EXPLANATORY MEMORANDUM TO

THE PATENTS (COMPULSORY LICENSING AND SUPPLEMENTARY PROTECTION CERTIFICATES) REGULATIONS 2007

2007 No. 3293

1. This explanatory memorandum has been prepared by the Department for Innovation, Universities and Skills and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 These Regulations amend the Patents Act 1977 (c.37) ("the Act") in order to apply certain provisions of the Act to EC supplementary protection certificates and EC compulsory patent licences.

2.2 To the extent that it deals with supplementary protection certificates, this instrument replaces the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 (SI 1992/3091) ("the 1992 Regulations") and the Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996 (SI 1996/3120) ("the 1996 Regulations").

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 The principal statute on patents is the Patents Act 1977 (c.37) ("the Act"), which provides that inventions may be protected by patents for up to 20 years. Furthermore, certain pharmaceutical products can be protected for a further period beyond the 20-year patent term by virtue of an EC supplementary protection certificate – see Council Regulation (EEC) No 1768/92 and Regulation (EC) No 1610/96 of the European Parliament and of the Council.

4.2 The 1992 Regulations and the 1996 Regulations extend and apply the provisions of the Act to supplementary protection certificates. This instrument replaces those Regulations, and is made under s.2(2) of the European Communities Act 1972.

4.3 This instrument also amends the Act to state for the first time which provisions apply to EC compulsory patent licences. Such a licence is available, under Regulation (EC) No 816/2006 of the European Parliament and of the Council, for the manufacture of patented medicines that are made solely for export to countries with public health problems.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

5.2 Separate provision will need to be made to give effect to the Regulations in respect of the Isle of Man.

6. European Convention on Human Rights

The Lord Triesman of Tottenham has made the following statement regarding Human Rights:

In my view the provisions of the Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007 are compatible with the Convention rights.

7. Policy background

7.1 The 1992 Regulations and 1996 Regulations have been criticised for only applying the provisions of the Act to supplementary protection certificates in a very general way. This instrument therefore replaces these Regulations and makes clear on the face of the Act which of its provisions apply to supplementary protection certificates, and in what manner.

7.2 The instrument also takes account of Regulation (EC) No 1901/2006 of the European Parliament and of the Council, which provides for a further 6-month extension to the term of a supplementary protection certificate if the medicine in question has undergone approved testing for paediatric use.

7.3 Furthermore, the instrument makes clear how provisions in the Act which refer to "licences" or "rights under a patent" apply to the EC compulsory patent licences introduced by Regulation (EC) No 816/2006 of the European Parliament and of the Council.

7.4 Rule-making powers in the Act are extended to apply to matters concerning EC supplementary protection certificates and EC compulsory licences. Therefore the detailed implementation of the various Regulations is carried out, under these powers, as part of the Patents Rules 2007 (SI 2007/3291), which will come into force on the same day as this instrument.

8. Impact

8.1 An Impact Assessment is attached to this memorandum.

9. Contact

James Porter at the UK-IPO/Patent Office (an executive agency of the Department for Innovation, Universities and Skills) can answer any queries regarding the instrument. Tel: GTN (1214) 4521 or e-mail: james.porter@ipo.gsi.gov.uk

Summary: Intervention & Options		
Department /Agency: Department for Innovation, Universities and Skills	Title: Impact Assessment of the Patents Rules 2007 and associated legislative changes	
Stage: **Final**	Version: **1**	Date: **19 November 2007**
Related Publications: **Consultation documents; guidance material**		

Available to view or download at:

http://www.ipo.gov.uk

Contact for enquiries: **James Porter** Telephone: **GTN (1214) 4521**

What is the problem under consideration? Why is government intervention necessary?

