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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BANMEET ANAND, ERIC STEFANICH, MEINA TANG, JENNIFER VISICH, MARNA WILLIAMS, and SHARON O'BYRNE

Appeal 2019-001845
Application 14/035,811
Technology Center 1600

Before ERIC B. GRIMES, DEBORAH KATZ, and MICHAEL A. VALEK, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review[2], under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, and 74–89. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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[1] We use the word "Appellant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party-in-interest as Genentech, Inc. (App. Br. 5.)

[2] We consider the Office Action issued March 26, 2018 ("OA"), the Appeal Brief filed September 26, 2018. ("Appeal Br."), the Examiner's Answer issued on October 26, 2018 ("Ans."), the Reply Brief filed December 26, 2018 ("Reply Br.") and the oral argument held on February 2, 2020, in reaching our decision.

Appellant's Specification is directed to treating gastrointestinal inflammatory diseases, such as ulcerative colitis and Crohn's disease, by administering antibodies targeting the protein integrin beta7. (Spec. ¶ 3.)

The Examiner rejects all of Appellant's claims under three separate grounds of obviousness: (1) as being obvious under 35 U.S.C. § 103(a) over Fong '236[3] and Fong '082[4] in view of the '508 publication[5]; (2) as being obvious under 35 U.S.C. § 103(a) over both Fong patents in view of the '508 publication and Fasanmade[6] as evidenced by a Declaration by the Tang Declaration filed May 1, 2017; and (3) under the doctrine of obviousness-type double-patenting over claims 1–14 of Fong '082 in view of the '508 publication and, optionally, Fasanmade. (*See* Ans. 3.)

Appellant claims a method of treatment using an anti-beta7 antibody at a flat dose falling within a recited range. Appellant's claim 13 recites:

> A method of treating a gastrointestinal inflammatory disorder in a human patient, the method comprising *administering subcutaneously to the patient a flat dose of an integrin beta7 antagonist*, wherein the flat dose is between about 100 mg and about 220 mg, and wherein the integrin beta7 antagonist is a monoclonal anti-beta7 antibody or a fragment thereof comprising six hypervariable regions (HVRs), wherein:
>
> (i) the HVR-L1 comprises amino acid sequence A1-A11, wherein A1-A11 is RASESVDTYLH (SEQ ID NO:1);

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[3] U.S. Patent 7,528,236 B2, issued May 5, 2009.
[4] U.S. Patent 8,124,082 B2, issued February 28, 2012.
[5] Gelzleichter et al., U.S. Patent Application Publication 2010/0255508 A1, published October 7, 2010.
[6] Fasanmade et al., "Population pharmacokinetic analysis of infliximab in patients with ulcerative colitis," Eur. J. Clin. Pharmacol., 65:1211–28 (2009).

> RASESVDSLLH (SEQ ID NO:7), RASESVDTLLH (SEQ ID NO:8), or RASESVDDLLH (SEQ ID NO:9);
>
> (ii) the HVR-L2 comprises amino acid sequence B1-B8, wherein B1-B8 is KYASQSIS (SEQ ID NO:2), or RYASQSIS (SEQ ID NO:20);
>
> (iii) the HVR-L3 comprises amino acid sequence C1-C9, wherein C1-C9 is QQGNSLPNT (SEQ ID NO:3);
>
> (iv) the HVR-H1 comprises amino acid sequence D1-D10 wherein D1-D10 is GFFITNNYWG (SEQ ID NO:4);
>
> (v) the HVR-H2 comprises amino acid sequence E1-E17 wherein E1-E17 is GYISYSGSTSYNPSLKS (SEQ ID NO:5); and
>
> (vi) the HVR-H3 comprises amino acid sequence F2-F11 wherein F2-F11 is MTGSSGYFDF (SEQ ID NO:6) or RTGSSGYFDF (SEQ ID NO:19); or comprises amino acid sequence F1-F11, wherein F1-F11 is AMTGSSGYFDF (SEQ ID NO:16), ARTGSSGYFDF (SEQ ID NO:17), or AQTGSSGYFDF (SEQ ID NO:18).

(App. Br. 46 (emphasis added).) Appellant does not argue for the separate patentability of any of the rejected claims, thus our analysis focuses on claim 13 as representative.

