

In the Matter of

**CERTAIN FLUIDIZED SUPPORTING
APPARATUS AND COMPONENTS
THEREOF**

Investigation No. 337-TA-182/188



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UNITED STATES INTERNATIONAL TRADE COMMISSION

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337-TA-182, the factors relevant to the discretionary grant of temporary relief, as well as the public interest factors which are by statute required to be considered, indicate that such relief should not be granted.

As to Inv. No. 337-TA-188, the Commission has determined to affirm the initial determination of the ALJ insofar as it is based on the finding that there is lack of sufficient proof of reason to believe that the respondents have committed the unfair practices alleged therein. However, the Commission does not adopt the ALJ's finding that there is reason to believe that there is an "industry . . . in the United States", within the meaning of section 337, in Inv. No. 337-TA-188, which, of course, constitutes an additional ground for determining that there is no reason to believe a violation of section 337 exists in Inv. No. 337-TA-188. In any event, the factors relevant to the discretionary grant of temporary relief, as well as the public interest factors which are by statute required to be considered, indicate that temporary relief should not be granted. The Commission neither approves nor disapproves any other findings made in Inv. No. 337-TA-188.

The reasons for the Commission's determinations are discussed below. Furthermore, since the subject ID involves the temporary relief phase of these investigations, with a trial and initial determination on violation (permanent relief phase) yet to come, ^{3/} the Commission also rules on certain questions of law relevant to further proceedings in these investigations.

^{3/} The Commission's determinations with respect to the subject ID were the subject of an Action and Order issued August 21, 1984. 49 Federal Register 34311 (August 29, 1984). Shortly thereafter, the Commission suspended these investigations under 19 U.S.C. § 1337(b)(1). The suspension was the subject of an Action and Order issued August 31, 1984. 49 Federal Register 35441 (September 7, 1984).

STANDARD FOR GRANT OF TEMPORARY RELIEF

Section 337(e) governs the issuance of temporary exclusion orders. It provides that if, during the course of a section 337 investigation, the Commission determines that there is "reason to believe that there is a violation" of section 337, "it may direct that the articles concerned . . . be excluded from entry into the United States," unless after consideration of certain enumerated public interest factors, it finds that the articles should not be excluded. [Emphasis supplied.] While a finding that there is "reason to believe" a violation exists requires less proof than a finding that a violation exists, 4/, it is important to note that section 337(d), which governs issuance of permanent exclusion orders, provides that when the Commission determines that a violation of section 337 does exist, "it shall direct that the articles concerned . . . be excluded from entry into the United States," subject to the same enumerated public interest factors just mentioned. [Emphasis supplied.] In other words, leaving aside the question of preclusion of relief by the enumerated public interest factors, if the relevant substantive elements are established, the issuance of temporary relief is largely discretionary, while the issuance of permanent relief is mandatory. 5/

The Commission has developed criteria as to how it will exercise its discretion to grant temporary relief. As reflected in the Commission's rules, the Commission balances the following four factors:

1. Complainant's probability of success on the merits;
2. Immediate and substantial harm to the domestic industry in the absence of the requested temporary relief;

4/ See, S. Rep. No. 93-1298, 93rd Cong., 2d Sess. 197-198 (1974).

5/ Statutory discretion is provided to issue cease and desist orders. 19 U.S.C. § 1337(f).

3. Harm, if any, to the respondents if the requested temporary relief is granted; and
4. The effect, if any, that the issuance of the requested temporary relief would have on the public interest. 6/

These factors are similar to and derived from factors governing the grant of preliminary injunctions in the Federal courts. 7/ A finding that these factors indicate that temporary relief should or should not issue occurs only

6/ 19 C.F.R. § 210.24(e).

7/ See, Certain Apparatus for the Continuous Production of Copper Rod ("Copper Rod II"), Inv. No. 337-TA-89, USITC Pub. No. 1132 (April 1981), citing, Washington Metropolitan Area Transit Commission v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977) ("WMATA") and Virginia Petroleum Jobbers Ass'n. v. FPC, 259 F.2d 921 (D.C. Cir. 1958) ("VPJ"). These two cases actually involved, not the grant of preliminary injunctions, but the stay of permanent injunctions pending appeal (WMATA) and the stay of administrative orders (VPJ). As the WMATA court noted, however, the factors apply to the grant of preliminary injunctions as well. WMATA, 559 F.2d at 842, n. 1.

It is important to note that a preliminary injunction jurisprudence peculiar to patent cases has grown up in the Federal courts. See, White, Patent Litigation: Procedure and Tactics, § 4.05; Dorr and Duft, "Patent Preliminary Injunctive Relief," 60 Journal of the Patent Office Society 597 (October 1978); Duft, "Patent Preliminary Injunctions and the United States Court of Appeals for the Federal Circuit," 65 Journal of the Patent Office Society 131 (March 1983). Until 1983, this jurisprudence often set a very high standard for the grant of preliminary injunctions in patent cases. However, in 1983, in a factually unusual case (the issue of validity had been finally adjudicated, infringement had been admitted, and only an accounting remained), the Court of Appeals for the Federal Circuit ("CAFC"), this agency's reviewing court, held that "where validity and continuing infringement have been clearly established, as in this case, immediate irreparable harm is presumed" and remanded the case to the district court to issue a preliminary injunction. Smith International, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1581 (CAFC 1983). That holding by its very terms appears to be limited to the facts of that case and cases with very similar facts. The CAFC was careful to point out that "Our holding on this issue does not abrogate the traditional requirement of a showing of irreparable harm by one seeking a preliminary injunction. As noted above, the trial court should balance the requisite factors. In cases where the showing of validity and infringement is less forceful than it is here, or in cases where equitable or public policy considerations are in favor of the infringer, a movant would have to make a stronger showing of irreparable harm in order to tip the balance of equity in his favor." Smith, 718 F.2d at 1581, n. 7. Thus the CAFC in Smith has moved patent cases from their peculiar position toward the mainstream of the jurisprudence of preliminary injunctions, which is represented by WMATA and VPJ.

