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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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CELGENE CORPORATION,)		
NOVARTIS PHARMACEUTICALS)		
CORPORATION, and)	Civil Action No. 2:07-cv-04819-SDW-MCA	
NOVARTIS PHARMA AG,)		
)		
Plaintiffs,)	DEFENDANT’S MEMORANDUM OF	
)	LAW IN SUPPORT OF ITS MOTION	
v.)	FOR SANCTIONS PURSUANT TO	
)	FED. R. CIV. P. 11	
KV PHARMACEUTICAL COMPANY,)		
)		
Defendant.)	(Filed Electronically)	
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Defendant KV Pharmaceutical Company (“KV”), through its undersigned counsel, respectfully submits this memorandum of law in support of its Motion, pursuant to Fed. R. Civ. P. 11 (“Rule 11”), for an order dismissing the patent infringement complaint filed by plaintiffs Celgene Corporation (“Celgene”), Novartis Pharmaceuticals Corporation and Novartis Pharma A.G. (collectively “Novartis”) (Celgene and Novartis are collectively “Plaintiffs”), and awarding KV its costs and attorneys’ fees.

PRELIMINARY STATEMENT

Plaintiffs are “branded” pharmaceutical companies that currently have the exclusive right to market Ritalin LA[®], an allegedly novel, long-acting formulation of an old drug—methylphenidate hydrochloride (originally marketed under the brand name

Ritalin[®] in 1957).¹ Ritalin LA[®] was approved by the federal Food and Drug Administration (“FDA”) on June 5, 2002 for the treatment of Attention Deficit Hyperactivity Disorder (“ADHD”) and certain other indications. The alleged novelty of Ritalin LA[®], according to the patents asserted in this suit, lies in its “pulsatile” release pattern, which produces two “pulses” of drug release separated by a period of several hours. These pulses can be detected in the pharmacokinetic plasma profiles of patients who have ingested Ritalin LA[®], as two distinct maxima separated by a period of about two to seven hours.

Defendant KV is a pharmaceutical company that is seeking FDA approval to market a generic version of Ritalin LA[®] (“Generic Ritalin”) pursuant to an Abbreviated New Drug Application (“ANDA”) filed under the provisions of the Hatch-Waxman Act, 21 U.S.C. §355 (the “Act”). As required by § 355(j)(2)(B)(iv) of the Act, on August 21, 2007, KV sent Plaintiffs a letter notifying them that KV was seeking FDA approval to market Generic Ritalin (the “Paragraph IV Notice Letter”).² The Paragraph IV Notice Letter explained in detail that KV’s Generic Ritalin would not infringe any of the patents that Novartis had listed in the FDA’s “Orange Book,” including the two patents in suit, because, *inter alia*, KV’s Generic Ritalin does not (i) have a pulsatile release pattern, a requirement of all asserted patent claims; (ii) contain ammonio methacrylate; or (iii) contain the pure *d-threo-methylphenidate* isomer of methylphenidate. KV’s Paragraph IV Notice Letter also offered to provide Plaintiffs with a copy of KV’s ANDA and

¹ The patents covering the original Ritalin[®] formulation expired in 1967, several years before the drug was approved for the treatment of ADHD in children.

² See Decl. Constance S. Huttner (June 2, 2008) (“Huttner Decl.”), Ex. A. Although the Paragraph IV Notice Letter was addressed to both Celgene and Novartis, Celgene was the only company to respond.

samples of KV's Generic Ritalin, subject to an appropriate confidentiality agreement, so that Plaintiffs could verify for themselves that there was no basis for alleging that KV's Generic Ritalin would infringe any of Celgene's patents.³

Although Celgene's outside counsel eventually asked for, and received, a draft of KV's proposed confidentiality agreement, Celgene never provided KV with any comments or counterproposal, and made no other effort to obtain KV's ANDA and samples of KV's Generic Ritalin to evaluate for itself whether KV's Generic Ritalin would infringe. Rather, on October 4, 2007, within the 45-day window established under the Act to determine the bona fides of any potential infringement litigation, Plaintiffs simply initiated this suit. By taking this step, Plaintiffs ensured the absence of generic competition and the continuation of their monopoly position (and profits) with respect to Ritalin LA[®] for the duration of the automatic 30-month injunction prescribed under the Act.