Findings of Fact

1. Fong '082 teaches treating a human for gastrointestinal inflammatory diseases (inflammatory bowel disease, Crohn's disease, ulcerative colitis, etc.), by subcutaneously administering a humanized antibody that binds integrin beta7. (*See* Fong '082, 91:64, 153:47–156:29 (claims 1–14); *see* Office Act. 3.)

2. Fong '082 teaches an anti-beta7 antibody that comprises the six hypervariable regions recited in Appellant's claim 13. (*See* Fong '082, 153:47–155:18 (claim 1); *see* Final Act. 3.)

3. Appellant's Specification defines a "flat dose" as "a particular amount of anti-beta7 antibody that is administered to every patient regardless of weight." (Spec. ¶ 189.)

4. Fong '082 teaches exemplary ranges of doses expressed as doses per body weight, for example 0.5 mg/kg to about 10 mg/kg. (*See* Final Act. 3, citing Fong '082 92:43–44.)

5. The '508 publication teaches methods of determining a dosing regimen of a humanized anti-integrin beta7 antibody, as recited in claim 13, for treatment of a gastrointestinal inflammatory disorder, wherein the method is based on comparisons of the levels of biomarker in a patient sample. ('508 publication ¶¶ 13, 14, 317 claims 3–25; *see* Final Act. 4.)

6. The '508 publication teaches the pharmacokinetic and pharmacodynamic effects of an anti-beta7 antibody after intravenous administration. (*See* '508 publication ¶ 418, Table 2-1; *see* Final Act. 4–5.)

7. Fasanmade teaches pharmacokinetic analysis of an antibody in patients with ulcerative colitis. (Fasanmade abstract.)

8. Fasanmade teaches using population pharmacokinetics with the program NONMEM to analyze concentration-time data for an antibody treatment. (Fasanmade abstract.)

9. Fasanmade teaches using models that include the effect of weight on clearance. (Fasanmade abstract.)

10. Fasanmade teaches that for the antibody infliximab, an antibody distinct from the antibody recited in claim 13, body weight-adjusted dosing is necessary to allow equivalent exposure to all patients to mitigate possible weight-related influences. (Fasanmade 1222–23.)

> 11. Inventor Tang testifies that
>
> population pharmacokinetic analysis is necessary to determine whether flat dosing or weight-based dosing is appropriate for a target antibody. This is also explained in Bai *et al.,* "A Guide to Rational Dosing of Monoclonal Antibodies", *Clin Pharmacokinet.* (2012 Feb 1);51 (2): 119-35 ("Bai"), which I co-authored. In Bai, a population pbarmacokinetic analysis was used to provide insights into conditions under which either a flat dose or a weight-based dose "would be superior in reducing pharmacokinetic variability and exposure differences between light and heavy subjects across the population. " *See* Bai at Abstract (Conclusions).

(Tang Decl., ¶ 24.)

> 12. Mould[7], which was presented by Appellant, explains that
>
> [t]here are several potential dose regimens that can be employed for mAbs: (i) a flat dose, where subjects all receive the same dose; (ii) an individualized dose, which usually involves a bodyweight or BSA-based dose; and (iii) a Bayesian individualized dose, where the dose is adjusted using a nomogram or the subject's individual concentration or response measurement.

(Mould 30 (Exhibit G of Appeal Br.).)

> 13. Mould teaches:
>
> For drug X, where weight was not an important predictor of clearance, a flat dose provides a uniform drug exposure (AUC= 83.6 mg• day/L) seen by a single curve in figure 5a. When weight-based dosing was considered for drug X, AUC for heavier subjects increased, as drug clearance was independent

[7] Mould and Green, "Pharmacokinetics and pharmacodynamics of monoclonal antibodies: concepts and lessons for drug development," *Biodrugs* 24:23–29 (2010).

> of weight (figure 5b). Conversely, for drug Y where weight does affect clearance, AUC decreased with weight when a flat dose was used (figure 5c) and can be 'normalized' by giving a weight-based (e.g. 0.5 mg/kg) dose (figure 5d).

(Mould 30.)

14. Mould states:

> Wang et al. [citation omitted] compared flat dosing to body size-based dosing for several approved mAbs. This work suggests that the choice between a flat or body size-based dose is dependent on the pharmacokinetic behavior of each mAb and the pharmacokinetic variability.