The Patents Rules 1995 govern procedures concerning patents and applications, but have evolved piece-meal since 1978. Some rules impose unnecessary, inconsistent or outdated restrictions (e.g. concerning patent litigation or paper-based procedures). The Rules therefore need substantial modernisation. Also, the Patents Act 1977 and Rules need updating to more clearly and consistently provide for EC supplementary protection certificates. Finally, changes are needed to implement clear procedural rules under recent EC legislation on paediatric medicines and patent compulsory licences.

What are the policy objectives and the intended effects?

New rules on litigation at the Patent Office, with flexible and user-friendly procedures and clearer case-management powers during proceedings. Modernised drafting throughout, reflecting current working practices such as e-filing of patent applications and internet availability of patent documents. Simplified and updated administrative requirements for filing patent applications. Bringing together of clear and consistent rules on patents and supplementary protection certificates. Implementing the recent EC legislation on paediatric medicines and patent compulsory licences.

What policy options have been considered? Please justify any preferred option.

Wholesale modernisation, increased flexibility and removal of burdens - the preferred option, which best reflects current litigation practice and is of most benefit to users of the patents system.

Continued piecemeal approach to amending the Patents Rules - not preferred, since even more amendments make it difficult for users to keep up with changes, dated and/or unnecessary provisions remain in force and the Rules do not reflect current

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

The operation of the Office under the new Rules will be continually monitored, with a review of the new litigation procedures taking place after 2 years.

Ministerial Sign-off **For final proposal/implementation stage Impact Assessments:**

> *I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.*

Signed by the responsible Minister:

Triesman – Parliamentary Under Secretary of State for Intellectual Property and Quality Department for Innovation, Universities and Skills

Date: 19 November 2007

Summary: Analysis & Evidence

Policy Option:	Description:

COSTS

ANNUAL COSTS

One-off **(Transition)** Yrs

£ 0

Average Annual Cost **(excluding one-off)**

£ 1000

Description and scale of key monetised costs **by 'main affected groups'** **Individuals or organisations of any size, in any part of the UK or beyond, and in any area of economic activity may apply for a patent or become parties to patent litigation. But estimate only very few applications for SPC paediatric extensions annually,with a new fee of £200.**

Total Cost **(PV)** £ 1000

Other key non-monetised costs **by 'main affected groups'** **Some costs arise because patent professionals will need to become acquainted with the new legislation. But these professionals have uniformly welcomed the new legislation during consultations.**

BENEFITS

ANNUAL BENEFITS

One-off Yrs

£ 0

Average Annual Benefit **(excluding one-off)**

£ 160000

Description and scale of key monetised benefits **by 'main affected groups'** **Individuals or organisations of any size, in any part of the UK or beyond, and in any area of economic activity may apply for a patent or become parties to patent litigation. Benefits for all are derived from removal of various administrative burdens and fees.**

Total Benefit **(PV)** £ 160000

Other key non-monetised benefits **by 'main affected groups'** **Benefits include clear and consistent legislation; modernised practices to encourage e-business (e.g. e-filing of documents); speedier litigation and more robust case-management; clear procedural rules under EC legislation.**

Key Assumptions/Sensitivities/Risks **Changes will affect all users of the patents system, from lone inventors to multi-national companies.**

Price Base Year	**Time Period Years 1**	Net Benefit Range **(NPV)** £ 140000 - 180000	NET BENEFIT **(NPV Best estimate)** £ 159000

What is the geographic coverage of the policy/option?			UK	
On what date will the policy be implemented?			December 2007	
Which organisation(s) will enforce the policy?			Patent Office /	
What is the total annual cost of enforcement for these			£ 0	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ 0	
What is the value of changes in greenhouse gas emissions?			£ 0	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline **(2005 Prices)** **(Increase - Decrease)**

Increase **£ 1000** **Decreas** **£ 160000** Net £ **159000**

Key: Annual costs and benefits: Constant Prices (Net) Present Value

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

Background

1. The Patents Rules 1995 have been amended 12 times since they came into force. These changes mean that the Rules as originally published are very different from those currently in force. Consequently, the Office has produced a variety of unofficial consolidations, the latest of which is available via our website at www.ipo.gov.uk/patentrules1995.pdf

