International Litigation

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IPTA 2014 ANNUAL CONFERENCE

THREE NEW SQUARE
INTELLECTUAL PROPERTY

Your speakers

Andrew Waugh QC, Barrister (United Kingdom)

Called to the English Bar – 1982, took silk (QC) 1998

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Called to the NSW Bar – 1993, took silk (SC) 2006

Katrina Howard

Katrina Howard specialises in the field of intellectual property, especially patents. Most of her patent related work has been in the biological sciences including pharmaceuticals and biotechnology. She has acted in most of the major cases in these areas in the last twenty years in Australia. Many of these cases have been part of multinational litigation, parallel to cases conducted in the UK and USA.

Andrew Waugh

Andrew Waugh has a general intellectual property practice but his background has led to a particular emphasis on chemical, pharmaceutical and bio-tech/genetic engineering matters as well as a broader commercial practice, including arbitrations involving a significant scientific/technical content. Tribunals in front of which Andrew Waugh most frequently appear include the Courts of England, the Court of Justice of the European Union, the United Kingdom Trade Marks and Patent Office, the European Patent Office in Munich, the Hague and Berlin and the High Court in Dublin.

International Litigation

A comparative study

Part I - The Opportunity

The benefit of litigating parallel patents in at least three separate jurisdictions, namely:

- Australia
- United Kingdom
- United States of America

.....and others

Disputed Subject Matter and the Clients

- **Zoledronic Acid ("Zol")** – a bisphosphonate to treat osteoporosis – client: ***Novartis***
- **Taxol-coated Stents ("Taxol")** – to treat coronary restenosis – client: ***Angiotech***
- **Erythropoietin ("EPO")** – red blood cell growth factor to treat the depletion of red blood cells in anemia and dialysis - client: ***Amgen***
- **Olanzapine/ sildenafil** (Viagra) – drugs to treat schizophrenia/ erectile dysfunction respectively – client: ***Eli Lilly***

The Questions we asked and Why

1. Claims and Amendment

- Were there any significant differences between the Patents and their claims in the US, UK and Australia? If so what were the main differences?
- Was there the ability/opportunity to amend the claims in the three jurisdictions?
- Was the ability/inability to amend a significant factor in the decision to litigate in the three jurisdictions?

Did claim format/amendment matter.....?

The Questions we asked and Why

2. The decision to litigate

- If you had a choice, what were the most significant factors in your choice of the US, UK and Australia as fora in which to litigate?
- Did you have a choice?

What were the most influential factors in driving the choice of fora……?

The Questions we asked and why

3. The structures of the legal / patent professions

- How did the structures of the legal/patent profession compare in each jurisdiction?
- What roles did patent attorneys (agents) / patent solicitors (lawyers) / barristers (trial attorneys) play in each jurisdiction?
- Which structure did you find most effective for your needs?

To compare the professional structures in each jurisdiction

The Questions we asked and Why

4. Timescales

- How did the timescales in each jurisdiction compare (from commencement to final result and any appeals?)
- Did you feel that the timescales were too short, too long or about right?
- Would you have wanted the timescales to have been either quicker or slower if you could have influenced them?

To compare the speeds at which litigation is conducted in each jurisdiction

The Questions we asked and Why

5. Pre-trial procedures

- What were the best aspects of each jurisdiction's procedures?
- What were the worst aspects of each jurisdiction's procedures?
- If you could change any particular aspect in each jurisdiction what would it be?

To compare the procedures leading up to trial

The Questions we asked and Why

6. Trial procedures

- What were the best aspects of each jurisdiction's procedures?
- What were the worst aspects of each jurisdiction's procedures?
- If you could change any particular aspect in each jurisdiction what would it be?

To compare the various trial procedures

The Questions we asked and Why

7. Outcomes

- How did the respective outcomes compare?
- How certain/predictable did you find the outcome in each jurisdiction?

Did the clients get what they expected?

The Questions we asked and Why

8. The Judges

- What was your impression of the competence of the Judges in each jurisdiction?
- Were specialist patent judges available? If not, did it matter to you?

To judge the judges!

The Questions we asked and Why

9. Costs

- How did the respective costs compare?
- Could you recover them from the other side?

To compare the jurisdictions' costs regimes

The Questions we asked and Why

10. Efficiency

- In terms of overall efficiency and cost effectiveness, how would you rank the various jurisdictions?

