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Report Q202

in the name of the United Kingdom Group
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The impact of public health issues on exclusive patent rights

Introduction

All references to the Patents Act 1977 are abbreviated as "PA 77". Although trade mark, regulatory and competition law provisions may be relevant to the questions posed below, the following comments have been considered in light of UK patent law alone.

Questions

I) Analysis of current law and case law

1) Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?

Yes.

Conditions: s.60(5)(b) PA 77 provides that an otherwise infringing act will not infringe if *"it is done for experimental purposes relating to the subject-matter of the invention"* (emphasis added).

Scope: PA 77 gives no definition of "experimental" but it is likely that an act is an "experiment" if it seeks to generate genuinely new information (and not if it seeks simply to verify existing knowledge).

Guidance was provided by the Court of Appeal in *Monsanto v Stauffer* [1985] RPC 155 (CA) where it was observed:

"…trials carried out in order to discover something unknown, or to test an hypothesis, or even in order to find out whether something which is known to work in specific conditions…will work in different conditions can fairly…be regarded as experiments."

This does not rule out an ultimate commercial aim, so long as the trials are *experiments*. On the other hand, trials to demonstrate to a third party (e.g. a regulator) that a product works as its maker claims are not "experiments".

2) Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?

Yes. s.60(5)(i) PA 77 implements European Directive 2004/27/EC and exempts such trials as are required under Art 10 of Directive 2001/83/EC on the Community code for medicinal products for human use and Art 13 of Directive 2001/82/EC on the Community code relating to veterinary medical products. These are essentially bioequivalence studies and such further studies as may be required to cater for any differences between the basic approved product and the "generic" or "biosimilar" product. It is limited to medicinal products, namely products for preventing disease in human beings or which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (Art 1(2) Directive 2001/83/EC) and the comparable definition for veterinary medicinal products (Art 1(2) Directive 2001/82/EC).

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Parallel importation is not dealt with specifically as a matter of UK patent law. The position differs according to whether parallel imports are from within or from outside the EEA. Within the EEA, it is well established under EC rules of free movement that a patented product, put on the market anywhere in the EEA by the patentee or with his consent, is then free to move anywhere in the EEA. The patent rights are exhausted.

As regards parallel imports from outside the EEA, national law applies. s.60(1) PA 77 provides that a product is infringed by certain acts including "importing without the consent of the proprietor".

Under pre-PA 77 English domestic law it was held that if the patentee itself markets the product anywhere without any restriction there is an "implied" consent. The purchaser obtains an absolute right to deal with the product, including the right to import into the UK (Betts v Willmott (1871) 6 Ch App 239). It remains to be decided definitively whether this applies now that s.60(1) PA 77 specifically defines which acts constitute infringement and requires absence of "consent".

If a patentee's licensee markets abroad then whether or not the UK patent rights are exhausted will depend on the scope of the licence granted (*Tilghman's Patent* [1884] LR 25 ChD 1).

In the case of compulsory licensing, the ECJ has held that there is no consent by the patentee, and so no exhaustion (*Pharmon v Hoechst* (Case 19/84 [1985] ECR 2281)).

There are also regulatory requirements (PL(PI)s) and trade mark and repackaging issues to consider. These are beyond the scope of this exercise. This response is confined to patent issues.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Yes. Subsection 60(5)(c) PA 77 exempts *"the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner"* and *"dealing with a medicine so prepared."* (emphasis added)

"Extemporaneous" is not defined but probably means "as and when required" so that medicines prepared for stock in advance of a specific need are probably not exempt.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Medical treatment methods are not in themselves patentable. Products for use in such methods are. Use of such products by practitioners in therapy not being patentable does not constitute infringement.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Yes. s.48 PA 77 provides that at any time after the expiry of three years from the date of grant of a patent, any person may apply to the UK Intellectual Property Office (the "UK-IPO") for a compulsory licence under the patent. Grounds differ depending on whether the proprietor of the patent is a WTO proprietor or not.

"WTO Proprietor" is defined widely. According to section 48(5) PA 77, a WTO Proprietor is someone who is a national of, or domiciled in, a WTO country or who has a real and effective industrial commercial establishment in that country.

If the proprietor of the patent is a WTO proprietor, the grounds available are:

- that a demand in the UK for the product is not being met on reasonable terms;
- the refusal of the patent proprietor to grant a licence on reasonable terms is unfairly prejudicing the exploitation in the UK of another patented invention which relies upon the technology for which a licence cannot reasonably be obtained;
- the conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent means that the establishment or development of commercial activities in the UK is unfairly prejudiced.