after the Commission finds that there is reason to believe a violation exists. However, evaluation of the first factor, probability of success on the merits, is closely related to the substantive determination of reason to believe a violation exists. The distinction is that the substantive determination is a determination that a threshold has been met, while evaluation of the first factor is a measure of the extent to which that threshold has been exceeded. The probability of success will vary from case to case and will be balanced with the other three factors.

The fourth factor, i.e., the public interest, refers at least to the enumerated public interest factors in section 337(d)-(f). 8/ The legislative history indicates that these enumerated factors are "overriding considerations in the administration of this statute" and that if the effect of the issuance of relief would have a greater adverse impact on the public interest than would be gained by protecting the patent holder, the relief should not be granted. 9/

The ALJ is authorized to make a record on the factors relevant to the discretionary grant of temporary relief, including the public interest factors, and to issue findings with respect thereto in his initial determination, and he has done so in this case. 10/

INVESTIGATION NO. 337-TA-182

Investigation No. 337-TA-182 was instituted to determine whether there is a violation of section 337 in the unlawful importation of certain fluidized

8/ The enumerated public interest factors are: ". . . the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, . . ." (19 U.S.C. § 1337(d)-(f), in relevant part).

9/ S. Rep. No. 93-1298, 93rd Cong. 2nd Sess. (1974), pp. 197-198.

10/ 19 C.F.R. §§ 210.24, 210.14(b).

supporting apparatus into the United States, or in their sale, by reason of alleged infringement of claims 1-3, 5-13, 16-18, and 21-23 of U.S. Letters Patent 3,428,973 (the '973 patent), the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. 11/ The complainant is Support Systems International, Inc. (SSI) of Charleston, South Carolina. The respondents are (1) UHI Corporation (UHI) of Los Angeles, California; (2) UHI Systems, K.K. (UHI Systems) of Tokyo, Japan; (3) Shigatu Katayama (Katayama) of Los Angeles, California; and (4) Fuji Electric Company, Ltd. (Fuji) of Japan. The claimed invention is a hospital bed ("burn bed") with fluidized support means which is particularly adapted for use by patients with severe burns or other injuries where it is painful or not conducive to recovery to lie on an ordinary bed.

SSI is the exclusive licensee under the '973 patent. SSI and UHI executed a "sublicense" agreement in 1979, 12/ now alleged by SSI to have been terminated. UHI is alleged to import and sell or lease infringing burn beds in the United States. UHI Systems is alleged to have the infringing burn beds manufactured for UHI in Japan by Fuji. Katayama is alleged to own or control both UHI and UHI Systems.

Both SSI and UHI generally lease their burn beds to hospitals and other health care institutions for use by specific patients. 13/

In 1983, SSI sued UHI and UHI Systems for breach of the sublicense agreement (UHI only) and patent infringement in the U.S. District Court for

11/ 49 F.R. 5840 (February 15, 1984).

12/ Complaint, Ex. 4; SSI Documentary Exhibit 32; UHI Documentary Exhibits 162-163. The agreement is entitled "Manufacturing and Marketing Agreement" and by its own terms is an "option" to take a sublicense, specifying how the option is to be exercised (which it apparently has been) and the terms of the sublicense if it is.

13/ ID 5-6, 57.

the Central District of California, an action which is still pending. 14/
This action was commenced after UHI refused to pay royalties because of
alleged failure of SSI to sue alleged third-party infringers and because of
the alleged weakness of the '973 patent. 15/

REASON TO BELIEVE A VIOLATION EXISTS 16/

A. Unfair Practices (Patent Infringement)

1. Patent Validity

Under 35 U.S.C. § 282, a patent is presumed valid and the burden of proof
of showing invalidity is on the alleged infringer who must meet that burden by
clear and convincing evidence.

The ALJ found the '973 patent valid. As set forth in the ID, respondents
argued that the '973 patent is invalid because the claimed invention had been
in public use or on sale in this country more than one year prior to the
filing of the '973 patent application (35 U.S.C. § 102(b)); because the
claimed invention would have been obvious to a person of ordinary skill in the
art at the time it was made (35 U.S.C. § 103); because the patent
specification does not adequately disclose how to make and use the claimed
invention (35 U.S.C. § 112); and misjoinder of inventors (35 U.S.C. § 116).
The ALJ rejected all these defenses. Respondents have not filed a petition

14/ ID 22; SSI Documentary Exhibit 86.

15/ ID 22.

