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European Biotech Patent Case Law Webinar

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Agenda

- Plausibility
  - Data relating to a different indication (T 2015/20)
  - Activity data falling outside claim scope (T 2320/16)
- Biological material “made available to the public” (T 1045/16)
- Entitlement to claim priority – T844/18 & beyond
  - T 0407/15
  - T 2431/17

The importance of plausibility

Article 83 EPC

Article 83[78]
Disclosure of the invention

Art. 78, 80, 100, 138
R. 31-34, 40, 42

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Plausibility Requirement under Article 83 EPC (Sufficiency)

- Format of a medical use claim:

  "*Substance X* ***for use in the treatment of disease Y***"

- Format of a Swiss-Type claim:

  "*Use of substance or composition X for the manufacture of a medicament* ***for therapeutic application Z***"

- It is established case law of the boards of appeal that for a medical use claim to fulfil the requirements of Article 83 EPC, the patent has to disclose the **suitability of the product for the claimed therapeutic application**, unless this is already known to the skilled person at the priority date.

Plausibility – Article 83 EPC

- **T609/02 (Salk Institute)** - related to the use of a steroid hormone which fails to promote transcriptional activation of glucocorticoid receptor or retinoic acid receptor responsive genes, for the treatment of AP-1 stimulated tumour formation, arthritis, asthma, allergies and rashes.
- However, no steroid hormone was identified as binding to the hormone receptor in such a way that it would disrupt AP-1 stimulated transcription and at the same time fail to promote steroid hormone regulated transcription;
- *If the description of a patent specification provides no more than a vague indication of a possible medical use for a chemical compound yet to be identified, later more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure of such subject-matter.*"

Plausibility – Article 83 EPC

- **T433/05**;
- “aking into account the intrinsic difficulties for a compound to be officially certified as a drug, it is the practice of the Boards of Appeal that for acceptance of a sufficient disclosure of a therapeutic application in a patent/patent application**, it is not always necessary that results of clinical trials are provided at the relevant date, but that it is required that the patent/patent application provides some information to that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease.**

Plausibility - Article 83 EPC

- Either the **application must provide suitable evidence** for the claimed therapeutic effect or it must be **derivable from the prior art or common general knowledge**.
- **Experimental results are not always required in the application** to establish sufficiency, in particular if the application discloses a plausible technical concept and there are no substantiated doubts that the claimed concept can be put into practice.

Plausibility under Article 56 EPC (Inventive Step)

- Often relevant for product claims
- It is established case law of the boards of appeal that there can only be an invention if the application makes it **at least plausible** that its teaching **indeed solves the problem it purports to solve**.
- If not, inventive step may be denied or problem may be reformulated.
- “Absolute proof" of the achievement of an effect is not required for the effect to be "plausible“.
- Opponent may need to **substantiate doubts** about the suitability of the claimed invention to solve the technical problem.

Plausibility – Data relating to a different indication

- T 2015/20 (Almirall, S.A.)

Claim 1 of the Main Request

"***A pharmaceutical composition comprising aclidinium*** *in the form of a dry powder of a pharmaceutically acceptable salt in admixture with a pharmaceutically acceptable dry powder carrier,* ***providing a metered nominal dose of aclidinium equivalent to 400 µg*** *(plus/minus 10%) aclidinium bromide* ***for use by inhalation in the treatment of asthma.***"

Examining Division did not consider application to make treatment of asthma plausible

- The data in the application related to a different therapeutic indication (COPD).
- The Examining Division considered that it was part of common general knowledge that COPD and asthma were different diseases with different mechanisms, as evidenced by a document on file (D5):

> It was early recognized that COPD is an inflammatory disease and that the mechanisms of airway obstruction differed from that observed in asthma. The pathologi-

Examining Division did not consider the prior art to make treatment of asthma plausible

- A document on file (D6) explicitly warned that a similar dose of the claimed product (aclidinium bromide) **should not be used in asthma** and that clinical studies in asthma had not been conducted.
- Hence the Examining Division considered that there were **no clinical studies which could make credible the therapeutic activity** of the claimed composition in asthma.
- The Examining Division also considered the warning in this document gave rise to **serious doubts** that the claimed treatment of asthma could be put into practice.

