The Franklin Pierce Center for Intellectual Property at the University of New Hampshire School of Law Educational Report:
Preliminary Report on Patent Literature, Search Methodology and Patent Status of Medicines on the WHO EML 2009



Fall 2010, Spring 2011

PROFESSORS
JON R. CAVICCHI, J.D., LL.M. (INTELLECTUAL PROPERTY)
STANLEY P. KOWALSKI, Ph.D, J.D.

ITTI CLINIC STUDENT MEMBERS
JENNIFER BRYAN
KEVIN CLARK, Ph.D
BRIAN DOIGAN
SPOORTHY GUDAVALLI
TRENT MERRELL
IAN MULLET
NATHAN NEWBOLD, Pharm.D
ANNA STANFORD

Acknowledgements

We would like to take the time to thank those who provided invaluable assistance in the completion of this project.

We are thankful to the University of New Hampshire School of Law (UNH-Law), Franklin Pierce Center for Intellectual Property (FPCIP) and Deans John Broderick, John Hutson, Susan Richey and John Orcutt for supporting this project.

We would like to express our sincere gratitude and appreciation to Jon R. Cavicchi, J.D., L.L.M.-I.P. and Stanley P. Kowalski, Ph.D., J.D., for their tireless effort, expert guidance, encouragement and support in the completion of this project.

We are thankful to Mr. Mark Bauer and Thomson-Reuters for graciously facilitating access to Thompson-Innovation®, and for providing invaluable guidance and training on other aspects of patent database mining and research. We are thankful to Mr. Scott Collins, Vice President of Law Schools, and Mr. Richard Garner, Product Director, Global IP, at Lexis for graciously facilitating access to LexisNexis® TotalPatent™ and for providing invaluable guidance and training on other aspects of patent database mining and research. We are thankful to Mr. Ron Kaminecki, M.S., J.D., Director of Intellectual Property Market, at ProQuest® Dialog™ for providing guidance and training on accessing the Merck Index online. We are also thankful to Ms. Bhargavi Nayak, for technical assistance with the report preparation.

We wish to extend our appreciation to Dr. Anatole Krattiger, Director, Global Challenges Division, World Intellectual Property Organization (WIPO), for providing the ITTI team with guidance, support and insight into the significance of this project, and to Dr. Richard Laing, Coordinator: Medicine Information and Evidence for Policy, Department of Essential Medicines and Pharmaceutical Policies, World Health Organization (WHO), for direction, encouragement, inspiration and critical inputs throughout the entire project. We wish to thank Mr. Thomas Bombelles, Global Challenges Division, WIPO, for providing balanced perspective and reasoned insights to the discussions, Dr. Zafar Ullah Mirza, Coordinator Department of Public Health, Innovation and Intellectual Property Director General's Office WHO, for advice and useful comments throughout our discussions, and Dr. Peter Beyer, Technical Officer at the Department of Public Health, Innovation, and Intellectual Property WHO for critical input at later stages of project development.

In addition, we would like to extend our appreciation to Professor Amir Attaran, Faculties of Law and Medicine at the University of Ottawa, for his pioneering work on an earlier patent literature survey of the WHO Essential Medicines List and helpful input and advice after presentation of the initial data at the Second Trilateral Technical Symposium in Geneva, Switzerland, February 18, 2011. This report builds upon the analysis Dr. Attaran undertook and analyzes what he identified as having patent protection and additions to the list since 2003. We also wish to thank Mr. Ernest Kawka, at the UNH-Law for additional help with finalizing this report, and express a special note of appreciation to Mrs. Joy Ouellette, for sharing her insight and knowledge of the Orange Book during the early stages of the project.

Finally, we wish to thank Ms. Gabriela Treso, Global Challenges Division, WIPO, for facilitating so many aspects of this project, including the participation of the UNH-Law Student Team at the Second Trilateral Technical Symposium in Geneva, Switzerland, February 18, 2011.