16/ It should be carefully noted that a determination of whether there is
reason to believe a violation of section 337 exists is independent of a
determination of whether a violation of section 337 exists. The same is true
of any subsidiary findings of fact or law on which that determination of
"reason to believe" is based. Thus, such determination and the findings
supporting it reflect only a preliminary assessment based on the current
record. Since the record will be augmented by a subsequent hearing on whether
a violation exists, this preliminary assessment is subject to change.

for review and have thus waived their right to argue patent validity for the purpose of determining whether there is reason to believe a violation of section 337 exists. 17/ We concur with the ALJ on the issue of patent validity.

2. Infringement

The burden of showing infringement is on the complainant. While the ALJ found that respondents' products did come within the claims of the patent, 18/ he found that there was no infringement because UHI was a sublicensee under the patent, which he regarded as a complete defense.

Complainant SSI argued that the sublicense had been terminated by UHI's refusal to make royalty payments or, in the alternative, that SSI had terminated the license by giving respondent UHI proper notice of termination via the complaint commencing the civil action in California and in a contemporaneous letter. The ALJ found that under Lear, Inc. v. Adkins 19/, as interpreted by Lee v. Lee Custom Engineering, Inc., 20/ UHI's refusal to pay royalties due under the sublicense did not terminate the sublicense and that SSI was precluded from terminating the license itself. 21/ The ALJ found that the recent decision of the CAFC in C. R. Bard, Inc. v. Schwartz 22/, also applying Lear, was distinguishable and thus not controlling. The ALJ also

17/ 19 C.F.R. § 210.54(a)(2).

18/ ID 112. Respondents, having not filed a petition for review, have waived their right to argue that their products do not come within the claims of the patent for the purpose of determining whether there is reason to believe a violation of section 337 exists. 19 C.F.R. § 210.54(a)(2).

19/ 395 U.S. 653 (1969).

20/ 476 F. Supp. 361 (E.D. Wisc. 1979).

21/ ID 111.

22/ 716 F.2d 874 (CAFC 1983).

found that, in any event, complainant SSI had not complied with the terms of the sublicense governing notice of termination.

The ALJ's finding of noninfringement is erroneous. Even if the sublicense were still in effect, it could not be a complete defense to infringement because, as SSI points out in its petition for review, the sublicense is limited geographically to the territory of the United States west of the Mississippi, and it is undisputed that UHI has entered markets east of the Mississippi. 23/ This constitutes patent infringement. 24/ Furthermore, as discussed below, there remains a serious question as to whether the sublicense has been terminated. If it has, UHI would infringe in the Western United States as well. Such termination is not precluded by Lear. The portion of Lee relied upon by the ALJ for his finding that SSI is precluded from terminating the sublicensee under Lear not only appears to lack adequate legal foundation, it clearly conflicts with the decision of the CAFC, our reviewing court, in Bard.

Lee involved a motion for partial summary judgment and an order declaring an exclusive license agreement covering eight patents in suit to be terminated by reason of failure of defendant to make royalty payments. The district court held that: (1) the existence of material issues of fact as to whether the license agreement had been modified by the acts of the parties with

23/ See, Complaint, Ex. 4; FF 327-328.

24/ As a general principle "whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (emphasis supplied). If the sublicense is still in effect, UHI's leasing in the Western United States is with the authority of SSI, but its leasing in the Eastern United States is "without authority" of SSI. It has been held that a licensee who operates outside the scope of his license is an infringer. General Talking Pictures Corporation v. Western Electric Co., 305 U.S. 124 (1938).

respect to timeliness of royalty payments precluded partial summary judgment and (2) plaintiff was not entitled to an order declaring the license terminated even though defendant had refused to make royalty payments during pendency of the litigation.

Lee relied on Lear for its second holding, recognizing that Lear itself did not make such a holding, but finding that the "principle" of Lear permitted such a holding. Lee recognized that the permissibility of such a holding was "not so clear" from Lear and that at least two circuit courts had interpreted Lear differently. 25/

The lack of an express holding in Lear itself, the admitted lack of clarity of even the dicta of Lear in this area, and the contrary decisions of two circuits would alone be sufficient to find Lee not controlling. However, beyond this apparent lack of legal foundation is the clear conflict between Lee and the decision of the CAFC in Bard.

In Bard, the CAFC held that a licensee can, in the absence of diversity jurisdiction, bring a Federal declaratory judgment action asserting patent invalidity even though the license has not been terminated if (1) there exists a case or controversy in the Constitutional sense, and (2) the case arises under the patent laws within the meaning of 28 U.S.C. § 1338(a). The Court stated:

Courts have interpreted the controversy requirement in the patent field to generally mean that the declaratory plaintiff has sufficient interest in the controversy and that there is a reasonable threat that the patentee or licensor will bring an infringement suit against the alleged infringer. [Emphasis supplied.] 26/

25/ Lee, 476 F. Supp. 362-364, citing, Nebraska Engineering Corp. v. Shivers, 557 F.2d 1257, 1259-60 (8th Cir. 1977) and Warner-Jenkinson Co. v. Allied Chemical Corp., 567 F.2d 184 (2nd Cir. 1977).

26/ Bard, 716 F.2d at 879.