The Board did not consider there to be serious doubt as to utility from the prior art

- The Board of Appeal considered that the evidence on file supported that the claimed product (aclidinium bromide) has a mechanism of action that is useful in the treatment of asthma.
- D5 – actually confirms that asthma is influenced by cholinergic mechanisms, be it to a lesser extent than COPD (aclidinium bromide has anticholinergic activity)
- The Board considered that document D6 merely warns that the use of this combination product in asthma had **not been officially authorised**, which is **not a ground for serious doubts** regarding the claimed utility of aclidinium in treatment of asthma.

The Board considered the application to disclose a significant technical teaching

- *the defined utility of aclidinium in treatment of asthma does not go against any prevailing opinion in the prior art…the Board considers the statement in the application, that the treatment of respiratory disorders, particularly asthma and COPD, with aclidinium is most effective upon administration by inhalation in a dosage of about 400 µg metered nominal dose (paragraph [0003]) to represent a significant technical teaching, which is far from an invitation to perform a research programme and which does not prima facie lack plausibility.*

The Board considered claim 1 plausibly disclosed

- The Board considered the teaching of the application to be falsifiable, in the sense that it is **open to challenge**, and is therefore considered to **represent information in the form of a specific technical contribution which goes beyond some insufficient verbal statement.**
- The Board of Appeal considered **no serious doubts** have come about with respect to the defined utility of the claimed product.
- Therefore, the Board considered that the sufficiency of the disclosure of the claimed invention is therefore **not to be denied**

Inventive Step – problem to be solved

- D1 describes the combination of a M3 muscarinic receptor antagonist such as aclidinium bromide with a PDE4 inhibitor for treatment of respiratory disorders such as asthma and COPD.
- Combination allows lower dosages to be used
- D1 mentions for the M3 muscarinic receptor antagonist a suitable dosage unit of 20-1000 µg, preferably 50-300 µg and describes in its examples formulations comprising 100 µg aclidinium bromide.
- The difference between the invention and D1 is the **particular dose of 400 µg**

Inventive Step – problem to be solved

- The Application stated that surprisingly the particular defined dose is **most effective** in the treatment of respiratory disorders, particularly asthma and COPD.

  - **corroborated by the results of Example 1** (a COPD trial)

The Board of Appeal considered it **reasonable to assume** that the optimized dose for COPD **also represents an optimized dose for asthma,** since documents on file support that the claimed product's mechanism of action would also be relevant to asthma treatment

The Board considered Claim 1 to be inventive

- The Board found **no information in the available prior art** in view of which the skilled person would arrive at the claimed subject-matter when **seeking to provide an optimized dose** for treatment of asthma.
- D1 aimed at lower dosages, thereby teaching away
- D2 discloses a dosages of 300 and 900 µg have similar effect - but only a single dose trial and so not chronic treatment
- **Claim 1 involves an inventive step.**

Conclusions

- The therapeutic indication of claim 1 *("for use by inhalation in the treatment of asthma")* was considered ***prima facie* plausible** and since there was no evidence of **serious doubts** the defined therapeutic effect could not be achieved.

- The problem of **providing an optimised dose use in asthma was considered plausible** from evidence relating to a **different therapeutic indication** (COPD), since documents on file support that the mechanism of action of the claimed product would also be relevant to asthma treatment.

Plausibility - Activity data falling outside of claim scope

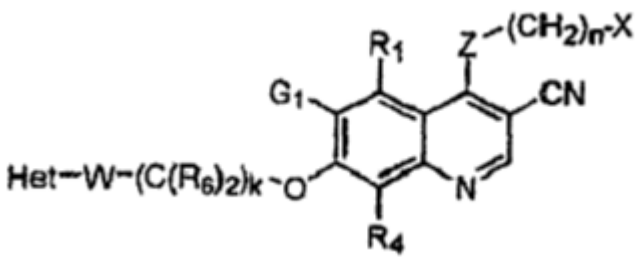
- T 2320/16 (Wyeth Holdings LLC)

Background - solving the technical problem

- If inventive step depends on a particular technical effect, the question as to whether or not a technical effect is achieved by all the compounds covered by a claim may arise under Article 56 EPC (T 939/92).

