

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., )  
NAPP PHARMACEUTICAL GROUP )  
LTD., BIOVAIL LABORATORIES )  
INTERNATIONAL, SRL, and ORTHO- )  
MCNEIL, INC., )

Civil Action No. 07-255-KAJ  
(CONSOLIDATED)

Plaintiffs/Counterclaim- )  
defendants, )

v. )

PAR PHARMACEUTICAL, INC., and )  
PAR PHARMACEUTICAL )  
COMPANIES, INC., )

Defendants/Counterclaim- )  
plaintiffs. )

**MEMORANDUM OPINION**

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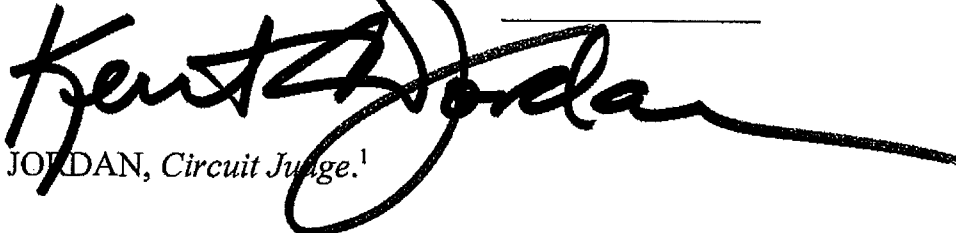
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JORDAN, Circuit Judge.<sup>1</sup>

## I. INTRODUCTION

Plaintiffs Purdue Pharma Products L.P. (“Purdue”); Napp Pharmaceutical Group LTD. (“Napp”); Biovail Laboratories International, SRL (“Biovail”);<sup>2</sup> and Ortho-McNeil, Inc. (“Ortho-McNeil”) filed this patent infringement action against Defendants Par Pharmaceutical, Inc. (“Par Pharmaceutical”) and Par Pharmaceutical Companies, Inc. (“Par Pharmaceutical Companies”) under the Hatch-Waxman Act, 35 U.S.C. § 271(e). The Complaint<sup>3</sup> is based on Par Pharmaceutical’s submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”). (D.I. 78 at 3 ¶ 12; D.I. 98 at 7 ¶ 15.) With the ANDA, Defendants seek FDA

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<sup>1</sup>Sitting by designation (Docket Item [“D.I.”] 241).

<sup>2</sup>The parties indicate that Biovail soon may be voluntarily dismissed from this case. (D.I. 259.)

<sup>3</sup>For ease of reference, Plaintiffs’ Amended Complaint (D.I. 78) is referred to herein as the “Complaint.”

approval to manufacture and market extended release tablets containing a generic version of the analgesic known as “tramadol.” (D.I. 78 at 3 ¶ 12; D.I. 98 at 3 ¶ 12.) At issue in this case is whether the ANDA submission infringes U.S. Patent No. 6,254,887 (the “887 patent”), whether the tablets described in the ANDA would, if manufactured and marketed, infringe U.S. Patent No. 7,074,430 (the “430 patent”), and whether those patents are valid and enforceable.

Before me are the parties’ requests that I construe the disputed claim language of the ‘887 and ‘430 patents. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff’d* 517 U.S. 370 (1996). The parties have fully briefed and argued their positions. Jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338.

## II. BACKGROUND

### A. The Parties

Plaintiffs Purdue and Napp are owners by assignment of the ‘887 and ‘430 patents. (D.I. 78 at 1-2.) Biovail is the holder of New Drug Application (“NDA”) No. 21-692 and manufactures the controlled release tramadol pain relief medication ULTRAM ® ER.<sup>4</sup> (*Id.* at 2 ¶ 6.) Ortho-McNeil is a licensee of the ‘887 patent and markets and distributes ULTRAM ® ER in the United States. (*Id.* at 2 ¶ 7.)

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<sup>4</sup>ULTRAM ® ER contains a salt of tramadol, specifically tramadol hydrochloride. (*Id.* at 2 ¶ 6; D.I. 161 at 4; D.I. 222, Exh. 3 at 7.)

Based on the parties' submissions, the division of labor between the Par entities is unclear. Suffice it to say that Par Pharmaceutical is a wholly-owned subsidiary of Par Pharmaceutical Companies (*Id.*; D.I. 98 at 2-3), and it appears as though the Par entities are in the business of developing, manufacturing, and marketing generic versions of FDA-approved pharmaceuticals.

