Advanced Patent Prosecution Workshop 2021:

*Claim Drafting & Amendment Writing*

**Chemical / Pharmaceutical**

In-Class Problems 1-8

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# PLI Chemical/Pharmaceutical PracticeIn Class Problem 1

# A patent application was filed January 2, 2019, which describes new fungicidal compounds.

# Claim 1 recites:

# 1. A compound having the formula

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or a salt, polymorph, or solvate thereof.

Claim 1 is rejected for lack of written description and enablement. The Examiner argues that the specification does not describe any polymorphs or solvates of the claimed compound. The Examiner further argues that polymorphism is unpredictable and that the specification does not describe any procedures for obtaining the claimed polymorphs.

Please draft a response to the rejection.

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 2

Professor DeGreat of First University and his graduate student Jason DeNormal invented a new class of fusion proteins. First University, having invested millions of dollars into Professor DeGreat’s research, filed a patent application (the ‘111 Application) directed to this new class of fusion proteins listing DeGreat and DeNormal as inventors. Claims 18-20 of First University’s application reads:

18. A bidomain protein or peptide comprising a transglutaminase substrate domain and a polypeptide growth factor.

19. The bidomain protein of claim 18, wherein the trans glutaminase substrate domain is a Factor XlIIa substrate domain.

20. The bidomain protein of claim 18, wherein the polypeptide growth factor is TGFβ.

Shortly after inventing the new class of fusion proteins, Professor DeGreat left First University for Second University. At Second University, Professor DeGreat made certain bidomain proteins containing a transglutaminase substrate domain (such as a Factor XIIIa substrate domain) and a growth factor (such as vascular endothelial growth factor (VEGF)). Second University filed a patent application and obtained the ‘222 Patent which includes the following claim:

1. A fusion protein, comprising:

(i) a first protein domain selected from the group consisting of the platelet derived growth factor superfamily and the transforming growth factor beta (TGFβ) superfamily;

(ii) a second protein domain, which is a crosslinking Factor XIIIa substrate domain; and

(iii) an enzymatic or hydrolytic cleavage site between the first and second domains.

Claims 18-20 of the ‘111 Application have now been rejected for obviousness-type double patenting over claim 1 of the ‘222 Patent.

**Questions**

Does obviousness-type double patent patenting apply when an application and a patent have one or more inventors in common but inventive entities are not identical and the application and the patent were never commonly owned?

Can a terminal disclaimer be filed to overcome the rejection?

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 3

A patent application claims the following process for making difluoromethane (CH2F2):

1. Process for the manufacture of difluoromethane consisting essentially of gas-phase catalytic fluorination of methylene chloride with anhydrous hydrofluoric acids in the presence of 0.1 to 5 moles of oxygen per 100 moles of methylene chloride, at a temperature of between 330 and 450° C and with a bulk or supported chromium catalyst.

Claim 1 has been rejected as anticipated by a Japanese prior art reference (JP 51-82206). JP ‘206 discloses the fluorination of methylene chloride with anhydrous hydrofluoric acids in the presence of 0.001 to 1 moles of oxygen per 100 moles of methylene chloride and at a temperature of 100 to 500 °C to yield difluoromethane. The fluorination reaction in the Japanese reference is performed with a supported chromium catalyst.

Is claim 1 anticipated?

Please draft an argument for why claim 1 is not anticipated.

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 4

# The CEO of Quack Pharma, who happens to be a multi-billionaire, hypothesized that gelatin topically applied could treat hair loss. Quack Pharma performs a clinical study on 60 balding Italian men between December 2018 and May 2019 to test this hypothesis. The clinical investigators (i.e., the doctors in charge of the study in Italy) signed confidentiality agreements with Quack Pharma, but the 60 patients did not. The 60 patients did sign consent forms acknowledging that they are taking part in a clinical study.

# Miraculously, the clinical study shows that gelatin is more effective for treating hair loss than Rogaine®.

# Quack Pharma files a patent application in July 2019.

1. Is the clinical trial prior art to the patent application?
2. Please assume that gelatin has previously been topically applied to strengthen long hair. Draft a claim to the method of treatment, which is arguably not anticipated.

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 5

# Chemical company DO-NOT-ROT filed two patent applications. While the two applications list different inventors, both are assigned to DO-NOT-ROT.

# The first application was filed on December 1, 2018 and published on June 5, 2019. The first application includes an example of a preservative formulation containing components A and B at a weight ratio of 1:5.

The second patent application was filed on April 1, 2019, without claiming priority to any other applications. The second application includes the following claim:

1. A preservative formulation comprising (i) component A and (ii) component B, wherein the weight ratio of A to B ranges from about 1:1 to about 1:7.

Claim 1 has been rejected as anticipated under 35 U.S.C. §102(a)(2) by the first patent application.

Is the rejection proper?

