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In re Application of :
Yoshiro Niitsu *et al.* :
Application No. 13/836,060 : DECISION ON PETITION
Filed: March 15, 2013 :
For: TARGETING AGENT FOR CANCER CELL OR CANCER-ASSOCIATED FIBROBLAST :

This is a decision on the petition filed under 37 CFR 1.181 filed September 27, 2016, requesting that the Director exercise her supervisory authority and overturn the decision of the Director of Technology Center 1600 (Technology Center Director) of July 28, 2016, which decision granted-in-part the petition under 37 CFR 1.144 of April 23, 2015 to withdraw the restriction requirement that was made final in the Office action of February 27, 2015.

The petition is **GRANTED** to the extent that the restriction requirement made final in the Office action of February 27, 2015 is withdrawn.

BACKGROUND

A review of the file history shows that the above-identified application was filed March 15, 2013, and included claims 1 through 50.

A non-final Office action (requirement for restriction under 35 U.S.C. § 121 only) was issued on September 26, 2014. The requirement for restriction in the Office action of September 26, 2014 stated, in part, as follows:

> This application contains claims directed to the following patentably distinct species (i.e. retinoid vs. $(lipid)_m$-linker-$(retinoid)_n$ wherein n is 0). The species are independent or distinct because a retinoid such as adapalene would be structurally divergent from a lipid-linker such as DOPE-PEG 2000 and thus would confer contrasting chemical and physical reactivity. In addition,

these species are not obvious variants of each other based on the current record. Consequently, a search for every single species would be a serious search and/or examination burden if restriction were not required.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1-50 are generic.

* * *

Specifically, applicant is required to elect a particular retinoid or a particular $(retinoid)_m$-linker-$(retinoid)_n$, or a particular $(lipid)_m$-linker-$(retinoid)_n$ to be utilized in the instant composition. Alternatively, applicant may elect a particular retinoid or a particular $(retinoid)_m$-linker-$(retinoid)_n$, or a particular $(lipid)_m$-linker-$(retinoid)_n$ listed in claims 2, 3, 5, 6, 7, 8, 10, 12, 26, 27, 29, 30, 31, 32, 34 or 36.

Additionally, the claims require addition of a drug to be used in concert with the targeting agent or anti-cancer agent/composition. Thus, applicant is further required to elect a particular inhibitor or suppressor or apoptosis or siRNA or antisense nucleic acid to be utilized in the aforementioned composition. Alternatively, applicant may elect a particular inhibitor or suppressor or apoptosis or siRNA or antisense nucleic acid as listed in claims 43 or 46.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

A reply to the Office action of September 26, 2014 was filed on December 22, 2014. The reply of December 22, 2014 included an election, with traverse, of retinoic acid as the species of retinoid and siRNA as the species of drug. Claims 1-2, 4-26 and 28-50 were indicated to read on the elected species. Petitioners also amended claims 1 and 25 to require a retinoid by deleting the possibility that $n = 0$ in $(retinoid)_n$.

A non-final Office action was issued on February 27, 2015. The non-final Office action of February 27, 2015 made final the restriction requirement in the Office action of September 26, 2014. The Office action of February 27, 2015 treated claims 1, 2, 15 through 26, 39 through 43, 45, 46, and 48 through 50 on the merits, and held claims 3 through 14, 27 through 38, 44, and 47

withdrawn from consideration as being drawn to nonelected subject matter. A reply to the Office action of February 27, 2015 was filed on May 26, 2015.

A petition was filed on April 23, 2015 challenging the restriction made final in the Office action of February 27, 2015. A Technology Center Director decision was issued on June 8, 2015 upholding the restriction made final in the Office action of February 27, 2015.

A petition was filed on August 5, 2015, and supplemented on September 18, 2015, seeking supervisory review by the Director of the United States Patent and Trademark Office (USPTO) of the decision of June 8, 2015, and challenging the restriction made final in the Office action of February 27, 2015

The undersigned issued a decision on May 31, 2016 vacating the decision of June 8, 2015, and returning the above-identified application to the Assistant Deputy Commissioner for Technology Centers 1600 and 1700 for assignment to a different Technology Center Director for decision on the petition of April 23, 2015.

A different Technology Center Director issued a decision on July 28, 2016 granting-in-part the petition filed on April 23, 2015.

A non-final Office action was issued on August 31, 2016 maintaining the prior restriction requirement and treating previously withdrawn claims 44 and 47 on the merits.

The instant petition under 37 CFR 1.181 was filed on September 27, 2016. The petition of September 27, 2016 requests supervisory review by the Director of the USPTO of the Technology Center Director decision of July 28, 2016, and requests that the election of species requirement that was the subject of the petition of April 23, 2015 be vacated, the Office action of August 31, 2016 be vacated, and that the examiner be required to issue a new Office action that addresses petitioners' reply of May 26, 2015.

STATUTE AND REGULATION

35 U.S.C. § 121 provides that:

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and

Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Director may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

37 CFR 1.141 provides that:

> (a) Two or more independent and distinct inventions may not be claimed in one national application, except that more than one species of an invention, not to exceed a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form (§ 1.75) or otherwise include all the limitations of the generic claim.
>
> (b) Where claims to all three categories, product, process of making, and process of use, are included in a national application, a three way requirement for restriction can only be made where the process of making is distinct from the product. If the process of making and the product are not distinct, the process of using may be joined with the claims directed to the product and the process of making the product even though a showing of distinctness between the product and process of using the product can be made.