To compare overall efficiency

The Questions we asked and Why

10. Lessons Learned

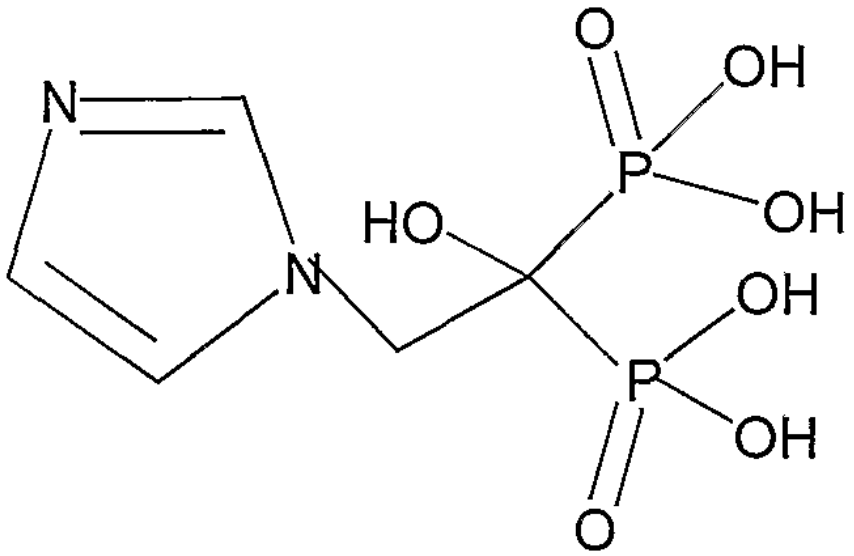
- If you had a choice, would you choose to re-litigate in each jurisdiction?
- If you had to decide to litigate in each jurisdiction again, what, if anything, you would wish to be done differently?

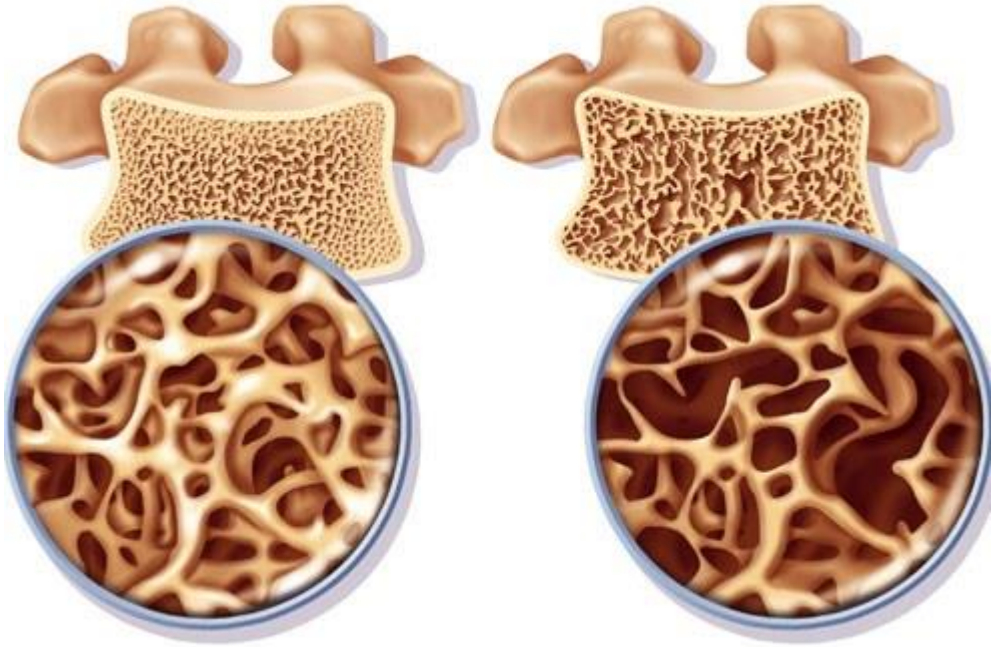
To see what lessons could be learned from the litigation experience.

The Cases Chosen for Study - 1

Hospira v *Novartis* – "Zol"

Zoledronic Acid – a bisphosphonate to treat osteoporosis **-** ***the invention - 6 monthly + IV infusion***

