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UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

SUBHAS **KUNDU**,
VIVEK DESAI, and ANDREA CAMERON
(09/621,623),
Junior Party,

v.

NARAYAN **RAGUNATHAN**,
JAMES C. CHAO, ROBERT A. FEMIA, and MALCOLM S.F. ROSS
(6,028,065; 6,268,356; and 09/757,261),
Senior Party.

Interference No. 104,843[1]

HEARD: 21 August 2002

Before SCHAFER, LEE, and TORCZON, Administrative Patent Judges.

TORCZON, Administrative Patent Judge.

JUDGMENT
(PURSUANT TO 37 CFR §1.617)

INTRODUCTION

[01] Kundu filed its involved 09/621,623 [623] application after Ragunathan's 6,028,065 [065] patent had issued and more than two years after Kundu alleges it had first reduced the interfering subject matter to practice. An administrative patent judge entered an order pursuant to Rule 617[2] requiring Kundu to show cause why judgment should not enter

[1] Related litigation: Pharmaceutical Resources, Inc. v. Alpharma USPD Inc., 02-CV-1015 (SDNY, McKenna, J.).

[2] Rules 37 C.F.R. part 1 are commonly known by section number alone. Hence, "Rule 617" refers to "37 C.F.R. §1.617".

against Kundu for abandonment, suppression, or concealment (Paper 3). This proceeding followed.

FINDINGS

The subject matter of the interference

[02] Both Ragunathan and Kundu engaged in an effort to produce a commercial, oral formulation for the drug megestrol acetate that would not infringe a Bristol-Myers Squibb Company patent [2004].[3] Bristol-Myers Squibb has a product, MEGACE®, within the scope of its patent that the Food and Drug Administration [FDA] has already approved and that could thus provide the basis for an abbreviated new drug application [ANDA] [2003 at ¶¶2, 5, & 7]. Bristol-Myers Squibb's early disclosure of an invention (its Atzinger patent) without have fully exhausted all possible avenues of development appears to have promoted the useful arts by enabling and inspiring others (Kundu and Ragunathan) to explore its possibilities as well.

[03] Count 1, the sole count, is "An oral pharmaceutical composition of Ragunathan 065 claim 1." Ragunathan 065 claim 1 is:

> An oral pharmaceutical composition in the form of a stable flocculated suspension in water capable of being redispersed after being allowed to settle at 40° C. and 75% relative humidity for a period of three months, said composition comprising:
>
> (a) about 10 to 200 mg per ml micronized megestrol acetate;

[3] A.E. Atzinger et al., "Megestrol Acetate Formulation", U.S. Patent 5,338,732 (16 August 1994) [2004]. Exhibits numbered 2xxx are Kundu exhibits; 1xxx, Ragunathan exhibits.

(b) about 10 to 40% by weight of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and

(c) about 0.0001 to 0.03% by weight of a surfactant, wherein polysorbate and polyethylene glycol are not simultaneously present in said composition.

[04] The composition of the count includes megestrol acetate, which is a water-insoluble, pharmaceutically active compound that can be used to combat loss of appetite in humans due to, for example, anorexia or cachexia (Paper 31,[4] admitted fact [0004]).

[05] Kundu has fifty-seven claims, of which 1-19, 23-33, and 36-57 correspond to the count. Although Rule 617(b) permits a party to file a motion to change the count, including claim correspondence, as well as the accorded benefit, Kundu elected to respond to the order without filing a motion.

[06] The declarants have not been cross-examined at this stage of the proceeding. The statements in the declarations are assumed to be true for the purposes of the Rule 617 proceeding.

Prima facie implication of suppression

[07] Ragunathan filed the 09/063,241 application on 20 April 1998. That application issued as the involved 065 patent on 22 February 2000 [2002].

[4] Kundu Response to Order to Show Cause Under 37 C.F.R. §1.617.

[08] Kundu filed its involved 623 application on 21 July 2000 (Paper 31, admitted fact 0049). Kundu has not claimed [2001] and was not accorded (Paper 1[5] at 3) the benefit of any earlier application.

[09] Kundu's 623 application was filed twenty-seven months after the application for Ragunathan's involved 065 patent was filed and one day short of five months after the 065 patent issued.

[10] Kundu has alleged an actual reduction to practice for the subject matter of the count of 29 August 1997 (Paper 31, contested fact [0007], which cites [2003, ¶¶3-7]), which is eight days short of thirty-five months before its earliest effective filing date.

