

## **Mallinckrodt, Inc. v. Medipart, Inc.**

United States Court of Appeals for the Federal Circuit, 1992.  
976 F.2d 700; 24 U.S.P.Q.2d (BNA) 1173.

This action for patent infringement and inducement to infringe relates to the use of a patented medical device in violation of a "single use only" notice that accompanied the sale of the device. Mallinckrodt sold its patented device to hospitals, which after initial use of the devices sent them to Medipart for servicing that enabled the hospitals to use the device again. Mallinckrodt claimed that Medipart thus induced infringement by the hospitals and itself infringed the patent.

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### **BACKGROUND**

The patented device is an apparatus for delivery of radioactive or therapeutic material in aerosol mist form to the lungs of a patient, for diagnosis and treatment of pulmonary disease. Radioactive material is delivered primarily for image scanning in diagnosis of lung conditions. Therapeutic agents may be administered to patients suffering various lung diseases.

The device is manufactured by Mallinckrodt, who sells it to hospitals as a unitary kit that consists of a "nebulizer" which generates a mist of the radioactive material or the prescribed drug, a "manifold" that directs the flow of oxygen or air and the active material, a filter, tubing, a mouthpiece, and a nose clip. In use, the radioactive material or drug is placed in the nebulizer, is atomized, and the patient inhales and exhales through the closed system. The device traps and retains any radioactive or other toxic material in the exhalate. The device fits into a lead-shielded container that is provided by Mallinckrodt to minimize exposure to radiation and for safe disposal after use.

The device is marked with the appropriate patent numbers, and bears the trademarks "Mallinckrodt" and "UltraVent" and the inscription "Single Use Only". The package insert provided with each unit states "For Single Patient Use Only" and instructs that the entire contaminated apparatus be disposed of in accordance with procedures for the disposal of biohazardous waste. The hospital is instructed to seal the used apparatus in the radiation-shielded container prior to proper disposal. The hospitals whose activities led to this action do not dispose of the UltraVent apparatus, or limit it to a single use.

Instead, the hospitals ship the used manifold/nebulizer assemblies to Medipart, Inc. Medipart in turn packages the assemblies and sends them to Radiation Sterilizers Inc., who exposes the packages to at least 2.5 megarads of gamma radiation, and returns them to Medipart. Medipart personnel then check each assembly for damage and leaks, and place the assembly in a plastic bag together with a new filter, tubing, mouthpiece, and nose clip. The "reconditioned" units, as Medipart calls them, are shipped back to the hospitals from whence they came. Neither Radiation Sterilizers nor Medipart tests the reconditioned units for any residual biological activity or for radioactivity. The assemblies still bear the inscription "Single Use Only" and the trademarks "Mallinckrodt" and "UltraVent".

Mallinckrodt filed suit against Medipart, asserting patent infringement and inducement to infringe. Mallinckrodt also asserted other counts including trademark infringement, unfair

competition under section 43(a) of the Lanham Trademark Act, and violation of Illinois unfair competition statutes. Both parties moved for summary judgment on all counts.

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#### THE RESTRICTION ON REUSE

Mallinckrodt describes the restriction on reuse as a label license for a specified field of use, wherein the field is single (i.e., disposable) use. On this motion for summary judgment, there was no issue of whether this form of license gave notice of the restriction. Notice was not disputed. Nor was it disputed that sale to the hospitals was the first sale of the patented device. The issue that the district court decided on summary judgment was the enforceability of the restriction by suit for patent infringement. The court's premise was that even if the notice was sufficient to constitute a valid condition of sale, violation of that condition can not be remedied under the patent law.

Mallinckrodt states that the restriction to single patient use is valid and enforceable under the patent law because the use is within the scope of the patent grant, and the restriction does not enlarge the patent grant. Mallinckrodt states that a license to less than all uses of a patented article is well recognized and a valid practice under patent law, and that such license does not violate the antitrust laws and is not patent misuse. Mallinckrodt also states that the restriction here imposed is reasonable because it is based on health, safety, efficacy, and liability considerations and violates no public policy. Thus Mallinckrodt argues that the restriction is valid and enforceable under the patent law. Mallinckrodt concludes that use in violation of the restriction is patent infringement, and that the district court erred in holding otherwise.

Medipart states that the restriction is unenforceable, for the reason that "the *Bauer* trilogy and *Motion Picture Patents* clearly established that *no* restriction is enforceable under patent law upon a purchaser of a sold article." (Medipart's emphasis). The district court so held. The district court also held that since the hospitals purchased the device from the patentee, not from a manufacturing licensee, no restraint on the use of the device could lawfully be imposed under the patent law.

