Advanced Patent Prosecution Workshop 2021:

Claim Drafting & Amendment Writing

Chemical/Pharmaceutical Answers for Homework Problem 1 and In-Class Problems 1-8

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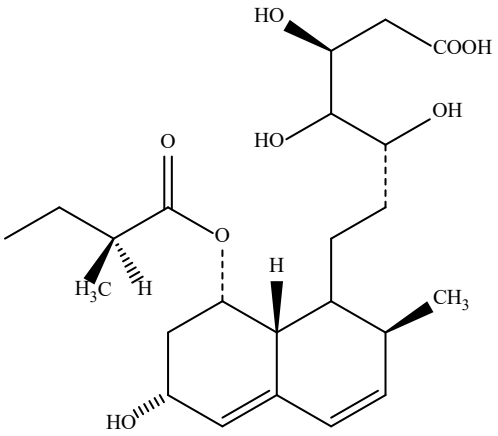
PLI Chemical/Pharmaceutical Homework Problem 1 Answer

Problem 1.1: answer

1. A compound of the formula:



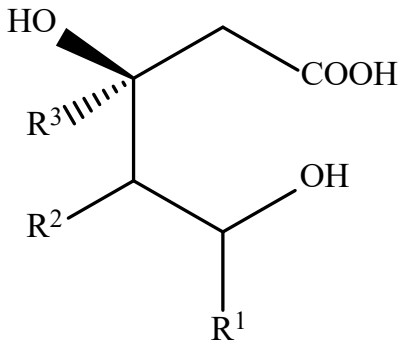
or a pharmaceutically acceptable salt thereof.

2. A pharmaceutical composition comprising the compound of claim 1 and at least one pharmaceutically acceptable excipient.

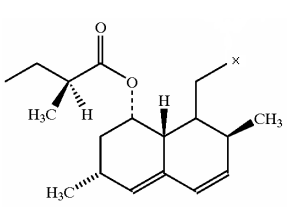
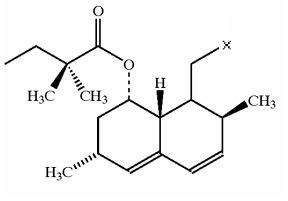
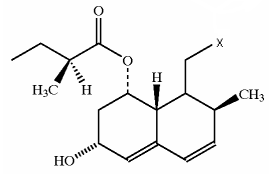
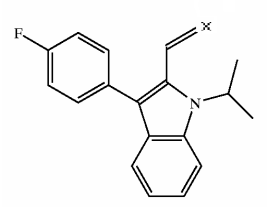
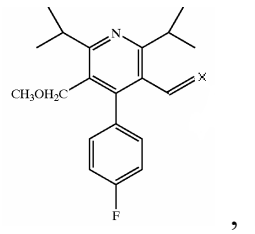
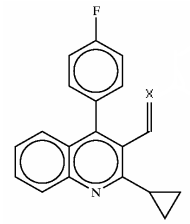
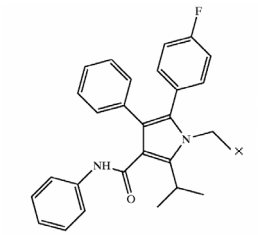
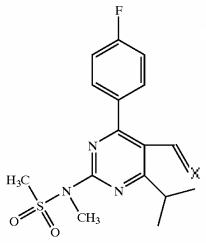
3. A method of reducing the amount of low density lipoprotein cholesterol (LDL) in the bloodstream comprising administering to a patient a therapeutically effective amount of a pharmaceutical composition according to claim 2.

Problem 1.2: answer

1. A statin analog of the formula:



or a pharmaceutically acceptable salt or a lactone derivative thereof, wherein R^1 is selected from . the group consisting of


, 
, 
, 
, 
, 
, 
, and 
,

where X is the point of attachment, R^2 is a hydroxyl, C_1-C_7 alkoxy or a halogen, and R^3 is hydrogen, hydroxyl, or C_1-C_7 alkoxy.

