UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTELLAS PHARMA, INC., et al.,	:	CIVIL ACTION NO. 05-2563 (MLC)
Plaintiffs,	:	**MEMORANDUM OPINION**
v.	:	
RANBAXY INC., et al.,	:	
Defendants.	:	

COOPER, District Judge

Plaintiffs, Astellas Pharma, Inc. ("Astellas Pharma"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") (collectively "Astellas") commenced this action against defendants Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd. (collectively "Ranbaxy") alleging Ranbaxy infringed upon United States patent number 4,703,063 (the "'063 patent") held by Astellas. (Compl., at 4.) Ranbaxy asserted affirmative defenses and a counterclaim based on the alleged invalidity and unenforceability of the '063 patent. (Dkt. entry no. 4.)

Currently before the Court are a motion and a cross motion for summary judgment pursuant to Federal Rule ("Rule") of Civil Procedure 56. (Dkt. entry no. 17.)[1] Pursuant to a stipulation entered into between the parties and approved by the Court,

[1] Astellas cross-moved for summary judgment at oral argument on defendants' motion. (Tr. of 2-02-07 Oral Arg., at 98-99; see dkt. entry no. 39.)

Ranbaxy admits to infringing upon the '063 patent and agreed to the dismissal with prejudice of its affirmative defenses alleging invalidity or unenforceability under 35 U.S.C. §§ 101, 102, 103, and 112. (Dkt. entry no. 32, at 2.) The only affirmative defense and counterclaim not dismissed through the stipulation is the invalidity of '063 for obviousness-type double patenting, and thus the parties agree this is the only issue remaining before the Court. (Id.) For the reasons stated herein, the Court will grant Astellas's cross motion and deny Ranbaxy's motion.

BACKGROUND

Yamanouchi Pharmaceutical Co. ("Yamanouchi"), one of the companies that subsequently merged in 2005 to become Astellas Pharma, Inc., filed a patent application in 1981 for a class of sulfamoyl-substituted phenethylamines, believed to be useful for treating hypertension and related disorders. (Pls. Stmt. of Facts, at ¶¶ 2, 11; Defs. Stmt. of Facts, at ¶ 6.) The application contained claims to the class of new chemical compounds, which included tamsulosin, as well as the pharmaceutical compositions containing those chemical compounds and the processes for making the chemical compounds. (Pls. Stmt. of Facts, at ¶ 13; Defs. Stmt. of Facts, at ¶ 9.)

The patent examiner rejected the pharmaceutical composition and chemical compound claims, only allowing the claims for the processes to make the compounds. (Pls. Stmt. of Facts, at ¶ 16;

Defs. Stmt. of Facts, at ¶ 8.) Patent number 4,373,106 (the "'106 patent") was issued to Yamanouchi in 1983 and it claimed the processes for making the new class of sulfamoyl-substituted phenethylamines. (Pls. Stmt. of Facts, at ¶ 19; Defs. Stmt. of Facts, at ¶ 9; see Decl. of Thomas R. Burns ("Burns Decl."), Ex. A.) The '106 patent expired on February 4, 2001. (Pls. Stmt. of Facts, at ¶ 20; Defs. Stmt. of Facts, at ¶ 12.)

Before the '106 patent was issued, Yamanouchi applied multiple times to the patent office to claim the pharmaceutical compositions and chemical compounds rejected by the examiner in the '106 application. (Pls. Stmt. of Facts, at ¶¶ 24-25; Defs. Stmt. of Facts, at ¶ 13.)[2] On October 27, 1987, the '063 patent claiming those pharmaceutical compositions and chemical compounds was issued to Yamanouchi. (See Burns Decl., Ex. B.) The eighteen claims in the '063 patent cover the chemical compounds (claims 1 & 3-18) and the pharmaceutical compositions (claim 2). (Id.) The '063 patent expires on October 27, 2009. (Pls. Stmt. of Facts, at ¶ 30; Defs. Stmt. of Facts, at ¶ 19.)