Since a license is ordinarily a complete defense to an infringement action, a reasonable apprehension that the licensor will bring an infringement action as to articles or processes covered by the license can only exist if the license can be terminated. The CAFC referred to the possibility of termination in Bard as follows:

. . . We hold that appellant Bard [the licensee], under the facts of this case, had a reasonable apprehension of an infringement suit even though the license agreement was still in effect. Thus, there was federal "arising under" jurisdiction under § 1338(a) and an actual controversy.

As stated, whether there is a federal controversy in the instant case can only be determined by an examination of the totality of the circumstances. Bard, the licensee, had ceased payment of royalties under the agreement to the licensor and patentee Schwartz. This was a material breach of the agreement that, under the very terms of the agreement, enabled Schwartz to terminate the agreement. Although Bard had ceased payment of royalties, its sublicensee Delmed continued to make the catheters subject to the Schwartz patent. Thus Schwartz could at any time take action against Bard by bringing an infringement suit. There was no action Bard could take to prevent such a lawsuit. [Emphasis supplied.] 27/

In short, the possibility of termination of a license is essential for Federal (non-diversity) jurisdiction of declaratory judgment actions by licensees asserting patent invalidity where the license has not been terminated. Since Bard also makes it clear that such declaratory judgment actions are just the type of actions encouraged by Lear, the clear implication in Bard is that, contrary to Lee, termination of a license for nonpayment of royalties is entirely consistent with Lear. Bard, of course, is controlling authority. 28/ We therefore cannot accept the proposition in Lee that Lear

27/ 716 F.2d at 880-881.

28/ We note that Bard cites with approval the very holding of the Second Circuit in Warner-Jenkinson which Lee specifically rejects. Compare, Bard, 716 F.2d at 880, with Lee, 476 F.2d at 363.

precludes the termination of a patent license for nonpayment of royalties. 29/ 30/

This, of course, does not settle the question of whether the sublicense has been terminated by its own terms (or otherwise). This is a question of contract law, i.e. state law, which would be California law in this case, as specifically provided in the sublicense. 31/ The ID does not completely address this question and does not refer to California law to support those aspects of the question which it does address. The ID states that neither SSI's filing and serving of the complaint in the parallel district court action nor its contemporaneous letter complied with the provisions of the sublicense governing termination and notice. However, no California authority is cited in support of this conclusion. Furthermore, the ID does not discuss

29/ The CAFC, citing Warner-Jenkinson, indicated that declaratory judgment jurisdiction would exist even if the licensee continued to make royalty payments and otherwise was not in breach of the license. Bard, 716 F.2d at 880. In such a case, an infringement suit is still a possibility, but a conditional possibility, the condition being non-payment of royalties (or other material breach) entitling the licensor to terminate the license. See, Warner-Jenkinson, 567 F.2d at 187.

30/ Vice Chairman Liebler concurs with the decision of the majority that a question of fact exists as to whether the license was terminated under California law but dissents from the majority's interpretation of Lee v. Lee Custom Engineering, Inc., 476 F. Supp. 361 (E.D. Wisc. 1979).

As noted by the majority, the Lee court addressed two issues: (1) whether the license had been terminated prior to the institution of the suit by the licensor by virtue of late payments by the licensee and (2) whether the licensee's nonpayment of royalties during pendency of the litigation was grounds for termination of the license agreement. Although courts have differed over the proper resolution of the second issue, compare Lee with Warner-Jenkinson Co. v. Allied Chemical Corp., 567 F.2d 184, 187-88 (2d Cir. 1977); Nebraska Engineering Corp. v. Shivers, 557 F.2d 1257, 1259-60 (8th Cir. 1977), only the first holding of Lee is relevant for our purposes. The instant case does not involve the issue of whether nonpayment of royalties during suit terminates a license agreement.

31/ See, Aronson v. Quick-Point Pencil Co., 440 U.S. 257, 261-62 (1979).

the argument of anticipatory breach and repudiation raised by SSI. 32/ These inquiries must be made. Because such inquiries have not been made, we are unable to determine whether or not there is reason to believe that the sublicense has been terminated. Nevertheless, as already discussed above, there is reason to believe that UHI has infringed the '973 patent, regardless of whether the sublicense has been terminated. Moreover, as will be discussed below, there is ultimately reason to believe a violation of section 337 exists regardless of whether the sublicense has been terminated.

B. Importation and Sale

The ALJ found that respondent UHI imports partly assembled burn beds made by Fuji into the United States through Fuji and UHI Systems, that UHI leases or sells the burn beds in the United States and that respondent Katayama owns or controls, directly or indirectly, respondents UHI and UHI Systems. 33/ None of the respondents has petitioned for review of this finding and we concur with it.

C. Industry . . . in the United States

The ALJ defined the industry in terms of the article (burn beds) resulting from exploitation of the '973 patent and found such an industry to exist in the United States. The ALJ found that the industry was composed of both complainant SSI and respondent UHI, since he found UHI to be a domestic sublicensee. 34/ The ALJ also stated that even if UHI were no longer a sublicensee it would still be part of the domestic industry because of the

32/ SSI Post-Hearing Memorandum, pp. 14-18

33/ ID 52, 121.

34/ ID 124.

value UHI adds to the various burn bed components it imports by assembly with domestic components into burn beds and its subsequent servicing of such burn beds.

Respondents have not petitioned for review of this finding, but complainant SSI has filed a petition for review arguing that UHI should not be included in the domestic industry because the sublicense has been terminated.