2. The 1995 Rules largely took the drafting style of previous Rules packages, and included some rules taken verbatim from the 1978 Rules, and a few taken from rules made under the Patents Act 1949. Each of the subsequent amendments has also been written in the drafting style prevalent at the time of writing. This means that there is now a wide range of styles in the Rules, as well as some inconsistencies. The modernisation will result in a clear, consistent set of rules written in the modern style. The basic approach taken to drafting is that:

the wording in the Act should not be repeated in the Rules;

each individual rule or paragraph is shorter, with generally only one concept per provision;

more detail, such as formalities requirements, lists of proceedings and time limits is placed in Schedules;

rules reflect current working practices such as e-filing, electronic case-files and internet availability of documents;

terms such as “without prejudice to”, “hereunder” and “aforementioned” are avoided unless necessary; and

forms have been renumbered to drop the “/77” part, as have other matters which flowed from the continued existence of rules covering 1949 Act cases e.g. Rule 67 and Form 58/77.

3. There are other substantive difficulties with the 1995 Rules. The large number of rules relating to litigation (current rules 7-14, 40, 43, 54-60, 62, 64-66, 68-76, 78, 88, 89 and 91) go into great details about what must or must not be done in particular circumstances. The rules, while rigid and detailed, are not always consistent for all types of proceedings; they differ in details and in the extent to which they prescribe procedures or leave them to the Office’s discretion. These rigid requirements often cause unnecessary difficulties for applicants and the Office. The 1995 Rules are also largely silent on some matters – including case management, which is increasingly used to simplify and accelerate proceedings and reduce their cost.

4. The new Rules replace the existing specific rules with a generic and flexible set, which will govern procedures and provide appropriate case management powers to assist in achieving the goal of achieving justice swiftly, at minimal cost, dealing with cases in ways proportionate to the circumstances, and with all parties on an equal footing. Many of the rules are based on the Civil Procedure Rules. The Rules will be supplemented by Practice Notices and other official guidance setting out how the Office will manage cases under the Rules.

5. Rules are also updated to reflect current circumstances such as the growth of e-business and levels of demand for Office services. For example, the requirement to file a form and fee

when requesting an amendment or correction, or when a restoration or extension of time has been agreed, is removed. So is the option of requesting rubber-stamped certified copies of documents because the demand for these has fallen and we will continue to offer uncertified or fully certified copies. The 1995 Rules require all documents making up a patent application to be in English, whereas the Rules will allow applications to be filed and prosecuted in Welsh. Rules relating to international applications under the PCT are complicated and confusing. The complicated and (in parts) obscure rule 85 is separated into distinct provisions to make these easier to follow and to bring all the rules relating to such applications into a single part. These are the sort of changes which have previously been made piecemeal by individual Statutory Instruments.

6. Separately, existing UK legislation sets out that, in general terms, the provisions of the Act apply to supplementary protection certificates ("SPCs"). Where a patent for a medicine or plant protection product has expired after 20 years, an SPC can give the patent holder up to an additional 5 years of exclusive rights. This extra period of protection is intended to compensate the patent holder for the fact that, during the patent lifetime, the product will have had to undergo a lengthy period of regulatory testing before being released to market. However, the existing UK legislation has been criticised as being too vague in meaning, and leaving users uncertain as to the detailed legal framework which implements SPCs in the UK.

7. The new Patents Regulations therefore amend the Act to show in detail, on the face of the Act, which of its provisions apply to SPCs, and which do not. Terms such as "patent" and "patent application" are glossed so that the provisions which apply to SPCs read correctly. This also ensures that the new Rules package – and particularly the provisions on litigation – can incorporate updated rules governing SPCs. This again brings more consistency between how patents and SPCs are treated, and more clarity as to the law which applies to SPCs in the UK.

