**Chemical / Pharmaceutical**

Online Homework Set

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Advanced Patent Prosecution Workshop 2021:

*Claim Drafting & Amendment Writing*

# PLI Chemical/PharmaceuticalProblem 1: Claim Drafting Homework

You receive an invention disclosure form in July 2019 from your client Moe which reads as follows:

Dear Patent Attorney,

This is Moe from the Russian Institute of Chemistry. I was very impressed with the last patent application that you drafted for me. I would like you to draft another application regarding my new invention directed to hydroxy modified statins.

As you know, the term statin refers to a class of pharmaceutical drugs which are used to treat patients with hypercolesterolemia, hyperlipoproteinemia, and atherosclerosis, and to prevent coronary disease and heart attacks. The statins act to lower the amount of LDL cholesterol (bad cholesterol) in the blood stream by inhibiting the HMG-CoA reductase enzyme which catalyzes the rate determining step in the biosynthesis of cholesterol. Decreasing the rate of production of cholesterol leads to a reduction of LDL in the bloodstream which in turn reduces the risk of coronary disease. Several different statins have been developed, including:





I have found that by adding a hydroxyl group to the fourth carbon of pravastatin as shown below, a five-fold increase in its activity is observed. I am very excited about this discovery, and would like to acquire a patent on it as soon as possible. I think that it would be important to get as much protection as possible, so I would like claims for the compound itself, its pharmaceutical composition, and its use for treatment of high cholesterol. If there are additional claims that would be permitted, please include them as well.

I used the same synthetic scheme as the prior art (US Patent No. 6,123,456) for synthesis of pravastatin, but I included a methoxymethyl (MOM) ether group (a protected hydroxy group) at the fourth carbon of pravastatin, and at the end of the reaction I deprotected the hydroxy group at this position.

As you know, the Russian Institute of Chemistry is a leading supplier of pravastatin because of a secret special reagent named the “Moe reagent.” The synthetic pathway depicted in US Patent No. 6,123,456 is prone to side reaction. The use of the “Moe Reagent” eliminates these side reactions altogether, drastically reducing the amount of impurities. Indeed all commercial processes for preparation of pravastatin use the Moe Reagent, as without the reagent, unacceptable levels of impurities form, and chromatography has to be performed to remove the impurities.

As you can appreciate, in anticipation of the continuing commercial success of this reagent, I do not want its chemical composition disclosed in the application. But to increase its sales and to create a buzz, please emphasize its criticality in the application for synthesis of hydroxy modified pravastatin.

I assume that I have given you all of the information that you need to draft a patent application for me, but I feel that I should mention one fact that is potentially troublesome. A scientist at a research institute published a journal article five years ago that obtained the hydroxy-modified pravastatin as a metabolite from the blood of patients taking pravastatin. Its structure, as a free acid, is illustrated in the article. There was no indication of its therapeutic activity in the article.

I would really appreciate if my colleague Curly could receive credit as a co-inventor. As I am sure that you are aware, in Russia inventors have an absolute right to share in the profits from a patent and I believe that Curly is entitled to a share. I first became aware of hydroxy-modified pravastatin when Curly presented me with the above journal article and exclaimed, “Hey Moe, take a look at this metabolite! I wonder if it has any therapeutic activity. It would be great if we could synthesize it, and it turns out to be even more therapeutically active than other statins.” I considered how the hydroxy-modified statin could be synthesized, and when I had decided on an approach, I gave instructions to Curly so that he could perform the synthesis. Curly then told me that he had synthesized the statin following my instructions, and asked how he should prepare it for testing. I told him that he should look to the pharmaceutical formulations given in the prior art for commercial pravastatin tablets, and use the same approach. Afterwards, I told Curly to run tests on laboratory animals to determine its effectiveness. As lab mice were in short supply, Curly recruited graduate students (who were told this was a requirement for graduation) to participate in the experiment. He divided the students into two groups, with the control group receiving pravastatin and the experimental group receiving hydroxy modified pravastatin. After testing the LDL content in the blood of the students following their treatment, Curly organized the data into a table which revealed the increased activity of hydroxy-modified pravastatin. He reported these results to me, and I agreed that they were conclusive.

In addition, my boss, Larry has strongly hinted to me that he should also be named as an inventor. He did not directly contribute to the discovery, but he has discussed my work with me at every step along the way, he provides all of the infrastructure necessary for me to have made my discovery, and pays my salary.

I would like to have a teleconference with you after you send us a draft of the application.