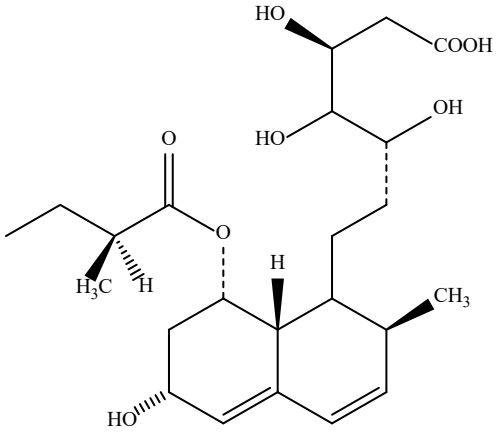
[*See also* U.S. Patent No. 6,777,552]

Problem 1.3: answer To be discussed in class. *See Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306 (Fed. Cir. 2002).

Note that many foreign countries do not have a best mode requirement. There are, however, several foreign countries which have some form of a best mode requirement, although in most such countries patents rarely, if ever, have been invalidated based on this failure to comply with this requirement. *See* Carlson et al., *IDEA* 45(3):267-292 (2005).

Problem 1.4: answer

1. A pharmaceutically acceptable salt of a compound of the formula: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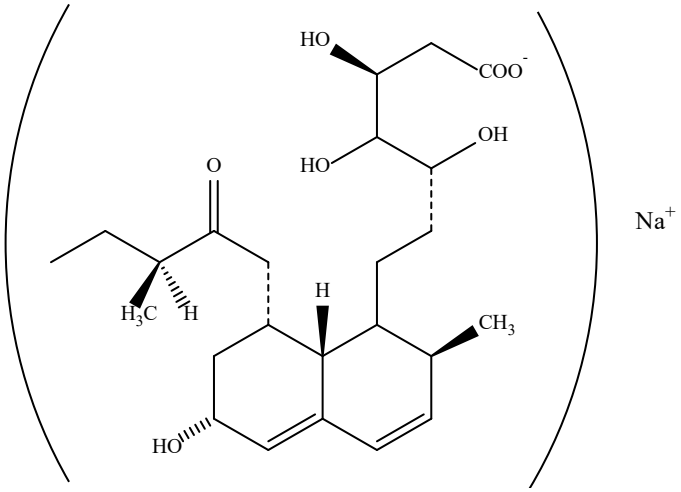
2. The pharmaceutically acceptable salt of claim 1, wherein the salt is an alkali metal or alkaline earth metal salt.

Problem 1.5: answer

1. A method of crystallizing a salt of the formula:



comprising the steps of:

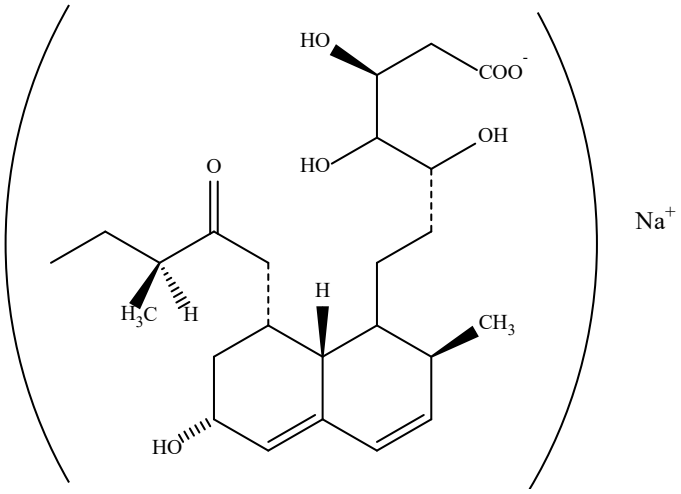
a) dissolving the salt in a C4-C6 alkane to obtain a solution,
b) cooling the solution to crystallize the salt, and
c) recovering the salt.