T 2320/16 – Background

- Appeal from the Opposition Division decision rejecting the opposition against EP 2253620.
- Opponent appealed solely on the point of inventive step.
- Claim 1 can be summarised as compounds having the following structure:



Note the presence of the cyano moiety (–CN), which was the sole distinguishing feature over the closest prior art.

T 2320/16 – Objective technical problem

- According to the patent, the inventive compounds are tyrosine kinase inhibitors useful in treating cancer.
- Technical problem: providing further kinase inhibitors.
- Point of contention: is the technical problem solved by the claimed compounds, across the whole scope of the claim?
- Claim breadth encompassed structural variation due to listed alternative “X” and “R” groups.

T 2320/16 – Data

- The patent gave numerous examples of kinase inhibitors, including those which fell both outside and within the scope of claim 1.
- Biological activity data was provided, but **only** for inhibitors falling *outside* the claim scope.
- Patentee also filed post-published data showing the biological activity of the claimed compounds.
- Could rely on post-published data because the data in the patent for similar but non-claimed compounds established plausibility (finding of the OD, not challenged on Appeal).

T 2320/16 – Was the problem solved?

- The Opponent-Appellant argued that it was not credible that substantially all of the compounds encompassed by claim 1 solved the technical problem.
- Evidence was provided that minor structural variations, similar to those encompassed by claim 1, resulted in a reduction of activity.
- Opponent alleged that the burden of proof resides with the Patentee (T 415/11).
- Conflated the variation in the claim (“X” and “R” groups) with Agrevo case law (T 939/92).

T 2320/16 – Findings of the Board

- T 415/11 "*When the credibility that a technical effect is achieved by substantially all claimed compounds is at issue and in a situation where, it is prima facie unlikely that this is credible, it is ... not the opponent..., but the patentee... who has the burden of proof that the effect is achieved*".
- Board distinguished present case from T 415/11 since in the present case biological data has been provided for a significant number of compounds falling within the claimed scope.
- The burden of proof lies with the opponent.

T 2320/16 – Findings of the Board

- The Board found that the patentee had already discharged the initial burden of proof with its post-published data
- Now, the burden was on the Opponent to prove that the technical problem was not solved across the claim scope
- The Opponent proved only *reduced* activity due to structural variation. It was mere speculation that further variation would result in unacceptable *loss* of activity

T 2320/16 – Findings of the Board

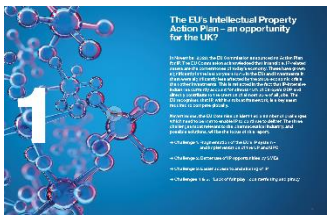
- The closed number of alternatives in claim 1 distinguishes this case from the open-ended claim language in Agrevo.
- Contrary to Agrevo, claim 1:

  "represents a reasonable generalisation of the compounds for which biological data was provided"

- This generalisation was from the cyano moiety, which the Board accepted as a pharmacophore giving a structure-activity relationship to the claimed compounds.

Special report

Patents and SPCs post-Brexit – pharma's big opportunity?



www.dyoung.com/brexit-pharma

Biological material “made available to the public”

T 1045/16 - Claim 1 as granted

"*A CYSDV-resistant plant of the species Cucumis melo,*

said plant comprising an introgression from ***a plant of melon accession PI313970****,*

which introgression comprises a CYSDV-resistance-conferring QTL or a CYSDV-resistance-conferring part thereof linked to at least one marker located on the chromosome equivalent to linkage group (LG) 6 ***of melon accession PI313970****,*

wherein said marker is E11/M49-239, and wherein said QTL or said part thereof is present in homozygous form."

