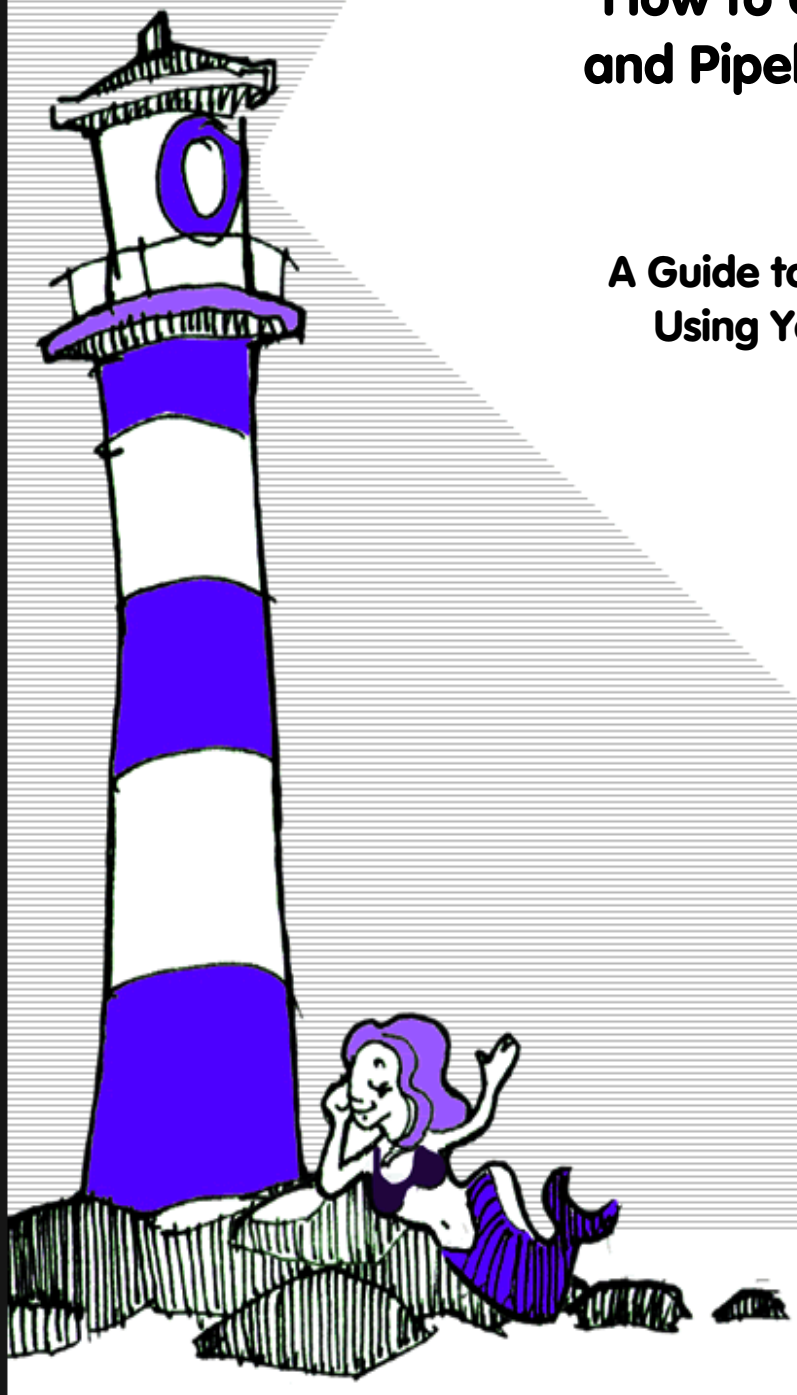
genericsweb.com
realising drug development opportunities

How to Use Pipeline™ Selector and Pipeline™ Developer Patent Intelligence

A Guide to Logging In, Managing, and Using Your GenericsWeb Account



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Logging In, Managing and Ordering Reports

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System Compatibility
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System Compatibility

GenericsWeb is optimised for viewing with monitors set to 1024 x 768 screen resolution. Use of other screen resolutions may result in blurring of images or page cropping.

GenericsWeb has been fully tested for compatibility with Internet Explorer version 6 or higher. Some functions and displays may not operate effectively when viewed using alternative web browsers.

Ensure that your web browser accepts all cookies from GenericsWeb.com and that JavaScript and pop-ups are enabled. For more information see our help sheet "Enabling JavaScript and Cookies for using GenericsWeb.com".

Logging In

Click on www.genericsweb.com or type the URL into your Internet browser address bar and hit Return.

Enter your login name and password into the spaces at the top left of the page then click the Log-in button.

If you have forgotten your password, click on 'forgot password'. Please then enter your registered email address and click 'Email password'. Your password will be reset and a new one sent to the registered email address. After logging in, you may then change this password to one of your choosing using the 'My Details' section. If you still have problems logging in please email admin@genericsweb.com.

Accessing Your Company Subscriptions

Click on the 'Patents' button in the menu bar.

Confirm that you have read and understood the Scope and Limitations of GenericsWeb Pipeline Patent Reports and agree with the terms and conditions referred to therein by checking the box. *Please note that this is an informative document that is vital for understanding the content of Pipeline patent reports.*

Contact us at this stage if you have any questions, otherwise click on the 'Proceed to Pipeline Patent Reports'. You will then proceed to your company subscriptions page where you can view and manage your Pipeline Patent Report subscriptions.

Purchasing, Upgrading and Renewing Reports

Please note that only Company Administrators and Company Power Users have the authority to purchase, renew and upgrade reports, whilst Company Users can only view existing reports. Company Administrators may grant access and assign authority levels to other users in their company using the 'my details' section after logging in. Any company may grant access to an unlimited number of users at any authority level, in any country, providing the users are members of that company.

Orders will not be processed until the company administrator has completed and returned the User Agreement.

- ***Purchasing Pipeline Selector Reports***

Click on the 'Order Pipeline Selector Reports' button.

Select from drugs currently on our list and/or type in names of required drugs that are not yet listed, then click on 'Proceed to Confirmation'.

You will be quoted a price in Australian dollars (use the live currency converters if required). Type in a purchase order number if required on the invoice and click 'OK'.

