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Welcome to:

Pharmaceutical Patent Term Extensions - The Good, The Bad and The Ugly

26 January 2023

Your speakers today

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PTE/SPC
Global snapshot

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Strategic global thinking

	US	EU	UK	AU
API/Compound	✓	✓	✓	✓
Formulation	✓	✓	✓	TBC (routinely granted)
Process	✓	✓	✓	X
Product by Process	✓	✓	✓	TBC
Method of Use	✓	✓	✓	X
Swiss Style	n/a	✓	✓	X
EPC 2000 (“for use”)	n/a	✓	✓	? Probably not
# patents/product?	1	1 per patentee	1 per patentee	Unlimited
PTEs per patent?	1	1 + PED	1 + PED	1
All claims?	X only claims to the approved product / use	X only claims to the approved product	X only claims to the approved product	✓ defence to infringement for ineligible claims
PTE on Third Party Products?	X	X	✓	✓

PTE/SPC
Global snapshot (2)

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Strategic global thinking

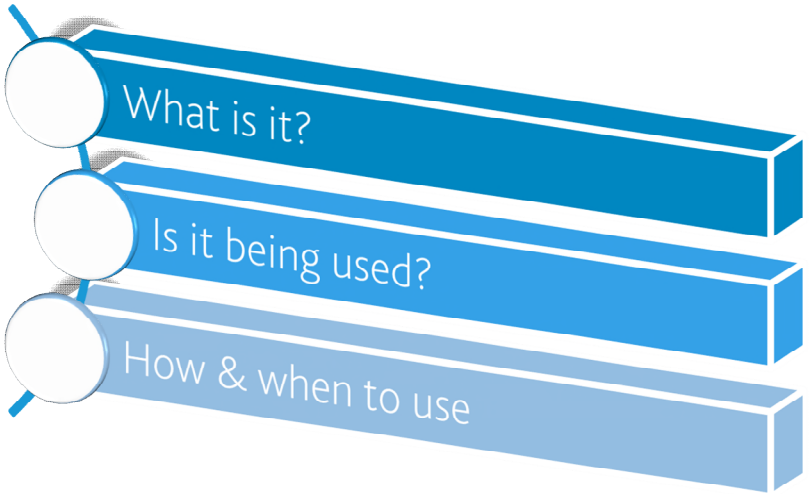
	US	EU	UK	AU
Multiple products claimed, which one must PTE be based on?	First approved	Patentee's election	Patentee's election	First approved
Maximum extension?	5 years	5 years (+ 6 months PED)	5 years (+6 months PED)	5 years
Manufacture for export (MFE) during PTE?	X	✓ (waiver)	✓ (waiver)	X
PTA for patent office delays?	✓	X	X	X

Supplementary Protection Certificates in the EU & UK: Manufacturing Waiver

Charlotte Weekes

EU SPC Manufacturing Waiver

- 2019 **Stockpiling** & **Export** waivers introduced
- 2020 UK left EU: UK legislation maintains waiver
- 2022 Transitional period ended in July



Regulation (EU) 2019/933 amending SPC Regulation 469/2009

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Export waiver

- Making of API* and/or FDF** for export ex-EU
- Related acts necessary for the making or export
- At any time during SPC term

Stockpiling waiver

- Making of API and/or FDF for storing in MS of making and Day 1 launch in the EU
- Related acts necessary for the making or storing
- Not earlier than 6 months before SPC expiry

**API: Active Pharmaceutical Ingredient*
*** FDF: Finished Dosage Form*

	Product intended for the EU	Product intended for the UK	Product intended for 3rd countries (inc. EEA ex EU)
Product manufactured in EU	Stockpiling waiver	Export waiver	Export Waiver
Product manufactured in UK	Stockpiling wavier	Stockpiling waiver	Export waiver

When might manufacturers use the waivers?

