



In re Metoprolol Succinate Patent Litigation Case Brief

ASTRAZENECA

v.

KV PHARMACEUTICAL CO.

ANDRX PHARMACEUTICALS

EON LABS, INC.

Authored by: Charles Niebylski, Ph.D.
[Official Cite] No. 2006-1254, July 23, 2007

JUDGES: Before MAYER, SCHALL, and GAJARSA, Circuit Judges.

OPINION BY: Circuit Judge GAJARSA. Circuit Judge SCHALL dissents in part.

Procedural Posture:

Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, and AstraZeneca LP (collectively “Astra”) filed multiple suits in various district courts asserting that the Abbreviated New Drug Applications (“ANDA”) filed respectively by Defendants KV Pharmaceutical Co. (“KV”), Andrx Pharmaceuticals, LLC, and Andrx Corp. (collectively “Andrx”), and Eon Labs, Inc. (“Eon”) under 21 U.S.C. § 355(j) infringe Astra’s patents. Specifically, Astra alleged that Defendants’ ANDAs seeking approval from the Food & Drug Administration to manufacture and market generic versions of Toprol-XL® infringed Astra’s patents pursuant to 35 U.S.C. § 271(e). The district court found Astra’s patents invalid and unenforceable, and granted Defendants’ motions for summary judgment. In re Metoprolol Succinate Patent Litigation (“Summary Judgment”), No. 04-1620, slip op. (E.D. Mo. Jan. 17, 2006).

Overview:

Clients need to carefully build their patent families to avoid unnecessary risks of invalidity. AstraZeneca’s Toprol-XL® is under new scrutiny, and one of its patents has been declared invalid for claiming an obvious improvement over the subject of another AstraZeneca patent. Your firm needs a vision for your entire patent family, so it can help you write appropriate claims and, when appropriate, file terminal disclaimers where one patent may be an “obvious” improvement over another.

WASHINGTON DC AREA

112 S. West Street • Alexandria, Virginia 22314
Tel: 703.548.NATH • Tel: 703.548.6284 • Fax: 703.683.8396

SAN DIEGO

12264 El Camino Real, Suite 400 • San Diego, CA 92130
Tel: 858.792.8211 • Fax: 858.792.8946



Facts:

- Astra manufactures and markets metoprolol succinate in “extended release” forms under the brand name Toprol-XL®. Metoprolol is a therapeutically active compound, which can form salts by reaction with acids and is used in the treatment of angina, hypertension, and congestive heart failure.
- In 1971, Astra employee Nitenberg synthesized metoprolol succinate as well as the tartrate and sulfate salts of metoprolol”. Similarly in 1982, another Astra employee named Lilljequist synthesized a number of metoprolol salts, including metoprolol succinate.
- U.S. Patent No. 4,780,318 (hereinafter referred to as “the ’318 Patent”) issued in October 1988 and was eventually obtained by Astra. The ’318 Patent is pertinent because the district court invalidated Astra’s U.S. Patent No. 5,081,154 (hereinafter referred to as “the ’154 Patent”) and U.S. Patent No. 5,001,161 (hereinafter referred to as “the ’161 Patent”) for double patenting over the ’318 Patent.
- Claim 6 of the ’318 Patent claims an improved release oral pharmaceutical composition having (i) “a core comprising the therapeutically active compound,” (ii) “a first inner layer coating on the core,” and (iii) “a second outer layer coating on the inner layer.” Dependent claim 8 recites eleven therapeutic species, including metoprolol succinate.
- The ’161 Patent issued in March 1991 . The only claim of the ’161 Patent reads: “A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier.” The ’154 Patent issued in January 1992. The only claim of the ’154 Patent simply reads, “Metoprolol succinate.” No terminal disclaimer was required.
- Defendants KV, Andrx, and Eon each filed an ANDA under 21 U.S.C. § 355(j) seeking approval from the Food & Drug Administration to market generic metoprolol succinate formulations with the bioequivalence of Astra’s Toprol-XL®, certifying under § 355(j)(2)(A)(vii)(IV) that the ’161 and ’154 Patents are invalid or will not be infringed. In 2003 and 2004, Astra filed multiple infringement actions based on the ’161 and ’154 Patents against the Defendants.
- All three defendants moved for summary judgment for invalidity of the ’161 and ’154 Patents based on double patenting and invalidity of the ’161 Patent based on anticipation. Defendant Andrx also filed, and defendants Eon and KV subsequently joined, a motion for summary judgment for unenforceability of both patents based on inequitable conduct. In January 2006, the district court issued a summary judgment decision and accompanying judgment in favor of the defendants,
- Astra only appealed the grant of summary judgment for invalidity of the ’154 Patent based on double patenting and the grant of summary judgment for unenforceability of both patents based on inequitable conduct.