- ***Purchasing Pipeline Developer Subscriptions***

Click on the 'Order Pipeline Developer Reports' button.

Select from drugs currently on our list and/or type in names of drugs that are not yet listed then click on 'Proceed to Confirmation'.

For listed drugs, you will be quoted a price in Australian dollars (use the live currency converters if required). For unlisted drugs, you will receive a quote within one business day. Type in a purchase order number if required on the invoice and click 'OK'.

- ***Purchasing Pipeline Developer Subscriptions (Upgrade)***

This function is available for existing Pipeline selector reports.

Check the box next to the corresponding drug name(s) in the 'Current Pipeline Selector Reports' section and click 'Upgrade'.

You will be quoted a price in Australian dollars (use the live currency converters if required). Type in a purchase order number if required on the invoice and click 'OK'.

- ***Renewing Pipeline Developer Reports***

This function is available for existing Pipeline Developer Subscriptions that expire within the next two months or have expired within the past 12 months. Please email admin@genericsweb.com to renew subscriptions that have expired more than 12 months ago. Renewing a subscription will add twelve months to the displayed end date of your current subscription.

Check the box next to the corresponding drug name(s) in the 'Current Pipeline Developer Subscriptions' section and click 'Renew'.

You will be quoted a price in Australian dollars (use the live currency converters if required). Type in a purchase order number if required on the invoice and click 'OK'.

A screen will appear confirming each order, and a confirmation email will be sent to the registered email addresses of all authorised users. Please re-submit any orders for which confirmation is not received, or email admin@genericsweb.com if problems persist.

An Invoice will be sent to the registered email address of the user who placed the order within 7 days. Hard copies of invoices can be requested by emailing admin@genericsweb.com.

Using Pipeline Selector Reports

Pipeline Selector Reports are designed to provide a cost-effective method of selecting suitable generic drugs for your development pipeline.

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Viewing Reports

From your company subscriptions page you can display the Pipeline Selector report for any drug to which you are currently subscribed (at either Selector or Developer level) by clicking on the 'View' button next to that drug.

Use the buttons at the top of the page to navigate to the various sections, clicking ‘back to top’ at any stage to view the navigation buttons again (the Patents in Detail interface will only be active for Developer level subscriptions). To return to your company subscriptions page at any stage, click on the ‘Pipeline’ button in the GenericsWeb toolbar.

General Information

This information defines the characteristics of the currently marketed innovator product in major territories, and can be used:

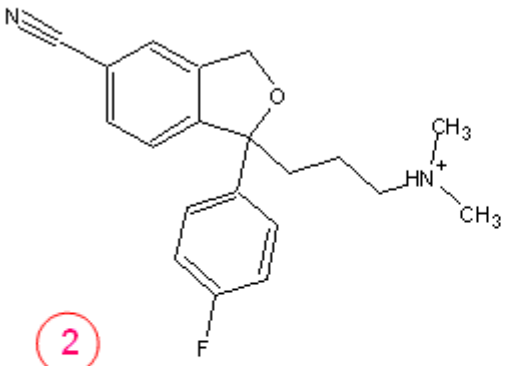
a) To indicate the required attributes of a generic equivalent

b) As a reference for determining the relevance of identified patents

Citalopram General Information

Printer Friendly

Molecular Structure



Chemical Name

1-[3-(dimethylamino)propyl]-1-(p-fluoro phenyl)-5-phthalancarbonitrile

General Indications (1)

Depression; Panic disorder

Innovator/Marketeer

Lundbeck (Cipramil, Ciazil), Forest Labs (Celexa, Lexapro)

(2)

Brand Product Attributes

Dosage Form	Route	Active Ingredient	Strengths
f/c Tablets	Oral	Citalopram hydrobromide	10, 20, 40 mg
Drops	Oral	Citalopram hydrochloride	40 mg/ml
Solution	Oral	Citalopram hydrobromide	10 mg/5 ml
f/c Tablets	Oral	Escitalopram oxalate	5, 10, 20 mg
Solution	Oral	Escitalopram oxalate	5 mg/5 ml

Information contained in 'General Indications' **(1)** and 'Brand Product Attributes' **(2)** is based on products containing the active pharmaceutical ingredient (API), which are currently registered in Australia, UK and the USA. Indications are summarised where appropriate and may vary between individual countries.

