United States District Court,
D. Delaware.

PURDUE PHARMA, L.P., and The Purdue Frederick Company,
Plaintiffs.
v.
F.H. FAULDING AND COMPANY, Faulding Inc., Purepac Pharmaceutical Co., and Zeneca Inc,
Defendants.

No. Civ.A. 96-427-JJF

April 23, 1999.

Holder of patent on time released oral analgesic, with once a day dosage, brought infringement action. The District Court, Farnan, Chief Judge, held that: (1) patent was invalid, due to failure to describe invention in specification, and omission of element listed in specification from patent claim, and (2) if valid, patent was literally infringed.

Order accordingly.

5,672,360. Construed and Ruled Invalid.

William J. Marsden, Jr., Joanne Ceballos, Potter Anderson & Corroon LLP, Wilmington, Delaware, S. Leslie Misrock, Stanton T. Lawrence, III, Victor N. Balancia, Todd A. Wagner, F. Dominic Cerrito, Pennie & Edmonds, New York City, for plaintiffs.

Jack B. Blumenfeld, Karen Jacobs Louden, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware, Edward J. Handler, III, Paul H. Heller, Steven J. Lee, Pamela G. Salkeld, William G. James, Kenyon & Kenyon, New York City, W. Charles Lucas, Laura Davies of Zeneca Inc., Wilmington, Delaware, for defendants.

MEMORANDUM OPINION

FARNAN**, Chief Judge.**

INTRODUCTION

This action was brought by Purdue Pharma L.P. and The Purdue Frederick Company (collectively, "Purdue") against Faulding Inc., Faulding Pharmaceutical Co., Faulding Services, Inc., Purepac Pharmaceutical Co. (collectively, "Faulding") and Zeneca, Inc. ("Zeneca") for infringement of U.S. Patent Number 5,672,360 (the " '360 Patent"). The '360 Patent issued to Purdue on September 30, 1997, and claims methods for-effectively treating pain by administering to an individual patient on a 24-hour basis an oral

opioid formulation, in this case morphine, which achieves a certain pharmacokinetic profile, including a relatively large fluctuation in blood concentration levels of the drug. Purdue contends that Faulding's method of using Kadian, a sustained release oral morphine product, on a once-a-day basis literally infringes Claims 2, 4 and 11 of the '360 Patent.

In defense to this action, Faulding contends that Purdue has not established that Kadian infringes the '360 Patent. In addition, Faulding raises the affirmative defenses of invalidity and unenforceability of the '360 Patent. Specifically, Faulding contends that the '360 patent is invalid on the grounds of lack of written description, obviousness, anticipation and public use and unenforceable due to alleged inequitable conduct by Purdue before the United States Patent and Trademark Office ("PTO").

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. s. 1338(a), because this action arises under the patent laws of the United States, Title 35, United States Code. Additionally, the Court has personal jurisdiction over Faulding and Zeneca, because they are incorporated in the State of Delaware, and therefore reside in this District. Likewise, venue is appropriate in this District under 28 U.S.C. s. 1391(b)-(c) and s. 1400(b), because all Defendants are Delaware corporations which are subject to personal jurisdiction in this District. Neither jurisdiction nor venue is contested by the parties.

The Court bifurcated the liability and damages issues for purposes of trial and conducted a seven-day bench trial on the issues of infringement, validity and enforceability of the '360 Patent. On the fourth day of trial, the Court dismissed Purdue's claims against Zeneca, finding that Purdue provided insufficient evidence to support a finding of liability for infringement by Zeneca. This Memorandum Opinion constitutes the Court's Findings of Fact and Conclusions of law on the remaining claims and defenses presented by Purdue and Faulding.

BACKGROUND

I. The '360 Patent

Prior to the development of the '360 Patent, Purdue developed and marketed MS Contin, a sustained-release oral morphine formulation recommended for dosing on a twice-a-day basis, i.e. every 12 hours. MS Contin was launched in the United States in 1984. MS Contin and other twice-daily morphine products represented a significant advance over immediate release oral morphine formulations, because immediate release morphine formulations only provide about 4 hours of pain relief, have to be administered up to six times a day, and subject the patient to a continuing cycle of painful episodes that are difficult to bring under control. (Tr. 44; PTX 126, pp. 631-632; D.I. 199 at para 12).

Following its development of MS Contin, Purdue contends that, in the mid to late 1980s, it sought to develop an oral, sustained-release opioid formulation that would be suitable for once-a-day administration. (Tr. 54:25-55:-11; 457:6-14). The Purdue physicians and scientists directing this effort contend that they had in mind the unique goal of developing a once-a-day oral opioid formulation that would provide relatively large fluctuations, in excess of 100% fluctuations, in blood plasma concentrations of the opioid analgesic drug following administration. (Tr. 55:17-56:20). Particularly, the Purdue inventors contend that they sought to develop an analgesic treatment meeting three specific criteria or design goals: (1) a T_{max} (or time to maximum plasma concentration) relatively early in the 24-hour dosing interval, which was considered to be about the first third or so of the 24-hour dosing interval and which corresponds to about 2 to 8 or about 10 hours; (2) larger fluctuation in plasma opioid concentrations than a 100% fluctuation; and

(3) effective treatment of pain for about 24 hours. (Tr. 55-75; 459:2-10). According to Purdue, this proposed treatment method was contrary to the accepted clinical view that sustained-release formulations in general should provide minimal fluctuations during the dosage interval. (Tr. 50:10-52:18; Tr. 249-250; PTX 162, p. 188; PTX 164, p. 744). As described by Purdue, these minimal fluctuations were plasma concentration levels of the active drug where the variation between the maximum and minimum concentrations did not exceed 100%, which corresponds to a peak or maximum plasma concentration that is twice or less the minimum concentration.

Purdue contends that by mid-1988, Dr. Goldenheim and Dr. Kaiko, two of the Purdue inventors, conveyed the design goals for their method to Mr. Oshlack, Purdue's senior scientist responsible for developing new dosage forms. (Tr. 63, 84:6-9, 42:17-21; 462:11-463:9; 561:20-562:9; 564:20-565:3). By July 1988, Mr. Oshlack developed two experimental morphine formulations for clinical testing to see if the results would meet the design goals. The results of the clinical study on the two experimental formulations ("Clinical Study MC88-0504") showed that the formulations met the first two design goals, achieving a T_{max} within the first third of the dosing interval and a plasma opioid fluctuation greater than 100%. (Tr. 59-63; 464:12-465:6, 465:25-467:1, 566:9-567:2, PTX 117). However, Clinical Study MC88-0504 failed to meet the third design goal of providing effective treatment of pain for 24 hours, because the results failed to achieve sufficiently high plasma opioid levels for the entire intended 24-hour dosing interval. (Id.) Despite its initial failure, Purdue contends that it continuedpursuing the development of a once-a-day formulation meeting its design criteria.

By 1993, Purdue contends that clinical work established that Purdue had developed a formulation that satisfied all of its design goals. Thereafter, Purdue worked with its outside patent counsel, Mr. Davidson to prepare a series of patent applications on the once-a-day oral opioid inventions, including U.S. Patent Application Serial No. 08/578,688 (the " '688 Application") that became the '360 Patent.

Despite the issuance of the '360 Patent, Purdue does not currently sell any once-a-day opioid analgesic products in the United States, nor does it have a New Drug Application ("NDA") pending for a once-a-day morphine product. (Tr. 113-114). In addition, Purdue has not conducted any clinical trials in the United States wherein a morphine formulation within the scope of the claims of the '360 Patent was administered on a once-a-day basis to a patient in pain. (Tr.480). At trial, Purdue announced its plan to seek an NDA for a drug that uses the '360 invention in the first quarter of 1999.