Sincerely,

Moe

**Problem #1.1** Draft claims to hydroxy-modified pravastatin, its pharmaceutical composition, and use thereof for treatment of cholesterol.

**Problem #1.2** Assume there is no prior art. You speak with Natasha, an intern at your firm, who tells you that she thinks you should draft broader claims for the compound. She says that you can extend the claim to include all of the statins with a hydroxyl substitution at the fourth carbon. She also suggests that you could generalize further to include, ratherthan just a hydroxy group, all of the C1 to C200 alkoxy groups. Finally, she says that in addition to the alkoxy groups, you should claim each of the halogens as substitutes at the fourth carbon. And perhaps also claim an alkoxy group on the third carbon. Draft a single claim to the compound broadly**,** incorporating Natasha’s suggestions only to the extent that they are appropriate.

**Problem #1.3** A teleconference has been set up between you and Moe to discuss your opinions regarding various issues. How would you discuss these issues during the teleconference:

a. Are there any problems with the best mode requirement?

b. Does the disclosure enable ‘‘how to make” the invention?

c. Who are the inventors for each type of claim (compound, composition, process of preparation, and method of treatment claims)?

d. Are any of the claims you drafted for Problem 1.1 anticipated, or obvious in light of the prior art?

 Does the journal article anticipate the claims?

 Is the clinical study performed on graduate students prior art?

**Problem #1.4** Assume there is no prior art. Moe has prepared the hydroxy-modified pravastatin as a sodium salt. This is the first salt ever reported for this compound. Draft the broadest claim possible (do not include other statins).

**Problem #1.5** Moe tells you, however, that there is another sodium salt in the prior art. The prior art teaches a crystallization process for obtaining the sodium salt of hydroxy-modified pravastatin in a toluene solution. Moe’s crystallization method uses a pentane solution. He heats up the solution to 40°C, then cools to 0°C to crystallize the salt, and obtains a salt with a higher melting point. You are asked to claim this method of crystallization. A summer associate offers you some unsolicited advice that you should broaden the claim to include all of the alkanes from C1 to C5 solvents. He also says that you can claim the method of crystallization utilizing water as a solvent instead of pentane. Draft the broadest claim to the process of preparing the salt that you find to be legitimate.

**Problem #1.6** Moe and Curly conceived of the hydroxy-modified compounds while in Russia. Shortly after conception of these compounds, Moe became a visiting professor in the U.S. Curly was received a grant to work at the same university in the U.S. While in the U.S., Curly synthesized and tested the compounds. Is a U.S. foreign filing license required before a patent application can be filed outside the U.S.?

**Problem #1.7** While looking through the file, you find an X-ray diffraction (XRD) pattern of Moe’ hydroxy modified sodium salt. Draft one or more claims to the hydroxyl modified sodium salt incorporating the XRD data. The most intense peaks in the XRD pattern are observed at 7.2, 7.8, 13.8, 15.9, 20.6, 21.8, 22.2, 23.3, and 24.5° 2Θ.

**PLI Chemical/Pharmaceutical****Problem 2: Amendment Writing Homework**

You are given the following disclosure, which had been previously filed in the European Patent Office (EPO) on May 8, 2017, and published on November 8, 2018. This application is assigned to your client, and you are handling its U.S. prosecution.

## THE INVENTION

A new alloy composition has been discovered of controlled proportions in respect of certain elemental constituents notably nickel, chromium, molybdenum, columbium, iron, titanium and aluminum, which provides desired levels of high strength, corrosion resistance, durability and other important characteristics, including good fabricability, useful in the production of wrought products and other manufactured articles. Thus, a particular object of the invention, though not limited thereto, is to provide a corrosion-resistant, high-strength, ductile alloy for production of tubing, particularly gas and/or oil well tubing.

## EMBODIMENTS OF THE INVENTION

Generally speaking, and in accordance with present invention, the alloy contemplated herein contains by weight about 15 % to 22% chromium, 10% to 28% iron, 6% to 9% molybdenum, 2.5 % to 5% columbium, 1% to 2% titanium, up to 0.5% aluminum, advantageously 0.05% to 0.1 % aluminum, with the balance being essentially nickel, the nickel constituting 45% to 55%. Auxiliary elements, including malleablizers and deoxidizers, can be present in small amounts such as: up to 0.1% carbon, up to 0.35% silicon, up to 0.5%, e.g., 0.35% manganese, up to 0.01 % boron, and also residual small amounts of cerium, calcium, lanthanum, misch metal, magnesium, neodymium and circonium such as may remain from additions totaling up to 0.2% of the furnace charge. Tolerable impurities include up to about 1%, e.g., up to 0.5%, copper, up to 0.015% sulfur and up to 0.015% phosphorous. Up to about 0.15% or 0.2% nitrogen and up to 3% vanadium can be present.