[11] Absent some compelling explanation, it is unreasonable to file an initial application thirty-five months after an actual reduction to practice and five months after the issuance of a patent to another for the subject matter of the actual reduction to practice.

[12] Filing the initial application five months after the issue date of the senior party patent and simultaneously seeking an interference with the patent creates an inference of spurring.

[13] Kundu does not dispute the length of the delay or the timing of the events relevant to the delay and apparent spurring. Instead, Kundu argues that activity during the contested period overcomes any inference of suppression (Paper 31 at 13-26).

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[5] Notice declaring interference.

Kundu's evidence of work toward disclosure of the invention

[14] Alpharma USHP Inc. [Alpharma] is Kundu's real party-in-interest. Kundu witness Peter Capella was Alpharma's team leader for its megestrol project during the relevant period [2003, ¶2].

[15] The subject matter of the count is a flocculated suspension. According to Dr. Capella, Alpharma was inexperienced in the preparation of flocculated suspensions, so it followed its reduction to practice with dissolution studies; short- and long-term stability and resuspendability analyses; design changes; floc size analyses; changes in surfactant, surfactant concentration, and process of manufacture to optimize floc size; and *in vivo* trials. Alpharma experienced foaming, lack of homogeneity, and problems in scaling up to manufacturing-size batches [2003, ¶3].

[16] Kundu alleges a list of material facts about activities that occurred during the contested period (Paper 31, [0014]-[0048]). Ragunathan has taken the position that it is "[u]nable to admit or deny, and [the facts are] not relevant to the interference" (Paper 41[6] at 2).[7] Kundu provides evidence that it was continuously working on problems related to the subject matter of the count during the contested period [2033]. Specifically:

[16.1] Dissolution studies. Alpharma conducted numerous dissolution studies in 500 g and 3 kg batches for various compositions [0014] & [0015]. The studies were repeated for 40 kg

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[6] Ragunathan's statement in support of the order to show cause.

[7] Since Kundu has the burden of proof in this instance, Ragunathan need not have provide any response. Nevertheless, Kundu's response must be considered, including the facts Kundu has identified as material. A blanket assertion of irrelevance is not helpful to fact-finders trying to produce a clear, complete, and timely decision. Similarly, these paragraphs present a wealth of facts, but Kundu's correlation of Alpharma's testing to Kundu's patent application disclosure is generally sparse and vague, leaving it to the fact-finders to provide much of the correlation.

batches [0017] & [0023]. Ultimately, Alpharma appears to have concluded that dissolution was not a useful test for bioequivalence to MEGACE® [0026] [2016 & 2018]. Kundu has not pointed to any disclosure of the dissolution studies. Ragunathan argues that they were not disclosed (Paper 41 at 17).

[16.2] Stability and resuspendability studies. Alpharma conducted numerous 3-month stability and resuspendability studies on 3 kg and 40 kg batches for various formulations [0016]-[0018]. Six- and 12-month stability studies were conducted on 40 kg "pre-pilot" batches [0018] & [0019]. In the summer of 1999, Alpharma tested the stability of 500 kg batches of a docusate sodium formulation [0038] & [0039]. Kundu notes that stability and resuspendability are desirable aspects in implementing the invention (Paper 31 at 22). In Kundu's disclosure, Examples 6 and 11-15 provide stability and resuspendability data for specified formulations [2001 at 21-23 & 25-27].

[16.3] Physical and assay testing. Alpharma also purports to have done physical and assay testing on the 40 kg batches [0017]. Kundu does not explain the nature and significance of the testing except by broad references to the record, which appear to provide little additional illumination, and does not correlate this testing to disclosure in Kundu's specification.

[16.4] Viscosity. Alpharma purports to have developed a method for determining viscosity for flocculated megestrol suspensions [0021]. Kundu does not explain the significance of viscosity to its disclosure. The disclosure appears only to make passing reference to viscosity [2001 at 12-13 & 15].

[16.5] Floccule size. Alpharma purports to have developed a method for determining particle size [0022] and floccule [floc] size [0035] in megestrol suspensions. Alpharma subsequently determined that floc size was its best indicator of bioequivalence with MEGACE® because it relates to the drug's absorption rate into the patient's blood [0026] & [0028] [2018]. Kundu purports to have discovered that floc size is a function of wetting agent concentration [0027]. From February to May 1999, Alpharma focused on optimizing floc size in its docusate sodium formulations [0033]-[0037]. In November 1999, Alpharma looked at floc size in batches that had been tested for 24-month stability [0041]. Kundu's specification discusses the importance of floc size and discloses preferred embodiments in terms of floc size [2001 at 2 and 9-10]. Examples 2, 3, and 6-10 disclose information about floc size and a method for its measurement [2001 at 19 & 21-25].