(Mould 30–31.)

16. Mould presents Table I, which indicates that eleven of the twenty-six listed monoclonal antibodies have been used with flat dosing. (Mould 25–26.)

Analysis

The Supreme Court instructs that

> [w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007). Thus, the availability of a finite number of identified, predictable solutions that are within the skill of the ordinary artisan may indicate that a solution to a

problem would have been obvious to try and, thus, unpatentable under 35 U.S.C. § 103.

Appellant does not contest that an anti-beta7 antibody with the hypervariable regions recited in claim 13 was known in the prior art or that it was known to be useful for subcutaneous administration in treating gastrointestinal inflammatory disorders in a human patient. (*See* Fong '082, 91:64, 153:47–155:29 (claims 1–14); *see* Office Act. 3.) Appellant does not contest that such treatment was previously known to involve dosing at specific concentrations based on the weight of the patient. (*See* Fong '082 92:43–44; *see* Office Act. 3.) Nor does Appellant contest that flat dosing (that is, using dosing that is the same for all patients regardless of weight (*see* Spec. ¶ 189)) was a known option for a dosing regimen that would be more convenient and would avoid potential dose calculation mistakes. (*See* Office Act. 6.)

Instead, Appellant argues that the prior art does not teach administration of a flat dose of beta7 antibody of between about 100 mg and about 220 mg and that the Examiner erred in performing a series of extrapolations to determine that doing so would have been obvious. (*See* Appeal Br. 11–12.)

Rejection over the Fong patents and the '508 publication

In the first rejection under 35 U.S.C. § 103, the Examiner determines that it would have been obvious to those of ordinary skill in the art to use a flat dose of the claimed anti-beta7 antibody because the '508 publication teaches a method of determining dosing regimens for the claimed antibody (which the '508 publication called "rhuMAb β7"), albeit in consideration of the effects of the antibody on a biomarker. (*See* Office Act. 4; *see* '508

publication ¶¶ 13, 14, 317, claims 3–25.) The Examiner finds that the '508 publication teaches evaluating pharmacokinetic and pharmacodynamic effects of a claimed anti-beta7 antibody, which, according to the Examiner, demonstrate a biphasic serum concentration with a fast initial distribution phase followed by a slower elimination phase. (*See* Office Act. 4.) The Examiner finds further that the data presented in the '508 publication indicates several other characteristics of the claimed anti-beta7 antibody, including dose-proportional pharmacokinetics in cynomolgus monkeys and full saturation of the beta7 receptors on peripheral blood T cell subsets. (*See* Office Act. 4–5.)

The Examiner concludes:

> That is the rate of elimination is first order kinetic in regard to rhuMAB β7 (i.e., proportional pk) concentration, the circulating level of drug decreases exponentially with time irrespective of the body weight. That is the effect of patient weight on rhuMAb β7 clearance and exposure was not considered clinically relevant. Accordingly, the rhuMAb β7 is a first order kinetic which qualifies the rhuMAb β7 for flat dose at a regular time interval base[d] on the rhuMAb β7 half-life of 14.5 days (~70 day to reach complete (97%) elimination). That is at steady state, the amount of drug lost in each interval equals the amount gained, that is the dose multiplied by the bioavailability.

(Office Act. 6.)

Appellant argues that the Examiner erred in concluding that the '508 publication provides the necessary information to determine that the claimed antibody would be appropriate for flat dose administration. (*See* Appeal Br. 21–39.) According to Appellant, one of ordinary skill would not derive a flat dose from a weight-based dose without knowing how body weight affects the pharmacokinetics, for example the clearance of the claimed

antibody. (*See id.*) Appellant points to the teachings of Mould in support of this argument. (*See* Appeal Br. 22–24.)

Mould, referring to Figure 5, explains that where weight is not an important predictor of clearance, a flat dose provides a uniform drug exposure, but that where weight affects clearance, flat dosing results in decreased drug concentrations and weight-based dosing is required to normalize drug concentrations. (*See* Mould 30; *see* FF 13.) Thus, the record supports Appellant's argument that the effect of weight on clearance is an important factor in deciding to use a flat dosing regimen. (*See also* Tang Declaration ¶ 8.)