8. It is also the right time to implement two related EC Regulations. The EC Paediatric Medicines Regulation (Regulation (EC) No 1901/2006) allows a further 6 months of SPC protection if the medicinal product in question is for use on children, and has gone through appropriate testing. The new Rules put in place procedures in respect of applying for such extensions. The other EC Regulation (Regulation (EC) No 816/2006) sets out that patent compulsory licences are to be made available for the manufacture of medicinal products which are solely for export to developing countries with a public health problem. Again, the new Rules put in place procedures governing how to apply for, modify and revoke such compulsory licensing applications at the Office.

Rationale for Intervention

9. If we do nothing, the Rules will continue to evolve piecemeal. Based on the rate of change since the 1995 Rules were introduced, we would expect the Rules to be amended about once a year, with each amendment making it more difficult for users to identify which rule is in force and adding to the range of drafting styles.

10. Leaving the litigation rules unchanged would leave in place Rules which have worked adequately, but which continue to impose unnecessary, inconsistent and outdated restrictions on the Office and on parties to litigation. The number of patent applications which become subject to some form of litigation is very small, but the cases will be of great importance to those involved.

11. Failing to make changes such as those to formalities requirements will leave customers having to comply with outdated rules which are more complicated than they need to be. This would mean customers having to do more work than they would under the changes. Similarly, leaving some PCT-related rules and those relating to time periods for divisional applications unamended would leave obscure and inconsistent provisions in place. The 1995 Rules also require users to file a form and fee when requesting an amendment or correction, or when a restoration or extension of time has been agreed, but the changes will remove these requirements.

12. The removal of the postal deeming provision reflects its uncomfortable role both in maintaining a legal fiction – namely, its contention that some post can be treated as if it had arrived at the Office earlier than the facts demonstrate – and its restriction to UK-only post.

13. The modernisation package addresses all the problems above, and will lead to a clear and consistent set of Rules and associated directions which allow flexibility where appropriate and which remove outdated, obscure and inconsistent provisions.

14. If we do nothing in respect of the SPC legislation, there will continue to be a lack of clarity as to how the provisions of the Act apply to SPCs, and similarly how the new rules on litigation will work for SPCs.

15. There would furthermore be no procedural rules governing the new paediatric SPC extensions – and users would be left in the dark as to how to apply for and obtain such extensions. Similarly, doing nothing would mean that there would be no procedural rules governing the operation of the new EC compulsory licences. Again, it would be unclear how to apply for, modify or challenge such licences in the UK. The amendments made to the Act by the Patents Regulations, along with the new Rules incorporating SPC matters, will deal with these issues.

Purpose of new legislation

16. The legislative package has the objectives of:

producing a set of Rules which includes all changes which have been made to the Patents Rules since they were previously revised and consolidated in 1995;

drafting the Rules in a clear, modern and consistent way throughout;

revising the rules about litigation to provide generic, flexible rules governing procedures and providing the Office with proper case-management powers – in particular to allow for effective operation of litigation in the Office which is in line with the Civil Procedure Rules;

removing some requirements for the filing of fees and forms, and simplifying and updating some requirements relating to formalities, sequence listings and divisional applications;

removing obscure and inconsistent rules relating to the Patent Co-operation Treaty ("PCT");

amending the rules relating to certified copies to reflect current timescales and demand;

removing the provision for treating post sent in the UK as if it had been received when it would have been delivered in the ordinary course of post;

allowing the Office to implement a Welsh language scheme and for patent applications to be filed and prosecuted in Welsh;

producing a set of Rules which incorporates relevant provisions in respect of supplementary protection certificates, and which implements the EC Paediatric Medicine Regulation and EC Compulsory Licensing Regulation, and making appropriate adjustments to the Patents Act 1977 ("the Act");

amending the Act to more clearly reflect how its provisions apply to supplementary protection certificates;

amending the Act to provide a basis for the new rules implementing the EC Paediatric Medicines and Compulsory Licensing Regulations; and

producing a correspondingly-updated set of Patents (Fees) Rules.