II. Faulding's Accused Product-Kadian

According to Faulding, its sustained-release morphine project began in 1987 under the internal project designation "Molly," and rapidly became Faulding's "number one priority." (Tr. 1036, 1040, 747, 806, 876). According to Faulding, the goal of the Molly project was to develop a formulation that would provide pain relief for a minimum of 12 hours. To this end, Faulding sought to develop a formulation that could be administered every 12 or 24 hours. (Tr. 749). In addition, Faulding contends that it specified ten desired characteristics for the formulation: (1) minimal peak-to-trough variation in blood morphine concentrations when administered twice daily; (2) minimal diurnal variation; (3) the co-administration of food should not alter the absorption rate when compared with administration in the fasted state; (4) minimal variation between inter- and intra-subject blood morphine pharmacokinetics; (5) with respect to items 1 to 4, significant advancement when compared to MST (Purdue's MST Continus, the overseas counterpart of MS Contin); (6) stability with respect to drug content and drug release rate; (7) polymer coats applied in aqueous or ethanol solutions for manufacturing rather than polymer coats applied in organic solvents such

as methanol and methylene chloride; (8) raw materials used in production must be supported by Certificates of Analysis meeting the appropriate pharmacopeial standards; (9) morphine raw material sourced from Australian production; and (10) patent protection. (Tr. 879-883; DTX 650 at FA 112342).

Under the direction of Dr. Angelo Morella, Faulding initially developed two formulations, designated Molly 1 and Molly 2, which were tested in human subjects in clinical trial MOB-2/88. Although Molly 1 and Molly 2 met many of Faulding's objectives, including an extended T_{max}, Faulding sought to create a formula with an even longer T_{max}. (Tr. 750, 896). Faulding's efforts resulted in a formulation designated Molly 3, which was clinically tested between November 1989 and February 1990 in Clinical Trial MOB-2/89. The results of Clinical Trial MOB-2/89 were published in Australian Patent No. AU-B-47732 /90 (the "Morella Australian Patent"). Because Molly 3 achieved the performance characteristics Faulding sought, Faulding contends that it was selected for further development and scale-up. (Tr. 759, 904-05, DTX 651 at FA155927).

Eventually, Faulding registered Molly 3 in Australia for twice-a-day use and licensed the product to Glaxo Wellcome, who named it Kapanol. (Tr. 768, 778-79). In 1991, Faulding decided to pursue once-a-day registration of Kapanol in the United States, a decision which initiated an extensive process, including numerous additional clinical trials. (Tr. 1037-38). Ultimately,Kadian was approved by the United States Food and Drug Administration on July 3, 1996 for administration on a once-a-day or twice a day dosage schedule to patients in moderate to severe pain. (Tr. 748-749, 759-760, 805, 866, DTX 826). At the time of trial, Kadian was the only oral morphine product approved for once-a-day dosing in the United States. (Tr. 781).

DISCUSSION

I. Whether the '360 Patent **is Valid**

[1] [2] An issued patent is presumed valid. 35 U.S.C. s. 282. In order to overcome this presumption, the party challenging validity bears the burden of proof by clear and convincing evidence that the invention fails to meet the requirements of patentability. Hewlett-Packard Co. v. Bausch & Lomb, 909 F.2d 1464, 1467 (Fed.Cir.1990). Clear and convincing evidence is evidence that "could place in the ultimate factfinder an abiding conviction that the truth of [the] factual contentions are 'highly probable.' " Colorado v. New Mexico, 467 U.S. 310, 316, 104 S.Ct. 2433, 81 L.Ed.2d 247 (1984).

[3] [4] The burden of proof regarding invalidity is particularly difficult to meet when the prior art relied on at trial was considered by the Patent and Trademark Office ("PTO"). As the Federal Circuit has stated:

When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed.Cir.), *cert. denied,* 469 U.S. 821, 105 S.Ct. 95, 83 L.Ed.2d 41 (1984). Despite the deference due to the PTO, the Court is the final arbiter on questions of law such as validity. Quad Envtl. Technologies Corp. v. Union Sanitary Dist., 946 F.2d 870, 875-76 (Fed.Cir.1991).

Faulding contends that the '360 Patent is invalid, and therefore, cannot be infringed. Faulding argues invalidity on four grounds: lack of a written description pursuant to 35 U.S.C. s. 112; anticipation by the Morella patents under 35 U.S.C. s. 102(a), (b); prior public use under s. 102(b), and obviousness under 35 U.S.C. s. 103. For the reasons set forth below, the Court concludes that the '360 Patent is invalid for lack of written description under 35 U.S.C. s. 112.

A. ***Legal Standard for the Written Description Requirement of*** 35 U.S.C. s. 112

In pertinent part, 35 U.S.C. s. 112 provides:

The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[5] [6] [7] [8] To satisfy the "written description" requirement, the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-1564 (Fed.Cir.1991). For purposes of this inquiry, the invention is whatever is now claimed. While the claimed subject matter need not be described *in haec verba* in the specification FN1, it must be described "in terms that establish that the applicant was in possession of the later-claimed invention, including all of the elements and limitations presented in the [claim], at the time of filing." Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed.Cir.1998). The policy behind the written description requirement is to prevent overreaching and *post hoc* claims that were not part of the original invention. As the Court of Appeals for the Third Circuit Stated in *Rengo Co. v. Molins Mach. Co.:*

FN1. *See* In re Wright, 866 F.2d 422, 425 (Fed.Cir.1989) (recognizing that fact that exact words in question are not in specification is "not important"); In re Herschler, 591 F.2d 693, 701 (C.C.P.A.1979).

Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.
657 F.2d 535, 551 (3d Cir.), *cert. denied,* 454 U.S. 1055, 102 S.Ct. 600, 70 L.Ed.2d 591 (1981).

B. ***The Parties' Contentions***

[9] In arguing that the '360 Patent fails to satisfy the written description requirement, Faulding contends that the specification of the '360 Patent does not discloses the $C_{max}/C_{24}>2$ limitation contained in each of the asserted claims of the '360 Patent and the T_{max} of about 2 to about 8 hours limitation contained only in Claim 2 of the '360 Patent. According to Faulding, Purdue did not invent what was claimed in the '360 Patent until June 1997, when it added a new set of claims during the prosecution of this case. Thus, Faulding contends that Purdue was not in possession of the claimed invention as of the filing date of the '360 Patent, and therefore, Purdue should be precluded from asserting claims that are beyond the scope of its original invention.

In addition to its argument that the claims of the '360 Patent are beyond the scope of Purdue's original invention, Faulding also raises an argument under the "omitted element test" of Section 112. *See* Reiffin v.

Microsoft Corp., 1998 WL 397915 (N.D.Cal. Jul.10, 1998) (relying on Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, (Fed.Cir.1998) to conclude that there is an omitted element test within the written description requirement of 35 U.S.C. s. 112). According to Faulding, the '360 Patent omits "essential elements" of the invention which were originally disclosed in the '688 application, and therefore, the '360 Patent is invalid.

In response to Faulding's contentions, Purdue contends that both the examples and the text of the '360 Patent clearly convey to a skilled reader that a C_{max}/C_{24} ratio greater than 2 is part of Purdue's invention. Purdue acknowledges that the specification does not expressly use the claim words "a maximum plasma concentration (C_{max}) which is more than twice the plasma level at about 24 hours" or state the ratio of C_{max}/C_{24}. However, according to Purdue, the inventors described this plasma opioid fluctuation by contrasting it with the conventional range of fluctuation considered desirable for sustained release drug formulations. Specifically, Purdue contends that the '360 Patent states that the treatment methods invented by Purdue "do not exhibit a substantially flat serum concentration curve," and that one skilled in the art understands that "substantially flat" means fluctuations of 100% or less. Thus, Purdue contends that by stating that the invention does not exhibit a flat profile, the specification clearly describes the invention as providing fluctuations above 100%.