Data Exclusivity

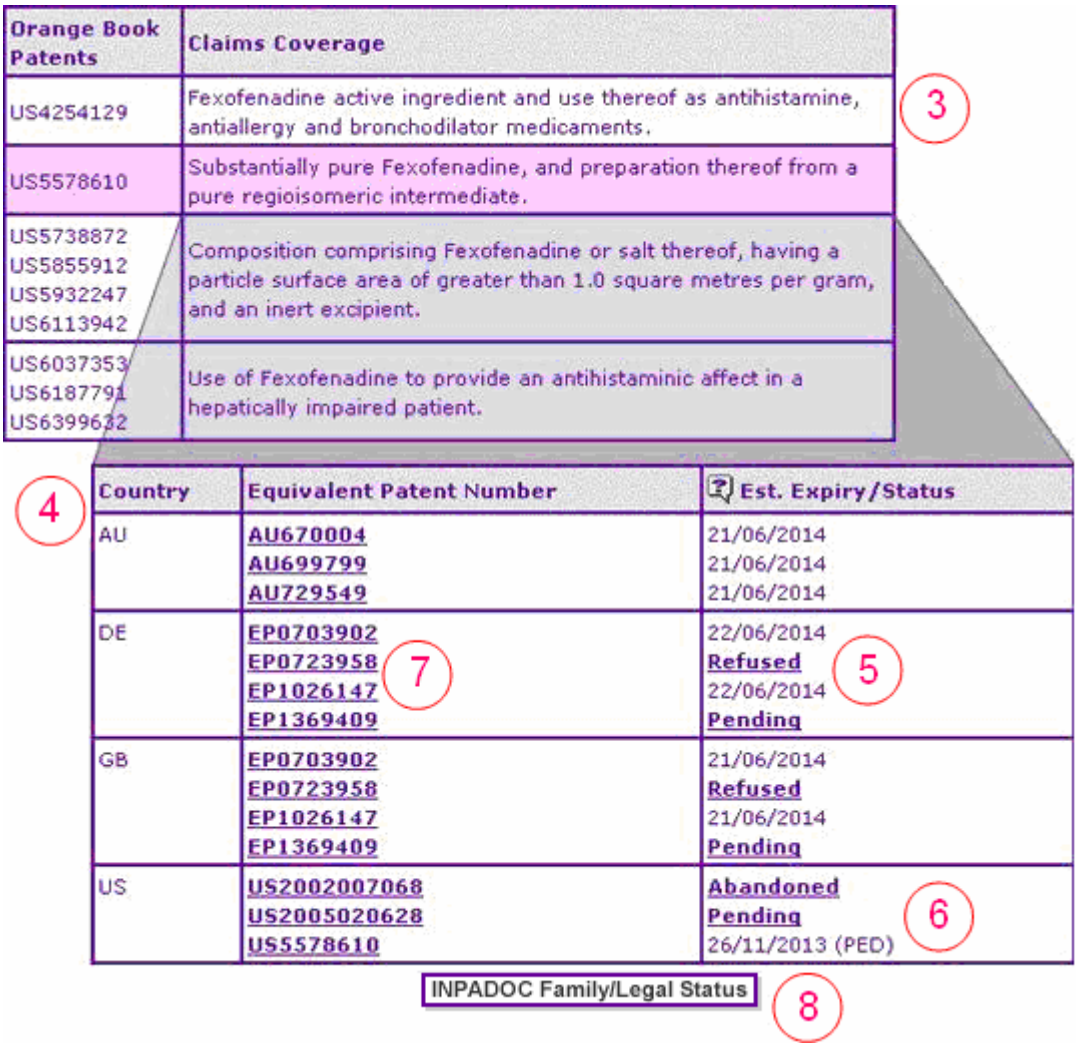
This section is intended to provide either a specific data exclusivity period or the necessary information to calculate such a period for the active pharmaceutical ingredient (API) of interest.

Country	Date	How to Calculate Data Exclusivity
Australia	14/08/1991	Australian
Europe (France)	08/03/1988	European

Click on the country/region to find a PDF document titled "How to Calculate Data Exclusivity".

Key Patent Indicator

This information is intended to identify patents that are a significant constraint to generic competition as well as their expiry dates, and is not a comprehensive list.



The claims coverage indicates the type of patent and its scope **(3)**. Click a row in the Key Patent Indicator table to display a pop-up window **(4)** containing the status and/or estimated expiry dates of selected patents in the family, including any granted extension **(5)**. PED **(6)** indicates that a paediatric patent term extension of 6 months should be added to the corresponding US patent expiry date. Clicking on the individual patent numbers **(7)** provides access to the corresponding patent image to allow analysis of the claims. Clicking on the 'View INPADOC Family / Legal status' button **(8)** provides access to data for equivalent patents in additional countries (see next page).

N.B. The 'Key Patent Indicator' section is intended only to provide an indication of the key patents pertaining to a generic drug, and is not based on a comprehensive patent search. This information is primarily based on the US FDA Orange Book, thus the following limitations must be recognised:

1) Only patent interests of the innovator are listed.

2) Claims of US patents may be substantially different from those in other countries.

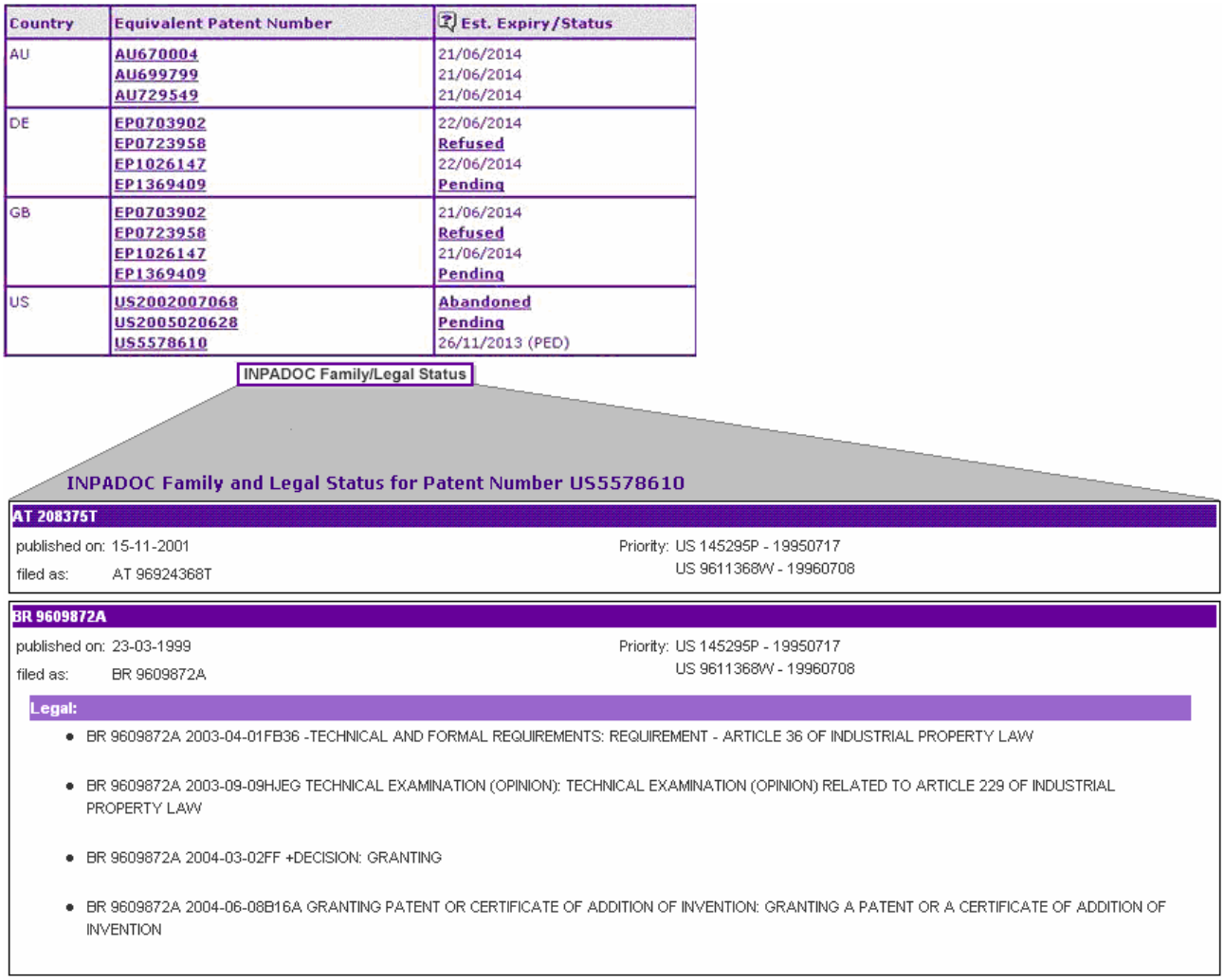
3) Not all patents have US equivalents, therefore key patents may exist in other countries that are not identifiable via the Orange Book method.

