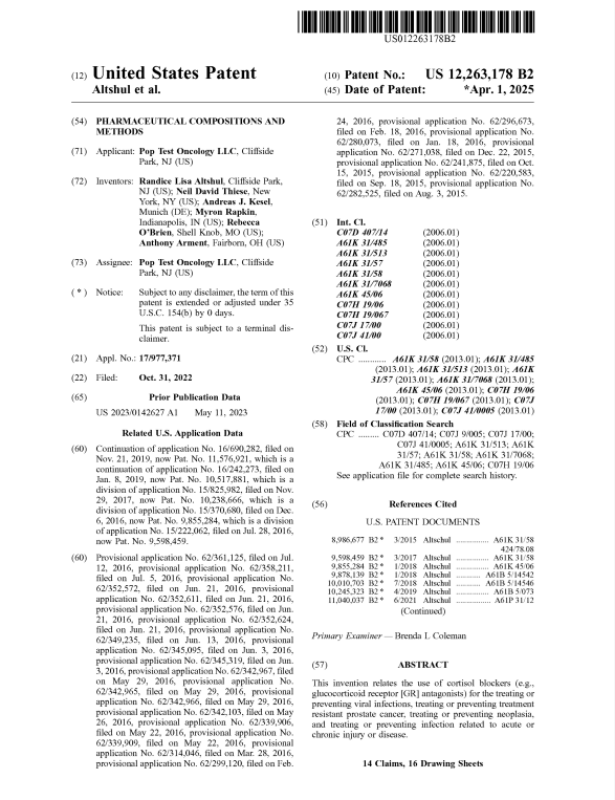
Palisades Therapeutics Granted Breakthrough Patent for Novel Addiction Treatment

Next-Generation Compounds Show Promise

Pop Test/Palisades Therapeutics



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Altshul et al.

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(54) **PHARMACEUTICAL COMPOSITIONS AND METHODS**

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(60) Continuation of application No. 16/690,282, filed on Nov. 21, 2019, now Pat. No. 11,576,921, which is a continuation of application No. 16/242,273, filed on Jan. 8, 2019, now Pat. No. 10,517,881, which is a division of application No. 15/825,982, filed on Nov. 29, 2017, now Pat. No. 10,238,666, which is a division of application No. 15/370,680, filed on Dec. 6, 2016, now Pat. No. 9,855,284, which is a division of application No. 15/222,062, filed on Jul. 28, 2016, now Pat. No. 9,598,459.

(60) Provisional application No. 62/361,125, filed on Jul. 12, 2016, provisional application No. 62/358,211, filed on Jul. 5, 2016, provisional application No. 62/352,572, filed on Jun. 21, 2016, provisional application No. 62/352,611, filed on Jun. 21, 2016, provisional application No. 62/352,576, filed on Jun. 21, 2016, provisional application No. 62/352,624, filed on Jun. 21, 2016, provisional application No. 62/349,235, filed on Jun. 13, 2016, provisional application No. 62/345,095, filed on Jun. 3, 2016, provisional application No. 62/345,319, filed on Jun. 3, 2016, provisional application No. 62/342,967, filed on May 29, 2016, provisional application No. 62/342,965, filed on May 29, 2016, provisional application No. 62/342,966, filed on May 29, 2016, provisional application No. 62/342,103, filed on May 26, 2016, provisional application No. 62/339,906, filed on May 22, 2016, provisional application No. 62/339,909, filed on May 22, 2016, provisional application No. 62/314,046, filed on Mar. 28, 2016, provisional application No. 62/299,120, filed on Feb. 24, 2016, provisional application No. 62/296,673, filed on Feb. 18, 2016, provisional application No. 62/280,073, filed on Jan. 18, 2016, provisional application No. 62/271,038, filed on Dec. 22, 2015, provisional application No. 62/241,875, filed on Oct. 15, 2015, provisional application No. 62/220,583, filed on Sep. 18, 2015, provisional application No. 62/282,525, filed on Aug. 3, 2015.