We agree with Appellant that the Examiner's rejection under 35 U.S.C. § 103(a) based on only the Fong patents and the '508 publication does not provide a teaching that the effect of weight on clearance of an antibody is determinative of whether an antibody can be used at a flat dose. (*See* Appeal Br. 24.) Although the '508 publication provides pharmacokinetic and pharmacodynamic data for anti-β7 antibodies as claimed, the Examiner does not point to specific data indicating the effect of weight on clearance. We are not persuaded that the Examiner's findings about a biphasic profile, dose-proportionality, or saturation would have suggested flat dosing of an anti-beta7 antibody. (*See* Office Act. 4–5; *see* Ans. 22–23.)

We are also not persuaded that the term "repeated administration" in the '082 patent refers to administration at a fixed dose, as the Examiner finds. (*See* Office Act. 3.) The '082 patent states that "[f]or repeated administrations over several days or longer, depending on the condition, the treatment is sustained until a desired suppression of disease symptoms

occurs." ('082 patent 92:40–43.) The rest of this portion of the '082 patent provides only weight-adjusted doses. The Examiner does not explain how repeated administration of a weight-adjusted dose would become a fixed dose. Rather, a dose dependent on the patient's weight could be administered repeatedly. Accordingly, the record does not support the Examiner's finding that this language in the '082 patent teaches a fixed dose.

Because we are not persuaded that the prior art cited by the Examiner in the rejection under 35 U.S.C. § 103 over the Fong '236 patent, the Fong '082 patent and the '508 patent suggests a method of treatment comprising administering an anti-β7 antibody at a flat dose, we reverse the rejection.

Rejection over the Fong patents, the '508 publication, and Fasanmade

The Examiner entered a separate rejection under 35 U.S.C. § 103 over the Fong '236 patent, the Fong '082 patent and the '508 patent, as well as Fasanmade. (*See* Office Act. 21–31.) Fasanmade teaches the use of a program, NONMEM, to analyze data from clinical trials for the determination of pharmacokinetic characteristics of a monoclonal antibody (infliximab) that is different from the anti-beta7 antibody claimed. (*See* Fasanmade abstract; *see* Office Act. 21.) Fasanmade teaches modeling the effect of weight on antibody clearance. (*See* Fasanmade 1220, Table 4; *see* Office Act. 21.) The recommendation of Fasanmade is that infliximab should be administered according to body weight, not as a flat dose. (*See* Fasanmade 1227.)

The Examiner finds that it would have been obvious to use a fixed dose of an anti-beta7 antibody as claimed because it was known in the art to

perform modeling as taught in Fasanmade. (*See* Office Act. 22–23.) Specifically, the Examiner states:

> Determining the fixed dose formulation of a drug such as rhuMAb β7 is based on a pharmacokinetic and computer modeling analysis such as the one disclosed by Fasanmade et al. Both pharmacokinetic and computer modeling simulations are known in the art at the time the invention was made. Those skilled in the art would apply the know[n] methods of determin[ing] fixed dose formulation of rhuMAb β7/ etrolizumab, and [their] result would have been expected.

(Office Act. 23.)

The Examiner finds further that selection of a specific dose range could have been achieved through routine optimization because the concentration (i.e., dose) of antibody is a result effective variable. (*See* Office Act. 22–23.)

We are persuaded by the teachings in the prior art that the Examiner did not err. Even though, as Appellant argues, Fasanmade fails to disclose a flat dose of an anti-beta7 antibody, we are persuaded that it would have been obvious for a person of ordinary skill in the art to try a flat dose of anti-beta7 antibody as claimed with a reasonable expectation of success because the prior art teaches how to determine whether flat dosing is appropriate with several other monoclonal antibodies. (*See* Fasanmade abstract, 1220, Table 4.)

Appellant argues that conducting a population pharmacokinetic clinical trial is not routine optimization because there would not have been a reasonable expectation of success from such experimentation. (*See* Appeal Br. 40–43; *see* Reply Br. 18–19.) According to Appellant, the unpredictable nature of how body weight affects antibody exposure is demonstrated by the

choice of body weight-adjusted dosing for infliximab. (*See* Appeal Br. 41–42.) Appellant argues that the results taught in Fasanmade show that it is not possible to simply convert from a body weight dose to a flat dose. (*See id.* 42.)