Problem 1.6: answer

A license from the USPTO is required for filing a patent application in a foreign country for an invention "made in this country" (unless a U.S. patent application was filed at least 6 months earlier). 35 U.S.C. §184(a). There is a paucity of guidance for determining when an invention is "made in this country." Chisum on Patents, Matthew Bender & Company (2018) at §1.06[3][a] ("Neither the statute nor the regulations thereunder provide guidance in determining when an invention is "made in this country"). In *Sealectro v. L.V.C. Industries*, 271 F.Supp. 835, 841 (E.D.N.Y. 1967), the court "held the place of reduction to practice, rather than conception, to be the critical event in determining where the invention was made." Chisum on Patents at §1.06[3][a].

Problem 1.7: answer

1. A compound of the formula:



that exhibits an X-ray diffraction pattern having characteristic peaks at about 7.8, 13.8, 15.9, 20.6, 21.8, 22.2, 23.3, or 24.5° ± 0.2° 2Θ. [or alternatively as "characterized by an XRD pattern as substantially depicted in figure 1

PLI Chemical/Pharmaceutical Practice
In Class Problem 1 - Answer

In *Ex parte Cai*, BPAI Appeal No. 2011-005302, U.S. Application No. 11/852,433, the BPAI (now the PTAB) found such a claim enabled.

> Solvates, hydrates, and polymorphs of a compound are the same compound, in different physical forms: Polymorphs are the same compound in different crystal structures (FF 2), while hydrates and solvates are crystal structures of the compound in which molecules of solvent (e.g., water) are included in the crystal structure (FFs 3, 4) but the compound and solvent molecules retain their chemical identities (FF 5).
>
> The evidence of record shows that high-throughput methods of crystal growth and analysis were known in the art at the time the instant application was filed (FF 13). Rodríguez-Spong states that such methods allowed skilled workers to test thousands of cystallization conditions using robotic liquid handling and automated screening through optical image analysis and Raman microscopy (FF 13). Thus, the Examiner's finding that it is unpredictable whether hydrates, solvates, and polymorphs exist appears to be moot, since thousands of different crystallization conditions can be tested via automated, and therefore routine, experimentation. The Examiner's finding that a study of hydrates, solvates, and polymorphs requires "a full research program" (FF 24) is based on guidelines that address experimentation required for "marketing approval of new drug products" (FF 27); such experimentation is not required by § 112. *See CFMT*, 349 F.3d at 1338 ("Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace.").
>
> The Examiner disputes that high-throughput crystallization testing obviates the need for undue experimentation, because after each crystallization experiment, a person of skill in the art could ask himself or herself "Can additional solvates or polymorphs form?" and at each case, the answer would be "I don't know." …
>
> This argument, however, applies an enablement standard that is not based on the state of the art at the time the instant application was filed. ...
>
> The evidence of record shows that those of skill in the art can routinely test thousands of different crystallization conditions to make new polymorphs of a given compound (FF 13), and the Examiner has not shown that such testing is insufficient to satisfy the enablement requirement of § 112.
>
> The Examiner has not pointed to any evidence showing that different solvates or polymorphs of a compound have different chemical properties in solution. Rather, the Examiner argues that different forms of a compound can vary in properties such as

dissolution (Answer 6) and therapeutic activity (*id*. at 7), and that "the generation of formulations containing crystalline forms is complex" (*id*.). The Examiner also argues that "it is arbitrary to say that a solvate has the properties of one of its components but not the other" (*id*. at 18) because a "solvate is no more a form of the compound found therein than it is of the solvent molecule, i.e. a hydrate of a compound instantly claimed is not a physical form of water" (*id*. at 13-14).

We do not agree that the evidence shows that using the claimed compounds in the form of a solvate, hydrate, or polymorph would have required undue experimentation. As discussed above, the evidence shows that different physical forms of a compound share "chemical identity" (FF 18) and are indistinguishable when dissolved (FF 7). Some forms of a compound might dissolve more readily than others (FF 18) and different forms may even differ in therapeutic activity (FF 19), but the Examiner has not adequately explained why these differences would result in the need for more experimentation than is routine in this art to use solvates, hydrates, or polymorphs of the claimed compounds in the same manner as the forms that the Examiner has indicated to be enabled.

