620 F.Supp.3d 108
United States District Court, D. Delaware.

EXELA PHARMA SCIENCES, LLC, Plaintiff,
v.
ETON PHARMACEUTICALS, INC., Defendant.

C.A. No. 20-365 (MN)
|
Signed August 8, 2022

Synopsis

Background: Patentee brought action against competitor pursuant to Hatch-Waxman Act, alleging infringement of three patents covering an injectable L-cysteine composition containing low aluminum levels and methods of using such composition.

Holdings: The District Court, Maryellen Noreika, J., held that:

[1] competitor directly infringed patent claim covering a method of treating a patient with an adverse health condition responsive to L-cysteine administration;

[2] prior art product did not anticipate claim;

[3] foreign manufacturer's certificate of analysis for single lot of prior art product was insufficient to prove anticipation;

[4] competitor failed to establish by clear and convincing evidence that it was obvious to use prior art product with particular vials;

[5] patentee's product filled long-felt need for low-aluminum cysteine composition; and

[6] competitor failed to meet its burden of proving patent claims were obvious with respect to specific aluminum-over-time and cystine-over-time claim limitations of each asserted claim.

Ordered accordingly.

Procedural Posture(s): Judgment.

West Headnotes (56)

[1] **Patents** Questions of law or fact

The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary.

[2] **Patents** Plain, ordinary, or customary meaning in general

Patents State of the art

The words of a patent claim are generally given their ordinary and customary meaning, which is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.

[3] **Patents** Context

Although the patent claims themselves provide substantial guidance as to the meaning of particular claim terms, the context of the surrounding words of the claim also must be considered.

[4] **Patents** Plain, ordinary, or customary meaning in general

Patents State of the art

The ordinary meaning of a patent claim term is its meaning to the ordinary artisan after reading the entire patent.

[5] **Patents** Specifications and Drawings; Written Description

The patent specification is always highly relevant to the claim construction analysis, as it is the single best guide to the meaning of a disputed term.

[6] **Patents** Contemporaneous construction

It is possible that the patent specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess; in such cases, the inventor's lexicography governs.

[7] **Patents** Preferred embodiment

Even when the patent specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.

[8] **Patents** Rejection and Amendment of Claims; Prosecution History

In addition to the patent specification, a court construing the claims of a patent should also consider the patent's prosecution history, if it is in evidence.

[9] **Patents** Rejection and Amendment of Claims; Prosecution History

A patent's "prosecution history," which is intrinsic evidence, consists of the complete record of proceedings before the Patent and Trademark Office (PTO) and includes the prior art cited during the examination of the patent.

[10] **Patents** Rejection and Amendment of Claims; Prosecution History

A patent's prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

[11] **Patents** Extrinsic Evidence

"Extrinsic evidence," for purposes of construing the claims of a patent, consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.

[12] **Patents** Expert and inventor testimony

Expert testimony can be useful, for purposes of construing the claims of a patent, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field; nonetheless, courts must not lose sight of the fact that expert reports and testimony are generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.

[13] **Patents** Extrinsic Evidence

Although extrinsic evidence may be useful to a court construing the claims of a patent, it is less reliable than intrinsic evidence, and its consideration is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.

[14] **Patents** Extrinsic Evidence

Where the intrinsic record unambiguously describes the scope of a patented invention, reliance on any extrinsic evidence, for purposes of claim construction, is improper.

[15] **Patents** In general; comparison with patent claims

Courts employ a two-step analysis in making a patent infringement determination: first, a court must construe the asserted claims; next, the trier of fact must compare the properly-construed

claims to the accused infringing product. 35 U.S.C.A. § 271(a).

[16] **Patents** In general; comparison with patent claims

Literal patent infringement occurs where every limitation in a patent claim is found in an accused product, exactly. 35 U.S.C.A. § 271(a).

[17] **Patents** Filing of applications for drug approval

In a patent infringement action brought pursuant to the Hatch-Waxman Act, the infringement inquiry is whether, if a particular drug were put on the market, it would infringe the relevant patent. 35 U.S.C.A. § 271(e)(2)(A).

[18] **Patents** As to Patentability and Validity

An issued patent is presumed to be valid. 35 U.S.C.A. § 282.

[19] **Patents** Degree of proof

To invalidate a patent, the party seeking invalidation must carry its burden of proof by clear and convincing evidence. 35 U.S.C.A. § 282.

[20] **Patents** Degree of proof

"Clear and convincing evidence," for purposes of the burden of proof of the party seeking to invalidate a patent, is evidence that proves in the mind of the trier of fact an abiding conviction that the truth of the factual contentions is highly probable. 35 U.S.C.A. § 282.

[21] **Patents** Questions of law or fact

Patent anticipation is a question of fact. 35 U.S.C.A. § 102(a).

[22] **Patents** Single reference disclosing every element or limitation of claim

Patents Inherent anticipation

A patent claim is anticipated if each and every limitation is found, either expressly or inherently, in a single prior art reference. 35 U.S.C.A. § 102(a).

[23] **Patents** Prior Art and Relation of Claimed Invention Thereto

The test for patent anticipation mirrors, to some extent, the test for infringement, and it is axiomatic that which would literally infringe, if later, anticipates, if earlier. 35 U.S.C.A. § 102(a).

[24] **Patents** Single reference disclosing every element or limitation of claim

In order to anticipate a patent, a reference must show all of the limitations of the claims arranged or combined in the same way as recited in the claims. 35 U.S.C.A. § 102(a).

[25] **Patents** Prior knowledge or use in general

If an invention was known to or used by others in the United States before the date of the patentee's invention, the later inventor has not contributed to the store of knowledge, and has no entitlement to a patent. 35 U.S.C.A. § 102(a).