Consultation

17. An informal consultation "Modernisation and consolidation of the Patent Rules" was held from 14 October to 30 November 2005 (see www.ipo.gov.uk/patentrules-inf.pdf). This included an overview of the proposed new rules structure, together with more detailed background on the proposed changes to the rules relating to patent litigation, and draft litigation rules. The informal consultation was held to test whether users broadly agreed with the structure of the proposed new rules, and to find out views on the more extensive changes proposed to the litigation rules.

18. Responses were limited to a few representative bodies and organisations. These represent the groups most likely to have highly developed procedures for dealing with patent applications, and hence those most likely to be significantly affected by changes to the content or structure of the Rules. Their responses were that they approved of the general thrust to modernise and consolidate and to modernise litigation rules in particular, but would wait to comment more fully once more detailed proposals were available.

19. A full public consultation on all the proposed changes to the Rules took place from March to June 2007 (see www.ipo.gov.uk/consult-patentrules.pdf). It contained an explanation of all the changes, including a detailed concordance between existing and proposed rules. It also contained the draft Patents Rules 2007 and Patents (Fees) Rules 2007.

20. Response came more widely than for the informal consultation, and supported the principles of the new legislation. Detailed points were made in relation to a number of specific proposals – all of which have been given full consideration from both a policy and legal viewpoint. As many as possible of the points raised have been adopted in the final legislation.

21. Finally, the public were shown a draft of the Patents Regulations (which amend the Act in respect of SPCs and EC compulsory licences, so as to underpin the new Rules). The draft Regulations were sent to specific interests and made available on the Office's website during October 2007 (see www.ipo.gov.uk/consult-draftpatregs.pdf)

22. Only very few comments were received – and those who did so welcomed the clarity brought by the new legislation, and made some detailed drafting points. Again, as many of these points as possible have been adopted in the final legislation.

Options

Do nothing

23. The 1995 Rules work acceptably for most applications and granted patents most of the time. However, as noted above, if we do nothing they will retain the following undesirable features:

a variety of writing styles,

users needing to check carefully to see what rules are currently in force,

lengthy, unnecessarily complex and rigid litigation rules,

no provision for accepting applications in Welsh,

inconsistent and obscure provisions relating to the PCT and to time limits for divisional applications,

formalities requirements which are unnecessarily complicated,

a requirement to file forms and fees when requesting an amendment or correction, or when a restoration or extension of time has been agreed.

24. Similarly, although the SPC regime works acceptably in most cases, the lack of clarity regarding the legal framework and relationship between patents and SPCs will not improve as time goes on. Doing nothing would also leave the new paediatric extensions unregulated in the UK, so that procedures in respect of applying for such an extension would not be clear.

25. Some of these problems will get more serious as time passes and as additional changes to the Rules lead to more drafting styles and an increasing difficulty in working out which of the 1995 Rules is still in force.

26. In terms of the new EC compulsory licences, doing nothing would leave an unregulated system in the UK in respect of applying for, modifying or revoking such licences. This would not provide a transparent system for those who wish to apply for and maintain these licences, nor for interested third parties who may be affected by the licences.

27. For these reasons, and the others set out in this Assessment, we believe that doing nothing is not in the best interests of users or the Office.

Continue to make incremental changes to the 1995 Rules

28. It would be possible to continue to make incremental changes to individual rules or groups of rules. For example, one or more statutory instruments could be used to provide for applications in Welsh; to improve provisions relating to the PCT, divisional applications and formalities; and to remove the need to file a form and fee when requesting an amendment or correction or when an extension of time or a restoration has been agreed. However, making these desirable changes would increase the problems caused by different drafting styles and further widen the gap between the 1995 Rules as originally made and those which would be in force. Over time, there would come to be fewer and fewer of the 1995 Rules which were actually in force and so users would have to rely increasingly on unofficial consolidations or cross-referencing the 1995 Rules against all the subsequent changes. For these reasons we consider that continuing to make changes to individual rules or groups of rules will lead to increasing confusion and is not in the best interests of the Office or its users.

