UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE METOPROLOL SUCCINATE PATENT LITIGATION	))	MDL DOCKET NO. 1620 ALL CASES

MEMORANDUM AND ORDER

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (collectively Astra) own patents claiming the pharmaceutically active compound metoprolol succinate and "sustained release" forms of that drug.[1] Defendants are drug makers seeking approval from the Federal Drug Administration to market extended release dosages of metoprolol succinate. Astra filed multiple lawsuits seeking declaratory judgments that Defendants' products infringe upon Astra's patents. Defendants have moved for summary judgment contending Astra's patents are invalid and/or are unenforceable. Because I find that the patents are invalid based on double patenting and anticipation I will grant Defendants' motion for summary judgment on those grounds. Because I find that Astra engaged in inequitable conduct during the prosecution of the patents I will also grant Defendants' motion for summary judgment on that ground.

Legal standard

Defendants have moved for summary judgment on Astra's claims. In considering whether to grant summary judgment, a district court examines the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any ...." Fed. R. Civ. P. 56(c). Summary judgment is appropriate if the evidence, viewed in the light most favorable to the nonmoving party, demonstrates that there is no genuine issue as to any material fact and that the

[1] The record before me established that AstraZeneca LP is the owner of the patents in suit. The legal standing of the other two Plaintiffs has never been formally explained by the parties.

moving party is entitled to judgment as a matter of law. Lynn v. Deaconess Medical Center, 160 F.3d 484, 486 (8th Cir. 1998)(citing Fed. R. Civ. P. 56(c)). The party seeking summary judgment bears the initial responsibility of informing the court of the basis of its motion and identifying those portions of the affidavits, pleadings, depositions, answers to interrogatories, and admissions on file which it believes demonstrates the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

When such a motion is made and supported by the movant, the nonmoving party may not rest on his pleadings but must produce sufficient evidence to support the existence of the essential elements of his case on which he bears the burden of proof. Id. at 324. In resisting a properly supported motion for summary judgment, the plaintiff has an affirmative burden to designate specific facts creating a triable controversy. Crossley v. Georgia-Pacific Corp., 355 F.3d 1112, 1113 (8th Cir. 2004).

Patents are presumed to be valid. 35 U.S.C. § 282. Because of this presumption, a patent challenger must prove invalidity of a patent with clear and convincing evidence. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991).

Background

Astra owns patents claiming the pharmaceutically active compound metoprolol succinate and sustained release forms of that drug.

Metoprolol succinate is an active chemical compound used in the treatment of angina, hypertension, and congestive heart failure. Metoprolol succinate was invented at Plaintiff Aktiebolaget Hassle's facilities in Sweden. Astra manufactures and markets different dosages of

metoprolol succinate in "extended release"[2] forms under the brand name Toprol-XL®. Astra holds two United States patents that claim "sustained release" formulations of metoprolol succinate and metoprolol succinate itself. These patents are United States Patent 5,001,161 (the '161 patent) and United States Patent 5,081,154 (the '154 patent) respectively. Astra asserts that its Toprol-XL® products are protected from infringement by these two patents.

Defendants KV Pharmaceutical Company (KV), Andrx Pharmaceuticals, LLC and Andrx Corporation (Andrx), and Eon Labs, Inc. (Eon)[3] are pharmaceutical companies who seek to market their own extended release dosages of metoprolol succinate. KV, Andrx, and Eon separately filed Abbreviated New Drug Applications (an ANDA) with the United States Food & Drug Administration (the FDA) seeking approval of their extended release metoprolol succinate formulations as the first step to placing these drugs on the market.[4] In their respective ANDAs, Defendants asserted that their extended release metoprolol succinate formulations have the bioequivalence of Astra's Toprol-XL®. Astra claims that Defendants' metoprolol succinate drugs are merely generic versions of Toprol-XL® and infringe upon Astra's '161 and '154 patents.

The Federal Food, Drug and Cosmetic Act, codified in pertinent part at 21 U.S.C. § 355 and 35 U.S.C. § 271, (Hatch-Waxman Act), creates a safe harbor from claims of patent

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[2] Astra refers to its Toprol-XL® as an "extended release" drug in its Complaints against Defendants and in various documents that are part of the record in this case including its memorandum of law in support of its motion to dismiss Defendant KV Pharmaceutical's counterclaims (E.D. Mo. Cause No. 4:03CV592, Doc. # 31).

[3] KV, Andrx, and Eon are collectively referred to as "Defendants".

[4] Defendants KV Pharmaceutical, Andrx, and Eon each seek to market 25, 50, 100, and 200 mg strengths of their respective metoprolol succinate formulations.

infringement for certain activities directed to preparing an ANDA. However, the filing of an ANDA seeking FDA approval to enter the market with a generic drug before the expiration of patents claiming the drug or its use is considered an act of infringement. 21 U.S.C. § 271(e)(2). In such a circumstance the owner of the patent is authorized to bring suit for injunctive relief to prevent the commercial manufacture, use, offer to sell, or sale of the generic drug within the United States. 21 U.S.C. § 271(e)(4).

Because Defendants seek to market their extended release metoprolol succinate drugs before the expiration of Astra's '161 and '154 patents, Astra filed the present lawsuits seeking declaratory judgments of infringement.[5] Defendants have countered that their products do not infringe on Astra's patents and, in the alternative, that Astra's patents are invalid based on double patenting and inequitable conduct.

Specifically, Defendants assert that Astra's '161 and '154 patents are invalid for double patenting over earlier issued patents United States Patent 4,780,318 (the '318 patent) and United States Patent 4,957,745 (the '745 patent); and that the '154 patent is invalid for double patenting over the '161 patent. Defendants also argue that the '161 is invalid as anticipated by prior art under 35 U.S.C. § 102(b).

Additionally, Defendants assert that patents '161 and '154 are unenforceable based on inequitable conduct by Astra during their prosecution of the patents before the United States Patent and Trademark Office (USPTO). Defendants allege that named inventors of metoprolol

[5] Astra brought suit against Defendant KV Pharmaceutical in this Court. Astra's suits against Defendants Andrx and Eon were filed in the United States District Court for the District of Delaware. These lawsuits were transferred to this Court by the United States Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.

succinate were intentionally misrepresented to the USPTO. Alternatively, Defendants assert that the three-year dispute between Astra and another drug company concerning inventorship of metoprolol succinate should have been disclosed to the USPTO.

Discussion

Invalidity based on double patenting

Defendants assert that Astra's '161 patent and '154 patents are invalid for obviousness-type double patenting. Obviousness-type double patenting, also referred to as nonstatutory double patenting (as distinguished from statutory double patenting under 35 U.S.C. § 101), is a judicially created doctrine that prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003). This doctrine prevents patent applicants from extending their patent term for an invention beyond the statutory limits by claiming a mere obvious variant of the claims in a prior patent. In re Emert, 124 F.3d 1458, 1460 (Fed. Cir. 1997).

The public policy behind this doctrine is to allow the public to freely use a patent upon its expiration. In re Longi, 759 F.2d 887, 892 (Fed. Cir. 1985)(citing In re Zickendraht, 319 F.2d 225, 232 (C.C.P.A. 1963)(Rich, J. concurring)). Not only should the invention claimed in the patent be available to the public upon its expiration "but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made ...." Id.

In deciding whether a challenged patent is invalid for obviousness-type double patenting, a court must determine whether the claims of the challenged patent define an obvious variation of the claim in an earlier issued patent. In re Emert, 124 F.3d at 1461; General Foods Corp. v.

Studiengesellschaft Kohle, 972 F.2d 1272, 1280 (Fed. Cir. 1992)(double patenting principles extend to merely obvious variants of what has been patented). In order to compare claims of patents a court must construe what the claims are in each patent.

Claim construction

Defendants assert that Plaintiff's '161 patent and'154 patent are invalid based on double patenting of claim 8 of the '318 patent. Defendants originally stated that they would apply Astra's construction of the '161 patent for purposes of their invalidity motion. That was before Defendants learned how Astra construed the term "sustained release" in the claim of that patent. The meaning of the term "sustained release" is disputed by the parties as is the construction of claim 8 of the '318 patent.