[16.6] Lead formulations. After manufacturing 40 kg batches, Alpharma manufactured 35 gal. batches of "lead formulations", which it describes as those using docusate sodium (which is in the count) or PLURONIC® F127 (which is not) [0024]. Alpharma subsequently made a test batch for its ANDA with the PLURONIC® F127 formulation [0025]. Alpharma considered this batch to be a failure because it was not bioequivalent to Bristol-Myers Squibb's product [2016]. Kundu does not explain the significance of this step. The batch size does not appear related to the disclosure. One could speculate that this process led to the identification of docusate sodium as a particularly preferred

embodiment [2001 at 8], but Kundu does not say so. PLURONIC® F127 is also listed as a preferred wetting agent [2001 at 10].

[16.7] Manufacturing reproducibility. Alpharma produced a large (159.4 kg) batch to determine reproducibility of a variant (one-pot) manufacturing process using docusate sodium [0030]. A one-pot method of making is discussed in Kundu's specification [2001 at 16-17 and 22-23].

[16.8] Placebo testing. Alpharma produced 500 kg batches of "placebo" [0029]. Alpharma's placebo was the formulation without the active ingredient. The purpose of these batches was to test the manufacturing process and optimize mixer speed [2003, ¶34]. Kundu discloses high and low shear mixing generally in its specification [2001 at 16], but does not appear to provide any insights gleaned from this testing.

[16.9] Preservative tests. Alpharma prepared docusate sodium and MYRJ® 52 formulations to test the preservative effectiveness [0029] & [0032]. Kundu discloses the use of antimicrobial agents and preservatives, particularly sodium benzoate, in its specification [2001 at 14].

[16.10] Clinical testing. In the second half of 1999, Alpharma conducted clinical testing of docusate sodium formulations with different floc sizes and prepared a final report [0040]. According to Dr. Capella [2003, ¶45], this study suggested that the two-pot method was most suitable for further clinical analysis (Paper 31 at 19). Kundu discloses that the two-pot formulation "was particularly well suited for further clinical evaluation" [2001 at 24].

[16.11] ANDA batches. In early December 1998, Alpharma decided to produce "ANDA batches" [0031], but these were considered a failure [2003, ¶37] because they indicated a failure to maintain bioequivalence with MEGACE® [2020]. A December 1999 attempt to prepare a 1489 kg ANDA batch failed from a lack of drug substance uniformity, which created manufacturing difficulties [0042]. Instead, in early 2000, Alpharma simulated a full ANDA batch by making 500 kg batches [0043]. Manufacturing difficulties continued, leading Alpharma to repair its entire processing line [0044]. Finally, on 1 March 2000, Alpharma attempted a 1489 kg ANDA batch, which Alpharma reports resulted in the desired drug substance uniformity and filling accuracy [0045]. Kundu does not identify where the ANDA batch data is reflected in Kundu's specification.

[17] On 31 December 2000, over five months after Kundu's filing date, Alpharma filed an ANDA with the Food and Drug Administration. According to Dr. Capella, Alpharma expects approval of its ANDA this year [2003, ¶7]. Kundu has not shown that Alpharma's ANDA will necessarily lead to a public disclosure or that its work has otherwise been publically disclosed.

[18] Key requirements of an ANDA are showings of bioequivalence to an already approved product, in this case MEGACE®, and a detailed manufacturing plan, including specification of equipment to be used. 21 C.F.R. §314.94(a)(7) & (9).

[19] Alpharma's efforts on the subject matter of the count appear to have been principally directed to preparation of its ANDA. Some of the results of Alpharma's years of development appear in Kundu's specification, but often in the form of very broad

preferences. Kundu was aware of its need to provoke an interference with Ragunathan's 065 patent when its application was being drafted.

Evidence on the question of spurring

[20] Kundu's brief relies on exhibits 2001-2051 (Paper 31 at 1). Exhibits 2052-2062 first appear with the reply. James Brady, a patent practitioner then advising Alpharma, declared [2057] that his firm provided legal services to Alpharma during 1999 (¶26), including services prior to October 1999 (¶27), and including in September 1999 a non-infringement analysis and a discussion of unexpected results and "the patentability of Alpharma's reformulated Megace" (¶29); also [2059 at 5]. The billing record [2058] has numerous September 1999 entries, but their significance is not explained except to say that it represents "counseling" on Alpharma's megestrol formulations (Paper 42[8] at 9). Kundu did not provide any further information about "Alpharma's reformulated Megace" or any statement that it was a formulation within the scope of the count.

