved for marketing in 14-, 28- and 42-tablet packages, wherein the tablets are in 7-tablet blister packages. In order to access a tablet, the consumer must peel, then push the tablet through foil. The packaging of Prilosec OTC tablets that has been approved for marketing is therefore within the scope of claim 17.
18. The composition according to claim 1 wherein the alkaline salt is a magnesium salt.	In Prilosec OTC tablets the active ingredient is the alkaline magnesium salt of omeprazole. Prilosec OTC tablets are therefore within the scope of claim 18.
19. The composition according to claim 22 wherein the separating layer further comprises at least one alkaline compound.	The Prilosec OTC tablet comprises pellets, which comprise a separating layer further comprising at least one alkaline compound. Prilosec OTC tablets are therefore within the scope of claim 19.
20. The process according to claim 11, wherein the pellet or granule further comprises at least one alkaline compound.	The Prilosec OTC tablet comprises pellets, which further comprise at least one alkaline compound. The process of manufacturing Prilosec OTC tablets is therefore within the scope of claim 20.
21. The process according to claim 11, further comprising the step of covering	The process of manufacturing Prilosec OTC tablets comprises a step of covering the pellet of step (a) with

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the pellet or granule of step (a) with a separating layer or a multiple thereof.	a separating layer and is therefore within the scope of claim 21.
22. The tablet composition according to claim 1, wherein the pellet or granule is further covered by at least one separating layer which comprises a pharmaceutically acceptable excipient which is soluble, or insoluble but disintegrating in water, the separating layer being located under the enteric coating layer.	The Prilosec OTC tablet comprises pellets covered by at least one separating layer (covered by an enteric coating layer) comprising a pharmaceutically acceptable excipient that disintegrates in water. Prilosec OTC tablets are therefore within the scope of claim 22.
23. The composition according to claim 1, wherein the enteric coating layer applied to a pellet or granule has a Vickers hardness value of less than 8.	The Prilosec OTC tablet comprises pellets which have an enteric coating layer that has a Vickers hardness value of less than 8. Prilosec OTC tablets are therefore within the scope of claim 23.
24. The process according to claim 11, wherein the enteric coating layer covering the pellet or granule has a thickness of at least 10 μm .	The process of manufacturing Prilosec OTC tablets comprises a step of covering the pellet with the enteric coating layer, which has a thickness of at least 10 μm . The process of manufacturing Prilosec OTC tablets is therefore within the scope of claim 24.
25. The process according to claim 11, wherein the pellet or granule of step (a) is shaped by layering the active ingredient on a seed ranging from about 0.1 to about 2.0 mm.	The process of manufacturing Prilosec OTC tablets comprises a step of shaping the pellet of step (a) by layering the omeprazole magnesium on a sugar sphere (seed) ranging from about 0.1 to about 2.0 mm. The process of manufacturing Prilosec OTC tablets is therefore within the scope of claim 25.