In re Metoprolol Succinate – Obviousness-Type Double Patenting

Walter B. Welsh
St. Onge Steward Johnston & Reens LLC
Stamford, Connecticut

I. INTRODUCTION

In *Metoprolol Succinate* the Court of Appeals for the Federal Circuit (CAFC) considered whether a later issued patent claiming the compound metoprolol succinate was invalid for obviousness-type double patenting over an earlier patent claiming a specific composition containing metoprolol succinate. *In re Metoprolol Succinate Patent Litigation*, 494 F.3d 1011, 1015 (Fed. Cir. 2007). The CAFC held that the patent was invalid for obviousness-type double patenting because it claimed an obvious variation of the earlier issued patent. *Id*. at 1017.

II. DOUBLE PATENTING

"The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent." MPEP 804 (citing *In re Zickendraht*, 319 F.2d 225, 232 (C.C.P.A. 1963) (Rich, J., concurring)). Double patenting occurs when the right to exclude by an earlier patent is unjustly extended by the grant of a later patent. *Id*. (citing *In re Van Ornum*, 686 F.2d 937, 943–44 (C.C.P.A. 1982)).

"Non-statutory, or 'obviousness-type' double patenting is a judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of the patent protection." *In re Metoprolol Succinate*, 494 F.3d at 1016 (citing *Perricone v. Medics Pharm. Corp.*, 432 F.3d 1368, 1373 (Fed. Cir. 2006)). The doctrine prevents the patentee from extending the term of its patent beyond the statutory limit by claiming an obvious variation of an earlier patented invention. *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997.) In other words, obviousness-type double patenting allows the public to use an invention after its patent expires. *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

In determining whether a claim is invalid for obviousness-type double patenting, the critical inquiry is whether that claim defines an obvious variation of an earlier issued claim. *In re Metoprolol Succinate*, 494 F.3d at 1016. To answer this inquiry courts apply a two-step test. *Id*. First, the court construes the reference claim and the challenged claim as a matter of law, and determines the differences. *Id*. Second, the court determines whether the differences in the claims render them patentably distinct. *Id.* A claim is invalid for obviousness-type double patenting if it is obvious over, or anticipated by, the reference claim. *Id*. The CAFC reviews a double patenting determination without deference. *Id*. at 1015.

III. BACKGROUND

Plaintiff AstraZeneca AB ("Astra") manufactures and markets metoprolol succinate in extended release forms under the brand name Toprol-XL®. *In re Metoprolol Succinate*, 494 F.3d at 1012. Metoprolol succinate is a compound used to treat angina, hypertension, and congestive heart failure. *Id*. Astra owns U.S. Patent No. 5,081,154 (the '154 patent), which broadly claims metoprolol succinate. *Id*. at 1014. The '154 patent issued in January 1992 and Astra listed it in the Orange Book with an expiration date of January 2009. (Appellee Br., 2006 WL 2191699 at *9.)

Lejus Medical AB ("Lejus") owns U.S. Patent No. 4,780,318 (the '318 patent). The '318 patent issued in October of 1988 and expired in 2005. Claim 6 of the '318 patent claims (i) "a core comprising a therapeutically active compound," (ii) "a first layer coating the core," and (iii) "a second outer layer coating the inner layer." *In re Metoprolol Succinate*, 494 F.3d at 1014. Dependent claim 8 claims the composition of claim 6, wherein the active compound is metoprolol succinate (or some other compound). *Id*. The '154 patent and the '318 patent are part of the same patent family. *Id*. The chart below illustrates the differences between the claims.

Patent Claim	Elements
'318 – Claim 8 Reference Claim	(A) metoprolol succinate (or one of several other drugs); (B) first outer layer; and (C) second outer later.
'154 – Claim 1 Challenged Claim	(A) metoprolol succinate.

Defendants KV Pharmaceutical Co., Andrx Pharmaceuticals Co., and Eon Labs (collectively, Defendants) filed Abbreviated New Drug Applications seeking to market metoprolol succinate formulations. *Id.* at 1015. Astra subsequently sued Defendants for infringement of the '154 patent and Defendants moved for summary judgment of invalidity based on obviousness-type double patenting over claim 8 of the '318 patent. *Id*.

The district court held the '154 patent was invalid for obviousness-type double patenting because the earlier issued claim 8 of the '318 patent was a species of the latter issued genus claim of the '154 patent. *In re Metoprolol Succinate*, MDL No. 1620, 2006 WL 120343 at *11 (E.D. Mo. Jan. 17 2007). The court relied on earlier CAFC precedent for the proposition that "a species/genus relationship is a form of double patenting wherein the second broader claim is deemed invalid because it is anticipated by, and therefore not patentably distinct from, an earlier species claim. *Id.* (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed. Cir. 2001)).

IV. ARGUMENTS ON APPEAL

The issue on appeal was whether a patent broadly claiming a compound was invalid for obviousness-type double patenting over an earlier patent claiming a composition including that compound. Astra raised four different arguments for validity of the '154 patent. First, Astra argued that the district court erred in holding the claims formed a species/genus relationship. *In re Metoprolol Succinate*, 494 F.3d at 1017. In Astra's view the claims formed a patentably distinct element/combination relationship. *Id*. Second, Astra argued that a controlling line of cases from the Court of Customs and Patent Appeals (CCPA) held there was no double patenting just because an earlier claim to a combination sets forth a later claimed element. *Id*. at 1017–18. Third, Astra argued the '154 patent was valid based on *General Foods Corp. v. Studiengesellschaft Kohle mbH*. *Id*. That case also held there was no double patenting simply because a later claimed element was set forth in an earlier claim to the combination. *Id*. at 1018 (citing Appellant Br. 52; 972 F.2d 1272, 1281 (Fed. Cir. 1992)). Finally, Astra argued that the district court erred by failing to analyze badges of distinctness between the reference claim and challenged claim. *Id*. at 1019.