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Executive Summary

Abstract

Over the past several decades the World Health Organization (WHO) has produced the Essential Medicines List (EML) to assist countries in deciding what medicines should be essential and available in National Essential Medicine Lists.[1] WHO, through the work of regional offices, supports nations using the EML to ensure the quality, availability, and affordability of pharmaceuticals required to promote and advance public health in nations across the globe. However in some cases, access to EML pharmaceuticals might be complicated by existing patents, i.e., where issued, patent rights might pose obstacles to access and inclusion in national EMLs. Indeed, in developed and emerging economy national jurisdictions patent protection may be in effect for a not insignificant number of the WHO EML pharmaceuticals (Figure 2A). However, in developing countries, it is uncertain whether these patents have been filed or issued. Without patent data predicated on an established, reproducible protocol for accessing and assembling patent information on the EML pharmaceuticals, discussions, debates and strategic approaches to understanding and managing patents with regard to access and delivery to developing countries remain in the dark. Indeed, it is absurd to make policy and formulate strategy without solid patent information: the critical foundation for rational debate.

To analyze the degree and scope of patenting of EML pharmaceuticals, WIPO (with WHO) approached the Franklin Pierce Center for Intellectual Property at the University of New Hampshire School of Law, specifically the International Technology Transfer Institute (ITTI) to generate a preliminary overview of patents appurtenant to recently added pharmaceutical updates to the EML.[2] As part of this work, with inputs from WHO and WIPO, ITTI developed novel methodology and a detailed protocol for identifying EML pharmaceutical patents in national jurisdictions, with an easily reproducible yet cost effective template. Herein is described the development of such a protocol and a preliminary pool of patent information that illustrates its utility. The protocol yields data in a layered approach thereby allowing a user to quickly and effectively obtain both broad and detailed patent information for medications on the WHO EML. In addition, the protocol can be used as an initial path for targeted strategic analysis of potentially relevant patent information in national jurisdictions.

In sum, the objectives for this project were:

1. To develop a robust methodology to assess the patent status of medicines on the WHO Model List of Essential Medicines;
2. To place in the public domain a detailed report on the present (2010) patent status of medicines that were on patent in 2003 and those medicines added to the Model List since 2003 by country and level of development; and
3. To analyze the patent status of these Essential Medicines by the development status of countries.

The report describes the development of the protocol and presents a preliminary list of EML and corresponding patents in certain jurisdictions to illustrate the utility of the approach. Results will be discussed both in terms of global access and patents, and in the context of

[1] World Health Organization, Continuity and Change: Implementing the third WHO Medicines Strategy 2008–2013 20 (WHO Press, 3rd ed. 2009).

[2] This report covers the EML up to and including updates until 2009.

establishing standard, systematic, protocols for periodic patent searches related to EML content.

EML Purpose, Policy, and Evolution

Through extensive collaboration with regional offices, WHO supports the development, implementation, and monitoring of the effectiveness of national medicinal guidelines to ensure the quality, availability, and affordability of medications effective against a broad range of indications.[3] WHO released the first of these guidelines, the EML, in 1977 to address the many problems faced by nations attempting to develop individualized national lists.[4]

Over time WHO has needed to continually update the EML, along with its efforts to implement national policies for pharmaceutical availability. The privatization of most pharmaceutical discovery and manufacture, along with an increase in patenting in both the public and private research and development sectors, has led to a patenting activity of medications in many national jurisdictions. This, in turn, creates challenges for WHO to continually monitor and appraise the patent status of EML pharmaceuticals within the context of potentially relevant and enforceable patent rights in any given national jurisdiction. A system/protocol that permits patent information to be reproducibly mined and analyzed will facilitate the ongoing process of ascertaining global access.

