Information Sources on Post-Grant Actions to Pharmaceutical Patents

Stephen Adams†

Magister Ltd., Crown House, 231 Kings Road, Reading, RG1 4LS, Great Britain

Received October 23, 2001

Over the past two decades, many industrialized countries have implemented changes in their patent laws to provide an extended period of protection for commerically marketed pharmaceuticals. The process has been adopted piecemeal, using widely different procedures. The information sources relating to such term extension are consequently scattered and poorly organized, compared with conventional patent legal status data. This paper reviews the legal processes behind term extension and provides a survey of the key principles and information sources available.

INTRODUCTION

This paper will discuss three topics in the area of pharmaceutical patents and the extension of their term. The first section will survey the arguments behind the need for term extension and the way in which legislation has been adopted in different parts of the world. The second section will refer to the principal organizations which release public data on term extensions and some of the pitfalls in accessing this information. Finally, some of the main information sources—electronic and paper—which can be used to derive term extension data will be discussed, from the point of view of the information specialist.

1. WHY DO WE HAVE TERM EXTENSION? —THE ADOPTION AND OPERATION OF THE LEGISLATION

In the pharmaceutical industry, it is extremely important to be able to determine the actual legal status—including the term—of a patent. This is based upon the fundamental truth that any manufacturing company (for example a generic manufacturer) is legally entitled to use the technology claimed in a given patent once that patent has expired. All patents will eventually expire, commonly after a 20 year term under modern legislation, but this is subject to some variation. Some expire earlier than their "natural" life-span, through legal events such as the nonpayment of renewal fees or terminal disclaimers. By contrast, some can last longer than the expected monopoly period, through the mechanism of term extension. To further complicate the picture, the term of patents from most countries is calculated from the date of application, whereas until recently patents in the United States counted their term from the date of issue. This situation was somewhat simplified by an amendment to the U.S. law in 1995, bringing it more into line with other countries, but many pharmaceuticals in today's market are still protected by patents granted under the old system.

There are essentially two approaches in use to establish a term extension. The first mechanism is to issue a decision which extends the term of the original patent but creates no new legal instrument. This is the approach which has been used in the U.S.A. and Japan. While the term extension decision is applied to the patent as originally granted, there may be supplementary restrictions on the actual monopoly cover obtained. For example, the appropriate United States law provides that a product patent when extended is limited in scope to the approved product for any *approved* use; that is, it will no longer cover other compounds within the original scope of the patent (such as those is a generic Markush-style claim) nor any nonpharmaceutical use of the approved product.[1]

The second mechanism, which is the one used in Western Europe, is to create a separate legal instrument, which only enters into force on patent expiry. The grant of this separate document (usually termed a Supplementary Protection Certificate or SPC) is subject to its own examination procedure by the granting national patent offices and usually contains a single claim to a specific marketed drug (possibly a single stereoisomer) or a formulation containing one or more medicinal compounds.

The importance of making the distinction between the two approaches, from the information scientist's point of view, is that legal status records relating to European extensions will feature both a notice of expiry of the "parent" patent and a corresponding entry into force of the SPC. These are apparently contradictory events which can confuse the unwary searcher.

1.1. Chronology of Adoption. The first country to adopt term extension provisions was the United States, in the form of the Drug Price Competition and Patent Term Restoration Act 1984 (commonly known as the Waxman/Hatch Act) and the later Generic Animal Drug and Patent Term Restoration Act of 1988. These individual pieces of legislation were later codified as 35 USC § 155 to 156. Readers interested in further general background to the U.S. situation are referred to the book by Beers.[2]

In Japan, corresponding legislation came into force on January 1, 1988 in the form of the revised Patent Law section 67(3). It was not until 1992 that the European Union passed regulations, initially in the form of Council Regulation (EEC) No. 1768/92,[3] which only covered medicinal products. Subsequent lobbying by the agrochemical industry resulted in a supplementary decision, published in 1996 as Council

† Corresponding author phone: (+44) (0)118 929 9515; e-mail: stevea@magister.co.uk.

10.1021/ci010112p CCC: $22.00
Published on Web 03/22/2002

Regulation (EC) No. 1610/96[4] which is devoted to plant protection products. It is worth noting that although the main intention of the 1992 Regulation was to allow extensions in the human pharmaceutical field, a number of quasi-agrochemicals (such as some insecticides and fungicides with veterinary applications) were processed under this legislation. This can affect the applicable information sources to be used in order to locate extension information.