The United States Court of Appeals for the Federal Circuit has recently summarized and clarified the claim construction process in its decision in Philips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005).[6] The "claims of a patent define the invention to which a patentee is entitled to the right to exclude." Id. at 1312. The claims are of primary importance in the effort to ascertain what it is that has been patented. Id. The words of a claim are generally given their ordinary and customary meaning. Id. The meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application. Id. at 1313. Importantly, the person of ordinary skill in the art is deemed to have read the claim term in the context of the claim as well as in the context of the entire patent, including the specification. Id.

To determine the meaning of a term in a field of art, a court "looks to those sources

[6] I have excluded all internal quotations and citations in my citations to Phillips.

available to the pubic that show what a person of skill in the art would have understood the disputed claim language to mean." Id. at 1314. Those sources include intrinsic evidence, which encompasses the words of the claims themselves, the specification, and the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. Id.

Claims "must be read in view of the specification, of which they are a part." Id. at 1315. The specification is the single best guide to the meaning of a disputed term. Id. It is entirely appropriate for a court, in the course of claim construction, to rely heavily on the written description in the specification for guidance as to the meaning of the claims. Id. at 1317.

Although a court may refer to extrinsic evidence in the form of expert and inventor testimony, dictionaries, and learned treatises, these sources are less significant than the intrinsic record in determining the legally operative meaning of claim language. Id. Conclusory or unsupported assertions by experts as to the definition of a claim term are not useful to a court performing a claim construction. A court should discount an expert's testimony regarding the meaning of a claim term if it is clearly at odds with the claim construction mandated by the intrinsic evidence of the claims themselves, the specification, and the prosecution history. Id. at 1318.

Defendants assert that claim 8 of the '318 patent is a specific extended release formulation of metoprolol succinate. They argue that the claim in the '161 patent for "sustained release" formulations of metoprolol succinate is merely an obvious variant of claim 8. The claim of the '154 patent simply claims the compound metoprolol succinate. Defendants contend that the claims in the '161 and '154 patents are a genus of the species identified in claim 8 of the '318

patent and are therefore void for double patenting.

To determine whether the '161 and the '154 patents are invalid for double patenting over claim 8 of the '318 patent, the inventions claimed in each patent must first be construed. Because Defendants initially represented that the claim of the '161 patent was not in dispute a formal claims construction hearing was not held. As the positions of the parties crystalized during the summary judgment briefing it became clear that the parties did not agree to the construction of the term "sustained release" used in the '161 patent. The parties were clearly aware of this dispute and fully briefed and presented evidence in support of their construction of that term in their cross motions for summary judgment. I held a summary judgment hearing at which the parties presented intrinsic and extrinsic evidence in support of their construction of the claims in the '161, '154, and '318 patents. As a consequence, the parties placed into the record both intrinsic and extrinsic evidence in support of their claim construction positions.

The '318 patent

This patent concerns a drug formulation that allows the delivery of active drugs to the small intestine. Claim 8 of this patent includes a delivery formulation for metoprolol succinate. The "Abstract" of the '318 patent states that "[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct ...."

Under the heading "Background Of The Invention" the patent states that

> [t]here exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect in the lower part of the

gastrointestinal tract.

Under the heading "Object Of The Invention" the patent states that

> [i]t has now surprisingly been shown possible to be able to solve the aforesaid problem by the present invention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and or which inner layer there is provided a second layer of at least one anionic polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

In the "Detailed Description Of The Invention" section the patent states that

> [b]y means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution upon passage of the composition into the small intestine with its higher pH, ***a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane***. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant, pH-independent way, and thereby in a very reproducible way. (emphasis added)

Defendants argue that the '161 patent and the '154 patent are invalid for double patenting over claim 8 of the '318 patent. Because claim 8 depends from claim 7, which depends from claim 6, the starting point for claim construction is claim 6. Claim 6 is directed to oral controlled release pharmaceutical compositions with a core of the active drug, surrounded by a coating that is a diffusion membrane, and a second coating that resists dissolving in the pH of the stomach. It also specifies the materials used in each coating. Claim 6, 7 and 8 are as follows:

6. Oral pharmaceutical composition having an improved release therefrom of a

> therapeutically active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers of the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.
>
> 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range 1 to 8 which exceeds 0.5 to 1 g per 100 ml.
>
> 8. Pharmaceutical composition according to claim 7, wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or furosemide, 5-aminosalicylic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8.

Distilled to its essence, and pertinent to this lawsuit, claim 8 is directed to 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 the metoprolol succinate close to or within the colon.

The meaning of the term "improved release" in claim 6 can be interpreted from the specification which states that the goal of the invention is to release the active drug as close to the colon as possible. The specification also states that the diffuse membrane surrounding the core of metoprolol succinate acts to allow a "slow but controlled release" of the drug. Claim 8 patents a particular type of formulation to allow the slow and controlled release of metoprolol succinate in or near the colon.

The '161 patent

The '161 patent "Abstract" states that "[t]he present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."

Under the patent heading "Technical Field" the patent states that "[t]he object of the present invention is to obtain a therapeutically active compound *intended to be released close to or within the colon*, and particularly to such active compounds which are soluble in the pH range 1 to 8" (emphasis added).

Under the heading "Description of the Present Invention" the patent states that

> "[t]his compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and15 to 90% by weight of a water insoluble polymer selected from the group of quaternary ammonium substituted acrylic polymers.
>
> ...
>
> When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered.
>
> When administering, in order to achieve a steady blood plasma level of the therapeutically active compound, a split dose unit of the therapeutically active compound provided with a coating *according to the present invention can be administered together with some particles/granules which are not coated.* (emphasis added)

The sole claim of the '161 patent is "[a][7]sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier."

For the purposes of their motion for summary judgment based on invalidity, Defendants agreed to the revised wording of the sole claim of the '161 patent.[8] Astra broadly construes the definitions of the terms used in this claim. Defendants disagree with Astra's definition of the term "sustained release." Astra contends that sustained release means dosage forms which, "upon ingestion, released active to achieve desired blood plasma levels and maintained relatively steady blood plasma levels for an extended period of time." (Pls.' Memo. in Opp. at 23.) Defendants assert that the term sustained release, as used in the mid 1980s by a person of ordinary skill in the art when this patent application was filed, was deemed interchangeable with the terms "extended release" and "controlled release."

The term "sustained release" does not appear in the specification of the '161 patent. The invention described by the specification is a core of "active," metoprolol succinate, coated by an anionic polymer with the goal of releasing metoprolol succinate close to or within the colon. The specification also states that uncoated particles/granules of metoprolol succinate may be combined with metoprolol succinate "provided with a coating according to the ***present invention***" (emphasis added) to achieve a steady blood plasma level of metoprolol succinate. This last specification clearly regards the invention as the coated metoprolol succinate. It does not state that the

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[7] The term "sustained release" was recently repositioned in the "claim" section of the '161 patent by the USPTO. The USPTO amended the patent to have the term follow the initial "a" in this claim sentence from following the second "a" as originally filed. The amendment was made at Astra's request.

[8] The USPTO had not yet approved Astra's request to change the location in the claim of the term sustained release when the briefing of this motion was filed.

invention is the coated metoprolol succinate combined with uncoated metoprolol succinate to achieve a steady blood plasma level. Astra contends that the invention claimed in the '161 patent is this latter construction which Astra labels "sustained release."

In support of its construction of the term "sustained release," Astra offers the affidavit of its expert Gerald S. Brenner. In paragraph 35 of his affidavit, Brenner states that one skilled in the art in the mid 1980s would "generally have considered a sustained release dosage form one that initially (upon ingestion) releases active to achieve desired blood plasma levels and maintains relatively steady blood plasma levels of the active for an extended period of time." (Pls.' Opp'n Summ. J. Ex. A) In support of this statement Brenner's affidavit refers to three documents without identifying them or vouching for their use by experts in his field as reference tools. The three documents are excerpts from what appear to be pharmaceutical texts. I presume that these are treatises used in the field of pharmacology.

