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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/528,011	11/16/2021	Adam Marc Silverstein	080618-2032	3309

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
05/17/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 17/528,011	Applicant(s) Silverstein et al.	
	Examiner Mina Haghighatian	Art Unit 1616	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 04/04/23.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-17 and 19-24 is/are pending in the application.

5a) Of the above claim(s) 21-24 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-17 and 19-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the **AIA**.

Receipt is acknowledged of Amendments, Remarks and Election filed on 04/04/23. Claims 12-17 and 19-20 have been amended, claim 18 has been canceled and no new claims have been added. Accordingly, claims 1-17 and 19-24 remain pending. Claims 21-24 are withdrawn and **claims 1-17 and 19-20** are under examination on the merits.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 04/04/23 is acknowledged.

Claims 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Suggestion:

In claim 16, the abbreviation FDKP should spelled out for clarity.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

Claims 1-2, 4-9, 11-14 and 19-20 are rejected under 35 U.S.C. 102(a)(2) as being anticipated by Dake et al (US 20200360377).

Dake et al teach inhalable **imatinib** formulations. Disclosed is a method of micronizing **imatinib particles**; suspending the micronized imatinib particles in a solution and spray drying the suspended micronized imatinib particles. The said micronized particles comprise a mass median aerodynamic diameter in the range of **0.5-5 µm** (See claims 1-2).

Dake et al disclose that **inhalable imatinib** compounds may be micronized to achieve the desired particle size for **dry powder** formulations for inhalation. Imatinib or appropriate salts thereof may be micronized to particle sizes of about 0.5 µm to **about 5 µm** mass median aerodynamic diameter (MMAD) for desired deep lung penetration (See [0007] and [0023]).

Disclosed are compounds and methods which can be used to treat PAH as well as **pulmonary hypertension**. Dose ranges can include between about **10 mg to about 100 mg per dose** for **inhalation** on a twice to four times per day schedule. About **0.1**

mg to about 20 mg of the active **imatinib** compound may then be present within the lungs after inhalation (See [0010]).

Dake et al disclose embodiments where, **imatinib or salts** thereof are provided in **dry powder formulations** for i**nhalation**. Dry powder can be administered via **dry powder inhalers**. Dry powder compounds may be divided into **single doses for single**, twice daily, three times daily, or four times daily inhalation to treat disorders such as PAH or other conditions of the pulmonary cardiovascular system. The single doses may be divided into **individual capsules** or other formats compatible with the **dry powder inhaler** to be used (See [0049]).

The said pharmaceutical compositions contain **from 0.1 to 99.5%** (more preferably, 0.5 to 90%) of **active ingredient** in combination with a pharmaceutically acceptable carrier (See [0071]).

The inhalable formulation may further include one or more carrier agents (See [0017]).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1-2, 4-14, 17 and 19-20 are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Surber (Wo 2015017728 or US20150044288) (the citations are from US document**).**

Surber teach formulations of **imatinib** or a phenylaminopyrimidine derivative compound for aerosolization and use of such formulations for inhaled aerosol administration of imatinib or a phenylaminopyrimidine derivative compound for the prevention or treatment of various fibrotic, diseases associated with the lung, heart, kidney, liver, etc. (See abstract).

Surber discloses a method for the treatment of lung disease in a mammal comprising administering a pharmaceutical composition comprising **imatinib** or salt thereof, wherein the said lung diseases is **pulmonary hypertension**, and the mammal is a human. The said pharmaceutical composition comprising imatinib or salt thereof is administered with a nebulizer, a metered dose inhaler, or **a dry powder inhaler**. The said dry powder composition comprises imatinib or salt thereof, at a concentration of **about 0.001% to about 100%** by weight of the weight of dry powder composition; optionally one of more carrier agents at a concentration of about 0.001% to about 99.999% by weight of the weight of dry powder composition and wherein the pharmaceutical composition is administered to the mammal with **a dry powder inhaler**. In some embodiments, the dry powder inhaler **delivers** from **about 0.001 mg to about 200 mg of imatinib** or salt thereof to the lungs of the mammal in less than about 10 breaths, wherein the mass median diameter (MMAD) particles sizes are from about 1 to about 5 microns (See at least [0021], claims 7 and 14-15).