The district court described the cases sustaining field of use and other restrictions as "in tension" with the cases prohibiting restrictions such as price-fixing and tying, and with the cases holding that the patent right is exhausted with the first sale. The court stated that policy considerations require that no conditions be imposed on patented goods after their sale and that Mallinckrodt's restriction could not "convert[] what was in substance a sale into a license." As we shall discuss, on the premises of this summary judgment motion the court erred in its analysis of the law, for not all restrictions on the use of patented goods are unenforceable.

The enforceability of restrictions on the use of patented goods derives from the patent grant, which is in classical terms of property: the right to exclude.

**35 U.S.C. § 154.** Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States . . . .

This right to exclude may be waived in whole or in part. The conditions of such waiver are subject to patent, contract, anti-trust, and any other applicable law, as well as equitable considerations such as are reflected in the law of patent misuse. As in other areas of commerce, private parties may contract as they choose, provided that no law is violated thereby:

The rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the [patented] article, will be upheld by the courts.

*E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91 (1902).

The district court's ruling that Mallinckrodt's restriction on reuse was unenforceable was an application of the doctrine of patent misuse, although the court declined to use that designation. The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy. The policy purpose was to prevent a patentee from using the patent to obtain market benefit beyond that which inheres in the statutory patent right.

The district court's holding that Mallinckrodt's restriction to single patient use was unenforceable was, as we have remarked, based on "policy" considerations. The district court relied on a group of cases wherein resale price-fixing of patented goods was held illegal, viz. *Bauer & Cie. v. O'Donnell*, 229 U.S. 1 (1913); *Straus v. Victor Talking Machine Co.*, 243 U.S. 490 (1917); *Boston Store of Chicago v. American Graphophone Co.*, 246 U.S. 8 (1918), ("the *Bauer* trilogy"), and that barred patent-enforced tie-ins, viz. *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917).

In *Bauer* the patentee had sold a product with a notice stating that the product "is licensed by us for sale and use at a price not less than one dollar. Any sale in violation of this condition, or use when so sold, will constitute an infringement." 229 U.S. at 8. The Supreme Court held the license unenforceable, stating that although

it was the intention of Congress [in promulgating the patent laws] to secure an exclusive right to sell, . . . there is no grant of a privilege to keep up prices and prevent competition by notices restricting the price at which the article may be sold.

*Bauer*, 229 U.S. at 17.

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In *Motion Picture Patents* a license notice was attached to patented movie projectors, stating that the purchaser had the right to use the machine only with motion picture films that were leased from the patentee. The defendant used a patented projector with films leased from other sources. The Court condemned the patentee's tie-in as illegal, since it extended the "scope of its monopoly" to materials which were not part of the patented invention. 243 U.S. at 516.

These cases established that price-fixing and tying restrictions accompanying the sale of patented goods were per se illegal. These cases did not hold, and it did not follow, that all restrictions accompanying the sale of patented goods were deemed illegal. In *General Talking Pictures* the Court, discussing restrictions on use, summarized the state of the law as follows:

That a restrictive license is legal seems clear. *Mitchell v. Hawley*, 83 U.S. 544, 16 Wall. 544 . As was said in *United States v. General Electric Co.*, 272 U.S. 476, 489, the patentee may grant a license "upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure" . . . .

The practice of granting licenses for restricted use is an old one, see *Rubber Company v. Goodyear*, 76 U.S. 788, 9 Wall. 788; *Gamewell Fire-Alarm Telegraph Co. v. Brooklyn*, 14 F. 255. So far as it appears, its legality has never been questioned.

305 U.S. at 127.

In *General Talking Pictures* the patentee had authorized the licensee to make and sell amplifiers embodying the patented invention for a specified use (home radios). The defendant had purchased the patented amplifier from the manufacturing licensee, with knowledge of the patentee's restriction on use. The Supreme Court stated the question as "whether the restriction in the license is to be given effect" against a purchaser who had notice of the restriction. The Court observed that a restrictive license to a particular use was permissible, and treated the purchaser's unauthorized use as infringement of the patent, deeming the goods to be unlicensed as purchased from the manufacturer.

The Court, in its opinion on rehearing, stated that it

[did not] consider what the rights of the parties would have been if the amplifier had been manufactured under the patent and had passed into the hands of a purchaser in the ordinary channels of trade.