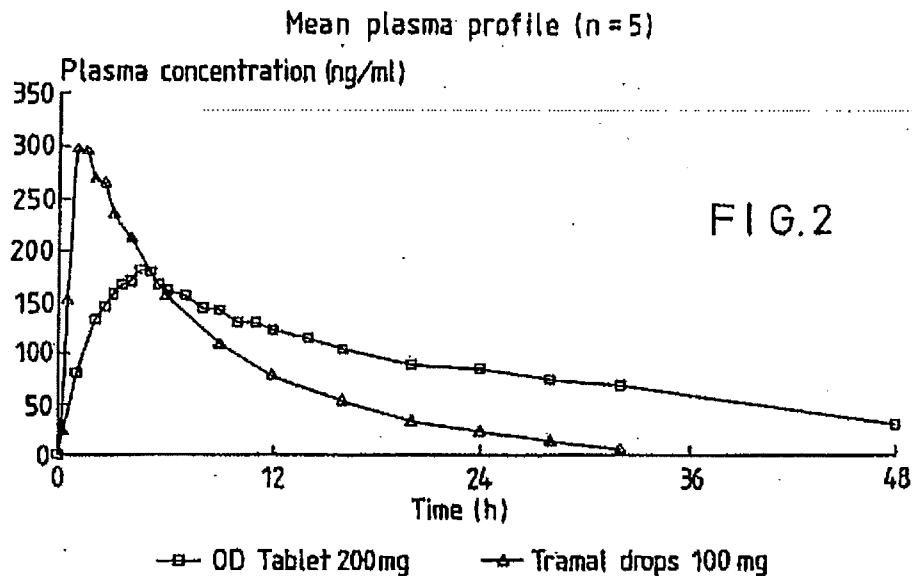
#### B. The Disclosed Technology

The application for the '887 patent was filed on July 10, 1996 as a divisional of U.S. Patent No. 5,591,452 (the "452 patent").<sup>5</sup> The '887 patent is directed to "a controlled release preparation comprising tramadol or a pharmaceutically acceptable salt thereof." ('887 patent at 1:8-9.) It has as an object "to provide an oral controlled release tramadol preparation suitable for at least twelve-hourly (e.g. up to twenty-four hourly) administration for pain." (*Id.* at 1:22-25.) Tramadol "is an orally active opioid analgesic ... [that has] been commercially available for many years for use in the treatment of moderate to severe pain." (*Id.* at 1:10-18.)

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<sup>5</sup>A "divisional" application is one carved out of an earlier application which disclosed and claimed more than one independent invention, the result being that the divisional application claims only one or more, but not all, of the independent inventions of the earlier application. *Transco Prods. Inc. v. Performance Contracting Group, Inc.*, 38 F.3d 551, 555 (Fed. Cir. 1994) (citing The Manual of Patent Examining Procedure (MPEP) § 201.06 (1988)).

The specification discloses the following figure comparing the plasma profile, in five healthy male volunteers, resulting from a single dose of controlled release tramadol ("OD Tablet 200mg") to immediate-release tramadol ("Tramal drops 100 mg"):



(*Id.* at Fig. 2, 12:11-14.)

Plaintiffs claim that the submission of Defendants' ANDA infringed claims 1, 3, 13, 15, 16, 19, 23, 27, 29 and 31 of the '887 patent. (D.I. 157 at 9.) All of the asserted claims either depend from or are closely related to claim 1. It reads as follows:

A controlled release oral pharmaceutical preparation suitable for dosing every 24 hours comprising

- a substrate comprising a pharmaceutically effective amount of tramadol or a salt thereof;
- said substrate coated with a controlled release coating;
- said preparation having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0,1 N hydrochloric acid at 37° C. and using UV detection at 270 nm,

between 0 and 50% tramadol released after 1 hour; between 0 and 75% tramadol released after 2 hours; between 3 and 95% tramadol released after 4 hours; between 10 and 100% tramadol released after 8 hours; between 20 and 100% tramadol released after 12 hours; between 30 and 100% tramadol released after 16 hours; between 50 and 100% tramadol released after 24 hours; and greater than 80% tramadol released after 36 hours, by weight, said preparation providing a therapeutic effect for about 24 hours after oral administration.

('887 patent at 12:16-34.)