The first excerpt is from Robert E. Notari, Biopharmaceuticals and Clinical Pharmacokinetics, An Introduction (Marcel Dekker, Inc., 3rd ed. 1980). Notari discusses the term sustained release and states that

> "[g]eneral terms such as timed release, time release, extended action, or long-acting may or may not be meant to indicate that the formulation is a sustained release preparation. Unfortunately, there are no standard definitions or classifications. The following distinction will be used as a starting point, and later more precise terminology and definitions will be given to sustained release dosage forms."

Id. at 152. Notari then goes on to define the meaning of the terms "repeat- action tablets," "sustained release dosage forms," and "prolonged-action preparations." He defines sustained action dosage forms as providing an "initial therapeutic dose that is available upon administration

of the product followed by a gradual release of medication over a prolonged period of time." Id. He states that prolonged-action preparations provide the slow release of a drug and may differ from sustained release dosage only in that no initial dose in included in the prolonged-action formulation. Id.

Although Notari's definition of sustained release at first blush appears to support Astra's definition, Notari specifically notes that there were no standard definitions or classifications of dosage terms including sustained release. Rather, Notari's article was his attempt to create definitions that would presumably be adopted at some time in the future by a person skilled in the art. As a result, Notari's text does not support Astra's contention that sustained release had a specific meaning to one skilled in the art as of the effective date of the patent application. Instead, Notari's article establishes the opposite position; that in the mid 1980s there was no consistent interpretation of the term sustained release.

The second document relied on by Brenner is equivocal in supporting his definition of sustained release. That excerpt is from Howard C. Ansel, Introduction to Pharmaceutical Dosage Forms, (Lea & Febiger 1969). Ansel states that

> [s]ome solid dosage forms are designed to release their medication to the body for absorption rapidly and completely; other products may be designed to release the drug slowly for more prolonged drug release and sustained drug action. The latter type of dosage form is commonly referred to by a designation such as a ***sustained-action, prolonged-action, sustained-release, prolonged-release, timed-release, extended-action,*** or ***extended-release*** tablet or capsule.

Id. at 274. Ansel then states that "most" sustained-action dosages are designed so that a single dosage provides the "immediate release of an amount of the drug that promptly produces the desired therapeutic effect and gradual and continual release of other amounts of drug to maintain

this level of effect over an extended period...." Id. Ansel uses the term "most" which indicates that his definition is not universal to all sustained-action dosages. As quoted above, Ansel notes the term sustained release was also referred to as extended release, timed release, extended action among other terms. These terms interchangeably referred to dosages, which Notari highlighted in his treatise published ten years after Ansel's, that may not be an indication of sustained release as defined by Ansel because there were still no standard definitions of any of these terms in 1980.

Finally, the third treatise Brenner relies on for his definition of sustained release is Remington's Pharmaceutical Sciences (Mack Pub. Co., Arthur Osol ed. 1980). That treatise states that long-acting oral products have been described by a variety of terms. Id. at 1596. The treatise then proposes classifying long-acting products into the following three types: sustained release, prolonged release, and repeat action. Id. This treatise does not state that sustained release is defined similarly by those skilled in the art. To the contrary, it offers a definition that may be adopted at some time in the future by those skilled in the art.

The three treatises relied on by Astra and its expert Brenner are consistent only in that none of the treatises state that sustained release had a uniform definition used by those skilled in the art in the mid 1980s. At best these treatises offer definitions which may or may not have been uniformly adopted. What is clear is that sustained, extended, or timed release dosages were deemed to be dosages that released more slowly over time than immediate release dosages.

The prosecution history of the '161 patent also demonstrates that Astra's own definition of sustained release was not consistently maintained during the prosecution of the patent. As previously noted, the term sustained release does not appear in the specification of the patent. When originally filed, the claims of the patent were directed to metoprolol succinate and a

"pharmaceutical composition, characterized in that the active compound is metoprolol succinate." (Defs.' Ex. Q at 145) The USPTO examiner rejected these claims as obvious over prior art. Id. at 167-169. Hassle (Astra) responded to the rejection with a declaration of Dr. John Anders Sandberg. Hassle represented that Sandberg's declaration showed that metoprolol succinate was "useful as a sustained release form of metoprolol." Id. at 174. Sandberg's declaration interchangeably used the terms extended release, sustained release, and controlled release in supporting the selection of metoprolol succinate. Id. at 181, 184, and 189. The examiner agreed to issue the '161 patent if the term sustained release was inserted into the claim. In his deposition for this case, Sandberg stated that he thought that controlled release, sustained release, and extended release dosages were essentially the same. (Defs.' Ex. V at 413) One of the named inventors of the '161 and '154 patents, Curt Appelgren, stated in his deposition that in 1983 the terms controlled release, extended release, and sustained release were use interchangeably. The other named inventor of the "161 and '154 patents, Eva Christina Eskilsson, stated in her deposition that sustained release could be the same as extended release, which could be a dosage form completely releasing an active drug from "one to many hours." (Defs.' Ex. T at 345)

Defendants have placed more treatises and articles into the record that state that sustained release, prolonged action, controlled release, extended action, and time release were all used interchangeably to describe preparations that release a drug over an extended period of time. (Defs.' Exs. AB, AC, and AD)

Astra itself uses the term "extended release" in their Complaints and various pleadings when they describe their drug Toprol-XL® which is the subject of this infringement action.

Based on the lack of a definition of sustained release in the '161 patent, the specification's

statement that the "object of the present invention is to obtain a therapeutically active compound *intended to be released close to or within the colon*" and the extrinsic evidence offered by the parties, I conclude that sustained release simply refers to a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon. Astra's definition requiring an immediate release is not supported by the specification. Astra's extrinsic evidence in the form of Brenner's affidavit "is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" and is discounted. Phillips, 425 F.3d 1318. In addition, Brenner's definition is not even supported by the treatises he relies on in support of his position.

The specification itself states that if a steady blood plasma level of the therapeutically active compound is desired, an optional formulation of uncoated metoprolol succinate can be combined with metoprolol succinate with a coating *according to the present invention*. That statement, read in context of the entire patent, indicates that the invention of the '161 patent is a coated forms of metoprolol succinate that provides for a controlled or extended release of the drug; it is not a pharmaceutical composition that includes an immediate release of metoprolol succinate as Astra would define the term sustained release.

The '154 patent

The only claim in the '154 patent is "metoprolol succinate." The invention is the composition itself.

Comparing the claims

Claim 8 of the '318 patent is directed to a specific type of controlled release formulation

of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon).

The claim of the '161 patent is directed to coated forms of metoprolol succinate that are designed to have a controlled release of the metoprolol succinate (the active) near or in the colon. The claim does not limit the method or structure by which controlled release is achieved. It is broadly directed to formulations that would provide a controlled release of metoprolol succinate near or in the colon.

Defendants argue that claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the '161 patent is a broad claim to any controlled release formulations of metoprolol succinate. Defendants assert that the relationship between the claim 8 of the '318 patent and the claim of the '161 patent is that of "species and genus," that is, the former discloses a specific embodiment within the latter's general scope.

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 patently distinct from, an earlier species claim. See In re Goodman, 11 F.3d 1046, 1053 (Fed. Cir. 1993); Eli Lilly & Co. v. Barr Labs, Inc., 251 F.3d 955, 971 (Fed. Cir. 2001); Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC, 349 F.3d 1373, 1383 (Fed. Cir. 2003).

Astra asserts that the relationship between claim 8 of the '318 patent and the claims of the '161 patent and the '154 patent should be viewed as that of combination/element which does not implicate the doctrine of double patenting. See In re Allen, 343 F.2d 482, 486 (C.C.P.A. 1965); In re Heinle, 342 F.2d 1001 (C.C.P.A. 1965). Astra contends that the claims of the '161 patent

and the ‘154 patent are independent elements of the combination claim of claim 8 of the ‘318 patent. Astra argues that metoprolol succinate was not a necessary element to the combination claim 8 of the ‘318 patent and that metoprolol succinate has utility by itself or in other combinations. As a result, Astra argues, its claims concerning metoprolol succinate cannot be invalidated for double patenting.

However, “‘[i]n situations in which an element or subcombination issues after the combination, the matter should be analyzed as one of a generic claim issuing after a later filed specific or improvement claim.’” In re Emert, 124 F.3d 1458, 1462 (Fed. Cir. 1997)(quoting 3 Donald S. Chisum, Chisum on Patents § 9.03[2][b][iii]).

