UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SAVIENT PHARMACEUTICALS, INC. Plaintiff, v. SANDOZ, INC and UPSHER-SMITH LABORATORIES, INC. Defendants.	:	Civil Action No. 2:06-cv-05782-PGS-RJH

PLAINTIFF'S REPLY IN SUPPORT OF ITS APPLICATION FOR A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION

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I. INTRODUCTION

Plaintiff Savient Pharmaceuticals, Inc. ("Savient") respectfully submits this memorandum in response to Sandoz's and Upsher's oppositions submitted to the Court. Defendants attempt to focus on Savient's proof of infringement as a basis to vacate the Court's proper grant of the TRO, but they fail to raise a substantial question concerning both of Savient's alternative and separate grounds of infringement — inducement and contributory. The principal reason defendants' challenge fails is that their approach to the critical issues on which they rely is divorced from the real world of pharmaceutical marketing, including incredible denials of intent to infringe and knowledge of infringement of Savient's patents. Savient's proofs in this regard go substantially uncontradicted and the TRO should stand.

On inducing infringement, defendants have demonstrated clear intent to induce infringement of Savient's five patents by their attempt to game the system: Defendants sought and obtained an AB rating to have their products substituted for all therapeutic uses, including Savient's patented uses. And they are implementing that intent in their sales efforts by selling their products for all therapeutic uses. But they also sought and obtained a misleadingly narrow indication that has nothing to do with how they intend the product to be used.

As set forth in the accompanying declarations, few, if any, doctors prescribe oxandrolone for defendants' indications – namely, to treat effects from corticosteroids or osteoporosis. While such indications from 30 or 40 years ago were indeed a use of the drug, since then, better therapies were developed to address corticosteroid and osteoporosis effects. As a result, it is simply impossible to believe the two defendants' assertions to the FDA and this Court that they have a new-found interest in old and abandoned therapies. Similarly, defendants' request for a bond, claim of harm and their oppositions cannot be for the purported purpose of protecting sales of a drug for a use that is no longer followed and for which they will make almost no sales.

Rather, defendants' actions and words admit to a clear intent to take a large market share by inducing others to practice Savient's patented uses.

On contributory infringement, Sandoz's president and Upsher's senior director of medical affairs state that their companies have no idea how oxandrolone is used. Hampl Decl., ¶ 12; Halvorsen Decl., ¶ 21. This alone defeats the defendants' challenge to this ground of infringement, which is premised on the lack of substantial noninfringing uses for oxandrolone (and largely supports, if not conclusively establishes, Savient's claim of willful infringement). It also further demonstrates defendants' lack of sincerity in seeking approval for the disused indications and arguing to the FDA and this Court an intent to market these uses. It defies logic that both defendants could independently invest in products for a use that has been abandoned in favor of better therapies and intend to make almost no sales.

Defendants' other challenges largely fail with their lack of a meritorious defense against Savient's infringement showing.

II. RESPONSE TO NEW FACTS PROVIDED BY DEFENDANTS

A. The Defendants' Attempt To Re-Write The Oxandrolone History

Both defendants assert that a broad indication in Savient's labeling ("to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight") somehow invalidates Savient's five patents. Incongruously, and at the same time, however, defendants argue that the "third indication" is so unrelated to the five patents that Savient cannot market the use of its product for its patented uses. This argument by both

defendants is another red herring since it is not Savient's marketing that is at issue.[1] It is the defendants' efforts to gain the entire market that is in issue, and their view of the oxandrolone history does not fit the facts.

Defendants are correct that the labeling for branded oxandrolone products has contained roughly three parts. However, defendants are incorrect on what that labeling has meant to the FDA, physicians and pharmacists, and the United States Patent and Trademark Office ("Patent Office") over time. At the time the indications were put in the labeling, the FDA used broad language. Horowitz Decl., ¶ 19; Kolassa Decl., ¶¶ 42-45. Oxandrolone was used for these general purposes (although not for the Savient patented purposes), but as time went on, other therapies came into favor. Demling Decl., ¶¶ 3-5; Horowitz Decl., 5-13; Ottery Decl., ¶¶ 5-21. In 1989, oxandrolone was in such disuse that it was abandoned and no longer offered for sale in the United States. Ottery Decl., ¶¶ 5-8.