To further complicate the issue, both France and Italy implemented national SPC legislation before the EC Regulations entered into force. Consequently, information sources covering these particular states may contain references to extensions passed either under their national law or EU law, and the absence of one type of record cannot preclude the presence of the other.

At the time of writing, a number of other countries have passed extension legislation for pharmaceutical patents. This list includes Australia, Cyprus, the Czech Republic, Estonia, Iceland, Israel, Mexico, Norway, several of the Eastern European candidate countries for EU membership, South Africa, South Korea, Switzerland, and Taiwan. Most of these countries have opted for a variable term extension, with a maximum extension period of between 2 and 7 years.

1.2. Operation in the European Union. The EU legislation is in the form of a Regulation rather than a Directive. This means that it is required to be implemented directly by the member states, rather than being an instruction for the states to amend domestic laws to a stated common minimum standard. It is important to note that the grant procedure is implemented on a *national* level, rather than by the administrative offices of the EU or the European Patent Office. The 1992 legislation stipulates that certificates may be granted for products which satisfy the following three criteria: (1) they constitute the active ingredient(s) of a medicinal product, (2) they are protected by a "basic patent" in force *within the member state*, and (3) they have received a first marketing authorization as a medicinal product *in the Community*.

This apparent disparity between the territorial requirements for the patent protection and the marketing authorization (MA) has implications which will be discussed later.

The maximum allowable duration of an SPC is 5 years. The actual term granted to the applicant will depend on the respective dates of patent filing and marketing authorization, under a formula which is designed to ensure a minimum 15 year monopoly from the MA date.

When originally enacted, Regulation 1768/92 had effect only in the 12 states which were party to the Community at the time, namely Belgium, Germany, Denmark, Spain, France, the United Kingdom, Greece, Ireland, Italy, Luxembourg, The Netherlands, and Portugal. Several of these states were able to negotiate a derogation on the entry into force of the law, but all were eventually subject to its terms. However, the geographical scope of the law was gradually extended to most of the member states of the European Free Trade Area (EFTA) as a result of the European Economic Area (EEA) Agreement. As of 2001, the Regulation has effect in a revised European Economic Area (EEA) comprising the 15 EU member states (Austria, Finland, and Sweden having joined the EU in 1996) plus 3 of the 4 EFTA member states (Iceland, Liechtenstein and Norway). The original 1992 and 1996 Regulations have been amended to take account of this extension.[5] At the time of writing, the only EFTA state to remain outside of the EEA is Switzerland.

This gradual extension has led to an apparent anomaly in the law, at least according to some of the national granting authorities. Since one of the criteria for grant of an SPC remains the existence of a valid MA in the *Community*, this is now interpreted to mean any state *belonging to the EEA*, including Liechtenstein. However, as a result of agreements between Liechtenstein and neighboring Switzerland creating a common legal environment for many regulatory affairs, Liechtenstein no longer grants its own marketing authorizations but instead automatically recognizes Swiss MAs. Consequently, a Swiss MA may be regarded as a valid first MA for the purposes of applying for SPC protection, even though Switzerland does not itself belong to the EEA. It should be emphasized that not all national patent offices agree with this interpretation. As a result of this anomaly and other national variations, the current situation in Europe is that it is possible to be granted an SPC in one member state and be refused it for the same product in another member state or to be granted different SPC terms according to the MA which is recognized by the granting office.

2. PUBLIC INFORMATION ON THE APPLICATION PROCEDURE

The principal publishing sources for SPC application data are the national patent offices and the pharmaceutical regulatory authority for each country or region.

The national offices vary in the extent of the data which they release. Most will announce when an SPC has been granted, and many will also release application data, but fewer publish (or have announced that they intend to publish) information when an application has been denied or withdrawn. Fuller details can be found from a 1993 survey published as section 7.2 in the "Handbook of Industrial Property Information and Documentation" published by the WIPO.[6]

As regards regulatory authorities, the Food and Drug Administration (FDA) in the United States publishes data when term extension has been applied for in the U.S. and information on the regulatory review period in the Federal Register, but this level of public disclosure is not found in many other countries.

The crucial step in obtaining useful SPC data is that of making the link between the trivial or approved name of the medicinal product and the corresponding patent for which extension is sought. This step would a priori suggest a number of search keys which might be expected to provide an entry point to the desired data. However, none is entirely successful, and there are a number of cautions which must be expressed in the use of these search keys.