Rule 31(1)(a) EPC

Rule 31 [43], [44]
Deposit of biological material

Art. 78, 83, 128, 129
R. 26, 34

(1) If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the European patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed as prescribed in **Article 83** if:

(a) a sample of the biological material has been deposited with a recognised depositary institution on the same terms as those laid down in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 not later than the date of filing of the application;

T 1045/16 - Background

- Appeal from decision of the Opposition Division to revoke the Patent for insufficiency.
- It was common ground that, to comply with Article 83 EPC:

  - Access to propagating material (e.g. seeds) containing the CYSDV-resistance-conferring QTL and marker were required.

  - These must be identical to or derived from melon accession PI313970.
- There was no deposit of such material with a recognised depositary institution as set out in Rule 31(1)(a) EPC.
- It needed to be determined whether or not the relevant biological material was **available to the public**.

T 1045/16 - "Available to the public" in Rule 31(1) EPC

- Appellants argued that melon accession No. PI313970 was publically available on filing date & date of writing Statement of Grounds of Appeal.

  - Board considered that to be "available to the public“ (Rule 31(1) EPC) a biological material must be available for the lifetime of a patent.

- Brewers yeast, *Escherichia coli &* melon plants in general would be “available to the public”.
- **Specific, non-generic strains of microorganism or accessions of plants only available from a non-Budapest Treaty institution are not considered available**.

T 1045/16 - Decision of Board of Appeal

- G2/93 – Rule 31 EPC is subordinate to Article 83 EPC.
- Deposit with a non-Budapest Treaty institution cannot ensure availability to the public because Rule 31(1) EPC stipulates that biological material which is "not available to the public" is to be "deposited with a recognised depositary institution on the same terms as those laid down in the Budapest Treaty".
- Thus, the claimed invention does not meet the requirements of Article 83 EPC (Appeal was dismissed).

T 1045/16 – Lessons

- **The availability of plants of the accession PI313970 from the US National Plant Germplasm System is not sufficient** to ensure that skilled person can practice the claimed invention during the term of the patent at issue.
- Strict standard in order for a biological material to be considered not to need to depend on a deposit:
  - It must be available at least over the lifetime of the patent
  - It must not alter over time
- If possible, make a deposit under Budapest treaty.

Entitlement to claim priority

Priority at the EPO - Article 87(1) EPC

"***Any person*** *who has duly filed […] an application for a patent, […] or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application.*"

Priority at the EPO - interpretation

- "*Any person*" is considered to be all Applicants of the priority application, or their successors in title.
- This is referred to as the "*all Applicants*" approach.
- It requires all Applicants for a priority application, or their successors in title, to be Applicants of a subsequent application.
- Plausible interpretation of the Paris Convention.
- The "*all Applicants*" approach is required to prevent one Applicant of a priority application filing a subsequent application as a sole Applicant and excluding the other Applicants of the priority application.

