Advanced Patent Prosecution Workshop 2021:

Claim Drafting & Amendment Writing

Chemical/Pharmaceutical Answers for Homework Problem 2 and In-Class Problems 9-12

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PLI Chemical/Pharmaceutical Homework Problem 2 Answer

Problem 2.1: answer

A nickel-based alloy characterized by good workability and fabricability and further characterized in both the cold-rolled and aged conditions by high strength, good ductility and resistance to pitting, hydrogen embrittlement and stress-corrosion cracking said alloy consisting essentially in weight percent, about 10-28% iron, 15 to 22% chromium, about 6.5 to 9% molebdenum, about 2.5 to 5%-columbium, about 1% to 2.5% titanium, up to about 0.5% aluminum and the balance nickel with nickel constituting about 45 to about 55% of the alloy.

Problem 2.2: answer

A nickel-based alloy characterized by good workability and fabricability and further characterized in both the cold-rolled and aged conditions by high strength, good ductility and resistance to pitting, hydrogen embrittlement and stress-corrosion cracking said alloy consisting essentially of, in weight percent, about 15 to 25% chromium, about 5 to about 15% iron, about 6.5 to 9% molybdenum, about 2.5 to 5% columbium, from 0.5 to 2.5% titanium ***with the proviso that when the titanium is less than* 1% *the columbium is at least 3.5%***, up to about 0.5% aluminum and the balance nickel with nickel constituting about 45 to about 55% of the alloy.

Problem 2.3: answer

See Eiselstein v. Frank, 34 USPQ2d 1467, 1470-71:

The first paragraph of § 112 reads as follows:

> The specification shall contain a ***written description of the invention****,* and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. §§ 112, ¶ 1 (emphasis added)

"Satisfaction of the description requirement insures that subject matter presented in the form of a claim subsequent to the filing date of the application was sufficiently disclosed at the time of filing so that the prima facie date of invention can be fairly be held to be the filing date of the application." *Vas-Cath Inc.* v. *Mahurkar,* 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) quoting *In re Smith,* 481 F.2d 910, 914, 178 USPQ 620, 623-24 (CCPA 1973). In order to determine whether a prior application meets the "written description" requirement with respect to later-filed claims, the prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed. *Id.* at 1563, 19 USPQ2d at 1116; *see In re Wertheim,* 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976) ("[L]ack of literal support ... is not enough ... to support a rejection under § 112."). **The test is whether the**

disclosure of the application relied upon reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date. *Ralston Purina Co. v. Far-Mar·Co.*, *Inc.,* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (emphasis added). "Precisely how close the original description must come to comply with the description requirement of a § 112 must be determined on a case-by· case basis." *Vas-Cath,* 935 F.2d at 1561, 19 USPQ2d at 1116.

We submit that the quoted language from the specification does support the breadth of the claim.

The specification discloses:

> An alloy containing *about* 15% to 22% chromium, 10% to 28% iron, 65 to 9% molybdenum, 2.5% to 5% columbium, 1% to 2% titanium, up to 1% aluminum, advantageously 0.05 to about 0.1% aluminum, ***and balance essentially nickel in a weight proportion of 45% to 55% of the alloy***. (emphasis added).

Although in the specification the word "about" does not immediately precede the nickel range limits, according to standard English usage, the word "about" used before the first term of a series of elements applies to all members of that series. To require the use of "about" before every range would be both cumbersome and redundant.

The specification need not contain precisely the same words as are found in claim 8-18, *see Ralston,* 772 F.2d at 1576, 227 USPQ at 180; rather, the application simply must indicate to a person skilled in the art that the range 45% to 55% was intended to be approximate, *i.e.,* to mean "about." That is unmistakably the case.

