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**Appeal Filed by** HELSINN HEALTHCARE S.A. v. TEVA PHARMACEUTICALS USA, INC, Fed.Cir., April 4, 2016

2016 WL 832089
Only the Westlaw citation is currently available.
United States District Court,
D. New Jersey.

Helsinn Healthcare S.A., et al., Plaintiffs,
v.
Dr. Reddy's Laboratories Ltd., et al., Defendants.

CIVIL ACTION NO. 11-3962 (MLC)
|
Signed March 3, 2016

**Synopsis**

**Background:** Assignees of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting brought action under the Hatch-Waxman Act against drug manufacturers that filed Abbreviated New Drug Applications (ANDA) with the Food and Drug Administration (FDA) seeking to market generic versions of the product and challenging those patents as invalid or unenforceable. Manufacturer raised a written description claim against the patents and asserted invalidity of the patents under the on-sale bar.

**Holdings:** The District Court, Cooper, J., held that:

[1] on-sale bar to patentability under America Invents Act (AIA) required public sale or offer for sale of claimed invention;

[2] agreement between purchaser and assignee constituted a sale pursuant to pre-AIA on-sale bar to patentability;

[3] agreements between manufacturers and assignee for developmental batches of product for clinical trials and data-gathering were not sales or offers for sale under pre-AIA on-sale bar to patentability;

[4] agreements between manufacturers and assignee for developmental batches of product for clinical trials and data-gathering were not "public" sales under post-AIA on-sale bar to patentability;

[5] agreement between purchaser and assignee was not a "sale" under post-AIA on-sale bar to patentability;

[6] claimed invention of asserted claims of patents were not "ready for patenting" as of critical date, as required under on-sale bar to patentability;

[7] specification of patent provided an adequate written description of the efficacy of the invention claimed; and

[8] ANDA specification for generic product with 0.075 mg / 1.5 ml dosage strength did not infringe asserted claims of patent covering intravenous solution which included 0.25 mg / 5 ml solution dosage.

Ordered accordingly.

West Headnotes (46)

[1] **Patents**
Patents

Patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.

Cases that cite this headnote

[2] **Patents**
In general; nature, purpose, and elements of statutory bar

"On-sale bar" serves as a bar to patentability if the claimed invention is (1) made the subject of a commercial offer for sale and (2) the invention is ready for patenting. 35 U.S.C.A. § 102.

Cases that cite this headnote

[3] **Patents**
What Constitutes Sale

A sale under the on-sale bar to patentability occurs when the parties offer or agree to reach a contract to give and pass rights of property for

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consideration which the buyer pays or promises to pay the seller for the thing bought or sold. 35 U.S.C.A. § 102.

Cases that cite this headnote

[4] **Statutes**
Clarity and Ambiguity; Multiple Meanings
**Statutes**
Plain language; plain, ordinary, common, or literal meaning

Court's first inquiry in interpreting a statute is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case; court's inquiry must cease if the statutory language is unambiguous and the statutory scheme is coherent and consistent.

Cases that cite this headnote

[5] **Statutes**
Wisdom, practicality, and common sense

Court is guided by common sense approach to statutory interpretation.

Cases that cite this headnote

[6] **Statutes**
Plain language; plain, ordinary, common, or literal meaning

In interpreting a statute, the court must begin with the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose.

Cases that cite this headnote

[7] **Statutes**
Technical terms, terms of art, and legal terms
**Statutes**
Common or civil law

In interpreting a statute, the use of a term of art, or a "common-law term," generally carries with it the assumption that the term comes with a common law meaning, absent anything pointing another way.

Cases that cite this headnote

[8] **Statutes**
Technical terms, terms of art, and legal terms

For purposes of statutory construction, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken.

Cases that cite this headnote

[9] **Patents**
Purpose and construction in general

In the context of patent law, guidelines published by the United States Patent and Trademark Office (USPTO) are instructive in interpreting a statute as they provide a practitioner's perspective on a given issue.

Cases that cite this headnote

[10] **Patents**
Purpose and construction in general

While the United States Patent and Trademark Office (USPTO) guidelines typically serve as a guide to patent attorneys and patent examiners on procedural matters, a court may take judicial notice of guidelines in interpreting a statute so long as the USPTO's interpretation does not conflict with the statute; the guidelines are not binding on the court.

Cases that cite this headnote

[11] **Statutes**
Language and intent, will, purpose, or policy
**Statutes**
Design, structure, or scheme

In determining the meaning of a statute, court must give effect to congressional intent by looking not only to the particular statutory

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language, but to the design of the statute as a whole and to its object and policy.

Cases that cite this headnote

[12] **Statutes**
Reports and analyses

In interpreting a statute, committee reports, which represent the considered and collective understanding of Congress in drafting and studying proposed legislation, are crucial when considering an issue of first impression.

Cases that cite this headnote

[13] **Statutes**
Drafts and earlier versions

In determining the meaning of a statute, prior versions of statutory provisions may supply evidence of congressional intent.

Cases that cite this headnote

[14] **Statutes**
Legislative history

When looking to prior versions of legislation in interpreting a statute, courts should not assume that Congress intended to enact statutory language that it has earlier discarded in favor of other language.

Cases that cite this headnote

[15] **Statutes**
Context

Meaning of statutory language, plain or not, depends on context.

Cases that cite this headnote

[16] **Statutes**
Statutory scheme in general

The importance of interpreting a statute in the context of the larger statutory scheme is crucial, as Congress does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.