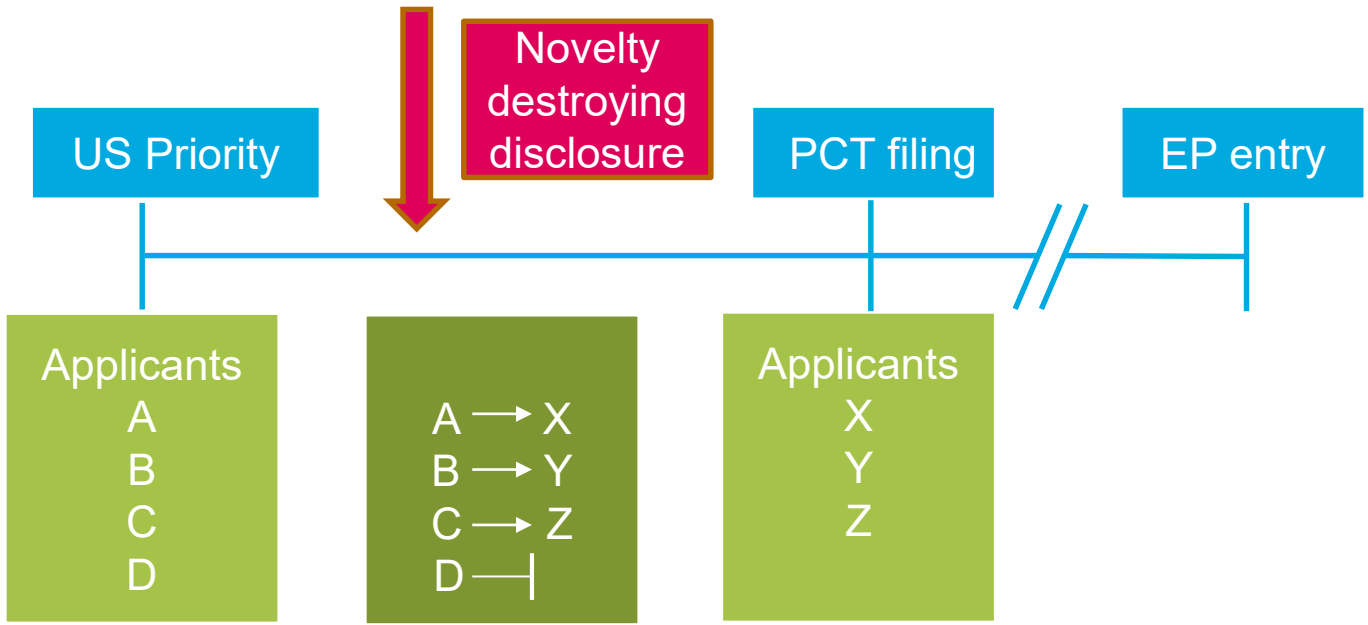
EP2771468 – Overview of T0844/18

- Broad Institute's CRISPR Patent.
- The two earliest provisional applications (US201261736527P & US201361748427P) listed an Applicant-Inventor who was not listed as an Applicant on the PCT application (WO2014093712).
- There was no transfer of rights to a PCT Applicant before the PCT application was filed.
- Patent not entitled to earliest two priority dates.
- Intervening prior art meant claims lacked novelty.

EP2771468 - Background

- Patent related to CRISPR-Cas9 technology.
- Patentees were The Broad Institute, Massachusetts Institute of Technology & President and Fellows of Harvard College.
- Opposed by 9 parties.
- EP2771468 claimed priority to 12 US provisional applications.
- The 12 US provisional applications each list different combinations of Applicant-Inventors
- P1, P2, P5 & P11 list Mr Maraffini as an Applicant-Inventor.
- Mr Maraffini assigned his rights to the Rockefeller University of New York (USA) who were not an Applicant of the PCT application.

EP2771468 - Timeline



EP2771468 - Opposition Division

- The Opposition Division concluded that the patent lacked priority because the priority application did not list the same Applicants as the PCT application, or their successor in title.
- Due to the lack of entitlement to P1 & P2 the patent lacked novelty.
- Patentees appealed.

EP2771468 - Appeal (T 0844/18)

- The Patentees appealed against the lack of priority leading to lack of novelty.
- The appeal focussed on three questions:

  - Should entitlement to priority be assessed by the EPO?

  - How is the expression "*any person*" in Article 87(1) EPC to be interpreted?

  - Does national law (in this case US law) govern the determination of "*any person*" who has "*duly filed*" in Article 87(1) EPC?

T 0844/18 - Should entitlement to priority be assessed by the EPO?

- Patentees argued that the EPC exhaustively lists the requirements for a priority claim.
- Proof of priority right is not expressly required by the EPC.
- Board of Appeal concluded that Article 87(1) EPC requires the EPO to examine who can claim priority.
- The EPO will merely carry out a formal assessment of the person filing the application (& priority application).

T 0844/18 - How is the expression "*any person*" in Article 87(1) EPC to be interpreted?

- The ordinary meaning of the term "*any*" could be interpreted as "*any one person*".
- Patentees argued that neither the EPC nor the Paris Convention specifies that all Applicants of the priority application must be Applicants on subsequent applications.
- Board confirmed that the "*any one person*" approach could allow one Applicant of a priority application to file a subsequent application excluding the other Applicants of the priority application.
- No difference between internal & external priority claims.

T 0844/18 - Does national law (in this case US law) govern the determination of "*any person*" who has "*duly filed*" in Article 87(1) EPC?