Surber discloses a pharmaceutical composition for pulmonary delivery, comprising **a dry powder** containing **imatinib** or salt thereof, having a dosage content greater than about 1%, a **single-use container** comprising from **about 0.01 mg to about 100 mg dry powder** or from about 0.001 mg to about 200 mg dry powder

containing imatinib or salt thereof. In some embodiments, **the dose** content is at least 1 mg or 4 mg imatinib or salt thereof (See [0068]).

In some embodiments, the inhaling step is performed **in less than about 3 breaths** or in 1 breath (See [0043]). The imatinib may be the **mesylate** salt (See [0111], [0134] and [0144]).

Surber discloses that the said formulations may comprise a carrier or excipient, including solid carriers or excipients such as starch, lactose, dicalcium phosphate, sucrose, and kaolin (See [0217] and [0341]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 and 19-20 are rejected under 35 U.S.C. 103 as being unpatentable over Surber (Wo 2015017728 or US20150044288) (the citations are from US document**) in view of Wilson et al (WO 2014144895).**

Surber's teachings are delineated above and incorporated herein.

Surber lacks a specific disclosure on the excipient being diketopiperazine of FDKP. This is known in the art as shown by Wilson et al.

Wilson et al teach DKP microcrystals made by an improved method where they do not irreversibly self-assemble into microparticles. The microcrystals can be dispersed by atomization and re-formed by spray drying into particles having spherical shell morphology. Active agents and excipients can be incorporated into the **particles** by spray drying a solution containing the components to be incorporated into microcrystalline **diketopiperazine particles**. In particular, the microcrystalline particle compositions are suitable for **pulmonary drug delivery** of one or more peptides, proteins, etc, (see Abstract).

Disclosed are **powders** comprising a plurality of substantially uniform, microcrystalline particles, wherein the particles have a substantially hollow spherical structure and comprise a shell which can be porous, and comprises crystallites of a diketopiperazine that do not self-assemble (see [0007]-[0008]).

Wilson et al disclose an inhalation system comprising a **dry powder inhaler**, a dry powder formulation comprising microcrystalline particles of **fumaryl diketopiperazine** having an FDKP trans isomer content between 45% and 65% and

one or more than one active agents, the dry powder formulation being in a **unit dose** cartridge. Alternatively, the dry powder formulation can be preloaded in the inhaler. The inhalers can discharge greater than 85% of a powder medicament contained within a container during dosing. In certain embodiments, the inhalers can discharge greater than 85% of a powder medicament contained in **a single inhalation**. In one embodiment, the inhalers can discharge greater that 90% of the cartridge contents or container contents in less than 3 seconds at pressure differentials between 2 and 5 kPa with fill masses ranging up **to 30 mg** (See [0039]-[0041]).

The drug or active agent may be any active agent or biologic. drug content to be delivered on microcrystalline particles formed from FDKP can typically be greater than 0.01 % (w/w), such as from about 0.01 % (w/w) to about 75 % (w/w) (See [0083]-[0084]).

The stability of the particle can be enhanced by small amounts of a surfactant, such as polysorbate-80, in the DKP solution from which the particles are precipitated (See [0071] and claim 15).

Wilson et al disclose drug delivery systems comprising an inhaler with or without a cartridge, wherein the cartridge is a **unit dose** dry powder medicament **container** comprising the particles disclosed herein and an active agent. The delivery system for use with the dry powders includes an inhalation system comprising a high resistance inhaler having air conduits which impart a high resistance to airflow through the conduits for deagglomerating and dispensing the powder.

It would have been *prima facie* obvious to a person of ordinary skilled in the art at the time the invention was made to have combined the teachings of Wilson et al with that of Surber to arrive at the instant invention. It would have been obvious to do so because Surber teach dry powder formulations comprising imatinib mesylate and a carrier/excipient for effective delivery of the imatinib to the subject's lung for treating diseases such as pulmonary hypertension. On the other hand, Wilson et al disclose improved delivery by providing crystalline diketopiperazine compositions comprising microcrystalline diketopiperazine particles having high capacity for drug adsorption yielding powders having high drug content of one or more active agents. Said powders can deliver increased drug content in lesser amounts of powder dose, which can facilitate drug delivery to a patient. As such one of ordinary skill in the art would have been motivated to have taken guidance from Wilson et al's teachings and have incorporated Wilson et al's diketopiperazine, especially FDKP into the dry powder formulations of Surber to produce a more efficient dry powder formulation comprising and delivering imatinib to a subject in need thereof.

In other words, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Claims 1-2, 9-14 and 17 are rejected under 35 U.S.C. 103 as being unpatentable over Egashira (WO 2007119601).

