RE: Consultation on Regulation of Patent Agency Services

Dear Sirs,

I understand that the Hong Kong Intellectual Property Department of the HKSAR is currently requesting the submission of views on regulation of patent agency services, with the ultimate goals of permitting only qualified persons or firms to provide patent-related services and use particular title.

Although I have not been specifically invited to comment on this consultation, I believe that based on my background and experience in this industry, my views and input on this issue would be constructive and useful to the Government.

I am also delighted to learn that the Government is now taking an active role in building a regulatory regime to ensure that patent services involving technical expertise are vigilantly controlled for public's interest and to avoid confusion between patent law and other IP law.

"Qualifications" in Question

In this instant submission, I would like to focus on Question 4(b)(iii) as this question in my opinion would be the fundamental question that must be addressed, prior to setting out the specific ways of implementation.

Question 4(b)(iii) is reproduced below:

What are the criteria to be adopted in determining qualified persons or firms? For example, should qualifications (foreign or local), passing accredited examinations, or taking accredited courses be adopted as the criteria?

I believe that there are at least three basic criteria which should be adopted in determining if a person is qualified to handle services involving technical expertise, and such criteria are listed below in the order of importance in my view.

(i) Professional tertiary technical degree in science or engineering from a well-recognized university;
(ii) Traineeship under a Qualified/Registered Patent Attorney of no less than 2 years; and
(iii) Passing of Examination on Patent Law.

Although the specific terms and requirements for traineeship program and the specific examinations required for assessment of patent knowledge must be carefully designed with a view to eventually arrive at an indigenous qualification system, I believe that HKSAR should be aware of the outmost importance of ensuring that only technically qualified persons with a professional tertiary technical degree in science or engineering should be allowed to be qualified as a Qualified Person.

Based on my experience gained from handling highly technically complex and advance patent matters in countries with original grant patent system, I believe that I am in a position to explain to members of the Advisory Committee who are not familiar with patent related work the reasons for the necessity for including this criterion (i.e. (i) above)) as the fundamental requirement.

This criterion, as I understand, would be in line with the requirements of countries with well developed OGP system, such as China, Europe and the US.

Supporting Evidence

It should be noted that, in sharp contrast with re-registration patent services, patent services within OGP system involve application of technical knowledge and scientific understanding, in order to fully grasp the meaning of a patent document, and to allow meaningful daily communication exchange from clients, which are often scientists or engineers.

The subject matters claimed and described in patent documents concern highly technical topic and pioneer areas in science. A typical biochemical type invention may pertain to screening of onogenes, enantiomers, crystalline chemical compounds, animal cell manipulation based on cell markers, 3D cell constructs for implantation, biogenetics, drug screening, antibody synthesis, immunogenic composition for use in vaccine development, treatment regime and diagnostics, etc.

Without the appropriate technical knowledge, it is difficult to envisage how a person (legally qualified or not) can perform basic job duties, such as, drafting of patent specification and claims for gene based therapy or vaccine type invention, or to perform analysis of patent documents and scientific documents without knowing the basic technical terms, chemical formula, or genetic codes.

Taking patent prosecution as an example, the daily work of a patent professional involves reviewing and comparing patent documents containing words and definitions which are only meaningful to scientists. For a patent application filed to pursue a new developed protein, such a document would contain claims directed to genetic materials and the like, which are defined by genetic codes (namely, sequences of amino acids and nucleotides).

As a mere example for sole illustrative purposes, I have enclosed herewith claims of two patents, relating to "EPO" - erythropoietin and an EPO analog (which are publicly disclosed documents).

First Invention

What is claimed is:

1. A purified and isolated DNA sequence encoding erythropoietin, said DNA sequence selected from the group consisting of:
   (a) the DNA sequences set out in FIGS. 5 and 6 or their complementary strands; and
   (b) DNA sequences which hybridize under stringent conditions to the DNA sequences defined in (a).

2. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

3. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding monkey erythropoietin.

4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

5. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 1, 2, or 3.

6. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 5.

7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

8. A cDNA sequence according to claim 7.

9. A monkey species erythropoietin coding DNA sequence according to claim 8.

10. A DNA sequence according to claim 9 and including the protein coding region set forth in FIG. 5.

11. A genomic DNA sequence according to claim 7.

12. A human species erythropoietin coding DNA sequence according to claim 11.

13. A DNA sequence according to claim 12 and including the protein coding region set forth in FIG. 6.

14. A DNA sequence according to claim 7 and including one or more codons preferred for expression in *E.coli* cells.

15. A DNA sequence according to claim 14, coding for expression of human species erythropoietin.

16. A DNA sequence according to claim 15 including the protein coding region set forth in FIG. 7.

17. A DNA sequence according to claim 7 and including one or more codons preferred for expression in yeast cells.

18. A DNA sequence according to claim 17, coding for expression of human species erythropoietin.

19. A DNA sequence according to claim 18 including the protein coding region set forth in FIG. 8.

20. A DNA sequence according to claim 7 covalently associated with a detectable label substance.

21. A DNA sequence according to claim 20 wherein the detectable label is a radiolabel.

22. A single-strand DNA sequence according to claim 20.

23. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim 7, 8, or 11 in a manner allowing the host cell to express said polypeptide.