Despite the abandonment of the product, the inventors of the five Savient patents collected data (e.g., as set forth in the patents) and discovered new, specific and non-obvious uses for oxandrolone for treating patients with HIV/AIDS, burns, wounds and COPD. Demling Decl., ¶¶ 3-7; Ottery Decl., ¶¶ 5-21. Savient has helped educate the medical community concerning these uses and created the market as it exists today, centered on these uses. Ottery Decl., ¶¶ 5-11.

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[1] Defendant Upsher argues that Savient's marketing activities are inconsistent with FDA regulations. *E.g.*, Upsher Opposition p. 2; Halvorsen Decl., ¶ 20. This argument is wholly without merit. As Upsher is fully aware, all marketing materials, including Savient's Oxandrin® materials, are sent to the FDA for review. Savient has not received any warning letter or actions from the FDA in connection with Savient's marketing efforts for Oxandrin®. Horowitz Decl. at ¶ 21.

The Patent Office was well aware of the past history of oxandrolone use and its labeling. In fact, the specifications of the '799 and '351 patents expressly state that the use of oxandrolone with HIV/AIDS patients was "consistent with current FDA-approved labeling for AZT and oxandrolone." Rhoads Decl., Exh. C, at col. 7, lines 23-26, Exh. D, at col. 7, lines 23-26. In addition, the 1988 PDR for oxandrolone was cited to the Patent Office, as indicated on the face of the '351 patent, as well as expressly addressed in a declaration submitted to the Patent Office to demonstrate that it was not obvious to treat AIDS patients with oxandrolone. Rhoads Decl., Exh. E, Amend. dated 4/19/99 at 3-8; Exh. F, Declarations of Drs. Berger and Fisher. As a result, the PDR labeling relied upon by both defendants neither anticipated nor rendered obvious Savient's new uses. *E.g.*, Demling Decl., ¶¶ 3-7; Horowitz Decl., ¶¶ 14-18; Kolassa Decl., ¶¶ 42-45. The prosecution history, unacknowledged by both defendants, establishes that the patented methods were unexpected and novel over the prior art, including the labeling for the product. *Id.*

Defendants also attempt to argue that the current labeling of Savient's product prohibits Savient from marketing it for the patented uses. Defendants are incorrect. Savient has the data and evidence it needs to market its product for the patented uses and defendants and their declarant misconstrues FDA practice and rules. Demling Decl., ¶¶ 3-5; Horowitz Decl., ¶¶ 14-21; Kolassa Decl., ¶¶ 6-18, 42-49. Nevertheless, it is immaterial here how Savient markets its drug. What is at issue is how defendants market their products.

B. New Facts Provided By Defendants

The defendants have now provided their product labeling to Savient. The labeling is also now available from the FDA's website. Both defendants' have similar labeling that contains very important information. Rhoads Decl., ¶¶ 2-3, Exhs. A and B. First, the labeling demonstrates that the defendants intentionally sought and obtained an AB rating for their drugs.

That means the defendants intentionally sought and obtained a rating that not only encourages, but in most cases requires, the substitution of their drugs for Savient's drug for all therapeutic uses. Kolassa Decl., ¶¶ 6-27, Exhibit B. As explained in the declaration of Savient's expert, Dr. Kolassa, these therapeutic uses would necessarily include the infringing uses from Savient's five patents. Kolassa Decl., ¶¶ 6-18, 24-26; 42-49.[2]

Third, the defendants' labeling indicates that defendants sought very narrow indications for use of the drug, namely:

> Oxandrolone is [or "Oxandrolone Tablets, USP, are"] indicated as adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.