WASHINGTON DC AREA

112 S. West Street • Alexandria, Virginia 22314
Tel: 703.548.NATH • Tel: 703.548.6284 • Fax: 703.683.8396

SAN DIEGO

12264 El Camino Real, Suite 400 • San Diego, CA 92130
Tel: 858.792.8211 • Fax: 858.792.8946



Issue: (1) Whether the district court properly held that the '154 patent was invalid for double patenting over the '318 patent; and (2) whether the '154 and '161 patents were properly found unenforceable by the district court due to inequitable conduct.

Holding: The CAFC affirmed the district court's invalidity holding regarding the '154 Patent, vacated its inequitable conduct unenforceability holding regarding the '161 and '154 Patents, and remanded the case.

Regarding invalidity due to obviousness-type double patenting, Claim 1 of the '154 Patent claiming a compound (A1) is an obvious variation of Claim 8 of the '318 Patent claiming a composition comprised of one compound of an enumerated list (A1, A2, A3, etc.), an inner layer (B), and an outer layer (C). Specifically, it would have been an obvious variation of Claim 8 of the '318 Patent to omit the inner layer (B) and the outer layer (C). Further, the composition of the earlier '318 patent claim includes the compound of the later '154 patent claim in its entirety. Specifically, the earlier patent not only discloses but also claims a composition comprised-in-part of metoprolol succinate.

Regarding unenforceability due to inequitable conduct, the record reveals a genuine factual dispute of whether Astra had an intent to deceive the U.S. Patent & Trademark Office regarding inventorship. The district court improperly resolved this factual dispute on summary judgment and thus, erred in holding on summary judgment that the '161 and '154 Patents are unenforceable based on inequitable conduct.

Analysis:

The CAFC upheld the district court finding of obviousness-type double patenting, and that In re Emert applies. In re Emert 124 F.3d 1458 (Fed. Cir. 1997).

In *Emert*, the CAFC held the claims of an application unpatentable for double patenting, finding that "the application's claimed invention, an oil soluble dispersant comprising B1, while not anticipated due to the slight modification of three claim limitations, would have been prima facie obvious in light of the claim to the combination [A and B]" because the patentee "effectively conceded that the differences between B and B1 are not material and would have been obvious to a person having ordinary skill in the art."

In this case, Claim 1 of the '154 Patent claiming a compound (A1) is an obvious variation of Claim 8 of the '318 Patent claiming a composition comprised of one compound of an enumerated list (A1, A2, A3, etc.), an inner layer (B), and an outer layer (C). Specifically, it would have been an obvious variation of Claim 8 of the '318 Patent to omit the inner layer (B) and the outer layer (C). The composition of the earlier patent claim includes the compound of the later patent claim in its entirety. Specifically,

WASHINGTON DC AREA

112 S. West Street • Alexandria, Virginia 22314
Tel: 703.548.NATH • Tel: 703.548.6284 • Fax: 703.683.8396

SAN DIEGO

12264 El Camino Real, Suite 400 • San Diego, CA 92130
Tel: 858.792.8211 • Fax: 858.792.8946



the earlier patent not only discloses but also claims a composition comprised-in-part of metoprolol succinate.

Dissent: Judge Schall dissented that “[t]he law of double patenting is concerned only with what patents claim. ‘Double patenting,’ therefore, involves an inquiry into what, if anything, has been claimed twice.” The critical point is that, in this case, the compound metoprolol succinate has not “been claimed twice.”

Claim 8 of the '318 Patent is a three-element composition having (i) a core with any one of eleven possible compounds, one of them being metoprolol succinate; (ii) an inner coating; and (iii) an outer coating. Anything less than a composition with all three of these elements is not what is claimed. In contrast, what is claimed by claim 1 of the '154 patent is a single compound: metoprolol succinate. In short, the two claims involve different inventions.

According to Judge Schall, a later patent claim to compound A is patentably distinct from an earlier patent claim to composition A-B-C. In support of this assertion Schall cites General Foods, in which the Court held that a later patent claim to step A is patentably distinct from an earlier patent claim to steps A-B-C-D.

Judge Schall distinguished Emert – In Emert, both the patent claim and the application claim were to an oil soluble dispersant and the inquiry focused on whether the content of one claimed dispersant was patentably distinct from the content of the later claimed dispersant. In the present case, there is an earlier claim to a three-element composition and a later claim to a single compound, which prevents applicability of Emert.

Lessons: Heightened care must be taken by Applicants and patent practitioners regarding improvement inventions that might be characterized as a genus/species relationship. Furthermore, it may be easier now to show that improvement inventions trigger obviousness-type double patenting, which might require filing of a terminal disclaimer.

Client message: In some situations, it may be easier now to show that improvement inventions trigger obviousness-type double patenting, which might require filing of a terminal disclaimer shortening of patent term.