The grandparent application describes an alloy comprised of a series of inexact ranges of elements with the balance of that composition described as "essentially nickel." "Essentially"' is a vague term. The description also connotes a degree of approximation, or imprecision, in that the nickel comprises the "balance" of the composition, an amount that varies with the amounts of the other components. The amount of nickel is clearly not the critical aspect of the invention, but only the residual amount, depending upon the amounts of the more critical elements. Furthermore; the grandparent specification contains the following statement after the alloy's description: "Auxiliary elements, including malleablizers and deoxidizers, can be present in permissible small amounts ... and residual small amounts of [other substances] can remain [with] tolerable impurities possibly present. The specification further instructs that, for certain applications, the composition of the alloy can be more "specially restricted" or "closely controlled" for more consistent or advantageous results.

In "Table 1" of the specification the chemical analysis of 3 sample alloys are set forth. The weight percent of each element in each alloy is listed to one-hundredth of a percent. Such a description indicates that the applicant knew how to be precise when he intended to, and supports the conclusion that otherwise, when a whole number was stated, a precise amount was not intended. Thus the applicant disclosed the invention of an alloy of various elements and the balance nickel, the nickel being an imprecise quantity, ***i.e.*** **from** ***about*** **45% to** ***about*** **55%** of said alloy and, on the basis of that disclosure, one skilled in the art reading the grandparent application would readily know that the applicant possessed that invention. The applicant need .

not be bound to maximum precision for the nickel content when the whole tenor of his disclosure indicates approximation.

In this case, it was clear error to find that a person skilled in the art would not have considered the grandparent application to describe an approximate range of nickel. The later use of the term "about" to describe the range of nickel did not constitute a change to a distinct and different invention, since the finding of the board concerning the disclosure of the grandparent application was clearly erroneous, the rejection of claims 8-18 based on that error was perforce erroneous as a matter of law.

Problem 2.4: answer

While it is correct that the word "about" in a later added claim can broaden an original disclosure that indicates to one skilled in the art that his or her invention is to a precise, not an approximate, amount range, or limit. Under such circumstances, the term "about" in the later added claim is new matter and may not receive the benefit of an earlier filing date. The meaning of the word . "about" is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art. *See In re Wertheim,* 541 F.2d at 262, 191 USPQ at 96. We are also mindful that the word "about" may lead to indefiniteness under 35 U.S.C. §112, second paragraph; *see Amgen, Inc.* v. *Chugai Pharmaceutical Co.,* 927 F.2d 1200, 1218, 18 USPQ2d 1016, 1031 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991), but that is not at issue here.

Either the specification would have to be amended to add the new matter, with a table of data in support, and a CIP application filed, or alternatively, you can attempt to stand on the original - claims, and argue later that they encompass compositions with nickel in the range 50-60%.

In the prosecution of U.S. Patent No. 4,788,036, it was decided to submit a new claim, reciting the preferred levels of nickel:

> A nickel-based alloy characterized by good workability and fabricability and further characterized in both the cold-rolled and aged conditions by high strength, good ductility and resistance to pitting. hydrogen embrittlement and stress-corrosion cracking said alloy consisting essentially of, in weight percent, about 15 to 25% chromium, about 5 to about 15% iron, about 6.5 to 9% molybdenum, about 2.5 to 5% columbium, from 0.5 to 2.5% titanium with the proviso that when the titanium is less than 1% the columbium is at least 3.5%, up to about 0.5% aluminum and the balance nickel with nickel constituting about 50 to about 60% of the alloy.

Problem 2.5: answer

Examiner's rejection:

> Claim __ is rejected under 35 U.S.C. § 102(b) as anticipated by the published EP application.

A potential response:

> The present application has been amended to claim priority to U.S. Patent Application No. _" filed May 8, 2018, which claims the benefit of European Patent Application No. _ filed May 8, 2017. The earlier filed U.S. application discloses a nickel content of "about 45 to about 55%." 50% is about 45% and 60% is about 55%. Thus the applicants have claimed a 10% range of nickel values, which is "about 45 to about 55% nickel."

If the priority claim in the new application is filed more than 4 months after its filing date, a , petition to accept art unintentionally delayed priority claim under 37 C.F.R. §1.78(a)(3) must be filed.

Problem 2.6: answer

To be discussed during the session. Below are some considerations for the discussion.

