

Keywords: false patent marking, qui tam, unpatented article, patent misuse

General: The District Court finds that the Harrington failed in *qui tam* action to demonstrate that CIBA Vision Corp. falsely marked the packaging of products since the product was not found to be an unpatented article but rather a physical embodiment of patented method claims.

Harrington v CIBA Vision Corp.

No. 3:08-cv-00251 (U.S. District Court, Western District of North Carolina)

Decided July 21, 2010

I. Facts

CIBA Vision Corp. (hereinafter “CIBA”) owns several patents relating to methods of disinfecting contact lenses. The first, U.S. Patent No. 4,889,689 (hereinafter “the '689 patent”), includes claims directed toward a method of disinfecting soft contact lenses. The remaining patents, U.S. Patent No. 5,558,846 (hereinafter “the '846 patent”), U.S. Patent No. 5,609,264 (hereinafter “the '264 patent”), and U.S. Patent No. 5,609,837 (hereinafter “the '837 patent”), include claims directed toward a disposable disinfection apparatus as well as sealing and venting means for the disinfection apparatus. CIBA marked the bottles of its AOSEPT® hydrogen peroxide based disinfecting solution for contact lenses with the '689 patent, and marked the outer packaging with the '689, '846, '264, and '837 patents as well as the statement “and other patents pending.”

Plaintiff James M. Harrington (hereinafter “Harrington”) pursued a *qui tam* action against CIBA under 35 U.S.C. § 292 for “falsely” marking the outer packaging and bottles of AOSEPT® solution. Section 292 prohibits false marking done “for the purposes of deceiving the public” and allows third parties to bring suit against potential violators. Harrington argued that while claims in the issued patents recited the disinfecting apparatus in addition to methods of disinfecting contact lenses using the apparatus with the disinfecting solution, the disinfecting solution itself was an “unpatented item.” Citing case law, the District Court considered the two elements of a §292 false marking claim to be (1) marking an unpatented article and (2) intent to deceive the public. *Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1300 (Fed. Cir. 2009) (citing *Clontech Labs, Inc. v. Invitrogen Corp.*, 406 F.3d 1347, 1352 (Fed. Cir. 2005)).

II. Issues

- 1) Was the AOSEPT® Disinfecting Solution an “unpatented item”?
- 2) Did CIBA err in including the “and other patents pending” marking on the outer packaging of the AOSEPT® Disinfecting Solution?
- 3) Did CIBA demonstrate an “intent to deceive the public”?

III. Discussion

1) Regarding the question of an unpatented article, the '689 patent recites a method of using the AOSEPT® Disinfecting Solution with the AOSEPT® Disposable Cup & Disc to disinfect soft contact lenses. In particular, the District Court relied upon the Supreme Court's holding in *Quanta Computer, Inc. v. LG Electronics, Inc.* that a product whose use is covered by a patent containing only method claims is a “patented item” for purposes of the doctrine of patent exhaustion. 128 S. Ct. 2109, 2119 (2009). Accordingly, the District Court found that since method claims can be embodied in an article and considered a “patented item” for the purposes of patent exhaustion, the AOSEPT® Disinfecting Solution should be considered a “patented item” under 35 U.S.C. § 292 as well. Furthermore, the

District Court determined that “[w]here there is a tangible product to mark, failure to mark the product with the patent containing the method claims could prevent recovery of damages for infringement of those claims.” With regard to the other three patents, '846, '264, and '837, the Court considered the fact that the packaging also contained pictures of the entire AOSEPT® Cleaning and Disinfecting System, including the AOSEPT® Disinfecting Solution and the AOSEPT® Disposable Cup & Disc. Additionally, the package clearly states that the AOSEPT® Disinfecting Solution must be used with the AOSEPT® Disposable Cup & Disc to prevent injury. As such, the Court found that it was proper to mark the outer packaging with all four patents.

2) With regard to “and other patents pending” statement, the Court found that Gorman, CIBA's former Chief Patent Counsel, credibly testified he believed that there were other patent applications pending that were relevant to the AOSEPT® Disinfecting Solution. Harrington produced no evidence to the contrary, and, accordingly, the Court found that Harrington failed to meet his burden of proof.

3) Regarding the question of intent to deceive the public, the Court heard evidence presented by CIBA that, in fact, claims to the solution were present in the original '689 application that were subsequently cancelled during prosecution, leaving behind several claims to the method of disinfecting a soft contact lens with a stabilized aqueous hydrogen peroxide solution in addition to compositions for use in such a method. Furthermore, Gorman testified that was his understanding of the federal policy encourages patent holders to inform the public of patents that are embodied in a product and that “where a method patent exists and there is something to mark, the product should be marked.” Additionally, Gorman testified that it was his understanding that the '846, '264, and '837 patents were marked on the outer packaging for safety reasons consistent with FDA regulations, especially since failure to use the AOSEPT® Disposable Cup & Disc with the AOSEPT® Disinfecting Solution as instructed could result in painful exposure of the user's eye to the hydrogen peroxide of the solution. Based upon these findings, along with CIBA's presented evidence of good faith reliance on the advice of counsel, the Court found that CIBA had a good faith belief that it should mark the packages as they did.

IV. Conclusion

While the Court left open the question of whether CIBA was *required* to mark the AOSEPT® Disinfecting Solution, the Court did find that when there is a tangible product that is the embodiment of a method claim, failure to mark the product with the patent containing the method claim could result in a failure to recover damages for infringement. Furthermore, the Court determined that CIBA had reasonable belief that their markings were proper, and that the high bar for proving deceptive intent was not met. Accordingly, Harrington failed to establish a preponderance of the evidence that CIBA had violated 35 U.S.C. § 292.

V. Related Case

In another recent “false marking” case, *Unique Prod. Solutions, Ltd. v. Hy-Grade Valve, Inc.*, the Northern District Court of Ohio determined that the *qui tam* provision of 35 U.S.C. § 292 is unconstitutional by violating the Appointments and Take Care Clauses of the United States Constitution in failing to give the Executive Branch sufficient control over the litigation. In particular, the District Court opined the following regarding the False Marking statute:

It is unlike any statute in the Federal Code with which this Court is familiar. Any private entity that believes that someone is using an expired or invalid patent can file a criminal lawsuit in the name of the United States, without getting the approval of the Department of Justice. The case can be litigated without control or oversight by the Department of Justice. The government has no statutory right to intervene nor does it have a right to limit the participation of the relator. The government does not

have the right to stay discovery which may interfere with the government's criminal or civil investigations. The government may not dismiss the action. Finally, the relator may settle the case and bind the government without any involvement or approval by the Department of Justice.

Unique Prod. Solutions, Ltd. v. Hy-Grade Valve, Inc., No. 5:10-CV-1912, 2011 WL 924341 (N.D. Ohio March 14, 2011)