[21] In an October 1999 memorandum, Alpharma noted that Ragunathan's real party-in-interest [Par] had filed an ANDA for MEGACE® and that Bristol-Myers Squibb had initiated a suit against Par. The memorandum indicates an intent to consult patent counsel about the significance of these events [2026, ¶11].

[22] Mr. Brady declared that patent protection for Alpharma's megestrol formulations was discussed on 23 November 1999 [2037, ¶4]. Mr. Brady further declared that he proposed the preparation of a patent application for Kundu's megestrol formulations in December

[8] Kundu's reply Ragunathan's statement in support of the order to show cause.

1999 [2037, ¶5]. Billing records indicate the commencement of work at Mr. Brady's firm on "Megestrol Acetate Composition and Method (Patent)" on 23 December 1999 [2042]. Inexplicably, Kundu does not refer to work before March 2000 in its brief (Paper 31 at 23-26) when discussing its work on the Kundu application, but did point to it at the oral argument (Paper 48[9] at 22-23).

[23] On 22 February 2000, Ragunathan's involved 065 patent issued.

[24] Dr. Capella states that Alpharma's patent counsel was directed to prepare an application in March 2000 [0046] [2003, ¶7]. Mr. Brady concurs that his firm was instructed to prepare and file an application on Kundu's invention in mid-March 2000 after completion of a successful ANDA batch [2037, ¶¶7 & 8]. The billing records also indicate that billing for application drafting on "Megestrol Acetate Composition and Method (Patent)" resumed in mid-March 2000 [2042]. A confirmatory letter on 24 March 2000 shows that Alpharma was aware of Ragunathan's 065 patent and intended to provoke an interference. Alpharma was also working on new formulations intended to avoid both the Atzinger and Ragunathan patents [2043]. Since Kundu did not identify the December 1999 work in its brief, it did not explain either the gap or the apparent discrepancy on when drafting work on the invention of the count began. The December 1999 draft was not submitted for comparison, so it is not possible to determine what precise invention that application covered or whether it included the invention of the count.

[9] Oral argument transcript.

[25] Alpharma and its counsel continued to review and revise Kundu's application until it was filed 21 January 2002 [0047]-[0049].

[26] Kundu filed its application about four months after Alpharma's final request to prepare an application on the invention of the count, about five months after Ragunathan's 065 patent issued, about eight months after Alpharma and its counsel first discussed seeking patent protection to a megestrol formulation, and about nine months after it was aware of litigation over Par's ANDA directed to MEGACE®, the product Alpharma was targeting with its megestrol formulations.

DISCUSSION

A. Nature of the proceeding

Under Rule 608, an examiner may require a prospective junior party to show why it would be entitled to a judgment on priority under 35 U.S.C. 102(g)(1) if the senior party does no more than rely on its effective filing date.[10] A Rule 617 proceeding is a relatively rare interference proceeding in which the Board sua sponte explores problems in a junior party's showing under Rule 608. Basmadjian v. Landry, 54 USPQ2d 1617, 1618-19 (BPAI 1997), provides an extensive discussion of practice under Rule 617.

In the present case, Kundu provided a prima facie showing of an earlier actual reduction to practice, but §102(g)(1) requires the prior inventor not to abandon, suppress, or conceal the invention. The remarkable unexplained delay between Kundu's reduction to practice and filing

[10] The phrase "prima facie" is used in this context to indicate a showing that overcomes the senior party's effective date. It does not indicate a lowered threshold of proof on the question of priority. Basmadjian, 54 USPQ2d at 1623.

date, coupled with the intervening issuance of Ragunathan's patent, begs the question of whether Kundu abandoned, suppressed, or concealed its invention. Since Rule 608 does not require an applicant to answer that question, the issue can only be fully joined during an interference. Holmwood v. Cherpeck, 2 USPQ2d 1942, 1944 (BPAI 1986).