The application for the '430 patent was filed on March 6, 2001 and is a continuation of the application that became the '887 patent.<sup>6</sup> Plaintiffs assert that the tablet described in Defendants' ANDA would infringe claims 1, 3, 5, 6, 7, 11, 12, 13, 14, and 15 of the '430 patent. (D.I. 157 at 9.) Claim 1 is the only independent claim in the '430 patent. It reads as follows:

A solid controlled release oral dosage form, comprising,  
a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a normal release matrix,  
said matrix overcoated with a controlled release coating comprising a polymethacrylate or a water insoluble cellulose,

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<sup>6</sup> A "continuation" application claims the same invention claimed in an earlier application, although there may be some variation in the scope of the subject matter claimed. *Transco Prods.*, 38 F.3d at 555 (citing MPEP § 201.07). Both a divisional and a continuation application share the same disclosure as the original application. *Id.* The '430 specification incorrectly states that the '887 patent application was filed as a continuation of the application that became the '452 patent. The file history for the '887 patent confirms that its application was filed as a divisional, rather than a continuation, of the application that became the '452 patent. (D.I. 163, Exh. C at PAR046152.)

said dosage form providing a therapeutic effect for at least about 24 hours.

('430 patent at 12:41-51.)

### C. The Procedural History

In January 2007, Defendants submitted an ANDA seeking FDA approval to sell generic tramadol extended release tablets. (D.I. 161 at 4.) Pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355(j)(iv), Defendants submitted information to show that its proposed generic tablet is bioequivalent to ULTRAM® ER. (D.I. 161 at 4.) Because the FDA lists ULTRAM® ER as covered by the '887 patent,<sup>7</sup> Defendants also certified that the '887 patent is invalid or will not be infringed by the manufacture, use, or sale of its generic tablets. (*Id.*; 21 U.S.C. § 355(j)(2)(A)(vii)(IV).)

Plaintiffs filed the current action on May 9, 2007. They allege that the submission of Defendants' ANDA infringed the '887 patent and they request a declaratory judgment that Defendants' tablets, if manufactured and marketed, would infringe the '430 patent.

(D.I. 78.)

### III. APPLICABLE LAW

The rules of claim construction are well known and need not be repeated here. It is sufficient to note that “the claims themselves provide substantial guidance as to the

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<sup>7</sup>For a description of the manner in which the FDA publishes information on drug products, see *Abbott Laboratories v. Teva Pharmaceuticals USA*, 432 F. Supp. 2d 408, 414-15 (D. Del. 2006).

meaning of particular terms” and that a patent’s specification “is always highly relevant to the claim construction analysis.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed Cir. 2005) (en banc) (citations omitted).

#### IV. CLAIM CONSTRUCTION

##### A. “therapeutic effect”

##### 1. The Parties’ Proposed Constructions

The parties appear to agree that the term “therapeutic effect” can be defined as “an effective treatment for pain.” Defendants explicitly adopt this understanding by using the synonymic term “analgesic efficacy” in their proposed claim construction (D.I. 161 at 1) and defining “therapeutic effect” as “pain relief” in their briefing.<sup>8</sup> Plaintiffs, on the other hand, initially defined “therapeutic effect” as “effective for the treatment of one or more clinical conditions, e.g., pain,” suggesting that “therapeutic effect” may apply to some condition other than pain. (D.I. 157 at 12.) At the *Markman* hearing, however, Plaintiffs conceded that the only clinical condition treated by the invention is pain (D.I. 249 at 45:15-20)<sup>9</sup> and defined “therapeutic effect” as “effective for the treatment of pain.”

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<sup>8</sup> See, e.g., “Given that the pharmaceutical or therapeutic effect of tramadol is analgesia (pain relief)...” (D.I. 181 at 12.); “And the term ‘therapeutic effect’ as it relates to tramadol, a known analgesic agent, would be considered to mean that the product described by the claims causes an analgesic effect, which is ‘reduced response to painful stimuli’...” (D.I. 161 at 15 (quoting Weinberger Dec., ¶ 15).); “[T]herapeutic effect for about 24 hours’ as it relates to orally administered tramadol is assessed for a duration of 24 hours from the time that pain relief begins, i.e., onset of action.” (D.I. 161 at 18.)

<sup>9</sup> D.I. 249 is the transcript of the *Markman* hearing.