The first entry point which might be expected to yield extension data is the national patent number which claims the pharmaceutical compound itself (i.e. the compound per se case.). However, this is not necessarily as useful as it might seem at first sight. It is not uncommon for the SPC extension to be sought not for the per se case, but for a later patent devoted to a method of treatment or a specific formulation of the main compound.

The second entry point might be by way of information from the appropriate regulatory authority. Unfortunately, as

mentioned previously, not all national regulatory authorities are involved in the term extension process, and even the data which are released at the time of the first national MA may not make the crucial link between product and patent number. In addition, the regulatory approval process in Europe is such that the appropriate information may be released by either the national authority (e.g. the Medicines Control Agency in the United Kingdom) or the corresponding regional authority (e.g. the European Agency for the Evaluation of Medicinal Products, EMEA).

The third entry point could be by chemical structure. The unambiguous identification of a specific chemical compound is usually thought to be possible by the use of a CAS Registry Number or similar identifier, which itself may be derived from the molecular structure. However, in the case of pharmaceuticals, there are added complications to this route. The actual product placed on the market may be a technical mixture of stereoisomers, of which one may the principal active ingredient. Each single isomer may have its own CAS Registry Number, as may the mixture of isomers, or indeed may the mixture of any one of the above with additional active or nonactive ingredients in the commercial formulation. Before using the structure or CAS Registry Number as a search key to determine the relevant patent(s) which may be candidates for extension, it is necessary to know exactly which mixtures are registered and what is in the marketed product. Furthermore, there is some controversy over the question of interpretation of the term "product" in the SPC regulation; a number of cases have been referred to the European Court of Justice for an opinion on whether a specific marketing authorization (for example, for a given stereoisomer ratio) may be cited in support of an application for an SPC linked to a given patent (for example, claiming an improved ratio). This uncertainty makes the simple equation "CAS Registry Number = product" rather more unreliable than normal. The most comprehensive electronic information sources for obtaining CAS Registry Numbers are the Registry file on STN (using the exact or family search options) and the corresponding EURECAS structure file on Questel-Orbit, searched under the Generic DARC software.

Finally, there is the question of the name of the applicant for the SPC. This might be expected to be useful as a search key when researching or monitoring SPC application data. Unfortunately, there is a potential confusion even here. Article 6 of the 1992 Regulation states that an SPC may only be *granted* to "the holder of the basic patent or their successor in title". The legislation is silent on the question of who may be entitled to *apply for* an SPC. There is nothing to prevent a patent licensee, or the company which applied for marketing authorization, from applying for an SPC on the patent under which they conduct their business. While in practice it would be unusual for this to take place without some consultation with the basic patent holder, it can lead to the situation where the company name indexes for the various data sources (patent assignees, MA holders, SPC applicants) are each showing a different name in relation to the same marketed product.

3. SOURCES OF INFORMATION

As mentioned above, there are essentially two basic sources for SPC data: the pharmaceutical regulatory agencies and the national patent-granting authorities. There are a few commercial information providers who have produced products attempting to collate these primary data. The medium of distribution can vary from paper, to both free-of-charge and fee-based Internet files and a number of fee-based online files on vendor systems.

3.1. Regulatory Agencies. The United States' Food & Drug Administration issues approval listings for new drugs via its Center for Drug Evaluation & Research (CDER), and these can be found on the FDA website at www.fda.gov/cder/orange/adp.htm. For many years, these data have been collated into the so-called "Orange Book", which is available in its entirety on the same site, at www.fda.gov/cder/ob/default.htm. There is at least one nonofficial reformatting of Orange Book data on the Internet, for example at the website http://home.earthlink.net/~mac_stacks/—but users should exercise caution with such sources, particularly in relation to their currency.

Outside the U.S.A., information searchers who are unfamiliar with the structure of regulatory authorities may find the listing at the Ceres website useful, which provides a set of links to many national data sources at www.ceres.co.uk/links/piag.html. For the United Kingdom, the appropriate authority listing from the Medicines Control Agency (MCA) can be found at www.open.gov.uk/mca/inforesources/inforesources.htm. The corresponding site for EMEA is at www.emea.eu.int/.