Boehringer, Astellas Pharma's marketing partner in the United States, filed a New Drug Application ("NDA") for

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[2] The '063 patent application originally included process claims but they were rejected by the patent examiner. Our analysis, however, does not rest on that aspect of the '063 patent history. The parties agree that no restriction was imposed by the patent examiner reviewing the first filed application resulting in the '106 patent.

tamsulosin with the Food and Drug Administration ("F.D.A.") on April 15, 1996. (Pls. Stmt. of Facts, at ¶ 39.) The NDA was approved exactly one year later and Boehringer began marketing tamsulosin in the United States under the trade name Flomax. (Id.) Flomax is used to treat benign prostatic hyperplasia. (Pls. Stmt. of Facts, at ¶¶ 4, 42.)

Ranbaxy filed an Abbreviated New Drug Application ("ANDA") on December 20, 2004, seeking approval to market generic tamsulosin hydrochloride capsules. (Dkt. entry no. 17, Decl. of Jay R. Deskmukh, at ¶ 4.) On April 6, 2005, Ranbaxy notified Astellas of the F.D.A.'s acceptance of Ranbaxy's ANDA. (Id. at ¶ 5.) Ranbaxy also provided Astellas with notice of its opinion that the '063 patent was invalid for, inter alia, double patenting over the claims of the '106 patent. Astellas subsequently filed the complaint for patent infringement against Ranbaxy in this Court. (Dkt. entry no. 1.)

DISCUSSION

Claim 3 of the earlier issued '106 patent states:

> A process for producing sulfamoyl-substituted phenethylamine derivatives represented by the formula [DRAWING OF CHEMICAL FORMULA] wherein R1 represents an amino group or a mono- or di-lower alkylamino group; R_2 represents a hydroxy group, a lower alkyl group or a lower alkoxy group; R_3 represents a hydrogen atom or a lower alkoyl group, R_4, R_5, R_6, R_7, R_8 and R_9 each represent a hydrogen atom or a lower alkyl group; R_{10} represents a hydrogen atom, a lower alkyl group, or a lower alkoxy group; and Y represents an oxygen atom or a methylene group; said Y being an oxygen atom when R_2 is a hydroxyl group, or the salts thereof which

> comprises reacting a compound represented by the formula [DRAWING OF CHEMICAL FORMULA] wherein R represents a hydrogen atom or a lower alkyl group and R_1, R_2, R_4, R_5, R_6, R_7, R_8, R_9, R_{10} and Y have the same significance as in the above formula with a halogenating agent and reducing the halogenated product.

(Burns Decl., Ex. A, at 28.) Claim 4 of the earlier issued '106 patent states: "The process as defined in claim 3 for the preparation of 5-[2-[2-(2-ethoxyphenoxy)ethylamino]-2-methylethyl]-2-methoxybenzensulfonamide." (Id.)

Claim 1 of the later issued '063 patent states:

> Sulfamoyl-substituted phenethylamine derivatives represented by the general formula [DRAWING OF CHEMICAL FORMULA] wherein R_1 represents an amino group or a mono- or di-lower alkylamino group; R_2 represents a hydroxyl group, a lower alkyl group, or a lower alkoxy group; R_3 represents a hydrogen atom, a lower alkoxy group or a lower alkyl group; R_4, R_5, R_6, R_7, R_8, and R_9 each represents a hydrogen atom or a lower alkyl group; R_{10} represents a hydrogen atom, a lower alkyl group, or a lower alkoxy group; and Y represents an oxygen atom, and the salts thereof.

(Id., Ex. B, at 26-27.) Claim 2 of the '063 patent states: "A pharmaceutical composition containing an effective []-adrenergic antagonistic amount of a compound of claim 1 and a pharmaceutically acceptable excipient." (Id. at 27.) Claim 14 of the '063 patent states: "The compound of claim 1 which is 5-{2-[2-(2-ethoxyphenoxy)ethylamino]-2-methylethyl} benzenesulfonamide." (Id. at 28.) Claims 4, 8, 10 & 14 of the '063 patent are dependent claims that directly or indirectly depend on claim 1. (See id., at 27-28.)