We are not persuaded by this argument because the issue in the Examiner's second obviousness rejection is not whether the Examiner properly converted the body weight doses reported in the Fong patents and the '508 publication, but whether a method of treating gastrointestinal inflammation with the flat doses recited in claim 13 would have been obvious over those references in combination with Fasanmade. The Examiner's second obviousness rejection is not based solely on the conversion of a weight-based dose to a flat dose. Rather, it is based on the knowledge in the art of the pharmacokinetic and computer modeling techniques taught in Fasanmade. (*See* Office Act. 23.)

Despite the recommendation in Fasanmade of a body weight dose for infliximab, we are not persuaded by Appellant's arguments that there would not have been a reasonable expectation of success in treating a patient using a flat dose with the claimed anti-beta7 antibody. (*See* Appeal Br. 41–42; *see* Reply Br. 19.) Fasanmade concludes that "a body weight-adjusted dosing (as is approved for infliximab) is necessary to allow equivalent exposure among all patients to mitigate a possible weight-related influence of infliximab exposure." (Fasanmade 1223.) Thus, Fasanmade demonstrates that those of ordinary skill in the art were aware of the criteria that determine success with a flat dose — the effect of weight on antibody clearance.

> The teaching of Fasanmade is reflected in Mould, which states:
>
> Wang et al. [citation dated 2009 omitted] compared flat dosing to body size-based dosing for several approved mAbs. This work suggests that the choice between a flat or body size-based dose is dependent on the pharmacokinetic behavior of each mAb and the pharmacokinetic variability.

(Mould 30–31.) Mould also provides a table of antibodies and their corresponding dosing means, with flat dosing for eleven out of the twenty-six listed antibodies. (*See* Mould 25–26, Table I.) Thus, Mould, along with Fasanmade, demonstrates that not only were the criteria for flat dosing known in the art, it was known that these criteria had been met for several other antibodies. The claimed anti-beta7 antibody was not the first antibody to be found appropriate for flat dosing. We find that in light of these other antibodies those of ordinary skill would have had a reasonable expectation that flat dosing of the claimed anti-beta7 antibody would have been successful.

The case law tells us that a "reasonable" expectation of success does not require absolute certainty of success. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165–66 (Fed. Cir. 2006), *citing In re O'Farrell,* 853 F.2d 894, 903–04 (Fed.Cir.1988) ("Obviousness does not require absolute predictability of success . . .[A]ll that is required is a reasonable expectation of success."). The question of whether there would have been a reasonable expectation of success depends on the facts of the situation. *See Par Pharm., Inc. v. TWI Pharm., Inc.,* 773 F.3d 1186, 1196 (Fed. Cir. 2014).

When other methods similar to a claimed method have been successful, the court has determined there would have been a reasonable expectation of success. For example, in *Velander v. Garner*, 348 F.3d 1359,

1379 (Fed. Cir. 2003), a reasonable expectation of success was found for a method of producing a particular protein when several other proteins had been produced in a similar way.

The court has also determined that the availability of specific instructions to achieve the claimed subject matter can form the basis for a reasonable expectation of success. In *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1367–68 (Fed. Cir. 2007), a reasonable expectation of success was found where the prior art included several references with directions for narrowing the possible salts previously approved and the result could be verified by routine trial-and-error procedures.

In contrast, where a method or product was the first of its kind, the case law has indicated there would not have been a reasonable expectation of success in achieving the result. *See Amgen, Inc. v. Chugai Pharm. Co.,* 927 F.2d 1200, 1207–08 (Fed. Cir. 1991) (holding that there was not a reasonable expectation of success in isolating a gene encoding a specific protein where none of the prior art references suggested that screening a human genomic library would be likely to succeed in pulling out the gene of interest and no one else had successfully used the technique for that purpose).

Both Fasanmade and Mould indicate that flat dosing had previously been considered, and used, with antibody therapies and Fasanmade provides a framework for determining whether antibody clearance is affected by body weight. Thus, we are not persuaded that those of ordinary skill in the art would not have had a reasonable expectation of success in using the claimed anti-beta7 antibody at a flat dose.

Furthermore, Mould explains that there were three known dosing regimens at the time: (1) flat dosing, (2) body-weight dosing, and (3) Bayesian individualized dosing in response to a measurement. (*See* Mould 30.) Accordingly, there were a finite number of solutions to the problem of drug dosing.