EML criteria selection and current list

Medications listed on the EML are those that satisfy the priority health care needs of the nation, with respect to the prevalence of particular disease states, while maintaining a level of efficacy, safety, and reasonable cost effectiveness.[5] The EML is not designed as the only available list nor is it designed as a global standard.[6] Rather, the EML is designed to promote the concept of essential medicines to establish health equity in a given nation.[7] The current EML provides a listing of medications for a variety of disease states from relatively simple to considerably more complex preparations, such as vitamins that reduce nutritional deficiencies to the latest HIV/AIDS medications.[8] The EML is sufficiently broad that when used together, the medications provide safe and effective treatment for the majority of communicable and non-communicable diseases.[9]

As some of these medicines are relatively new and thus may lack generic equivalents, potential patent rights in some national jurisdictions might condition availability of some medicines on the EML. With patent protection existing for some of the EML pharmaceuticals, WHO recognizes it is important that countries placing these medicines into National lists be aware of local and global patenting activities.[10] However, undertaking such research can be an onerous task and can also fail to identify with 100% certainty the current patent protection of medications on the EML in any given national jurisdiction. The latest EML contains a broad range of medications, making verification of patent protection for each medication in this report difficult.

By employing a combination of patent search approaches, the method outlined herein seeks to establish the basis for an effective search methodology for patents covering EML

[3] THE SELECTION AND USE OF ESSENTIAL MEDICINES, WHO TECHNICAL REPORT SERIES, NO. 914 (WHO Press, 2002).
[4] *Id.*
[5] Continuity and Change, *supra* 29.
[6] *Id.* at 19-20.
[7] *Id.*
[8] World Health Organization, WHO Model List of Essential Medicines (WHO Press, 16th ed. 2009).
[9] *Id.*
[10] Continuity and Change, *supra* 24-25.

pharmaceuticals. It is hoped, and indeed anticipated, that this will then serve as a launching point for further refinements and application of patent searching and analyses as a basis for policy formulation and assessment of strategic options to facilitate access to EML pharmaceuticals in all countries across the globe.

Methodology

Previous analyses to gauge patent protection for medications on the EML demonstrated that the breadth and scope of searching necessary for accuracy presented a challenge.[11] Ultimately, this complexity necessitated approaching pharmaceutical companies to obtain individual patent portfolios to identify patent protections for medications listed on the EML.[12] Such a methodology was the approach of Dr. Amir Attaran and colleagues in 2003,[13] who surveyed 319 products on the WHO EML to identify the subset recent enough to still be subject to patent protection at that time.[14] Initially searching several pharmaceutical patent reference sources for each specific product on the WHO EML, they identified the earliest U.S. patent for the EML pharmaceuticals or their combinations.[15] They subsequently searched two commercial patent databases, (INPADOC and Derwent WPI) which yielded preliminary international patent data, followed by written surveys to the manufacturer of each product to further ascertain and elucidate global patent coverage for each EML pharmaceutical.[16]

While similar, the ITTI approach differed in several key respects from that of the Attaran group's methodology. The goal was to develop a comprehensive yet readily *transferrable* methodology to identify patent filings for medications on the WHO EML. Creating such a protocol required use of both free and fee-based, value-added patent searching tools and platforms, along with the development of in-house value-added resources. While the concept is fundamental, identifying base patents and FDA Orange Book listings for each medication on the EML and their corresponding global filing trends (in practice, obtaining comprehensive results) is complex, ultimately requiring iterative rounds of additional searching and analysis.[17] ITTI-developed methodology was designed to initially locate base patents for each medication, via a platform capable of facilitating more in-depth and complex patent searches for EML pharmaceuticals. Hence, assessing actual patenting activity in the EML should be viewed as a tiered, stepwise process, with the results and protocol presented herein as an initial gateway into the field of global patenting activity.

As a consequence, ITTI focused on generating a preliminary list of potentially relevant patent literature and a preliminary methodology applicable to a more general audience, to both illustrate how to manage patent information appurtenant to the EML and to present a sample data set. The methodology thus serves as a guide to patent trends rather than as a methodology for locating all available patents for a given medication. However, the report still is capable of leading a user to the more complex stage of searching as articulated throughout.

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[11] Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* 23(3), Health Affairs, 155.

[12] *Id.* at 156-57.

[13] *Id.* at 155.