Under these circumstances, as explained in greater detail below, Plaintiffs' Complaint must be dismissed under Rule 11. When Plaintiffs initiated this suit, there can be no dispute that their *only* information about KV's Generic Ritalin was the information set forth in KV's Paragraph IV Notice Letter, which unambiguously explained why KV's Generic Ritalin would not infringe Celgene's patents. Neither KV's ANDA filing, nor the details of its proposed Generic Ritalin, was publicly available, and Plaintiffs did not avail themselves of KV's offer to provide its ANDA and samples of Generic Ritalin.

³ See Huttner Decl., Ex. A at 18 ("KV also hereby offers to provide Novartis with actual samples of KV's Methylphenidate Capsules for which KV is seeking approval to market from the FDA, under a mutually agreeable confidentiality agreement. KV will also promptly respond to any requests that Novartis may have with respect to obtaining additional information from KV regarding KV's ANDA Should Novartis desire to accept KV's offer to provide samples of the aforementioned capsules, or should Novartis seek additional information, please contact the undersigned.").

Finally, KV's Paragraph IV Notice Letter did not contend that Celgene's patents were invalid. Thus, there was no basis for initiating litigation against KV on a declaratory judgment theory.

Even after KV wrote to Plaintiffs urging them to withdraw this litigation on the grounds that it was baseless, Plaintiffs were unable to identify any factual theory for asserting that KV's Generic Product is covered by any claims of Celgene's patents. Plaintiffs instead asserted (contrary to law) that "KV's submission of [its] ANDA . . . was itself an act of infringement sufficient to justify this lawsuit." Letter from Charles M. Lizza to Stefan C. Grant (Feb. 29, 2008) (Huttner Decl., Ex. I).⁴ Although Plaintiffs did request and receive a copy of KV's ANDA, they declined to avail themselves of KV's renewed offer to provide samples of Generic Product to a pharmacy or other facility licensed to receive methylphenidate, which is a Drug Enforcement Agency ("DEA") regulated Schedule II drug. Plaintiffs instead stated, in the same high-handed, cavalier way they have approached the merits of this lawsuit:

⁴ As KV explained to Plaintiffs, while it is true that the filing of an ANDA constitutes a "highly artificial" act of infringement under the patent statutes, it does not excuse Plaintiffs from complying with their ethical obligations under Rule 11. Specifically, the Federal Circuit has clarified that Hatch-Waxman "does not make the filing of an ANDA . . . an act of infringement unless the ANDA seeks approval to manufacture, use, or sell the drug prior to the expiration of a patent *that would otherwise be infringed* by such [action] *apart from* the provisions of § 271(e)(2)." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355-56 (Fed. Cir. 2003) (emphasis in original). "*Once jurisdiction is established . . . the substantive determination whether actual infringement . . . will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits.*" *Id.* at 1365 (emphasis added).

“[Y]ou state that DEA regulations preclude KV from shipping these samples to a law firm, instead, you contend that the samples can only be shipped to a facility licensed to handle Schedule II drugs. Assuming this is the case, we will need to respond to your letter at a later date with the contact information of a licensed facility. Presently, we are not prepared with such information.”

Letter from Jordan A. Gimbel to Stefan C. Grant (Mar. 27, 2008) (Huttner Decl., Ex. L).

As of today, more than two months since the date of this statement, Plaintiffs have yet to supply the name of a licensed facility.

This Court should not reward Plaintiffs for their flagrant violation of Rule 11, or their efforts to unfairly suppress generic competition to the detriment of consumers and insurance providers. Plaintiffs’ Complaint should be dismissed, and KV should be awarded its attorneys’ fees and costs as Rule 11 sanctions.

STATEMENT OF FACTS

A. The Patents

The Celgene patents asserted in this case are U.S. Patent Nos. 5,837,284 (the “’7,284 Patent”)⁵ and 6,635,284 (the “’5,284 Patent”),⁶ both entitled, “Delivery of Multiple Doses of Medications;” they are related patents. Both patents include independent claims directed to “pulsatile” dosage forms of methylphenidate, whereby a group of immediate release particles of methylphenidate are combined with one or more groups of delayed release particles of methylphenidate in a once-a-day pill. The ’5,284 Patent also claims methods of treating disease with such pulsatile dosage forms.

⁵ Huttner Decl., Ex. C.

⁶ Huttner Decl., Ex. D.