That is the situation in the present case. Even if the ‘161 claim and the ‘154 claims are classified as elements, they issued after the combination claim of claim 8 of the ‘318 patent issued. It is therefore appropriate to analyze these claims as a species/genus relationship. I find that claim 8 of the ‘318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the ‘161 patent is a broad generalized claim to controlled release formulations of metoprolol succinate. Because the earlier issued claim 8 of the ‘318 patent is a species of the later issued genus claim of the ‘161 patent, the ‘161 claim is invalid for obviousness type double patenting.

The sole claim of the ‘154 patent is “metoprolol succinate.” Such a claim encompasses any formulation that uses this chemical composition without limitation. Claim 8 of the ‘318 patent is directed to certain pharmaceutical compositions containing metoprolol succinate. The ‘154 patent broadly claims any pharmaceutical compositions containing metoprolol succinate. The relationship between these claims is that of species/genus. The ‘154 patent is a genus of the

species claimed in the ‘318 patent. Consequently, the claim of the ‘154 patent is anticipated by claim 8 of the ‘318 patent and is void for double patenting because it is not patently distinct form claim 8 of the ‘318 patent.

If the ‘161 and ‘154 patents were valid, they would prevent the public from using the earlier issued invention of claim 8 of the ‘318 patent upon its expiration because they completely encompass claim 8 as to metoprolol succinate. Such a result would defeat the public policy behind the double patenting doctrine which is to allow the public to freely use a patent upon its expiration.

As a result, I find by clear and convincing evidence that the ‘161 patent and the ‘154 patent are invalid on the basis of double patenting over claim 8 of the ‘318 patent.

Terminal disclaimers

Defendants also asserted that the ‘161 and ‘154 patents are invalid for double patenting over earlier issued patent United States Patent 4,957,745 (the ‘745 patent); and that the ‘154 patent is invalid for double patenting over the ‘161 patent.

Claim 7 of the ‘745 patent is another controlled release formulation of metoprolol succinate. It claims a formulation of metoprolol succinate wherein the metoprolol is released through a coating over a period of at least fifteen hours. Base on the same analysis applied to claim 8 of the ‘318 patent, I find that claim 7 of the ‘745 patent is a species of the later filed genus in the claims of the ‘161 and ‘154 patents. The claim of the ‘161 patent and ‘154 patent would be invalid for double patenting over claim 7 of the ‘745 patent if not for the question of terminal disclaimers.

By the same analysis the claim of the ‘154 patent would also be invalid for double

patenting over the ‘161 patent.

However, Astra filed terminal disclaimers under 35 U.S.C. § 253 as to the ‘161 patent and the ‘154 so that they expire at the same time that the ‘745 patent expires.[9] Astra contends that these terminal disclaimers cure any double patenting issues that may have arose between the ‘154 patent and the ‘161 patent and those two patents and the ‘745 patent.

Defendants argue that the terminal disclaimers should have been made while the ‘161 and ‘154 patents were being prosecuted. Defendants assert that Astra’s disclaimers, filed years after the patents have issued, are ineffective based on public policy. Defendants contend that a listing of pharmaceutical patents and their expiration dates in the Orange Book[10] deters others from competing with the patent holder on those patents. Defendants assert that allowing a patent holder to avoid a double patenting litigation by filing a terminal disclaimer years after a patent was issued gives the patentee an unfair advantage by suppressing competition.

The terminal disclaimer statute doe not set a time limit to file a disclaimer. The language of the statute clearly contemplates that a disclaimer can be filed by a patentee regarding a patent that has already issued. 35 U.S.C. § 253 (“patentee ... may disclaim ... the entire term, or any terminal part of the term, of the patent granted....”). The United States Court of Appeals for the Federal Circuit has recently confirmed that a terminal disclaimer may be filed after a patent is issued. Perricone v. Medicis Pharmaceutical Corp., 2005 WL 3468126, at *5 (Fed. Cir. December 20, 2005). The Perricone opinion also states that a “terminal disclaimer can indeed

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[9] Defendants state that the expiration date of the ‘745 patent is September 18, 2007.

[10] The United States Food & Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, commonly referred to as "the Orange Book," is a register that provides notice of patents covering name brand drugs.

supplant a finding of invalidity for double patenting." Id. The opinion strongly infers that a terminal disclaimer filed years after a judicial finding of invalidity can reinstate the validity of the patent. Id. The court in Perricone did not raise concerns that equity or public policy should prevent terminal disclaimers from being effective if filed years after a patent has issued.

Based on the language of the terminal disclaimer statute and the opinion in Perricone, I find that Astra's terminal disclaimers of the '161 patent and the '154 patent effectively avoids a finding of double patenting of those patents over the '745 patent and the '154 patent over the '161 patent.

The '161 patent not entitled to priority and is therefore invalid as anticipated

Defendants also argue that the '161 invalid as anticipated by prior art under 35 U.S.C. § 102(b). Defendants contend that the '161 patent was not entitled to priority to the '318 patent application. Through the use of priority, its possible for a patentee to avoid the consequences of any prior art which existed before his present patent application was filed. That is because a priority entitles the patentee to adopt the earlier filing date of a related patent application.

The '161 patent issued from a continuation-in-part patent application filed in March 1988. The application claimed priority to the United States application for the '318 patent which was filed on January 10, 1985 (the '318 patent application in turn claimed priority to the Swedish patent application (SE 8400085) filed on January 10, 1984). If the '161 patent is not entitled to priority to the '318 patent application, its effective filing date would be March 1988. Any references with sustained release metoprolol succinate formulations that existed before March 1988 might qualify as prior art that anticipates the '161 patent.

Patent law allows a patent applicant to claim priority to an earlier filed patent application. 35 U.S.C. § 120. For a claim in a later-filed application to be entitled to the filing date of an earlier application under section 120, the earlier application must comply with the written description requirement of paragraph one of 35 U.S.C. § 112. Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998).

Paragraph 1 of section 112 requires that the specification "contain a written description of the invention, and of the manner and process of making and using it ." To meet this requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed." Id. (citations omitted.) A disclosure in a parent application that "merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations." Id. (citation omitted).

As previously discussed, the '318 patent is directed to, in pertinent part, a specific type of controlled release formulation of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two specified coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon). The specification of the '318 patent is limited to this dual-coating system. The specification does not describe other systems for the sustained release of metoprolol succinate.

The '161 patent broadly claims sustained release formulations of metoprolol succinate with little, if any, limitation. The specification of the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161

patent at the time the ‘318 application was filed. To be entitled to a priority the disclosure in the ‘318 patent must describe the ‘161 patent invention with all its limitations. The ‘318 patent does not contain this information.

Because the specification of the ‘318 patent does not meet the written description requirement of invention of the ‘161 patent, the ‘161 patent is not entitled to priority to the ‘318 patent. As a result, the effective filing date of the ‘161 patent is March 25, 1988.

Swedish patent application SE 8400085 is the parent of the ‘318 patent and the grandparent of the ‘161 patent. The Swedish application published on July 17, 1985. The Swedish application discloses, among other things, the species of sustained release metoprolol succinate that becomes claim 8 of the ‘318 patent. The disclosure of the species in Swedish patent anticipates the genus of sustained release metoprolol succinate which is the invention of the ‘161 patent. Because the species in the Swedish patent application was published (July 1985) more than one year before the ‘161 patent application was filed (March 1988), the ‘161 patent is invalid under 35 U.S.C. § 102 (b) (a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States).

Similarly, as already discussed, the ‘745 patent and the ‘161 patent have a species/genus relationship. The ‘745 patent was filed in September 1986. An issued United States patent qualifies as prior art as of its filing date. 35 U.S.C. § 102(e). Because the ‘745 patent application was filed more than one year before the ‘161 patent application, the ‘745 patent is prior art which anticipates the ‘161 patent and renders it invalid.

As a result, I find by clear and convincing evidence that the ‘161 patent is not entitled to

priority to the ‘318 patent and that the ‘161 patent is invalid as anticipated by the publication of the Swedish patent application and the filing of the ‘745 patent application.