(*Id.* at 45:4, 8-9.) Since Plaintiffs have adjusted their position, the parties share the understanding that “therapeutic effect” means “an effective treatment for pain.”

The parties’ remaining dispute regarding this term is whether the therapeutic effect must be “demonstrated by scientifically valid placebo-controlled clinical evidence.” (D.I. 247 at 3.) Defendants argue that a person of ordinary skill in the art would expect a “therapeutic effect” to be shown by a scientifically valid study. (D.I. 181 at 3.) Such a study, Defendants maintain, would necessarily include controls to account for the placebo effect.<sup>10</sup> (*Id.*) In support of that position, Defendants rely on the opinions of their experts, Dr. Weinberger and Dr. Grond. (D.I. 161 at 16-17 (citing Weinberger Dec. ¶ 18-20, 23); D.I. 181 at 3-4 (citing Grond Dec., ¶ 23).) Dr. Grond bases his opinion, in part, on two scholarly articles<sup>11</sup> from the applicable time period. (D.I. 181 at 3-4 (citing Grond Dec., ¶ 23).)

Defendants also contend that the prosecution history of the '430 patent supports their position. (D.I. 161 at 12-13.) Specifically, Defendants contend that during the prosecution of the '430 patent, the patentees distinguished a prior art reference, European Patent No. 0147780 (“the Bondi reference”), by arguing that “there are no clinical trials

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<sup>10</sup> “A placebo effect is a change in a patient’s illness attributable to the symbolic import of a treatment rather than a specific pharmacologic or physiological property.” Turner, J.A. et al. (1994) “The Importance of Placebo Effects in Pain Treatment and Research,” JAMA 271(20): 1609 (“Turner”).

<sup>11</sup>Dr. Grond cites Turner, JAMA 271(20): 1608-1614 and Wall, P.D. (1993) “Pain and the placebo response,” Ciba Foundation Symposium, 174:187-211.

reported therein, there are no indications that the dosage forms described therein were ever administered to human subjects, and there is no teaching or suggestion of any desired pharmacokinetic parameters ... ." (*Id.*) Defendants assert that this is an acknowledgment by the patentees that a claim of therapeutic effect must be demonstrated by scientifically valid clinical evidence. (D.I. 161 at 13.)

Plaintiffs argue that it would be improper to accept Defendants' proposed limitation because it is not supported by the intrinsic evidence. (D.I. 157 at 14 (citing *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340-41 (Fed. Cir. 1999)).) They also contend that, in distinguishing the Bondi reference, the patentees did not specify how therapeutic effect is to be proven. (D.I. 178 at 5.) Rather, they simply listed clinical trials and pharmacokinetic parameters as alternative approaches that could be used to prove therapeutic effect. (*Id.*) Thus, Plaintiffs stress that pharmacokinetic parameters can be established in clinical testing that does not involve controls for the placebo effect. (*Id.* (citing Smith Dec., ¶ 7 and Davies Dec., ¶¶ 31-32).)

## 2. The Court's Construction

The intrinsic evidence does not support a limitation that therapeutic effect must be demonstrated by scientifically valid placebo-controlled clinical evidence. Neither the claims nor the specifications mention placebo-controlled clinical evidence or imply that it is necessary to prove therapeutic effect. To the contrary, the specification reveals that the

therapeutic effect of tramadol is already accepted in the art,<sup>12</sup> stating that it has been “commercially available for many years for use in the treatment of moderate to severe pain.” (‘887 patent at 1:15-17.) In addition, the portion of the prosecution history cited by Defendants militates against, rather than for, such a limitation. It indicates that the inventors believed that tramadol’s therapeutic effect for a 12- or 24-hour period could be proved using pharmacokinetic parameters, which can be measured in clinical trials that do not control for the placebo effect. In short, there is no support in the intrinsic evidence for adding Defendants’ proposed limitation, and I decline to do so. Accordingly, I will construe the term “therapeutic effect” to mean “an effective treatment for pain.”