Each of the asserted claims of the patents in suit requires one or more of the following limitations to be satisfied:

- a controlled release coating containing “*ammonio methacrylate*” (e.g., independent claims 1 and 27 of the ’7,284 Patent, and independent claims 1 and 3 of the ’5,284 Patent);
- a “*pulsatile*” release pattern, wherein a portion of the methylphenidate formulation (consisting of immediate release particles) is released from the dosage form immediately after ingestion by a patient, and another portion (consisting of particles coated with a controlled release coating containing ammonio methacrylate) is released after a delay of two to seven hours, so that the post-ingestion plasma concentration profile of the patient has two maxima separated by a time delay (all of the claims of the ’5,284 and ’7,284 Patents); or
- the single pure *d-threo-methylphenidate* isomer of methylphenidate (e.g., independent claim 27 of the ’7,284 Patent, and independent claims 1, 10 and 11 of the ’5,284 Patent).⁷

Claim 1 of the ’7,284 Patent is exemplary of those claims that require an “ammonio methacrylate” coating. It provides as follows:

A dosage form for the oral administration of a methylphenidate drug, comprising two groups of particles, each containing said drug, wherein:

. . . .

b) said second group of particles comprises coated particles, said coated particles . . . said coating comprising a pharmaceutically acceptable ammonio methacrylate in a quantity sufficient to provide a dose of said medication delayed by from about 2 hours to about 7 hours following said ingestion.

Claims requiring a pulsatile release pattern are exemplified by Claim 2 of the ’5,284 patent, which specifies:

⁷ Like many biologically active compounds, methylphenidate has at least two isomeric forms—*i.e.*, forms with the same molecular formula but with different structural formulas. These structural formulas, or “stereoisomers,” are “*d-threo-methylphenidate*” and “*l-threo-methylphenidate*,” which rotate light respectively in the right and left-handed directions. Ritalin LA[®], to which KV’s Generic Ritalin is bioequivalent, consists of a “racemic” mixture of these stereoisomers, with equal amounts of the left and right-handed compounds. The patents in suit, however, require a pure *d-threo* methylphenidate isomer.

A dosage form of a pharmaceutically acceptable salt of a methylphenidate providing an in vivo plasma concentration of said methylphenidate comprising two maxima, wherein said maxima are temporally separated by from about two hours to about seven hours and wherein the magnitude of said maxima differ by no more than about 30%.

See also '5,284 Patent, Claim 10, below.

Finally, claim 10 of the '5,284 Patent is typical of those claims that require d-threo-methylphenidate:

A method for treating disease amenable to treatment with a phenidate drug . . . comprising administering to the patient a dosage form of a pharmaceutically acceptable salt of d-threo-methylphenidate, said dosage form providing an in vitro release profile comprising two pulses of drug release, wherein said pulses are temporally separated by from about 2 hours to about 7 hours.

As discussed below, and as was clearly explained in KV's Paragraph IV Notice Letter, KV's Generic Ritalin satisfies *none* of these limitations, and does not infringe either of Celgene's patents literally or under the doctrine of equivalents.

B. KV's Generic Ritalin Is A Non-Pulsatile Extended Release Formulation Which Does Not Contain Ammonio Methacrylate Or A Pure Isomer Of d-Threo Methylphenidate

As set forth in KV's ANDA and Paragraph IV Notice Letter, KV's Generic Ritalin is a *non*-pulsatile extended release formulation of methylphenidate hydrochloride, which does *not* contain an ammonio methacrylate coating, or comprise a pure d-threo methylphenidate isomer. Rather, KV's Generic Ritalin is (i) a mixture of d- and l-threo-methylphenidate isomers (a racemic mixture), (ii) which uses ethyl cellulose, not ammonio methacrylate, as a controlled release coating, and (iii) which does not release in a pulsatile manner, but rather in a continuous release pattern. *See* Declaration of Robert F. Green, Esq. in Support of Defendant KV Pharmaceutical Co.'s Motion for Sanctions

Pursuant to Rule 11, at 2 (Feb. 7, 2008) (hereinafter “Green Decl.”); Huttner Decl., Ex. A at 9-12 & Ex. B at KV0000090, KV0000154-156, KV0001297-1301.

The non-pulsatile release profile of KV’s Generic Ritalin is demonstrated by the *in vitro* dissolution data set forth in its ANDA. *See* Huttner Decl., Ex. A at 12 & Ex. B at KV0006316-37. These data show that KV’s Generic Ritalin formulation has an essentially “zero order” release profile, whereby methylphenidate is released at an almost constant rate following an initial period of rapid release; the profile does not include a two to seven hour “wash-out” period during which no drug is released. This profile contrasts markedly with the release profile shown in Figure 1 of the ’7,284 and the ’5,284 Patents, which depicts an initial immediate release of about 50% of the active ingredient, followed by a period of about three hours during which only about 5% of the active ingredient is released, followed by release of about 30% over the next two hours. *See* Huttner Decl., Ex. A at 11-12 & Ex. B at KV0006319-20.