The parties do not dispute the process claimed in the '106 patent, when practiced, will produce tamsulosin, as well as other compounds within the class of sulfamoyl-substituted phenethylamines. Nor do the parties dispute the compound claimed in the dependent claim 14 of the '063 patent is tamsulosin.[3]

Ranbaxy argues that claims 1, 2, 4, 8, 10 & 14 of the '063 patent are invalid for obviousness-type double patenting. More specifically, Ranbaxy argues: (1) the '063 patent covers the same compound already patented in claim 4 of the '106 patent, (2) claim 4 of the '106 patent falls within the "genus and subgenus" of the compounds in claims 1, 4, 8, 10 & 14 of the '063 patent (the "'063 claims"), or in other words claim 4 of the '106 patent anticipates claims 1, 4, 8, 10 & 14 of the '063 patent, and (3) claim 2 of the '063 patent would have been obvious in view of claim 4 of the '106 patent. (Defs. Br., at 17, 22.)

Astellas argues that the '106 and '063 patents are patentably distinct because the '106 patent claims distinct processes for making "new classes of sulfamoyl substituted phenethylamins," including tamsulosin, while the '063 patent claims the chemical compound tamsulosin and its pharmaceutical compositions, regardless of the process used to make them. Astellas further argues (1) the case law concerning anticipation,

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[3] The fact there are other isomers that can be produced using the process in the '106 patent is undisputed by the parties, but not material to the Court's analysis.

genus and sub-genus, does not apply because '106 claimed a process, not a product, (2) Ranbaxy improperly relies upon the specification of the '106 patent, and (3) claim 2 of the '063 patent is patentably distinct from the claims in the '106 patent because it claims unexpected properties of "adrenergic antagonists" that were not in the earlier process claims of the '106 patent.

I. Standard

A patent is presumed to be valid, and each of its claims are presumed valid independent of the validity of other claims. 35 U.S.C. § 282. A party asserting the invalidity of a patent or one or more of its claims has the burden of establishing such invalidity, which is satisfied only by clear and convincing evidence. Id.; Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed. Cir. 1986). "It is black letter law that the ultimate question of obviousness is a question of law." Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997).

II. Obviousness-type Double Patenting[4]

"The judicially-created doctrine of obviousness-type double patenting [prohibits] a party from obtaining an extension of the

[4] Obviousness-type double patenting is also commonly referred to as "nonstatutory double patenting." See generally Geneva Pharm., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373 (Fed. Cir. 2003).

right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001). In analyzing a claim of obviousness-type double patenting, the Court determines (1) the differences between the claims of the earlier and later patent and (2) whether the differences make the claims patentably distinct. Id. at 968. A claim that defines more than an obvious variation is patentably distinct. Geneva Pharm., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1383 (Fed. Cir. 2003). "A claim cannot be patentably distinct over anticipatory subject matter." Id.; Eli Lilly, 251 F.3d at 968 (same); In re Goodman, 11 F.3d 1046, 1053 (Fed. Cir. 1993) (holding that an earlier species claim anticipates and therefore is not patentably distinct from a later genus claim).

"[T]he law of double patenting is concerned only with what patents claim" and therefore double patenting "involves an inquiry into what, if anything, has been claimed twice." Gen. Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1275 (Fed. Cir. 1992). Claim interpretation is a question of law. Id. at 1277. A patent contains two main parts: "(1) a written description of the invention, which may . . . include drawings, calling the 'specification,' enabling those skilled in the art to practice the invention, and (2) claims which define or delimit

the scope of the legal protection which the government grant gives the patent owner, the patent 'monopoly.'" Id. at 1274.

Whereas a court's inquiry into obviousness under 35 U.S.C. § 103 compares claimed subject matter to the prior art, the proper inquiry for obviousness-type double patenting "does not include an examination of the motivation to modify the prior art, nor does it involve an inquiry into objective criteria suggesting non-obviousness." Applera Corp. v. MJ Res. Inc., 363 F.Supp.2d 261, 264 (D. Conn. 2005). The distinctions between obviousness under § 103 and obviousness-type double patenting include:

> (1) The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; [obviousness-type] double patenting compares claims in an earlier patent to claims in a later patent or application;
>
> (2) Obviousness requires inquiry into a motivation to modify the prior art; [obviousness-type] double patenting does not;
>
> (3) Obviousness requires inquiry into objective criteria suggesting non-obviousness; [obviousness-type] double patenting does not.