- B. “A [solid] controlled release oral [dosage form/pharmaceutical preparation/pharmaceutical tablet] ... said [dosage form/pharmaceutical preparation/pharmaceutical tablet] providing a therapeutic effect for [at least] about 24 hours”

1. The Parties’ Proposed Constructions

The parties’ dispute over this term is focused on the type of dosing environment the claims require to determine whether there is a therapeutic effect for about or at least

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<sup>12</sup>Plaintiffs suggest that the qualifications of a person having ordinary skill in the art would be one with experience as a formulator (one who makes a drug), a pharmacokineticist (one who researches and characterizes the drug), and a clinician (one with experience in treating pain). (D.I. 249 at 13:14-16:1.) Defendants would not include a pharmacokineticist in their list of qualifications. (*Id.*) However, a number of the claims, such as claim 16 of the ‘887 patent, refer to pharmacokinetic parameters. I therefore believe that the Plaintiffs’ suggestion better captures what a person of skill in the art would need to know in order to practice the invention, and I will adopt it.

about 24 hours.<sup>13</sup> Plaintiffs contend that it is common to characterize controlled release formulations in terms of their performance at “steady state,” or the point where the absorption and elimination of a drug are such that each successive dose provides a predictable blood plasma level. (D.I. 221, Exh. A at 7 (citing *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 374-76 (S.D.N.Y. 2000)).) While disclaiming any intent to insert a steady state requirement into the claims, Plaintiffs argue that the claims necessarily imply that a patient will take repeated doses and that a person skilled in the art would understand that a first dose would not immediately produce pain relief. (*Id.*) Plaintiffs thus propose that the claims should be understood to mean that “the 24-hour therapeutic effect can be measured in an environment of repeated dosing, and is not limited to the therapeutic effect of any single tablet.” (D.I. 247 at 7.)

Defendants argue that the 24-hour therapeutic effect must be measured with a single dose, taken in isolation. Specifically, Defendants propose the following construction:

The dosage form [pharmaceutical preparation, or coated tablet] provides a therapeutic effect for about [or at least about] 24 hours. The therapeutic effect shall be provided by the specific dosage form, [pharmaceutical preparation, or coated tablet] in question, not provided by other sources, including additional or previously administered dosage forms [pharmaceutical preparations, or coated tablets].

(*Id.*)

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<sup>13</sup>The “at least” addition to the phrase “about 24 hours” is a feature of claim 1 of the '430 patent.

Both sides argue that the claim language is in their favor. Plaintiffs rely on the rule of claim construction, applicable to both patents, that the word “a” in a claim with the term “comprising” means “one or more.” See *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). Thus, Plaintiffs argue that the term “a solid controlled release oral dosage form” means that one or more solid controlled release oral dosage forms may be used to achieve a 24-hour therapeutic effect.<sup>14</sup> (D.I. 249 at 22:20-23:6.) Plaintiffs also assert that the “suitable for dosing every 24 hours” language in the independent claims of the '887 patent supports their argument that the claimed formulation is intended for multiple dosing. (D.I. 221, Exh. A at 8.)

Defendants respond that the word “a” should not be understood to mean “one or more” because it is used in the preamble rather than after the word “comprising.” In this context, Defendants argue that “a” means only one. (D.I. 249 at 36:7-22.) Defendants also argue that the phrase “said dosage form providing a therapeutic effect for at least about 24 hours” makes clear that the 24-hour therapeutic effect is a property of the claimed dosage form, not a result achieved from a sequential dosing regimen. (D.I. 205, Exh. A at 6.) Defendants warn that Plaintiffs are trying to transform a product claim into

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<sup>14</sup>While claim 1 claims a “pharmaceutical preparation,” independent claim 13 claims a “pharmaceutical tablet” and claim 1 of the '430 patent claims a “dosage form.” For purposes of claim construction, both sides conceded at oral argument that “pharmaceutical preparation,” “pharmaceutical tablet,” and “dosage form” have the same meaning, namely a tablet. (D.I. 249 at 37:20-38:16.) I will therefore use these terms interchangeably.

a method claim for the treatment of pain. (*Id.*) Finally, as to the claim language, Defendants contend that because some of the dependent claims refer to certain pharmacokinetic parameters, and because those parameters measure properties of a single tablet, therapeutic effect must also be measured by the response to a single tablet.<sup>15</sup>