29. In any case, this approach would not address the issues regarding SPCs, paediatric extensions and EC compulsory licences, as set out above.

Modernisation and consolidation

30. This is our preferred option. It involves the most changes to the Rules, both to content and to presentation, but will result in a consistent set of Rules written in a consistent modern style and including all the substantive amendments which are currently desirable. These new Rules will inevitably themselves be amended in future but the impact of any such changes will be clearer as they would be made to consolidated Rules rather than to the 1995 Rules as already amended on multiple occasions.

31. It also enables the Rules to put in place procedures dealing with the new paediatric extensions and the EC compulsory licences – so that users can see clearly how to apply for, modify or challenge these rights.

32. It furthermore involves some changes to the Act, to provide the right framework for the new Rules, and to more clearly reflect how its provisions apply to SPCs and the new EC compulsory licences.

Costs and Benefits

Sectors and groups affected

33. Individuals or organisations of any size, in any part of the UK or beyond, and in any area of economic activity (including not-for-profit organisations) may apply for a patent, an SPC or a compulsory licence, or become parties to litigation over these matters. We believe that a consolidated and modern set of rules, along with an updated Act, will benefit all such users. In particular, clarity over SPC law will benefit those users with patent rights in the fields of medical and plant protection products, who may choose to extend their protection using SPCs.

34. As an indication of the numbers affected by the changes, the number of patent applications received by the Office is around 28,000 annually. Around 13,000 of these are published, and 8-9,000 patents are granted as a result. The Office also expects to receive some 4,000 PCT applications during 2006/2007. The numbers of cases which are involved in litigation is very small in comparison, probably fewer than 2,000 a year in relation to matters including ownership, licences, revocation, amendments, restoration, surrender or declaration of non-infringement. Nevertheless, as noted above, anyone involved in patent litigation is no doubt involved in a matter which is of significant importance to them or their business. Similarly, the

number of applications for SPCs is very small in comparison to patent applications – but any such applications are undoubtedly commercially very significant for the rights-holder and so are of significant importance to them or their business.

Benefits

35. A modernised and consolidated Rules will provide a clear statement of the rules currently in effect, avoiding the need to cross-reference the 1995 Rules against subsequent amendments. A clear and consistent drafting style will also make for easier understanding of what is intended.

36. Changes to the litigation rules will remove unnecessary procedures which cause users and the Office additional work and delay the decision making process. Generic provisions, supported by Practice Notices and other guidance setting out case management practices, will provide greater flexibility and consistency, leading to simpler procedures and improved access to justice. As noted above, the number of such cases is probably fewer than 2,000 a year, but the changes should have a significant impact on those that do end up in litigation at the Office.

37. Specific changes to the Rules are intended to remove unnecessary procedures, such as the filing of certain forms (with fees). For example, users requesting an amendment or correction will benefit from no longer having to file a Form 11/77 and £40 fee. Similarly, those whose application for restoration or for an extension of time has been agreed, will no longer have to file a Form 53/77 and £135 fee. We expect about 700 users a year to benefit from the abolition of the Form 11/77 and some 250 a year to benefit from the abolition of the Form 53/77. Other users will benefit from not having to supply a document if it is available to the Office already, including available over the internet.

38. The new rules will encourage the electronic filing of sequence listings (for amino acid and gene sequences) while retaining the option of paper listing for those for whom e-filing is not reasonably possible. This is likely to be of significant benefit to those (admittedly fairly small number of) users involved in drafting and prosecuting patent applications which involve sequence listings, and will also be of benefit to the Office in increasing efficiency (the e-filed sequence listings being machine-readable).