305 U.S. at 127. The district court interpreted this reservation as requiring that since the hospitals purchased the UltraVent device from the patentee Mallinckrodt, not from a manufacturing licensee, no restraint on the purchasers' use of the device could be imposed under the patent law. However, in *General Talking Pictures* the Court did not hold that there must be an intervening manufacturing licensee before the patent can be enforced against a purchaser with notice of the restriction. The Court did not decide the situation where the patentee was the manufacturer and the device reached a purchaser in ordinary channels of trade.

The UltraVent device was manufactured by the patentee; but the sale to the hospitals was the first sale and was with notice of the restriction. Medipart offers neither law, public policy, nor logic, for the proposition that the enforceability of a restriction to a particular use is determined by whether the purchaser acquired the device from a manufacturing licensee or from a manufacturing patentee. We decline to make a distinction for which there appears to be no foundation. Indeed, Mallinckrodt has pointed out how easily such a criterion could be circumvented. That the viability of a restriction should depend on how the transaction is structured was denigrated as "formalistic line drawing" in *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 57-59 (1977), the Court explaining, in overruling *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365 (1967), that the legality of attempts by a manufacturer to regulate resale does not turn on whether the reseller had purchased the merchandise or was merely acting as an agent of the manufacturer. The Court having disapproved reliance on formalistic distinctions of no economic consequence in antitrust analysis, we discern no reason

to preserve formalistic distinctions of no economic consequence, simply because the goods are patented.

The district court, holding Mallinckrodt's restriction unenforceable, described the holding of *General Talking Pictures* as in "some tension" with the earlier price-fixing and tie-in cases. The district court observed that the Supreme Court did not cite the *Bauer*, *Boston Store*, or *Motion Picture Patents* cases when it upheld the use restriction in *General Talking Pictures*. That observation is correct, but it should not be remarkable. By the time of *General Talking Pictures*, price-fixing and tie-ins were generally prohibited under the antitrust law as well as the misuse law, while other conditions were generally recognized as within the patent grant. The prohibitions against price-fixing and tying did not make all other restrictions per se invalid and unenforceable. Further, the Court could not have been unaware of the *Bauer* trilogy in deciding *General Talking Pictures*, because Justice Black's dissent is built upon those cases.

Restrictions on use are judged in terms of their relation to the patentee's right to exclude from all or part of the patent grant, see, e.g., W.F. Baxter, *The Viability of Vertical Restraints Doctrine*, 75 Calif. L. Rev. 933, 935 (1987) ("historically, legal prohibition began with [resale price control and tie-in agreements] and, with rare exceptions, now continues only with those devices"); and where an anticompetitive effect is asserted, the rule of reason is the basis of determining the legality of the provision. In *Windsurfing International, Inc. v. AMF, Inc.*, 782 F.2d 995 (Fed. Cir. 1986):

To sustain a misuse defense involving a licensing arrangement not held to have been per se anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market.

*Id.* at 1001-1002 (footnote omitted). See also *Continental T.V. v. GTE Sylvania*, 433 U.S. at 58-59 (judging vertical restrictions under the rule of reason); *Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 735-36 (1988) (vertical non-price restraints are not per se illegal). The district court, stating that it "refuse[s] to limit *Bauer* and *Motion Picture Patents* to tying and price-fixing not only because their language suggests broader application, but because there is a strong public interest in not stretching the patent laws to authorize restrictions on the use of purchased goods", *Mallinckrodt*, 15 USPQ2d at 1119, has contravened this precedent.

In support of its ruling, the district court also cited a group of cases in which the Court considered and affirmed the basic principles that unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device; and that the sale of patented goods, like other goods, can be conditioned. The principle of exhaustion of the patent right did not turn a conditional sale into an unconditional one.

*Adams v. Burke*, 84 U.S. (17 Wall.) 453, (1874), dealt with patented coffin-lids that an assignee had the exclusive right to make, use, and sell within a ten-mile radius of Boston. The coffin was "sold [to Burke, an undertaker] within said circle by said [assignee], without condition or restriction", and used by Burke in the town of Natick, outside of the Boston circle. 84 U.S. at 455 (statement of the case). Adams, who owned the patent rights outside of the Boston circle, sued Burke for patent infringement. The Court stated that "when the patentee . . . sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use." *Id.* at 456. The Court remarked that the

coffin-lid "perishes in the first use of it", *id.* at 456, and that to imply a geographic limitation on the purchaser "would be to engraft a limitation upon the right of use not contemplated by the statute nor within the reason of the contract". *Id.* This holding is in accord with the other cases of that era, e.g., *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539 (1852), wherein the Court held that when the sale of the patented device was without restriction, the purchaser need not pay an additional sum when the patent term was extended; and *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544 (1873), wherein the Court stated:

Sales of the kind may be made by the patentee with or without conditions, as in other cases.