With regard to Faulding's argument concerning the "omitted element test," Purdue does not address the *Reiffin* decision. However, Purdue contends that there is no disparity between what is claimed and what is disclosed in the '360 patent specification, and therefore, the facts of the *Gentry* decision, the decision upon which the *Reiffin* court relied for its "omitted element" test, are not analogous to the instant case. (D.I. 320 at 25, n. 22).

Lastly, Purdue contends that the PTO concluded that Purdue's new claims were supported. Specifically, Purdue contends that it addressed the matter of support for its new claims with the Examiner and informed him that new matter had not been added. According to Purdue, the Examiner agreed with Purdue because he did not make a new matter rejection. Because the Examiner did not make a new matter rejection, Purdue contends that the claims in issue satisfy the written description requirement of Section 112.

C. *Findings of Fact and Conclusions of Law*

After careful review of the record in this case, the Court finds that the '360 Patent fails to meet the written description requirement of 35 U.S.C. s. 112. Specifically, the Court finds that neither the text of the specification, nor the meaning ascribed to Purdue's selected portions of the text by those skilled in the art, nor the examples in the specification convey that the $C_{max}/C_{24}>2$ limitation of Claims 2, 4 and 11 was encompassed in Purdue's original invention. In addition, the Court finds that the '360 Patent omits critical elements of the invention as originally disclosed in the patent application. Because the Court finds that the '360 Patent fails to meet the written description requirement of Section 112, the Court concludes that the '360 Patent is invalid.

1. The Text of the '360 Patent **Specification**

In arguing that the specification describes the $C_{max}/C_{24}>2$ limitation of Claims 2, 4 and 11, Purdue relies on language in the specification describing its invention as not "substantially flat." However, read in its entirety, the sentence from which Purdue extracts the "substantially flat" language contradicts Purdue's position that the specification adequately describes the $C_{max}/C_{24}>2$ limitation of the claimed invention. The

full sentence of the specification on which Purdue relies for the "substantially flat" language states:

It has now been surprisingly discovered that quicker and greater analgesic efficacy is achieved by 24 hour oral opioid formulations, which do not exhibit a substantially flat serum Concentration curve, *but which instead provide a more rapid initial opioid release so* that the minimum effective analgesic concentration can be more quickly approached in many patients who have measurable if not significant pain at the time of dosing.

(PTX 1, col. 5, lines 40-47) (emphasis added). In context, the sentence fragment upon which Purdue relies describes a formulation that quickly releases part of its dose to provide patients with an immediate burst of morphine. This becomes particularly evident, when the specification is viewed in the context of the original claim language. At the time of filing the '688 application, the claims defined the formulation and its use in terms of "an initially rapid rise ... by providing [$T_{1/2(abs)}$] from about 1 to 8 hours." FN2 (DTX 5). Although this language was later dropped from the claims that eventually issued as the '360 Patent, the abstract and specification of the '360 Patent, both as issued and at the time of filing, contain numerous references to the T *1/2(abs)* and the concept of an initially rapid rate of rise of opioid plasma concentration. For instance, the '360 Patent specification describes the invention as "designed to provide an initially rapid rate of rise in the plasma concentration of said opioid characterized by providing an absorption half-life from about 1 to about 8 hours." (PTX 1, col. 6 lines 1-9). In addition, the specification describes this initial rapid rate of rise as "critical" to the invention:

FN2. The original Claim 1 in the '688 application was:

An oral sustained release opioid formulation comprising:

an opioid analgesic,

an effective amount of at least one retardant material to cause said opioid analgesic to be released at an effective rate to provide an analgesic effect

In accordance with the above objects and others, the present invention is related in part to the surprising discovery that in order to provide a 24 hour dosage form of an opioid analgesic, it is *critical* to formulate a sustained release formulation in pain with an analgesic preparation which provides an initially rapid opioid release so that the minimum effective analgesic concentration can be quickly approached in many patients who have measurable if not significant pain at the time of dosing.

(PTX 1, col. 3, lines 29-37; DTX 5 at PUR 46-3110) (emphasis added). While the specification fails to elaborate on the claimed $C_{max}/C_{24}>2$ element of the '360 Patent, the specification defines phrases and terms such as "rapid rate of rise" and T *1/2(abs)*, which were part of the originally claimed invention, but which Dr. Goldenheim admitted at trial were "not part of the claims" of the '360 Patent. (PTX 1, col. 4, lines 23-33; Tr. 135-136).

In sum, upon reviewing the text of the specification as a whole and in the context of the '688 application as originally filed, the Court finds no textual or contextual support for Purdue's contention that "substantially flat" refers to fluctuations of 100% or less. The phrase "substantially flat" is not quantified in the patent, and the patent does not define or describe Purdue's invention in terms of degree of fluctuations. (DTX 227).

2. Meaning to One Skilled in the Art

To the extent that Purdue contends that one skilled in the art understands "flat" to mean a fluctuation of precisely 100% or less, the Court is not persuaded by Purdue's evidence. For example, Purdue relies on Dr. Goldenheim's testimony that "we thought that fluctuations around 100 percent were what other people were suggesting was appropriate for a variety of therapeutics and we thought that was flat." (Tr. 56:5-20). However, Dr. Goldenheim's testimony is not consistent on this point. In discussing Roxanol, a drug which Dr. Goldenheim recognized has a fluctuation of greater than 100%, Dr. Goldenheim testified that Roxanol was "flat." (Tr. 192-194).

In addition, Purdue relies on publications, which it contends demonstrate that "flat" means 100% or less. For example, Purdue relies on a published patent application of another pharmaceutical company, Kabi Pharmacia, which discloses a sustained release morphine formulation referred to as "CR-B", that provides "low fluctuations" and a profile where the C_{max} (about 15) is less than twice the C_{24} (about 10), i.e. a fluctuation of less than 100%. However, the Kabi Pharmacia patent also discloses a second sustained release morphine formulation, referred to as "CR-A", which has a C_{max}/C_{24} of approximately 2 0/5 nmol/l, i.e. a fluctuation greater than 100%. Both the formulation having a fluctuation less than 100% and the formulation having fluctuations greater than 100% are described in the Kabi Pharmacia patent as having "low" fluctuations. (PTX 17 at PUR 0046-2411). As such, the Court finds the Kabi Pharmacia patent fails to support Purdue's contention that one skilled in the art understands "flat" to mean fluctuation of less than 100%.

Indeed, based on the evidence offered by Purdue on this issue, it appears to the Court that those skilled in the art do not set a precise "cut-off" of less than 100% or no more than exactly 2 to 1 for a "flat profile." Further, the specification language upon which Purdue relies uses the term "substantially flat." Thus, even if the Court were to accept that flat is understood to mean less than 100% or no more than exactly 2 to 1, as Purdue urges, the use of the modifier "substantially" in the specification, indicates that the word "flat" as used in the '360 Patent specification, does not even refer to the precise quantification urged by Purdue. (PTX 1, col 5, line 42).

Essentially, Purdue attempts to define its patent, for purposes of the written description requirement, by what it is not. Purdue describes its invention as not "substantially flat." While negative descriptions of inventions are permissible in some contexts, courts have difficulty with negative descriptions which may be too broad or indefinite. *See e.g.* Jepson v. Coleman, 50 C.C.P.A. 1051, 314 F.2d 533, 536 (C.C.P.A.1963) (finding negative defined embodiment insufficient because device may or may not have features found in claim); In re Bankowski, 50 C.C.P.A. 1548, 318 F.2d 778, 782-83 (C.C.P.A.1963) (discussing negative limitations). As the Court stated previously, it appears that those skilled in the art do not have a precise definition for the term "flat." Given the lack of textual and contextual support for Purdue's construction of the phrase "substantially flat", as well as the lack of consensus regarding the meaning of "substantially flat" by those skilled in the art, the Court finds Purdue's description of its invention in the specification as "not substantially flat" insufficient to meet the written description requirement.