- Comply with conditions
  - ✓ Notification – who, when, what
  - ✓ Supply chain due diligence – who, what, how
- Engage in correspondence
- No verification
- When to notify?
- Secondary patent/SPC landscape
- Litigation

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SPC referrals to the CJEU

Ann Henry

Partner

Pinsent Masons (Ireland)

SPC Referrals

- Courts in **Ireland, Finland and Sweden** and have referred questions concerning **Articles 3a and 3c of the current SPC Regulation** to the CJEU, to clarify the granting of second or subsequent SPCs in relation to combination products.

- Discussion Points

1. Article 3 of the SPC Regulation
2. Questions referred to CJEU by Irish Supreme Court

SPC – Article 3 conditions

- Regulation 469/2009 – Article 3
- Conditions for obtaining a certificate.
- A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:-

  - 3(a) the product is protected by a basic patent in force;

  - 3(b) a valid [marketing] authorisation to place the product on the market as a medicinal product has been granted…;

SPC – Article 3 conditions

- 3(c) the product has not already been the subject of an SPC;

- 3(d) the [marketing] authorisation referred to in point (b) is the first [marketing] authorisation to place the product on the market as a medicinal product."

Questions raised by the Supreme Court – *Merck Sharp & Dohme Corp v Clonmel Healthcare Ltd [2022] IESC 11*

- Question 1
- Does it suffice that the product for which the SPC is granted is expressly identified in the patent claims OR
- Is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent.
- If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC?

Questions raised by the Supreme Court

- Question 2
- Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under **Article 3(a)** of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for **any or all** of the combination products identified in the claims in the patent?

Questions raised by the Supreme Court

- Question 3
- Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

Questions raised by the Supreme Court

- Question 4
- If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC:-
- (a) only to the single molecule if marketed as a product;
- (b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or
- (c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?
- And if any of the above, why?

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The US Perspective - PTE/PTA/ODP

Gaby L. Longsworth, Ph.D., Esq.

January 26, 2023

Technical Minds. Legal Muscle.

Terminology: PTE/PTA/ODP

- PTE = Patent Term Extension
  - Delays at the US Food and Drug Administration (FDA)
- PTA = Patent Term Adjustment
  - Delays at the US Patent and Trademark Office (USPTO) during prosecution
- ODP = Obviousness-Type Double Patenting
  - If cured with a terminal disclaimer (TD), may reduce patent term
  - A single inventor can trigger ODP
  - Common ownership or JRA required for a TD

US Patent Term Extension (PTE)

- 35 U.S.C. § 156
- Can extend patent term lost due to regulatory delays if the patent claims:
  - a product that requires regulatory approval prior to being sold, or
  - a method of using the product, or
  - a method of manufacturing the product
- Products include human drugs, human biological products, animal drugs, veterinary biologics, food additives, color additives, and medical devices
- PTE is a maximum of 5 years
- PTE cannot extend the patent term over 14 years from the date of receipt of marketing approval

US Patent Term Extension (PTE) and ODP

- Would a successful ODP challenge reduce patent term to which the patent may be entitled?
  - ODP can be cured by filing a terminal disclaimer (TD)
    - Common ownership or Joint Research Agreement needed
  - During the PTE extension period, the right to exclude applies only to **the approved drug and indication**
  - The Federal Circuit has held that ODP does not invalidate an otherwise validly obtained PTE under 35 U.S.C. § 156. *Novartis AG v Ezra Ventures LLC*, 909 F.3d 1367 (Fed. Cir. 2018)
  - The filing of a TD does not affect PTE to which a patent is entitled (*Merck v. Hi-Tech* (Fed. Cir. 2007))

Patent Term Adjustment (PTA) and ODP

- 35 U.S.C. §§ 154(b)(2) and 253
- Time lost during prosecution at the USPTO
- Extends the term of the patent
- Would a successful ODP challenge reduce patent term adjustment to which the patent may be entitled?
  - During the PTA extension period, the right to exclude applies to **all the claims**
  - Still unclear if filing a terminal disclaimer (TD) to obviate an ODP rejection or in litigation can reduce PTA

Best Practices and Challenges

- To lessen the risk of ODP and loss of patent term:
  - draw a RRQ
  - file proper divisionals
  - maintain consonance
- An incorrectly filed TD is not an “error” correctable by reissue.
- Beware of inventor collaborations as a single overlapping inventor can trigger ODP
- All the patents for which a TD was filed must retain common ownership

Helpful Links

- How do I find out if a PTE request has been filed or granted?
  - Review the file history of the patent on the PTO's Patent Center System (https://www.uspto.gov/patents/search)
  - Check the issued patent for a certificate of correction indicating that a PTE has been granted

- A list of extended patents is available at:

  http://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156

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Strategic global thinking

Pharmaceutical PTE
The Good, The Bad and The Ugly

Naomi Pearce

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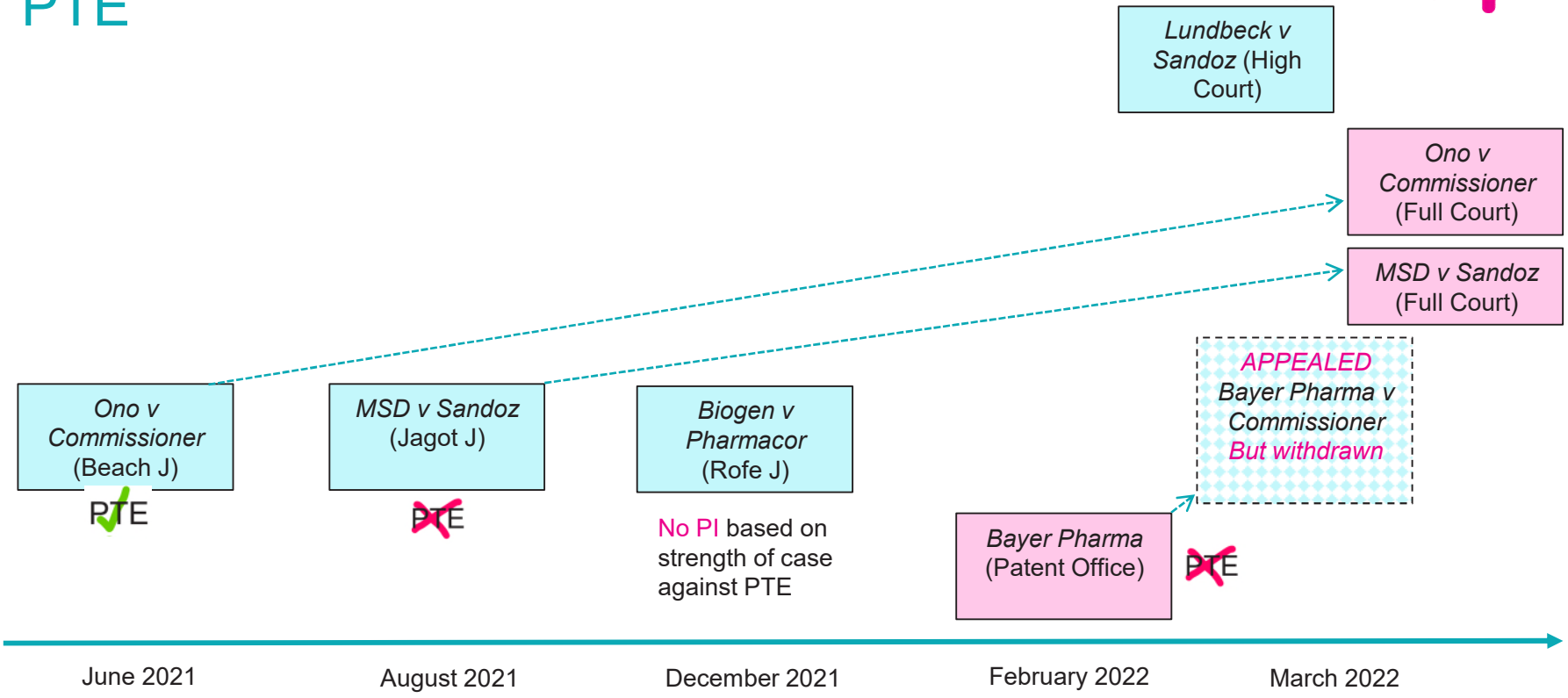
26/01/2023

AU 2021/2022: hard lessons for patentees for PTE



AU PTE statutory provisions

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- Ss 70 - 79 of the *Patents Act*
- Requirements (s70)
  - The patent must relate to a **pharmaceutical substance *per se*** or a **pharmaceutical substance when produced by recombinant DNA technology**.
  - The substance must be disclosed in the specification and must fall within the scope of the claims
  - The substance must be included on the Australian Register of Therapeutic Goods (ARTG) before the 20-year term of the patent expires
- 5 year cap
  - PTE for time between the patent filing date and the ARTG listing date, minus five years, to a maximum of 5 years.
  - policy: compensate the patentee for delay of more than five years in obtaining ARTG listing

AU PTE nuances:

- One PTE *per patent* only
- Unlimited PTEs *per product*
- PTE extends the entire patent, but there is a defence to infringement for:
  - Other uses (other than therapeutic use)
  - Other forms (other than pharmaceutical substance *per se* or pharmaceutical substance when produced by recombinant DNA technology)
- Protection is extended for all pharmaceuticals (*per se*/recombinant DNA technology)

AU PTE: future challenges

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Tally:

- Product/API - PTE
- MOT – NO PTE
- Swiss Style claims – NO PTE
- Process (other than recomb DNA) – NO PTE

Additional patent office “overreach” ripe for challenge:

- EPC 2000 claims ? (likely no)
- Formulation patents ?
  - Particle size patents ?
  - Polymorph patents ?
- Product by process patents (other than recomb DNA) ?

Key issues determined over the last 18 months

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- The **multiple substance problem**: *MSD v Sandoz* [2022] FCAFC 40 March 22
  - Januvia™ sitagliptin/ Janumet® (sitagliptin & metformin)
  - First regulatory approval is key
- The **multiple sponsor problem**: *Commissioner v Ono* [2022] FCAFC 39 March 22
  - OPDIVO (patentees' product) and KEYTRUDA (competitor's product - Merck)
  - PTE must be based on first approved, irrespective of sponsor
- The **"for use" problem**: *Biogen v Pharmacor* [2021] FCA 1591 16 Dec 21
  - Tecfidera™ (DMF)
  - Pharmacor: "EPC 2000" claims (the successor to "Swiss-style" claims) in the form of "*[product x] for use in the treatment of [disease y]*" are inextensible
  - Sufficient strength in invalidity of PTE to avoid PI
- **Timing is everything** *Lundbeck v Sandoz* [2022] HCA 4 9 Mar 22
  - Lexapro (escitalopram)
  - Failure to obtain PTE pre expiry may compromise damages position as cause of action arises only on the grant of the PTE

Practical implications
New Opportunities to challenge PTE

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- New opportunities to challenge PTE in AU
- Breadth of the claims and the timing of PTE requests - critical
- Strength of PTE challenge may result in PI avoidance
- Rectification (patent office) (s191A)
  - Streamlined & *anonymous* way to remove PTE (where facts fall within Federal Court precedent)
  - *Bayer Pharma Aktiengesellschaft* [2022] APO 7 (7 Feb 22)
    - YAZ/Yasmin contraceptive products
    - Indistinguishable from *Merck*

Practical implications
Prosecution

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- Ensure at least one family member covers only the target pharmaceutical substance
  - To ensure your pipeline, or that of a competitor, does not compromise your PTE position for this molecule.
- Consider crafting claims to include competitor pharmaceutical substances where appropriate
  - (Complex strategic considerations here)
  - To obtain PTE based on competitor product
- NB: we are seeing a number of PTE withdrawals!

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Thank you

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