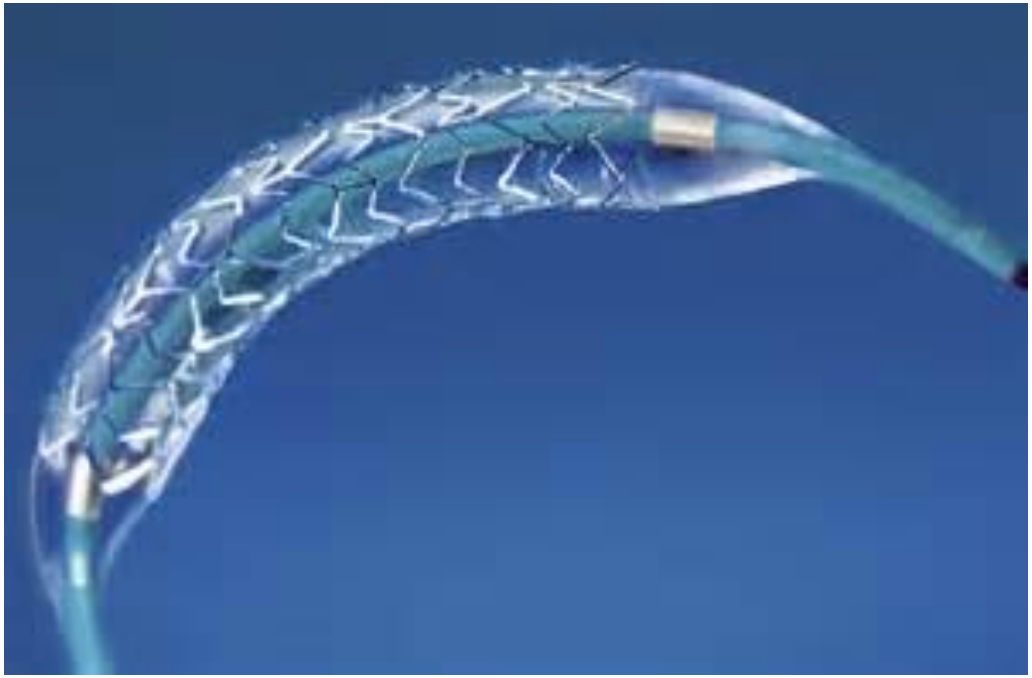


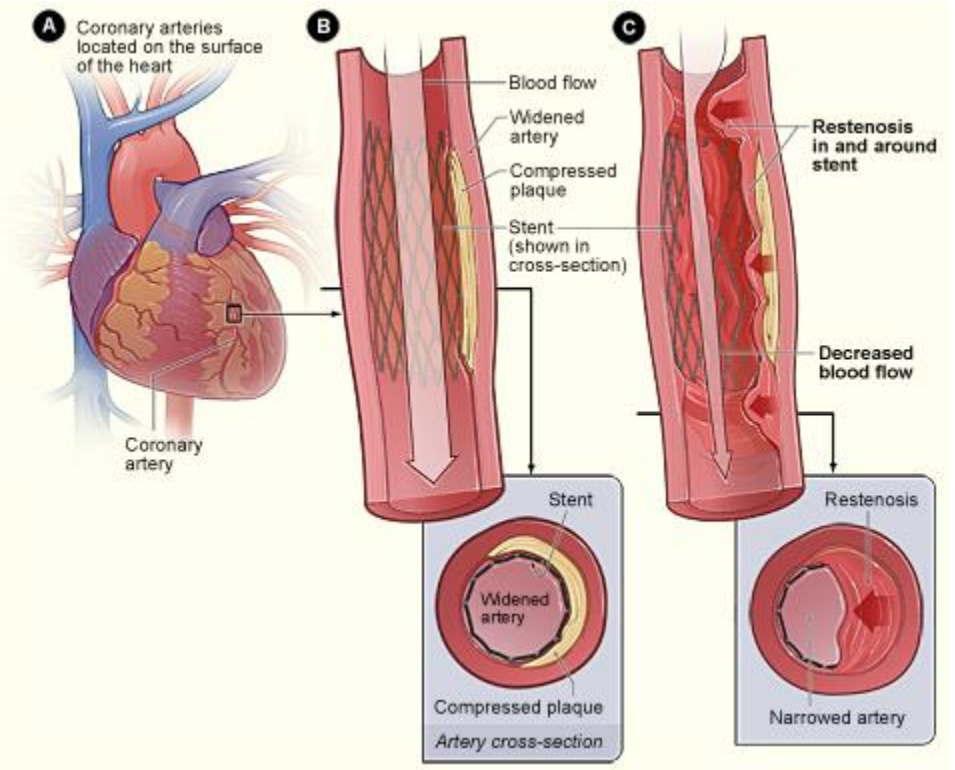


The Cases Chosen for Study - 2

Conor v Angiotech - "Taxol"

The invention - Taxol-coated Stents to treat coronary restenosis

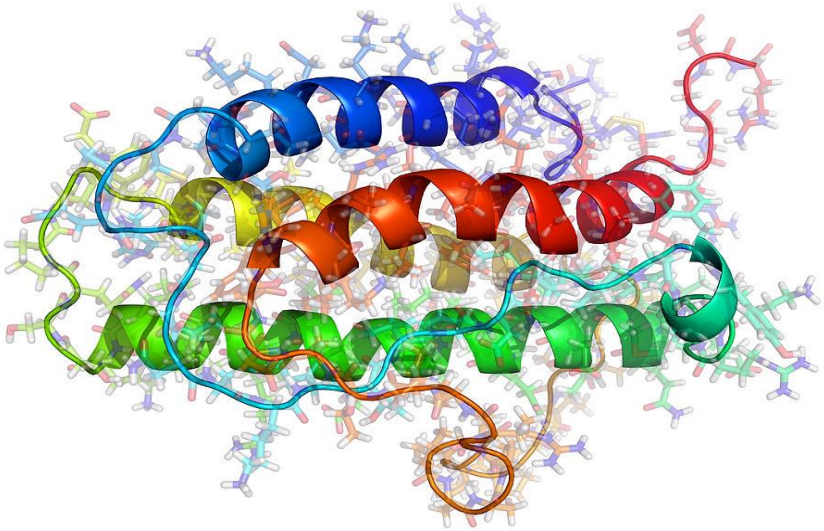




The Cases Chosen for Study - 3

Amgen v Roche / TKT- "EPO"