PLI Chemical/Pharmaceutical Practice
In Class Problem 2 – Answer

The CAFC, in *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013), held that obviousness-type double patenting does indeed 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. The court at p. 9 cited MPEP 804(I)(A):

> "[d]ouble patenting may exist between an issued patent and an application filed by the same inventive entity, or by a *different inventive entity having a common inventor*, and/or by a common assignee/owner." [emphasis added]

The court took judicial notice of MPEP 804(I)(A) to conclude that common ownership is not required and that obviousness-type double patenting applied since the '685 patent and the '509 application had two common inventors.

The court also held that a terminal disclaimer could not be filed to overcome the obviousness-type double patenting rejection. The court at p. 14 citing 37 C.F.R. § 1.321(c)(3) that a terminal disclaimer

> "filed to obviate judicially created double patenting in a patent application" must include "a provision that any patent granted on that application . . . shall be enforceable only for and during such period that said patent is *commonly owned* with the application or patent which formed the basis for the judicially created double patenting." [emphasis added]

Since the '685 patent and the '509 application were not commonly owned, filing of a terminal disclaimer was not possible.

PLI Chemical/Pharmaceutical Practice
In Class Problem 3 - Answer

In *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006), claim 1 was found to be novel over JP ‘206.

> On appeal, Atofina argues that JP 51-82206 does not anticipate any claim of the '514 patent because it does not disclose the manufacture of difluoromethane, recited in the preamble of claim 1; its disclosure of a broader temperature range does not anticipate the specific temperature range claimed in the '514 patent; its disclosure of an oxygen to methylene molar ratio of 0.001 to 1.0 is not a disclosure of the claimed range of 0.1 to 5.0 percent; and it does not disclose the contact times required in claims 6 and 10. According to Atofina, the court's reliance on Titanium Metals was misplaced because that case stands for the proposition that a species can anticipate a genus, not the reverse.
>
> Great Lakes responds that JP 51-82206 anticipates claims 1, 2, 6, 7, 9, and 10 of the '514 patent because the claimed ranges are within the disclosure of ranges in the prior art. According to Great Lakes, JP 51-82206's disclosure of a preferred temperature range of 150 to 350 °C encompasses the temperature range disclosed in the '514 patent of 330 to 450 °C. Great Lakes also contends that JP 51-82206's disclosure of the oxygen to methylene chloride molar ratios of 0.001 percent to 1.0 percent encompasses the ratios claimed in the '514 patent of 0.1 percent to 5.0 percent. In addition, Great Lakes argues that even though JP 51-82206 does not disclose the contact times as required by claims 6 and 10 of the '514 patent, the contact times are "typically and easily determined through calculation, by a person of ordinary skill in the art."
>
> … Anticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently. … However, each limitation of the '514 claims is not in JP 51-82206. It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus. See, e.g., In re Baird, 16 F.3d 380, 382 (Fed. Cir.1994). There may be many species encompassed within a genus that are not disclosed by a mere disclosure of the genus. On the other hand, a very small genus can be a disclosure of each species within the genus. *In re Petering*, 49 C.C.P.A. 993, 301 F.2d 676, 682 (1962); *see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc*., 246 F.3d 1368, 1380 (Fed. Cir.2001) ("[T]he disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited."). That is not the case here, however. A temperature range of over 100 degrees is not a small genus and the range of temperatures of JP 51-82206 does not disclose Atofina's temperature range.