Geneva Pharm., 349 F.3d at 1378 n. 1. "It cannot be said – though it often is, incorrectly, by the uninitiated – that a part of the claim is 'claimed' subject matter." Gen. Foods, 972 F.2d at 1274. Each claim in a patent "is an entity which must be considered as a whole." Id.

Applying these principles, we construe claim 4 of the '106 patent to be a claim for a process to make the named compound, 5-

[2-[2-(2-ethoxyphenoxy)ethylamino]-2-methylethyl]-2-methoxybenzensulfonamide. We construe independent claim 1 of the '063 patent and its dependent claims 4, 8, 10 & 14 to be claims for the compound sulfamoyl-substituted phenethylamine derivatives. We construe individual claim 2 of the '063 patent as a claim for a pharmaceutical composition of the named compound, having the stated pharmaceutical properties. In rendering this claim construction, we have considered the fact that the intrinsic evidence relating to both patents is a virtually identical specification. (Compare, Burns Decl., Ex. A, at 2, with id., Ex. B, at 2.) However, we decline to read into the process claim of claim 4 of the '106 patent the compound or the pharmaceutical composition and properties that are distinctly claimed in the '063 patent. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 970 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996), Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005), Gen. Foods, 972 F.2d at 1274.

The Federal Circuit found that the district court in General Foods had erred in its comparison of the earlier and later claims at issue, and explained what the district court should have done:

> Where there is a second patentable invention, as there is here, because the difference is not an obvious one, it is important to bear in mind that comparison can be made only with what invention is claimed in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim defines and not looking to the claim for anything that

> happens to be mentioned in it as though it were a prior art reference.

Id. at 1280. The approach advocated by Ranbaxy would, in our view, result in a similar error in comparing the claims of the '063 patent to more than only the claims of the '106 patent. Defendants rely on the type of comparisons that are required under the test for obviousness under § 103, and not the more limited comparisons between claims utilized pursuant to the test for obviousness-type double patenting. See Applera Corp., 363 F.Supp.2d at 264.

Defendants, in support of their argument, impermissibly characterize the compounds named in the processes claimed in the '106 patent as if the compounds were also themselves claimed. In order to reach the conclusion that defendants desire, the Court would have to go beyond what is claimed by the two patents and compare the '063 claims with the compounds merely named and not claimed in the '106 patent, contrary to the law of obviousness-type double patenting. See Gen. Foods, 972 F.2d at 1274 (noting that "one cannot properly speak of any single step as being 'claimed,' for it is not; all that is claimed is the process consisting of the combination of all three steps"). Defendants' arguments do nothing more than show how the two patents are related, and do not meet the burden of showing by clear and

convincing evidence that the '063 patent is invalid for obviousness-type double patenting.

Defendants have also not persuaded the Court that the rule of anticipation, holding that an earlier claim to a species defeats a later claim to a genus containing that species, controls the result in this case. See Geneva, 349 F.3d at 1383-84 (applying genus/species argument in nonstatutory double patenting case). A "reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently." Eli Lilly, 251 F.3d at 970. "A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations." Id. (citation and quotations omitted). Similarly, "a later patent claim that fails to provide novel invention over an earlier claim is not patentably distinct from the other claim." Id.

Defendants make two arguments concerning anticipation: (1) "Claim 14 [of the '063 patent] recites a compound by the name . . . and Claim 4 [of the '106 patent] recites a process wherein the compound of the same name is the product of the process" and (2) "The only difference between Claims 1, 4, 8, and 10 of the '063 patent . . . and Claim 4 of the '106 patent . . . is that the former each recite various genuses of compounds and the latter recites a process to make a compound that is encompassed by each

genus." (Defs. Br., at 17, 20.) In other words, "once the Court concludes Claim 14 of the '063 patent is invalid for double patenting, the remainder of the compound claims (claims 1, 4, 8, & 10) are also invalid." (Defs. Reply Br., at 13.)

Defendants do not point to, and the Court could not find, one double-patenting case where a later product claim was anticipated by the earlier process claim for making that product, or where a product or the compounds comprising that product were found to be a "genus" anticipated by the "species" of the earlier process claims. In the absence of such caselaw, and in light of the Court's consideration of Geneva, supra, and Taylor, infra, the Court concludes that it cannot find claims 1, 4, 8, 10 & 14 in the '063 patent invalid based upon defendants' species/genus argument. In order to reach such a conclusion the Court would have to compare the '063 claims with the compounds merely named as part of the claimed processes in the '106 patent, contrary to the law of obviousness-type double patenting. See Gen. Foods, 972 F.2d at 1280.