If the sublicense has been terminated, complainant is correct since UHI would be nothing more than an infringer, which cannot be part of the industry no matter how much value it adds to its imported components. 35/

If the sublicense were still in force, the Commission would be faced with the unusual situation of UHI being an infringer in the Eastern United States but acting lawfully in the Western United States. Only its activities in the Western United States could be considered in determining whether it should be included as part of the domestic industry. We note that even in these circumstances there would be no reason to believe UHI should be included in the domestic industry, because the nature and significance of UHI's activities do not provide a reason to believe it should be so included; it appears that UHI essentially imports nearly complete burn beds. 36/

The ALJ found that UHI imports from Fuji a disassembled fluidized supporting apparatus consisting of the base of the bed, which contains the compressor unit, motor, heating device and temperature controls; the electrical equipment, the blower; the tank; some glass beads; means for

35/ See, Spring Assemblies and Components Thereof, Inv. No. 337-TA-88, USITC Pub. No. 1172 (August 1981).

36/ ID 124-125; see, Certain Miniature, Battery-Operated, All Terrain, Wheeled Vehicles, Inv. No. 337-TA-122, USITC Pub. No. 1300 (October 1982), affirmed, Schaper Manufacturing Co. v. U.S. International Trade Commission, 717 F. 2d 1368 (C.A.F.C. 1983).

attaching the filter sheet; and wheels. 37/ The disassembled units are shipped to UHI by sea from Japan and are packaged as two units per crate. 38/ On arrival, UHI assembles these units.

The ALJ did find that some components of UHI's fluidized support apparatus are procured in the United States. 39/ The cost of these materials with respect to the cost of the imported disassembled burn bed is small 40/ and UHI's activities with respect to these components and its assembly of the imported burn beds are not sufficient to justify finding that there is reason to believe that UHI should be included in the domestic industry. UHI argued that its activities in the United States added significant value to the imported disassembled burn beds. This value-added argument was raised to establish that the nature and significance of UHI's activities in the United States were such as to justify treatment as an "industry . . . in the United States." The evidence, however, is indefinite on the value added by UHI's activities in the United States. We note that a value-added analysis is simply one factor in considering the nature and significance of a party's relevant activities in the United States. It is not necessarily dispositive. 41/

37/ FF 264.

38/ FF 265.

39/ FF 266.

40/ FF 265-266.

41/ If UHI were found to be a sublicensee and a part of the domestic industry, the complainant and the primary respondent would be members of the same domestic industry, raising serious jurisdictional and substantive questions. For example, the ALJ, who found UHI and SSI to be part of the same domestic industry, concluded that as a matter of substantive law, no injury could occur within the meaning of section 337. Since we have found that UHI is not part of the domestic industry, this question was not presented to us.

The foregoing circumstances indicate that, whether the sublicense is terminated or not, it would be inappropriate to find that there is reason to believe that UHI should be included in the domestic industry. 42/ Of course, there remains reason to believe that there is an "industry . . . in the United States" (composed solely of SSI).

D. Efficient and Economic Operation

The ALJ found that the industry was efficiently and economically operated, stating that "both SSI and UHI are efficiently and economically operated." 43/ Respondents have not contested this finding and the elimination of UHI from the industry does not alter the correctness of the ultimate finding that the industry (composed solely of SSI) is efficiently and economically operated.

E. Injury; Immediate and Substantial Harm 44/

The ALJ found that since SSI and UHI were both part of the industry, any "injury" amounted to a shifting of sales between them and could not, as a

42/ Apparently alternatively, the ALJ found that UHI could be treated as a "service industry." This question arises only if UHI is a sublicensee. However, it turns on the nature and significance of UHI's service activities, including the value they may add to the product. Clearly, if, as noted above, production and service related activities taken together are insufficient to support a finding of reason to believe that UHI is part of the domestic industry, then service activities alone are insufficient. Furthermore, inclusion of UHI would, as mentioned, raise serious jurisdictional and substantive questions.

43/ ID 132.

44/ A finding of reason to believe that the alleged unfair practices have "the effect or tendency . . . to . . . substantially injure" a domestic industry is an element of the substantive finding of reason to believe a violation exists. A finding of whether there is immediate and substantial harm goes to the exercise of the Commission's discretion as to whether temporary relief should be granted if there is reason to believe a violation exists.

matter of law, constitute injury under section 337. 45/ SSI correctly points out, and we have already noted, that there is insufficient basis to find reason to believe that UHI should be part of the domestic industry. Thus, this finding is in error. 46/

We find there is reason to believe that there is at least a tendency to substantially injure SSI as a result of respondents' alleged unfair practices, given what appear to be clearly infringing sales. 47/ If UHI were found to still be a sublicensee and there were no consequent jurisdictional or substantive impediments, the injury analysis would be limited to the Eastern United States. Since there would still be infringing sales and/or rentals by UHI in the Eastern United States, there would still be at least a tendency to substantially injure SSI.

With regard to "immediate and substantial harm." the ALJ defined this phrase as follows:

The concept of 'immediacy' means that the anticipated harm must be likely to occur before the Commission is able to issue permanent relief. 'Substantial' harm requires the injury to the domestic industry to be so significant that the industry would not fully recover from the harmful effects of the § 337 violation, even after permanent relief was granted. [citations omitted]. The standard of immediate and substantial harm in a motion for temporary relief is more difficult to meet than the level of injury required in a permanent relief investigation. Whether immediate and substantial harm is shown depends on the factual circumstances of each investigation. 48/

45/ ID 133-134.