KV’s Generic Ritalin also exhibits a non-pulsatile *in vivo* release pattern after ingestion by a patient *See* Huttner Decl. Exs. A at 9-12 & B at KV0001297-1301. Specifically, as shown in KV’s ANDA, there is an initial rise in plasma concentration of methylphenidate after ingestion that slowly tails off during the ensuing twelve hour period. *See* Huttner Decl. Exs. A at 9-12 & B at KV0001301. In contrast, Figure 2 of the patents in suit shows a plasma profile with two distinct maxima separated by a trough corresponding to the two to seven hour delay period discussed above, during which comparatively no methylphenidate is released. *See* ’7,284 Patent, FIG. 2 (Huttner Decl., Ex. C); ’5,284 Patent, FIG. 2 (Huttner Decl., Ex. D).

C. Celgene Has Previously Admitted That Its Patents Do Not Cover The Type Of Extended Release Pattern Exhibited By KV's Generic Ritalin.

Before initiating this lawsuit, Celgene itself expressly acknowledged to the U.S. Patent and Trademark Office ("USPTO") that the patents in suit do not cover an extended release profile like the one detailed in KV's ANDA for Generic Ritalin. Specifically, as noted herein, during the prosecution of the '5,284 Patent, Celgene argued that its claims were not anticipated by KV's own U.S. Patent No. 5,133,974, entitled "Extended Release Pharmaceutical Formulations" (the "'974 Patent"), issued more than four years *before* the earliest priority date of Plaintiffs' patents in suit.⁸ The '974 patent discloses an extended release formulation comprising a mixture of immediate and extended release particles coated with a controlled release coating which can contain, *inter alia*, ammonio methacrylate or ethyl cellulose. This formulation can be used with a variety of drugs, including central nervous system drugs like methylphenidate.

Celgene asserted to the USPTO that its claimed methylphenidate formulations were patentable over KV's earlier '974 Patent because:

the 974 patent does not describe a pulsatile dosage form.

Rather, the 974 patent is directed to extended release dosage forms that are adapted to produce **zero order** release of drug over a 12 to 24 hour time period. . . . wherein

. . . less than 50% of the drug is released within 1 hour of measurement and not less than 70% of the drug is released at the targeted dosing period, such as a 12 to at least 24 hour period.

. . . . These data demonstrate that drug is released from the 974 compositions continuously over time, and **do not show the pulsatile release described by the present claims.**

⁸ Huttner Decl., Ex. E.

. . . . The definition of ‘delayed release’ provided in the present specification states that the profile ‘includes a period during which no more than about 10 percent of the drug in a particular dosage form is released . . .’; thus, giving rise to a pulsatile release. This feature is not taught or suggested anywhere in the 974 patent, or in the examples thereof.

See ’5,284 File History, Preliminary Amendment, at 3-5 (Mar. 7, 2001) (Paper No. 17) (citations omitted) (emphasis added).⁹

Significantly, the *in vitro* release profile of the formulations disclosed in KV’s ’974 Patent is substantially the same as the *in vitro* release profile of KV’s Generic Ritalin set forth in its ANDA. Compare Huttner Decl., Ex. E, Col. 3, l. 18-Col. 5, l. 12, with Ex. B at KV0001297-1301.

In filing the instant action, Plaintiffs are charged with knowledge of Celgene’s patent prosecution of the patents in suit, including Celgene’s disclaimers to the USPTO of the coverage of the patents in suit over non-pulsatile drugs and Celgene’s own distinguishing of the patents in suit from KV’s prior patent covering non-pulsatile extended release drugs such as KV’s proposed Generic Ritalin. Accordingly, Celgene’s admission that the release profile disclosed in KV’s ’974 Patent is non-pulsatile and that the patents in suit cover only pulsatile products applies with equal force to KV’s Generic Ritalin, especially after KV disclosed in its Paragraph IV Notice Letter the non-pulsatile nature of its Generic Ritalin:

Following an initial period of rapid drug release, KV’s Methylphenidate Capsules provide a steady release of methylphenidates, which slowly tapers off toward the end of the release period. Thus, KV’s Methylphenidate Capsules do not provide an *in vitro* release profile have two pulses of drug release

⁹ Huttner Decl., Ex. F.