4) Process patents are not listed in the US Orange Book.

The absence/expiry of a constraining patent in this section should not be considered to indicate freedom to market a generic product, as consideration of many more patents is required (as found in Pipeline Developer reporting).

INPADOC Family/Legal Status

Clicking on the INPADOC Family/Legal status button takes you to a window that displays the complete INPADOC patent family, together with legal status and transaction history.



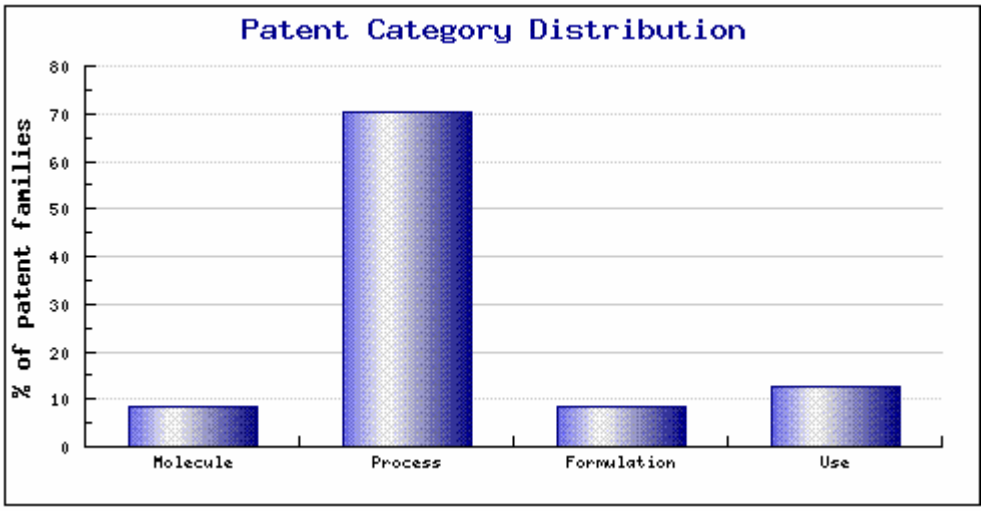
Country	Equivalent Patent Number	Est. Expiry/Status
AU	AU670004 AU699799 AU729549	21/06/2014 21/06/2014 21/06/2014
DE	EP0703902 EP0723958 EP1026147 EP1369409	22/06/2014 Refused 22/06/2014 Pending
GB	EP0703902 EP0723958 EP1026147 EP1369409	21/06/2014 Refused 21/06/2014 Pending
US	US2002007068 US2005020628 US5578610	Abandoned Pending 26/11/2013 (PED)

N.B. This features is also found in Pipeline Developer reporting in the 'Bibliographic Details' window.

Patent Risk Analysis

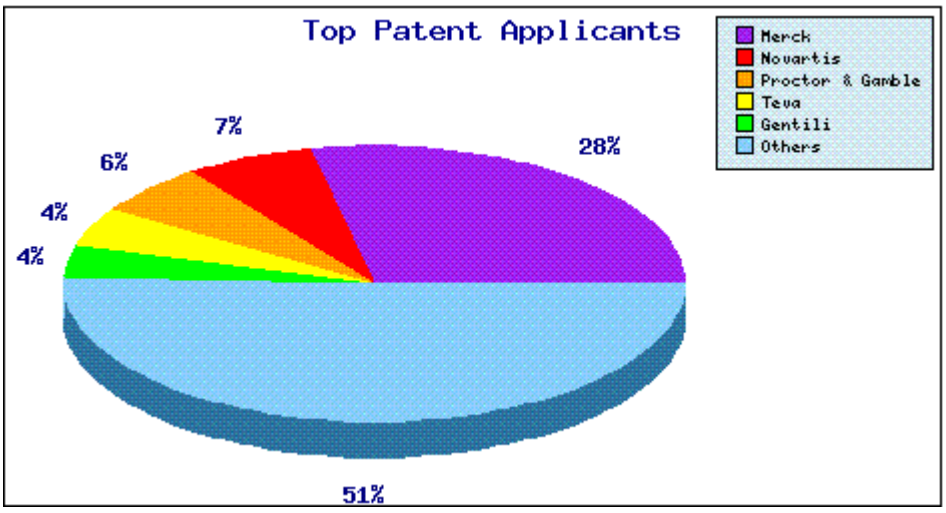
This graphical information is dynamically generated from the comprehensive patent information identified in the Pipeline Developer report, all of which has been filtered to include only data relating to development of a generic, and sorted into development categories (Please note that 'Pipeline Developer Quicklinks' are only available if you have access to the full Pipeline Developer report).