According to one panel of the Federal Circuit, a continuation-in-part is never entitled to double patenting shielding under 35 U.S.C. §121. *See Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc*., 518 F.3d 1353 (Fed. Cir. 2008).

A divisional application may be entitled to double patenting shielding pursuant to 35 U.S.C. §121 so long as the claimed subject matter of the divisional is commensurate in scope with the restricted subject matter from the parent application.

In *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.3d 1272 (Fed. Cir. 1992), the Federal Circuit stated that the claims must be considered as a whole in a double patenting analysis.

PLI Chemical/Pharmaceutical Practice
In Class Problem 9 - Answer

1. Is the best mode rejection proper?

The claims are arguably entitled to the filing date of the provisional application. At the time of the filing of the provisional application, the RP-1001 besylate salt was not known.

2. The '111 Application publishes on October 8, 2019. Assume the provisional application to the besylate salt of RP-1001 is filed November 1, 2019. Is the besylate salt obvious over the '111 Application?

In *Pfizer v. Apotex,* 480 F.3d 1348 (Fed. Cir. 2007), the court found the besylate salt of amlodipine obvious since there are only 53 previously FDA-approved anions.

> We similarly are not persuaded by Pfizer's second argument, as clear and convincing evidence shows that a skilled artisan would have been motivated to combine the '909 patent and Berge to make amlodipine besylate. Pfizer's expert, Dr. Anderson, testified that there were an unlimited number of anions, many of which could be used to form pharmaceutically-acceptable acid addition salts. Yet a reasonable fact-finder could not accept Dr. Anderson's testimony that the number of acceptable anions was "unlimited." Of course, new salts can always be made or attempted. However, irrefutable evidence shows that a skilled chemist at the time would simply make known pharmaceutically-acceptable salts of whatever active ingredient with which he or she was working at the time. Indeed, Mr. Davison, an inventor of the '303 patent, testified that it "would have been a mistake" to choose a novel anion. Rather, "part and parcel of pharmaceutically accepted[] was to look in pharmacopoeias and compendia" to find an anion having "precedence for use within the pharmaceutical industry." ….
>
> This is true especially given the fact that the genus of FDA-approved anions at the time was small, i.e., only 53. That benzene sulphonate was only used in creating 0.25% of FDA-approved drugs is not highly probative, much less dispositive. Indeed, beyond hydrochloride, which was used in approximately 43% of approved drugs, almost all other salts could be characterized as "rarely used." See Berge, Table 1 (showing that 40 out of 53 anions were used in less than 1% of drugs and 23 out of 53 were used in 0.25% or less of drugs).
>
> But the outcome of this case need not rest heavily on the size of the genus of pharmaceutically-acceptable anions disclosed by Berge because clear and convincing evidence establishes that, out of the list of 53 anions, one of ordinary skill in the art would have favorably considered benzene sulphonate because of its known acid strength, solubility, and other known chemical characteristics as reported in several other publications Pfizer has admitted are prior art. …

PLI Chemical/Pharmaceutical Practice
In Class Problem 10 - Answer

1. Text of amendment:

Claims 1-9 have been rejected as anticipated by or, in the alternative, as obvious over Quack.

Applicants respectfully traverse this rejection and request reconsideration.

Quack does not disclose or suggest that an extended release formulation of an erythromycin derivative would reduce the gastrointestinal side effects as recited in claim 1-4. Specifically, Quack does not disclose or suggest an extended release formulation containing a pharmaceutically acceptable polymer in combination with an erythromycin derivative.

The Examiner contends that it was known that extended release formulations reduce side effects. The Examiner has not cited any support for this assertion. Furthermore, not all extended release formulations reduce the side effects of a drug. For example, patients administered the drug OLD in both immediate and extended release formulations exhibit the same incidence of side effects. *See* Dang et al., … Accordingly, a skilled artisan would not have been motivated to reduce the gastrointestinal side effects of an erythromycin derivative, such as clarithromycin, by incorporating it into an extended release formulation.

It was also not known that the pharmacokinetic profile of the presently claimed extended release formulation would reduce side effects. It is only with the improper use of hindsight that a skilled artisan would have arrived at the presently claimed invention.