Unenforceablility based on inequitable conduct

For more that three years, from October 1985 through the late fall of 1988, Astra and a competitor named Lejus Medical contested the issue of who invented metoprolol succinate. This dispute was uncovered during discovery in this lawsuit. Astra never revealed its inventorship dispute with Lejus to the USPTO during the prosecution of the patents in suit. Astra’s failure to disclose this long-running inventorship dispute is one basis for Defendants’ motion for summary judgment for inequitable conduct.

Defendants also assert that Astra intentionally did not name the correct inventors in Astra’s prosecution of the patents in suit. Curt Appelgren and Eva Eskilsson are the two named inventors of the ‘161 patent and the ‘154 patent. Defendants assert that Appelgren and Eskilsson are not the inventors of the patents in suit and that listing them as the named inventors on the patent applications was a material misrepresentation to the USPTO.

Defendants contend that Astra’s naming the wrong inventors on the patents and Astra’s failure to disclose to the USPTO the inventorship dispute each independently constitute an act of inequitable conduct which render the patents in suit unenforceable.

Astra denies these allegations. It asserts that it named the correct inventors of the ‘161 and the ‘154 patents. Astra also contends that, through its United States patent counsel, it fully satisfied its duties of candor and disclosure to the USPTO during the prosecution of these patents.

Standard regarding inequitable conduct

“Inequitable conduct includes affirmative misrepresentations of a material fact, failure to

disclose material information, or submission of false material information, coupled with an intent to deceive." PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1318 (Fed. Cir. 2000)(citation omitted). Because the defense of inequitable conduct is entirely equitable in nature, it is an issue for the court and not a jury to decide. Id.

To determine whether inequitable conduct exists requires the trial court to determine whether the conduct meets a threshold level of materiality and whether the evidence shows a threshold level of intent to mislead the USPTO. Id. at 1318-19. Materiality and intent must be established with clear and convincing evidence. Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1234 (Fed. Cir. 2005). Once threshold levels are established, the trial court is required to weigh materiality and intent. PerSeptive Biosystems, Inc., 225 F.3d 1319. "The more material the conduct, the less evidence of intent will be required in order to find that inequitable conduct has occurred." Id. (citation omitted). In "the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." Bruno Indep. Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F. 3d 1348, 1354 (Fed. Cir. 2005). After weighing materiality and intent, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable. PerSeptive Biosystems, Inc., 225 F.3d 1319. Defendants assert that Astra engaged in inequitable conduct towards the USPTO by (1) misrepresenting the inventors of the '161 patent and the '154 patent, and (2) failing to disclose the inventorship dispute between Astra[11] and it

[11] This dispute was actually between Hassle and Lejus. Hassle is now part of AstraZeneca and I will use the term "Astra" to refer to both Hassle and Astra as the parties have done in their briefs.

competitor Lejus.[12] Defendants argue that this information about inventorship was material to the prosecution of the patents.

Information is material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. Id. at 1322 (quotations and citations omitted). Because it is a critical requirement for obtaining a patent, the issue of inventorship is highly material in the patent prosecution process. Id. at 1321; 35 U.S.C. § 102(f) (A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented.). In turn, conduct that would mislead the USPTO as to the identity of the true inventors of a patent or conduct that fails to disclose information about a dispute concerning inventorship would be highly material to the question of inequitable conduct because of the patentee's duty of candor and disclosure. See 37 C.F.R. § 1.56 ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

Disputes concerning inventorship are material information that need to be disclosed. PerSeptive Biosystems, Inc., 225 F.3d at 1321 (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004). Because conduct concerning inventorship is so highly material, less evidence of intent is required in order to find that inequitable conduct has occurred.

Inventorship of metoprolol succinate

[12] Defendants' allegations of inequitable conduct arose from information uncovered in discovery concerning who originally conceived and synthesized metoprolol succinate and a dispute over inventorship of that compound.

The compound metoprolol was invented in the 1960's by Hassle, at the time, a Swedish pharmaceutical research and development company located in Mölndal, Sweden. Metoprolol was discovered to be very useful in treating heart disease. Astra (Hassle) began work to develop a commercial metoprolol product. Astra investigated various salts of metoprolol to be used in a drug formulation. It is undisputed that in 1971, an Astra chemist named Toivo Nitenberg synthesized metoprolol succinate as well as the tartrate and sulfate salts of metoprolol. Nitenberg recorded the synthesis of these salts in his lab notebook. The tartrate salt was chosen for commercialization and became Astra's product known as Lopressor.

In the 1980's Astra perceived a need for a once-daily dosing formulation of metoprolol. Because this goal could not be effectively achieved with metoprolol tartrate, Astra formed a research group to develop an extended release form of metoprolol. Curt Appelgren and Eva Eskilsson were part of that group.

In 1982, Appelgren and his colleague Ulf Jonsson went to Astra's facility in Södertälje, Sweden and asked chemists there to form some metoprolol salts with a lower solubility than the tartrate for evaluation as an extended release form of metoprolol. They met with Urban Stenhede, a chemist and head of the research department. Jonsson (Astra's Rule 30(b)(6) witness)[13] testified in his deposition that he and Appelgren asked Stenhede to make some salts of metoprolol, other than the tartrate, with lower solubility. Jonsson testified that there was no specific request made to Stenhede to make metoprolol succinate.

In Appelgren's deposition, when asked about his and Jonsson's meeting with Stenhede,

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[13] A Rule 30(b)(6) witness must be able to gives binding answers on a corporation's behalf. Reilly v. Natwest Markets Group Inc., 181 F.3d 253, 268 (2nd Cir. 1999).

Appelgren could not recall specific details of the meeting. He did not testify that he gave Stenhede a list of salts to make, including metoprolol succinate. But in his later filed declaration submitted in opposition to summary judgment on the issue of inequitable conduct, dated ten months after his deposition, Appelgren states that he did give Stenhede a list of salts to make that included metoprolol succinate. No such list was produced in discovery.

Stenhede, in turn asked chemist Lars Lilljequist to form salts of metoprolol with a lower solubility than the tartrate salt. Lilljequist is the person who actually synthesized metoprolol succinate. In his deposition, Lilljequist did not recall who suggested which salts of metoprolol to form nor could he recall if he was given a list of salts to make. Yet he clearly testified that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). (Def. Andrx's Memo in Reply Ex. 3 at 87) But in his later filed declaration submitted in opposition to summary judgment, dated seven months after his deposition, Lilljequist states that he received a list of salts to make that included metoprolol succinate.

In their depositions, both Appelgren and Eskilsson testified that they were unaware that Nitenberg had formed metoprolol succinate at their company in 1971. They testified that they had never seen his lab book entry showing the formation of that salt. In her deposition, Eskilsson states that she did not recall asking anyone to make metoprolol succinate and that she never made metoprolol succinate. She also did not recall why she was a named inventor of metoprolol succinate in United States Patent Application No. 172,897 (the application that became the '161 patent and through a continuation the '154 patent). (Defs. Memo in Supp. Ex. 16 at 496) However, in her later filed declaration submitted in opposition to summary judgment, dated ten

months after her deposition, she asserts that she did invent metoprolol succinate and the basis for that belief.

In December 1982, Appelgren left Astra to found Lejus Medical, a Swedish pharmaceutical research and development company. A few months later Eskilsson also became employed at Lejus.

On January 10, 1984, Lejus filed a patent application (SE 8400085) with the Swedish Patent Office. That application published as EP 148811 on July 17, 1985. The Swedish patent application was for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate. Appelgren and Eskilsson are listed as the named inventors.

On January 1, 1985, the same application was filed in the United States as United States Application No. 690,197 which issued on October 25, 1988, as the '318 patent discussed above. The '318 patent is the parent and grandparent of the patents in suit, the 161 patent and the '154 patent, respectively.

When the Swedish patent application published in July 1985 it was noticed by Astra. Astra believed that metoprolol succinate had been invented by its employee Toivo Nitenberg and that extended release dosage formulations of metoprolol succinate were also Astra's invention. In an internal memorandum dated September 19, 1985, Astra's in-house counsel, Bengt Wurm, stated that it appeared Lejus was trying to appropriate Astra's claim to metoprolol succinate and extended release dosage formulations of metoprolol succinate. Wurm warned that "the important principle is that the use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty reference with respect to later applications that concern preparations containing substances such

as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10) In other words, the publication could constitute potentially invalidating prior art of any subsequent Astra application seeking to patent metoprolol succinate.