To find anticipation here, the district court relied on our opinion in Titanium Metals. The court stated that "the '514 patent's claim limitation of 330 to 450 °C is entirely within JP 51-82206's temperature range of 100 and 500 °C. Consequently, this limitation of claim 1 is also disclosed by JP 51-82206." Opinion, slip op. at 41. However, Titanium Metals stands for the proposition that an earlier species reference anticipates a later genus claim, not that an earlier genus anticipates a narrower species. 778 F.2d at 782. Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500 °C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450 °C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim. Because the court's determination that JP 51-82250 disclosed the temperature range in claims 1, 2, 6, 7, 9, and 10 of the '514 patent was grounded in its erroneous application of Titanium Metals, we must reverse its finding of anticipation based on the temperature range.

Further, we reject Great Lakes' argument that the district court's finding of anticipation was correct because JP 51-82206 discloses a preferred embodiment using a specific temperature range (a species) that anticipates the '514 patent's claim of a broader temperature range (a genus). JP 51-82206 discloses a preferred temperature range of 150 to 350 °C that slightly overlaps the temperature range claimed in the '514 patent. But that slightly overlapping range is not disclosed as such, i.e., as a species of the claimed generic range of 330 to 450 °C. Moreover, the disclosure of a range of 150 to 350 °C does not constitute a specific disclosure of the endpoints of that range, i.e., 150 °C and 350 °C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of each of the intermediate points. Thus, JP 51-82206 does not disclose a specific embodiment of the claimed temperature range.

The district court also clearly erred in finding that the claimed oxygen to methylene chloride molar ratio of 0.1 to 5.0 percent was disclosed in JP 51-82206. JP 51-82206 discloses an oxygen to methylene chloride ratio of 0.001 to 1.0 percent that overlaps but does not fall within the range of ratios claimed in the '514 patent. Moreover, the disclosure of a 0.001 to 1.0 percent range in JP 51-82206 does not constitute a specific disclosure of 0.1 percent to 5.0 percent, as Great Lakes asserts. Once again, although there is a slight overlap, no reasonable fact finder could determine that this overlap describes the entire claimed range with sufficient specificity to anticipate this limitation of the claim. The ranges are different, not the same. Indeed, the lower end of the ratio in the reference differs by a factor of one hundred from what is claimed. In addition, the disclosure of a 0.001 to 1.0 percent range is not a disclosure of the end points of that range. Thus, there is no anticipation. Because JP 51-82206 does not expressly or inherently disclose the claimed range of ratios, JP 51-82206 does not anticipate claims 1, 2, 6, 7, 9, and 10 of the '514 patent.

PLI Chemical/Pharmaceutical Practice
In Class Problem 4 - Answer

1. In *Dey v. Sunovion*, slip no. 2012-1428, Federal Circuit May 20, 2013, the Court refused to hold on summary judgment that a clinical trial was a prior public use barring the patent. The Court stated that the "degree of confidentiality necessary to avoid a finding of public use naturally depends on the circumstances." Slip Op. at 7-8. In this case, the fact that "the practicalities of the [clinical] study required self-administration at home rather than physician administration in a closed facility, does not preclude a reasonable jury from concluding that the use of Batch 3501A was sufficiently controlled and restricted, rather than unfettered and public." Slip Op. at 9. The Court further noted that it has "never required a formal confidentiality agreement to show non-public use" and instead considers whether the circumstances created a similar expectation of secrecy. Slip Op. at 11.

Public uses anywhere in the world can be prior art. *See* post-AIA 35 U.S.C. §102(a)(1). Pre-AIA, only public uses in the U.S. were prior art. *See* pre-AIA 35 U.S.C. §102(b).

2. A method of treating hair loss in a human subject in need thereof, comprising topically administering an effective amount of gelatin to the hair of the human subject.

The phrase "in need thereof" may be construed to require that the human patient have the subjective intent to administer the gelatin in order to strengthen long hair. *Jansen v. Rexall Sundown, Inc*., 342 F.3d 1329 (Fed. Cir. 2003) ("in need thereof" interpreted to mean that the combination of folic acid and vitamin B12 must be administered to a human with a recognized need to treat or prevent macrocytic-megaloblastic anemia").

PLI Chemical/Pharmaceutical Practice
In Class Problem 5 - Answer

The rejection is improper. 35 U.S.C. 102(b)(2)(C) [post-AIA] provides that "A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if … the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person."