[26] **Patents** Accessibility to public of prior art; concealed inventions

For prior art to anticipate a patent claim because it has been "used," the use must be accessible to the public. 35 U.S.C.A. § 102(a).

[27] **Patents** Prior knowledge or use in general

The prior knowledge and use of prior art by a single person is sufficient to anticipate a patent claim. 35 U.S.C.A. § 102(a).

[28] **Patents** Incorporation by reference

Material not explicitly contained in a single prior art document may still be considered, in determining whether a patent claim is anticipated, if that material is incorporated by reference into the document. 35 U.S.C.A. § 102(a).

[29] **Patents** Incorporation by reference

"Incorporation by reference," for purposes of determining whether a patent claim is anticipated, provides a method for integrating material from various documents into a host document by citing such material in a manner making clear that the material is effectively part of the host document as if it were explicitly contained therein. 35 U.S.C.A. § 102(a).

[30] **Patents** In general; multiple factors

Patents Questions of law or fact

Patent obviousness is a question of law based on underlying factual findings concerning: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective considerations of nonobviousness. 35 U.S.C.A. § 103(a).

[31] **Patents** Combination of prior art references; "teaching, suggestion, or motivation" test

Patents Expectation or probability of success; predictability

Patents Level of Ordinary Skill in the Art

To prove that a patent is obvious, a party must demonstrate that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so. 35 U.S.C.A. § 103(a).

[32] **Patents** Combination of prior art references; "teaching, suggestion, or motivation" test

Although an analysis of any teaching, suggestion, or motivation to combine known elements is useful to a patent obviousness analysis, the overall obviousness inquiry must be expansive and flexible. 35 U.S.C.A. § 103(a).

[33] **Patents** Level of Ordinary Skill in the Art

Patents Time of evaluation; hindsight

The use of hindsight is not permitted when determining whether a patent claim would have been obvious to one of ordinary skill in the art. 35 U.S.C.A. § 103(a).

[34] **Patents** In general; multiple factors

To protect against the improper use of hindsight when assessing patent obviousness, the court is required to consider objective or secondary considerations, or indicia, of non-obviousness, such as commercial success, failure of others, unexpected results, and long-felt but unmet need. 35 U.S.C.A. § 103(a).

[35] **Patents** Particular products or processes

Patents Drugs and medicines

Term "about," as used in patent claim covering a method of treating a subject having an adverse health condition that is responsive to L-cysteine administration, meant approximately, and was not indefinite.

[36] **Patents** Particular products or processes

Patents Drugs and medicines

Term "pharmaceutically acceptable amount of cystine," as used in patent for stable and highly pure L-cysteine compositions for injection and methods of use, meant an amount of cystine that was compatible chemically and/or toxicology with the other ingredients comprising

a formulation and/or the mammal being treated therewith, and was not indefinite.

[37] **Patents** Drugs and medicines

Term "stable L-cysteine composition," in patent claim for method of treating a subject having an adverse health condition that is responsive to L-cysteine administration, meant an L-cysteine composition that had the component profiles described therein, for example, aluminum, L-cystine, and pyruvic acid, at the levels described and for the amount of time identified; in other words, a stable composition that contained the specified levels of all components for sufficient period of time to enable the composition to be commercially manufactured, stored, shipped, and administered in a clinical setting.

[38] **Patents** Drugs and medicines

Term "pyruvic acid relative to L-cysteine not more than about 2.0 wt %," as used in patent claim covering a method of treating a subject having an adverse health condition that was responsive to L-cysteine administration, had its plain and ordinary meaning, which set a limit to the amount of pyruvic acid when present, but did not require the presence of pyruvic acid.

[39] **Patents** Drugs and medicines

Competitor's abbreviated new drug application (ANDA) product met all limitations of patent claim covering a method of treating a patient with an adverse health condition responsive to L-cysteine administration, and thus competitor directly infringed claim, even if ANDA product did not contain pyruvic acid, where court construed asserted claim to require only that the amount of pyruvic acid not exceed the maximum stated, such that claim did not require any amount of pyruvic acid to be present. 35 U.S.C.A. § 271(e)(2).

[40] **Patents** Filing of applications for drug approval

What an Abbreviated New Drug Application (ANDA) applicant asks for and receives approval to market, if within the scope of a valid claim, is a patent infringement. 35 U.S.C.A. § 271(e)(2).

[41] **Patents** Scope of inquiry and power of court in general

Competitor, whose abbreviated new drug application (ANDA) product met all limitations of patentee's patent claim covering a method of treating a patient with an adverse health condition responsive to L-cysteine administration, waived its argument in parties' infringement dispute that if claim limitation "not more than" could mean zero, then patent claim was invalid, where competitor raised argument for the first time in post-trial brief, and did not present argument at trial or in pre-trial order.

[42] **Patents** Drugs and medicines

Competitor's abbreviated new drug application (ANDA) product, which met all limitations of patent claim covering a method of treating a patient with an adverse health condition responsive to L-cysteine administration, was not the same as prior art product, and thus prior art product did not anticipate claim; ANDA product and prior art product differed as to amount of aluminum over time, ANDA product required additional sterilization step and oxygen controls that were material to integrity of product, prior art product used different vial which could affect how much aluminum leached into product, and products were made with cysteine sourced from different companies, which sold ingredients with different impurity profiles. 35 U.S.C.A. § 102(a).

[43] **Patents** Drugs and medicines

Foreign manufacturer's certificate of analysis for single lot of prior art product, which competitor alleged anticipated patent claim

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.