On October 21, 1985, Astra filed an action in the Swedish Patent Office to transfer the metoprolol succinate inventions of the Lejus' Swedish application to Astra. Astra's petition, signed by Astra's in house counsel Wurm, asserted that metoprolol succinate had *not* been invented by Appelgren or Eskilsson, but rather it had been invented by an Astra chemist named Toivo Nitenberg. (Defs.' Memo in Supp. Ex. 11) In 1985, Astra's petition at the Swedish Patent Office noted that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." Id. In making this assertion, Wurm relied on information from John Sjogren, the head of the formulation department at Astra. (Defs.' Memo in Supp. Ex. 12)

Wurm advised Astra, however, that seeking transfer of the metoprolol succinate invention under Swedish patent law could be time consuming, expensive, uncertain and of questionable future value because the Lejus publication could be cited as prior art to "later applications that concern preparations containing substances such as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10)

As an alternative to pursing its action in the Swedish Patent Office, Astra attempted to reach an accommodation with Lejus. In the fall of 1985, Astra approached Lejus and asserted that metoprolol succinate (and its pharmaceutical compositions) had not been invented by Appelgren and Eskilsson but had, in fact, been invented by Nitenberg at Astra. Lejus did not dispute Astra's claim. Lejus agreed to file new patent applications on the metoprolol succinate

inventions (to be carved from the 1984 Swedish patent application and each of its foreign counterparts, e.g. the '318 patent application) and then assign these applications to Astra. In exchange Astra agreed to withdraw its ownership claim with the Swedish Patent Office claiming that Toivo Nitenberg was the actual and sole inventor of metoprolol succinate. In April 1986, Astra and Lejus entered a written agreement incorporating these terms.

Prior to the signing of the formal agreement, Lejus had already filed, in January 1986, the required new application in Sweden on the metoprolol succinate inventions (Swedish Patent Application No. 8600202-9).

Wurm was succeeded by Rune Nasman as Astra's in-house attorney. On February 12, 1988, almost two years after Astra and Lejus entered the agreement regarding the metoprolol inventions, Nasman wrote two letters to Lejus' outside patent agent Ulf Inger still asserting that Toivo Nitenberg was the sole inventor of metoprolol succinate. In the first letter, entitled "Metoprolol succinate - divided application in the United States," Nasman reasserts Astra's position that Toivo Nitenberg was **the** inventor of metoprolol succinate ("As we understand it, and as was stated in the objection to the Swedish Patent Office, **the inventor is Toivo Nitenberg**, employed by Hassle.") (emphasis added) (Defs.' Memo in Supp. Ex. 23)

In the second letter of February 12th, entitled "Swedish patent application 8600202-9, AB Hassle," Nasman tells Inger that Toivo Nitenberg should be named as the inventor of metoprolol succinate. He states that Appelgren and Eskilsson can remain as co-inventors with Nitenberg because the application also "pertains to a pharmaceutical composition, and Appelgren and Eskilsson appear to have invented a special form of pharmaceutical composition under this patent claim." (Defs.' Memo in Supp. Ex. 24)

On March 25, 1988, a little over a month after Nasman sent these letters, Lejus filed United States Patent Application No. 172,897 (which became the '161 patent). This application was the United States counterpart to the Swedish Application No. 8600202-9 discussed in Nasman's letters. Like its Swedish counterpart, the United States application claimed: 1) metoprolol succinate and 2) "a pharmaceutical composition, characterized in that the active compound is metoprolol succinate." The named inventors were Appelgren and Eskilsson. The application was filed as a continuation-in-part of United States Patent Application No. 690,197 (which became the '318 patent). By filing the application as a continuation-in-part of the '197 application and naming the same inventors, the '897 application was entitled to priority to the earlier filing date of the '197 application, January 10, 1985. A material benefit of the January 10, 1985, filing date would be to avoid a potential hurdle of prior art revealed in the publication of EP 148811 on July 17, 1985. The issue of a potential prior art problem had been specifically identified by Wurm two and a half years earlier in his September 19, 1985 internal memorandum at Astra.

On May 31, 1988, ***two months after*** the '897 application is filed in the United States, Nasman writes another letter to Inger stating that he looks forward to Lejus' assignment of the European and United States metoprolol succinate patent applications to Astra per their agreement. Nasman again reemphasizes Astra's desire for Nitenberg to be named as the inventor of metoprolol succinate because "***[t]here can be no doubt*** that the invention as specified in claim 1 was made in connection with Toivo Nitenberg's synthesis of the salt." (emphasis added) (Defs. Memo in Supp. Ex. 25.) He further states that Appelgren's and Eskilsson's roles as inventors to claim 2 (a generally specified pharmaceutical composition of metoprolol succinate) "should be

limited to the special form of pharmaceutical composition that is specified in Lejus' original application." Id.

In late 1988, the prosecution of the '897 patent application was transferred from Lejus' United States patent counsel to Astra's United States patent counsel, Edward Filardi. On January 9, 1989, Nasman wrote to Filardi for advice with respect to inventorship, which Nasman described as an "*open question*" with respect to the '897 application. (emphasis added) (Defs. Memo in Supp. Ex. 27) His letter states, in pertinent part, as follows:

> The background, to my knowledge, is that metoprolol [succinate] was first synthesized on September 6, 1971 by the Hassel chemist Toivo Nitenberg. I enclose a copy of Mr. Nittenberg's lab protocol of the synthesis (in Swedish).
>
> In 1985 we discovered that a Swedish patent application (no. 8400085-0) filed by Lejus Medical AB and naming two former Hassle employees, Kurt Appelgren and Christina Eskilsson, mentioned metoprolol succinate as an active component for an invented pharmaceutical composition. Hassle took action against Lejus in the Swedish patent office asserting rights under the patent based on Hassle's view that the invention of metoprolol succinate was made by Mr. Nitenberg and that Appelgren and Eskilsson had used secret Hassle know-how in making reference to metoprolol succinate in the Lejus patent application. After negotiations between the parties a settlement was reached stipulating inter alia that Lejus w[as] to divide out the parts of their applications pertaining to metoprolol succinate into separate applications, which were to be assigned to Hassle, and that Hassle w[as] to withdraw all actions for rights under the patents.
>
> As I understand it, there remains an open question who is the proper inventor of the invention claimed in the instant U.S. patent application [the '161 patent application], and your advice on this would be appreciated. I may inform you that we have [u]nofficially proposed to Lejus, via Ulf Inger, to add Mr. Nitenberg as an inventor in the Swedish counterpart to the instant application, but so far Lejus h[as] not agreed to do this.

Id. The letter does not inform Filardi that Astra also sought to have Lejus name Nitenberg as the inventor of metoprolol succinate in the United States patent applications. See Nasman's letters to

Inger above.

On January 10, 1989, Filardi sent a letter to Nasman stating that he discussed the inventorship issue with Peder Berntsson and Gerhard Miksche but had several questions that could not be resolved. (Defs.' Memo in Supp. Ex. 28) Filardi proposed that he call Nasman the next day, January 11, 1989, with Berntsson and Miksche participating in the call, to discuss the issue further.

The call was made on January 11th. Nasman writes a letter to Filardi the same day referring to patent application '897 (and two other applications). (Defs.' Memo in Supp. Ex. 29) The letter refers to "the very useful telephone conversation today with you." Berntsson, Miksche, and a Margareta Linderoth also participated in the call. The issue of inventorship is not mentioned in the letter. This letter ends the paper trial of how the open question of inventorship was addressed by Nasman and Filardi.

On April 19, 2005, Filardi was deposed for this lawsuit. He was asked if he reviewed documents in preparation of his deposition. He said that he had and that some of the documents helped refresh his recollection of what occurred during the prosecution of the patent applications as issue. He testified that he could not recall anything that was said during the January 11, 1989 telephone call with Nasman. He specifically states that he could not recall anything that was said about the inventorship of the '897 application. He could not recall if he did, or did not, render any opinion regarding inventorship of the '897 application during the phone call. Aside from Nasman's January 11th letter, the record does not contain any other contemporaneous evidence of Filardi's advice regarding the "open question" of inventorship raised by Nasman.