Claims 5-9 further recite that the pharmaceutical composition includes 5-50% of a pharmaceutically acceptable polymer. Quack does not disclose or suggest such a pharmaceutical composition.

Claims 1 and 5-9 have been rejected for lack of written description due to the term "erythromycin derivative." This term does not encompass any derivative as suggested by the Examiner. Rather, the term is explicitly defined in the specification and encompasses certain discrete derivatives. A skilled artisan reading the specification would understand that the applicants had possession of these derivatives as of the filing date of this application.

Claims 1 and 5-9 have been rejected for lack of enablement. A skilled artisan could make and use the recited pharmaceutical compositions containing an erythromycin derivative. The erythromycin derivatives defined in the specification have been previously disclosed. Syntheses for them are also known. See, for example, U.S. Patent Nos. XXX. Accordingly, applicants respectfully submit that the claims are enabled.

Based on *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 473 F.3d 1196 (Fed, Cir. 2007).

2. Claims 1-4 – There is an issue as to whether this claim covers an approved use. It appears to cover the use of clarithromycin for treating tonsillitis.

Claims 5-9 – There is an issue whether these claims which recite up to "about 50%" of pharmaceutically acceptable polymer would encompass a formulation with 57% of a polymer.

New claims:

10. A pharmaceutical composition for extended release of an erythromycin derivative in the gastrointestinal environment, comprising an erythromycin derivative and a pharmaceutically acceptable polymer, so that upon oral ingestion, maximum peak concentrations of the erythromycin derivative are lower than those produced by an immediate release pharmaceutical composition, and area under the concentration-time curve and the minimum plasma concentration are substantially equivalent to that of the immediate release pharmaceutical composition.

11. A method of treating a bacterial infection comprising administering an effective amount of an extended release pharmaceutical composition comprising an erythromycin derivative and a pharmaceutically acceptable polymer, wherein when ingested orally, the composition induces statistically significantly lower mean fluctuation index in the plasma than an immediate release composition of the erythromycin derivative while maintaining bioavailability substantially equivalent to that of the immediate release composition of the erythromycin derivative.

Use code: Pursuant to 21 C.F.R. 314.53(b)(1),

> "[the use code] must describe only the approved method(s) of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. If the method(s) of use claimed by the patent does not cover an indication or other approved condition of use in its entirety, the applicant must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. For approved NDAs, the NDA holder submitting information on the method-of-use patent must identify with specificity the section(s) and subsection(s) of the approved labeling that describes the method(s) of use claimed by the patent submitted."

See also 21 C.F.R. 314.53(c)(2)(ii)(P)(3). "[T]he scope of the use code must not extend beyond the scope of the patent claim(s) and, within the boundary established by the patent claim(s), the use code must only describe a patented method of use that has been approved by FDA as reflected in approved product labeling." 81 Fed. Reg. 69580, 69598 (Oct. 6, 2016). With

respect to patented methods of use that are broader than the approved indication, “the use code [needs] to be phrased more narrowly than the patent claim to only describe the specific patented method of use that is described in FDA-approved product labeling.” *Id*. at 69598-599. Accordingly, a possible use code is “Treatment of tonsillitis due to *S. pyogenes*.”

3. DumbCo may argue that the specification uses a closed definition of the term "pharmaceutically acceptable polymer," and the claim term should be limited to the examples listed in the specification (“a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidine, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.”). In particular, the specification states that the term “"pharmaceutically acceptable polymer is” selected from a list of possible polymers. Furthermore, DumbCo may argue that "claim drafters often use the term “group of” to signal a Markush group, which lists specified alternatives in a patent claim.... By its nature, a Markush group is closed." As DumbCo’s product does not have one of these polymers, there is no literal infringement.

DumbCo may also argue that its formulation does not include a polymer. GMS is not a polymer.

PlaceboPharma may argue that the term "pharmaceutically acceptable polymer" is not limited to the particular groups listed in the Markush language in the specification. The specification does not contain an express definition of the term "pharmaceutically acceptable polymer." Furthermore, limiting claim scope based on Markush language only applies when the phrase is used in the claims, not in the written description.

