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intellectual property

Update from the frontline: a selection of international patent “war stories”

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Disclaimer...

→ I'm not a lawyer!

War stories

- Count your claims
- Unity problems in Europe...
- *In vivo* data is important!
- The 3-D inventor

Count your claims!

Count your claims!

- Many patent applications in the biotech space include large numbers of claims, often in excess of 100.
- Excess claim fees may be payable at several stages through the life of an application/patent, for example:
 - on national phase entry (eg. US, EP)
 - at request for examination (eg. JP)
 - at acceptance of application (eg. AU)
 - at grant or renewal (eg. KR)
- Excess claim fees can be unexpected and, in some cases, very onerous.

Excess claim fees in EP

- Payable on national phase entry
- Claims 16 to 50 are charged €200 each. Claim 51 (and all subsequent claims) incur a fee of €500 per claim!
- These are only the fees – foreign attorneys are likely to add a service charge as well

10 claims	€ 0
20 claims	€ 1,000
50 claims	€ 7,000
100 claims	€ 32,000

Excess claim fees in US

- Payable on national phase entry
- More complex calculation than Europe – but lower fees
- A multiple dependent claims counts once for each dependency.

Claims in excess of 20	\$52/ \$26
Independent claims in excess of 3	\$220/ \$110
Multiple dependent claims	\$390/ \$195

Some claims are more dependent than others!

- For the purposes of calculating excess claim fees in US, a dependent claim ***must narrow an earlier claim.***

- Consider:
 1. A nucleic acid encoding a protein comprising the amino acid sequence set forth in SEQ ID NO: 1.
 2. A cell comprising the nucleic acid of claim 1.
 3. A nucleic acid according to claim 1 comprising the nucleotide sequence set forth in SEQ ID NO: 2.

- When calculating excess claim fees, ***claim 2 is not considered a proper dependent claim*** and is treated as an independent claim. Claim 3, however, is treated as a dependent claim.

Excess Claim Fees in JP

- ➔ Request for examination fee based on number of claims
- ➔ JPO fee (not including attorney charges) for requesting examination (for most Australian applicants using the PCT) is:
¥151,700 + **¥3,600 per claim.**

10 claims	~ AU\$ 2350
20 claims	~ AU\$ 2800
50 claims	~ AU\$ 4150
100 claims	~ AU\$ 6400

Australia

- Excess claim fee is payable at acceptance of an application.
- Fee is AU\$100 per claim over 20 in the application at acceptance.
- Can usually be dealt with during examination.

Solution?

- Always review claim sets prior to national phase entry (particularly for US and EP), with a view to minimise excess claim fees where possible.
- Review claim numbers when requesting examination and during examination to see if costs can be reduced.
 - Elimination of unnecessary claims (ie. those claims not likely to ever be novelty conferring)
- Why draft huge numbers of claims for a PCT application only to delete them later?
 - consideration of whether claims are needed at PCT stage?

Unity problems in Europe...

Unity of invention 101

- Typically, the claims in a patent application must all relate to the same invention.
- Claims are generally considered to relate to the same invention when all the claims share a feature which differentiates them from the prior art (ie. a novelty conferring feature)

Unity problems in Europe...

- Lack of unity in Europe can present unique pitfalls:
 - Limitation of Supplementary European Search
 - Limitation on divisional application filings

Searching issues

- The EPO assesses unity when preparing a Supplementary European Search Report (which occurs before substantive examination in Europe).
- If a lack of unity is found, the search will be limited to ***the invention appearing first in the claims at the time of the supplementary European search.***
- Unless the unity objection is later overcome, later examination is limited to the searched invention.
- Applicant may only be alerted to unity problem after examination has been limited!

Case study

- Company X entered national phase in Europe with a claim set covering a range of microbial inoculants for improving agricultural productivity.
- Inoculant of main interest was claimed well down in the claim set.
 - the first mentioned inoculant was of no commercial interest.
- In Europe, the SESR and later prosecution was limited to the first mentioned inoculant in the claims
 - Searched claims of little value to applicant.

Solution?

- Only solution is to file a divisional application with a new set of claims directed to the desired inoculant.
 - This is expensive!
- Better option:
 - A pre-national phase review of the claims to determine if a lack of unity objection may arise; and/or
 - ensure that the most relevant invention appears first in the claims

More unity problems in Europe?