3. The Examples in the '360 Patent Specification

In addition to its argument concerning the text of the '360 Patent specification and the meaning of the text to those skilled in the art, Purdue also relies on the examples in the specification. According to Purdue, Examples 1 and 3 explicitly show C_{max}/C_{24} ratios greater than 2, and thus, provide sufficient written

description of the invention.

[10] In *Vas-Cath,* the Court of Appeals for the Federal Circuit recognized that "under proper circumstances, drawings alone may provide a 'written description' of an invention as required by s. 112." 935 F.2d at 1565. The use of drawings or figures, however, does not change the nature of the inquiry. The drawings must convey with reasonable clarity to those skilled in the art that, as of the filing date, the applicant was in possession of the later-claimed invention, including all the limitations and elements presented in the claim. *See* id. at 1563-1564; Hyatt, 146 F.3d at 1354-55.

In this case, the '360 Patent specification does contain examples illustrating C_{max}/C_{24} ratios greater than 2, i.e. greater than 100%. However, the specification also contains examples illustrating C_{max}/C_{24} ratios less than 2, i.e. less than 100%, and nothing in the patent indicates that this ratio is outside of the scope of the claimed invention. Purdue suggests that the written description inquiry must start with the words of the claim, and that taken together the claim language and examples describe the invention as exhibiting a C_{max}/C_{24} ratio greater than 2. (Tr. 126). While the Court must necessarily look to the claim language to determine if the specification supports what is now claimed, the claims themselves cannot be used to determine which examples meet the claimed characteristics in this case, because the claims of the '360 Patent did not appear in the application as filed. *See* In re Rasmussen, 650 F.2d 1212, 1214-15 (C.C.P.A.1981). The very purpose of the written description requirement is to show that at the time of filing, the inventor was in possession of what is now claimed. At the time of filing, the $C_{max}/C_{24}>2$ limitation did not exist in the claims, and therefore, this later added element cannot be used in hindsight to show which of the examples in the specification embody the claimed invention.

The Court's finding that the examples fail to satisfy the written description requirement is further evidenced by the testimony of the inventors of the '360 Patent, Dr. Goldenheim and Dr. Kaiko. Dr. Goldenheim testified that one could not interpret the data in the examples without referring to the claims of the '360 Patent. (Tr. 125-126, 132-133). Similarly, Dr. Kaiko testified that the specification did not contain enough information to determine whether Examples 4,5,6 and 7 fall within the scope of the claims of the '360 Patent. (Tr. 481-82). Thus, viewing the examples collectively, as the Court believes must be done because there is no way to determine which embody the invention and which do not, the examples illustrate a C_{max}/C_{24} range between 1.48 and 3.43. As such, the Court finds that the examples are insufficient to describe an invention with the claim limitation of a C_{max}/C_{24} ratio greater than 2.

4. The Omitted Element Test

In *Gentry Gallery, Inc. v. Berkline Corp.,* the Court of Appeals for the Federal Circuit evaluated a patent pertaining to reclining seats of a sectional sofa to determine whether certain claims of the patent satisfied the written description requirement of Section 112. 134 F.3d 1473 (Fed.Cir.1998). The specification of the patent in issue described the invention as the placement of controls on a console between two recliners facing the same direction, so that the console may accommodate the controls for both reclining seats and eliminate the need to position recliners at the exposed ends of the sofas. Id. at 1474. Despite the language of the specification, the claims in issue did not limit the location of the recliner controls to the console. In holding the claims invalid for failure to comply with the written description requirement, the Federal Circuit held that "locating the controls anywhere but on the console is outside the stated purpose of the invention," because "when viewed in its entirety, the disclosure is limited to sofas in which the recliner control is located on the console." Id. at 1479.

In interpreting *Gentry,* the Northern District of California recently coined the *Gentry* analysis as the "omitted element test" of the written description requirement. Reiffin, 1998 WL 397915 at *7. According to the *Reiffin* court's analysis of *Gentry,* a patentee is prevented from asserting claims that omit elements which were essential to the invention as originally described. *Id.* at *5. In support of its "omitted element test", the *Reiffin* court relied on "older case law", including the Supreme Court's 1942 decision in *U.S. Industrial Chemicals* that "the omission from a reissue patent of one of the steps or elements prescribed in the original, thus broadening the claims to cover a new and different combination renders the reissue void." *Id.* (citing 315 U.S. 668, 677-78, 62 S.Ct. 839, 86 L.Ed. 1105 (1942)).

While the Court hesitates to refer to the *Gentry* analysis as a "test" under the written description requirement absent further guidance from the Federal Circuit, the Court believes that whether the claimed invention omits an element which was essential to the invention as originally described is at least part of determining whether the applicant was in possession of the invention at the time of filing.

[11] As the Court discussed in its analysis of the text of the '360 Patent specification FN3, the specification and the original claims of the '688 application disclose a formulation directed at providing a "more rapid initial opioid release," described in terms of a $T_{1/2(abs)}$ between about 1 and about 8 hours. (PTX 1 at col. 3, lines 29-37, 48-51, col. 6, lines 1-9). Although this element is described in the specification as "critical," it is not, as Dr. Goldenheim admitted, part of the '360 Patent. (Tr. 135-136). Thus, the Court finds that the '360 Patent omits an element which was essential to the invention as originally disclosed. This finding, coupled with the Court's previous finding that the $C_{max}/C_{24}>2$ limitation is not supported by the '360 Patent specification, supports the Court's finding that Purdue was not in possession of the invention claimed in the '360 Patent at the time it filed its application. In the Court's estimation, to find otherwise, would vitiate the policy behind the written description requirement of preventing overreaching through the addition of later-filed claims which were not contemplated by the original invention.

FN3. *See supra* Section I.C.1.

5. The Patent Examiner's Conclusion

[12] To the extent that Purdue contends that the Patent Examiner's failure to make a new matter rejection is proof that the patent specification adequately describes the new claims, the Court is not persuaded by Purdue's argument. First, while the issue of "new matter" is related to the written description requirement, the two are not synonymous. New matter under 35 U.S.C. s. 132 should not be used to reject amendments to claims or claims added after the original filing date. *See* In re Rasmussen, 650 F.2d at 1214-1215 (discussing difference between the new matter prohibition of s. 132, and the written description requirement of s. 112, first paragraph). Rather, the appropriate basis for a rejection of such claims is 35 U.S.C. s. 112. *Id.* New matter is a basis for objection to amendments to the abstract, specifications, or drawings attempting to add disclosure to that originally presented. *Id.* Accordingly, that the Examiner did not make a new matter rejection tells little about whether the specification, at the time of filing, supported the newly added claims. At most, the Examiner's failure to make a new matter rejection suggests that Purdue did not add anything new to the specification, abstract or drawings it originally presented to the Examiner.

