lished and uniform practice ("EUP") under 19 U.S.C. § 1315(d) and *Heraeus-Amersil, Inc. v. United States*, 795 F.2d 1575 (Fed. Cir. 1986). We may overturn Customs' determination that an EUP did not exist only for "a clear abuse of discretion." *Heraeus-Amersil*, 795 F.2d at 1580 n.7. There was no clear abuse of discretion here.

[8] A so-called de facto EUP arises when Customs consistently classifies a particular type of merchandise under a specific HTSUS heading prior to some distinct point in time. *Kent II,* 466 F.Supp.3d. at 1368. The requirements for establishing a de facto EUP are stringent. *See Jewelpak Corp. v. United States*, 297 F.3d 1326, 1332 (Fed. Cir. 2002). In denying Kent's claim that the agency violated a de facto EUP, Customs relied on the fact that the 2005 Ruling was never revoked, that the Long Beach entries were classified under heading 8714, that hundreds of entries at 14 ports of entry over a 10-year period classified the same goods under heading 9401 and that similar goods imported by three of Kent's competitors were initially classified under heading 9401 and later reclassified under heading 8714. *Kent II*, 466 F.Supp.3d at 1369. The Trade Court ultimately decided that under these facts, it could not reasonably conclude that Customs engaged in a uniform practice of classifying these goods or that there was a lack of uncertainty regarding classification.

Kent has failed to show a clear abuse of discretion in denying its claim of a de facto EUP.

Conclusion

For the foregoing reasons, we vacate-in-part the Trade Court's determination of no treatment previously accorded and remand for a determination of whether there was such a treatment, excluding consideration of the bypass entries. We also remand for a determination in the first instance of the proper time period in which to consider the treatment previously accorded question. Finally, we affirm-in-part the Trade Court's determination that there was no de facto EUP.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED.

Costs

Costs are awarded to Kent.

CELGENE CORPORATION, Plaintiff-Appellant

v.

MYLAN PHARMACEUTICALS INC., Mylan Inc., Mylan N.V., Defendants-Appellees

2021-1154

United States Court of Appeals, Federal Circuit.

Decided: November 5, 2021

Background: Patentee brand-drug sponsor of pomalidomide, a drug used for treating multiple myeloma, brought patent infringement action against generic-drug sponsors and foreign pharmaceutical company that was sponsors' alleged parent corporation arising from abbreviated new drug application (ANDA) for generic pomalidomide. The United States District Court for the District of New Jersey, Esther Salas, J., dismissed and denied leave to amend. Brand-drug sponsor appealed.

Holdings: The Court of Appeals, Prost, Circuit Judge, held that:

(1) generic-drug sponsors did not commit past acts of infringement in New Jersey for venue purposes;

(2) sponsors' employee-associated locations in New Jersey were not a place of business for venue purposes;

(3) New Jersey office of defunct corporate subsidiary could not be imputed to sponsors, under alter ego theory, as a place of business for venue purposes;

(4) brand-drug sponsor failed to state claim against foreign company;

(5) scheduling deadline from first of two cases applied in determining request for leave to amend; and

(6) district court acted within its discretion in denying request to amend.

Affirmed.

1. Health ⚿319

The process under the Hatch-Waxman Act allowing for a generic competitor to file an abbreviated new drug application (ANDA) is designed to speed the introduction of low-cost generic drugs to market. Federal Food, Drug, and Cosmetic Act § 505(j)(2), 21 U.S.C.A. § 355(j)(2).

2. Patents ⚿1590

A generic-drug sponsor may not market a drug in a way that infringes a brand-drug sponsor's patents. Federal Food, Drug, and Cosmetic Act § 505(j)(2), 21 U.S.C.A. § 355(j)(2).

3. Health ⚿319
Patents ⚿1590

If a brand-drug sponsor waits more than 45 days after receiving notice of a generic's abbreviated new drug application (ANDA) that seeks approval to market a drug while that drug is on-patent, the brand-drug sponsor is not entitled to an automatic 30-month stay of Food and Drug Administration (FDA) approval so the infringement and validity questions can be worked out in court, but it also is not precluded from suing later for infringement. Federal Food, Drug, and Cosmetic Act § 505, 21 U.S.C.A. § 355(j)(5)(B)(iii); 35 U.S.C.A. § 271(e)(2).