The cases relied upon by Ranbaxy are all distinguishable from the instant case. Ranbaxy relies upon two "method of use" cases: (1) Geneva Pharm., 349 F.3d at 1385-86, where the court held that an earlier claim to a compound whose only use was to combat bacteria was not patentably distinct from a later claim to the method of using the compound for the same purpose, and (2) In

re Lonardo, 119 F.3d 960, 968 (Fed. Cir. 1997), where the court held that the earlier claim for a device for healing foot injuries was not patentably distinct from the later claim for a method of using the same device. These two cases do not control here because the later "method of use" patents are not analogous to the later "product" patent at issue in this case, for all of the aforementioned reasoning by the Court as to the product/process distinction.

In re Freeman, 166 F.2d 178 (C.C.P.A. 1948), also cited by Ranbaxy, is also distinguishable from this case. In Freeman, the court affirmed the patent examiner's finding of double patenting on the grounds that the earlier process claims precluded a later claim to the composition resulting from the same process, because the composition, i.e. product, could only be described by the earlier patented process for making it. Id. at 180-81. In this case, however, it is generally recognized by both parties that tamsulosin can be made by processes other than those claimed by the '106 patent, thereby distinguishing Freeman. (See Burns Decl., Ex. J, at 83-84.)

Defendants also argue that claim 2 of the '063 patent is obvious, under double-patenting principles, in view of claim 4 of the '106 patent. (Defs. Br., at 22.) Plaintiffs argue that the adrenergic antagonists in claim 2 of the '063 patent are "unexpected and unpredictable pharmaceutical properties" that

make the later '063 patent patentably distinct from the earlier '106 patent. (Pls. Br., at 35.) Plaintiffs' argument is bolstered by defendants' concession:

> Claim 2 of the '063 patent therefore differs from Claim 4 of the '106 patent in that (1) the compound is part of the pharmaceutical composition, (2) the pharmaceutical composition contains an excipient, and (3) the pharmaceutical composition contains an effective []adrenergic antagonistic amount of the compound, which is merely a recitation of the inherent property of the compound.

(Defs. Br., at 23.) Defendants' subsequent attempts to argue that these differences do not render claim 2 of the '063 patent patentably distinct from the compound in claim 4 of the '106 patent are unpersuasive.

Claim 2 of the '063 patent distinguishes that patent from claim 4 of the '106 patent because, as plaintiffs argue, it claims unexpectedly potent adrenergic antagonists that are not claimed in the earlier patent. Defendants' expert, Professor Mitscher, even testified that claim 2 of the '063 patent contains unexpectedly potent elements that are not present in the earlier claims. (Burns Decl., Ex. L, at 187-88, 192.) When comparing only what is claimed, as we must, the unexpected and unique potency of the adrenergic antagonists in claim 2 of the '063 patent render claim 2 patentably distinct from claim 4 of the '106 patent.

The Court finds Ranbaxy's reliance on Brenner v. Manson, 383 U.S. 519 (1966), in support of its argument that Claim 2 is

obvious, is misplaced. In Brenner, the Supreme Court construed a patent for "a chemical process which yields an already known product whose utility-other than as a possible object of scientific inquiry-has not yet been evidenced." Id. at 529. The Court affirmed the Court of Customs and Patent Appeals's holding that the process sought to be claimed by the applicant's patent application "did not disclose a sufficient likelihood" of achieving the claimed utility and therefore was not patentable. Id. at 532. Nothing in Brenner lends support to Ranbaxy's argument that the claim in the '106 patent for the process of making adrenergic antagonists with unique blocking capabilities makes obvious the later claim in the '063 patent for the adrenergic antagonists themselves.

The Court concludes that the '063 claims are patentably distinct from claim 4 in the '106 patent. The following excerpt from In re Taylor, 360 F.2d 232 (C.C.P.A. 1966), is instructive. In analyzing whether two claims defined the same invention, the court noted:

> [D]o the claims in fact define the same invention, i.e., a process? The answer is no. The appealed claim defines a product per se in terms of its physical properties as well as in terms of a process for making it. The invention defined by the appealed claim is a product. The patent claims define a process. Thus, two independant [sic], albeit related inventions are presented, the appealed claim covering a product and the issued patent claiming a process.