Ordinarily, a junior party subject to a Rule 617 proceeding may not introduce additional evidence absent a showing of good cause. Rule 617(b). The lack of a requirement in Rule 608 to justify a delay in filing, however, provides the "good cause" to permit a junior party to provide an additional showing addressing the reason for the delay (but not other issues). Holmwood, 2 USPQ2d at 1944. Abandonment does not appear to be the issue in this case, so the focus of the proceeding has been on whether Kundu suppressed or concealed[11] the invention. For the purposes of a Rule 617 proceeding declaration testimony is ordinarily presumed to be true. Basmadjian, 54 USPQ2d at 1624.

1. Burden of proof

Despite its name "Summary judgment against applicant", Rule 617 shares little in common with a summary judgment under the Federal Rules of Civil Procedure. One particularly significant difference is that the junior party applicant, the non-movant, has the burden of proof to show why it is entitled to judgment on priority. Rule 617(a); Schendel v. Curtis, 83 F.3d 1399, 1402, 38 USPQ2d 1743, 1746 (Fed. Cir. 1996). In this sense, it is a logical extension of the placement of the ultimate burden of proof for priority on the junior party. See Rule 657(a)

[11] The case law cited and the arguments of record do not appear to draw any significant distinction between suppression and concealment. For simplicity, this decision will speak of the issue as one of suppression.

(creating a rebuttable presumption that the parties invented in the same order that they filed); Brown v. Barbacid, 276 F.3d 1327, 1332, 61 USPQ2d 1236, 1238 (Fed. Cir. 2002).

Although the ultimate burden of proof stays with the junior party, the burden of going forward on the question of suppression normally lies with the proponent of the issue. Young v. Dworkin, 489 F.2d 1277, 1279, 180 USPQ 388, 390 (CCPA 1974). If, however, there is an unreasonably long delay between reduction to practice and disclosure (to the public or the United States Patent and Trademark Office [USPTO]) suppression may be inferred. Lutzker v. Plet, 843 F.2d 1364, 1367, 6 USPQ2d 1370, 1372 (Fed. Cir. 1988). In the present case, the administrative patent judge administering the interference found the unexplained at least twenty seven month delay to be unreasonably long and issued an order to show cause under Rule 617. Hence, it is incumbent on Kundu to establish priority over Ragunathan's effective filing date, both as a result of the procedural inference of suppression and also as a consequence of its ultimate burden on priority as junior party.

In meeting its burden of proof, it is the responsibility of each party to precisely identify and clearly explain the evidence on which it relies. Dana Corp. v. American Axle & Mfg., 279 F.3d 1372, 1377, 61 USPQ2d 1609, 1612 (Fed. Cir. 2002); Biotec Biologische Naturverpackungen v. Biocorp., Inc., 249 F.3d 1341, 1353, 58 USPQ2d 1737, 1746 (Fed. Cir. 2001) (refusing to impose duty on fact-finder to search record for possible evidence).

2. Evidentiary standard

Since Kundu did not file its application until after Ragunathan had received its 065 patent, this case invokes Rule 657(c), which requires the junior party to establish priority by clear

and convincing evidence.[12] Price v. Symsek, 988 F.2d 1187, 1190-91, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993) (explaining the policy of applying the invalidity standard to patents challenged by late filing applicants in terms of social disutility). "Clear and convincing evidence" is evidence that produces in the mind of the trier of fact an abiding conviction that the truth of a factual contention is highly probable. Price, 988 F.2d at 1191, 26 USPQ2d at 1034.

3. Test for suppression

In order for there to be an actual reduction to practice, the inventor must have (1) constructed an embodiment or performed a process that met all the limitations of the count; and (2) determined that the invention would work for its intended purpose. The inventor must contemporaneously appreciate that the embodiment worked and met all of the limitations in the count. Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). In theory, the invention is complete and ready for patenting as soon as there is an actual reduction to practice. In the real world, however, nothing happens instantaneously. An inventor needs time to prepare any disclosure to the public or USPTO. Moreover, social utility may be enhanced by refinements in the disclosure, such as the identification of a best mode, which may require additional time. Thus, a suppression analysis is a pragmatic balancing of reasonable real-world delays and of the enhanced value of further perfecting of the invention against the social disutility of further delay in disclosure. As this case shows, Kundu (and Ragunathan) benefitted from the

[12] We need not decide if a different standard would apply to Ragunathan's other involved patent and application (the 6,268,356 patent and the 09/757,261 application) even though they were co-pending with Kundu's application for two reasons. First, Kundu did not argue that a different standard should apply for them. Second, if Kundu cannot prevail against Ragunathan's 065 patent, it would lose anyway, so the effect of Ragunathan's 261 application and 356 patent is moot. Cf. Berman v. Housey, 291 F.3d 1345, 1355, 63 USPQ2d 1023, 1030 (Fed. Cir. 2002) (holding subsequent issuance of other patents did not affect a 35 U.S.C. 135(b) bar based on the first issued patent).

early disclosure of the Atzinger patent, which promoted progress in a useful art by inspiring their efforts to design around it.