39. The law in relation to SPCs will be clarified. Uncertainty over whether, and how, certain provisions of the Act apply to SPCs will be removed. Rules of procedure governing patents and SPCs will be made consistent, and procedures under the EC Paediatric Medicines Regulation and the EC Compulsory Licensing Regulation will be set out for the first time.

Costs

40. Most of the costs associated with the changes would appear to arise because patent attorneys and others familiar with the existing Act and Rules will need to become acquainted with the changes, and accustomed to the renumbering of individual rules. This will be a more substantial change than if we continued to introduce changes to individual rules on a piecemeal basis. However, as noted above, the consultations received positive responses from patent attorneys and groups representing regular users, who recognised the value of a comprehensive redrafting. The Office will issue guidance explaining the changes, and in particular has been liaising with the Chartered Institute of Patent Attorneys (CIPA) and other key interest groups, so that they remain informed of progress and the changes to come.

41. Users requesting certified copies of documents will no longer have the option of a rubber stamped copy. The current provision is for uncertified copies at £5, rubber stamped at £16 and sealed certified copies at £22, all available by filing a Form 23/77. Use of the stamped copies is very low, with some 200 provided in 2005/6, compared with 18,400 sealed copies and some

1,900 uncertified copies. Any cost is therefore negligible, and offset by a modest reduction in the fee for a fully-certified copy.

42. The abolition of old rule 97 on "postal deeming" may mean that applicants who choose to send items by post are accorded a later filing date than with the provision intact. This may mean that an application is given a later filing date than another application for the same invention or, more likely, that a deadline is missed. If the latter, existing remedies (recently introduced into the 1995 Rules) are replicated in the new Rules, to remedy the situation where a delay in any means of communication with the Office has resulted in an official deadline being missed.

Enforcement, sanctions and monitoring

43. Nobody has to apply for any form of intellectual property and so the changes will not be enforced. Applicants who wish to obtain patents or SPCs, or licences under these rights, or to maintain their rights once granted, will have to comply with the new legislation as they would with the current legislation, and in many cases the requirements are either reduced or are the same but more clearly worded. The only sanction is that if applicants or proprietors do not comply with the legislation, then their applications will not be processed or their granted rights will cease. Monitoring compliance will be on a case-by-case basis, ensuring that the legislation is complied with as it applies to the individual case. The new legislation does not change any existing enforcement, sanctions or monitoring regimes.

44. The Office will assess the effects of the changes. There are well established mechanisms for customers to comment about any aspect of Office services (including a feedback form at www.ipo.gov.uk/about/about-ourorg/about-contact/about-contact-feedback.htm and a dedicated e-mail account at customer.feedback@ipo.gov.uk). The Office also has quarterly focus group meetings with the key interest groups, where views can be discussed. Feedback of all types is regularly collated and checked to ensure that individual complaints are dealt with and any underlying problems are identified and addressed. The Office recognises that external circumstances will change and that there will almost inevitably be further changes to the Act and Rules in the future to meet or anticipate such changes.

Specific impact tests

Competition Assessment

45. Patents or SPCs may be applied for or owned by any individual or by any organisation of any size, based in the UK or abroad, and in any economic sector or market. The same applies to those who are not patent or SPC applicants or owners but who become involved in legal proceedings concerning patents or SPCs.

46. We believe that no firm has more than 10% market share in the broad market for intellectual property rights and no three firms together have 50% of the market share.

47. The changes will affect firms which file large numbers of applications for patents, or maintain those rights when they have been granted, more than organisations which do not. However, the changes are intended to update and simplify the legislation and so we do not believe that they affect some firms substantially more than others.

48. There is no evidence that the changes will affect market structures, or change the number or size of firms.

49. The changes will apply equally to new or established firms, and so there will not be higher set-up or ongoing costs for new or potential firms that existing firms do not have to meet.

50. Intellectual property rights are all concerned with innovation, so there will be some sectors affected which are characterised by rapid technological change. However, the changes do not affect the nature or scope of any of those rights.