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 6

A pending patent application discloses certain coumarin compounds useful as dyestuffs. Claim 1 reads as follows:

1. Coumarin compounds useful as dyestuffs, which in one of their mesomeric limiting structures correspond to the general formula

wherein

X represents aldehyde, azomethine, or hydrazone,

R1 represents hydrogen or alkyl,

Z1 represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2-or 3-membered alkylene radical connected to the 6-position of the coumarin ring and

Z2 represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2-or 3-membered alkylene radical connected to the 8-position of the coumarin ring

and wherein

Z1 and Z2 conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dyestuff chemistry.

Claim 1 has been rejected on the judicially-created basis that it contains an improper Markush grouping of alternatives. The Examiner argues that the alternatives do not share a substantial structural feature. Each of the species listed falls into a different USPTO subclass. The Examiner argued:

A reference anticipating one member of the listed groups would not render any other member obvious under 35 U.S.C. §103. The members are not so few in number or so closely related that a search and examination of the entire claim cannot be made without serious burden.

Furthermore, the types of derivatives encompassed by the Markush claim may include polyfused N-heterocyclics, cyclic, acyclic and aromatic amines, aryloxyalkylamines, amides, sulfonamides, phthalimides, quaternary ammonium salts, phosphorous heterocyclics, phosphates, aldehydes, azomethines, hydrazones, ethers, esters, halogens, alcohols, nitriles, piperidines, furanes, pyrroles, indoles, amongst others. It is clear that the compounds cannot be considered functionally equivalent.

1. Please draft a response to this rejection.

2. Is the rejection proper?

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 7

On October 17, 2012**,** a compound known as "A1,"

A1:

which is an inhibitor of enzyme E and potentially useful for treatment of Alzheimer's Disease, was disclosed in the U.S. on a Power Point slide at a conference by a University graduate student. The student had obtained information about A1 from the lead inventor, who is a professor at University. The disclosure was not authorized by the University or the professor.

On December 20, 2012, a third party researcher who was present at the October 17, 2012 conference disclosed the graduate student's material (including the structure of A1) in a blog entry about novel methods of treating Alzheimer's Disease. The third party researcher went on to speculate about additional structurally similar compounds which may be active as inhibitors of enzyme E and for treatment of Alzheimer's Disease:

 I suspect that derivatives with other halogen or small

alkoxy groups at the phenyl group would also be active against

Enzyme E. I’m thinking of filing a patent on this once I figure

out how to make them. Does anyone know how to file a patent?

On April 30, 2013, University files a first provisional patent application 001P, claiming novel compounds of genus A, and discloses their utility for inhibiting enzyme E and for treatment of Alzheimer's Disease. Application 001P discloses species A1-A50, all of which are within genus A.

**GENUS A:**

X, Y and Z are each independently selected from the group consisting of C1-4 alkyl and C1-4 alkoxy, each of which are optionally substituted with halogen and cyano;

R1, R2 and R3 are each independently selected from the group consisting of hydrogen, halogen, C1-4 alkyl, and C1-4 alkoxy.

On April 30, 2014, University files a PCT application and a US non-provisional application 001NP, which are identical to 001P.

**Questions:**

1. Does the University have a valid claim to species A1 in the US? What about in the EPO and Japan? What about a claim to genus A?
2. Would the answers change if 001P was filed 3/3/2013?
3. Assume for this answer that 001P was filed 3/3/2013. In early July 2013, your client comes to you and says his group has identified a new species A51:

He suggests that you “supplement the application that we already filed to add this compound.” How do you respond to the inventor’s request on A51? What’s the best strategy for obtaining patent protection for A51?

1. Your application was filed 4/3/2013. It is later discovered that Innovator Company independently synthesized species A1 on 12/20/2012 and filed a Japanese patent application on 1/2/2013. Who has patent rights to species A1?
2. Does your answer change if your application was filed 3/3/2013?

# PLI Chemical/Pharmaceutical PracticeIn Class Problem 8

You are prosecuting a patent application claiming compounds for treating schizophrenia. Your application has a US provisional filing date of 1/2/2017, and a non-provisional US filing date of 1/2/2018. The application is owned by New York University, and the inventors are Ben Franklin, John Adams and George Washington.

Claim 1 is a species claim for the following compound:

On April 1, 2019, claim 1 is rejected on obviousness-type double patenting grounds over claims 1 and 15 of a granted U.S. patent, also to New York University, in which Ben Franklin is the sole inventor. The patent application was filed as a US non-provisional on 1/4/2017, and granted March 1, 2019:

wherein

R1 is selected from the group consisting of hydrogen, C1-6 alkyl, or C1-4 alkyl–phenyl;

R2 is hydrogen;

R3 is selected from the group consisting of hydrogen or C1-6 alkyl;

R4 is selected from the group consisting of hydrogen or C1-6 alkyl;

R5 is selected from the group consisting of phenyl, which may be substituted by 1 to 3 identical or different groups selected from halogen, C1-4 alkyl or C1-4 alkoxy;

X is halogen;

m is 0, 1 or 2;

n is 0, 1 or 2; and

q is 1 or 2;

or a pharmaceutically acceptable salt thereof.

Dependent claim 15 is a species claim for the following compound:

How do you respond to the double patenting rejection?