Astra states that Peder Berntsson was Nitenberg's boss at Astra and was very familiar

with Nitenberg's synthesis of metoprolol succinate. Berntsson met with Filardi on January 10th and was involved in the conversations between Nasman and Filardi on January 11th. However, there is no evidence in the record of what Berntsson specifically discussed with Filardi on January 10th and 11th. Berntsson has submitted a declaration in opposition to summary judgment on the issue of inequitable conduct. Berntsson's declaration does not mention these meetings with Filardi. Nor does it reveal that he ever provided any information to Filardi or Nasman about inventorship of metoprolol succinate.

According to Astra's memorandum in opposition to summary judgment:

> During the January 11 telephone call, Filardi advised Nasman with the requested legal advice on inventorship. In particular, Filardi advised Nasman that, in his opinion, Nitenberg was not an inventor or co-inventor of metoprolol succinate, that there was no doubt about it, that none of the information set forth in Nasman's letter to Filardi was material, and that, therefore, the information did not need to be disclosed to the USPTO.

(Pls.' Memo in Opp. at 20) Astra cites to the declarations of Nasman and Filardi in support of this assertion.

Astra's assertion of what was discussed during the January 11th phone call is not supported by the record in this case. In his deposition, Filardi stated that he had no recollection of what was discussed about inventorship in his conversation with Nasman on January 11th. Filardi made a declaration, however, three months after his deposition which has been submitted in opposition to summary judgment. In pertinent part of his declaration concerning the inventorship issue, Filardi does not state that he recalls what happened but rather what is "clear" to him based on review of some documents. In other words, Filardi still does not recall the relevant conversation. Filardi never declares what he actually knew, considered or said. His declaration

reflects that he is surmising or guessing at what he must have told Nasman.

> For example he states that based on the contemporaneous documents:
>
> ***it is clear*** that I considered the five items of information provided to me by Mr. Nasman and consulted with a senior Astra scientist who knew Mr. Nitenberg; I concluded that, under U.S. law, Mr. Nitenberg was not an inventor.
>
> ***it is clear*** to me that I gave an opinion to Mr. Nasman that Mr. Nitenberg was not an inventor
>
> ***it is clear*** to me that I concluded that the information provided to me by Mr. Nasman, including the assertions he had made to Lejus that he considered Nitenberg to be an inventor under Swedish law, were not "material" under Rule 56 and need not be disclosed to the USPTO.

(emphasis added) (Declar. of Filardi ¶ 10) Also, "I believe that I discussed the question of inventorship with Astra's Peder Berntsson and Astra's Gerhard Miksche, both of whom happened to be in my New York City offices on another Astra matter." (Declar. of Filardi ¶ 12) These are not recollections of what happened but rather are a guess of what must have of happened in Filardi's opinion. I find that this declaration contradicts Filardi's deposition testimony about his recall of events and should be discounted. See Dotson v. Delta Consol. Industries, Inc., 251 F.3d 780, 781 (8th Cir. 2001) (a party may not create a question of material fact, and thus forestall summary judgment, by submitting an affidavit contradicting his own sworn statements in a deposition).[14]

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[14] I note here that Astra has maintained a pattern of submitting witness declarations that contradict their own deposition testimony. For example, compare Appelgren's deposition testimony that he could not recall the particulars of his meeting with Stenhede in Södertälje with his post-deposition declaration that he provided a list of salts to make which included metoprolol succinate. This declaration contradicts not only Appelgren's deposition responses but also the deposition of Astra's Rule 30(b)(6) witness, Ulf Jonsson, who stated that when he and Appelgren met with Stenhede they did not specifically direct him to make metoprolol succinate. A party cannot avoid summary judgment by filing a declaration that contradicts that party's Rule 30(b)(6)

Even if I were to ignore Filardi's deposition testimony and I were to rely solely on Filardi's declaration, Filardi's conclusion that "there was no inventorship issue for the USPTO to decide" (Declar. of Filardi ¶ 12) is flawed because it is undisputed that Filardi was not provided with all of the facts or documents regarding the inventorship dispute. Two assumptions made by Filardi in his declaration highlight the lack of full disclosure made by Astra to Filardi which materially prevented Filardi from being fully apprised of the inventorship dispute.

The first assumption concerns the question of what Filardi was told about the inventorship dispute with Lejus regarding Appelgren and Eskilsson. In his declaration, Filardi states that he "does not recall being aware of **any information** that called into question whether Appelgren and Eskilsson were the true and correct inventors." (emphasis added) And that "**the only question raised by Astra** was whether, under U.S. law, Nitenberg should be **added** as an additional inventor ...." (emphasis added) (Declar. of Filardi ¶ 10)

The reason that Filardi's is not able to recall "any information that called into question" Appelgren's and Eskilsson's roles as inventors is that it is undisputed that Astra never gave Filardi copies of Nasman's letters to Ulf Inger dated February 12, 1988 and May 31, 1988. Astra's contention that Appelgren and Eskilsson did not invent metoprolol succinate was the subject of a long-running dispute between Astra and Lejus. As discussed above, Nasman's letters clearly

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deposition testimony. See Rainey v. American Forest and Paper Ass'n, Inc., 26 F. Supp.2d 82, 95 (D. D.C. 1998). In his deposition, Lilljequist did not recall who suggested which salts of metoprolol nor could he recall if he was given a list of salts to make. Yet he clearly stated that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). Yet in his post-deposition declaration he states that he did receive a list of salts to make that included metoprolol succinate. Similarly, in her deposition Eskilsson could not recall why she was a named inventor of metoprolol succinate. Yet in her post-deposition declaration she asserts that she did invent metoprolol succinate and the basis for her belief.

assert that Nitenberg is **the** inventor of metoprolol succinate and that Appelgren's and Eskilsson's inventorship "**should be limited** to the special form of pharmaceutical composition that is specified in Lejus' original application" which was claim 2 of the Swedish and United States applications. (emphasis added)

In adition, Astra initiated an action in the Swedish Patent Office asserting that Nitenberg was true inventor of metoprolol succinate and that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." (Defs.' Memo in Supp Ex. 11) It is undisputed that Astra did not give Filardi a copy of the Swedish Patent Office submission filed by Astra contesting the Lejus patent based on the dispute over inventorship. It is also undisputed that Astra did not provide Filardi with a copy of the agreement reached between Astra and Lejus regarding dividing up the patents.

Based on Filardi's "recollection" of events, it is apparent that he was not told the whole story of the long-running dispute between Astra and Lejus concerning who invented metoprolol succinate. Because Filardi "had no information that would cause [him] to question whether Appelgren and Eskilsson were the correct inventors ... there is nothing to indicate to [him] that any further "inquiry" into the issue was needed." Id. at ¶ 17. As a result of Astra's undisputed failure to fully disclose to Filardi Astra's position that Appelgren and Eskilsson did not invent metoprolol succinate, Filardi did not attempt to interview them or investigate the role of Stenhede and Lilljequist (the chemists at Södertälje) regarding its invention.

The second flawed assumption involves putting the horse before the cart or, at best, circular reasoning. In his declaration, Filardi states that

it made no difference as to priority whether Nitenberg was added or not added [as

> an inventor to the U.S. application] as a far as claiming priority on the January 1985 U.S. priority application. In either case, the '161 patent would have been entitled to at least the January 1985 U.S. priority date, which is prior to the July 1985 publication date of the Lejus Swedish application.

(Declar. of Filardi ¶ 18) Astra had not given Filardi a copy of the September 19, 1985, memorandum drafted by Wurm highlighting the fundamental issue that the "use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty reference" to any of Astra's future claims concerning metoprolol succinate. Because Filardi was not provided with the memorandum he was not informed of Wurm's concern that even a victory in the Swedish Patent Office regarding inventorship may be hollow because of the prior art effect of the Lejus publication.

Without this information, Filardi could not have appreciated that Astra's later equivocation of the inventorship issue in January 1989 might need to be disclosed to the USPTO, or at a minimum, might require further investigation as to the true inventor of metoprolol succinate. Because Filardi's legal analysis was directed toward the sole issue of **adding** Nitenberg as an inventor in the '897 patent application, he not aware that there was a genuine dispute that Appengren and Eskilsson were improperly named inventors and that the '897 application may not be entitled to priority to the January 1985 United States application.

