Advanced Patent Prosecution Workshop 2021:

Claim Drafting & Amendment Writing

Biotechnology Answers for Homework Problem 2 and In-Class Problems 8-10

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PLI Biotech Practice - Answer
Homework Problem 2

1. Only one antibody is described in the specification. Without some guidance as to the structural features necessary for forming other antibodies with the described K_d and K_{off} values and/or other examples, the claims will not likely be considered to have been in the possession of the patent applicant at the time of filing. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002) (remanding case to determine whether the disclosure of three nucleic acid probes that selectively hybridize to the DNA of N. gonorrhoeae relative to the DNA of N. meningitidis were sufficient to meet the written description requirement for the claimed genus).

One possible solution would be to make claim 4 the base independent claims, cancel claims 1-3, and add claims identical to claims 1-3 but depend from claim 4.

Another possible solution would be to draft a claim to a single chain antibody with the VL sequence given in the specification, and another independent single chain antibody claim with the VH sequence given in the specification.

2. To be enabled, those skilled in the art must have been able to practice the claimed invention without undue experimentation. *In re Angstadt*, 537 F.2d 498 (CCPA 1976); *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). In *Wands*, the Court listed the following factors to be assessed to determine whether a claimed invention could be practiced without undue experimentation:

> The Wands Factors
> "(1) the quantity of experimentation necessary;
> (2) the amount of direction or guidance presented;
> (3) the presence or absence of working examples;
> (4) the nature of the invention;
> (5) the state of the prior art;
> (6) the relative skill of those in the art;
> (7) the predictability or unpredictability of the art; and
> (8) the breadth of the claim."
> 858 F.2d at 737.

Here, the prior art may help you. According to the background section, by 2007, M-CSF was a well known protein, and the prior art taught the desirability of making antibodies to that protein. Techniques for making such antibodies was known. One could argue that using these known techniques to find other antibodies with the claimed properties would have been routine experimentation. On the other hands, a large quantity of experimentation may be necessary to find other antibodies with the desired properties, the specification does not provide much guidance as to the structural elements of the other claimed antibodies, and there is only one working example. Claim 1, therefore, is unlikely to be found enabled. Possible amendments to overcome this rejection are provided in the answer to problem 1.

3. M-CSF was a well known protein at the time the application was filed, there were known techniques for forming antibodies to a protein, and the desirability of such an antibody also existed in the prior art. As a result, an Examiner may have basis for the rejection of claim 1 which does not provide any structure for the antibody. Claim 4 and the other proposed claims in the answer to problem 1 have structure which is not disclosed in the cited prior art. Therefore, it can be argued that a skilled artisan would not have been motivated to make such a construct. The best scenario would be to show that the claimed antibody had "surprising" properties over the prior art (e.g., significantly higher dissociation rates than prior antibodies).

PLI Biotech Practice - Answers
In Class Problem 8

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.

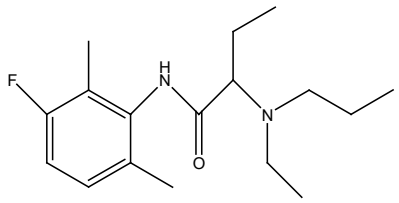
2. **Would the answers change if 001P was filed 3/3/2013?**

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 Biotech Practice - Answers
In Class Problem 9

In *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc*., 941 F.3d 1149 (Fed. Cir. 2019), the claims at issue were from U.S. Patent No. 7,608,597 (shown below).

1. A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine β-D-2′-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

2. The method of claim 1, wherein the nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof, is a pyrimidine nucleoside.

3. The method of claim 1, wherein the nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof, is a purine nucleoside.

….

In *Idenix*, the Court found that the quantity of experimentation required to determine which 2'-methyl-up nucleosides meet the claim is very high, especially since the claims cover millions of compounds. The patent specification failed to provide meaningful guidance as to which 2'-methyl-up nucleosides are or are not effective against hepatitis C virus (HCV). Only four examples on a single sugar were provided and found insufficient to support enablement. The nucleoside area was also found to be highly unpredictable in view of expert testimony that small changes can have dramatic effects on the activity and toxicity.

PLI Biotech Practice - Answers
In Class Problem 10

See U.S. Patent No. 6,867,031 and its prosecution history (including the Declaration submitted September 8, 2004, which is available on the USPTO's PAIR system).

Claims of U.S. Patent No. 6,867,031:

1. A variant of a parent *Bacillus stearothermophilus* alpha-amylase, wherein the variant has an amino acid sequence which has at least 95% homology to the parent *Bacillus stearothermophilus* alpha-amylase and comprises a deletion of amino acids 179 an 180, using SEQ ID NO:3 for numbering, and wherein the variant has alpha-amylase activity.

2. The variant of claim 1, wherein the variant further comprises a substitution of a cysteine at amino acids 349 and 428, using SEQ ID NO:3 for numbering.

3. A variant alpha-amylase, wherein the variant has at least 95% homology to SEQ ID NO:3 and comprises a deletion of amino acids 179 and 180, using SEQ ID NO:3 for numbering and wherein the variant has alpha-amylase activity.

4. The variant of claim 3, wherein the variant further comprises a substitution of a cysteine at amino acids 349 and 428, using SEQ ID NO:3 for numbering.

5. A variant of a *Bacillus stearothermophilus* alpha-amylase, wherein the alpha-amylase variant consists of a deletion of amino acids 179 and 180, using SEQ ID NO:3 for numbering.