Patent Category Distribution



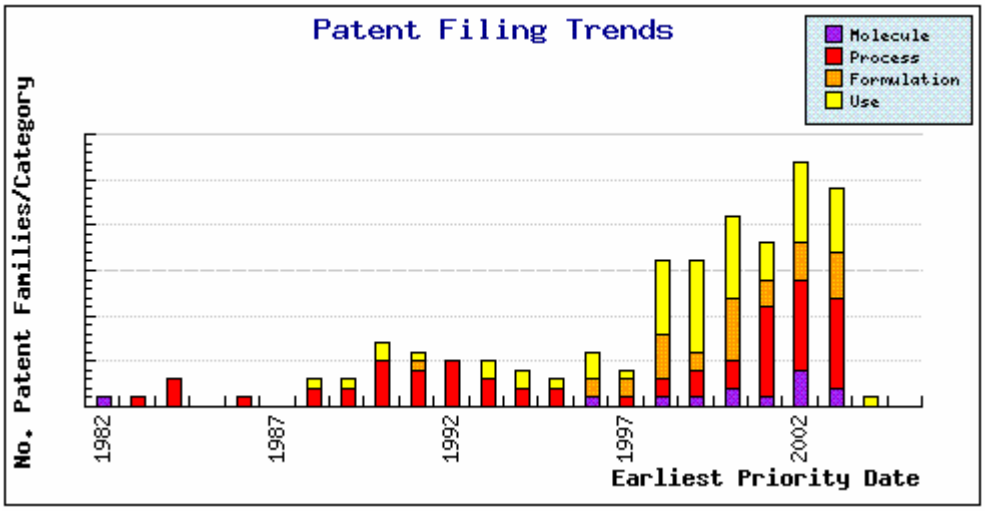
The Patent Category Distribution may be used to determine which development area will represent the most significant challenge in developing a generic. High proportions of process or formulation patents indicate that expertise in this area may be required to interpret and circumvent the patents relating to this particular drug.

Top Patent Applicants



The Top Patent Applicants highlights the top five patent applicants and indicates which innovator and generic companies are actively conducting research and development on this drug. The proportion of the total number of patents filed that are attributable to the top five applicants also indicates the number of other interested parties and therefore the likely level of competition that will be experienced upon launch.

Patent Filing Trends



The patent filing trends highlights patent application activity over the life of the active ingredient, in terms of date and category. Patents applied for early in the drug's life cycle are likely to be broader and/or stronger due to the limited amount of relevant public domain information at that time. Significant patenting activity in this early section may therefore indicate problematic generic development from a patent perspective. Patents applied for towards the end of a drug's life cycle are typical as generics companies actively conduct research and development. Significant patenting activity in this later section may therefore indicate that generics companies have already invested heavily to circumvent existing patents and block other companies from using such technology.

N.B. Due to patent publishing procedures, there is usually an 18-month 'black box' between priority application and patent publication where details of patents filed are inaccessible.

Printer Friendly

To view a printer friendly version of the entire Pipeline Selector report, including all details contained in the pop-up windows, click the 'Printer Friendly' button at the top of the page and click the 'Print' button that appears in the displayed pop-up window containing the full Pipeline Selector report.

Please email us if you have any difficulties in using GenericsWeb Pipeline patent reports, or would like to offer some feedback.

Using Pipeline Developer Reports

Pipeline Developer reports are designed to allow development of generics with complete knowledge of any patent-related risks. These reports allow effective management of patent infringement risk by initially identifying patent families relating to a particular drug and monitoring changes to those families on a regular basis.

All patent information displayed in the Pipeline Developer report is based on a professional, global patent search conducted by experienced searchers using a complex variety of techniques. All information has been filtered to include only data relating to development of a generic equivalent of the reported drug (see scope and limitations for further details).

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Viewing Reports

From your company subscriptions page, click on the 'View' button next to any drug for which you currently have a 'Developer' level subscription. Click on the 'Patents in Detail' button at the top of the page, or scroll down to the 'Patents in Detail' section.

Quick Reporting

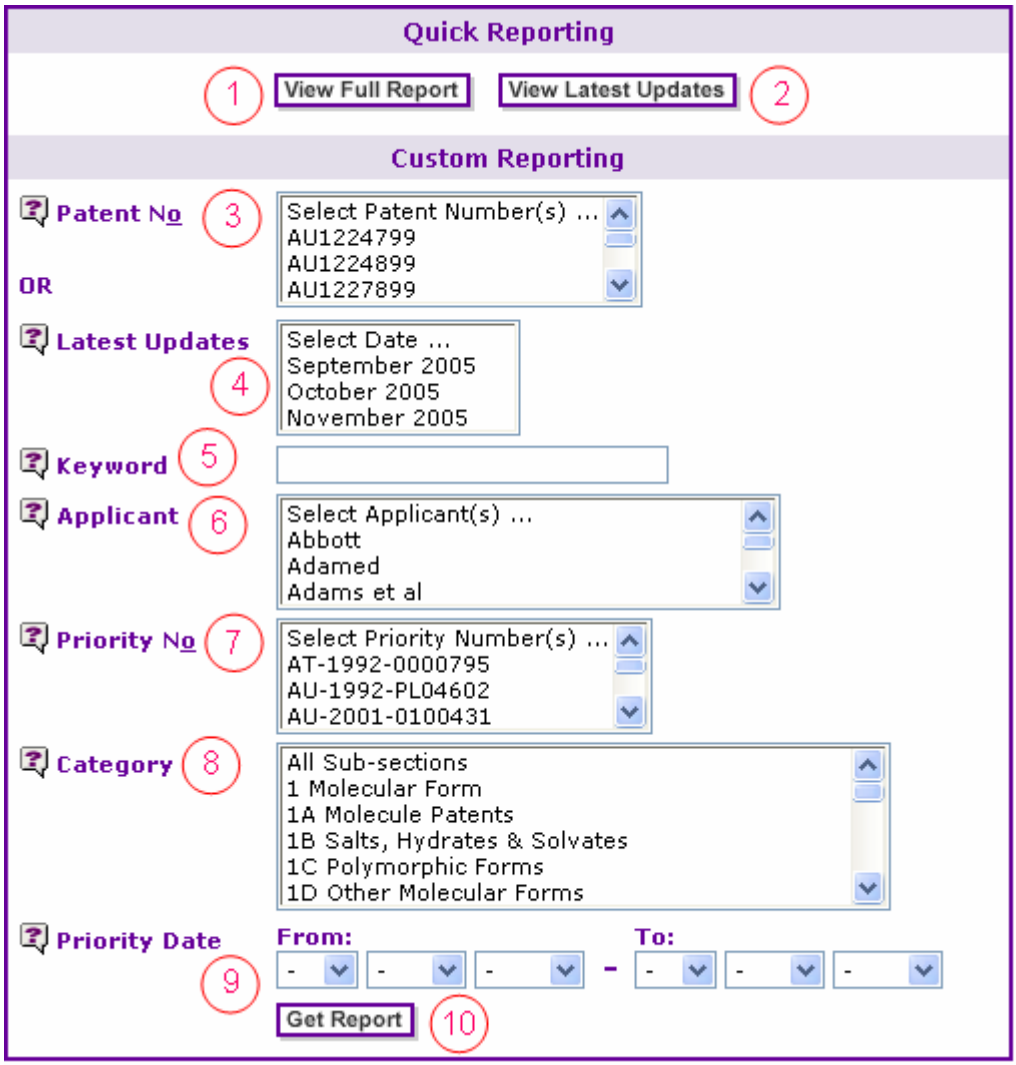
To instantly view summary details of all patent families identified for this drug, click on the 'View Full Report' **(1)** button in the Quick Reporting section.