Further, even if the Court were to consider the Examiner's decision not to reject the amended claims as evidence that the claims were supported, the Examiner's inaction does not tell the Court what the Examiner

believed to be the adequate support for the new claims. Whether the patent specification adequately describes a patent for purposes of Section 112 must be determined by the text and examples of the specification and their meaning to those skilled in the art, and not by the Patent Examiner's failure to act. As discussed previously, the Court has examined the specification, its text, examples, and meaning to those skilled in the art, and finds no support for the $C_{max}/C_{24}>2$ limitation of Claims 2, 4 and 11 of the '360 Patent. Accordingly, the Court cannot accept Purdue's interpretation of the Examiner's failure to act as sufficient proof that the claims of the '360 Patent are adequately described. Further, the Court finds that any deference due to the Patent Examiner has been overcome by Faulding's clear and convincing evidence that the specification does not support the asserted claims of the '360 Patent.FN4

FN4. In arguing that there is adequate written description for its claims, Purdue also directs the Court to portions of its July 1993 patent applications. (D.I. 321 at 28-31). Purdue contends that the '360 Patent has a claim of priority from these previous applications. In analyzing whether the written description requirement has been met in the context of later-amended claims, the Court must inquire as to whether "the newly claimed subject matter was described as the invention of the applicant *in the patent application when filed*." Harmon, *Patents and the Federal Circuit* s. 5.5, 134 (emphasis added). The original application from whence the '360 Patent issued was the '688 application. By referencing the other patent applications in its discussion of whether the written description requirement is satisfied, Purdue merges two concepts: the written description requirement as an independent basis for invalidity and the written description requirement as a component in the priority inquiry, i.e. whether the patent should have an effective filing date other than its actual filing date. In determining whether a patent has an effective filing date other than its actual filing date, the Court must determine whether the claimed subject matter is supported in the previous applications. Stated another way, the Court must determine whether the written description requirement is met by the previous applications. However, for purposes of the written description requirement as an independent basis for invalidity, which is Faulding's contention here, the Court need only consider the '688 application. Because the Court finds that the '688 application does not support the newly amended claims, the Court need not examine Purdue's priority claim which implicates other applications and is not relevant to this defense.

6. Conclusion

In sum, the Court concludes that the '360 Patent fails to satisfy the "written description" requirement of 35 U.S.C. s. 112. Specifically, the Court finds no support in the text, the interpretation of the text by those skilled in the art, or the examples of the '360 Patent specification for the $C_{max}/C_{24}>2$ limitation set forth in each of the asserted claims. In addition, the Court further finds that the '360 Patent omits essential elements of the invention as originally filed, which further supports the Court's finding that Purdue was not in possession of the invention set forth in the '360 Patent at the time it filed its application. Because Faulding has established by clear and convincing evidence that the '360 Patent fails to meet the "written description" requirement of Section 112, the Court concludes that the '360 Patent is invalid.FN5 Given the Court's conclusion of invalidity under Section 112, the Court will not address the other grounds of invalidity or unenforceability raised by Faulding.

FN5. Because the Court's holding concerning the lack of support for the $C_{max}/C_{24}>2$ limitation affects all of the asserted claims, the Court need not consider Faulding's argument concerning the T_{max} range, which affects only Claim 2 of the '360 Patent.

The Federal Circuit FN6 counsels trial courts to adjudicate the question of infringement, despite a holding that the patent in issue is invalid. *See* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed.Cir.1983). Accordingly, the Court will address Purdue's claim that Faulding's use of Kadian on a once-daily basis literally infringes the '360 Patent.

FN6. *See e.g.* Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1565 (Fed.Cir.1991) (Rich, J. dissenting) ("Validity and infringement are unrelated questions. Invalid claims can perfectly well be infringed, which is simply a matter of construing the words of the claim and then determining whether they can be read on the accused structure. Courts constantly hold claims infringed but invalid. Validity vel non should have no effect on how the infringement issue is decided.").

II. Whether Faulding's Use of Kadian **Infringes Purdue's** '360 Patent

Purdue contends that Faulding should be liable for inducing infringement of the '360 Patent under 35 U.S.C. s. 271(b). A finding that a party has induced infringement cannot be made without a finding of direct infringement under 35 U.S.C. s. 271(a). In this regard, Purdue alleges that the method of using Kadian on a once-a-day basis literally infringes Claims 2, 4 and 11 of Purdue's '360 Patent.

A. ***The Law of Infringement***

A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States during the term of the patent...." 35 U.S.C. s. 271(a). In addition, whoever actively induces infringement of a patent or sells a material for use in practicing a patented process is liable as an infringer. 35 U.S.C. s. 271(b), (c).

[13] [14] Generally, in ascertaining whether a patent has been infringed, the patent owner has the burden of proof, and must meet its burden by a preponderance of the evidence standard. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed.Cir.1988) (citations omitted). The preponderance of the evidence standard is met when a party provides evidence regarding a certain issue that is more convincing than the evidence offered in opposition to the issue. Hale v. Dep't of Transp., F.A.A., 772 F.2d 882, 885 (Fed.Cir.1985) (citations omitted).

[15] [16] [17] [18] A patent owner may prove infringement under either of two theories: literal infringement or the doctrine of equivalents. Under the theory of literal infringement, infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed.Cir.1987); Robert L. Harmon, *Patents and the Federal Circuit* 195 & n. 31 (3d ed.1994). A claim in a patent can only be infringed if it reads on each and every element of the alleged infringer's product. American Hoist & Derrick Co. v. Manitowoc Co., Inc., 603 F.2d 629, 630 (7th Cir.1979); *see also* Amstar Corp. v. Envirotech Corp., 730 F.2d 1476, 1484 (Fed.Cir.), *cert. denied,* 469 U.S. 924, 105 S.Ct. 306, 83 L.Ed.2d 240 (1984) (infringement avoided only if element present in alleged infringing process absent in patented invention); Hormone Research Found., Inc. v. Genentech, 904 F.2d 1558, 1562 (Fed.Cir.1990), *cert. dismissed,* 499 U.S. 955, 111 S.Ct. 1434, 113 L.Ed.2d 485 (1991) (infringement only if each claim or equivalent found in accused invention). If a patent has a series of claims, and one claim is infringed, then the entire patent is infringed. Panduit, 836 F.2d at 1330 n. 1. Under the theory of the doctrine of equivalents, however, infringement may be established even where elements in the claimed invention are missing from the alleged infringer's product, if the "accused device performs

substantially the same function in substantially the same way to achieve substantially the same result as the claimed device." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950); Warner-Jenkinson Company. Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) (declining to overrule *Graver Tank*); Malta v. Schulmerich Carillons, Inc., 952 F.2d 1320, 1325 (Fed.Cir.1991).

[19] To find infringement under either theory, the Court must undertake a two-step process. First, it must interpret the claims at issue by evaluating the language of the claims ("claim interpretation"). Miles Lab., Inc. v. Shandon, Inc., 997 F.2d 870, 876 (Fed.Cir.1993), *cert. denied,* 510 U.S. 1100, 114 S.Ct. 943, 127 L.Ed.2d 232 (1994). Claim interpretation is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-978 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 388-390, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

[20] [21] [22] [23] When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 978. A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in construing the true meaning of the language used in the patent. Id. at 980 (citations omitted). A court should interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984). However, if the patent inventor clearly supplies a different meaning, the claim should be interpreted accordingly. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 & n. * (Fed.Cir.1984) (citations omitted).

The second step to determine infringement requires a court to compare the accused products with the properly construed claims of the patent at issue to determine whether the accused products infringe on the patent under either the theory of literal infringement or under the theory of the doctrine of equivalents ("infringement analysis"). Miles Lab., 997 F.2d at 876; SRI Int'l v. Matsushita Elec. Corp. of America, 775 F.2d 1107, 1121 (Fed.Cir.1985).

B. *Claim Construction of* the '360 Patent

[24] In arguing that the once-a-day administration of Kadian does not infringe the '360 Patent, Faulding raises two claim construction issues: (1) whether the claims of the '360 Patent require only the administration of a drug that produces the specified pharmacokinetic ("PK") results *on average* and (2) the meaning of the phrase "effective treatment of pain." Other than these two issues, the parties do not dispute the meaning of the claims. As to the remainder of the claims, the Court finds that interpretation beyond the plain and ordinary meaning of the language of the claims is unnecessary.