3.2. National Patent Office Websites. 3.2.1. The United States Patent and Trademark Office (USPTO). Extension data relating to proceedings under 35 USC § 156 are released on the USPTO website at www.uspto.gov/web/offices/pac/dapp/opla/term/156.html. However, it should be noted that these are the final decisions only and that interim extensions under § 156(e)(2) or § 156(d)(5) are not included. Users wishing to find further explanatory material on the process can do so at www.uspto.gov/web/offices/pac/dapp/opla/term/. The actual form of issue of a term adjustment under 35 USC § 156 is as a Certificate of Correction entry and an Official Gazette notice. The full text of all Certificates of Correction are displayable as separate segments in the image portion of the USPTO patent search file, but they are not searchable. At the time of writing, it appears that the USPTO is making plans to add this information, possibly into the PAIR system. Finally, the Freedom of Information Act (E-FOIA) section of USPTO site contains all Notices of Final Determination, prior to publication in the Official Gazette, at the URL www.uspto.gov/web/offices/com/sol/foia/comm/pte/pte.htm.

3.2.2. The European Patent Office (EPO). The new Internet version of the EPO Register is currently in public beta-test at www.epoline.org/register.html. This file contains *no data* on any SPC applications which may cite an European Patent designating a particular state as the "basic patent", since the application process falls outside the jurisdiction of the EPO. In general terms, this file contains little national data once the granted patent has passed through the 9-month post-grant opposition period. Since a large number of SPC applications in Europe will cite a granted European Patent as the basic patent, it would be convenient to have this information collated into the EPO Register, but this is not currently one of the pieces of so-called "Rule 92" data which the EPO is obliged to collect.

Table 1. Commercial Online File Coverage

country	INPADOC	IMS DrugPat[a]	CLAIMS/ CPLS	PAST	EPAT	PATDPA	FPAT
Australia	√	√					
Austria	√	√					
Belgium	√	√					
Cyprus							
Czech Republic		√					
Denmark	√	√					
Estonia							
Finland	√	√					
France	√	√			√		√
Germany	√	√				√	
Greece		√					
Iceland							
Ireland	√	√					
Israel							
Italy	√	√					
Japan		√					
Korea (South)							
Luxembourg	√	√					
Mexico							
Netherlands	√	√					
New Zealand		√					
Norway		√					
Portugal		√					
South Africa							
Spain		√					
Sweden	√	√					
Switzerland/ Liechtenstein	√	√					
Taiwan							
United Kingdom	√	√					
United States	√	√	√	√			

[a] N.B. − the full extent of country coverage has not been audited; this list is based on claims from the database producer.

3.2.3. The German Patent and Marks Office (DPMA). Information on SPC applications since 1997 is available via the electronic version of the official gazette (*Patentblatt*) at www.patentblatt.de/eng/index.htm. Some data may be found using the expert search form and searching all fields for the commercial drug name (any="drugname"). Applications for SPC can be recognized by the form of the standard numbering system. The same basic format as for patent applications is used, but a specific block of serial numbers is reserved for use to denote SPC applications. Hence the application number will be in the form DE 1 YY NNNNN, in which "1" is the document type series (patent), the digits YY correspond to the year of application, and NNNNN is a 5-digit serial number, starting from 75000 upward.

3.2.4. The United Kingdom Patent Office. The national status register for patents valid in the U.K. can be found on the main Patent Office website at www.patent.gov.uk. The only retrospective search key is the patent number of the basic patent, which may be a national (GB) case or a European Patent designating the United Kingdom (EP(U.K.)). In either case, the patent number is searchable as a 7-digit number e.g. EPnnnnnnn or GBnnnnnnn. It is also possible to monitor for new applications or the announcements of decisions on applications by using the weekly PDF version of the Patents & Designs Journal.

3.2.5. The Japanese Patent Office (JPO). The JPO only releases a small amount of current data via its own website. Larger search files are mounted by the JAPIO organization, of which one is the fee-based "Patolis-e" service in English, at patolis-e.japio.or.jp. This extensive file contains legal status information for Japanese patents from 1964 onwards and is searchable by a variety of criteria, including the JP-A, JP-B, or JP-C (old Act) publication numbers. There is a limited amount of term extension data, including notification that an extension has been granted, but no explicit statement of the duration or the anticipated new expiry date is given.