[14] *Id.* at 156.

[15] *Id.*

[16] *Id.* at 157.

[17] 91 medicines were assigned to ITTI for this study. 70 base patents were identified along with 152 listed patents within the FDA Orange Book.

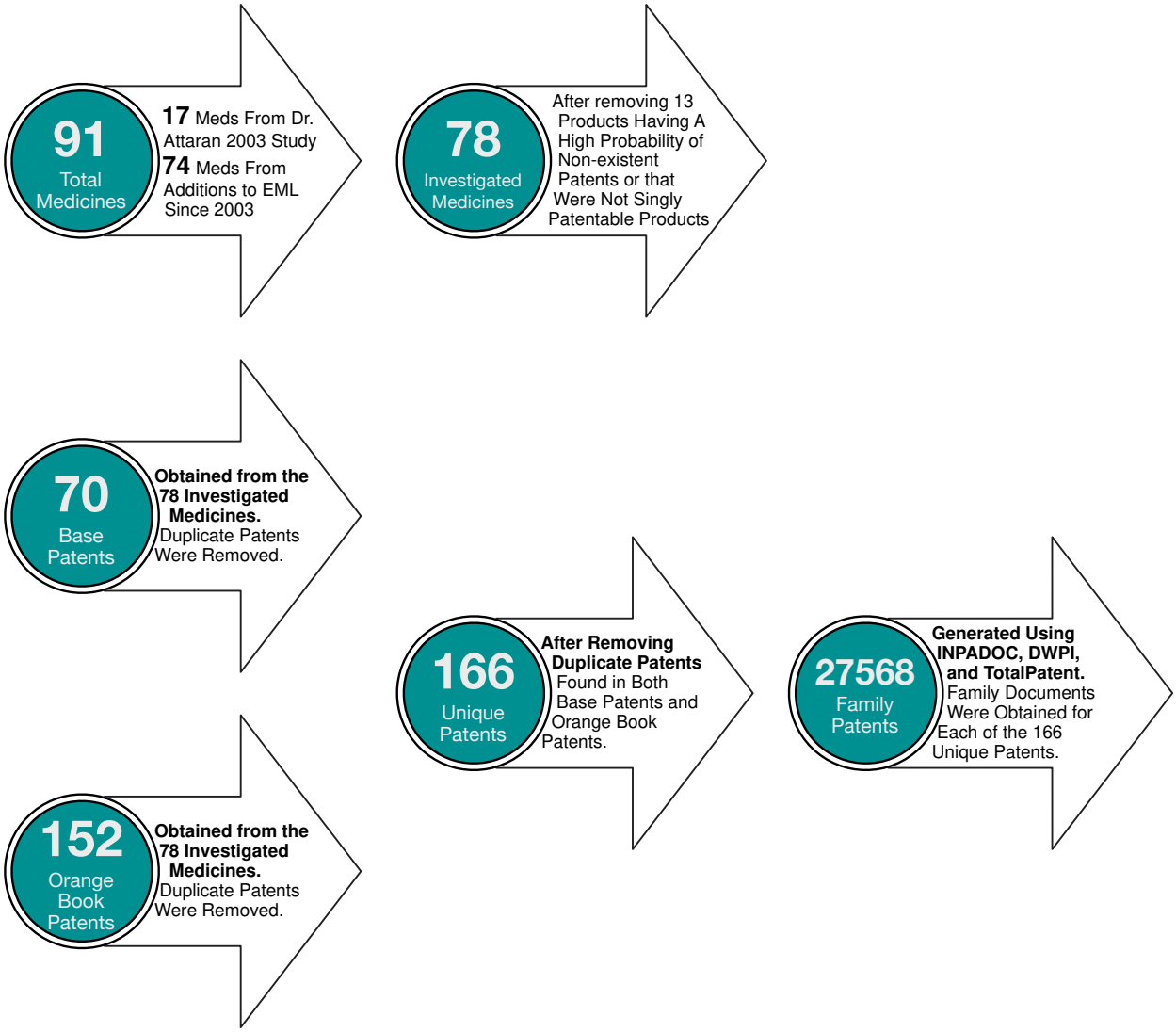


Figure 1: Flowchart for Results and How the Data was Generated for this Report. 91 total medicines were reduced to 78 after removing products that likely did not have existing patent coverage because of the age of the drug or because they were not singly patentable products. From the 78 investigated medicines, 70 base patents and 152 orange book patents were obtained that were reduced to 166 unique documents after removing redundancies. The 166 unique documents were expanded using family data to 27568 patent documents.