PLI Chemical/Pharmaceutical Practice
In Class Problem 6 - Answer

The test for whether a Markush group is proper is whether all of the compounds in the group have in common a functional utility and a substantial structural feature disclosed as being essential to that utility. *Ex parte Raghavan*, BPAI Appeal No. 94-2280 (Appl. No. 07/627,175); *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (BPAI 1984); *In re Harnisch*, 631 F.2d 716 (CCPA 1980).

In *In re Harnisch*, 631 F.2d 716 (CCPA 1980), the CCPA found the claim here to be in proper Markush format since the claimed compounds are dyes and have a single structural similarity, i.e., the coumarin group.

PLI Chemical/Pharmaceutical Practice
In Class Problem 7 - Answer

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?**

ANSWER:

US: Yes, the claim to A1 is valid in the US under the AIA. The student's disclosure of A1 is excluded from prior art under 102(b)(1) – disclosure made by inventor or another who obtained the subject matter directly or indirectly from the inventor.

Also, the third party researcher's disclosure of A1 is excluded from prior art under 102(b)(2).

The answer may be different for the entire genus. The scope of the exclusion from prior art is for the same subject matter – see 77 Fed Reg. 43767 (July 26, 2012). However, the disclosure of speculative compounds may be prior art under 102(a)(1), provided that it is "available to the public."

EP: Under EPC Article 55(1) there is a 6-month grace period for publications that took place against the inventor's wish, where there is an "evident abuse in relation to the applicant." Both disclosures were without the inventors' consent. However, here the filing was more than 6 months from the disclosure, so the grace period does not apply and University is not entitled to the claim for A1. In addition, the grace period only applies to a European application (either in the EPO or a PCT application designating the EPO) within 6 months of the disclosure, so the provisional filing within 6 months would not support a claim to A1 at the EPO.

JP: For applications filed before June 9, 2018, there is a 6-month grace period for publications that took place against the inventor's wishes. (For applications filed on or after June 9, 2018, there is a 12 month grace period.) Here the filing was more than 6 months from the disclosure, so the grace period does not apply and University is not entitled to the claim for A1. Also, the grace period needs to be met by filing a Japanese application (either in JPO or a PCT application designating Japan) within 6 months of the disclosure, so the provisional filing within 6 months would not support a claim to A1 in Japan.

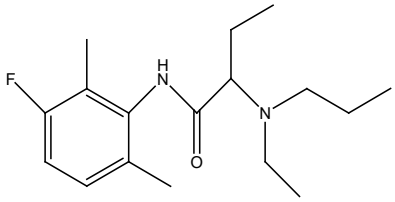
2. **Would the answers change if 001P was filed 3/3/2013?**

US: Same answer for species A1, different reason. Here the application is subject to pre-AIA law, so the University would be entitled to the patent since the disclosure is not old 102(a) art (not described in a printed publication before the invention) nor is it old 102(b) art (not more than one year before the US filing date). Also, for the genus the University could try to pre-date the disclosure.

EP: Same answer. The grace period only applies to a European application (either in the EPO or a PCT application designating the EPO) within 6 months of the disclosure, so the provisional filing within 6 months would not support a claim to A1 at the EPO.

JP: Same answer, since the provisional filing is not sufficient under Japanese law. The grace period needs to be met by filing a Japanese application (either in JPO or a PCT application designating Japan) within 6 months of the disclosure, so the provisional filing within 6 months would not support a claim to A1 in Japan.

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?

ANSWER: If you file a second provisional and then combine them both in a single non-provisional, the non-provisional will be subject to the AIA (same result if claims to A51 were canceled after filing). However, if A 51 was filed in a second application and the non-provisional was limited to subject matter first filed pre-3/16/2013, then the pre-AIA law would apply to the first non-provisional.

