

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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TYCO HEALTHCARE GROUP LP and	:	
MALLINCKRODT INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	
	:	
	:	
PHARMACEUTICAL HOLDINGS	:	
CORPORATION, MUTUAL	:	Civil Action No. _____
PHARMACEUTICAL COMPANY, INC. and	:	
UNITED RESEARCH LABORATORIES, INC.	:	
	:	
Defendants.	:	
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**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Tyco Healthcare Group LP and Mallinckrodt Inc. (hereinafter “Plaintiffs”), for their Complaint against Defendants Pharmaceutical Holdings Corporation, Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. allege as follows:

**NATURE OF ACTION**

1. This is an action for patent infringement.

**PARTIES**

2. Plaintiff Tyco Healthcare Group LP (“Tyco Healthcare”) is a limited partnership organized and existing under the laws of the State of Delaware, having its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048.

3. Plaintiff Mallinckrodt Inc. (“Mallinckrodt”) is a corporation organized and

existing under the laws of the State of New York, having its principal place of business at 675 McDonnell Boulevard, P.O. Box 5840, Hazelwood, Missouri 63042.

4. On information and belief, Defendant Pharmaceutical Holdings Corporation (“Pharmaceutical Holdings”), is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

5. On information and belief, Defendant Mutual Pharmaceutical Company, Inc. (“Mutual Pharmaceutical”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

6. On information and belief, Defendant United Research Laboratories, Inc. (“United”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124.

7. On information and belief, Mutual Pharmaceutical and United are both wholly-owned subsidiaries of Pharmaceutical Holdings, and all three Defendants have common officers and directors.

8. Defendants Pharmaceutical Holdings, Mutual Pharmaceutical and United are hereinafter collectively referred to as “Mutual”.

**JURISDICTION AND VENUE**

9. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, Mutual sells various products and conducts business throughout the United States, including within this District.

11. On information and belief, Mutual manufactures pharmaceutical products that are regularly sold and used throughout the United States, including within this District.

12. On information and belief, Mutual Pharmaceutical and United have previously submitted to the jurisdiction of this Court.

13. This Court has personal jurisdiction over Pharmaceutical Holdings, Mutual Pharmaceutical and United by virtue of, *inter alia*, the facts alleged in paragraphs 4-7 and 10-12.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 (c) and 1400(b).

**FIRST CLAIM FOR RELIEF -  
INFRINGEMENT OF THE '632 PATENT**

15. Plaintiffs reallege paragraphs 1-14 as if specifically set forth here.

16. Plaintiff Tyco Healthcare holds an approved Supplement (No. S-022) to an approved new drug application ("NDA") No. 18-163 for Restoril<sup>®</sup> capsules (7.5 mg), which contain the active ingredient temazepam. By way of NDA Supplement (No. S-022) Restoril<sup>®</sup> 7.5

mg capsules were approved by the United States Food and Drug Administration (“FDA”) on October 25, 1991 for the treatment of transient insomnia.

17. Temazepam is described in chemical nomenclature as 7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one.

18. Mallinckrodt is the owner of United States Patent No. 5,030,632 (“the ‘632 patent”), which discloses and claims a method of treating transient insomnia consisting essentially of administering to a human in need of treatment for transient insomnia a hard gelatin capsule containing not more than 5 to 10 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having particle size diameters of less than 65 microns. The ‘632 patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on July 9, 1991. A true copy of the ‘632 patent is attached hereto as Exhibit A .

19. Mutual submitted to the FDA an Abbreviated New Drug Application (“ANDA”) under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of generic temazepam capsules in a dosage strength of 7.5 mg (hereinafter referred to as “Mutual’s Temazepam Capsules”) before the expiration of the ‘632 patent.

20. By filing its ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of Mutual’s Temazepam Capsules before the expiration of the ‘632 patent, Mutual has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). Further, the commercial manufacture, use, offer for sale, sale and/or importation

of Mutual's Temazepam Capsules will also infringe one or more claims of the '632 patent.

21. Each of Mutual's Temazepam Capsules, if approved by the FDA, will be used in a method of treating transient insomnia, consisting essentially of administering to a human in need of treatment for transient insomnia a hard gelatin capsule containing not more than 5 to 10 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having particle size diameters of less than 65 microns. Such administration will constitute direct infringement of the '632 patent under 35 U.S.C. § 271(a).

22. On information and belief, Mutual, with knowledge of the '632 patent, and knowing that such administration mentioned in paragraph 21 above will directly infringe the '632 patent, and with the intent to cause the acts which constitute such direct infringement, will actively induce, encourage, aid and abet such acts, thus itself infringing the '632 patent under 35 U.S.C. § 271(b).

23. On information and belief, Mutual, with knowledge of the '632 patent, and knowing that such administration mentioned in paragraph 21 above will directly infringe the '632 patent, will contribute to the infringement of the '632 patent under 35 U.S.C. § 271(c) by offering for sale and selling in the United States Mutual's Temazepam Capsules, which are a component and a material part of the patented method, and not a staple article or commodity of commerce suitable for substantial non-infringing use. Mutual will conduct such activities knowing that Mutual's Temazepam Capsules are especially made and/or adapted for use in infringing the '632 patent. Patients using Mutual's Temazepam Capsules will infringe the '632 patent under 35 U.S.C. § 271(a).