Early disclosure has been identified as the linchpin of the patent system because the purpose of the patent system--progress of the useful arts--is best served by rewarding prompt disclosure. Shindelar v. Holdeman, 628 F.2d 1337, 1341 n.7, 207 USPQ 112, 116 n.7 (CCPA 1980). An inventor delays in filing at his own peril. Id., 628 F.2d at 1341, 207 USPQ at 116. The case law distinguishes between two types of suppression. In the first, the inventor actively suppresses his invention from the public. In the second, suppression is inferred from unreasonable delay in filing the application. Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334, 1342, 60 USPQ2d 1519, 1524 (Fed. Cir. 2001). The order to show cause focused on the extensive delay and the facial case of spurring as the basis for proceeding under Rule 617 (Paper 3). Suppression must be determined on the basis of the specific facts of each case. Dow Chem. Co., 267 F.3d at 1342, 60 USPQ2d at 1525. The case law has established two guideposts for determining suppression: delay and spurring. Delay does not itself prove suppression, but can support an inference in the absence of an adequate explanation for the delay. Spurring is relevant to, but not necessary for, a suppression determination. Young, 489 F.2d at 1281, 180 USPQ at 391.

Rather than focus on the length of delay, suppression must be determined from the reasonableness of the inventor's total conduct in working toward disclosure of the invention. Fujikawa v. Wattanasin, 93 F.3d 1559, 1568, 39 USPQ2d 1895, 1902 (Fed. Cir. 1996). A variety of explanations are possible that can, with the right set of facts, excuse delay and overcome the

appearance of spurring. Generally, slow (even fitful), but inexorable progress toward disclosure can overcome the inference of suppression from long delay. Fujikawa, 93 F.3d at 1567, 39 USPQ2d at 1902. Significant steps toward perfecting the invention and preparing an application indicate that the invention was not suppressed. 93 F.3d at 1568, 39 USPQ2d at 1903. The work used to overcome the inference, however, must not be directed only to commercialization and should be reflected in the patent application. Lutzker, 843 F.2d at 1367, 6 USPQ2d at 1372. Work to prepare the involved application prior to the issuance of the allegedly spurring patent can overcome the inference of spurring. Fujikawa, 93 F.3d at 1568, 39 USPQ2d at 1902-03. A showing of intent to file eventually, however, will not negative a holding of suppression. Shindelar, 628 F.2d at 1342, 207 USPQ at 117.

B. Kundu suppressed the invention of the count

1. Kundu's development work did not show an inexorable effort leading to disclosure to the public or to USPTO

The FDA has extremely stringent standards for the submission of an ANDA. 21 C.F.R. §314.94. Among other things, an ANDA applicant must demonstrate the bioequivalence of the new drug to the listed drug (§314.94(a)(7)), must provide precise details about any variances from the labeling for the listed drug (§314.94(a)(8)), and must provide details about the plan for producing commercial lots of the drug (§314.94(a)(9)). Kundu has offered an extensive record showing efforts to produce a product that would meet the ANDA standards.

Prior to approval, the FDA treats the existence of, and information about, an ANDA as confidential information. 21 C.F.R. §314.430(b) & (d). Moreover, Alpharma abandoned all development avenues that did not lead to an ANDA filing. If it had not found a bioequivalent

formulation, there is no indication the public would ever have benefitted from its discovery. Thus, work toward an ANDA is weak evidence of an inexorable effort to place the invention in the possession of the public since an ANDA development program would not necessarily become public or lead to a publically used product. Kundu's patent application was the only alternative strategy that Kundu pursued that would have placed the invention in the hands of the public in the event that Alpharma's ANDA failed.[13]

The first evidence[14] of Kundu's intent to file a patent on any megestrol formulation comes in November 1999, more than two years after Kundu's alleged actual reduction to practice. Kundu does not rely on this evidence in its brief, but instead points to work starting in March 2000, more than two and a half years after Kundu's alleged reduction to practice. It is not clear whether the difference in start dates for the patent application reflects an oversight on Kundu's part or a significant shift in the focus of the patent application being drafted. Since Kundu has the burden of proof to show it was making inexorable progress toward filing, we cannot make any assumptions in Kundu's favor regarding what, if anything, the patent application work before March 2000 means. A 2-2½ year delay before beginning work on a patent application would defy characterization as even fitful progress toward public disclosure