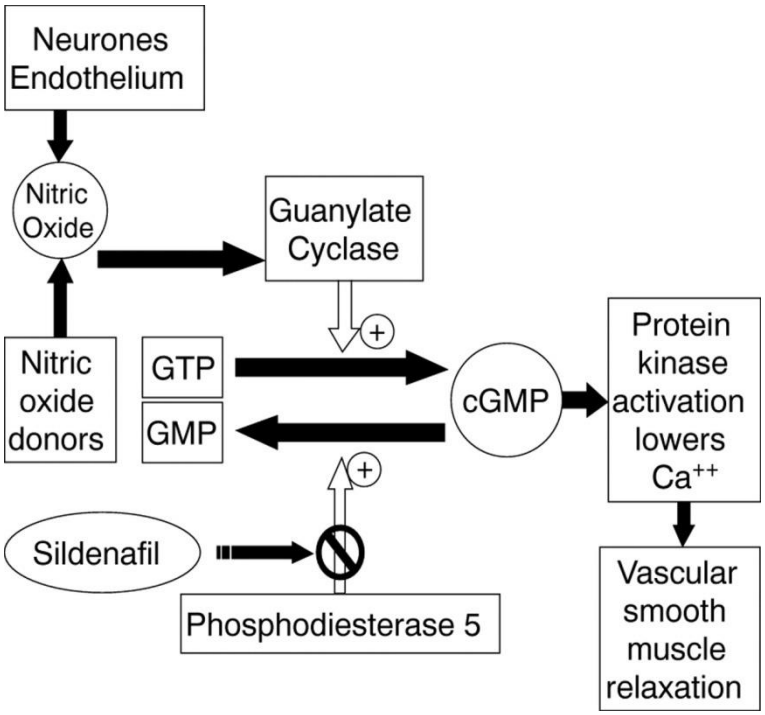
EPO - the invention – erythropoietin to treat the depletion of red blood cells in anemia and chemotherapy – and cycling….



The Cases Chosen for Study – 4(a)

Eli Lilly v Pfizer – "PDEv"s

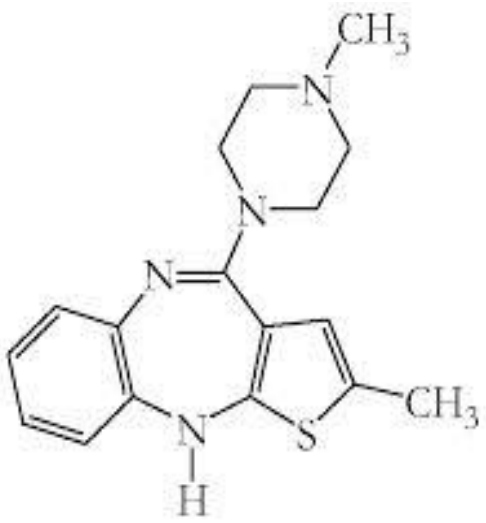
The *alleged* invention – use of any cGMP PDEv inhibitor to treat erectile dysfunction - as well as sildenafil (Viagra)



The Cases Chosen for Study – 4(b)

Eli Lilly v Dr Reddy's – "olanzapine"

The invention – olanzapine – a compound used to treat schizophrenia



olanzapine

In the following slides the attempt is to capture the

CLIENTS' PERCEPTION

Not just our views

Common themes emerge

1. Claims - Zol

- Differences were in the precise form of the claim (e.g. Swiss-type claims, method claims, use claims, pharmaceutical composition for use, compound for use claims, pharmaceutical composition claims, kit claims).
- Other differences related to the specific combination of integers in the claims, e.g. whether route of administration was specified, whether dose was specified, how interval between administrations was specified. Also whether disease to be treated was "conditions of abnormally increased bone turnover", osteoporosis or a specific type of osteoporosis.

1. Amendment - Zol

The option was there in all jurisdictions, but only pursued in the UK.

Nb Discretionary factors now play a part only in AUS.

UK in line with European Practice

Nb central pan-European amendments now possible in EPO

NB Recent UK APPLE v SAMSUNG decision

1. Claims - Taxol

- Same claims across Europe –

  1. A stent for expanding the lumen of a body passageway, comprising a generally tubular structure coated with a composition comprising an anti-angiogenic factor and a polymeric carrier, the factor being anti-angiogenic by the CAM assay, and wherein said anti-angiogenic factor is taxol, or an analogue or derivative thereof. …..

  [11. A stent according to any one of claims 1 to 5 for treating narrowing of a body passageway.]

  12. A stent according to claim 11 for treating or preventing recurrent stenosis.

- Similar in Australia

1. Amendment - Taxol

- AUS – yes, possible
- UK – yes, but amended in EPO Opposition
- U.S. – No, effectively fixed –

NB but note the new post-Grant Opposition Procedures (Inter-Partes Reviews or "IPRs" taking off rapidly in the US alongside litigation) - see

http://www.uspto.gov/aia_implementation/faqs_post_grant_review.jsp

1. Claims - EPO

Diversity of claims in the US related to the product

UK/Aus more limited claims

Amendment ability did not matter – didn't choose to fight in any jurisdiction – suits started by Roche

1. Claims – Olanzapine/PDEv

- PDEv: US patent was a method of treatment whereas AUS and UK patents were Swiss-use claims.
- Olanzapine: Compound claims (olanzapine) and method/use claims.

NOTE Landscape has changed significantly since EPC 2000 and "use of X for [treatment]" claims

Major Unanswered Questions on Infringement when us is Off-Label – ie sold for an old indication, but in practice used for the new indication.

1. Amendment - Olanzapine/PDEv

- **Viagra** - Pfizer could have amended in EPO whilst parallel proceedings on foot as part of the proceedings (to narrow [sildenafil] claims to treat ED) – but badly handled and left too late in the EPO
- **Olanzapine** – not in practice – the narrowest of claims – just olanzapine in any event.