Huttner Decl., Ex. A at 11.

This express admission by Celgene to the USPTO pertaining to the patents in suit necessarily alerted Plaintiffs to the fact that their infringement allegations were baseless with respect to KV's Generic Ritalin, a conclusion that would have been buttressed further had Plaintiffs bothered to review KV's ANDA before rushing into this Court.¹⁰

D. KV's Compliance With The Advance Notice Requirements Of Rule 11

On February 8, 2008, KV provided Plaintiffs with a copy of KV's Rule 11 Motion papers and written notice of its intent to proceed with this Motion if Plaintiffs did not withdraw their Complaint within twenty-one days. *See* Letter from Mary Sue Henifin to Charles M. Lizza and William J. O'Shaughnessy (Feb. 8, 2008).¹¹ Plaintiffs responded on February 29. *See* Letter from Charles M. Lizza to Stefan C. Grant (Feb. 29, 2008).¹² In response to KV's contention that Plaintiffs had not met their obligations under Rule 11 by failing to investigate the factual basis of their infringement allegations before filing suit, Plaintiffs asserted that they "had no obligation to review [KV's] ANDA or test product samples before filing suit" because allegedly, the mere filing of KV's ANDA was a sufficient basis for proceeding. *Id.* ¶ 4. Plaintiffs further asserted that the confidentiality terms KV had originally proposed for the disclosure of its ANDA were "wholly unreasonable," even though the terms proposed by KV were less onerous than

¹⁰ *See also* Amendment at 3 (Nov. 26, 1999) (Paper No. 10) (Huttner Decl., Ex. G) (reflecting Celgene's argument during the '5,284 Patent prosecution that the claimed pulsatile dosage were not obvious over a sustained release dosage form of methylphenidate disclosed in U.S. Patent No. 5,593,694 (the "'694 Patent") because a pulsatile dosage form "permits the once daily administration of drug, but . . . effect two or more effectively separate administrations of the drug separated by a predetermined time—a pulsatile dosage form.").

¹¹ Huttner Decl., Ex. H.

¹² Huttner Decl., Ex. I. The response was submitted on behalf of both Celgene and Novartis.

the terms of the Protective Order that Celgene agreed to in *Celgene v. Abrika*, No. 06-5818 (D.N.J. Aug. 13, 2007) (doc. 65). *See* Attachment to Huttner Decl., Ex. I.

KV responded to Plaintiffs' letter on March 7 by agreeing to produce its ANDA and Generic Ritalin samples under a "highly confidential" designation, according to the terms of the *Abrika* Protective Order. *See* Letter from Stefan C. Grant, M.D. to Charles M. Lizza and William J. O'Shaughnessy, at 2-3 (Mar. 7, 2008).¹³ KV's response also discussed the cases cited in this Motion, which make clear that the filing of an ANDA alone is not sufficient to relieve a branded drug company of its Rule 11 obligations. *See id.* at 2.

After the production of KV's ANDA, KV wrote Plaintiffs on March 21 to remind them of DEA restrictions on the shipment of Schedule II drugs like methylphenidate. KV requested that Plaintiffs provide the address of the DEA-approved facility to which samples of the Generic Product should be sent. *See* Letter from Stefan C. Grant, M.D. to Charles M. Lizza and William J. O'Shaughnessy (Mar. 21, 2008).¹⁴ As noted above, Celgene responded on March 27 by stating that it would contact KV "at a later date" to provide the name of a licensed facility to which KV's Generic Ritalin samples should be shipped. *See* Letter from Jordan A. Gimbel to Stefan C. Grant (Mar. 27, 2008).¹⁵ Two months have now passed, and Plaintiffs have yet to provide the name of any licensed facility to which KV's samples should be sent. Consequently, Plaintiffs have no legitimate basis for contesting the data concerning KV's Generic Ritalin set forth in KV's

¹³ Huttner Decl., Ex. J.

¹⁴ Huttner Decl., Ex. K.

¹⁵ Huttner Decl., Ex. L.

ANDA and summarized in KV's Paragraph IV Notice Letter. Those data demonstrate conclusively that KV's Generic Ritalin does not infringe any of the claims of the patents in suit.