The written description does not provide an explicit definition of “pharmaceutically acceptable polymer.” Further, there is "no intentional disclaimer or disavowal of claim scope of the polymer limitation." Instead, the specification "merely identifies exemplary polymers that are suitable for use in the invention and does not provide a definition." Note that the specification explicitly defines other terms in the patent using the phrase “as used herein, [the term] means.”

Limiting the term "pharmaceutically acceptable polymer" to the groups recited in the specification would also "violate the doctrine of claim differentiation because claims 2 and 3, which depend from claim 1 expressly claim the more specific types of polymers to which the court limited the term."

PlaceboPharma may also argue that the correct construction of “pharmaceutically acceptable polymer” is the plain and ordinary meaning of the term, as understood by one of skill in the art upon reading the patent - for example, “any polymer, suitable for use in pharmaceutical compositions to be administered in humans that, alone or together with other polymers, is capable of forming a matrix to control and extend drug-dissolution release into the bloodstream.”

See Abbott, pages 1208-09.

There may be infringement under the doctrine of equivalents. The court found that Abbott demonstrated likelihood of success on infringement under the doctrine of equivalents. Andrx argues that GMS cannot be an equivalent of the "pharmaceutically acceptable polymer" term for two reasons: first, because it would violate the specific exclusion principle; and second, because a finding of equivalence would vitiate the claim limitation. We address each of these arguments in turn.

The specific exclusion principle limits what can be claimed under the doctrine of equivalents by mandating that "the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." According to Andrx, the pharmaceutically acceptable polymer excludes other forms of polymers such as hydrophobic or water insoluble substances such as waxes. Therefore, any equivalence that encompasses hydrophobic or water insoluble substances would violate the specific exclusion principle.

Andrx also argues that the doctrine of equivalents cannot vitiate a claim limitation, and that because GMS "is the exact opposite of the material recited in the claims of the '718 patent (polymer vs. nonpolymer (or hydrophilic water soluble polymer vs. hydrophobic water insoluble nonpolymer))."

Andrx also argues that GMS was well known in the prior art, but not claimed by Abbott in its claims. Therefore, Andrx contends, allowing GMS to infringe as an equivalent would seriously undermine the public notice function required by patent claims. Abbott argues that GMS is an equivalent of the polymer limitation under the function-way-result test. Andrx may also argue that "[a] finding of equivalency under the doctrine of equivalents is a fact-specific inquiry. It does not require a revision of the claim language or limitation."

PLI Chemical/Pharmaceutical Practice
In Class Problem 11 - Answer

Problem 11.1: answer

A process for the dehydration of a colloidal dispersion of liposomes in an aqueous liquid medium, which comprises mixing a·hydrophilic compound with the liposome dispersion and dehydrating the mixture to form a stable liposome containing powder which can be stored and reconstituted in an aqueous medium as a liposome dispersion.

Problem 11.2(a): answer

You may argue that the term "hydrophilic compound" has a definite meaning in the context of the patent specification:

> therefore, said hydrophilic compound is actually a stabilizing additive which protects the liposomes of the dehydrated product and keeps them in a condition suitable for further use

"Hydrophilic compound" thus means a compound which is hydrophilic enough to stabilize the liposomes in the dehydrated state.

[This argument was successful in *Liposome Co. v. Vestar, Inc.* 36 USPQ2d 1295 (Fed. Cir. 1994), both at the district court and before the Federal Circuit.]

Problem 11.2(b): answer

A process for the dehydration of a colloidal dispersion of liposomes in an aqueous liquid . medium, which comprises mixing a hydrophilic compound capable of stabilizing and protecting a dehydrated liposome containing powder, with the liposome dispersion and dehydrating the mixture to form a stable liposome containing powder which can be stored and reconstituted in an aqueous medium as a liposome dispersion, said hydrophilic compound being present in an amount sufficient to stabilize and protect the liposome containing powder.