- Currently, a divisional application may be filed at any time while parent is pending.
- ***After 1 April 2010 applicants will have 24 months from either a first Office Action or first unity rejection (if initially raised in a later Office Action) to file a divisional application.***

In vivo data is important!

In vivo data is important!

- USPTO practice is to generally require *in vivo* data to support *in vivo* therapeutic or *in vivo* prophylactic claims.
 - Data directed to therapy does not necessarily enable claims to prevention.
 - Scope of *in vivo* data may limit scope of therapeutic / prophylactic claims.

Case study

- Company Z entered national phase in US claiming methods for treating and preventing cancer using an agent.
- The only data in the specification was cell-culture data showing the activity of the agent against two cancer cell lines *in vitro*.
- ***All in vivo therapeutic/prevention claims (ie. claims to methods of treating or preventing cancer) were rejected for lack of enablement.***

Solution?

- Experimental data showing *in vivo* activity of the agent in an animal model was prepared and submitted to the USPTO in a Declaration under 37 CFR 1.132.
- Claims directed to treatment (but not prevention) of a limited range of cancers were allowed.
- But at what cost?
 - Generation of experimental data at short notice was expensive.
 - Also, the US attorney charged over AU\$20,000 to prepare and file the Declaration (even though nearly all of the content was prepared in Australia).

Better Solution?

- Where claims are directed to an *in vivo* therapy, review the data at complete application (eg. PCT) filing and try, wherever possible, to ***include in vivo data to enable in vivo claims*** over the claimed scope
- Consider:
 - Range of claimed therapeutic indications
 - Therapy vs. prevention
 - Ability to extrapolate existing data
 - Timing of filing

The 3-D inventor (that is difficult, disappearing or dead!)

The 3-D inventor

- In the United States, an Oath or Declaration must be signed by each inventor shortly after national phase entry.
- USPTO sets a deadline for submission of executed declarations. If the deadline is missed the application may lapse!
- What if an inventor won't sign or can't sign?

It depends...

- Whenever all of the inventors refuse to execute an application for patent, or cannot be found or reached after diligent effort, a person to whom an inventor has assigned or agreed in writing to assign the invention, or who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for all the inventors. The oath or declaration in such an application must be accompanied by a petition including proof of the pertinent facts, a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage, the fee set forth in § [1.17\(g\)](#), and the last known address of all of the inventors. An inventor may subsequently join in the application by filing an oath or declaration complying with § [1.63](#)<

➤ 37 CFR 1.47 Filing when an inventor refuses to sign or cannot be reached.

Solution?

- *“...a person to whom an inventor has assigned or agreed in writing to assign the invention, or who otherwise shows sufficient proprietary interest in the matter justifying such action, may make application for patent on behalf of and as agent for all the inventors.”*
- Thus, a clear assignment from the inventor showing the assignee is entitled to the invention is extremely helpful!

More reasons to assign early...

- Australia after *UWA vs. Gray* – do your employees have a duty to invent? If unsure, assign!
- Canada – Declaration of Entitlement system has become more onerous than the assignment-based system it was designed to replace.
 - Assignment of application effective at PCT date seems most efficient
- It is good general procedure! Would you simply assume you owned your house or car?

Any Questions?

Epilogue – Update on method of medical treatment claims in EP

→ Many countries ban claims to methods of medical treatment on the human body, including, for example EP, JP and NZ.

→ This ban is typically overcome by drafting claims that define the manufacture of a medicament ('Swiss-style' claim) rather than a method of treatment.

→ *“Use of substance X in the manufacture of a medicament (for the treatment of disease Y).”*

→ Swiss style claims are typically enforceable against a drug manufacturer rather than administering doctor or patient.

2007 changes

→ Since December 2007, the EPO has also accepted claims of the form:

“Substance X for use in the treatment of disease Y.”

→ How is this different to: A method of treating disease Y by administering compound X? (which is not allowable in EP)

→ Who is the new form claim enforced against?

EPO decision G 2/08 – 19 Feb 2010

→ This Enlarged Board of Appeal decision states that claims of the new form may be patentable even when defining a known agent for treatment of a known disease but in a new way.

→ eg. A dosage regimen

→ The Swiss-style format is not considered to be suitable for these claims.

→ In practice, what does the EPO ban on claims to methods of medical treatment now prevent?