This narrow indication is remarkable as it is no longer a use made of oxandrolone. Horowitz Decl., ¶¶ 5-13. As explained in the accompanying declaration of Savient's chief medical officer, Dr. Zeb Horowitz, oxandrolone is not a preferred treatment for the effects of corticosteroids or osteoporosis. Further, defendants' indications reflect an apparent attempt to game the Hatch-Waxman system and unfairly circumvent Savient's five patents: defendants cannot in good faith assert that they intend to have their sales limited to treat effects of corticosteroids and osteoporosis because that is no longer a use of the drugs. *Id.*

Fourth, the defendants provide a Clinical Pharmacology section and information on COPD in their labeling that necessarily informs physicians and pharmacists of Savient's patented methods. The defendants' labeling states:

> Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the androgenic

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[2] Using the ANDA route for approval, instead of the NDA route, also evidences defendants' intent to have its products be substituted for Savient's product in the infringing uses. Hamelin Decl., ¶¶ 6-12; Kolassa Decl., ¶¶ 6-18.

> properties of this class of drugs. Complete dissociation of anabolic and androgenic effects has not been achieved.

Today (but not fifteen years ago), it is known that the anabolic ("anabolic" means promoting the storage of protein and the growth of tissue) clinical effects of oxandrolone lead to the patented uses to treat muscle wasting in HIV/AIDS, burns and wounds. The labeling also contains a specific reference to instructing the use of the drug for COPD in particular:

> Patients with moderate to severe COPD or COPD patients who are unresponsive to bronchodilators should be monitored closely for COPD exacerbation and fluid retention.

Thus, the defendants' labels explicitly communicate (i.e., instruct and inform) to the knowledgeable physician and pharmacist that the defendants' products can be used for Savient's patented uses.

The defendants do not substantively challenge with any evidence whatsoever (1) Savient's explanation of how generic products with an AB rating are substituted for brand products for the same uses as the brand products as confirmed in the accompanying declaration of Dr. Kolassa; and (2) Savient's explanation of the market and the therapeutic uses of the product as confirmed in the accompanying declarations of Dr. Kolassa and Mr. Hamelin; *see* Kolassa Decl., ¶¶ 16-18, 24-27; Hamelin Decl., ¶¶ 13-18.

The defendants also do not challenge Savient's proof that the defendants have taken the first steps to launch their products for <u>all</u> therapeutic uses of oxandrolone as confirmed in the accompanying declaration of Paul Hamelin. Hamelin Decl., ¶¶ 8-12, Instead, the defendants provide declaration and argument that admit that they intend to capture all or most of the oxandrolone market. *E.g.*, Halvorsen Decl., ¶¶ 29-32.

III. ARGUMENT

A. Likelihood Of Success

Defendants fail to raise a substantial question concerning whether Savient is likely to succeed on the merits of its claims to defeat the Court's TRO. To do so, defendants must raise a substantial question as to (1) their inducement to infringe and their contributory infringement, or (2) the validity of the five Savient patents. *See Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

1. Defendants' Intent To Induce Infringement

Sandoz and Upsher-Smith infringe Savient's Patents under 35 U.S.C. § 271(b) which states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Although Sandoz argues that "[e]stablishing active inducement of infringement requires ***concrete*** proof," (Sandoz brief at 6) (emphasis added), no such standard exists and the cases cited by Sandoz make no such claim. Rather, Savient need only prove two elements for inducement of infringement — first direct infringement (which is properly assumed here from the established uses of the products) and "second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *Minn. Mining and Mfg. Co. v. Chemique, Inc.*, 303 F.3d 1294, 1304-05 (Fed. Cir. 2002) (reversing the district court and finding as a matter of law that defendant induced infringement). Moreover, proof of such intent "may be shown by circumstantial evidence." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990).