Cases that cite this headnote

[17] **Patents**
What Constitutes Sale

Amended text of "on-sale bar" to patentability under the America Invents Act (AIA) requires a public sale or offer for sale of the claimed invention. 35 U.S.C.A. § 102.

Cases that cite this headnote

[18] **Patents**
Sale

Supply agreement between purchaser and assignee of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting, made more than one year prior to the application date of the patents for future commercial products that had not yet received Food and Drug Administration (FDA) approval at the time of contracting, constituted a sale pursuant to pre-America Invents Act (AIA) on-sale bar to patentability. 35 U.S.C.A. § 102; U.C.C. § 2-105(2).

Cases that cite this headnote

[19] **Sales**
Nature and Essentials of Contract for Sale of Personal Property in General

A "sale" is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold.

Cases that cite this headnote

[20] **Patents**
Sale

Supply agreements between manufacturers and assignee of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting for developmental batches of product for clinical trials and data-gathering were not sales or offers for sale under pre-America Invents Act (AIA) on-sale bar to patentability; agreements were not for the commercialization

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of assignee's product or for the purpose of assignee conducting its own secret, personal use of its product, and agreements were not entered into for purpose of stockpiling commercial product while anticipating Food and Drug Administration (FDA) approval and commercial launch, rather, assignee entered into agreements for purpose of pursuing FDA approval, which included analytical development, formulation development, batches preparation for clinical trials, and stability data generation. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[21] Patents**

Sale

Supply agreements between manufacturers and assignee of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting for developmental batches of product for clinical trials and data-gathering were not “public” sales under the post-America Invents Act (AIA) on-sale bar to patentability, given that the agreements were entirely subject to and performed under confidentiality restrictions. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[22] Patents**

Attempts to sell; offers

**Patents**

Completion of sale; acceptance and delivery

An agreement that relates specifically to a supply of worldwide requirements for what are clearly commercial purposes constitutes an offer to sell that has been accepted, within meaning of on-sale bar to patentability. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[23] Patents**

What Constitutes Sale

Determinative factor under the sale prong of the on-sale bar to patentability is the contractual language of the agreement. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[24] Patents**

Attempts to sell; offers

Agreement may not be considered a sale or offer for sale under the on-sale bar to patentability if the agreement lacks material terms that are common to commercial documents. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[25] Patents**

Sale

Supply and purchase agreement between purchaser and assignee of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting was not a “sale” under post-America Invents Act (AIA) on-sale bar to patentability; although the product had not yet received Food and Drug Administration (FDA) approval, agreement contained contractual terms relating to quantity of product that would be sold and at which price, and specified the exact dosages and concentrations that were in the pending FDA filings, and therefore the agreement was not indefinite or uncertain, and agreement did not make the claimed invention available to the public. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[26] Patents**

Number of uses or sales

Post-America Invents Act (AIA) on-sale bar to patentability requires that the sale or offer for sale make the claimed invention available to the public; it is not sufficient that a sale or offer for sale merely occur. 35 U.S.C.A. § 102.

Cases that cite this headnote

**[27] Patents**

Reduction of Invention to Practice

**Patents**

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Demonstration of utility; tests

To demonstrate reduction to practice, for patent purposes, a party must prove that the inventor (1) constructed an embodiment or performed a process that met all the limitations and (2) determined that the invention would work for its intended purpose.

Cases that cite this headnote

[28] **Patents**

Presumptions and burden of proof

**Patents**

Weight and Sufficiency

As patents are presumed valid, the patent challenger must prove by clear and convincing evidence that the claimed formulation was "ready for patenting" at the time of the critical date, for purposes of on-sale bar to patentability. 35 U.S.C.A. § 102.

Cases that cite this headnote

[29] **Patents**

Questions of law or fact

Whether a claimed formulation has been reduced to practice, for patent purposes, is a fact-driven analysis that may require an analysis of the parties' claim construction.

Cases that cite this headnote

[30] **Patents**

Sale

Claimed invention of asserted claims of patents covering intravenous solution for treating chemotherapy-induced nausea and vomiting were not "ready for patenting" as of critical date, as required under on-sale bar to patentability, where trial testing and preliminary data of solution were insufficient at that time to support any valid scientific knowledge of efficacy as claimed. 35 U.S.C.A. § 102.

Cases that cite this headnote

[31] **Patents**

Written Description Requirement

Hallmark of written description requirement for patents is disclosure. 35 U.S.C.A. § 112(a).

Cases that cite this headnote

[32] **Patents**

Disclosure as directed to one skilled in the art

To meet written description requirement for patents, the disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. 35 U.S.C.A. § 112(a).

Cases that cite this headnote

[33] **Patents**

Disclosure as directed to one skilled in the art

**Patents**

Possession of claimed invention

To satisfy written description requirement for patents, the disclosure need not contain either examples or an actual reduction to practice, rather, the critical inquiry is whether the patentee has provided a description that in a definite way identifies the claimed invention in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing; this is an objective inquiry into the four corners of the specification. 35 U.S.C.A. § 112(a).

Cases that cite this headnote

[34] **Patents**

Written Description Requirement

A claim that recites a property that is necessarily inherent in a formulation that is adequately described is not invalid as lacking written description merely because the property itself is not explicitly described. 35 U.S.C.A. § 112(a).

Cases that cite this headnote

[35] **Patents**

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