24. Mutual made, and included in its ANDA, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV Certification”) that, in its opinion and to the best of its knowledge, Mutual does not infringe the ‘632 patent.

25. In early February 2007, Mutual sent to Plaintiffs Tyco Healthcare and Mallinckrodt a notice letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto (“Notice Letter”), in which Mutual represented that it had filed an ANDA for its Temazepam Capsules, including its certification with respect to the ‘632 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

26. In its Notice Letter, Mutual did not allege that the ‘632 patent was unenforceable or invalid.

27. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mutual’s Temazepam Capsules be a date which is not earlier than July 9, 2008, the expiration date of the ‘632 patent, or any later date of exclusivity to which Plaintiffs are or become entitled.

28. Plaintiffs also are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or importation of Mutual’s Temazepam Capsules, and any act committed by Mutual with respect to the subject matter claimed in the ‘632 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

29. On information and belief, when Mutual filed its ANDA, it was aware of

the '632 patent and that the filing of its ANDA seeking approval prior to the expiration of the '632 patent was an act of infringement of that patent.

**SECOND CLAIM FOR RELIEF -  
INFRINGEMENT OF THE '954 PATENT**

30. Plaintiffs reallege paragraphs 1-14 and 16-17 as if specifically set forth here.

31. Mallinckrodt is the owner of United States Patent No. 5,211,954 ('the '954 patent") which discloses and claims hard gelatin capsules containing a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having a particle size of less than 65 microns. The '954 patent was duly and legally issued by the USPTO on May 18, 1993. A true copy of the '954 patent is attached as Exhibit B.

32. Mutual submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '954 patent.

33. By filing its ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '954 patent, Mutual has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Mutual's Temazepam Capsules will also infringe one or more claims of the '954 patent.

34. The manufacture, use, offer for sale, sale and/or importation of Mutual's

Temazepam Capsules, if approved by the FDA, will constitute direct infringement of the '632 patent under 35 U.S.C. § 271(a).

35. Mutual made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, Mutual does not infringe the '954 patent.

36. In early February 2007, Mutual sent to Plaintiffs Tyco Healthcare and Mallinckrodt a notice letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto ("Notice Letter"), in which Mutual represented that it had filed an ANDA for its Temazepam Capsules, including its certification with respect to the '954 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

37. In its Notice Letter, Mutual did not allege that the '954 patent was unenforceable or invalid.

38. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mutual's Temazepam Capsules be a date which is not earlier than May 18, 2010, the expiration date of the '954 patent, or any later date of exclusivity to which Plaintiffs are or become entitled.

39. Plaintiffs also are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or importation of Mutual's Temazepam Capsules, and any act committed by Mutual with respect to the subject matter claimed in the '954 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).



40. On information and belief, when Mutual filed its ANDA, it was aware of the '954 patent and that the filing of its ANDA seeking approval prior to the expiration of the '954 patent was an act of infringement of that patent.

**THIRD CLAIM FOR RELIEF -  
INFRINGEMENT OF THE '758 PATENT**

41. Plaintiffs reallege paragraphs 1-14 and 16-17 as if specifically set forth here.

42. Mallinckrodt is the owner of United States Patent No. 5,326,758 ("the '758 patent") which discloses and claims a method of treating transient insomnia which comprises administering orally to a human in need of treatment for transient insomnia a temazepam formulation consisting essentially of 5 to 10 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1m<sup>2</sup>/g and 95% of the temazepam having a particle size of less than 65 microns. The '758 patent was duly and legally issued by the USPTO on July 5, 1994. A true copy of the '758 patent is attached as Exhibit C.

43. Mutual submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '758 patent.

44. By filing its ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '758 patent, Mutual has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). Further, the commercial manufacture, use, offer for sale, sale and/or importation

of Mutual's Temazepam Capsules will also infringe one or more claims of the '758 patent.

45. Each of Mutual's Temazepam Capsules, if approved by the FDA, will be used in a method of treating transient insomnia which comprises administering orally to a human in need of treatment for transient insomnia a temazepam formulation consisting essentially of 5 to 10 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having a particle size of less than 65 microns. Such administration will constitute direct infringement of the '758 patent under 35 U.S.C. § 271(a).

46. On information and belief, Mutual, with knowledge of the '758 patent, and knowing that such administration mentioned in paragraph 45 above will directly infringe the '758 patent, and with the intent to cause the acts which constitute such direct infringement, will actively induce, encourage, aid and abet such acts, thus itself infringing the '758 patent under 35 U.S.C. § 271(b).

47. On information and belief, Mutual, with knowledge of the '758 patent, and knowing that such administration mentioned in paragraph 45 above will directly infringe the '758 patent, will contribute to the infringement of the '758 patent under 35 U.S.C. § 271(c) by offering for sale and selling in the United States Mutual's Temazepam Capsules, which are a component and a material part of the patented method, and not a staple article or commodity of commerce suitable for substantial non-infringing use. Mutual will conduct such activities knowing that Mutual's Temazepam Capsules are especially made and/or adapted for use in infringing the '758 patent. Patients using Mutual's Temazepam Capsules will infringe the '758 patent under 35 U.S.C. § 271(a).