Defendants assert via unsupported attorney argument that they intend to market their product for treating the effects of corticosteroids and osteoporosis (e.g., Sandoz Opposition, p. 3). This is unbelievable and cannot be true. Kolassa Decl., ¶¶ 42-49. These simply are not current uses of their products and they cannot be the target of large, sophisticated pharmaceutical

companies. Horowitz Decl., ¶¶ 5-13. Further, such arguments are legally irrelevant. Defendants' superficial characterization of the law of inducement would eviscerate the purpose of § 271 and run contrary to the Supreme Court's recent decision in *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 125 S. Ct. 2764 (2005). The Supreme Court in *Grokster* made it clear that a while "[t]he classic instance of inducement is by advertisement or solicitation that broadcast a message designed to stimulate others to commit violations," that was "not [the] exclusive way of" demonstrating inducement. *Id*. at 2780-81. The intent of the defendants was to target infringing users. *Id.*

Similar to the defendants in *Grokster*, defendants' actions and words provide strong evidence of specific intent to have their products substituted for Savient's products in all of its current uses. This was expressed by the defendants at the hearing when they acknowledged that their intent was to win the largest accounts. That cannot be done by focusing on the treatment of the effects of corticosteroids and osteoporosis. *See Cable/Home Comm. Corp. v. Network Productions, Inc.*, 902 F.2d 829, 847 (11th Cir. 1990) (legitimate and advertised alternatives, failed to convince Court that defendant used, promoted and sold devices for any purpose other than infringing purpose.) It was also expressed by the defendants when they demanded a substantial bond and argued they would lose substantial market share if Watson, Savient's patent-licensed partner, were not enjoined. Seven attorneys do not appear out of thin air at a hearing with an hour's notice to attempt to gain insignificant market share. It is obvious and implied in defendants' actions that they are here to protect potentially lucrative financial forecasts with the intentional substitution of their products for all of the Savient product's therapeutic uses. *See Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1372,

1379 (Fed. Cir. 2001). This is confirmed from information from the field (*See* Hamelin Decl., ¶¶ 8-12) and the declaration of Mr. Halvorson (¶¶ 26 and 29-32).

Defendants' intent is also shown by their seeking an AB rating for their products. An AB rating permits and most often requires substitution for all therapeutic uses. Kolassa Decl., ¶¶ 6-27. The declarations of Dr. Kolassa and Mr. Hamelin show that generic companies such as the defendants know that AB rated products will be substituted for the brand-name product by physicians, pharmacists, institutions, insurance companies and the government. Hamelin Decl., ¶¶ 6-12; Kolassa Decl., ¶¶ 6-18, 24-27. This is common knowledge to any person who has experience with prescription pharmaceuticals. Demling Decl., ¶¶ 3-7. It is notable that defendants could have, but did not, added to their labeling a statement that their products should not be used for the methods claimed in Savient's patents. To Savient's knowledge, defendants are trying to replace all sales of Savient's product, not just sales for any noninfringing uses. Defendants have never claimed that they would try to stop infringing sales or had corporate policies to respect valid patents. *Id.*

Furthermore, although defendants feign ignorance, the fact that the substantial of the uses of oxandrolone are infringing could not have escaped the notice of large, sophisticated pharmaceutical companies. Additionally, the Federal Circuit has found inducement of infringement even where the plaintiff "only offered evidence indicating that [defendant] knew its products would be used for liposuction, but not that they would necessarily be used in the patented method." *Mentor H/S*, 244 F.3d at 1372. In *Mentor*, the defendant was aware of the patent but argued that there were other non-infringing uses and presented an opinion letter of noninfringement. The jury discredited such uses. The Federal Circuit stated that the defendant "induced infringement because it sold the device with the intention that doctors would use it to

perform the patented method." *Id*. at 1379; *see also Grokster*, 125 S.Ct. at 2768-69; *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1343 (Fed. Cir. 2001) (stating "sale of a device may induce infringement of a method claim, even if the accused device is capable of non-infringing modes of operation in unusual circumstances.").