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CPC ***A61K 31/58*** (2013.01); ***A61K 31/485*** (2013.01); ***A61K 31/513*** (2013.01); ***A61K 31/57*** (2013.01); ***A61K 31/7068*** (2013.01); ***A61K 45/06*** (2013.01); ***C07H 19/06*** (2013.01); ***C07H 19/067*** (2013.01); ***C07J 17/00*** (2013.01); ***C07J 41/0005*** (2013.01)

(58) **Field of Classification Search**

CPC C07D 407/14; C07J 9/005; C07J 17/00; C07J 41/0005; A61K 31/513; A61K 31/57; A61K 31/58; A61K 31/7068; A61K 31/485; A61K 45/06; C07H 19/06

See application file for complete search history.

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Primary Examiner — Brenda L Coleman

(57) **ABSTRACT**

This invention relates the use of cortisol blockers (e.g., glucocorticoid receptor [GR] antagonists) for the treating or preventing viral infections, treating or preventing treatment resistant prostate cancer, treating or preventing neoplasia, and treating or preventing infection related to acute or chronic injury or disease.

14 Claims, 16 Drawing Sheets

US Patent 12,263,178

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Next-Generation Compounds Show Promise

At the heart of this innovation are newly developed compounds known as PT155, PT156, PT157, and PT158. These are advanced analogs of PT150, a Phase 2 clinical-stage therapeutic that has already demonstrated safety and efficacy in preclinical and clinical studies.

PT150 has been successfully tested preclinically for alcohol use disorder, addiction and sign-

tracking by Mark Prendergast, PhD, Professor, University of Kentucky Neuroscience Program-Substance Use.

In addition, Michael Bardo, PhD, Professor, University of Kentucky Cognitive Neuroscience Program, has been testing PT150 successfully for opioid use disorder in preclinical models.

What sets these new compounds apart is their ability to achieve greater effectiveness at lower doses compared to PT150.

These next-generation compounds represent a significant leap forward in addiction treatment. By improving on PT150's already promising results, we're opening doors to more effective therapies with potentially fewer side effects.

Personalized Treatment Approach
The patented method introduces a personalized approach to addiction treatment. It involves a unique testing process to measure a patient's cortisol levels - a hormone associated with stress. This allows healthcare providers to determine if a patient is suitable for treatment with these new compounds, which act as glucocorticoid receptor (GCR) antagonists.

Building on Strong Foundations
The development of these compounds builds upon the success of PT150, which has been the subject of extensive research. Recent studies funded by the Department of Defense (DoD) with Principal Investigator Christopher Verrico, PhD, at the Michael E. DeBakey VA Medical Center, have yielded successful results in a pharmacokinetic (PK) study entitled: Effects of Ethanol on the Pharmacokinetics of PT-150 and in an alcohol interaction study entitled: Clinical Trial to Evaluate the Safety of PT150 When it is Taken Concurrently With Alcohol. This success has led to further investigations, with ongoing studies including at the University of Kentucky entitled: PT150 Drug for Use in Alcohol Use Disorder with Principal Investigator Mark Fillmore, PhD, funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

Versatile Delivery Methods
The patent covers various delivery methods for these compounds, including traditional capsules and tablets, as well as our cutting-edge smart pill and smart capsule delivery devices. This versatility ensures that the treatment can be adapted to meet individual patient needs.

Comprehensive Care Potential
The patent also allows for the potential combination of these new compounds with existing medications, including certain anxiolytics, antidepressants, and neuroleptics. This multi-faceted approach aims to provide more comprehensive care for individuals struggling with addiction.

A New Hope in Addiction Treatment
As communities worldwide continue to grapple with the opioid crisis and other addiction-related issues, innovations like this offer new hope. This patented approach represents a significant step

forward in the field of addiction treatment, potentially offering more effective, tailored therapies to those affected by substance use disorders.

With its combination of advanced compounds, personalized approach, and versatile delivery methods, this newly patented treatment strategy stands poised to make a significant impact in the ongoing battle against addiction.

An Industry Call to Action
With government funding for addiction research facing cuts, Palisades Therapeutics is inviting industry leaders such as GlaxoSmithKline (NYSE: GSK), Pfizer Inc (NYSE: PFE) and Otsuka Holdings Co., Ltd. (OTSKF); to explore partnerships. This is an opportunity for private-sector innovators to step in and accelerate the development of life-changing therapies in the fight against addiction.

As addiction rates continue to rise globally, this breakthrough marks a critical step forward in addressing one of society's most pressing health crises.

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