To view summary details of only those patent families that have added or been changed since the last update, click on the 'View Latest Updates' **(2)** button.

Custom Reporting

To view a subset of the patent families in your Pipeline Developer report, hold the ctrl key to make multiple choices from the available fields in 'Custom Reporting', which includes Patent Number **(3)**, Latest Updates **(4)**, Keyword **(5)**, Applicant **(6)**, Priority Number **(7)**, Category **(8)** and Priority Date **(9)**. Then click on 'Get Report' **(10)**, and a report will be generated that contains all the identified patent families that fall within your selected criteria.

Custom reporting features may be used to identifying potential licensing opportunities, to analyse trends in the identified patent families, or to report specific patent information to different development areas.

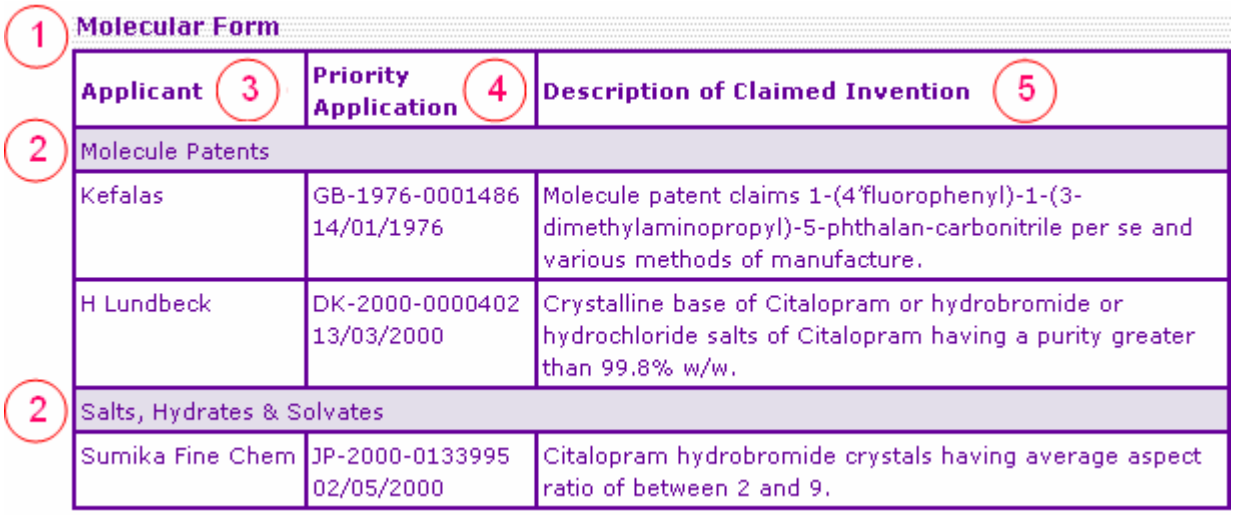


Patent Summary Report

This view is intended to allow efficient identification of the patent families that are most relevant patents to your company's development.

Summary details of patent families that meet the selected reporting criteria are displayed, separated and sorted by development category **(1)** and sub-category **(2)**. Applicant **(3)**, earliest priority application number and priority date **(4)** are displayed for each family, as this information is shared by individual patents within the family.

The independent claims of each member of the patent family have been analysed and interpreted to prepare the Description of the Claimed Invention **(5)**. Each patent family may appear in more than one development category, depending on the nature of the patent claims.



1 Molecular Form		
Applicant 3	Priority Application 4	Description of Claimed Invention 5
2 Molecule Patents		
Kefalas	GB-1976-0001486 14/01/1976	Molecule patent claims 1-(4'fluorophenyl)-1-(3-dimethylaminopropyl)-5-phthalan-carbonitrile per se and various methods of manufacture.
H Lundbeck	DK-2000-0000402 13/03/2000	Crystalline base of Citalopram or hydrobromide or hydrochloride salts of Citalopram having a purity greater than 99.8% w/w.
2 Salts, Hydrates & Solvates		
Sumika Fine Chem	JP-2000-0133995 02/05/2000	Citalopram hydrobromide crystals having average aspect ratio of between 2 and 9.

The Description of the Claimed Invention may be used to select which patent familles are of particular relevance, however caution should be used as variations in the claims of individual members of the patent family mean that patents belonging to the same family may have different scope.