ARGUMENT

A. The Applicable Legal Standards Under Rule 11

In this Circuit, Rule 11 sanctions are appropriate where a claim or pleading is legally or factually baseless from an objective point of view, and made without a reasonable and competent inquiry: "Rule 11 sanctions are based on 'an objective standard of reasonableness under the circumstances.'" *Martin v. Brown*, 63 F.3d 1252, 1264 (3d Cir. 1995). "The Third Circuit has defined 'reasonableness' in the context of Rule 11 as 'an objective knowledge or belief at the time of the filing . . . that the claim was well-grounded in fact and law.'" *Clement v. Pub. Serv. Elec. & Gas Co.*, 198 F.R.D. 634, 637 (D.N.J. 2001). No showing of bad faith is required. *Martin*, 63 F.3d at 1264.

The Third Circuit has not addressed Rule 11 in the context of a patent infringement action. The Federal Circuit, however, has "interpreted Rule 11 to require, at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement." *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300-01 (Fed. Cir. 2004); *see also Bus. Guides, Inc. v. Chromatic Comms. Enters., Inc.*, 498 U.S. 533, 548 (1991) (holding that Rule 11 requires "unambiguously that any signer must conduct a 'reasonable inquiry' or face sanctions").

"The presence of an infringement analysis plays the key role in determining the reasonableness of the pre-filing inquiry made in a patent infringement case under Rule

11.” *View Eng’g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 986 (Fed. Cir. 2000) (affirming an award of sanctions based on a lawyer’s failure to make a reasonable factual inquiry prior to filing infringement counterclaims); *Judin v. United States*, 110 F.3d 780, 784 (Fed. Cir. 1997) (“No adequate explanation was offered for why they failed to obtain, or attempted to obtain, a sample of the accused device from the Postal Service or a vendor so that its actual design and functioning could be compared with the claims of the patent. Under these circumstances, there is no doubt that Judin failed to meet the minimum standards imposed by Rule 11”). Where, as here, the claim is based on an ANDA filing, the focus of the infringement inquiry is on the drug that will be sold by the generic company after the FDA gives its final approval. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Thus, information about KV’s Generic Ritalin was critical to the fulfillment of Plaintiffs’ Rule 11 obligations.

“Once a litigant moves based upon non-frivolous allegations for a Rule 11 sanction, the burden of proof *shifts* to the non-movant to show it made a reasonable pre-suit inquiry into its claims.” *Digeo, Inc. v. Audible, Inc.*, 505 F.3d 1362, 1368 (Fed. Cir. 2007) (citing *View Eng’g, Inc.*, 208 F.3d at 986). Accordingly, Plaintiffs bear the burden of persuading this Court that Plaintiffs conducted a reasonable pre-suit inquiry under the circumstances. This is a burden that Plaintiffs plainly cannot meet.

B. Plaintiffs Plainly Violated Their Rule 11 Obligations

As discussed above, Plaintiffs were offered a copy of KV’s ANDA and samples of its Generic Ritalin in KV’s Paragraph IV Notice Letter. Celgene asked for, and received, a copy of KV’s Confidentiality Agreement, but then let the matter drop without

any further response or effort to obtain a sample of, or information about, KV's proposed Generic Ritalin. *See* Green Decl. ¶¶ 8-10.¹⁶

Thus, besides the *non-infringement* position set forth in KV's Paragraph IV Notice Letter, Plaintiffs had *no* factual information about KV's Generic Ritalin before filing suit. *A fortiori*, this non-infringement position did not give Plaintiffs an objectively reasonable basis for filing an infringement suit against KV.¹⁷

The Federal Circuit's decision in *View Engineering* is applicable to the instant case. There, the plaintiff had the opportunity to inspect the accused product and speak with its sales force to learn what they knew about the defendant's accused machines before filing suit. Neither the plaintiff nor its attorneys, however, availed themselves of this opportunity before suing for infringement. Under these circumstances, the Federal Circuit had no difficulty concluding that the plaintiff had violated Rule 11. The Court explained:

[L]ittle inquiry, much less a reasonable one, was undertaken by [plaintiff and their attorneys] in the instant case. Before filing counterclaims of patent infringement, Rule 11, we think, must be interpreted to require the law firm to, at a bare minimum, apply the

¹⁶ In response to KV's notification of its intent to file this Motion, Plaintiffs now argue that the language in KV's Paragraph IV Notice Letter did not constitute an offer to provide KV's ANDA. Plaintiffs' newly-concocted argument is demonstrably false.