To think otherwise is to not apply common sense. No company would invest in the manufacture and sale of a pharmaceutical only to have almost no sales. It is not logical that defendants did that here. *See, e.g., Pickholtz v. Rainbow Techs., Inc.*, 260 F. Supp. 2d 980, 989 (N.D. Cal. 2003) (Where the defendant's proffered indications were "not commercially viable, efficient, or recommended uses" the court denied defendant's motion for summary judgment of non-infringement) (citation omitted).

Moreover, as discussed above, the defendants' labeling communicates to physicians and pharmacists the anabolic and COPD uses of their products, which today means the use in the Savient patented methods. It is now known (but was not 15 years ago) that the anabolic clinical effects of oxandrolone lead to the uses to treat muscle wasting in HIV/AIDS, burns and wounds, all of which are the patented uses for oxandrolone. Demling Decl., ¶¶ 3-7. Again, such labeling is not a coincidence, it is a backhanded way to provide instructions to physicians and pharmacists to engage in direct infringing uses of oxandrolone.

Similarly, the COPD labeling instructs doctors that when they are using oxandrolone in COPD patients they should take specific monitoring steps in certain types of patients (e.g., those with moderate to severe COPD) and establishes that in those patients with mild COPD, there is not necessarily a need to follow the monitoring steps. The presence of this COPD instruction is, again, not a coincidence, because in fact, COPD is one of Savient's patented uses for oxandrolone. Thus, the defendants' labeling explicitly communicates (i.e., instructs and informs)

to the knowledgeable physician and pharmacist that the defendants' products can be used for Savient's patented uses.

This is all more than mere knowledge of potential infringement. This is specific intent to game the system and gain sales that are 80% to 90% infringing. *See Aventis Pharms., Inc. v. Barr Labs., Inc.*, 411 F. Supp. 2d 490, 517-518 (D.N.J. 2006) ("Thus, Defendants' argument that the label does not instruct, direct or encourage infringement, even if accepted as true, does not suffice when the law creates liability for the broad range of affirmative steps that may be taken to foster infringement"); *Takeda Chem. Indus., Ltd. v. Watson. Pharm., Inc.*, 329 F. Supp. 2d 394, 402 (S.D.N.Y. 2004) (Paragraph viii Statement ANDA filer took significant steps toward inducing infringement in developing generic version of reference drug, applying for FDA approval, and designing a label "it hopes will succeed in defeating any claim of infringement"). The Supreme Court's decision in *Grokster* has made clear that evidence of intent to induce infringement may be found where (i) defendants aimed "to satisfy a known source of demand for copyright infringement," (ii) defendants did not attempt to diminish infringing activity (iii) defendants directly profited from infringing activity. *Grokster*, 125 S.Ct. at 2768-2769.[3]

Defendants' arguments fair no better than the arguments made before the Supreme Court. On remand from the Supreme Court, the District Court for the Central District of California noted that:

> StreamCast argues that a defendant could be found liable for secondary infringement only if it: (1) for the purpose of inducing infringement, (2) took actions beyond distributing infringement-enabling technology, and (3) which actually resulted in specific instances of infringement. (Opp'n at 15.) In StreamCast's view,

[3] The above evidence demonstrates that Mr. Halvorsen's carefully worded declaration and failure to identify and explain the information Upsher has already provided to customers encouraging unrestricted sale of Upsher's product is not forthcoming. Halvorsen Decl., ¶¶ 16-17 and 25.

> even if it distributed peer-to-peer software with the intent for it to be used for infringement, liability does not attach unless it took further actions, such as offering instructions on infringing use, that actually caused specific acts of infringement. Much of StreamCast's brief is devoted to arguing that Plaintiffs failed in proving the second and third elements of its proposed test. ***However, StreamCast's legal theory is plainly contrary to the Supreme Court's holding in Grokster. As the Supreme Court explained,***
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> It is not only that encouraging a particular consumer to infringe a copyright can give rise to secondary liability for the infringement that results. ***Inducement liability goes beyond that, and the distribution of a product can itself give rise to liability where evidence shows that the distributor intended and encouraged the product to be used to infringe.*** In such a case, the culpable conduct is not merely the encouragement of infringement but also the distribution of the tool intended for infringing use.

Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., __ F. Supp. 2d__, 2006 WL 2806882, *15 (C.D. Cal. Sept. 27, 2006) (emphasis added). Facts that make Savient's case compelling and that overwhelmingly support the Court's TRO include the substantial infringing uses, defendants' narrow approved use indications and assertions that they are seeking to market their products for this use, the information that defendants have attempted to replace all sales of Savient's brand-product with their own products now and for the next six months or more, and the fact that this is not a Hatch-Waxman action — here both defendants have approval and have already begun to launch their products. *E.g.*, Halvorsen Decl., ¶¶ 26 and 29-32.

The term active inducement is "as broad as the range of actions by which one in fact causes, or urges, or encourages, or aids another to infringe a patent." 248 F.3d at 1379. Defendants' manufacture, use, marketing and sales activities constitute affirmative acts to facilitate or actively induce infringement. The very case cited by Sandoz sheds light on this issue. In *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1378 (Fed. Cir. 2001), the Federal Circuit stated that facilitation "requires some affirmative action such as using a

telephone to 'facilitate' a narcotics sale, see *United States v. Mertilus*, 111 F.3d 870, 872 (11th Cir.1997)."

Defendants have not simply permitted generic oxandrolone tablets to enter the stream of commerce. Rather, defendants have taken an active role. First, defendants affirmatively pursued the lengthy and expensive process of developing generic oxandrolone tablets, testing and submitting data to the FDA and took numerous steps in an effort to facilitate the approval of their generic oxandrolone tablets. Second, defendants have prepared sales sheets, pricing schedules, and employed sales personnel that have made telephone calls or otherwise contacted distributors in an effort to facilitate the bulk distribution of oxandrolone — knowing that it will result in massive infringing sales. *See* Hamelin Decl., ¶¶ 8-12. This is not mere "permission." This is affirmative conduct.

2. Defendants' Contributory Infringement

Defendants have not raised a substantial question relating to Savient's showing that oxandrolone is "not a staple article or commodity of commerce suitable for substantial noninfringing use." 35 U.S.C. § 271(c). Savient has shown by declaration that 80% to 90% of the uses are infringing. Hamelin Decl., ¶¶ 13-18. This only makes sense since the revival of oxandrolone and Savient's marketing efforts have focused on these infringing uses. Hamelin Decl., ¶ 18. Instead of confronting Savient's proofs, defendants claim ignorance of how their own products will be used (Hampl Decl., ¶ 12; Halvorsen Decl., ¶ 22). This is not believable. *See, e.g.,* 2nd Hampl Decl. (contending that Sandoz is a large and sophisticated company).

Defendants also attempt to construct some sort of an infringement/invalidity argument (Opposition, pp. 8-9). To the extent we understand what they argue, they appear to contend that if their products are construed to fall within the scope of the patents and infringe, Savient's patents are invalid. This argument was specifically addressed by the United States Patent and

Trademark Office ("Patent Office") and rejected. The promoting weight gain language in the early package insert meant something different to physicians than it does now, and, as shown above, does not invalidate Savient's patents. *See* Kolassa Decl. at ¶¶ 43-45.

At the hearing, counsel for Upsher informed the Court that the principal case they were relying on was *Warner Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003). This case is distinguishable because the accused infringing uses in *Warner Lambert* only made up 2.1% of the uses and these uses did not relate in any way to the labeling for the drug. *Id.* at 1365. Here, the accused infringing uses make up the vast majority of the uses and directly relate to the labeling for the drug as understood and applied by physicians and pharmacists today. Hamelin Decl., ¶¶ 13-18. *See C.R. Bard, Inc. v. Advanced Cardiovascular Systems, Inc.*, 911 F.2d 670 (Fed. Cir. 1990) (as much as 40% to 60% noninfringing uses may be — not are — substantial).