The Defendants argued that the '154 patent was invalid because a composition that includes a compound anticipates that compound *per se*. (Appellee Br., 2006 WL 2191699 at *10.)

V. THE CAFC'S ANALYSIS

A. Opinion of the Court.

First, under the obviousness-type double patenting test, the CAFC construed the claims and compared their differences. The CAFC construed claim 8 of the reference '318 patent as:

> an oral pharmaceutical composition that has (i) a core that contains metoprolol succinate (or one of several other drugs), (ii) the core is surrounded by an inner coating that allows a controlled release of metoprolol succinate, and (iii) an outer coating that resists dissolving in the stomach with the goal of releasing metoprolol succinate close to or within the colon.

Id. The CAFC construed claim 1 of the '154 patent as simply claiming the compound metoprolol succinate itself. *Id*. Analyzing the differences, the CAFC determined that reference claim 8 "is directed to certain pharmaceutical compositions containing metoprolol succinate" and that challenged claim 1 "broadly claims any pharmaceutical composition containing metoprolol succinate." *Id*.

Previously the CAFC has held that a claim for an element was an obvious variation of a claim for a combination including that element. *In re Emert*, 124 F.3d 1458, 1463 (Fed. Cir. 1997). In that case, the challenged claim was for an

oil dispersant comprising B, while the reference claim was for an oil dispersant comprising A and B. *Id*. In *Metoprolol Succinate* the CAFC stated that *Emert* dictated that it affirm the district court's holding that claim 1 of the '154 was an obvious variation of claim 8 of the '318. *Id*. In support of its reliance on *Emert* the CAFC cited *KSR v. Teleflex* for the proposition that "the omission of the known elements from a composition is 'the product not of innovation but of ordinary skill and common sense.'" *Id*. (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007)). The CAFC concluded that a claim for a compound is invalid for double patenting over an earlier patent claiming a specific composition comprising that compound.

B. Dissenting Opinion.

The dissent agreed with the majority's interpretation and comparison of claims, however disagreed that '154 patent was invalid. The dissent argued that the '154 patent was valid in view of *General Foods* which it interpreted as standing for the principle that there is no double patenting simply because a later claimed element is set forth in an earlier claim to a combination. *Id*. at 1023. The dissent interpreted *General Foods* as comparing a claim for A to a reference claim for ABC. Based on *General Foods* and the apparent factual similarities with *Metoprolol Succinate* the dissent argued that the patent claim to compound A (metoprolol succinate) was patentably distinct from the earlier claim to composition A-B-C (metoprolol succinate-inner coating-outer coating.) *Id*.

The majority held that *General Foods* was distinguished from *Metoprolol Succinate* on the basis of the claimed subject matter. Unlike the dissent, the majority held that the reference claim in *General Foods* did not include all of the elements of the challenged claim, and therefore was patentably distinct. *Id*. For example, the dissent interpreted *General Food* as comparing ABC to A, while the majority interpreted that case as comparing ABC to AD. As a result of the D element in the challenged claim the CAFC held that *General Foods* did not preclude a finding that a claim on a compound A cannot be an obvious variant of an earlier composition comprised of ABC. *Id*. at 1019. The CAFC further explained that to adopt the dissent's position would completely "eviscerate obviousness-type double patenting, thereby reducing invalidity based on double patenting to the § 101 statutory prohibition against claims of the same invention." *Id*.

C. Majority's Response to Astra's Arguments.

In response to Astra's element/combination argument, the CAFC, citing *Emert*, stated that reliance on semantic argument did not overcome the determination of double patenting because the critical inquiry remained whether claim 1 defined an obvious variation of claim 8 of the '318 patent. *In re Metoprolol Succinate*, 494 F.3d at 1017. The CAFC held that claim 1 was an obvious variation of claim 8 regardless of whether the claims were labeled species/genus or element/combination. *Id*.

Next, the CAFC held that the line of CCPA cases cited by Astra did not bind the court because they were overruled by a latter CCPA decision. *Id*. (noting that CCPA precedent is not binding when it conflicts with later CCPA precedent because the CCPA always sat *in banc*). The CAFC cited a later CCPA decision that had overturned the previous CCPA decisions cited by Astra. *Id*. (holding that *In re Schneller*, 397 F.2d 350 (C.C.P.A. 1968) overturned the previous CCPA line of cases cited by Astra).

Finally, the CAFC distinguished Astra's 'badges of distinctness' argument by noting that the authority cited by Astra dealt with "same invention" double patenting and was issued prior to the CCPA's development of obviousness-type double patenting. *Id*. at 1019. Moreover, the court noted that Astra failed to cite any case law that supported its "badges of distinction" argument. *Id*.

VI. CONCLUSION

In *Metoprolol Succinate* the CAFC held that a claim for a compound is invalid for obviousness-type double patenting over an earlier claim for a specific composition including that compound. The decision further distinguished the CAFC's previous holding in *General Foods* based on the differences between the claims.