46/ Our conclusion should not be taken as an indication that we would make the same finding that the ALJ did if UHI and SSI were both part of the same domestic industry. This question is a serious one, but, in view of our finding that UHI is not part of the domestic industry, it is not presented to us here.

47/ See, *Bally/Midway Mfg. Co. v. U.S. Intern. Trade Com'n.*, 714 F. 2d 1117 (CAFC 1983).

48/ ID 133, citing, *Certain Slide Fastener Stringers ("Stringers")*, Inv. No. 337-TA-85, USITC Pub. No. 1141 (April 1981).

The ALJ found that even if UHI were not part of the industry, SSI has not shown that it will suffer "immediate and substantial harm" if temporary relief is not granted, i.e., during the few months remaining in this investigation.

The ALJ noted that UHI has allegedly opened sales facilities in the Eastern United States in direct competition with SSI, and that SSI's leasing has decreased (was below budget) slightly in those Eastern cities where UHI is present. However, he also noted that leasing of SSI units had decreased (below budget) in areas where UHI was not present and in instances prior to any direct competition between UHI and SSI.

As to SSI's alleged lost customers and forced price reductions, the ALJ found the evidence for this not sufficiently reliable, probative or substantial. He found the proffered SSI lost customer list flawed because it did not show the number of units placed by UHI in the Eastern United States hospitals listed, nor the past volume of SSI business with those hospitals. The ALJ also noted that SSI could not place a value on its alleged lost revenue from those placements and stated that, assuming that one bed was placed by UHI in each institution, lost profits amount to less than [] percent of SSI profits for the first half of fiscal 1984. 49/ 50/

49/ He also noted that SSI's lost sales analysis does not account for any UHI units placed in the mentioned Eastern United States hospitals which may have been the subject of earlier payments prior to the alleged termination of the sublicense. ID 135. This proposition is unclear. For example, it is not clear that prior royalties are relevant to the subject placements. Further, even if the sublicense were in effect at the relevant time, it would appear that any UHI units leased in the Eastern United States would be outside the sublicense, i.e., would be infringing.

50/ As to alleged increased importation by UHI, the ALJ found that this will not cause immediate and substantial harm to SSI because the approximately [] units per month to be imported for the remainder of 1984 is only [] percent of SSI's assembly rate of [] units per month. ID 136. As SSI correctly points out, this calculation is in error since the rate of [] units per month reflects capacity not actual production. Compare, FF 401 with FF 402.

Importantly, the ALJ noted that the burn bed market in the United States is expanding, as are SSI's personnel, facilities and profits. 51/

As to new models of infringing products to be introduced by UHI, the ALJ found this would not cause harm to SSI, noting that SSI also plans to introduce a new model. 52/ 53/

Finally, the ALJ, noting that the patent is to expire in 1986, almost a year after the expected Commission decision in this case, distinguished the present case from Stringers where it was stated that "potential for substantial harm . . . is greater where the life of the patent will end at or about the time of a final determination."

While we disagree, as noted, 54/ with several of the points underlying the ALJ's finding that SSI has failed to demonstrate immediate and substantial harm during the few months remaining in this investigation if temporary relief is not granted, we agree with other points and with the finding itself. We note that SSI's rental income has more than doubled every year from fiscal 1979 through 1983, and appears to be continuing to increase. 55/ A similar trend exists for the number of units in SSI's rental pool. 56/ SSI plans to increase the number of its service centers (through which its burn beds are leased). 57/ The market potential for burn beds is about [] units,

51/ ID 136.

52/ ID 136.

53/ The ALJ noted that since burn beds are leased rather than sold there may be no such thing as an irretrievably lost sale. ID 136. There could, of course, be lost leasing opportunities.

54/ See, footnotes 49, 50, 53.

55/ SSI Documentary Exhibit 25; FF 322.

56/ SSI Documentary Exhibit 25; FF 323.

57/ FF 325, SSI Documentary Exhibit 47, TR 302-304.

[] times as large as present use. 58/ A decade or more may be required to achieve this market potential. 59/ SSI's production is also increasing. 60/ While there have been decreases (below budget) or deficits in several markets, many of these were markets where UHI was not present or where decreases or deficits occurred prior to UHI's entry. 61/

In its petition for review, SSI argues that the ALJ failed to consider the most significant evidence of injury and to follow the law on injury as established by the Commission. SSI points to the increasing rate of importation and stockpiling by UHI and, conceding the rising market for the patented burn beds and its own rising sales, argues that it would have done even better but for UHI's unfair acts. SSI argues that, in the absence of temporary relief, neither the Commission nor the courts will be able to repair the damage caused by UHI's importation and sales during the interim period because the need for these units will be irretrievably filled by imports. SSI argues that it will probably never regain the market share it may lose.

While SSI is correct that a patent owner (or exclusive licensee) may suffer injury or that a tendency to injure may be shown by infringing sales even in an expanding market, the existence of some injury or tendency to injure is not the same as the existence of immediate and substantial harm. Furthermore, it would appear that in a growing market, a permanent exclusion order freezing the number of imported beds would clearly permit substantial recovery of any market share lost to imports on a percentage basis. A permanent cease and desist order would not only have that result, it could

58/ FF 343-344.