48. Mutual made, and included in its ANDA, a Paragraph IV Certification that, in its opinion and to the best of its knowledge, Mutual does not infringe the '758 patent.

49. In early February 2007, Mutual sent to Plaintiffs Tyco Healthcare and Mallinckrodt a notice letter, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B)(iv)(II) and the FDA regulations relating thereto ("Notice Letter"), in which Mutual represented that it had filed an ANDA for its Temazepam Capsules, including its certification with respect to the '758 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

50. In its Notice Letter, Mutual did not allege that the '758 patent was unenforceable or invalid.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mutual's Temazepam Capsules be a date which is not earlier than July 9, 2008, the expiration date of the '758 patent, or any later date of exclusivity to which Plaintiffs are or become entitled.

52. Plaintiffs also are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or importation of Mutual's Temazepam Capsules, and any act committed by Mutual with respect to the subject matter claimed in the '758 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

53. On information and belief, when Mutual filed its ANDA, it was aware of the '758 patent and that the filing of its ANDA seeking approval prior to the expiration of the

'758 patent was an act of infringement of that patent.

**FOURTH CLAIM FOR RELIEF -  
INFRINGEMENT OF THE '310 PATENT**

54. Plaintiffs reallege paragraphs 1-14 and 16-17 as if specifically set forth here.

55. Mallinckrodt is the owner of United States Patent No. 5,629,310 ("the '310 patent") which discloses and claims a method of treating insomnia which comprises administering orally to a human in need of treatment for insomnia a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having a particle size of less than 65 microns. The '310 patent was duly and legally issued by the USPTO on May 13, 1997. A true copy of the '310 patent is attached as Exhibit D.

56. Mutual submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '310 patent.

57. By filing its ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use or sale of Mutual's Temazepam Capsules before the expiration of the '310 patent, Mutual has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Mutual's Temazepam Capsules will also infringe one or more claims of the '310 patent.

58. Each of Mutual's Temazepam Capsules, if approved by the FDA, will be used in a method of treating insomnia which comprises administering orally to a human in need of treatment for insomnia a temazepam formulation consisting essentially of 6 to 8 milligrams of crystalline temazepam having a surface area of from 0.65 to 1.1 m<sup>2</sup>/g and 95% of the temazepam having a particle size of less than 65 microns. Such administration will constitute direct infringement of the '310 patent under 35 U.S.C. § 271(a).

59. On information and belief, Mutual, with knowledge of the '310 patent, and knowing that such administration mentioned in paragraph 58 above will directly infringe the '310 patent, and with the intent to cause the acts which constitute such direct infringement, will actively induce, encourage, aid and abet such acts, thus itself infringing the '310 patent under 35 U.S.C. § 271(b).

60. On information and belief, Mutual, with knowledge of the '758 patent, and knowing that such administration mentioned in paragraph 58 above will directly infringe the '310 patent, will contribute to the infringement of the '310 patent under 35 U.S.C. § 271(c) by offering for sale and selling in the United States Mutual's Temazepam Capsules, which are a component and a material part of the patented method, and not a staple article or commodity of commerce suitable for substantial non-infringing use. Mutual will conduct such activities knowing that Mutual's Temazepam Capsules are especially made and/or adapted for use in infringing the '310 patent. Patients using Mutual's Temazepam Capsules will infringe the '310 patent under 35 U.S.C. § 271(a).

61. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4),

including an Order of this Court that the effective date of any approval of the aforementioned ANDA relating to Mutual's Temazepam Capsules be a date which is not earlier than July 9, 2008, the expiration date of the '310 patent, or any later date of exclusivity to which Plaintiffs are or become entitled.

62. Plaintiffs also are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or importation of Mutual's Temazepam Capsules, and any act committed by Mutual with respect to the subject matter claimed in the '310 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

63. On information and belief, when Mutual filed its ANDA, it was aware of the '310 patent and that the filing of its ANDA seeking approval prior to the expiration of the '310 patent was an act of infringement of that patent.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully request the following relief:

A. Judgment that Mutual has infringed one or more claims of the '632, '954, '758 and '310 patents by filing the aforesaid ANDA relating to Mutual's Temazepam Capsules;

B. A permanent injunction restraining and enjoining Mutual and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States, of drug products claimed, or the use of which is claimed, in the '632, '954, '758 and '310 patents;

C. An Order that the effective date of any approval of the aforementioned ANDA relating to Mutual's Temazepam Capsules be a date which is not earlier than the later of July 9, 2008, the expiration date of the '632, '758 and '310 patents, or May 18, 2010, the expiration date of the '954 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. Damages from Mutual for any commercial activity constituting infringement of the '632, '954, '758 and '310 patents; and

E. Such other and further relief as the Court may deem just and proper.

Dated: March 22, 2007

LMS2607

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