1. Whether the claims of the '360 Patent **require only administration of a drug that produces the specified pharmacokinetic results on average**

Faulding's argument that the claims of the '360 Patent require only administration of a drug that produces the specified pharmacokinetic results on average pertains to an overall reading of the claims in issue and is not directed to any specific term or phrase used in the language of the claims. According to Faulding, Purdue's experts admitted that the specification of the '360 Patent only sets forth average data, and does not contain, refer to, or mention individual patient data. (DTX 3; Tr. 139, 1231). Based on the data provided in the specification of the '360 Patent, Faulding contends that the claims cover a formulation that "on average"

produces the claimed PK results of $C_{max}/C_{24}>2$ and T_{max} from about 2 to about 8 or 10 hours.

In opposition to Faulding's proposed claim construction, Purdue contends that the asserted claims of the '360 patent are directed to methods for treating individual patients. According to Purdue, Faulding's interpretation ignores the plain language of the claims and is an attempt to over-emphasize the significance of the prior art Morella patents, which Faulding raises in the context of its obviousness and anticipation defenses.

The starting point for a claim construction analysis is the language of the claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). While the court may consider the patent specification and prosecution history as relevant intrinsic evidence in its analysis, the court need not accord this evidence the same weight as the claims themselves. CCPI v. American Premier, Inc., 966 F.Supp. 276, 278 (D.Del.1997). Rather, "[t]he claim language itself is of paramount importance," and therefore the specification, prosecution history and other relevant evidence need only be consulted to give the necessary context to the claim language. *Id*. Thus, the specification may assist in determining the meaning of a claim, but it may not be used to impose limitations on a claim not found in the words of the claim, itself. Electro Medical Sys., S.A. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994). Courts do not rewrite claims; they merely interpret them. Intervet America, Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989).

In this case, the claim language does not include the words "average" or "mean" as modifiers of the specified PK claim requirements. Indeed, the words "average" or "mean" do not appear at all in the asserted claims. To the contrary, the claims explicitly state that the treatment methods are accomplished by administering a sustained-release oral, opioid dosage form to "a human patient" and achieving the specified PK and efficacy results in "the patient." The Court finds that such phrases, taken in their ordinary and plain meaning, unambiguously refer to an individual patient, rather than patients on average. (PTX 1, claims 2, 4, 11). Had Purdue wanted to obtain patent claims directed to treatment methods achieving the claimed PK elements on average, Purdue undoubtedly could have written the claims to include the "average" or "mean" language.

Further, consideration of the specification of the '360 Patent does not alter the Court's finding that the claims relate to individual patients. Like the claims of the patent, the specification is devoid of any reference to "average" results. In fact, the specification refers to individual patients at least 22 times, including the discussion of such concepts as providing the proper doses of opioid medication to meet the needs of "each individual patient" (PTX 1, col. 1, line 57), assessing "the patient's" PK response to the opioid treatment (PTX 1, col. 2, lines 22-29), and assessing the pain relief "achieved in a given patient." (PTX 1, col. 4. lines 38-43). In this regard, the Court finds the specification to be consistent with the plain and unambiguous language of the claims.

Faulding contends that the word "average" should be read into the claims because the Examples in the specification of the '360 Patent include average PK data. The Court finds Faulding's contention both factually and legally unsupportable. First, the plain language of the '360 Patent prefaces the Examples with the following cautionary statements: "The following examples illustrate various aspects of the present invention. They are not to be construed to limit the claims in any manner whatsoever." (PTX 1, col. 14, lines 57-60). Second, as Purdue's technical expert Dr. Lipman testified, the average results presented in the examples are a convenient and accepted way to summarize the results of clinical studies, and as such serve only to "illustrate" the desired PK results that are to be achieved in individual patients. (Tr. 260:21-22). Lastly, as a legal matter, the Court may not use the Examples in the specification to limit the scope of the

claims. Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed.Cir.), *cert. denied,* 488 U.S. 892, 109 S.Ct. 228, 102 L.Ed.2d 218 (1988); Elf Atochem North America, Inc. v. Libbey-Owens-Ford Co., Inc., 894 F.Supp. 844, 859 (D.Del.1995). Accordingly, the Court cannot accept the claim construction urged by Faulding. Faulding's construction is an impermissible limitation on the claims. Based on the plain and unambiguous language of the clams and the context provided by the '360 Patent specification, the Court finds that the proper construction of the '360 Patent refers to individual patients.

2. The meaning of the phrase "effective treatment of pain"

[25] Based on the testimony of its medical expert, Dr. Gelmann, Faulding contends that the phrase "effective treatment of pain" in clinical practice means "control of pain that is acceptable to the patient in the context of an acceptable level of side effects." (Tr.1091). According to Faulding, the effective treatment of pain does not require complete alleviation of pain, but patient satisfaction. In Dr. Gelmann's words, "If the patient is satisfied, then that is sufficient." (Tr. 1091-92). Faulding also contends that an effective pain regimen includes the use of "rescue medication," meaning additional doses of immediate release morphine in addition to the sustained release morphine, as well as the use of nonopioid analgesics such as aspirin, acetaminophen or ibuprofen, and adjuvant drugs that enhance the effectiveness of opioid therapy or control side effects such as laxatives. (Tr. 1086, 1134). Faulding points out that an inventor of the '360 Patent, Dr. Goldenheim, testified that the '360 Patent contemplates the use of rescue medication and "other medicines" in combination with morphine sulfate. (Tr. 199-200). Thus, according to Faulding, the plain meaning of the claims encompasses a treatment regimen which includes the appropriate use of rescue medication, nonopioid analgesics and adjuvants.

In their Answering Brief To Defendants' Opening Post-Trial, Purdue contends that there is "no real dispute" concerning the proper meaning of the phrase "effective treatment of pain" as used in the asserted claims. (D.I. 320 at 11). Further, Purdue agrees with Faulding that the claimed methods of the '360 Patent include the appropriate use of rescue and other medication in combination with the sustained release opioid dosage form. Thus, according to Purdue, "[b]oth Purdue and Faulding agree that the language 'effective treatment of pain' means that the individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects." (D.I. 320 at 11).

In its Post-Trial Reply Brief, Faulding seemingly agrees with Purdue that there is no "real dispute" concerning this language, because it does not revisit its claim construction argument about the effective treatment of pain as it does with its previous claim construction argument concerning patients "on average." However, in its Response to Plaintiffs' Additional Findings Of Fact, Faulding states that it "does not agree" (D.I. 330 at 7, emphasis in original) with Purdue's statement that "[b]oth Purdue and Faulding agree that the language 'effective treatment of pain' means that the individual patient is provided with adequate relief from the sustained release opioid dosage form without unacceptable side effects," because (1) Purdue has not defined "adequate relief," and (2) Purdue uses the "redundant requirement" that " 'the sustained release opioid dosage form' provide the 'adequate' pain relief." (D.I. 330 at 8).

The Court finds that Faulding's disagreement with Purdue's characterization is a disagreement of form over substance. The Court finds that there is no "real dispute" between the parties over what is meant by the phrase "effective treatment of pain." Both parties agree that rescue medication and other drugs are contemplated by the claims of the '360 Patent, and both parties discuss effective pain treatment in relation to the individual-Purdue using the word "adequate" to the individual and Faulding using the word "acceptable" to the individual.

In its definition, Purdue seeks to emphasize that the "adequate" or "acceptable" balance of pain relief and side effects for the patient primarily *comes from* the sustained release opioid dosage form, rather than from a combination of the drugs that the patient received. Although the construction Faulding urges does not expressly state what provides the "control of pain that is acceptable to the patient in the context of an acceptable level of side effects," Faulding does not dispute Purdue's contention, and in fact, acknowledges that "the morphine contributes the majority of pain relief." (D.I. 330, at 8; Tr. 1092, 1177).