24. A transformed or transfected host cell according to claim 23 which host cell is capable of glycosylating said polypeptide.

25. A transformed or transfected mammalian host cell according to claim 24.

26. A transformed or transfected COS cell according to claim 25.

27. A transformed or transfected CHO cell according to claim 25.

28. A biologically functional circular plasmid or viral DNA vector including a DNA sequence according to claim 7.

29. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 28.

30. A DNA sequence according to claim 7 coding for [Phe^{15}]hEPO, [Phe^{49}]hEPO, [Phe^{145}]hEPO, [His^{7}-]hEPO, [Asn^{2}des-Pro^{2} through Ile^{6}]hEPO, [des-Thr^{163} through Arg^{166}hEPO, or [Δ27-55]hEPO.

31. A purified and isolated DNA sequence as set out in FIGS. 5 or 6 or the complementary strand of such a sequence.

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FIG.5A

Translation of Monkey EPO cDNA

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Sau3A
GATCCCGCGCCCCCTGGACAGCCGCCCTCTCCTCCAGGCCCGTGGGGCTGGCCCTGCCC

CGCTGAACTTCCCGGGATGAGGACTCCCGGTGTGGTCACCGCGCGCCTAGGTCGCTGAG

                      -27                             -20
                      Met Gly Val His Glu Cys Pro Ala Trp
GGACCCCGGCCAGGCGCGGAGATG GGG GTG CAC GAA TGT CCT GCC TGG

                                    -10
Leu Trp Leu Leu Leu Ser Leu Val Ser Leu Pro Leu Gly Leu Pro
CTG TGG CTT CTC CTG TCT CTC GTG TCG CTC CCT CTG GGC CTC CCA

         -1  +1                                      10
Val Pro Gly Ala Pro Pro Arg Leu Ile Cys Asp Ser Arg Val Leu
GTC CCG GGC GCC CCA CCA CGC CTC ATC TGT GAC AGC CGA GTC CTG

                                20                  *
Glu Arg Tyr Leu Leu Glu Ala Lys Glu Ala Glu Asn Val Thr Met
GAG AGG TAC CTC TTG GAG GCC AAG GAG GCC GAG AAT GTC ACG ATG

         30                                 *       40
Gly Cys Ser Glu Ser Cys Ser Leu Asn Glu Asn Ile Thr Val Pro
GGC TGT TCC GAA AGC TGC AGC TTG AAT GAG AAT ATC ACC GTC CCA
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FIG.5B

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                                    50
Asp Thr Lys Val Asn Phe Tyr Ala Trp Lys Arg Met Glu Val Gly
GAC ACC AAA GTT AAC TTC TAT GCC TGG AAG AGG ATG GAG GTC GGG

          60                                              70
Gln Gln Ala Val Glu Val Trp Gln Gly Leu Ala Leu Leu Ser Glu
CAG CAG GCT GTA GAA GTC TGG CAG GGC CTG GCC CTG CTC TCA GAA

                                    80          *
Ala Val Leu Arg Gly Gln Ala Val Leu Ala Asn Ser Ser Gln Pro
GCT GTC CTG CGG GGC CAG GCC GTG TTG GCC AAC TCT TCC CAG CCT

          90                                             100
Phe Glu Pro Leu Gln Leu His Met Asp Lys Ala Ile Ser Gly Leu
TTC GAG CCC CTG CAG CTG CAC ATG GAT AAA GCC ATC AGT GGC CTT

                                   110
Arg Ser Ile Thr Thr Leu Leu Arg Ala Leu Gly Ala Gln Glu Ala
CGC AGC ATC ACC ACT CTG CTT CGG GCG CTG GGA GCC CAG GAA GCC

         120                                             130
Ile Ser Leu Pro Asp Ala Ala Ser Ala Ala Pro Leu Arg Thr Ile
ATC TCC CTC CCA GAT GCG GCC TCG GCT GCT CCA CTC CGA ACC ATC