¹⁷ Nor can Plaintiffs meet their Rule 11 obligations by relying on the fact that KV must demonstrate that its Generic Ritalin is bioequivalent to Ritalin LA[®] in order to obtain FDA approval. First, it is not at all clear that Ritalin LA[®] is covered by the patents in suit, as it appears to be made by a different method than the one described in those patents. Second, and more importantly, FDA bioequivalence only requires proof that the proposed generic product absorbed in the bloodstream is "substantially equivalent" to the approved product in relation to two specific pharmacokinetic parameters—Area Under the Curve ("AUC") and "Cmax," or maximum plasma concentration following administration. *See* CTR. DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUS. BIOAVAILABILITY & BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS—GENERAL CONSIDERATIONS (draft guidance) § III.A.8 (stating that Cmax and AUC can be used as measures for bioequivalence). In short, the FDA focuses its bioequivalence decisions on *how much* of the given drug is delivered, not on the *technical means* by which the delivery is made. These parameters can be met by a non-pulsatile dosage form, which would not infringe the patents in suit.

claims of each and every patent that is being brought into the lawsuit to an accused device and conclude that there is a reasonable basis for a finding of infringement of at least one claim of each patent so asserted . . . [Plaintiff and their attorneys] *performed neither a formal nor an informal analysis of any sort. This cannot be found to be a reasonable inquiry for the purpose of filing patent infringement claims.*

208 F.3d at 986 (emphasis added).

The Federal Circuit's conclusion in *View Engineering* is equally applicable here. Neither Plaintiffs nor their counsel made *any* reasonable effort to review KV's ANDA or evaluate KV's Generic Ritalin capsules during the forty-five day evaluation period the Act contemplates for the assessment of the appropriateness of litigation, following the patentee's receipt of the ANDA notification letter. *See* 21 U.S.C. §§ 355(j) (5) (B) (iii) & 355(j) (5) (C) (i) (III). Plaintiffs therefore cannot be found to have complied with their Rule 11 obligations.

The outcome in *Judin v. United States* also is instructive for the present case. In *Judin*, the plaintiff accused the government of infringing patent claims for a bar code reader, which required *inter alia* an "optical fiber source" and a "converging aspherical lens." *Judin*, 110 F.3d at 781. The district court found that that the plaintiff "should have known that these two elements were critical, due to his difficulty in obtaining the patent." *Id.* at 782. The plaintiff brought his suit after observing the use of the accused devices from a distance at the Post Office. *Id.* at 781-82. From this distance, the plaintiff could not tell whether the critical elements were present. *Id.* Moreover, neither the plaintiff nor his attorney obtained a copy of the accused device from the government or from any vendor prior to filing suit. *Id.*

In response to the defendant's motion for Rule 11 sanctions, the plaintiff argued that a vendor's technical description would not have been useful, because the devices were made to government specification. The plaintiff also contended that the devices were not readily available for disassembly because they were in use at government facilities. *Id.* at 783. Based on these arguments and the plaintiff's erroneous assumption about the breadth of his claims, the trial court determined that additional knowledge about the accused devices would not have made a difference, and refused to award Rule 11 sanctions. *Id.*

The Federal Circuit reversed. *Id.* at 784. Specifically, the Federal Circuit held that

[Knowledge gained by observation of the accused devices from a distance] may have been sufficient to put [plaintiff] on inquiry But Rule 11 requires more. It requires that the inquiry be undertaken *before* the suit is filed, not after.

Id. Because neither the plaintiff nor his counsel made any reasonable effort to determine if the two key claim limitations were met, the Federal Circuit found that "there is no doubt that [the plaintiff] failed to meet the minimum standards imposed by Rule 11." *Id.*

Similarly, here Celgene was on notice that there was close prior art, including KV's own '974 Patent. Celgene even was required to distinguish to the USPTO the release profile of its pulsatile compositions from the extended release compositions disclosed in KV's own, earlier '974 Patent in order to overcome an anticipation rejection and obtain allowance of the patents in suit. Plaintiffs also were on notice of the continuous, non-pulsatile release of KV's Generic Ritalin. Plaintiffs further knew that their patent claims required ammonio methacrylate and/or pure d-threo methylphenidate, which they were advised are absent from KV's Generic Ritalin. Thus, Plaintiffs knew

their patent claims were limited to a small subset of methylphenidate formulations, and could not have reasonably relied on the mere filing of KV's ANDA to satisfy their Rule 11 obligations prior to filing this suit. *See Q-Pharma*, 360 F.3d at 1300-01 (holding that Rule 11 "require[s], at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement.")