The construction urged by Purdue includes the connection between the sustained release opioid dosage form and the control of pain, which both parties agree is part of the claim's requirement, as well as the individual frame of reference for pain relief, which again both parties agree is part of the claim's requirement. Thus, the Court finds that the construction urged by Purdue comprehensively embodies what is essentially the parties' substantive agreement over the meaning of the phrase "effective treatment of pain." Accordingly, for purposes of claim construction, the Court finds that the "effective treatment of pain" means that an individual patient is provided with adequate pain relief from the sustained release opioid dosage form without unacceptable side effects.

C. *Literal Infringement Analysis*

In order to determine whether the use of Kadian on a once-a-day basis literally infringes Claims 2, 4 and 11 of the '360 Patent as Purdue contends, the Court must compare the language of the claims in issue with the accused product. In this case, the asserted claims are all dependent claims, meaning they incorporate all of the elements of the independent claim to which they refer and add some further limitations. Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108 (Fed.Cir.1987). Claims 2 and 4 of the '360 Patent are dependent on Claim 1 of the '360 Patent. Claim 11 of the '360 Patent is dependent on Claim 9 of the '360 Patent, but shares the method set forth in Claim 1 of the '360 Patent. With this understanding, the Court will proceed to examine whether the elements of the asserted claims are present in the accused use of Kadian.

1. Whether the once-a-day administration of Kadian **meets every element of Claim 2 of** the '360 Patent

[26] After comparing the accused use of Kadian to the language of Claim 2 of the '360 Patent, the Court finds that Purdue has established by a preponderance of the evidence that all of the elements of Claim 2 of the '360 Patent are present in the accused use of Kadian.FN7

FN7. Claim 2 of the '360 Patent reads as follows:
The method of claim 1 wherein the T_{max} occurs in about 2 to about 8 hours after oral administration of said dosage form.

(PTX 1). For purposes of its infringement analysis, the Court will set forth all the elements of Claim 1, and substitute the T_{max} element set forth in Claim 2 for the one set forth in Claim 1 of the '360 Patent.

A method of effectively treating pain in humans, comprising
orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof

The Court finds that Kadian is an oral, sustained-release dosage form containing an opioid analgesic that is orally administered to human patients on a once-a-day basis. The Court bases its finding on the testimony

of Dr. Lipman, which the Court finds credible, the FDA-approved product labeling for Kadian, and Faulding's responses to Request for Admissions. First, Dr. Lipman testified that this element is satisfied by Kadian. Second, the product labeling for Kadian explicitly indicates that "Kadian is ... an opioid analgesic", containing "sustained release pellets of morphine sulfate for oral administration," which can be administered "on either a once-a-day or twice-a-day schedule." Lastly, in its responses to requests for admission, Faulding acknowledged that Kadian is a "sustained-release dosage form" containing a "therapeutically effective amount of morphine, which is an opioid analgesic," that "may be administered on a once-a-day schedule for treatment of moderate to severe pain." (PTX 143, Response to Admission Requests 2, 3, and 22). Accordingly, the Court finds that this element is present in the accused use of Kadian.

which upon administration provides

a time to maximum plasma concentration (T_{max}) of said opioid in about 2 to about 8 hours

The Court finds that after the administration of Kadian the time to maximum plasma concentration of the opioid in some patients is about 2 to 8 hours. The Court bases its finding again on the testimony of Dr. Lipman, the product labeling of Kadian and Faulding's Responses to Requests for Admission. First, Dr. Lipman testified that, after reviewing the pharmacokinetic data, some patients receiving Kadian would meet this T_{max} criteria. (Tr. 263-264). Second, the product labeling of Kadian reports an average T_{max} of 10.3 hours (along with the applicable statistical variation) for Kadian at steady rate when administered on a once-a-day basis. While the Court acknowledges that this average rate falls outside of the language of the claim, the Court accepts as credible the testimony of Dr. Lipman that the individual T_{max} values for patients will be distributed around this average value and therefore, for some patients the T_{max} will fall within the 2 to 8 hours limitation of this claim. (Tr. 260-265). Lastly, in its responses to Requests for Admission, Faulding admitted that both the Kadian product labeling and the data available to Faulding indicates that after administration of Kadian products to humans on a once-a-day regimen, the T_{max} for morphine was reached, in some patients, between 2 and 8 hours after administration. (PTX 143, Response to Admission Request No. 5-6, 29). Accordingly, the Court finds this element present in the accused use of Kadian.

a maximum plasma concentration (C_{max}) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form

The Court finds that about 24 hours after the administration of Kadian, some patients will exhibit a maximum plasma concentration which is more than twice the plasma level of the opioid. The Court bases its finding on the testimony of Dr. Lipman and the product labeling for Kadian. The average pharmacokinetic profile for Kadian depicted in Graph 2 in the Kadian product labeling shows a C_{max} above 30 ng/ml and an average plasma morphine concentration at 24 hours of below 15 ng/ml for the once-a-day administration of Kadian. Thus, Graph 2 depicts that, on average, the use of Kadian on a once-a-day basis provides a C_{max} which is more than twice the plasma morphine concentration at 24 hours following administration. Further, according to Dr. Lipman's testimony, which the Court credits and which is consistent with the Kadian product labeling, some individuals using Kadian once-a-day will exhibit a C_{max} that is more than twice the plasma morphine concentration at 24 hours following administration. (Tr. 240-267). Accordingly, the Court finds this element present in the accused use of Kadian.

and which dosage form provides

effective treatment of pain for about 24 hours or more after administration to the patient.

The Court finds that the once-day-administration of Kadian provides effective treatment of pain for about 24 hours or more in some patients. The Court bases its finding on the FDA's conclusions regarding Kadian, the promotional material for Kadian and Faulding's responses to Requests for Admission. First, based on Faulding's new drug application for Kadian, the FDA concluded that Kadian "is safe and effective for use as recommended" in the product labeling, which indicates that the drug can be administered on a once or twice daily dosing schedule. (PTX 23, cover page). Second, the promotional material for Kadian states that Kadian provides effective pain control for 24 hours when used on a once-a-day basis. (PTX 28, p. 3; PTX 27 p. 2). Lastly, in its responses to Requests for Admissions, Faulding acknowledged that Kadian "may provide effective pain relief for 24 hours." (PTX 143, Response to Admission Request No.19). Accordingly, the Court finds this element present in the accused use of Kadian.

In sum, the Court finds that each element of Claim 2 of the '360 Patent is present in the accused use of Kadian in some patients. Therefore, the Court concludes that the accused use of Kadian literally infringes Claim 2 of the '360 Patent.

2. Whether the once-a-day administration of Kadian **meets every element of Claim 4 of** the '360 Patent

[27] After comparing the accused use of Kadian to the language of Claim 4 of the '360 Patent, the Court finds that Purdue has established by a preponderance of the evidence that all of the elements of Claim 4 of the '360 Patent are present in the accused use of Kadian. Claim 4 of the '360 Patent FN8 contains all the elements set forth in Claim 2 of the '360 Patent, with two exceptions: (1) the opioid analgesic is specified as morphine sulphate, and (2) the T_{max} claim states "a time to maximum plasma concentration (T_{max}) of said opioid at about 2 to about 10 hours." FN9 With respect to the elements Claim 4 shares with Claim 2, the Court finds, for the reasons set forth in its discussion of Claim 2, that these elements are present in the accused use of Kadian. With regard to the Claim 4 requirement specifying the opioid analgesic as morphine sulfate, the Court finds, based upon the product labeling, that Kadian contains morphine sulfate. (PTX 23, p. 1; DTX 821).