[13] The courts have repeatedly noted that the patent and drug-approval processes are distinct. E.g., Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1368, 51 USPQ2d 1700, 1703 (Fed. Cir. 1999), citing In re Watson, 517 F.2d 465, 474-76, 186 USPQ 11, 19 (CCPA 1975). Just as the use of utility and enablement rejections to police drug efficacy improperly confuses the respective roles of USPTO and FDA, strict adherence to the process for filing an ANDA cannot by itself justify a delay under §102(g). Each body of law must be approached on its own terms.

[14] For reasons explained below, the exhibits showing earlier patenting efforts has been suppressed. In any case, Kundu did not show a nexus between what was then being considered for patenting and the present count.

unless the intervening period were spent "perfecting" the invention. Lutzker, 843 F.2d at 1367, 6 USPQ2d at 1372.

Kundu's problem in this case, however, is that the standard indicium of perfecting efforts--a reflection of such work in the patent application--has less credibility than usual. First, the perfecting in the present case is defined in terms of having a successful ANDA batch, the stated trigger for the ultimate instruction to draft an application. A successful ANDA batch indicates greater interest in achieving a critical commercialization milestone (a demonstrated ability to meet the rigorous requirements of drug approval) than in satisfying the very different patentability requirements of utility and enablement. On the question of commercialization, Lutzker cites Fitzgerald v. Arbib, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959), which holds that investigating manufacturing details does not excuse delay, yet much of Alpharma's effort was directed to developing an ANDA-sufficient method of manufacturing its MEGACE®-equivalent megestrol formulation. Second, in Lutzker and the cases it cites on reporting perfecting work in the application, the applicants did not have Kundu's advantage of knowing what was in the other parties' disclosures when they filed. Applications filed after the other side's patent has issue have the lowered credibility of any post litem motam statement, particularly when as in this case the applicant seeks to provoke a patent interference. The case law provides ample motivation for a new applicant seeking to provoke an interference with a patent, and facing the need to overcome an appearance of suppression, to include any and all remotely related work in the specification.

Even with the advantage of knowing what it was up against, Kundu provided relatively little detailed disclosure of Alpharma's work toward perfecting the invention. While Kundu pointed to many obstacles overcome in its justification for the delay, the obstacles are either not disclosed or are disclosed as alternate embodiments. For instance, Kundu lost much time exploring the PLURONIC® F127 formulation, which it ultimately regarded as a failure because it was not bioequivalent to MEGACE®, but which it disclosed as a preferred embodiment. Had Kundu prepared its application isolation, these defects would have been easier to overlook, but here Kundu knew it had a higher standard to meet. Similarly, Kundu's brief discloses numerous facts about Alpharma's development efforts, but provides much less guidance on how these efforts improved the resulting disclosure. A party with the burden of proof leaves the work of making the connections to the fact-finders at its own peril.

2. Kundu's evidence does not overcome the inference of spurring

Kundu argues that its extensive work shows it was not spurred into disclosing its invention (Paper 31 at 26). The record, however, indicates that Alpharma was focused on filing an ANDA, not timely public disclosure. As explained above, ANDA development is very weak evidence of an intent to publically disclose. The two efforts to disclose through patenting both come very late and shortly after Alpharma became aware of activity by Par. The first instance,[15] the November-December 1999 patenting activity followed Alpharma's awareness in October 1999 of a Par ANDA targeting MEGACE®. The second instance starting after a lapse of over two months in March 2000 followed publication of Ragunathan's 065 patent. Hence, far from

[15] Which Kundu did not brief. The evidence of even earlier work is suppressed.

overcoming an inference of spurring, Kundu's record supports the inference. It is important to remember that spurred filing is not a bad thing per se. Indeed, it may simply reflect a change in disclosure strategy based on new information. Where, however, the record already supports an inference of suppression (i.e., a failure to have a disclosure strategy), spurring indicates not a change in disclosure strategy, but rather a belated decision to disclose.