  Was it a factor?

  Not in these cases; but it is a factor where it is readily done.

2. The decision to litigate - Zol

Any choice? Did not choose to litigate in UK – revocation proceedings in UK by Hospira

Took the choice in AUS and USA given the sizes of market to seek Preliminary Injunctions

Factors? Market size, international legal status of each jurisdiction/precedent setting value of UK for other European Jurisdictions

The market size of each jurisdiction justified starting/ defending the litigation.

In the UK the potential was seen for a good decision which could have been referred to in the other EP states.

2. The decision to litigate - Taxol

- UK/AUS – no choice – actions to revoke begun by challenger (Conor)
- Europe – Netherlands seen as preferred Jurisdiction
- US – Proactive because "*the U.S. currently represents the most profitable market for healthcare innovations, patentees are often careful to initiate litigation as early as permitted. In favor of doing so are such significant forum-specific factors as the right to a jury trial, well-defined laws governing the admissibility of evidence, and the availability of permanent injunctive relief*".

2. The decision to litigate - EPO

- Initiated in US – flagship product for Amgen – Amgen owned all rights – US more patentee friendly.
- Had no choice in AUS – filed counterclaims once initiated – licenced to Ortho/J&J – UK seen as less patentee friendly – AUS perceived as becoming less patentee friendly than in the past
- Market size US >> UK ~ Aus

2. The decision to litigate - Olanzapine/PDEv

Main factors in decision making:

- the competency of the court to give a thorough and fair hearing on the issues:
- Rule of law/ consistent precedent and reasonably predictable
- Discovery
- Availability of injunctive relief
- Damages
- Anti-patent bias (or the absence of bias as most often Lilly is the patentee)

2. The decision to litigate – Olanzapine/PDEv, cont'd

Preference - US - typically the largest market and any inconsistency in a position can be most detrimental. Best to develop the case/thoroughly understand the facts in the US proceeding first.

In Europe – preferred jurisdiction is the UK - best opportunity to get a full, complete and fair hearing on the issues - the most authoritative - rationale of the decision can be exported to the EPO or other EU countries in the EU

Of the 3 jurisdictions **AUS is typically last** due to

- the pace of litigation (too slow)
- the AUS rules on dealing with experts also disfavors leading with AUS.

2. The decision to litigate – Olanzapine/PDEv, cont'd

A CHOICE?

- **PDEv- yes.**

  Lilly needed to clear the way; but were strategic in the "batting order" and led with strong, competent forums in hopes of early wins (successfully so).

- **Olanzapine – not really**

  Lilly as Patentee subject to revocation challenges

3. Professional Structures - ZoI

UK and AUS have similar systems

day to day case is run by solicitors and the case presented at Court by barristers.

Patent attorneys deal with patent amendment issues.

In the US the case is run and presented at Court by the same team of lawyers, some of whom may also have prosecution experience.

No system regarded as any better than the other by Novartis

3. Professional Structures - Taxol

- Both AU and the UK have the barrister/solicitor system. No significant differences. Except –
- In the UK, access to the barristers generally proceeded through clerking staff, while in Aus, direct access to the barristers was easier.
- In the U.S., a single litigation team encompasses the skill sets of both barristers and solicitors. Need for local counsel to ensure compliance with local rules. Can have teams of lawyers (at times from different firms) deployed to prepare separately the infringement, validity, and remedies portions of the case. Also consultants are retained to orchestrate mock trials, aid in jury selection, and assist in the preparation and presentation of graphics and video/animation.

3. Professional Structures - EPO

- Amgen keen to get *all* members of team on board early with full awareness of case/strategy and with shared aims/objectives.
- Layered professional structure *can* inhibit this – but not need not. Barristers/Solicitors more prone not to immerse themselves in the issues.
- US structure tends to lend itself more to team approach and shared responsibilities.

3. Professional Structures - Olanzapine/PDEv

- **US -** Single bar. Patent attorneys also acted as the trial attorneys. Lilly have used trial attorneys, who are not members of the patent bar, in certain cases.
- **AUS and UK** – split bar – Lilly generally retains patent attorneys, solicitors and barristers, although recently in an AUS case Lilly has retained patent attorneys more in an effort to minimize costs.

3. Professional Structures – Olanzapine/PDEv, cont'd

Roles generally similar in the **UK and AUS** -

- **the patent attorneys** know the nuances of patent law and the facts/science better
- **the solicitors** know the rules of civil procedure and practical case management.
- **the barristers** act as the orators, think on their feet in XX or in response to the court, and know the law and the court, including any idiosyncrasies of the court to enable the most effective presentation of the case.

These areas of expertise often blur, however; certainly by trial the entire team is well versed on the facts/science.

3. Professional Structures – Olanzapine/PDEv cont'd

- **In the US** the trial team is not too dissimilar despite not having a split bar.
- Generally, there will be 1-2 lawyers (patent trial lawyers or just trial lawyers), who will be the trial/oral advocates.
- Others on the team will wear the solicitor hat and/or the patent attorney hat to develop the evidence and deal with pre-trial issues (motions, discovery, etc) and discovery, particularly depositions.
- The biggest difference is that the US trial lawyer is typically fully immersed in the file at an earlier stage than the UK or AU barrister (although as you appreciate this depends a great deal on who the barrister is).