Problem 11.3(a): answer

Why not: the claim is limited to processes where a hydrophilic compound [such as sucrose] is mixed with preexisting liposomes. In the competitor's process, the sucrose is·mixed with the lipids and amphotericin B before liposomes are formed, and during the time when liposomes are forming.

Why: the term "mixing" in claim 1 means any process by which one obtains a mixture of a .hydrophilic compound and a liposome dispersion prior to dehydration, not merely

those processes where a preexisting liposome solution is mixed with sucrose. Mixing does not mean "adding." Note that Example 1 separates the activities of "adding" and "mixing."

The Federal Circuit affirmed the judgment of non-infringement, holding that the phrase "'mixing it hydrophilic compound·with the colloidal dispersion of liposomes" describes mixing a compound with existing liposomes, not with lipids that will form liposomes.

The court also observed that even if the invention was the practice of obtaining a mixture of a hydrophilic compound and a liposome dispersion prior to dehydration by any method whatsoever, the claim language does not describe such a process. Thus the patent claimed less than what was discovered.

Problem 11.3(b): answer

A process for the dehydration of a colloidal dispersion of liposomes in an aqueous liquid medium, which comprises dehydrating a: mixture of a hydrophilic compound and a liposome dispersion to form a stable liposome containing powder which can be stored and reconstituted in an aqueous medium as a liposome dispersion.

or

A process for the dehydration of a·colloidal dispersion of liposomes in an aqueous liquid medium, which comprises dehydrating a liposome dispersion containing a hydrophilic compound to form a stable liposome containing powder which can be stored and reconstituted in an aqueous medium as a liposome dispersion.

PLI Chemical/Pharmaceutical Practice
In Class Problem 12 - Answer

Question 1: answer

1. A lubricating oil composition suitable as a crankcase lubricant in internal combustion engines comprising:

(a) a major amount of lubricating oil;

(b) a dispersing amount of ashless lubricating oil dispersant selected from the group consisting of:

(i) oil soluble salts, amides, imides, oxazolines, esters, and mixtures thereof, of long chain hydrocarbon substituted mono- and dicarboxylic acids or their anhydrides;

(ii) long chain aliphatic hydrocarbons having a polyamine attached directly thereto; and

(iii) Mannich condensation products formed by condensing about a molar proportion of long chain hydrocarbon substituted phenol with from about 1 to 2.5 moles of formaldehyde and from about 0.5 to 2 moles of polyalkylene polyamine; wherein said long chain hydrocarbon group is a polymer of C2 to C5 monoolefin, said polymer having a molecular weight of from about 700 to about 5000;

(c) from about 0.01 to 5.0 parts by weight of oil soluble zinc dihydrocarbyl dithiophosphate wherein the hydrocarbyl groups contain from 1 to 18 carbon atoms;

(d) an antioxidant effective amount, within the range of from about 5 to about 500 parts per million by weight, of added copper in the form of an oil soluble copper compound; and

(e) a lubricating oil detergent additive which comprises at least one magnesium or calcium salt of a material selected from the group consisting of sulfonic acids, alkyl phenols, sulfurized alkyl phenols, alkyl salicylates and naphthenates, wherein said parts by weight are based upon 100 parts by weight of said lubricating composition and said weight %is based on the weight of said lubricating composition.

Question 2: answer [based on the answer for #1]

No. It contains (a) lubricating oil, (d) a suitable amount of an oil soluble copper compound, and (e) a calcium salt of sulfonic acid, but does not contain (b) an ashless dispersant, or (c) a zinc dihydrocarbyl dithiophosphate.

Question 3: answer [based on the answer for #1]

No. Claim 1 is not a recipe for making a motor oil composition, or a product-by-process claim, but a composition which contains the listed ingredients. Consequently; as properly interpreted, the claims are to "a composition that contains the specified ingredients at any time from the moment at which the ingredients are mixed together." 35 USPQ2d at 1807.