Appellant presents the declaration of inventor Meina Tao Tang in support of its arguments. (*See* Declaration Under 37 C.F.R. § 1.132, submitted May 1, 2017 (Exhibit H) ("Tang Declaration").) Dr. Tang does not address Fasanmade or the knowledge in the art of determining whether weight affects clearance of antibodies. Accordingly, the Tang Declaration does not persuade us that the Examiner erred.

Appellant also argues that there would not have been a reasonable expectation of success in the claimed method because the success rate in developing large molecule drugs is extremely low. (*See* Appeal Br. 42.) This argument is unpersuasive because the Fong patents demonstrate it was known the claimed anti-beta7 antibody could be used to treat gastrointestinal inflammatory diseases. (*See, e.g.,* Fong '082, 153:47–156:29, claims 1–14.) The issue of this appeal is not whether it would have been expected that the claimed antibody would work, but rather whether the claimed anti-beta7 antibody could successfully be used in a flat dose. Appellant fails to persuade us that success would not have been reasonably expected.

The Examiner finds further that the specific flat dose recited in claim 13, "between about 100 mg and about 220 mg" would have been obvious because concentration is an art-recognized result-effective variable, which can be routinely determined and optimized in the pharmaceutical arts. (*See* Office Act. 22–23.) Although we agree with Appellant that the Examiner's

conversion of the weight-based doses taught in the prior art to flat doses does not prove by itself that the flat dose range recited in claim 13 would have been obvious, we are persuaded that optimization to achieve the recited range would have been obvious.

As the Examiner notes, a change in concentration is normally not a patentable modification. *See In re Aller*, 220 F.2d 454, 456 (CCPA 1955). The Examiner's calculations do not provide the reason why one of ordinary skill would have chosen the claimed doses, but the calculations demonstrate that the claimed doses are not significantly different from the ranges of doses known in the art. That is, the Exmainer's calculations demonstrate that the claimed range of about 100 mg to about 220 mg is not drastically different from, but rather overlaps, the range of about 0.05 mg/kg to about 10 mg/kg taught in the Fong '082 patent for an average man of 70 kg (calculated to be 3.5 to 700 mg). (*See* Office Act. 3.)

Appellant argues that the Examiner inappropriately shifts the burden of presenting evidence that optimization of the doses reported in the prior art would not have been routine. (*See* Reply Br. 20.) Because we are persuaded that the prior art provides the reason, means, and expectation of success in choosing a flat dose for the claimed anti-beta7 antibody, and the claimed flat doses are not dramatically different from the doses taught in the prior art if they were administered as a flat dose, we are not persuaded that the Examiner erred.

Appellant does not present any separate arguments against the rejection of independent claims 74 or 77 or the claims that depend on claims 13, 74, and 77. Accordingly, we are not persuaded that the Examiner erred in rejecting these claims either.

Obviousness-type double-patenting

The Examiner rejected all of Appellant's claims under the doctrine of obviousness-type double-patenting over claims 1–14 of the Fong '082 patent in view of the '508 publication and optionally in view of Fasanmade. (*See* Office Act. 31–32.)

Appellant argues that the Examiner erred in theses rejections for the same reasons cited against the rejections under 35 U.S.C. § 103(a). As explained above, we are not persuaded that the Examiner erred in the §103(a) rejection over the Fong patents, the '508 publication, and Fasanmade. Accordingly, we are not persuaded that the Examiner erred in rejecting the claims under the doctrine of obviousness-type double-patenting either.

Conclusion

Upon consideration of the record and for the reasons given, we affirm the Examiner's rejection of Appellant's claims.

In summary:

Claims Rejected	**35 U.S.C. §**	**Basis**	**Affirmed**	**Reversed**
13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	103(a)	Fong '236, Fong '082, '508 publication		13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89
13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	103(a)	Fong '236, Fong '082, '508 publication, Fasanmade	13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	

13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	Obviousness-type Double Patenting	Fong ’082, ’508 publication, optionally Fasanmade	13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	
Overall Outcome			13, 17–19, 25, 26, 28–30, 33, 34, 65, 68, 69, 74–89	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136.

AFFIRMED