If the proprietor of the patent is not a WTO proprietor, the grounds available are:

- the patented invention is capable of being commercially worked in the UK;
- where the patented invention is a product, a demand for the product in the UK is not being met on reasonable terms or is being met to a substantial extent by importation from a country which is not a Member State;
- where the patented invention is capable of being commercially worked in the UK, that it is being prevented or hindered from being so worked by the importation of the product from a country which is not a Member State (where the invention is a product) or by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied (where the invention is a process);
- that by reason of the refusal of the patent proprietor to grant a licence or licences on reasonable terms, a market for the export of any patented product made in the UK is not being supplied or the working or efficient working in the UK of any other patented invention which makes a substantial contribution to the art is prevented or hindered or the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced;
- that by reason of conditions imposed by the patent proprietor on the grant of licences under the patent, or on the disposal or use of the patent product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the UK, is unfairly prejudiced.

"Member State" is not defined but is generally accepted as extending to any member of the EEA.

The UK-IPO will not grant a compulsory licence under a patent, unless, prior to making an application, the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions and his efforts have not been successful within a reasonable period.

Once the applicant has established a case for a compulsory licence to be granted, the UK-IPO has no discretion as to whether or not to grant one. However, in fixing the terms of such a licence, it will take into account many factors including the nature of the invention, the time period since the patent was granted, measures taken by the proprietor or licensees to use the invention, the ability of the applicant to work the invention to the advantage of the public, and the risks of the applicant in terms of providing capital and working the invention.

Any compulsory licence granted will not be exclusive; it cannot be assigned unless it is assigned with the enterprise that enjoys the use of the patented invention; it will be predominantly for the supply of the market in the UK; it will include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case and it shall be limited in scope and in duration to the purpose for which the licence was granted.

Other provisions

Under s.51 PA 77 a Government Minister has the right to apply for a licence under a patent, or seek an entry in the register that licences are obtainable as of right, in each case when "a report of the Competition Commission has been laid before Parliament" relating to findings following a monopoly, merger or competition reference that a situation, practice or course of conduct "operates [or "may be expected to operate"] against the public interest."

ss.55-59 PA 77 provide in effect for compulsory licences for Crown use of a patented invention, though they are not "licences" in law because Crown use of a patented invention is deemed not to be an act of patent infringement.

Under Article 82(1) EC Treaty a compulsory licence could be a consequence of a finding of "abuse of a dominant position".

We are not aware of any compulsory licences granted in the UK under ss.48 & 51 PA 77 for the domestic manufacture and supply of pharmaceutical products. A number of licences of right were granted under the transitional provisions and compulsory licences granted under the 1949 Act. In those cases the Courts sought to provide patentees with proper compensation, recognising that the drugs concerned were established and successful, taking into consideration factors such as expected return on R&D, promotion and return on capital investment to compute the royalty rate.

7) Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

Article 31*bis* TRIPS has been ratified by the UK in its capacity as a member of the EU.

The Member States of the EU (and Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland and the United States) will not use the system as importing Members as set out in Article 31bis.

No compulsory licences have been granted in the UK for exportation of pharmaceutical products.

8) Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?

ss.55-59 PA 77 provide in effect for compulsory licences for Crown use of a patented invention, though they are not "licences" in law because Crown use of a patented invention is deemed not to be an act of patent infringement.

Under s.55, any government department and any person authorised in writing by a government department may make use of a patented invention without previous licence. The term "government department" is not defined in the Act and it can be sometimes difficult to discover the status of a public body; the National Health Service's use of an invention has been deemed to be Crown use (*Dory v Sheffield Health Authority* [1991] FSR 221). By s.55(1)(b) if the invention is a process, the Crown has broad rights in relation to the process, or the product obtained directly by means thereof. This includes specifically the right to sell or offer to sell the invention where it, or the product directly obtained by it, is a "specified" drug or medicine, i.e. one required for the services set up as part of the National Health Service.

Under s.57 Crown use of an invention is not inhibited by the existence of any licence, assignment or agreement made between the patentee and a third party. s.58 PA 77 specifies the procedure to be followed if a dispute arises concerning the use or the terms of use, by the Crown of a patented invention, or compensation.

s.59 PA 77 provides wider powers during a declared emergency for use by the Crown of inventions.

Compensation is available for the patentee under both ss.55(4) & 57A PA 77. Under s.55(4) compensation will normally be on a willing licensor/willing licensee basis, not taking into account loss of manufacturing profit. s.57A provides for compensation in respect of loss that a manufacturing patentee or licensee incurs as a result of not being awarded a contract which, but for the exercise of powers under s.55, he might reasonably be expected to have received. This compensation is additional to compensation under s.55(4) and can be paid either to the patentee or an exclusive licensee of the patent. Regarding quantum, regard is to be had to the profit that would have been made on such contract and to the extent to which manufacturing or other capacity was under-used.

In addition to the PA 77, The Defence Contracts Act 1958 provides powers for a Secretary of State to authorise persons to make use of technical information for the purpose of any contract or order for the production of defence materials without restriction under any agreement which the supplier may have with another.