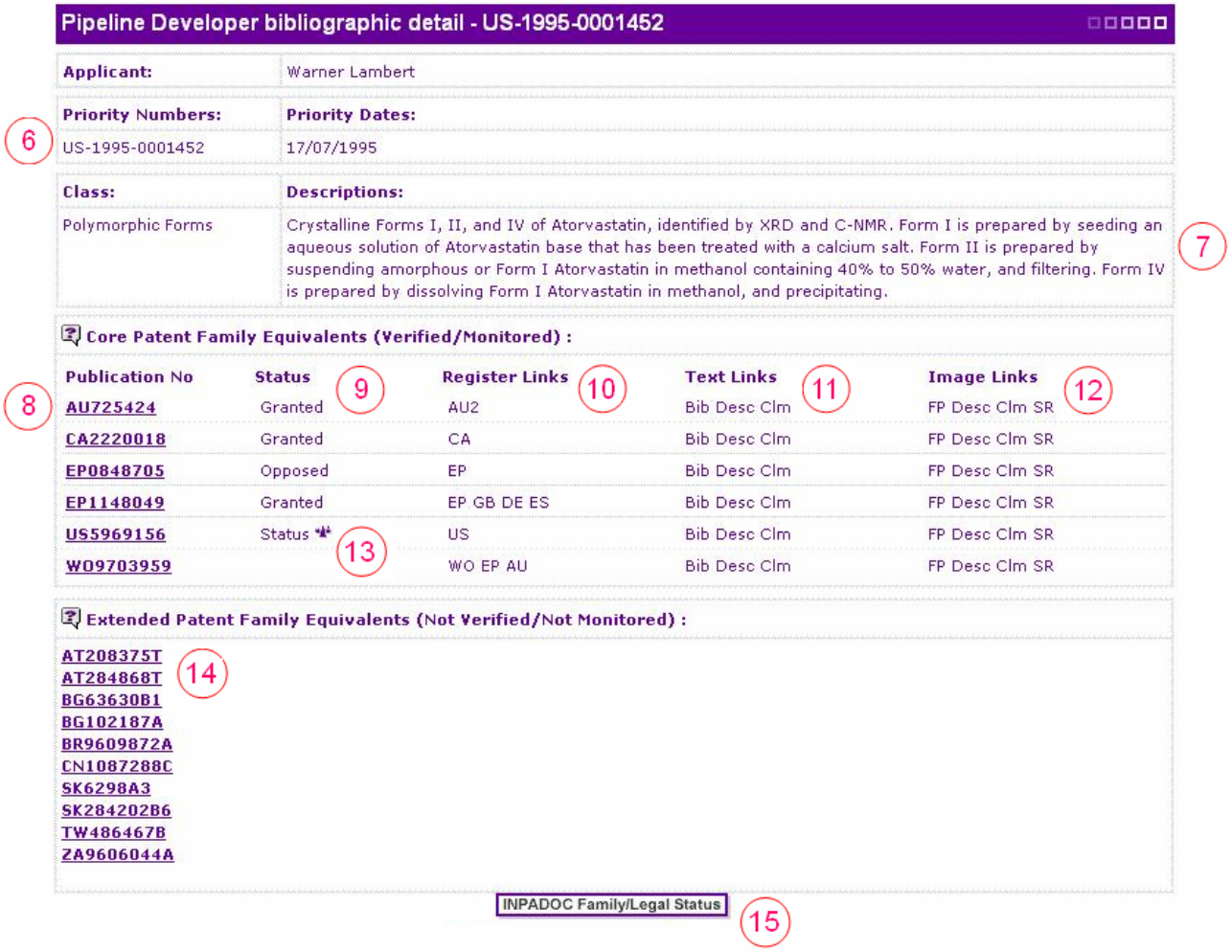
Upon identifying a patent family of particular relevance, click anywhere in the box as it becomes highlighted. A pop-up window will then appear containing bibliographic detail information for that patent family.

To report a different set of results, or to return to the Pipeline Selector report view, click on the 'Search Again' button. To return to your company subscriptions page, click on the 'Pipeline' button in the GenericsWeb toolbar.

It is important that you read the Scope & Limitations to ensure you are clear on what has been included in a Pipeline Developer patent search.

Bibliographic Detail

This view is intended to facilitate understanding the technical and geographical scope of individual patents within a patent family by allowing the user to drill down to specific patents and registers in the countries of interest.



Detailed information regarding the selected patent family is displayed, including additional related priority applications **(6)**, a description of the claimed invention including additional development categories **(7)**, and publication numbers of individual patent members **(8)**. 'Core Patent Family Equivalents' consists of related patents published in those countries/territories that we have searched independently and monitor for changes. These include United States, Canadian, British, French, German, Spanish, Australian, European and World (PCT) publications.

Clicking on a listed patent/application number will launch a pop-up window containing an image of the patent (you can also click through to the various sections of patent documents by clicking on the 'text' and 'image' links, **(11 & 12)**). This enables analysis of the claims to determine scope, or of the preamble to determine the inventive aspect of the patent.

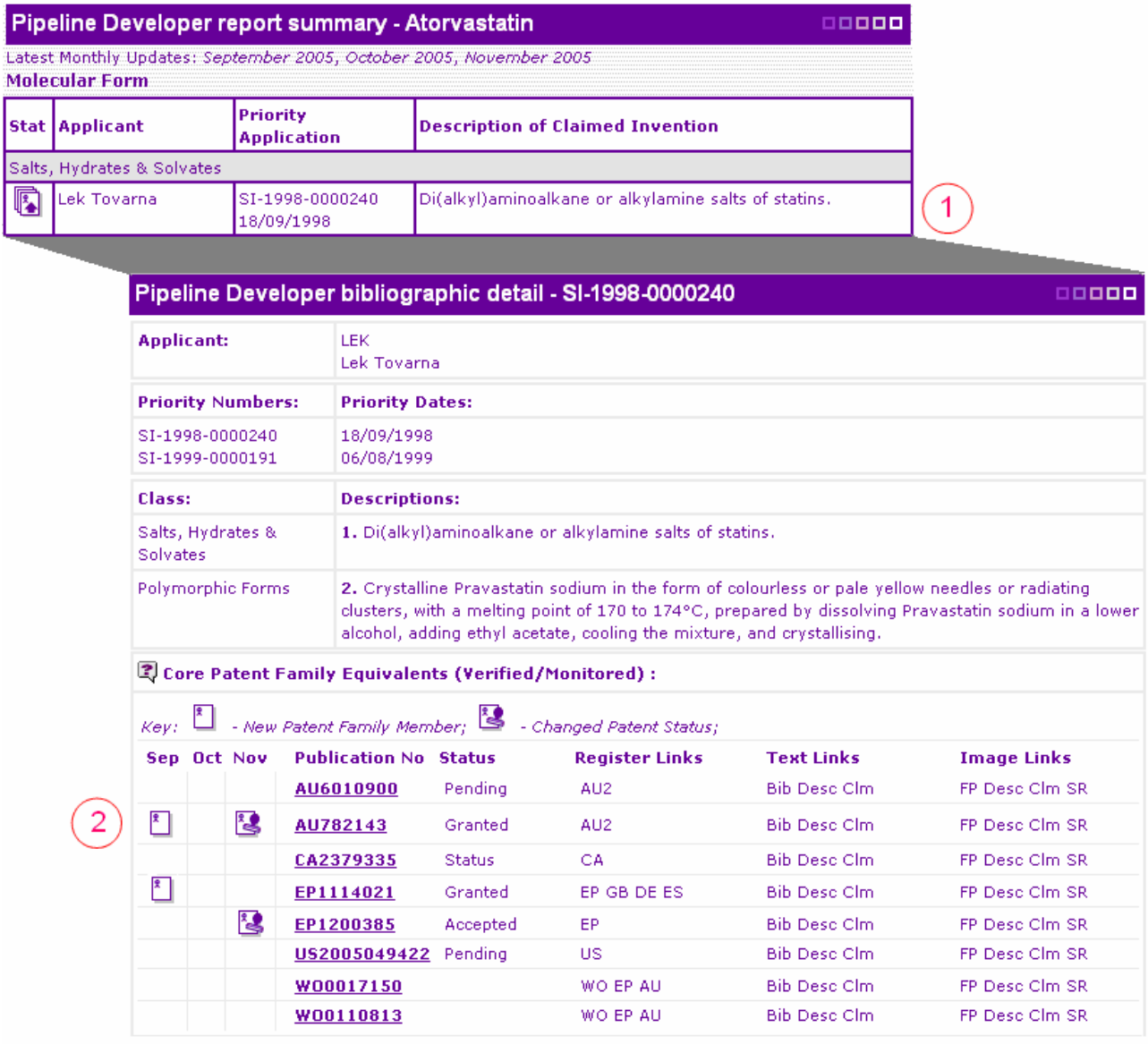
Where a patent status is shown next to the publication number **(9)**, clicking on the register link **(10)** will launch a pop-up window with the patent office register extract for that patent. This allows investigation into the examination status of a pending patent, opposition of a granted patent and/or payment of maintenance fees (you can also find legal status and transaction history by clicking on the INPADOC Family/Legal Status button **(15)**; click here to read more). Where we are not able to efficiently monitor statuses, they will not be shown. This is to maintain high accuracy of information and remain cost-effective.

Litigation alerts are accessed by clicking on the symbol next to the status **(13)**. Please note that this feature appears only on selected reports. Please contact GenericsWeb staff if you are unsure whether a certain report has litigation alerts activated.

To ascertain the patent situation beyond 'Core Patent Family Equivalents', 'Extended Patent Family Equivalents' are also listed **(14)**. 'Extended Patent Family Equivalents' consists of related patents published in those countries/territories that have not been searched independently and are not monitored for changes. They are identified by finding equivalents in INPADOC based on priority data and have not been verified for accuracy. You can view these patent documents (where available) by clicking on the hyperlinked patent number.

Updating

All Pipeline Developer reporting is updated on a monthly basis. You will receive email notification when updates are ready for viewing, upon which you can view latest updates or select the previous 3 months of updates (see 'advanced reporting' above).



Pipeline Developer report summary - Atorvastatin

Latest Monthly Updates: *September 2005, October 2005, November 2005*

Molecular Form

Stat	Applicant	Priority Application	Description of Claimed Invention
Salts, Hydrates & Solvates			
	Lek Tovarna	SI-1998-0000240 18/09/1998	Di(alkyl)aminoalkane or alkylamine salts of statins.

1

Pipeline Developer bibliographic detail - SI-1998-0000240

Applicant:	LEK Lek Tovarna
Priority Numbers:	**Priority Dates:**
SI-1998-0000240 SI-1999-0000191	18/09/1998 06/08/1999
Class:	**Descriptions:**
Salts, Hydrates & Solvates	**1.** Di(alkyl)aminoalkane or alkylamine salts of statins.
Polymorphic Forms	**2.** Crystalline Pravastatin sodium in the form of colourless or pale yellow needles or radiating clusters, with a melting point of 170 to 174°C, prepared by dissolving Pravastatin sodium in a lower alcohol, adding ethyl acetate, cooling the mixture, and crystallising.

Core Patent Family Equivalents (Verified/Monitored) :

Key: - *New Patent Family Member;* - *Changed Patent Status;*

Sep	Oct	Nov	Publication No	Status	Register Links	Text Links	Image Links
			AU6010900	Pending	AU2	Bib Desc Clm	FP Desc Clm SR
			AU782143	Granted	AU2	Bib Desc Clm	FP Desc Clm SR
			CA2379335	Status	CA	Bib Desc Clm	FP Desc Clm SR
			EP1114021	Granted	EP GB DE ES	Bib Desc Clm	FP Desc Clm SR
			EP1200385	Accepted	EP	Bib Desc Clm	FP Desc Clm SR
			US2005049422	Pending	US	Bib Desc Clm	FP Desc Clm SR
			WO0017150		WO EP AU	Bib Desc Clm	FP Desc Clm SR
			WO0110813		WO EP AU	Bib Desc Clm	FP Desc Clm SR

2

The updating system identifies new patent families or changes within patent families **(1)**. The bibliographic details screen then displays what has changed within a patent family (new patent family member, or change in patent status) and in what month that change occurred **(2)**.

Printer Friendly

From the Patent Summary Report page, a printer friendly version of the report which includes all summary information and bibliographic detail can be displayed by clicking on the 'Printer Friendly' buttons at the top or bottom of the page.

In addition to the patent information, this report displays the scope and limitations of the search, details of databases searched and description of the development categories. This report is ideal for taking into meetings or for providing to legal professionals for patent infringement opinions.

Please remember that the records shown in the printed report correspond to your initial reporting criteria. All identified patent families should be considered for the basis of any commercial decision.

Export

From the Patent Summary Report page, the reported patent information can be exported into a spreadsheet format (e.g. Microsoft Excel) for further manipulation of the data for internal reporting purposes.

Please remember that the records shown in the exported file represent your initial reporting criteria.

Please consider the copyright restrictions as well as the sensitive and valuable nature of this patent information before providing it to any external recipients.

Please email us if you have any difficulties in using GenericsWeb Pipeline patent reports, or would like to offer some feedback.

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