4. Patents ⚿1970(1)

Court of Appeals reviews de novo whether venue is proper in a patent infringement action. 28 U.S.C.A. § 1400(b).

5. Courts ⚿96(7)

Whether venue is proper in a patent infringement action is an issue unique to patent law and is governed by Federal Circuit precedent. 28 U.S.C.A. § 1400(b).

6. Patents ⚿1813

The plaintiff has the burden of establishing proper venue in a patent infringement action. 28 U.S.C.A. § 1400(b).

7. Patents ⚿1727

Patent venue statute rather than general venue provision governs Hatch-Waxman cases of patent infringement involving an abbreviated new drug application (ANDA) by a generic-drug sponsor. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2).

8. Patents ⚿1729

Past acts of infringement, for purposes of venue in Hatch-Waxman Act cases, occur only in districts where a generic-drug sponsor submits its abbreviated new drug application (ANDA) to the Food and Drug Administration (FDA), and not wherever future distribution of the generic drug is contemplated. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2).

9. Patents ⚿1729

Generic-drug sponsors that were headquartered in West Virginia and Pennsylvania did not commit past acts of infringement in New Jersey, and thus venue was not proper in New Jersey for patent

infringement action that patentee brand-drug sponsor brought surrounding an abbreviated new drug application (ANDA) for generic pomalidomide, even though one generic sponsor sent the ANDA notice letter to brand-drug sponsor's headquarters in New Jersey; Hatch-Waxman Act and regulations treated the infringing ANDA submission and the notice letter as different things. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2); 21 C.F.R. § 314.95(a, e).

10. Patents ⚿1729

A patentee brand-drug sponsor's receipt of a generic-drug sponsor's notice letter following the submission of abbreviated new drug application (ANDA) pursuant to Hatch-Waxman Act is not part of the act of infringement for venue purposes in a patent infringement action. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2); 21 C.F.R. § 314.95(a, e).

11. Patents ⚿1730

To show that a defendant has a regular and established place of business in the district, for purposes of venue in a patent infringement action: (1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant. 28 U.S.C.A. § 1400(b).

12. Patents ⚿1730

A regular and established place of business in the district, for purposes of venue in a patent infringement action, must be of the defendant, not solely of the defendant's employee, and accordingly, a defendant must establish or ratify the place of business, and it is not enough that the employee does so on his or her own. 28 U.S.C.A. § 1400(b).

13. Patents ⚿1730

Employee-associated locations in New Jersey, consisting of 17 employee homes, could not be imputed to generic-drug sponsors, as employers, as a regular and established place of business for venue purposes in patent infringement action that patentee brand-drug sponsor brought against generic-drug sponsors, which were headquartered in other states, surrounding an abbreviated new drug application (ANDA) for generic pomalidomide, where generic-drug sponsors had tens of thousands of employees, sponsors did not pay for homes or require employees to store materials in homes, there was no advertising or marketing identifying homes as places of business, and employees were simply allowed to work from New Jersey. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2).

14. Patents ⚿1730

Employee-associated locations in New Jersey, consisting of two small storage lockers rented by sales or marketing employees to store pharmaceutical samples, could not be imputed to generic-drug sponsors, as employers, as a regular and established place of business for venue purposes in patent infringement action that patentee brand-drug sponsor brought against generic-drug sponsors, which were headquartered in other states, surrounding an abbreviated new drug application (ANDA) for generic pomalidomide, where lockers were rented in employees' own names, lockers were not used for order fulfillment, wholesaling, or retail, sponsors did not require employees to store materials in New Jersey, and sponsors did not own or lease lockers or hold them out as places of business. 28 U.S.C.A. § 1400(b); 35 U.S.C.A. § 271(e)(2).

15. Patents ⚿1730

New Jersey office of defunct corporate subsidiary could not be imputed to generic-drug sponsors, under an alter ego theory, as a regular and established place of business for venue purposes in patent

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