Tungsten and tantalum may be present in incidental percentages, such as are often associated with commercial sources of molybdenum and columbium, respectively, e.g., 0.1% tungsten or 0.1 % tantalum. Tungsten may be employed in amounts up to 3% in certain instances in lieu of an equivalent percentage of molybdenum. Even so, it is preferred to hold the tungsten level to a low percentage to avoid occurrences of deleterious amounts of undesired phases, e.g., laves phase, particularly at the higher percentages of chromium, molybdenum and iron. Tantalum can be substituted for columbium in equi-atomic percentages, but is not desired in view of its high atomic weight.

In carrying the invention into practice, and to derive the benefits conferred by chromium, iron, molybdenum, columbium, titanium, aluminum, and nickel, etc. including strength, ductility, corrosion resistance, fabricability, and also good durability in the type of corrosive environments above-mentioned, care should be exercised in respect of achieving proper compositional balance. For example, reducing chromium and molybdenum much below the levels given above can result in a needless loss of corrosion resistance. Chromium can be employed up to 25% with enhanced corrosion resistance to be expected. Molybdenum contents down to 5%, though not recommended, can be used, particularly at the higher chromium levels, e.g., 22-25%, and particularly where less aggressive corrosive media are involved.

In striving for optimum corrosion resistance the molybdenum content advantageously should be at least 6.5% and, preferably, at least 7%, together with a chromium content of at least 20%, the sum of the chromium plus molybdenum preferably being 27% or more. However, this focuses attention on workability. Unless care is exercised there is the risk that objectionable precipitates may form, e.g., laves phase, in detrimental quantities, which, in turn, can lead to cracking during, for example, hot and/or cold rolling to produce sheet and strip. This is particularly true when high percentages of columbium, 4% are present together with molybdenum percentages of 7-7.5% or more. It is deemed that columbium exercises a greater adverse impact on workability than does molybdenum.

With regard to the percentage of iron, amounts down to 5% can be utilized. It is believed that the higher iron levels, say above 20%, assist in H2S environments but may detract from resistance to stress corrosion cracking. At the lower iron levels, resistance to stress corrosion cracking is improved though resistance to the effects of H2S may not be quite as good. An iron range of from 5 to 15% is deemed advantageous.

Aluminum imparts strength and hardness characteristics, but detracts from pitting resistance if present to the excess. Accordingly, it should not exceed about 0.5%, and, preferably, is held below about 0.25 or 0.3%;

While it is preferred that 1% of more titanium be present in the alloys of the instant invention, percentages as low as 0.5% can be employed, particularly in conjunction with columbium at the higher end of its range, say 3.5 or 4% and above. Titanium up to 2.5% can be utilized in the interest of strength.

Where particularly close control is desired, possibly for promoting consistency of desired results, the composition can be specially restricted with one or more of the ranges of 54% to 58% nickel, 18.5% to 20.5% chromium, 13.5% to 18% iron, 6.5% to 8% molybdenum, 3% to 4.5% columbium, 1.3% to 1.7% titanium and 0.05% to 0.5% aluminum.

For achieving advantageously high strength and maintaining good ductility, workability and other desired results, the alloy composition is more closely controlled to have titanium and columbium present in amounts balanced according to the proportioning sum: %Ti plus ½ (% Cb) equal to at least 3% and no greater than 4%. For instance, about 1.5% titanium and about 4% columbium, such as 1.3% to 1.7% Ti and 3.6% to 4.4% Cb, are advantageous in alloys of the invention.

## EXAMPLE I

A furnace charge of metal in weight percent of 50Ni/20Cr/18Fe/7Mo/3Cb/1.5Ti/0.1Al/0.03Mg was vacuum induction melted and cast-to-ingot form, the chemical analysis thereof (Alloy 10 and of certain other alloys of the invention, being set forth in Table 1.)

## Table I

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Cr | Fe | Mo | Cb | Ti | Al | C | Mn | Si | B | Cu | Mg | Ni |
| 1 | 20.09 | 17.55 | 7.06 | 3.02 | 1.49 | 0.13 | 0.03 | 0.18 | 0.26 | 0.0006 | NA | 0.011 | 50.23 |
| 2 | 18.73 | 13.89 | 6.60 | 4.29 | 1.45 | 0.35 | 0.02 | 0.29 | 0.19 | 0.0007 | 0.26 | 0.021 | 53.91 |
| 3 | 19.89 | 16.61 | 7.18 | 3.10 | 1.51 | 0.08 | 0.03 | 0.22 | 0.16 | 0.0006 | 0.06 | 0.016 | 51.14 |

NA - Not Analyzed.