- Patentees argued that priority right arises before a subsequent application is filed & should be interpreted under national law.
- Under US law an Inventor is only an Applicant for subject-matter (s)he invented.
- Article 87(1) EPC refers to the person who filed the application, not the Inventor or Applicant.
- Board concluded that US law was not relevant.

T 0844/18 - Outcome

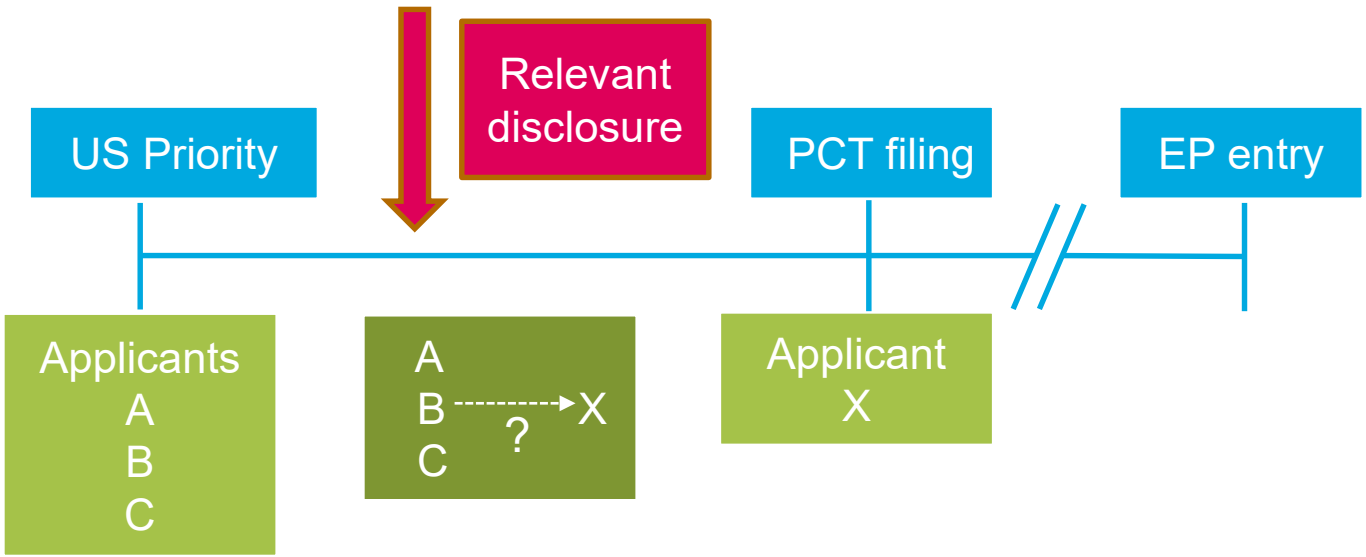
- The patent was found not to be entitled to P1, P2, P5 or P11.
- In view of the lack of entitlement to P1 & P2 the patent lacked novelty.
- The patent was revoked.

Entitlement to claim priority – beyond T 0844/18

T 0407/15

- PCT application filed by University of Western Ontario (“UWO”).
- 2 priority documents (US provisional applications) each filed by 3 Inventor-Applicants who were not Applicants for the PCT application.
- EP2252901 refused by Examining Division for lack of clarity & added matter.
- Priority not considered by Examining Division.
- Board of Appeal identified relevant intervening prior art & found claims to lack inventive step.