FN8. Claim 4 provides:
The method of claim 1, wherein said opioid analgesic is morphine sulfate.

(PTX 1).
FN9. The T_{max} element of Claim 4 mirrors the T_{max} element of Claim 1 of the '360 Patent.

With respect to the element of Claim 4 requiring a T_{max} of about 2 to about 10, the Court finds, based upon the testimony of Dr. Lipman, the product labeling of Kadian and Faulding's responses to Request for Admission, that after the administration of Kadian the time to maximum plasma concentration of the opioid in some patients is about 2 to 10 hours. As discussed in the context of Claim 2, the product labeling of Kadian reports an average T_{max} of 10.3 hours (along with applicable statistical variation) for Kadian at steady rate, when administered on a once-a-day basis. (PTX 23, Table 1, Kadian "q24h" data). As Dr. Lipman testified, this average indicates that T_{max} values for individual patients will be distributed in the vicinity of that average figure, and therefore some individual patients will exhibit a T_{max} within the range of

about 2 to 10 hours. (Tr. 260-61, 263-65). Lastly, in its responses to Requests for Admission, Faulding admitted that both the Kadian product labeling and the data available to Faulding indicates that after administration of Kadian products to humans on a once-a-day regimen, the T_{max} for morphine was reached, in some patients, between 2 and 8 hours after administration. (PTX 143, Response to Admission Request No. 5-6, 29). A T_{max} value that is within the range of about 2 to 8 hours necessarily falls within the range of 2 to about 10 hours. (Tr.265). Accordingly, the Court finds this element present in the accused use of Kadian.

In sum, the Court finds that each element of Claim 4 of the '360 Patent is present in the accused use of Kadian in some patients. Therefore, the Court concludes that the accused use of Kadian literally infringes Claim 4 of the '360 Patent.

3. Whether the accused use of Kadian **infringes Claim 11 of** the '360 Patent

[28] After comparing the accused use of Kadian to the language of Claim 11 of the '360 Patent, the Court finds that Purdue has established by a preponderance of the evidence that all of the elements of Claim 11 of the '360 Patent are present in the accused use of Kadian. Claim 11 of the '360 Patent contains all the elements set forth in Claim 4 of the '360 Patent, with the additional element that PK parameters are reached at a "steady-state" administration of the drug.FN10 With respect to the elements Claim 11 shares with Claim 4, the Court finds, for the reasons set forth in its discussion of Claims 2 and 4, that these elements are present in the accused use of Kadian.

FN10. Claim 11 provides:
The method of claim 9, wherein said opioid analgesic is morphine sulfate.

Claim 9 provides:
A method of effectively treating pain in humans comprising orally administering to a human patient on a once-a-day basis an oral sustained release dosage form containing an opioid analgesic or salt thereof which at steady-state provides a time to maximum plasma concentration (T_{max}) of said opioid in about 2 to about 10 hours and a maximum plasma concentration (C_{max}) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form, and which dosage form provides effective treatment of pain for about 24 hours or more after administration to the patient.

(PTX 1).
With regard to the additional element set forth in Claim 11, "steady-state" is expressly defined in the '360 Patent to mean that a patient's dose of the claimed opioid analgesic has been adjusted to the point where successive doses produce relatively consistent plasma opioid levels after each administration and that the levels are effective to treat the patient's pain. (PTX, col. 4, lines 34-42). The Court finds this element present in the accused use of Kadian, based on the testimony of Dr. Lipman and the PK data available for steady state administration of the drug. As Dr. Lipman testified, the steady-state data indicates that the administration of Kadian meets the PK parameters set forth in Claim 11 of the '360 Patent, which mirror the PK parameters set forth in Claim 4 of the '360 Patent. Indeed, the examples the Court discussed in the

context of Claims 2 and 4 refer to the PK parameters at "steady-state," and therefore, to the extent applicable, the Court incorporates its findings regarding Claims 2 and 4 to Claim 11. Accordingly, the Court finds this element present in the accused use of Kadian.

In sum, the Court finds that each element of Claim 11 of the '360 Patent is present in the accused use of Kadian in some patients. Therefore, the Court concludes that the accused use of Kadian literally infringes Claim 11 of the '360 Patent.

D. *Faulding's Non-Infringement Arguments*

In addition to its affirmative defenses to infringement, Faulding contends that Purdue has failed to carry its burden of proving infringement. In particular, Faulding contends that Purdue has not shown that Kadian is actually administered on a once-a-day basis in the United States, and therefore, has not shown that any person has taken Kadian once-daily and met every limitation of the '360 patent since September 30, 1997, the date on which the '360 Patent issued.

In response, Purdue contends that it was not required to show an actual patient who used Kadian on a once-day-basis after September 30, 1997, and met all of the claim elements. According to Purdue, the fact that Kadian is on sale and being used to treat patients in pain in the United States, combined with the fact that the Kadian product labeling instructs once-a-day use, is sufficient evidence to prove that some patients have actually used Kadian on a once-a-day basis in the United States during the relevant time period.

[29] It is well-established that literal infringement need not be proven by direct evidence alone. Moleculon Research Corp. v. CBS, Inc., 594 F.Supp. 1420, 1440 (D.Del.1984). As with other legally relevant facts, a party in a patent infringement case "can carry its burden of proof as to the fact of direct infringement with circumstantial evidence." *Id*. The use of circumstantial evidence is particularly sufficient in cases such as this, where the PK elements of the asserted claims take place inside a patient's body. *See* Zenith Labs., Inc. v. Bristol-Myers Squibb Co., 24 U.S.P.Q.2d 1652, 1664, 1671-74, 1992 WL 171910 (D.N.J.1992). As stated previously, the burden of proof in a case of literal infringement is by a preponderance of the evidence.

[30] In this case, Faulding admitted both at trial, through its counsel and its Vice-President of Business Development, and in its Answer to the Complaint in this lawsuit, that Faulding currently offers for sale and sells the Kadian product in the United States. As such, the Court finds that Kadian has been offered for sale and/or sold in the United States subsequent to the issue date of the '360 Patent. Further, the Kadian product label indicates that it may be used on a once-a-day basis. That the accused daily use of Kadian will more likely than not meet the PK parameters claimed in the '360 Patent in at least some patients is indicated by the data on the Kadian product labeling and by Faulding Responses to Requests for Admission, which the Court has previously discussed in its infringement analysis. Taken together, the Court concludes that these facts are sufficient to establish by a preponderance of the evidence that patients have actually used Kadian on a once-a-day basis since the issuance of the '360 Patent, and that at least some of these patients have exhibited the claimed PK profiles. Accordingly, the Court rejects Faulding's argument that Purdue has failed to prove infringement.

CONCLUSION

For the reasons discussed, the Court concludes that Faulding has established that the '360 Patent is invalid for lack of a written description under Section 112. The Court further concludes that if the '360 Patent were valid, Faulding's method of using Kadian on a once-a-day basis would literally infringe Claims 2, 4 and 11

of the '360 Patent, and Faulding would be liable for direct infringement under 35 U.S.C. s. 271(a) and inducing infringement under 35 U.S.C. s. 271(b).

An appropriate Order will be entered.

ORDER

At Wilmington this 23 day of April 1999, for the reasons set forth in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that:

1. U.S.Patent No. 5,672,360, is invalid under 35 U.S.C. s. 112, for lack of a written description.

2. If U.S.Patent No. 5,672,360 were valid, Defendants, F.H. Faulding and Company, Faulding Inc., and Purepac Pharmaceutical Co. would literally infringe Claims 2, 4, and 11 of U.S.Patent No. 5,672,360.