3. Professional Structures – Olanzapine/PDEv cont'd

Which is most effective?

- Each has merits. Lilly finds the most effective system is one where the trial lawyer (whether it is the barrister or trial patent lawyer) is fully engaged early with case strategy and evidence preparation. The rest of the trial team (whether it is solicitors or patent attorneys or a mix) then execute the strategy with on-going input from the trial lawyer.
- However, Lilly would be uncomfortable with a trial team without a patent attorney – or someone who has the technical qualifications to understand the science at issue. During the preparation of the evidence, this is a critical skill set to probe the experts and place the issues in the context of the art.
- In UK and AUS, clients often sideline Patent Attorneys by the time of trial (if not well before)

4. Timescales - Zol

- UK was the quickest with decision of first instance Court in 15 months. CA first instance decision in 1.5 years, with both UK and CA appeals after a total of about 2 years.
- AUS two years from commencement of infringement action to decision on merits and a further 6-9 months for appeal decision.
- US case will take longer than 2 years to first instance.
- UK was OK, AU and US somewhat slow.
- Prefer quicker for enforcing; slower timescale usually OK for defending

4. Timescales - Taxol

UK

- start to trial – 12 months (inc 4 months for judgment)
- to Court of Appeal – 11 months (quicker now)
- To Supreme Court – 18 months (still slow, but rare)

AUS

- Started Mar 2005, full trial anticipated in Sept 2007 (never happened before the case settled – blown off course by decisions on entitlement (Finkelstein J., then full Federal Court remitting the matter back to Finkelstein)

US – generally 1-3 yrs (to trial), CAFC within a year, SC 2 years

4. Timescales - EPO

- When can the first decision be obtained that impacts on the Defendant?
- Summary judgment and preliminary injunctions are most important - an early result is valuable.
- US more amenable than most to these – UK less so but because of generally more rapid result (less than a year to first instance result).

4. Timescales - Olanzapine/PDEv

US:

- **PDEv**– never went to trial (patent called in for ReX by the USPTO)
- **Olanzapine** - under HatchWaxman requires no more than a 30 month time scale.

UK: - about 18 months in the UK and a bit longer **for AUS** trial.

- **Opinion** - It is about right within each system. The US has more extensive discovery and motion practice, so you need a bit more time. A time table of 18 months in the US would be very, very quick.
- For a complex patent case, 18 to 30 months is about right.

5. Pre-trial procedures - Zol

Best - US leaves no stone unturned but lengthy/tedious and very costly; **UK** costly but about right in terms of length and details; **AUS** too many pre-trial briefs/posturing

Worst – US and UK: cost **AUS**: slowness

What should be better? Simpler, quicker, cheaper – e.g. with requirement for disclosure of all material facts by both sides at the outset (transparency).

5. Pre-trial procedures - Taxol

BEST - In the U.S.

- full pre-trial discovery (including the production of documents and depositions of fact and expert witnesses) is afforded.
- The scope of the claims-in-suit is defined via *Markman* hearings.
- Frivolous contentions can be removed from the case before trial via motions to dismiss, for summary judgment, and in limine. Provisional remedies such as preliminary injunctions are available.

5. Pre-trial procedures, cont'd - Taxol

WORST - In the U.S., the scope and costs of discovery can be daunting and the courts at times can be overwhelmed with work and thus unable or unwilling to curb bad behavior by counsel.

Because the Federal Circuit at times has a higher reversal rate of trial judges than of juries, trial judges can either defer too much to the jury leaving frivolous contentions to persist in the case for too long or decide too much by summary judgment to get interim guidance from the Federal Circuit but thereby lengthen the case and drive up the costs.

5. Pre-trial procedures - EPO

- **Best – US** - Summary Judgments, Potential of discovery if in reasonable bounds, Markman hearings (especially when paired with dispositive motions), depositions valuable for an early understanding of the case and evaluation of the witnesses
- **Worst – US** – Abuse of discovery – erroneous belief that electronic searching/record keeping helps – associated costs – often driven by attorneys to avoid criticism of their obligation
- **UK/AUS** – mirror of above – would look the tools of summary judgment and early claim construction to be available (though less important where the timetable is quicker – but still a role to play in settlement)

5. Best Pre-trial procedures – Olanzapine/PDEv

- **Disclosure** - document production highest in the US, followed by Canada and AUS and then the UK. BUT the number of documents that were put into evidence at trial was remarkably similar across all. UK boundaries on discovery still produce the most relevant documents that lead to a fair and just decision.
- **US - Depositions and more extensive motion practice**. Pre-trial opportunity to probe efficiently the boundaries of the expert's opinion outside of the context of the limited time in the witness box during trial. Allows for very efficient cross examination when the witness is "live" in the box.
- **Dispositive motions** (e.g., summary judgment or partial summary judgment) allow for a quick disposal of all or part of the case if there are no disputed facts needing full trial on all the issues. In theory available but rarely used (hurdle of a serious issue to be tried is a very low one).