Both sides attach meaning to the specification's silence as to a dosing regimen. Plaintiffs argue that it was unnecessary to detail a multiple-dosing regimen in the specification because the fundamental purpose of the invention, as set forth in the title of both the '887 and '430 patents, is to provide a controlled release tramadol formulation, and the purpose of controlled release formulations generally, as understood by those with skill in the art, is to treat patients who require repeated dosing for an extended period of time. (D.I. 221, Exh. A at 11.) Plaintiffs look to Biovail's package insert for ULTRAM® ER as support for the argument that it is common to characterize controlled release formulations in terms of their steady state performance. (D.I. 221, Exh. A at 7.) In particular, the insert explicitly provides performance statistics at steady state (D.I. 222, Exh. 7 at PUR1015268) and indicates that ULTRAM® ER is to be used for "the management of moderate to moderately severe *chronic* pain in adults who require around-

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<sup>15</sup>For example, dependent claim 11 of the '887 patent refers to "W<sub>50</sub>." The parties agree that W<sub>50</sub> means "[t]he width of the plasma profile at 50% C<sub>max</sub>, i.e., the duration over which the plasma concentrations are equal to or greater than 50% of the peak concentration." (D.I. 247 at 10.) Plaintiffs acknowledge that W<sub>50</sub> is measured over a single dosing interval, but contend that it need not be measured with a single pill taken in isolation. (D.I. 249 at 26:11 - 28:9.)

the-clock treatment of their pain for an *extended period of time.*” (*Id.* at PUR1015269 (emphasis added).)

Defendants contended at oral argument that a person of ordinary skill in the art would not understand “controlled release” to imply multiple doses. They argued that extended release medications may be prescribed for acute pain, such as for providing 24-hour pain relief following a surgery. (D.I. 249 at 32:16-22.) Defendants included in one of their expert reports a study that Biovail conducted in 2000 to measure the efficacy of tramadol HCl extended release tablets<sup>16</sup> when used to prevent acute dental pain following molar extractions. (Weinberger Expert Rep., Ex. 17 at BVF00274354.) Moreover, Defendants emphasize that the only data on drug efficacy provided in the shared specification of the '887 and '430 patents was measured following the administration of a single dose.<sup>17</sup> (D.I. 205, Exh. A at 8-9.)

## 2. The Court’s Construction

As a preliminary matter, I am persuaded that a person of ordinary skill would understand the term “controlled release” as it is used in the patents-in-suit to describe the

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<sup>16</sup>Plaintiffs allege, and Defendants do not appear to seriously dispute, that “extended release” – a term that does not appear in the patent claims but does appear in the FDA submissions of both Biovail and Defendants – and “controlled release” have identical meanings. (D.I. 222, Ex. 7 at 6.)

<sup>17</sup>See '887 patent at 8:51-53 (“In a trial involving 12 healthy volunteers the serum levels of tramadol following *administration of one tablet* according to Example 2 was found to be as illustrated in FIG. 1.” (emphasis added)); 12:11-14 (“In a trial involving five healthy male volunteers the plasma profile resulting from *single dose administrations* of the above tablet are shown in FIG. 2.” (emphasis added)).

composition of an individual pill. I cannot conclude that one of skill in the art would understand the term so expansively as to also encompass a repeated-dosing environment within which the efficacy of the pill is tested. As Plaintiffs acknowledged at oral argument, the inventors disclosed in the specification the data for controlled release tramadol that they had available at the time they filed the '452 patent, the parent of the patents-in-suit. (D.I. 249 at 54:20-24.) That data related to a single-dose environment only, yet it did not prevent the inventors from calling their invention a “controlled release” formulation. Even absent Plaintiffs’ concession, the specification defines a “controlled release preparation” without reference to multiple doses: “A controlled release preparation according to the present invention is one that achieves slow release of a drug over an extended period of time, thereby extending the duration of drug action over that achieved by conventional delivery.” '887 patent at 1:34-37. This definition must control. *Phillips*, 415 F.3d at 1316.<sup>18</sup>

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<sup>18</sup>The contents of the ULTRAM® ER package insert do not alter my opinion. Biovail, a company that is not now and has never been an assignee of the patents-in-suit, submitted its NDA for ULTRAM® ER in December of 2003, approximately nine years after the '452 patent was filed and over two years after the filing of the '430 patent. (Perkins Expert Rep., Ex. 5 at SBA000040.) Even if I were inclined to go in search of extrinsic evidence, this later-developed information regarding a product that Plaintiffs claim to be covered by the patents-in-suit provides little insight into what the patent claims meant at the time they were filed. *See PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1363 (Fed. Cir. 2005) (“[A claim’s] meaning must be interpreted as of its effective filing date.”).