Using this protocol, ITTI located base patents and FDA Orange Book Patents, totaling 166 unique patents, for nearly every medication on the EML updates since 2003, to provide a snapshot of relative patent filings currently in 2010 while also guiding a user to more complex searching strategies.[18]

Preliminary Results: Global Patent Filing for EML Pharmaceuticals

Assembling and organizing data from the identified patents into patent families and displaying this information on world (geographical) maps provides an overview of global patent filing trends for EML pharmaceuticals. These data, expanded to encompass all of the nations where a family had, at least, been filed for one medication from the EML (Figure 2), suggests that nations with developed economies, established health programs and resources have

[18] ITTI defines unique patents as patents that may exist for multiple medicines but are only listed once for more in-depth analysis.

greater patenting activity for EML pharmaceuticals. In contrast, developing countries lacking adequate health programs or having little resources appear to have a dearth of patent filings in their jurisdictions. This is perhaps not surprising, and not inconsistent with the overall observations of the Attaran group.[19]

Thus generally, developed country jurisdictions like, North America, Australia and Europe, as well as emerging economies such as China, India and Brazil appear to have higher levels of patent filing for many of the EML pharmaceuticals. In contrast, much of South America, Africa, and the Middle East, i.e., developing economies, appear to have little to no patent filing activity for the EML pharmaceuticals. This apparent lack of patent protection, while seemingly beneficial for eliminating potential infringement concerns, instead may actually require more in depth analyses in order to ascertain the true patenting situation in these countries, as their patent data may not be reliably reported, or available, in conventional patent search databases and platforms. However, it is crucial to note that an actual, and verified, absence of patents in these countries could facilitate a way for WHO/WIPO to create new healthcare plans and establish generic-based National EMLs with broad coverage of the EML. The methodology presented herein, along with the preliminary results, provides a step towards making such informed determinations.

It must be duly noted that applications were identified for the regional patenting authorities, such as WIPO, EPO and ARIPO. These applications might have patent filings in many nations not colored on the global maps, and might therefore provide additional national jurisdictional patent protection not readily apparent.

[19] Amir Attaran, *supra* 163.