5. Worst Pre-trial procedures - Olanzapine/PDEv

- **US** - discovery: too expansive. "Markman hearings": Good - can give clear direction as to claim terms going into to the trial. Bad - if too early/judge uninformed, can lead to relatively high reversal rate on construction, which is reviewed de novo
- **AUS** "hot tub" practice - "nightmare". Now exported to **UK** since April 2013 - but no enthusiasm or use as yet
- **UK/AUS** laxity on the rules of evidence regarding hearsay and the use of leading questions. In AUS in particular, the rules regarding what the witness can or cannot see before preparing any statement are becoming onerous and unhelpful, e.g., showing the expert the patent and providing context as to the issues being debated.

5. Changes to Pre-trial procedures? - Olanzapine/PDEv

- **US** – (1) limit discovery; (2) read in expert reports as evidence in chief rather than many hours of direct examination
- **UK** – allow for limited depositions
- **AUS** – allow for limited depositions; (1) no hot tubs; (2) more relaxed guidance on dealing with party experts (but not as an open invitation to influence a party witness to a particular view; but rather to provide the right context from which the expert can form a view that is relevant to the questions at issue).
- **Both UK and AUS** could use the benefit of an early claim construction.

6. Trial procedures - Zol

BEST - US; no stone unturned;

UK: quality of judges/barristers;

AUS: quality of judges/barristers

WORST - US – cost, discovery, "privilege mania";

UK: "wigs and gowns mentality";

AUS: length of trial

What should be better - All - simpler, quicker, cheaper.

6. Trial procedures -Taxol

- **BEST** - *"In the U.S., only competent evidence is admissible. Thus, junk science, unsubstantiated witness assertions, and irrelevant matter are rarely allowed to derail or distract proceedings. Likewise, because all witnesses (fact and expert) are sworn under penalty of perjury, they are less likely to lie given the severe consequences. And, because counsel are bound by a duty of candor to the court, they are less likely to make materially false or inaccurate or unsubstantiated assertions given the severe consequences."*

6. Trial procedures -Taxol

- **WORST** - *In the U.S., difficult for a trial judge to come up to speed on both the relevant science and specific law and maintain that level of expertise throughout the handling of the case. On appeal, few of the appellate judges have extensive experience as trial court judges and often have a tendency to conflate the trial record in a manner that serves their point of view but ignores the demeanor evidence that only the trial judge observed.*

6. Trial procedures - EPO

- **UK/AUS** interaction with expert witnesses – moves to retain the independence of the experts has come at a cost of the necessary interaction with the experts and their education – experts less informed as a result. (Court appointed experts an extreme example where no control and no testing of their views possible)
- **US** the opposite of the above.
- Hot tubs in **AUS (now UK)** do not help.

6. Trial procedures – Olanzapine/PDEv

BEST:

- US - discovery system and depositions are good at getting to the key facts. Done properly and in a timely way, a Markman hearing is helpful.
- UK – limited discovery; use of a primer
- UK/AUS – cost recovery from loser – limits the willingness of the other side to run weak points.

6. Trial procedures – Olanzapine/PDEv

WORST - AUS –

- hot tubs;
- expert rules;
- use of a primer

WORST - US –

- cost and unnecessary breadth of discovery;
- Markman Hearings – if done poorly;
- Limited cost recovery

WORST - UK - No depositions.

6. Trial procedures – Olanzapine/PDEv

CHANGE?

- Allow limited depositions in the UK and AUS
- Ease the standard under which US costs are awarded (under review by US Supreme Court)

7. Outcomes - Zol

US and AUS - Ongoing

UK - Patent held to be invalid at first instance and on appeal in UK and CAN.

Neither UK decisions were based on usual novelty/obviousness type arguments, but in the UK a harsh decision was received on entitlement to priority. In CAN illogical decision that the patent protected a method of medical treatment.

Surprisingly unpredictable (i.e. wrong) in UK, also CA.

7. Outcomes - Taxol

- Patentees won in the NL [expected]
- Lost in the UK before Pumfrey J. and at the Court of Appeal [not surprised] but won in the UK at the House of Lords (Supreme Court) [pleasantly surprised]
- In AUS the case did not proceed to a final judgment
- In the US the case settled before a suit was filed.

7. Outcomes - EPO

- **US -** Desired outcome obtained – v Roche (CHO) and TKT (Homologous Recombination) - ✓
- **UK** – correct result v Roche – win at first instance followed by settlement – not v TKT (on appeal), but about the same time as patent expired! But TKT had their manufacturing in US where won – moved into the UK but with significant time delay - ✓ But increasing role of Competition Authorities makes settlement harder and encourages litigation.
- **AUS** –Win v Genetics Institute ✓ and TKT not litigated in AUS.

7. Outcomes - Olanzapine/PDEv

GOOD/PREDICTED RESULTS:

- As hoped, PDEv patent revoked in each jurisdiction in issue ✓
- As hoped, Olanzapine patents upheld in each jurisdiction ✓ bar Canada (least predictable)

8. The Judges - Zol

Impressions?

- **UK**: highly competent, but a bit too academic (ie merits of case less relevant);
- **AUS**: appeared competent but still awaiting result (generally too slow)

Specialist patent judges?

Available at first instance and at least 1 out of 3 in Court of Appeal in UK and AUS. Specialist judges not available in US.