4. **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?**

ANSWER:

US: University enjoys an exemption from Innovator Co.'s disclosure as prior art since University publicly disclosed (October 2012 PowerPoint presentation) before Innovator first filed a patent application, and University filed its own patent application within one year after University first publicly disclosed. Thus, University will have patent rights.

EP: Under EP first to file rules, Innovator's company's filing will predate your filing, assuming that Innovator company proceeds with a subsequent EPO filing (either direct or via PCT).

JP: Under JP first to file rules, Innovator's company's filing will predate your filing.

5. Does your answer change if your application was filed 3/3/2013?

US: You can establish an earlier date of invention under interference practice

EP, JP: No change

PLI Chemical/Pharmaceutical Practice
In Class Problem 8 - Answer

Adapted from *In re Otsuka*, 678 F.3d 1729 (Fed. Cir. 2012):

The analysis is whether it would be obvious for one of ordinary skill in the art. In the *Otsuka* case, the court found that there was no obviousness-type double patenting, because it was not obvious to one skilled in the art to modify the granted patent to arrive at the claimed species.

Here is the pertinent text from the decision:

> "Double patenting of the obviousness type rejection is analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103." . . . Important differences remain, however. The patent principally underlying the double patenting rejection need not be prior art. *Id.* Moreover, when analyzing obviousness-type double patenting in cases involving claimed chemical compounds, the issue is not whether a skilled artisan would have selected the earlier compound as a lead compound. That is so because the analysis must necessarily focus on the earlier claimed compound over which double patenting has been alleged, lead compound or not. *See Ortho Pharma. Corp. v. Smith,* 959 F.2d 936, 943 [22 USPQ2d 1119] (Fed. Cir. 1992) ("[I]t is the claims that are compared when assessing double patenting.").
>
> "Unless the earlier claim anticipates the later claim under § 102, the question whether the two claimed compounds are "patentably distinct" implicates the question of obviousness under § 103, *Longi,* 759 F.2d at 892, which in the chemical context requires identifying some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success, *see Takeda,* 492 F.3d at 1357, 1361.
>
> "The Defendants rely on *Geneva Pharm., Inc. v. GlaxoSmithKline PLC,* 349 F.3d 1373, 1377 n.1 [68 USPQ2d 1865] (Fed. Cir. 2003), which states in a footnote that "[o]bviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not." *Geneva,* however, involved nonstatutory double patenting based on anticipation, not obviousness. *Id.* ("This genus-species relationship makes the claims patentably indistinct, because the earlier species … anticipates the later genus… ."). For anticipation, of course, motivation in the prior art is unimportant. *See, e.g., Callaway Golf Co. v. Acushnet Co.,* 576 F.3d 1331, 1347 [91 USPQ2d 1705] (Fed. Cir. 2009) (noting that, in an "anticipation argument, … motivation to combine is not an issue"). The statement from *Geneva* was later recited in dictum in *Procter & Gamble Co. v. Teva Pharm. USA, Inc.,* 566 F.3d 989 [90 USPQ2d 1947] (Fed. Cir. 2009), in which we concluded under § 103 that there would have been no motivation to modify the prior art compound, *id.* at 995, and then stated: "Having concluded that [the asserted compound] was

not obvious under 35 U.S.C. § 103, we *similarly conclude* that the [asserted] patent is not invalid for obviousness-type double patenting," *id.* at 999 (emphasis added). Contrary to the Defendants' arguments, neither *Geneva* nor *Procter & Gamble* stands for the proposition that, in considering whether one compound is an obvious variant of another for purposes of nonstatutory double patenting, analyzing the compound of the prior claim for a reason or motivation to modify is irrelevant.

In the context of claimed chemical compounds, an analysis of nonstatutory obviousness-type double patenting—like an analysis under § 103—entails determining, *inter alia,* whether one of ordinary skill in the art would have had reason or motivation to modify the earlier claimed compound to make the compound of the asserted claim with a reasonable expectation of success. There is no other way to consider the obviousness of compound B over compound A without considering whether one of ordinary skill would have had reason to modify A to make B. That is traditional obviousness analysis.