Cobalt, phosphorous and sulfur, when analyzed, were found present in percentages of 0.011% or lower. Columbium percentages include possible small proportions of tantalum.

**Problem #2.1**  Draft a broad claim to an alloy of the invention.

**Problem #2.2** The examiner rejects a claim comprising 0.5-2% titanium on the grounds, that it is not supported by the specification, citing page 1, line 11 of the specification**:** (a) draft an argument that the claim is supported by the specification; (b) draft a claim which acceptably encompasses compositions containing 0.5% titanium (hint: Use proviso language to reflect the specified conditions in the specification).

**Problem #2.3**  The examiner also rejects a later added claim containing the phrase “and the balance nickel with nickel constituting about 45 to about 55% of the alloy” under section 112, on the ground that it is not supported by the specification. The Examiner argues:

The specification discloses that the invention is “An alloy containing about 15% to 22% chromium; 10% to 28% iron, 6.5 to 9% molybdenum; 2.5% to 5% columbium, 1% to 2% titanium, up to 1% aluminum, advantageously 0.05 to about 0;01% aluminum, ***and balance essentially nickel in a weight proportion of 45% to 55% of the alloy”.*** (emphasis added). The claim however, is not limited to the disclosure of the specification, but more broadly, and impermissibly, claims “about 45 to about 55%**.”**

The original disclosure lacks the term “about” before the percentages of the alloy, but the newly added claim has the word “about” before the percentages, unlike the original disclosure. The word “about” in the later added claim broadens the applicants original disclosure that indicates to one skilled in the art that his or her invention is to an approximate, not a precise, amount, range, or limit.

Furthermore, the word “‘about” makes the claims indefinite under § 112, ¶ 2, *see Amgen, Inc. v. Chugai Pharmaceutical Co*., 921 F.2d 1200, 1218,18 USPQ2d 1016; 1031 (Fed. Cir.), *cert. denied*; 502 U.S. 856 (1991).

## Draft a response to the rejection

**Problem#2.4** Meanwhile, on September 18, 2018, you are informed by the client that high levels of columbium adversely affect the workability of the alloy, and, to counter this undesirable occurrence, it has been found that the nickel content should be at least 52%, and most advantageously 54%, and up to 60%. Moreover, it has been found that such nickel levels markedly contribute to corrosion resistance. In this connection an upper nickel level of 58% is preferred since at 60% strength tends to drop off.

Draft an appropriate claim which is supported by the specification.

**Problem #2.5** You submit the drafted claim from Problem 2.4 in a new application on November 9, 2019. The examiner rejects the new application over the EP application which was published on November 8, 2018. Explain the examiner’s rejection, and present an argument in support of your new claim. Would it have made more sense to have filed a continuation application or a continuation in part (CIP) application instead of a new application which does not claim priority to any earlier applications?

**Problem #2.6** Based on this specification, a patent application was filed containing the following two claims:

1. An alloy consisting of the following percentage amounts of each of the following elements:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cr | Fe | Mo | Cb | Ti | Al | C | Mn | Si | B | Cu | Mg | Ni |
| 18.73 | 13.89 | 6.60 | 4.29 | 1.45 | 0.35 | 0.02 | 0.29 | 0.19 | 0.0007 | 0.26 | 0.021 | 53.91 |

2. A method of preparing an alloy comprising:

 (A) vacuum induction melting the following metals at the recited percentages:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cr | Fe | Mo | Cb | Ti | Al | C | Mn | Si | B | Cu | Mg | Ni |
| 18.73 | 13.89 | 6.60 | 4.29 | 1.45 | 0.35 | 0.02 | 0.29 | 0.19 | 0.0007 | 0.26 | 0.021 | 53.91 |

; and

 (B) casting the melt from step (A).

A restriction requirement was issued. The Examiner considered claims 1 and 2 to be two distinct inventions. The applicant elected claim 1 for further prosecution. The patent issued as U.S. Patent No. 8,888,888.

Just prior to issuance of the patent, a continuation-in-part (CIP) application was filed. The CIP application was identical to U.S. Patent No. 8,888,888 except it included one additional example. The CIP application also included only one claim -- claim 2 of the parent application.

Claim 2 has been rejected for obviousness-type double patenting over claim 1 of U.S. Patent No. 8,888,888. Please prepare a response to the rejection.