Very important to have specialist judges

8. The Judges - Taxol

- In the U.S., federal district court judges relative to state court judges tend to have greater credentials and experience in handling complex civil litigation.
- The consolidation of all appellate court jurisdiction concerning patent matters in the Federal Circuit was done to create an expert body of patent judges focused on creating more uniformity in patent jurisprudence.

8. The Judges - EPO

- **US** – Pilot program whereby judges volunteering to be the 'patent' judges where non-specialist judges would rather not hear cases – early days. But value in judges with general experience – parties keep their cases to the point and Judges have good case management powers.

  Jury trial in Roche on pegylated rEPO – issues to jury managed well. Right result with a well engaged judge (Young J.) – Roche opted for jury having lost previously before Young J. Juries like inventors, inventions and some US companies (but can be cynical – tarred by tobacco litigation);

- **UK** – not enough judicial caution, too overtly protective of the world at large (esp. given small size of UK market);

- **AUS** – a mixed bag, sometimes overburdened.

8. The Judges – Olanzapine/PDEv

- **US –** variation at district court level on IP matters. Generally bright and willing to learn. Inexperience can keep the parties from getting into peripheral issues.

  CAFC (Federal Circuit) is specialized re IP matters. Is critical to the development of a strong IP system in the US from which investment is based

- **UK** – specialised judges are generally excellent. But a significant risk that one poor judge or one with an anti-IP bias could change the effectiveness of the bench quickly.
- **AUS** – The judges experienced have been excellent.
- Conclusion – Strong, specialized IP judges are very important

9. Cost - Zol

Overall? –

All too expensive. **UK** and **AUS** comparable; **US** "ridiculous"

Recovery?

In the **UK** and **AUS** unsuccessful party usually ordered to pay successful party's costs of about 60-70% in the **UK** and 65-80% in **AUS** of the successful party's actual costs, subject to deductions to take account of circumstances.

US minimal costs recoverable.

9. Cost - Taxol

- UK greater than AUS, but no full trial in AUS
- Matter settled before litigation in US
- No direct comparisons

9. Cost - EPO

- **US** – much greater market so more tolerance of the highest costs (even though no recuperation from the loser);
- **UK** – most expensive for the value of the case;
- **AUS** – best balance between cost and value

9. Cost – Olanzapine/PDEv

- The **US** is the most expensive overall – driven by far more extensive discovery.
- On an hourly basis, the **UK** barristers are the most expensive, but they tend to be more efficient (less motion practice and written briefing). So, the barrister to US trial counsel difference is not materially different.
- **AUS** comparable to UK depending on currency exchange

10. Efficiency - Zol

Canada certainly more efficient and cost effective than any of **AUS, UK** or **USA**!

Lilly would beg to differ!

10. Efficiency - Taxol

"The UK was far more economical than Australia. However, in Australia there were a great many more issues raised by each side, and discovery disputes were aggressively fought. The Netherlands afforded an even more economical and efficient venue.

…. although it may seem counter-intuitive, relative to the size and profitability of the U.S. market and the extensive rights available in the U.S. courts (e.g., right to extensive pretrial discovery, right to a jury trial, right to preclude incompetent evidence, right to legal construction of the claims-at-issue, right to bring dispositive pretrial motions, etc.), the U.S. court system and attorneys are remarkably and extraordinarily efficient and cost effective".

10. Efficiency - EPO

- **US** – most efficient – benefit of pre-trial motions as tools to focus case and get dispositive motions resolved;
- **UK and AUS** – less efficient for this reason – and much the same.

10. Efficiency - Olanzapine/PDEv

- In terms of overall efficiency and cost effectiveness the various jurisdictions ranked as follows

  1. **UK**
  2. **US and AUS**

  (**AUS** is less expensive but **US** a bit more effective)

- From litigating around the world, these are the three top jurisdictions.

11. Lessons Learned - Zol

Would you choose to litigate there again?

- Yes (probably no choice in practice)

What would you do differently?

- Keep a broader overview of all potential issues during preparation/presuit/pretrial to avoid unexpected issues

  (The priority issue was something of an ambush in UK)

11. Lessons Learned - Taxol

- Initiating litigation in the Netherlands on a schedule that preceded the UK would be advisable for patentees. As long as counsel are amenable to substantial coordination, deferring U.S. litigation in favor of the Netherlands, UK and Australia may be prudent.
- More emphasis needs to be placed *ab initio* on telling and making a compelling record of the invention. It is particularly important to include tangible evidence of the break though that comprised the invention. In this case, the probative value of the time-elapsed video of the CAM assay was not truly appreciated until the hearing before the House of Lords.

11. Lessons Learned - EPO

- Decision to litigate purely driven by business – size of market against risk – how achievable is a good result. None of **US/UK/AUS** fall into the category of those markets to avoid at all costs – like India or Canada. No real chance of an injunction in Canada.
- Nothing to do differently when next confronted with litigation.

11. Lessons Learned - Olanzapine/PDEv

- **Yes** - would choose to re-litigate in each jurisdiction
- **Final point - length of trial - all three do pretty well**

A window that is too short does not let the facts and legal argument develop properly to educate the judge.

A window that is too long (which Canada notoriously does) allows the parties to spend too much court time on issues minimally relevant to the outcome (often in my view to confuse or otherwise taint the judge).

THREE NEW SQUARE

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