59/ FF 345.

60/ FF 367, 401.

61/ FF 368-370.

also be drafted to prohibit infringing use of UHI units which are now being imported, and, of course, there is the possibility of injunctive relief and damages in the parallel Federal court action.

SSI also argues that the ALJ failed to give the shortness of the remaining life of the patent sufficient weight. This is not a dispositive factor, however, and in view of the other facts noted above, the finding of no immediate and substantial harm is correct. 62/

SSI argues that the ALJ improperly applied the Stringers definition of "immediate and substantial harm" in such a way as to "preclude temporary relief . . . unless its [complainant's] entire business was in jeopardy." This overstates what the ALJ did; as noted above, it appears that the ALJ properly found no "immediate and substantial harm."

SSI argues that the standard of proof of injury adopted by the ALJ is in conflict with the purpose of temporary relief, i.e., maintenance of the status quo. SSI recognizes, however, that, in granting temporary relief, the Commission employs a balancing test similar to that used for preliminary injunctions in the Federal courts, citing WMATA. Noting that (1) the ALJ found the patent valid, (2) that in the absence of a license (which SSI says is terminated), the patent is infringed and (3) that under Bally/Midway, the requisite injury is present, SSI argues temporary relief should be granted. However, this argument relates only to the question of whether there is reason to believe a violation of section 337 exists and overlooks the balancing test which, as noted infra, indicates that temporary relief should not be granted.

62/ Many of SSI's arguments on points underlying the ALJ's finding of no "immediate and substantial harm" are correct and have been noted above. However, other points made by the ALJ do support that finding, which is correct.

SSI argues that the ALJ was incorrect in finding that the standard of immediate and substantial harm in a motion for temporary relief is more difficult to meet than the level of injury required in a permanent relief investigation. We find that the ALJ employed the correct definition of "immediate and substantial harm." We note that only a tendency to injure need be shown to find a violation of section 337 to exist; similarly, only reason to believe a tendency to injure exists need be shown to find reason to believe a violation of section 337 to exist. These requirements, however, relate to substance and are distinct from the factor of "immediate and substantial harm," which not only calls for a greater injury to occur in the interim period, but is a factor governing discretion to grant temporary relief, and, thus, even if found, must be balanced with other factors in determining whether to grant such relief.

F. Conclusion; (Reason To Believe a Violation Exists)

From the foregoing, it is clear that SSI has established reason to believe a violation exists, requiring a balancing of the four factors governing the discretionary grant of temporary relief to determine whether such relief should be granted, particular consideration being given to the public interest.

FACTORS GOVERNING DISCRETIONARY GRANT OF TEMPORARY RELIEF

A. Probability of Success on the Merits

From the foregoing, it is clear that there is a substantial probability SSI will succeed in showing a violation of section 337. This probability is,

of course, less than that in Smith, supra. 63/

B. Immediate and Substantial Harm

As noted above, it does not appear that SSI will suffer immediate and substantial harm during the interim period in the absence of temporary relief.

C. Harm to the Respondents if Temporary Relief is Granted

The ALJ found that if temporary relief is granted, UHI may be forced to seek alternative sources of supply in the United States which may be disruptive to its business. 64/ SSI does not dispute this finding in its petition for review.

D. Public Interest

SSI states, and the record supports, that the patented burn beds "provide benefits unavailable from any other device or method of treatment." 65/ The ALJ found that neither UHI nor SSI could supply the demand for new orders of the patented burn beds within a commercially reasonable length of time in what he found to be a growing market. 66/ He found that if a temporary exclusion order were issued some patients might not have access to burn beds at all in the interim period. 67/ He noted that prices of the patented burn beds have dropped where UHI and SSI have been competing and that decreasing competition by issuing temporary relief would result in a price increase which would effectively deny these beds to patients with limited means. 68/

63/ Smith International, Inc. v. Hughes Tool Co., 718 F.2d 1573 (CAFC 1983). See, note 7, supra.

64/ ID 139.

65/ SSI petition for review, p. 4.

66/ ID 140.

67/ ID 140.

68/ ID 140.

The SSI petition for review does not deny that the market is expanding, but argues that the ALJ impermissibly focussed on the advantages of price competition, stating further that there is no support for the ALJ's finding that SSI cannot supply existing demand within a commercially reasonable time, referring to SSI's capacity of [] units per month and its present production rate of [] units per month. SSI notes that it can increase production to [] units per month by adding a second shift and is now expanding facilities to increase capacity to [] units per month and could easily replace UHI's imports. SSI also noted that its prices today are the same as they were in 1983, except for Dallas and New Orleans, stating that SSI's prices have always been lower than UHI's. 69/

Contrary to SSI's petition for review, the ALJ was not focussing on the advantages of price competition per se, but on the potential effect of lack of price competition, resulting from the grant of temporary relief, on the public health and welfare, a consideration required by statute. Further, there is record evidence that SSI cannot satisfy the present demand within a short period of time. The inability to meet demand not only has to do with production (on which SSI's petition for review focuses) but on distribution as well. Even if SSI could replace UHI's imports during the interim period with increased production (which would take time to accomplish), it could not meet projected demand, which is several times what its production would be during the interim period. Further, the ALJ found that SSI cannot meet the present demand in large part because it can only effectively lease its burn beds within a two-hour driving radius of its service centers, which clearly do not

69/ This would seem to argue against finding immediate and substantial harm.

cover the entire United States. 70/ On the record as developed thus far, it appears that public health considerations override SSI's interests as an exclusive patent licensee, at least in this interim period.