> "Claim drafting is itself an art,·an art on which the entire patent system today depends. The language through which claims are expressed is not a nose of' wax to be pushed and shoved into a form that pleases and·that produces a particular result a court may desire. The public generally, and in particular, the patentee's competitors are entitled to clear and specific notice of what the inventor claims as his invention. That is not an easy assignment for those who draft claims, but the law requires it; and our duty demands that we enforce the requirement. There is no room in patent claim interpretation for the equivalent of the cypress doctrine: that would leave the claiming process too indefinite to serve the purposes which lie at the heart of the patent system." Id., 1808 (Plager, J.)

But see Judge Nies dissent:

> "The majority focuses principally on the claimed ashless dispersant which must remain in its view "ashless" in the required amount in the composition. I interpret "ashless dispersant" as simply the name or designation of an ingredient required as one of the additives. It does not mean the ingredient must remain inert." Id. at 1809.

Question 4: answer

Product-by-Process:

1. A lubricating oil composition suitable as a crankcase lubricant in internal combustion engines ***prepared by admixing in any order:***

(a) a major amount of lubricating oil;

(b) a dispersing amount of ashless lubricating oil dispersant selected from the group consisting of:

(i) oil soluble salts, amides. imides, oxazolines, esters, and mixtures thereof, of long chain hydrocarbon substituted mono- and dicarboxylic acids or their anhydrides;

(ii) long chain aliphatic hydrocarbons having a polyamine attached directly thereto; and

(iii) Mannich condensation products formed by condensing about a molar proportion of long chain hydrocarbon substituted phenol with from about 1 to 2.5 moles of formaldehyde and from about 0.5 to 2 moles of polyalkylene polyamine;

wherein said long chain hydrocarbon group is a polymer of a C_2 to C_5 monoolefin, said polymer having a molecular weight of from about 00 to about 5000;

(c) from about 0.01 to 5.0 parts by weight of oil soluble zinc dihydrocarbyl ,dithiophosphate wherein the hydrocarbyl groups contain from 1 to 18 carbon atoms;

(d) an antioxidant effective amount, within the range of from about 5 to about 500 parts per million by weight, of added copper in the form of an oil soluble copper compound; and

(e) a lubricating oil detergent additive which comprises. at least one magnesium or calcium salt of a material selected from the groups consisting of sulfonic acids, alkyl phenols, sulfurized alkyl phenols, alkyl salicylates and naphthenates, wherein said parts by weight are based upon 100 parts by weight of said lubricating composition and said weight % is based on the weight of said lubricating composition.

Note: here is some boiler plate language which attempts to address the *Lubrizol* decision:

> It is to he understood that the reactants and components referred to by chemical name or formula anywhere in the specification or claims hereof, whether referred to in the singular or plural, are identified as they exist prior to coming into contact with another substance referred to by chemical name or chemical type (e.g., another reactant, a solvent, or etc.). It matters not what preliminary chemical changes, transformations and/or reactions, if any, take place in the resulting mixture or solution or reaction medium as such changes, transformations and/or reactions are the natural result of bringing the specified reactants and/or components together under the conditions called for pursuant to this disclosure. In short, the reactants and components are identified as ingredients to be brought together in connection with performing a desired chemical reaction or in forming a mixture to be used in conducting a desired reaction. Accordingly, even though the claims hereinafter may refer to substances, components and/or ingredients in the present tense (“comprises”, “ “is”', etc.), the reference is to the substance, component or ingredient as it existed at the time just before "it was first contacted, formed in situ, blended or mixed with one or more other substances, components and/or ingredients in accordance with the present disclosure. Thus the fact that a substance, component or ingredient may have lost its original identity through a chemical reaction or transformation during the " course of contacting, in situ formation, blending or mixing operations, if conducted in accordance with this disclosure and with the application of common sense and the ordinary skill of a chemist, is thus wholly immaterial for an accurate understanding and appreciation of the true meaning and substance of this disclosure and the claims thereof.

from U.S. 5,861,538.

Sources: U.S. Patent 4,867;890; *Exxon Chemical Patents, Inc. v. Lubrizol Corp*. 64 F.3d 1553, 35 USPQ2d 1801, (Fed. Cir. 1995), *rehearing en banc denied with opinion*, 37 USPQ 3d 1767