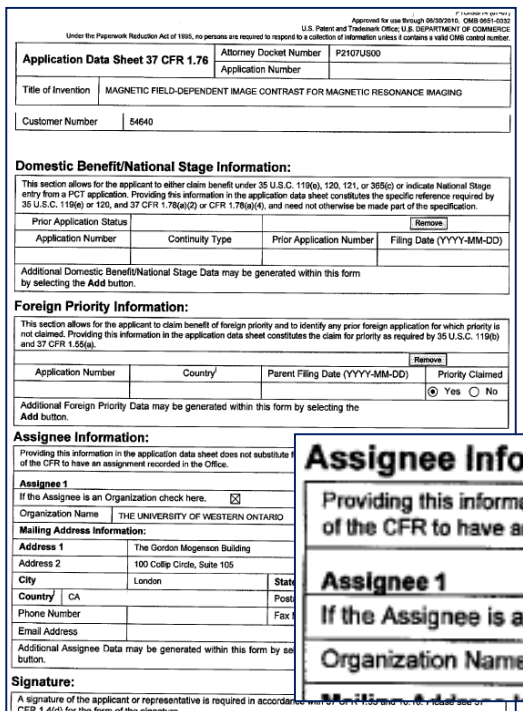
T 0407/15 - Timeline



T 0407/15 - Insufficient evidence

- UWO was asked to provide evidence of entitlement, but failed to do so.
- Both priority applications include a section entitled "*Assignee information*“ which identified UWO as the Assignee.
- There was considered to be insufficient evidence to establish valid transfer of priority right.
- “*This is a consequence of the fact that the filing of a first application gives rise to two different and independent rights, namely the right to the application in question, and the right of priority. While… the priority documents... appear to provide evidence of a transfer of the right to a patent, it is silent as to any right of priority based on said filings.*”
- Applicant/Patentee bears burden of proving priority entitlement.

T 0407/15 - "*Assignee*" of priority applications



Application Data Sheet 37 CFR 1.76

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	P2107US00
	Application Number	
Title of Invention	MAGNETIC FIELD-DEPENDENT IMAGE CONTRAST FOR MAGNETIC RESONANCE IMAGING	
Customer Number	54640	

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button.

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◉ Yes ○ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

Assignee Information:

Providing this information in the application data sheet does not substitute f
of the CFR to have an assignment recorded in the Office.

Assignee 1	
If the Assignee is an Organization check here.	☒
Organization Name	THE UNIVERSITY OF WESTERN ONTARIO
Mailing Address Information:	
Address 1	The Gordon Mogenson Building
Address 2	100 Collip Circle, Suite 105
City	London
Country	CA
Phone Number	
Email Address	

Additional Assignee Data may be generated within this form by se
button.

Signature:

A signature of the applicant or representative is required in accordance
CFR 1.4(d) for the form of the signature.

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1

If the Assignee is an Organization check here. ☒

Organization Name THE UNIVERSITY OF WESTERN ONTARIO

- The priority documents specified that UWO was the Assignee on their filing dates.
- No further information regarding assignment.

T 0407/15 – Is explicit transfer required?

- Article 87 EPC does not require an explicit transfer, or exclude an implicit transfer.
- The independence of a priority right and the right to an application does not mean that a valid transfer of a priority right inevitably requires a separate and express assignment declaration.
- Explicit transfer of a priority right may not be essential when other evidence is sufficient (e.g. T 205/14 and T 517/14).
- Merely indicating an assignment does not appear to be sufficient.
- Continuity of Inventors was also not considered sufficient evidence.
- The evidence required remains unclear.