E. Balancing the Factors; Public Interest

Balancing the four factors, it appears that temporary relief should not be granted. Further, on the present record, the public interest, i.e., public health considerations, indicates that temporary relief should not be granted.

INVESTIGATION NO. 337-TA-188

Investigation No. 337-TA-188 was instituted to determine whether there is a violation of section 337 in the unlawful importation of certain fluidized supporting apparatus and components thereof into the United States, or in their sale, by reason of (1) disparagement of complainant and complainant's fluidized supporting apparatus; (2) passing off; (3) false representation; and (4) interference with contractual relations, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States. 71/ The complaint which prompted this investigation is essentially a counter-complaint to the complaint which prompted Inv. No. 337-TA-182. The complainant is UHI. The respondents are SSI and Support Systems International (S.A.) of Montpellier, France (SSISA). The subject articles are hospital beds ("burn beds") which have fluidized support means which are particularly adapted for use by patients with severe burns or other injuries where it is painful or not conducive to recovery to lie on an ordinary bed. The burn beds of complainant UHI in Inv. No.

70/ See, FF 420, and TR 113-116.

71/ 49 F.R 11894 (March 28, 1984).

337-TA-188, of course, are the alleged infringing burn beds of Inv. No. 337-TA-182.

No petition for review of the ID as it relates to Inv. No. 337-TA-188 was filed, and the parties have thus waived their right to contest the findings of fact and conclusions of law therein for the purpose of determining whether there is reason to believe a violation of section 337 exists and the determination itself. 72/ The Commission may, of course, nevertheless review the portion of the ID as it relates to Inv. No. 337-TA-188 on its own motion and we have done so in this case. 73/ On the basis of that review, we have determined to affirm the ID insofar as it is based on the finding that there is lack of sufficient proof of reason to believe that the respondents have committed the unfair practices alleged. 74/ However, we do not adopt the ALJ's finding that there is reason to believe that there is an "industry in the United States" within the meaning of section 337 in Inv. No. 337-TA-188. Complainant UHI alleges the domestic industry in Inv. No. 337-TA-188 to be

... comprised of the domestic facilities devoted to the production, assembly, service, quality control, repair, research and development and distribution performed in connection with the fluidized supporting apparatus of UHI. 75/ [Emphasis supplied.]

As noted above, the UHI burn beds of Inv. No. 337-TA-188 are the alleged infringing burn beds of Inv. No. 337-TA-182. UHI does not dispute that its

72/ 19 C.F.R. § 210.54(a)(2).

73/ 19 C.F.R. § 210.55.

74/ ID 114-120.

75/ UHI Complaint, para. 27.

burn beds come within the claims of the '973 patent, and there is a serious question about whether UHI continues to be a sublicensee. 76/ This raises a serious question as to whether UHI is operating lawfully, i.e., whether the "domestic industry" as alleged in Inv. No. 337-TA-188 has a legal right to exist under the patent laws.

Secondly, even if UHI is acting lawfully, the nature and significance of UHI's activities in the United States with respect to the subject articles of commerce is such that it is inappropriate to find that there is reason to believe that UHI constitutes (or should be included in) an "industry . . . in the United States" with respect to the subject articles within the meaning of section 337. 77/

The ALJ found that there was reason to believe there is an "industry . . . in the United States" with respect to the subject articles and that the industry was composed of both UHI and SSI. As noted above, there is no reason to believe that UHI should be included as part of the industry. The inclusion of SSI presents a different and unusual problem. SSI is operating lawfully and has sufficient activities in the United States to justify treatment as an "industry . . . in the United States." However, SSI is the primary respondent in Inv. No. 337-TA-188 and UHI never pleaded or argued that SSI should be included as part of the industry. Obviously, if the industry in Inv. No. 337-TA-188 were defined as composed solely of SSI, the investigation would have to be terminated. 78/

76/ As noted above, even if the sublicense continues in force, UHI infringes since it is operating outside the limits of the sublicense.

77/ See, p. 13 ff., *supra*.

78/ As in Inv. No. 337-TA-182, if the industry in Inv. No. 337-TA-188 were defined to include both UHI and SSI, serious jurisdictional and substantive questions would be raised.

The foregoing circumstances make it inappropriate for us to adopt the ALJ's finding of reason to believe there is an "industry . . . in the United States" in Inv. No. 337-TA-188.

Finally, it is apparent that consideration of the discretionary factors for granting temporary relief, including the public interest, indicates that temporary relief should not be granted in any event. There is little probability that UHI will succeed on the merits, not only for the reasons given by the ALJ (which UHI does not dispute), but also for the additional reasons given above. Further, UHI does not dispute the ALJ's findings that UHI will suffer no immediate and substantial harm in the absence of temporary relief, that SSI will suffer harm if temporary relief is granted, and that temporary relief is contrary to the public interest.

We neither approve nor disapprove the other findings of the ALJ.