3.3. Commercial Directories. There are two commercial paper directories in existence. Some years ago, Derwent Information Ltd. began to issue a series of loose-leaf "Patent Extension" folders, one per country. Binders were issued for the United States, Germany, Japan, and United Kingdom (including Ireland). These first editions appeared during 1995, but production ceased after a short period and they are no longer updated. They provide extensive drug data, including the duration of extension in each country and the full Derwent patent family. Additionally, they have extensive indices including the drug approved and trivial name and the CAS Registry Number. While clearly of no value for later applications, they are still a useful archive for applications which had been processed at the time of printing.

FOI Services Inc. produces a book entitled "Drugs under Patent" which is based on FDA Orange Book data and covers some 2500 drugs marketed in the U.S.A. It is extensively indexed, including company, trade name, generic name, expiration date, dosage form, exclusivity code, patent number, and NDA number.

3.4. Commercial Online Files. Table 1 summarizes the national coverage of the range of online files discussed in this section.

3.4.1. INPADOC (Produced by the European Patent Office). At the time of writing, this file contains at least some

Table 2. INPADOC PRS Codes—Typical Format for SPC Legal Status

PRS code (text form)	code form
Application for SPC filed	GB/CTFF
SPC granted	GB/CTFG
SPC enters into force	GB/CTFE
Application for SPC rejected	GB/CTFR
Application for SPC withdrawn	GB/CTFW

extension data for 13 of the 18 EEA states, plus Australia, Switzerland, and the United States. In the cases of France and Italy, information relating to applications under both the national and EU legislation is available. The data are formatted in the form of standard PRS legal status codes, which are searchable in the text form or their corresponding codified form. The PRS codes for the United Kingdom are shown in Table 2. This file is available via the STN, Dialog, Questel-Orbit, and Lexis host systems as well as being progressively loaded onto the MicroPatent and Delphion websites (the latter two with reduced search functionality at present). For additional countries, the full listing of the PRS codes can be found at the EPO website (www.european-patent-office.org/inpadoc/faq/spc_cov.htm).

3.4.2. Drug Patents International (Produced by IMS Health). This file is the only other major online source covering multiple countries. The coverage as claimed by the database producer is listed at Table 1, but it was not possible to easily verify this by sample searching, partly because of the high cost of the file. In addition, the patent number format is not standardized, and the file is loaded in the form of one record per patent family member, which makes it relatively awkward to check upon extension data for a single product across the world. The file is available via STN, Questel-Orbit, Dialog, and DataStar.

3.4.3. CLAIMS Current Patent Legal Status (CPLS) (produced by IFI Claims Patent Services). This file covers U.S. cases only. The most convenient method of searching is to use the Document Type (DT) field and search for the term "EXTENDED". For each record, a cross-reference to the corresponding Official Gazette announcement is included. The file is available on STN, Questel-Orbit, and Dialog.

3.4.4. Patent Status (PAST) (Produced by Derwent Information). As with the CPLS file, this file only covers U.S. cases. It would be a useful exercise to compare the currency of the data release for these two files in future work on this subject. The record format in PAST is extremely brief, consisting of the notification of extension only, with a cross-reference to the Official Gazette entry—no dates are cited. The file is available on Questel-Orbit.

3.4.5. EPAT (Produced by the EPO, Data Supplemented by INPI). At first sight, this seems a surprising contradiction to the comments above concerning the EPO Register. However, the interest here is due to the additional work done by the French Institut National de la Propriété Industrielle (INPI) in preparing the file for loading on Questel-Orbit. For those SPC applications which cite a granted European Patent *designating France*, this file contains a range of searchable fields relating to applications under both the earlier French national law and the later Community law. Fields include the SPC number itself, the MA number, the assignee of the SPC, the drug name, and the calculated expiry date. These comments only relate to the file version on Questel-Orbit; the similar files Europatfull and PATOS-EP on STN do not include these data.

3.4.6. PATDPA (Produced by Deutsches Patent- und Markenamt). This file is derived from the official German register, the *Patentrolle*, which covers national German patents and EP cases and PCT transfers designating Germany. Unfortunately, much of the data is unsearchable. At the time of writing, it is only possible to locate whether SPC file data exists by the Field Availability (FA) operation, searching SPC/FA to determine the existence of the field. The text is potentially very valuable, including as it does the marketing authorization data including the relevant *Bundesgesundheitsamt* (BGA) number from the Federal Ministry of Health. The file is available on the STN system.