3. The totality of the evidence does not overcome the inference of suppression

Kundu has adduced considerable evidence of activity related to the subject matter of the count during the thirty-five months in question. A thorough review of the evidence cited and explained in its brief does not, however, produce an abiding conviction that Kundu was progressing inexorably to disclosure to the public or USPTO. Rather, Kundu appears to have been progressing hopefully toward the filing of an ANDA, which might never produce a public disclosure. The evidence of Kundu's work on a patent application is incomplete, inconclusive in its relationship to the present count, and very late in the period in question. Finally, Kundu appears to have been spurred to file either by the litigation over Par's ANDA filing or by the issuance of Ragunathan's 065 patent. Viewed in its totality, Kundu's evidence does not clearly and convincingly show that Kundu was reasonable in waiting nearly thirty-five months after its reduction to practice to file its patent application. We therefore conclude that Kundu suppressed the invention of the count within the meaning of §102(g).

C. Ragunathan's motion to suppress evidence

Ragunathan has moved (Paper 34) (1) to suppress Kundu exhibits 2012, 2021, 2042, 2043, and 2048-2051, which it contends violate the Federal Rules of Evidence, the interference

rules, and the Standing Order (Paper 2); (2) to suppress exhibits 2057-2059 for untimeliness; and (3) to suppress various parts of exhibits 2003, 2005, 2006, 2010-2020, 2022-2024, 2026, 2036, 2044, 2045, 2046, 2052, 2053, and 2054. The Federal Rules of Evidence apply generally in patent interference proceedings. Rule 671(b). Given the result on the merits, the first and third parts of the request are DISMISSED as moot. The second part of the request, however, requires further analysis.

With its reply, Kundu supplied additional exhibits purporting to show that Alpharma was working toward a patent disclosure of the subject matter of the count as early as September 1999, which is before the first indication in the record (October 1999) that Alpharma was aware of Par's ANDA efforts. As explained above, this evidence of earlier activity is entitled to little weight because Kundu has not shown a nexus between its nascent interest in a patent in September 1999 and the subject matter of the count. Nevertheless, to the extent it is probative, it should have been served and discussed in its brief so Ragunathan would have had an opportunity to respond. It is worth noting that Kundu's brief did not discuss any patenting activity before March 2000. A late-filed paper will only be excused on a showing of good cause. Rule 645(b).

Kundu contends (Paper 37[16] at 8) that exhibits 2057-2059 were properly submitted with its reply brief in response to Ragunathan's allegation of spurring, which first appeared in Ragunathan's statement in support of the order to show cause. The problem with this contention is that the order to show cause first raised the question of spurring (Paper 3 at 2). Kundu was aware of spurring as an issue because its own brief addressed spurring (Paper 31 at 26). The

[16] Kundu's opposition to Ragunathan miscellaneous motion 1.

order, however, only pointed to the intervening issuance of Ragunathan's patent on 22 February 2000. Hence, Kundu could have argued that it was only on notice that it had to overcome a spurring date of 22 February 2000. The problem with this hypothetical argument is that Kundu did not brief any patenting activity before March 2000. Instead, Kundu relied on Alpharma's ANDA developmental work to overcome the inference of spurring. Thus, in context, Kundu's new tack in its reply brief, with attendant new evidence, shows a change in strategy after Ragunathan's opportunity to respond. This effort was both too little and too late. Ragunathan's miscellaneous motion 1 is GRANTED with regard to Kundu exhibits 2057-2059.

ORDER

Upon consideration of Kundu's response to the order to show cause, it is:

ORDERED that judgment on priority as to Count 1 is awarded against Kundu;

FURTHER ORDERED that Kundu is not entitled to a patent containing claims 1-19, 23-33, and 36-57 of Kundu's 09/621,623 application, which correspond to Count 1;

FURTHER ORDERED that Ragunathan's miscellaneous motion 1 to suppress exhibits is GRANTED for Kundu exhibits 2057-2059, but is otherwise DISMISSED; and

FURTHER ORDERED that a copy of this decision be given a paper number and be entered in the administrative record of Kundu's 09/621,623 application and of Ragunathan's 6,028,065 and 6,268,356 patents and 09/757,261 application.

RICHARD E. SCHAFER
Administrative Patent Judge

JAMESON LEE
Administrative Patent Judge

RICHARD TORCZON
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

INTERFERENCE TRIAL SECTION

Notice: Any agreement or understanding between parties to this interference, including any collateral agreements referred to therein, made in connection with or in contemplation of the termination of the interference, shall be in writing and a true copy thereof filed in the United States Patent and Trademark Office before termination of the interference as between said parties to the agreement or understanding. 35 U.S.C. 135(c); 37 C.F.R. § 1.661.

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