                                   140
Thr Ala Asp Thr Phe Cys Lys Leu Phe Arg Val Tyr Ser Asn Phe
ACT GCT GAC ACT TTC TGC AAA CTC TTC CGA GTC TAC TCC AAT TTC
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FIG.5C

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         150                                             160
Leu Arg Gly Lys Leu Lys Leu Tyr Thr Gly Glu Ala Cys Arg Arg
CTC CGG GGA AAG CTG AAG CTG TAC ACG GGG GAG GCC TGC AGG AGA

         165
Gly Asp Arg OP
GGG GAC AGA TGA CCAGGTGCGTCCAGCTGGGCACATCCACCACCTCCCTCACCAACA

CTGCCTGTGCCACACCCTCCCTCACCACTCCCGAACCCCATCGAGGGGCTCTCAGCTAAG

CGCCAGCCTGTCCCATGGACACTCCAGTGCCAGCAATGACATCTCAGGGGCCAGAGGAAC

TGTCCAGAGCACAACTCTGAGATCTAAGGATGTCGCAGGGCCAACTTGAGGGCCCAGAGC

AGGAAGCATTCAGAGAGCAGCTTTAAACTCAGGAGCAGAGACAATGCAGGGAAAACACCT

GAGCTCACTCGGCCACCTGCAAAATTTGATGCAGGACACGCTTTGGAGGCAATTTACCTG

TTTTTGCACCTACCATCAGGGACAGGATGACTGGAGAACTTAGGTGGCAAGCTGTGACTT

CTCAAGGCCTCACGGGCACTCCCTTGGTGGCAAGAGCCCCCTTGACACTGAGAGAATATT

TTGCAATCTGCAGCAGGAAAAATTACGGACAGGTTTTGGAGGTTGGAGGGTACTTGACAG

GTGTGTGGGGAAGCAGGGCGGTAGGGGTGGAGCTGGGATGCGAGTGAGAACCGTGAAGAC

AGGATGGGGGCTGGCCTCTGGTTCTCGTGGGGTCCAAGCTT
                                        HindIII
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Second Invention

Claims

1. An analog of human erythropoietin having one or more changes in the amino acid sequence of human erythropoietin, as shown in Figure 5, which change(s) introduce at least one additional polypeptide site for glycosylation wherein a carbohydrate chain is attached to the additional site.

2. The analog of Claim 1 wherein an/the additional site is for an N-linked carbohydrate chain.

3. The analog of Claim 1 wherein an/the additional site is for an O-linked carbohydrate chain.

4. The analog of Claim 1 wherein the changes in the amino acid sequence are additions, deletions or substitutions of amino acid residues.

5. The analog of Claim 2 wherein an/the additional site is substituted at position 69 of the amino acid sequence of human erythropoietin as shown in Figure 5.

6. The analog of Claim 3 wherein the site is substituted at position 125 of the amino acid sequence of human erythropoietin as shown in Figure 5.

7. The analog of Claim 1 wherein an additional carbohydrate chain provides sites for sialic acid attachment.

8. The analog of any one of the preceding claims, which is the product of expression of an exogenous DNA sequence.

9. An analog according to Claim 1 selected from the group consisting of:

   Asn^{69} EPO;
   Asn^{69}, Thr^{71} EPO;
   Ser^{68}, Asn^{69}, Thr^{71} EPO;
   Thr^{125} EPO; and
   Pro^{124}, Thr^{125} EPO.

10. A DNA sequence encoding an analog of human erythropoietin of any one of the preceding claims.

11. A eucaryotic host cell transfected with a DNA sequence of claim 10 in a manner allowing the host cell to express an analog of human erythropoietin.

12. A composition comprising a therapeutically effective amount of an erythropoietin analog of any one of Claims 1 to 9, together with a pharmaceutically acceptable diluent, adjuvant or carrier.

Conclusion

Whilst a technically competent person would find no problem in analysing and comparing the above claim set, it is impossible for me to understand how a non-technical person can perform similar duties, with or without the helpful from textbooks or from another person.

I hope that the excerpts of patent documents above would make it clear and undebatable to non-patent practitioners that that patent-related work is not simple and straightforward, rather, such work is performed based upon direct application of scientific knowledge. Therefore, to advise on prosecution strategies, it is essential that the person responsible is equipped with the appropriate technical knowledge and scientific understanding.

As would be appreciated upon reviewing the above claims, it would be entirely inappropriate that drafting or analysis type work be entrusted to any person without the appropriate technical knowledge.

For the above reasons, I would like to emphasize to the Advisory Committee the importance of ensuring that any person entering this profession has a tertiary technical degree in science or engineering from a well-recognized university.

Kind regards,

[PLEASE DO NOT DISCLOSE MY IDENTIFY & EXPERIENCE]