3.4.7. FPAT (Produced by the Institut National de la Propriété Industrielle (France)). The final major online file is FPAT, which like its German counterpart covers French cases only, comprising grants under both the national and Community SPC legislation. The file is searchable by patent number, MA number, applicant, and drug name. The file is available from Questel-Orbit.

In addition to the files discussed above, there are a number of other sources which may be of use in making the vital link between approved name and patent number. These include Pharmaprojects (PJB Publications), Drug Data Report (Prous Science), Investext (Thomson Financial), and the Federal Register (U.S. Government Printing Office). Use of some of these files, particularly for identifying U.S. term extensions, has been discussed by Snow.[7]

4. SHORT CASE STUDY—ENROFLOXACIN

Patent applications for the protection of the Bayer antiseptic compound enrofloxacin were filed during the early 1980s, and granted patents would normally expect to have expired over a period from 2001 to 2003. The purpose of this exercise was to compare data from some nonelectronic sources, including private consultants, with those available from public electronic sources. The initial enquiry, using no online sources at all, yielded the information in Table 3.

By way of comparison, the public online files EPAT, FPAT, INPADOC, PAST, and PATDPA were used to try to obtain term extension data for the same compound. These files together yielded the same basic information for the U.S., United Kingdom, Germany, and Ireland, with additional details such as the numbers of the SPC applications.

Table 3. Term Extension Data for Enrofloxacin, from Paper Sources

country	patent number	original expiry date	new expiry date	extension period
Japan	JP 1515648 C	1 September 2001	22 November 2003	2 years, 2 months, 21 days
United States	US 4670444	9 December 2003	9 December 2006	3 years under 35 USC § 156
United Kingdom	EP 49355 B	20 August 2001	17 December 2001	3 months, 28 days
Germany	EP 49355 B (as DE 3166619 G)	as for U.K.		application for SPC withdrawn
Ireland	IE 51541 B			SPC refused (on appeal)

However, there was no corresponding data for Japan from these sources. In addition, INPADOC was the principal source for new data relating to the situation in Austria, Belgium, Switzerland, Denmark, France, Italy, Luxembourg, The Netherlands, and Sweden. The only source for Japan, with minimal content, was the Patolis-e system.

It is worth noting the different bibliographic formats which are being used to denote SPC documents in various countries. In the U.S., where the form is that of a Certificate of Correction, the original patent number is unchanged and no newly numbered document is issued, but in other countries the new SPC filing gains a number in its own right. In Japan and Germany, this closely resembles the format used for unexamined patent application numbers, such as JP 04-700014 (Imperial year followed by serial number in the 700,000 series) or DE 1 93 75030 (main patent series format, serial number from 75,000 upward each year). The United Kingdom, by contrast, issues documents with a unique series in the format SPC/GBYY/NNN (serial number starts from 001 each year).

ACKNOWLEDGMENT

This work was supported by generous assistance from the following individuals and organizations: Alice de Pastors (Conseil en Propriété Industrielle, Paris), Jason Bellia (United Kingdom Patent Office), Martin Paltnoi (Martin Paltnoi Associates, London), Derwent Information, and the British Library. This paper is derived from a presentation given in the symposium "Pharmaceutical and Biotechnology Patenting" held by the Chemical Information (CINF) Division of the American Chemical Society at the Spring National Meeting, April 1−5, 2001 in San Diego, CA. My attendance at that meeting was facilitated by a travel award from the CINF Division, sponsored by Alan Engel of ISTA Inc.

REFERENCES AND NOTES

(1) United States Code Title 35, § 156(b).
(2) Beers, D. O. *Generic and Innovator Drugs: a guide to FDA approval requirements*, 5th ed.; Aspen Publishers Inc.: 1998; ISBN 0735502811.
(3) Official Journal of the European Communities **1992**, *35*, L182, 1−5 (2 July).
(4) Official Journal of the European Communities **1996**, *39*, L198, 30−35 (8 August).
(5) Official Journal of the European Communities **1994**, *37*, L160, 138−139 (28 June) and *op. cit.* **1995**, *38*, L1, 175 (1 January).
(6) Handbook on Industrial Property Documentation and Information. WIPO Publication No. 208(E); WIPO: Geneva, 1999; ISBN 92-805-0352-9 (CD-ROM version).
(7) Bonnie, S. Drug patent extension information online: monitoring post-approval regulatory developments. *Online* **1994**, *18*(4), 95−100 (July).

CI010112P