*Id.* at 548. In *Mitchell v. Hawley* the accused infringer had purchased a patented machine that was licensed for use only during the original term of the patent grant. After the patent term was extended the defendant argued that by virtue of his purchase he had acquired title free of the license condition. The Court disagreed, upholding the restriction.

In *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659 (1895), the Court restated that the purchaser of a patented machine, without any conditions, may use or resell the device anywhere in the United States, explaining:

"[When a patentee] has himself constructed a machine and sold it without any conditions, or authorized another to construct, sell, and deliver it, or to construct, use, and operate it, without any conditions, and the consideration has been paid to him for the thing patented, the rule is well established that the patentee must be understood to have parted to that extent with all his exclusive right, and that he ceases to have any interest whatever in the patented machine so sold and delivered or authorized to be constructed and operated."

157 U.S. at 663, quoting *Mitchell v. Hawley*, 83 U.S. (16 Wall.) at 546-47 (emphases added).<sup>6</sup>

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Viewing the entire group of these early cases, it appears that the Court simply applied, to a variety of factual situations, the rule of contract law that sale may be conditioned.<sup>7</sup> *Adams v. Burke* and its kindred cases do not stand for the proposition that no restriction or condition may be placed upon the sale of a patented article. It was error for the district court to derive that proposition from the precedent. Unless the condition violates some other law or policy (in the

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<sup>6</sup> In *Keeler* the Court stated that "whether a patentee may protect himself and his assignees by special contracts brought home to the purchasers . . . would arise as a question of contract, and not as one under the inherent meaning and effect of the patent laws." 157 U.S. at 666. The question of whether a license restriction is binding on the purchaser is indeed one of contract law. However, the remedy for breach of a binding license provision is not exclusively in contract, for a license is simply a promise not to sue for what would otherwise be patent infringement.

The district court stated that it intimated no opinion as to whether *Mallinckrodt* might enforce the restriction on "contract law or property law" or on "equitable grounds". We agree that a patentee may choose among alternate remedies, but to deny a patentee access to statutory remedies is to withhold the protection of the law. Thus whether *Mallinckrodt* may also have a remedy outside of the patent law is not before us.

<sup>7</sup> In accordance with the Uniform Commercial Code a license notice may become a term of sale, even if not part of the original transaction, if not objected to within a reasonable time. U.C.C. § 2-207(2)(c).

patent field, notably the misuse or antitrust law, *e.g.*, *United States v. Univis Lens Co.*, 316 U.S. 241 (1942)), private parties retain the freedom to contract concerning conditions of sale. As we have discussed, the district court cited the price-fixing and tying cases as reflecting what the court deemed to be the correct policy, *viz.*, that no condition can be placed on the sale of patented goods, for any reason. However, this is not a price-fixing or tying case, and the *per se* antitrust and misuse violations found in the *Bauer* trilogy and *Motion Picture Patents* are not here present. The appropriate criterion is whether Mallinckrodt's restriction is reasonably within the patent grant, or whether the patentee has ventured beyond the patent grant and into behavior having an anticompetitive effect not justifiable under the rule of reason.

Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the inquiry. However, should such inquiry lead to the conclusion that there are anticompetitive effects extending beyond the patentee's statutory right to exclude, these effects do not automatically impeach the restriction. Anticompetitive effects that are not *per se* violations of law are reviewed in accordance with the rule of reason. Patent owners should not be in a worse position, by virtue of the patent right to exclude, than owners of other property used in trade. Compare *Tripoli Co. v. Wella Corp.*, 425 F.2d 932, 936-38 (3d Cir. 1970) (in a non-patent action, restriction on resale of certain potentially dangerous products does not violate antitrust laws where motivation was prevention of injury to public and protection against liability risk) with *Marks, Inc. v. Polaroid Corp.*, 237 F.2d 428, 436, 111 USPQ 60, 66 (1st Cir. 1956) (single use only restriction based on safety concerns not patent misuse, and enforceable by suit for patent infringement).

We conclude that the district court erred in holding that the restriction on reuse was, as a matter of law, unenforceable under the patent law. If the sale of the UltraVent was validly conditioned under the applicable law such as the law governing sales and licenses, and if the restriction on reuse was within the scope of the patent grant or otherwise justified, then violation of the restriction may be remedied by action for patent infringement. The grant of summary judgment is reversed, and the cause is remanded.

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