37 CFR 1.142 provides that:

> (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.
>
> (b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

37 CFR 1.143 provides that:

> If the applicant disagrees with the requirement for restriction, he may request reconsideration and withdrawal or modification of the requirement, giving

> the reasons therefor. (See § 1.111). In requesting reconsideration the applicant must indicate a provisional election of one invention for prosecution, which invention shall be the one elected in the event the requirement becomes final. The requirement for restriction will be reconsidered on such a request. If the requirement is repeated and made final, the examiner will at the same time act on the claims to the invention elected.

37 CFR 1.144 provides that:

> After a final requirement for restriction, the applicant, in addition to making any reply due on the remainder of the action, may petition the Director to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested (see § 1.181).

37 CFR 1.146 provides that:

> In the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable. However, if such application contains claims directed to more than a reasonable number of species, the examiner may require restriction of the claims to not more than a reasonable number of species before taking further action in the application.

OPINION

Petitioners assert that the Technology Center Director decision of July 28, 2016 should be reversed and vacated. Petitioners specifically argue that: (1) the Technology Center Director decision of July 28, 2016 did not comply with the undersigned's decision on May 31, 2016;[1] and

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[1] The decision on May 31, 2016 returned the application to the Assistant Deputy Commissioner for Technology Centers 1600 and 1700 for assignment to a different Technology Center Director for decision on the petition of April 23, 2015. The Assistant Deputy Commissioner for Technology Centers 1600 and 1700 assigned the decision to a different Technology Center Director and that different Technology Center Director rendered a decision (issued on July 28, 2016) on the petition of April 23, 2015. The decision of July 28, 2016, however, does not present the issues pertaining to the manner in which this decision was rendered as the decision of June 8, 2015. Nevertheless, given that this decision in essence decides the petition of April 23,

(2) the restriction requirement made final in the Office action of February 27, 2015 (as modified by the decision of July 28, 2016) does not comply with the requirements of section 808.01 of the Manual of Patent Examining Procedure (MPEP).

The Office action of September 26, 2014 required petitioners to elect a particular **retinoid** [Species Group A], or a particular **(retinoid)$_m$-linker-(retinoid)$_n$** [Species Group B], or a particular **(lipid)$_m$-linker-(retinoid)$_n$** [Species Group C], or alternatively petitioners could elect a particular retinoid or a particular (retinoid)$_m$-linker-(retinoid)$_n$, or a particular (lipid)$_m$-linker-(retinoid)$_n$ listed in claims 2, 3, 5, 6, 7, 8, 10, 12, 26, 27, 29, 30, 31, 32, 34 or 36. This restriction requirement was made final in the Office action of February 27, 2015.

A requirement for restriction must contain two aspects: (1) the reasons (as distinguished from the mere statement of conclusion) why each invention *as claimed* is either independent or distinct from the other(s); and (2) the reasons why there would be a serious burden on the examiner if restriction is not required. *See* MPEP § 808.

There is no adequate case of patentable distinctness between the Species Group A, Species Group B, and Species Group C as set out in the Office action of September 26, 2014. The examiner states that "[t]he species are independent or distinct because a retinoid such as adapalene would be structurally divergent from a lipid-linker such as DOPE-PEG 2000 and thus would confer contrasting chemical and physical reactivity." *See* Office action of September 26, 2014 at 2. This explanation addresses only distinctiveness between Species Group B and Species Group C (as originally presented). It does not address distinctiveness between Species Group A and Species Group B, or distinctiveness between Species Group A and Species Group C. Moreover, there is no explanation of distinctiveness between Species Group B **(retinoid)$_m$-linker-(retinoid)$_n$**) and Species Group C ((**lipid)$_m$-linker-(retinoid)$_n$**), where n is 1, 2, or 3 (*i.e.*, where n is not zero) as now claimed.

Accordingly, the election of species requirement as between a **retinoid** [Species Group A], or a **(retinoid)$_m$-linker-(retinoid)$_n$** [Species Group B], or a **(lipid)$_m$-linker-(retinoid)$_n$** [Species Group C] does not comply with MPEP § 808 and is withdrawn.

his decision does **not** foreclose the examiner from imposing a restriction (election of species) requirement, provided that the requirement for restriction (election of species) provides (1) the reasons (as distinguished from the mere statement of conclusion) why each invention *as claimed*

2015 *de novo*, and results in the withdrawal of the restriction requirement made final in the Office action of February 27, 2015, petitioners' concerns over the manner in which the decisions of June 8, 2015 and July 28, 2016 were rendered and request that the Assistant Deputy Commissioner review of any further Technology Center Director decision concerning the restriction requirement made final in the Office action of February 27, 2015 are now moot.

is either independent or distinct from the other(s), and (2) the reasons why there would be a serious burden on the examiner if restriction is not required. *See* MPEP § 808.

With respect to petitioners' request the Office action of on August 31, 2016 be vacated: The vacatur of an Office action is an extreme measure, and the above-identified application simply does not present a situation that would warrant vacatur of any of the Office actions of September 26, 2014, February 27, 2015, or August 31, 2016. In view of this decision, however, the Office action of on August 31, 2016 is withdrawn.

DECISION

For the reasons given above, the petition is **GRANTED** to the extent that the restriction requirement made final in the Office action of February 27, 2015 is withdrawn. This decision is **without** prejudice to the examiner imposing a new restriction (election of species) requirement, provided that the new requirement for restriction (election of species) complies with the requirements of MPEP § 808.

This decision moots the petition under 37 CFR 1.182 for expeditious review of the petition filed on September 27, 2016.

The above-identified application is being forwarded to Technology Center 1600 for an Office action on the pending claims that is consistent with this decision and responsive to the reply filed on May 26, 2015.

Robert W. Bahr
Deputy Commissioner for
Patent Examination Policy