If Astra had prevailed with either the Swedish Patent Office or with Lejus in naming Nitenberg as the sole inventor of metoprolol succinate, the claim to metoprolol succinate (in the '161 patent application and in the '154 patent application) would not have been entitled to priority to the January 1985 United States application which listed only Appelgren and Eskilsson as inventors. So Filardi's statement in his declaration that adding Nitenberg made no difference

would be correct if either Appelgren and Eskilsson were also still a named inventor. Filardi's statement would be incorrect, however, if Nitenberg replaced both Appelgren and Eskilsson as the inventor. Astra did not give Filardi a chance to consider such a scenario because it failed to provide him with the complete facts concerning its three year dispute with Lejus about inventorship.

Based on the Astra's failure to fully disclose the inventorship dispute to Filardi, I find that Filardi was prevented by Astra from considering information that would have led to a disclosure of the inventorship dispute to the USPTO.

Astra has submitted a declaration of then in-house counsel Nasman in opposition to summary judgment. Defendants assert that this evidence should not be considered based on Astra's failure to identify Nasman as a person with information regarding the inventorship dispute in Astra's Rule 26(a) disclosures and in responses to Defendants' discovery requests.

Even if I were to consider Nasman's declaration, however, it does not change my conclusion that he and Astra failed to be fully candid in providing information to Filardi so that Filardi could make informed decisions regarding the duty of candor and disclosure to the USPTO. Nasman's declaration states in a conclusory fashion that during the telephone call of January 11, 1989, Filardi provided him with advice on the issue of inventorship and that based on Filardi's advice Nitenberg "was not an inventor and that Mr. Appelgren and Ms. Eskilsson were the proper inventors." (Declar. of Nasman at ¶ 17) Because Nasman and Astra failed to provide Filardi with all the information that Astra had regarding its concern with Lejus' July 17, 1985 publication and Astra's three-year inventorship dispute with Lejus (seeking not just to **add** Nitenberg to the patent applications but asserting that Nitenberg be named as **the** inventor of metoprolol succinate)

Filardi's advice cannot be relied upon by Nasman to justify his conclusion concerning inventorship.

Nasman's declaration further states that he concluded from his own investigation that Nitenberg should not be a named inventor. However, in his deposition taken after this declaration was made, Nasman states that his investigation consisted of (1) reviewing the Nitenberg lab protocol document, (2) reviewing the Lejus Swedish Application to which Astra claimed priority, and (3) talking to Filardi by telephone in January 1989. (Defs. Reply Memo. Ex. 11 at 66, 73, and 77) I need not consider the contradictions between Nasman's declaration and his deposition testimony. Whether Nasman conducted a minimally competent investigation as to who invented metoprolol succinate does not matter at this stage of the lawsuit. In the present summary judgment context, the question of whether the correct inventors were named in the patents in suit is secondary because the undisputed question of inequitable conduct centers around the failure of Astra to inform the USPTO about its long-running inventorship dispute with Lejus. It is undisputed in the record that Nasman and Astra failed to fully disclose material information to its United States patent counsel, Filardi, concerning Astra's inventorship dispute with Lejus.

A finding of inequitable conduct

Contradictory evidence abounds concerning whether Appelgren and Eskilsson were the true inventors of metoprolol succinate. Although the contradictions are predominately created by Astra's post-deposition declarations and are subject to be discounted, enough material facts are in dispute to prevent summary judgment on the issue of whether Astra submitted false information regarding inventorship to the USPTO.

Clear and convincing evidence, however, has established that Astra and Lejus were

engaged in an prolonged dispute over inventorship of metoprolol succinate and this dispute was not disclosed to the USPTO. The undisputed documents establish that the dispute regarding inventorship spanned more than a three-year period. Inventorship is very material information in a patent prosecution. There was a substantial likelihood that a reasonable examiner would have considered the inventorship dispute between Astra and Lejus important in deciding whether to allow the '161 and '514 patent applications to issue.

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability as defined in this section. 37 C.F.R. § 1.56. "Close cases should be resolved by disclosure, not unilaterally by the applicant." LaBounty Mfg., Inc. v. United States International Trade Commission, 958 F.2d 1066, 1076 (Fed. Cir. 1992). Disputes concerning inventorship are material information that need to be disclosed. PerSeptive Biosystems, Inc., 225 F.3d at 1321.

On March 25, 1988, Lejus filed, on Astra's behalf, the '897 (which became the '161 patent and the '154 patent) naming Appelgren and Eskilsson as inventors. At that time Astra had been asserting to Lejus for more than two years that Nitenberg had solely invented metoprolol succinate through letters and by initiating an inventorship dispute with the Swedish Patent Office. ***Even after the patent application was filed*** Astra's counsel wrote to Lejus to demand that Nitenberg be listed as **the** inventor of metoprolol succinate in the European and United States patent applications filed per their agreement.

Yet Lejus failed to disclose this long-running material dispute to the USPTO in its filing and prosecution of the '897 application. Nor did Astra disclose this information to the USPTO.

Although Astra's United States patent counsel, Filardi, believed he made all of the disclosures necessary, Astra failed to provide him with important and material information concerning its dispute with Lejus. Astra cannot benefit from its failure to disclose material information to its United States patent counsel and then hide behind its argument that he acted in good faith and candor in his prosecution of the patent. It was Astra's own failure to disclose which led Filardi to believe he was disclosing all information known to be material to patentability. Astra's employee Nasman was an individual associated with the filing and prosecution of the patent application and had a duty of candor and good faith to the USPTO. Nasman was fully aware of the extent of the inventorship dispute. Nonetheless, Nasman and Astra failed to fully disclose the inventorship dispute with Lejus to Filardi which prevented the possibility of the dispute from being disclosed to the USPTO.

I do not believe that the question of whether to disclose the inventorship dispute was a close call. To find otherwise is to find that Astra's filing with the Swedish Patent Office and its three-year dispute with Lejus were pursued in bad faith.

Not only was the issue of the dispute of inventorship highly material, Astra had a strong incentive to not disclose the dispute. If a patent examiner had learned of the dispute and found Nitenberg to be the sole inventor of metoprolol succinate, the '897 patent application would not have been entitled to priority to the January 1985 United States application. The effective filing date for the '897 patent would have been March 25, 1988. As a consequence, Astra's metoprolol succinate patents may have been denied as anticipated by the prior art of the publication of the Lejus' European application on July 17, 1985.

I find by clear and convincing evidence that the inventorship dispute between Astra and

Lejus was highly material and should have been disclosed to the USPTO during the prosecution of the patents in suit. I also find by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol succinate inventions as anticipated by prior art. The intent to deceive is clearly present. Afer weighing materiality and intent I find that Astra's conduct was so culpable that its '161 patent and '154 patent are unenforceable.

Conclussion

I find by clear and convincing evidence that Astra's '161 patent and "154 patent are invalid on the basis of double patenting over the '318 patent. I also find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent application filing date. As a consequence I find that the '161 patent is invalid as anticipated.

Finally, I find by clear and convincing evidence that the '161 patent and '154 patent are unenforceable based on Astra's inequitable conduct in the prosecution of these patents in the United States Patent and Trademark Office. Astra failed to disclose to the USPTO the material dispute it had with Lejus concerning inventorship of metoprolol succinate. The failure to disclose was done with an intent to deceive the patent examiner as to this material dispute. Astra failed to provide material information in order to avoid questions concerning Astra's ability to claim priority to the '318 patent application and to avoid potential prior art concerning metoprolol succinate.

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion for Summary Judgment of

Invalidity [#120] is **GRANTED**. Plaintiffs' Motion for Partial Summary Judgment of No Invalidity of United States Patent 5,081,164 for Double Patenting [#297] is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion for Summary Judgment Seeking a Declaration that United States Patent Nos. 5,001,161 and 5,081,154 are Unenforceable for Inequitable Conduct [#241] is **GRANTED**.

IT IS FURTHER ORDERED that all other pending motions in this case are **DENIED** as moot.

RODNEY W. SIPPEL
UNITED STATES DISTRICT JUDGE

Dated this 17th day of January, 2006.