9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

There is no provision for this in the PA 77.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

UK patent law does not recognise any other such means.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  Yes, provided the exempted use is a genuine experiment and limited to experiments on the subject matter of invention.
- *Bolar exception;*
  Yes. AIPPI UK recommends that the exception should apply to all acts necessary for getting regulatory approval for any drug (not just generics).

– *parallel import of patented medicines;*
We believe AIPPI resolution 101 below remains appropriate:

"The AIPPI resolves that a patentee be able to invoke its patent against parallel import of a patented product, notwithstanding the circumstances under which such product has been put on the market in country B, subject to exception by contractual agreement authorizing import of the product into country A. The ability to invoke the patent against parallel import of patented products is a logical consequence of the fundamental principle of territoriality of patent rights. The inability to prevent parallel import diminishes the value of patents and the benefits deriving therefrom.

The AIPPI observes that arrangements may exist where a number of countries decide to form a single regional market, in effect defining a single regional territory. In such an arrangement, a requirement for freedom of movement of goods within the single market may lead to acceptance of the legitimacy of parallel imports between countries which are party to the arrangement, provided that those countries together agree among themselves that such a restriction of the rights of a patentee is necessary in the realization of such a single market."

Whether or not an importation infringes should simply be a matter of presence or absence of "consent". Such "consent" should be clear and unambiguous.

– *individual prescriptions exception;*
No harm if strictly limited? May not be particularly relevant given that most medicines are pre-packaged?

– *medical treatment defence;*
Patent law should not prevent doctors from being free to treat patients but proper protection must be available for innovators inventing new products and methods (e.g. dosage regimes) for such treatment. This may be a "defence" or as in Europe a simple exclusion from patentability of medical treatment methods as such.

– *compulsory licensing;*
This should only be granted in very limited circumstances. Compensation should be full and proper.

– *expropriation;*
We cannot see any practical justification for this. We cannot see how this would improve access to medicines.

– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*
We do not believe any further limitations are appropriate.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

We do not see any ways in which patent law should be modified. Patent law is an unlikely source of lack of access to medicines. The WHO estimates that one third of the world's population lacks access to essential drugs. However, the vast majority of the 300 odd drugs on the WHO's Model List of Essential Drugs are not under patent protection in any country. Further, prior to the Indian 2005 Patents Act around 70% of the population of India did not have access to pharmaceuticals despite the lack of product protection for pharmaceuticals.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

It would be useful if such rules were harmonised provided they are appropriately limited in accordance with our responses above.

Summary

UK patent law provides for various limitations to the scope of patent rights including Bolar-type provisions and exceptions for experimental use, individual prescriptions, compulsory licences and Crown use. Additionally, EC rules of free movement regulate parallel trade of patented products within the EEA. We believe that AIPPI resolution 101 on parallel imported patented medicines remains appropriate. AIPPI UK does not believe that any further limitations to UK patent law are necessary.

AIPPI UK believes that Bolar provisions should be harmonised and suggests that, as in Germany, exceptions should apply to all acts necessary for getting regulatory approval for any drug, not just generics.

Résumé

Le droit anglais des brevets prévoit certaines limites à l'étendue des droits de brevet telles que les dispositions Bolar, les exceptions d'usage expérimental, les prescriptions individuelles, les licences obligatoires et le privilège de la Couronne. De plus, les règles communautaires sur la libre circulation encadrent le commerce parallèle des produits brevetés à l'intérieur de l'Espace Economique Européen. Nous pensons que la résolution 101 de l'AIPPI sur l'importation parallèle des produits brevetés demeure adaptée. L'AIPPI UK ne croit pas que d'autres limitations dans la législation anglaise des brevets soient nécessaires.

L'AIPPI UK considère que les dispositions Bolar devraient être harmonisées et suggère que, à l'instar de l'Allemagne, les exceptions soient appliquées à tous les actes nécessaires à l'obtention d'une autorisation administrative pour tout médicament et pas seulement pour les génériques."

Zusammenfassung

Das Patentrecht des Vereinigten Königreichs sieht verschiedene Einschränkungen des Umfanges von Patentrechten vor einschliesslich der Roche-Bolar- Vorschriften und Ausnahmen für Versuche, individuelle Verschreibungen, Zwangslizenzen und dem Gebrauch durch die Krone. Zusätzlich regulieren die EU-Regeln über den freien Warenverkehr den parallelen Handel mit patentierten Produkten in der EWG. Wir glauben, dass die AIPPI Entschliessung 101 über parallel importierte Arzneimittel weiterhin angemessen ist. AIPPI UK glaubt nicht, dass irgendwelche weiteren Einschränkungen im Patentgesetz des Vereinigten Königreiches notwendig sind.

AIPPI UK meint, dass die Bolar Vorschriften harmonisiert werden sollten und schlägt vor, dass wie in Deutschland Ausnahmen für alle Handlungen gelten sollten, die für die Erlangung einer Genehmigung für jedes Arzneimittel notwendig sind, nicht nur für Generika.