Id. at 234. The court concluded that "while the patented process may produce a product which falls within the claim to a product

as defined in the appealed claim, this does not require the conclusion that double patenting exists." Id. at 236. Despite the different procedural posture in Taylor and this case, the Court finds this particular substantive issue sufficiently analogous to make the court's reasoning in Taylor persuasive.

There is no genuine issue of fact as to the product and process distinction between the claims of the two patents at issue here because the testimony of defendants' expert, Professor Mitscher, confirms that the '106 patent only claims the processes for making the compounds and the '063 patent only claims the compounds themselves. Mitscher testified during his deposition on several occasions that only the specifications for the '106 and '063 patents were identical, and that the claims were different to the extent that the '106 patent claimed the processes for making the compounds and the '063 patent claimed the compounds themselves. (Burns Decl., Ex. I, at 83 & 124; Ex. K, at 33 & 85.) When asked if what was claimed in each patent were different inventions, Mitscher's reply was "[t]hey really refer to the same compound. In one case it's how you make it. In the other case it's the compound." (Id., Ex. I, at 150.)

The Court's conclusion that the '063 product claims are patentably distinct from the '106 process claims is further supported by the United States Patent and Trademark Office's Manual of Patent Examining Procedure ("MPEP"), which

distinguishes between patents for product and process inventions. (Burns Decl., Ex. D., at §§ 802.02, 803, & 806.05(f).)[5] The MPEP states in relevant part:

> A process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process as claimed is not an obvious process of making the product and the process as claimed can be used to make another materially different product; or (B) that the product as claimed can be made by another materially different process.

MPEP § 806.05(f) (8th ed. 2005). The MPEP goes on to explain "[a] product defined by the process by which it can be made is still a product claim . . . and can be restricted from the process if the examiner can demonstrate that the product as claimed can be made by another materially different process." Id.

Ranbaxy's own expert testimony, again, resolves any genuine issue of material fact on this issue. Mitscher testified during his deposition that it "wouldn't surprise [him] in the slightest"

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[5] Ranbaxy correctly states that the prosecution history of the '106 patent did not include a restriction by the examiner, but rather a rejection of the compound/composition claims, and rather than opposing that rejection the applicant filed new applications eventually resulting in the issuance of the '063 patent. (Defs. Reply Br., at 7-10.) The law is clear that no obviousness-type double patenting arguments can be made where the examiner issued a restriction and the applicant agrees to a terminal waiver as to the later issued claims. See Goodman, 11 F.3d at 1052. Of course that is not the prosecution history of the '106 and '063 patents, and Ranbaxy has the right to raise the present issue of obviousness-type double patenting. We nonetheless find the quoted text from the MPEP to be instructive on the question of what is "patentably distinct."

if there were processes other than those claimed in the '106 patent that could be used to make tamsulosin in the form claimed by the '063 patent. (Burns Decl., Ex. J, at 83-84.) Also, if the Court were to adopt Ranbaxy's argument that the process claims in the '106 patent anticipate the product claims in the '063 patent, such a conclusion would run contrary to MPEP § 806.05(f)'s allowance of separate inventions for processes and the product resulting from the same processes where "the product as claimed can be made by another materially different process."

Astellas has presented ample evidence that claim 4 of the '106 patent is patentably distinct from claims 1, 2, 4, 8, 10 & 14 the '063 patent. Ranbaxy has not presented sufficient evidence in response and therefore there is no genuine issue of fact as to whether patent '063 is invalid for obviousness-type double patenting. See Eli Lilly, 251 F.3d at 971-72. The Court has compared the differences between the claims at issue as a whole and concludes that Ranbaxy has not met the burden of proving invalidity by clear and convincing evidence.

CONCLUSION

The Court, for the aforementioned reasons, concludes that the claims of the '063 patent are not invalid for obviousness-type double patenting. The Court will therefore grant Astellas's cross motion for summary judgment and deny Ranbaxy's motion for summary judgment. The Court will issue an appropriate order and judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge