

Protecting Public Interest in Patent Law

Withholding injunctions in the public interest

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When can an injunction be refused in the public interest? – statutory measures

Crown Use

- ss. 55 – 59 Patents Act 1977
- See *IPcom v Vodafone* [2020] EWHC 132 (Pat) for a recent overview
- s55(1) – permits use of a patented product or process without consent of the proprietor when authorised by a govt. dept. “for the services of the Crown” – including “for the production or supply of specified drugs and medicines...”

Compulsory Licensing

- ss.46 – 54 Patents Act
- s48: “Relevant grounds” for award of a compulsory licence include “*where patented invention is a product and demand for that product is not being met on reasonable terms*”
- Note period of 3 years after grant before compulsory licence can be sought

Discretion to refuse injunctions in the public interest

General

- *Coventry v Lawrence* [2014] UKSC 13
- More flexible approach to awarding damages in lieu of injunction
- “hard to see how there could be any circumstances in which [the public interest] arose and could not, as a matter of law, be a relevant factor” per L. Neuberger

Patents

- Consider statutory protections – courts should not be a route to effectively obtain compulsory licence without satisfying the statutory requirements: *Chiron v Organon No 10* [1995] FSR 325
- Enforcement Directive: remedies shall be “effective, proportionate and dissuasive”.
- Injunctive relief will normally be given unless enforcement would be “grossly disproportionate” – *Virgin Atlantic v Premium Aircraft* [2009] EWCA Civ 1512

Exercising the discretion – when/how can public interest be taken into account?

Recent example: *Evalve Inc. & Abbott v Edwards Lifesciences* [2020] EWHC 513 (Pat)

Concerned medical devices for treating a heart valve disorder -
Potentially life-saving treatment

Evalve/Abbott's product "MitraClip" already on the market and highly successful: Edwards had developed their own device "PASCAL" which the court had earlier found to infringe Abbott's Patents

Edwards argued that injunctive relief should be refused on the basis that PASCAL was, *in the reasonable judgement of clinicians* better for some patients

Some take-homes from Evalve v Edwards

- UK courts do have a discretion to withhold an injunction on public interest grounds
- But it is to be exercised with caution – Parliament is better equipped to determine the appropriate checks and balances.
- Factors to consider in the clinical setting:
 - The public interest will likely only be engaged for serious medical conditions, perhaps only for life-saving treatments
 - Nature of the competitive product important: generic drugs vs medical devices or biosimilars where tangible differences may exist
 - An injunction may be refused where it is established that patients can only be treated with the infringing product: but clinical preference is unlikely to be enough – there must be objective evidence (see also Arnold J. in *Edwards v Boston* [2018] EWHC 1256 (Pat))

Enforcement of patent rights in the current pandemic

- Treatment or vaccine where there is no alternative:
 - Statutory carve outs provided by crown use or compulsory licensing likely to be engaged (especially in the case of a public health emergency);
 - A court would be very likely to refuse injunctive relief in such circumstances (if it was ever sought: c.f. *Edwards v Boston*; *GSK v Wyeth* [2017] EWHC 91 (Pat)).
- More of a grey area where an infringing product/process is in an area where demand already being met – e.g. think a new type of ventilator:
- What about supply of generics?

“I doubt a generic version of a life-saving drug would usually engage the public interest in this way at all. I say “usually” because one can think of special cases, such as a novel pandemic disease; but if that happened then the Government could invoke Crown use.”

Per Birss J in *Evalve v Edwards* at [77]

International comparisons

Is common law flexibility better suited to accommodate public interest concerns?

Germany:

- Compulsory licence can be awarded on public interest grounds – but no discretion not to award injunction upon finding infringement: *Herzklappen* case 4a O 137/15 LG Düsseldorf

Netherlands

- Again no discretion: statutory protection for public interest through compulsory licensing: *Boehringer v Kirin-Amgen* Supreme Court 21-04-1995 no. 15623; *Nikon v ASML* Hague District Court 18 July 2018

Switzerland

- Appears to follow Germany: *Evalve, Abbott v Edwards* Federal Patent Court case S2019_002 15 Aug 2019

US: protecting the public interest a core factor (*eBay Inc v MercExchange*)

- *Cordis v Boston* 99 Fed.Appx 928 (2004): strong public interest supports a broad choice (stents)
- But see *Amgen v Sanofi* (2017) 872 F.3d: mere choice is not enough (biosimilars)

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