Egashira teach **nanoparticles** comprising a platelet-derived growth factor (PDGF) receptor tyrosine kinase inhibitor such as **imatinib** with bio-absorbable polymeric nanoparticles for the treatment of vascular smooth muscle cells growth diseases (See abstract).

It is disclosed that very preferably, **imatinib** is used in the form of its **monomesylate** salt (See page 7, 2nd para and claim 5).

Egashira also disclose that it was now surprisingly found that intracellular delivery of PDGF receptor tyrosine kinase inhibitors by nanoparticle technology represent an advantageous therapeutic strategy for vascular smooth muscle cells growth diseases such as primary **pulmonary hypertension**. Hence, teaching nanoparticles comprising a PDGF receptor tyrosine kinase inhibitor (See page 1, last para and page 7, 5th para).

It is also disclosed that, the term "nanoparticles" refers to particles of a mean diameter of about 2.5 nm to **about 1000 nm** (See page 7, last para).

The administration may be by one or more routes including intravascularly, intranasally, intra-bronchially, **respiratory tract**, etc, (See page 12, last para).

The said pharmaceutical compositions comprise approximately from 1 % to 100 %, especially from approximately 1 % to approximately **20 %**, **active ingredient** (See page 20, 1st para).

It would have been *prima facie* obvious to a person of ordinary skilled in the art at the time the invention was made to have followed the teachings of Egashira to arrive at the instant invention. It would have been obvious to do so because Egashira

teach particulate formulations comprising active agents including imatinib mesylate for treating diseases such as pulmonary hypertension via respiratory tract. While the term inhalation is not expressly used by Egashira, it is clear from the disclosure that the delivery route may be via respiratory tract that inhalation is clearly envisioned.

As such one of ordinary skill in the art would have been motivated to have followed Egshira's teaching by preparing a dry powder formulation comprising imatinib mesylate for inhalation into the lung of the subject for treating pulmonary hypertension with a reasonable expectation of success

The claims would have been obvious because a person of ordinary skill has good reasons 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.

Claims 1-17 and 19-20 are rejected under 35 U.S.C. 103 as being unpatentable over Smutney et al (8,636,001 or US 20090308391) (the citations from US '391**) in combination with Egashira (WO 2007119601).**

Smutney et al teach a breath-powered, **dry powder inhaler**, a cartridge, and a pulmonary drug delivery system, which can be provided with or without **a unit dose cartridge** comprising a drug delivery formulation comprising a **diketopiperazine** and **an active ingredient** (See Abstract and [0008]).

The **fumaryl diketopiperazine** (**FDKP**) is one preferred diketopiperazine for pulmonary applications (See [0199]).

In one embodiment, a dry powder inhalation kit is provided comprising a dry powder inhaler, one or more medicament cartridge comprising a dry powder formulation for treating a disorder or disease such as **respiratory tract disease**, diabetes and obesity (See [0029] and [0231]).

Smutney et al disclose a dry powder medicament comprising a **diketopiperazine** and a pharmaceutically **active ingredient**. The said pharmaceutically active ingredient or active agent **can be any type** depending on the disease or condition to be treated (See [0196]). It is disclosed that the said active agents may be interleukin 2-inducible tyrosine kinase, Bruton's tyrosine kinase (BTK), inositol-requiring kinase 1 (IRE1), or analogs, active fragments, etc, (See [0226]).

Smutney et al disclose a method of delivering an active ingredient comprising: a) providing dry powder inhaler containing a cartridge with a dry powder formulation comprising a diketopiperazine and the active agent; and b) delivering the active ingredient or agent to an individual in need of treatment. The dry powder inhaler system can deliver a dry powder formulation such as insulin **FDKP** having a respirable fraction greater than 50% and **particles sizes** less than **5.8 µm** (See [0228]).

Microparticles having a diameter of between **about 0.5 and about 10 microns** can reach the lungs, successfully passing most of the natural barriers (See [0202] and [0217]).

Smutney et al disclose that cartridges can be configured to deliver **a single unit,** pre-metered dose of **a dry powder medicament,** such as a dose of **from 0.1 mg to about 50 mg** of a dry powder formulation (See [0168]). The flow rates result in greater than 75% of the cartridge contents dispensed in fill masses between **1 and 30 mg** of

powder. A **single inhalation** maneuver can produce a cartridge dispense percentage of greater **than 90%.** The said inhaler and cartridge system are configured to provide a **single dose** by discharging powder from the inhaler as a continuous flow, or **as one** or more pulses of powder delivered to a patient (See [0187]).

Smutney et al lack a specific disclosure on the active agent being imatinib or the disorder being pulmonary hypertension. These are known in the at a shown by Egashira.

Egashira's teachings are delineated above and incorporated herein.

It would have been *prima facie* obvious to a person of ordinary skilled in the art at the time the invention was made to have combined the teachings of Egashira with that of Smutney et al to arrive at the instant invention. It would have been obvious to do so because Smutney et al teach dry powder formulations comprising the combination of a drug and a diketopiperazine can impart improved drug stability and/or absorption characteristics, which can be administered by inhalation to specific areas of the respiratory system, including the lung, as a dry powder. While Smutney et al list a number of suitable active agents, they lack a express disclosure on including imatinib or treating pulmonary hypertension. Egashira also teach particulate formulations comprising active agents including imatinib mesylate for treating diseases such as pulmonary hypertension via respiratory tract.

As such one of ordinary skill in the art would have been motivated to have substituted Egshira's active agents into the dry powder formulations of Smutney et al

with a reasonable expectation of success because Smutney et al disclose that combining diketopiperazine, especially FDKP with any active agent improves the stability and absorption of the active agent and would therefore improve the treatment.

It is generally considered to be prima facie obvious to substitute components which are taught by the prior art to be well known and useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for substituting them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the substituting conventional active agents for a dry powder formulation delivered by inhalation and for treating a disorder. It therefore follows that the instant claims define prima facie obvious subject matter. Cf. *In re Ruff,* 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

Additionally, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Claims 1-9, 11-16 and 19-20 are rejected under 35 U.S.C. 103 as being unpatentable over Dake et al (US 20200360377) in view of Smutney et al (8,636,001 or US 20090308391) (the citations from US '391**).**

Dake et al teach inhalable **imatinib** formulations. Disclosed is a method of micronizing **imatinib particles**; suspending the micronized imatinib particles in a

solution and spray drying the suspended micronized imatinib particles. The said micronized particles comprise a mass median aerodynamic diameter in the range of **0.5-5 µm** (See claims 1-2).

Dake et al disclose that **inhalable imatinib** compounds may be micronized to achieve the desired particle size for **dry powder** formulations for inhalation. Imatinib or appropriate salts thereof may be micronized to particle sizes of about 0.5 µm to **about 5 µm** mass median aerodynamic diameter (MMAD) for desired deep lung penetration (See [0007] and [0023]).

Disclosed are compounds and methods which can be used to treat PAH as well as **pulmonary hypertension**. Dose ranges can include between about **10 mg to about 100 mg per dose** for **inhalation** on a twice to four times per day schedule. About **0.1 mg to about 20 mg** of the active **imatinib** compound may then be present within the lungs after inhalation (See [0010]).

The inhalable formulation may further include one or more carrier agents (See [0017]).

Dake et al lack a specific disclosure on the formulations comprising diketopiperazine. This is known in the art as shown by Smutney et al.

Smutney et al's teaching are delineated above and incorporated herein.

Specifically, Smutney et al teach a breath-powered, dry powder inhaler, and a pulmonary drug delivery system, comprising a drug delivery formulation comprising a diketopiperazine and an active ingredient. The diketopiperazine is preferably fumaryl

diketopiperazine (FDKP) and the said formulations are effective for treating disorders or diseases such as respiratory tract disease.

It would have been *prima facie* obvious to a person of ordinary skilled in the art at the time the invention was made to have combined the teachings of Smutney et al and Dake et al to arrive at the instant invention. It would have been obvious to do so because Dake et al teach a method of treating pulmonary hypertension by administering an inhalable imatinib particulate formulation to the subject in need of such treatment. Smutney et al teach dry powder formulations comprising the combination of a drug and a diketopiperazine which can impart improved drug stability and/or absorption characteristics, which can be administered by inhalation to specific areas of the respiratory system, including the lung, as a dry powder. As such one of ordinary skill in the art would have been motivated to have incorporated Smutney et al's diketopiperazine especially FDKP into the particulate formulations of Dake et al with a reasonable expectation of success because Smutney et al disclose that combining diketopiperazine, especially FDKP with any active agent improves the stability and absorption of the active agent and would therefore improve the treatment.

In other words, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Claims 1-17 and 19-20 are rejected. Claims 21-24 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached M-F, 7-5 EST.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on 571-272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616