Despite their knowledge of their patents' narrow scope, Plaintiffs continue to assert that they "ha[ve] no obligation to review [KV's] ANDA or test product samples before filing suit." *See Huttner Decl.*, Ex. I at ¶ 4. Even in the face of the present Motion, Celgene's recent correspondence makes clear that, even eight months after receiving KV's Paragraph IV Notice Letter, they conferred with KV to obtain its ANDA and samples "**solely to advance** the litigation" rather than to comply with their Rule 11 duties. *See Huttner Decl.*, Ex. L (emphasis added).

If Plaintiffs had availed themselves of the opportunity to review KV's ANDA and evaluate KV's Generic Ritalin, they would have realized that their infringement allegations were frivolous. Specifically, they would have confirmed that KV's Paragraph IV Notification Letter accurately reflected the fact that KV's proposed Generic Ritalin does not contain ammonio methacrylate or optically pure d-threo methylphenidate, and that it does not exhibit a pulsatile release pattern, either *in vitro* or *in vivo*. There is no legitimate excuse for their failure to do so, and KV should not be forced to bear the expense and delay occasioned by this case while Plaintiffs and their lawyers scramble to come up with an after-the-fact theory of infringement. *See Clement*, 198 F.R.D. at 636

(finding that an attorney violated Rule 11 because she “failed to conduct even a rudimentary pre-complaint investigation prior to filing”).

C. Plaintiffs Also Cannot Justify This Lawsuit Merely Because KV Filed An ANDA.

In their Complaint, Plaintiffs allege that the mere “submission of ANDA 79-004 . . . constitutes infringement of one or more of the claims of the [patents-in-suit].” *See* Compl. ¶¶ 22, 27. This statement does not accurately represent the law as it pertains to the infringement analyses required to pass muster under Rule 11.

While 35 U.S.C. § 271(e) (2) characterizes the filing of an ANDA as “an act of infringement,” the Supreme Court made clear more than 17 years ago that this is a “highly artificial” act of infringement having a “very limited and technical purpose”—to create a “case or controversy” sufficient to confer subject matter jurisdiction on the courts so that the question of infringement can be resolved in a time frame that does not unduly delay generic competition. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78, 110 S.Ct. 2683 (1990); *see also Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

The Federal Circuit has further clarified “that the statute does not make the filing of an ANDA . . . an act of infringement unless the ANDA seeks approval to manufacture, use, or sell the drug prior to expiration of a patent *that would otherwise be infringed* . . . *apart from* the provisions of § 271(e)(2).” *Warner-Lambert Co.*, 316 F.3d at 1355-56 (emphasis in original). “*Once jurisdiction is established . . . the substantive determination whether actual infringement . . . will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement cases.*” *Id.* at 1365.

Therefore, the creation of an artificial act of infringement to allow for subject matter jurisdiction does not and cannot relieve Plaintiffs of their obligation to undertake a proper pre-filing infringement analysis under Rule 11 of the actual product alleged to be infringing.

D. KV Has Satisfied All Conditions Of Rule 11 For Bringing This Motion

A litigant that seeks Rule 11 sanctions must first provide notice of its intention to do so, and give the opposing party twenty-one days to withdraw or correct the challenged pleading before filing its Motion. Fed. R. Civ. P. 11(c)(1). KV has satisfied this requirement by providing Plaintiffs' counsel with a copy of KV's Motion papers and written notice of its intent to proceed with this Motion if Plaintiffs did not withdraw their Complaint within twenty-one days.

Nearly four months have lapsed and, despite repeated solicitations by KV, Plaintiffs have not withdrawn their Complaint. Accordingly, the conditions of Rule 11 have been satisfied.

CONCLUSION

For the reasons stated herein, this Court should grant Defendant KV Pharmaceutical Company's motion for sanctions pursuant to Rule 11 dismissing the Complaint with prejudice, and awarding KV its attorneys' fees and costs.¹⁸

Dated: June 2, 2008

Respectfully submitted,

s/ Christopher J. Dalton

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¹⁸ Given the sanction of dismissal requested in this Motion, the Court could (but need not) treat this submission as a motion for summary judgment under Rule 56 of the Federal Rules of Civil Procedure.

CERTIFICATE OF SERVICE

I hereby certify that on the date set forth below, I caused to be filed electronically the attached Motion For Sanctions Pursuant to Rule 11 with the United States District Court for the District of New Jersey through the Court's Electronic Filing System. I also certify that on the date set forth below, I caused a copy of the foregoing to be served by overnight delivery on the following counsel as follows:

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I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: June 2, 2008

By: s/ Christopher J. Dalton _____
Christopher J. Dalton