Upsher's opposition letter raises a new issue, contending that its product is not specially adapted to infringe. In fact, Upsher's generic oxandrolone tablets are especially made and approved to be bioequivalent to Savient's Oxandrin® tablets as they are now used and thus to practice Savient's Patents. Upsher also suggests that it cannot be contributorily liable for infringement because its uses approved by the FDA cannot infringe any claim of the Savient Patents. (Dec. 6, 2006 Letter at 3). This argument utterly fails in view of the Supreme Court's decision in *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176, 221-222 (1980) which explicitly states:

> It is perhaps, noteworthy that holders of "new use" patents on chemical processes were among those designated to Congress as intended beneficiaries of the protection against contributory infringement that § 271 was designed to restore.
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> * * *
>
> The number of chemicals either known to scientists or disclosed by existing research is vast. It grows constantly, as those engaging in

> "pure" research publish their discoveries. ***The number of these chemicals that have known uses of commercial or social value, in contrast, is small. Development of new uses for existing chemicals is thus a major component of practical chemical research. It is extraordinarily expensive.*** It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed.

Id. at 221-222. (footnotes omitted; emphasis added). The three uses for oxandrolone, which Upsher argues saves it from contributory infringement, are those where the "commercial or social value, in contrast, is small." Upsher's argument would render "the rewards available to those willing to undergo the time, expense, and interim frustration of such practical research … at best a dubious incentive." *Id* at 222.

B. Irreparable Harm

Defendants' lack of a defense with substantial merit compels a finding of irreparable harm. Opening Brief, p. 3. Defendants cannot deny that entry of their generic drugs would irreversibly and adversely effect Savient's branded drug's price, profit, market share and the goodwill, reputation and status as a company. This establishes the requisite irreparable harm. In fact, defendants admitted such would result *to them* when they demanded that Savient's licensed partner, Watson, also be enjoined. No one who reads a newspaper or watches TV news is unaware of the vast and irreparable harm done from unlawful generic entry into a market.

Defendants' argument that Savient's loss would just be financial (Sandoz Opposition, pp. 9-10) is not supported by fact or law. The declaration of Paul Hamelin and the declaration of Dr. Kolassa both establish irreparable harm that is not compensable by money, namely, the loss of employees that cannot be replaced, the loss of reputation and goodwill, the loss of the value of the patents and the loss of the value of the creation of the new and beneficial uses of oxandrolone.

C. Balance Of Hardships And Public Interest

The balance of hardships and public interests tip decidedly in favor of Savient. Neither Sandoz nor Upsher will suffer if the status quo is maintained for a short period of time. Defendants and Savient's patent-licensed partner, Watson, cannot presently market or sell oxandrolone products. Defendants' argument that the TRO works "a grave injustice to Sandoz as well as the public" because it enjoins them from marketing their products for their approved indications (Sandoz Opposition, p. 10) cannot be taken seriously. There is no use for these indications anymore. Horowitz Decl., ¶¶ 5-13.

Defendants have presented no argument of merit that can demonstrate that Savient's duly issued patents should not be respected. The inventors of the five Savient patents took an abandoned product and breathed life into it with new and non-obvious uses that have benefited mankind. Demling Decl., ¶¶ 3-7; Ottery Decl., ¶¶ 5-21. Savient has done everything right here in bringing new therapies to the practice of medicine and should fully benefit from taking the risks and developing the market for its patented uses. *See* Opening Brief, p. 2.

IV. CONCLUSION

For all the foregoing reasons, Savient respectfully requests that the Court maintain its temporary restraining order and advance the action to a preliminary injunction proceeding with briefing and hearing.

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