51. The changes will not in any way restrict the ability of firms to choose the price, quality, range or location of their products. The nature and extent of patent rights will remain exactly the same as under the existing regime, save for the implementation of the EC compulsory licensing regime. The nature and extent of SPC rights will remain exactly the same as under the existing regime, save for the implementation of the 6-month SPC extension available under the EC Paediatric Medicines Regulation.

Small Firms Impact Test

52. The Office does not have information from users on the size of organisation they belong to. However, it is able to identify patent applicants or proprietors who are not represented by an agent of any kind and refers to these as private applicants ("PAs"). While any size or type of organisation may be unrepresented, we believe that most PAs are SMEs or individuals working alone. Conversely, many SMEs or private individuals may employ agents and so fall outside our PA category. Nonetheless, information about PAs is the best approximation we have to SMEs.

53. Our figures suggest that about a quarter of patent applications are filed by PAs, but only about 10% of search requests are from PAs. PA cases are proportionately less likely than others to be pursued to grant, and to be renewed after grant. Consequently, PAs are proportionately less likely to be affected by either costs or benefits of the changes.

54. As noted above, we believe that most of the costs arising from the changes will fall on patent attorneys and experienced users of the patent system. While some SMEs are regular users of the patent system, they and PAs are less likely to have established a developed understanding of patent procedures, and so will not need to expend effort understanding many of the more detailed or technical changes. In any case, the Office provides extra help and guidance to PAs (including a dedicated support unit and a central enquiry unit), and takes particular care to explain the legal requirements and procedures involved in obtaining patent protection. This will of course continue to apply to the procedures under the new legislation.

55. We have no evidence that previous redrafts or amendments to the Rules have caused any increase in agents' fees. Thus SMEs who do choose to use a patent attorney or other agent are not likely to be affected in this way.

56. Overall, we conclude that the changes will not have any significant adverse impact on SMEs. Indeed, SMEs will benefit along with other users from rules which are up-to-date and easier to understand, and from improved litigation procedures and other changes to specific rules.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	**Yes**	**No**
Small Firms Impact Test	**Yes**	**No**
Legal Aid	**No**	**Yes**
Sustainable Development	**No**	**Yes**
Carbon Assessment	**No**	**Yes**
Other Environment	**No**	**Yes**
Health Impact Assessment	**No**	**Yes**
Race Equality	**No**	**Yes**
Disability Equality	**No**	**Yes**
Gender Equality	**No**	**Yes**
Human Rights	**No**	**Yes**
Rural Proofing	**No**	**Yes**

Annexes

Specific impact tests

Competition Assessment

A1. The Competition Assessment is dealt with in paragraphs 45 to 51 of the Evidence Base.

Small Firms Impact Test

A2. The Small Firms Impact Test is dealt with in paragraphs 52 to 56 of the Evidence Base.

Legal Aid

A.3 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes will have no impact on legal aid in the UK.

Sustainable Development

A.4 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes will have no impact on sustainable development.

Carbon Impact Assessment

A.5 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes will have no carbon impact.

Other Environment

A.6 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes will have no other environmental impact.

Health Impact Assessment

A.7 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes will have no impact on public health in the UK.

Race Equality Assessment

A.8 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes have no bearing on race equality. The procedures and fees apply equally to all users of the patents system, regardless of race. The Office has no information about how many applications come from different ethnic groups.

Disability Equality

A.9 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes have no bearing on disability equality. The procedures and fees apply equally to all users of the patents system, regardless of any disability. The Office has no information about how many applications come from people with disabilities.

Gender Equality

A.10 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes have no bearing on gender equality. The procedures and fees apply equally to all users of the patents system, regardless of gender.

Human Rights

A.11 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes have no impact on human rights.

Rural Proofing

A.12 The nature of the changes and the manner in which the patents system will continue to operate mean that the changes have no impact on rural areas or life.