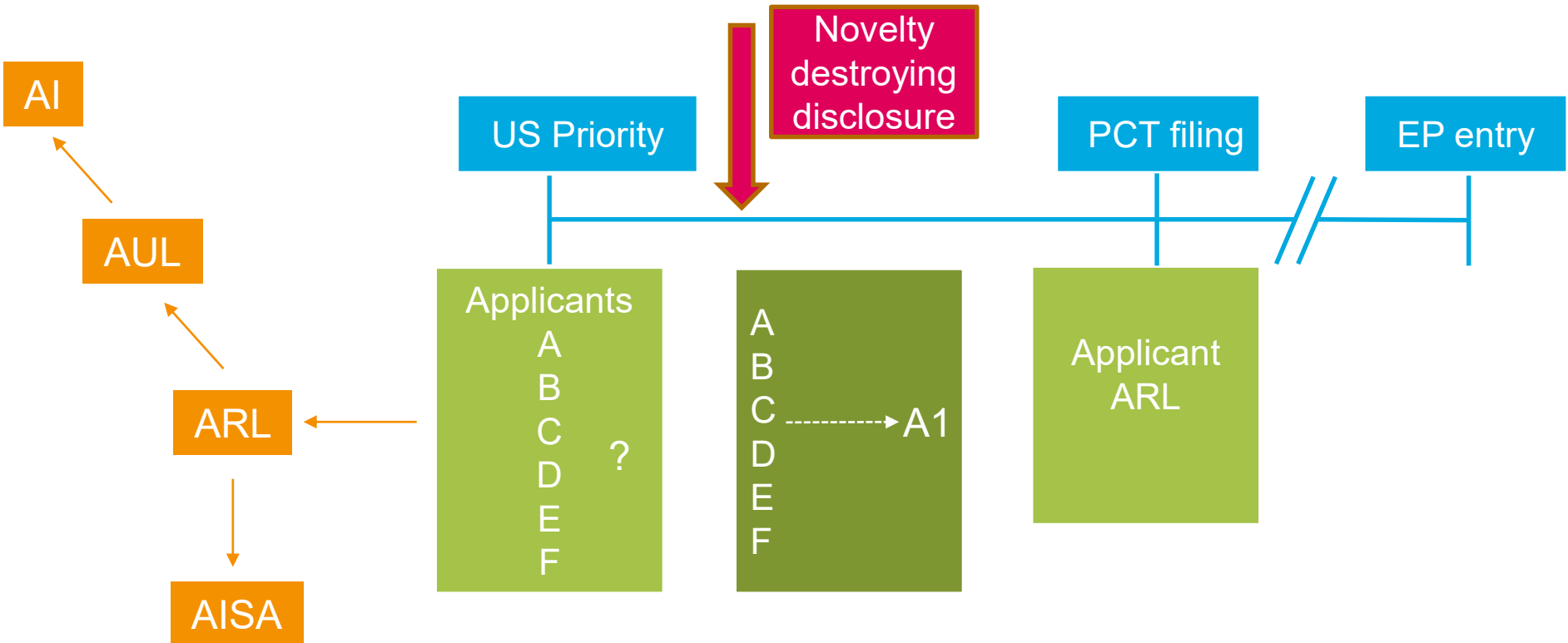
Entitlement to claim priority – beyond T 0844/18

T 2431/17

- EP2265251B granted to Alcon Research Ltd (ARL).
- 2 priority documents (US provisional applications) filed by 13 Inventor-Applicants who were not Applicants for the PCT application.
- Only priority from P1 (6 inventors) was relevant.
- Intervening Article 54(3) EPC prior art considered novelty destroying.

T 2431/17 - Timeline

ARL



T 2431/17 - Chain of title

- Alcon Research Ltd (ARL) employed the inventors.
- Employment contract assigned rights to "*inventions heretofore or hereinafter conceived*" to AUL.
- AUL changed its name to AI.
- ARL entered licencing agreement with AISA which stated that AISA "*has acquired and assumed the economic benefits and burdens with respect to AI's intellectual property*" & that any future discoveries *"shall be the sole and exclusive property of the appropriate R&D Principal(s) funding such Discoveries*".

T 2431/17 – Unconvincing chain of title

- Priority not found to be valid & claims lack novelty in view of intervening disclosure.
- No evidence that the right to claim priority was transferred from AI to AISA with *“AI’s Intellectual Property”.*
- Licence agreement between AISA & ARL not considered to supersede the employment contract which granted the rights to AI (formally AUL).

Lessons on priority

- The EPO requires all Applicants of the priority application, or successors in title, to be listed as Applicants on a subsequent European application (or PCT).
- All Applicants (or successors in title) from the priority application must be listed as Applicants on a PCT or European application.
- If a priority application lists Applicant-Inventors, the Inventors must assign their rights to the European (PCT) Applicant before the European (PCT) application is filed.

Priority – Avoiding the pitfalls

- There is no formal requirement for explicit transfer of priority right, but evidence of the transfer may be required.
- Transfer of a priority application is not enough as the priority right is considered a separate right

    - Consider assigning this right separately.

- The test remains “balance of probabilities” but this threshold appears to be rising.
- Following AIA it is advisably to file US provisional applications in the name of the PCT Applicant rather than the inventors if at all possible.

Further information

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Save the date

Our next webinar will broadcast on Tuesday **21 September 2021**.

- Presented by Simon O’Brien and Antony Latham.
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