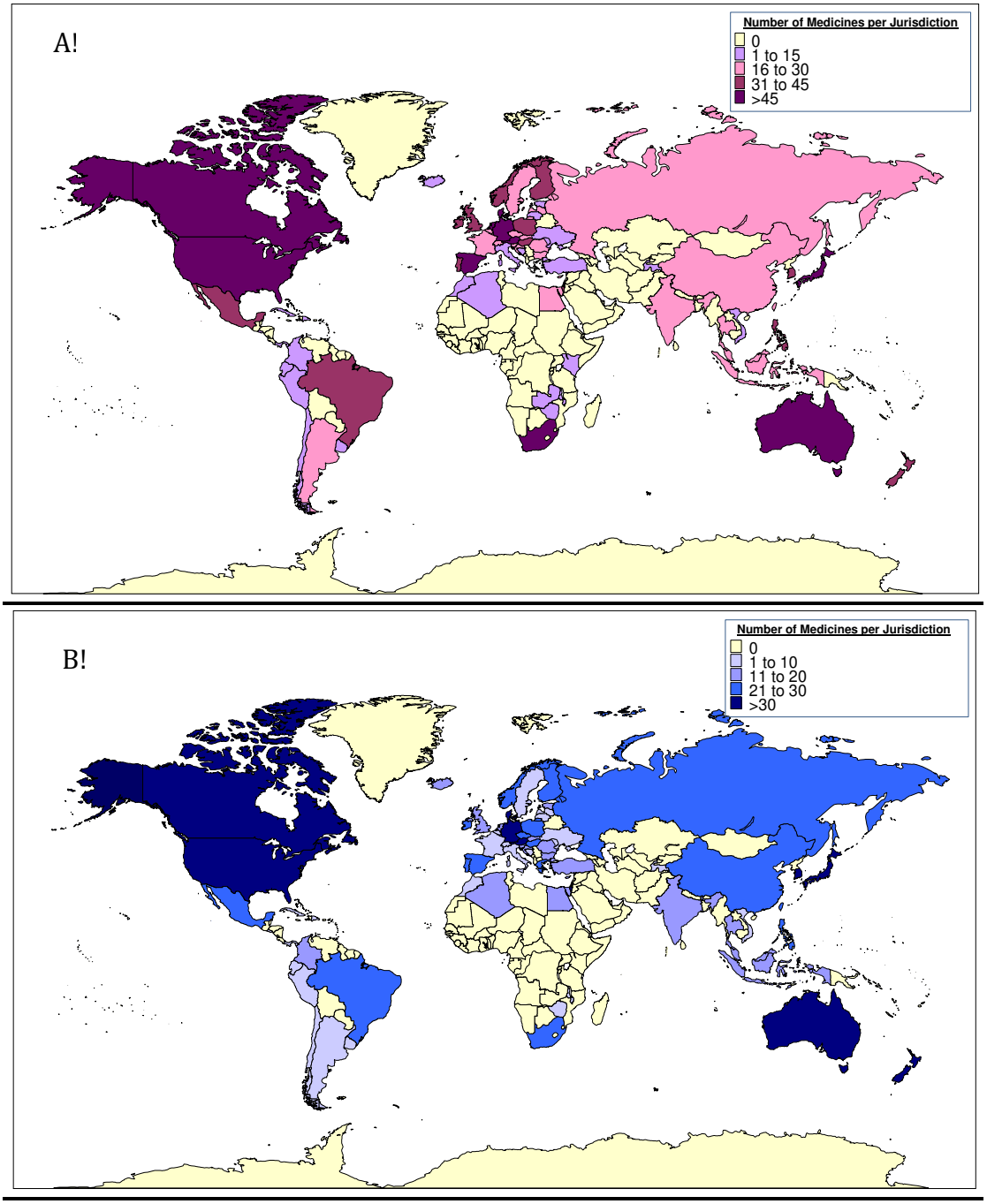


Figure 2: Number EML Medicines Patented or Pending in National Jurisdictions. Consolidation of a total of 27568 patents identified for medications on the EML and its related family members. 166 unique patents identified using the ITTI Clinic's approach were subjected to family data analysis using INPADOC, DWPI, and LexisNexis® TotalPatentTM generating a total of 27568 patents in multiple families. The patents were de-duplicated prior to consolidation. **A)** Number of medicines patented per jurisdiction for all years. *Regional office filings were detected: ARIPO=15, OAPI=17, EAPO=13, EPO=41, WIPO=30.* **B)** Number of medicines patented per jurisdiction post 1990. *Regional office filings were detected: ARIPO=14, OAPI=11, EAPO=14, EPO=34, WIPO=30.*

Patent Filing and Income Level

To assess the global filing trends of the EML pharmaceutical patentees, patent families were analyzed and compiled in developed and developing country jurisdictions. Figure 3 shows the compilation of those data. Interestingly, and consistent with Figure 3, the majority of patent filing activity for EML pharmaceuticals appears to be in higher income rather than lower income nations (see Figure 3). The disparity between filings in higher income nations and lower income nations is not inconsistent with the general principle, as elucidated by Attaran, that patentees file in national jurisdictions where the markets are developed to the point where patent protection makes economic sense; in other words, as the economy develops, so do markets with patenting following as markets mature.

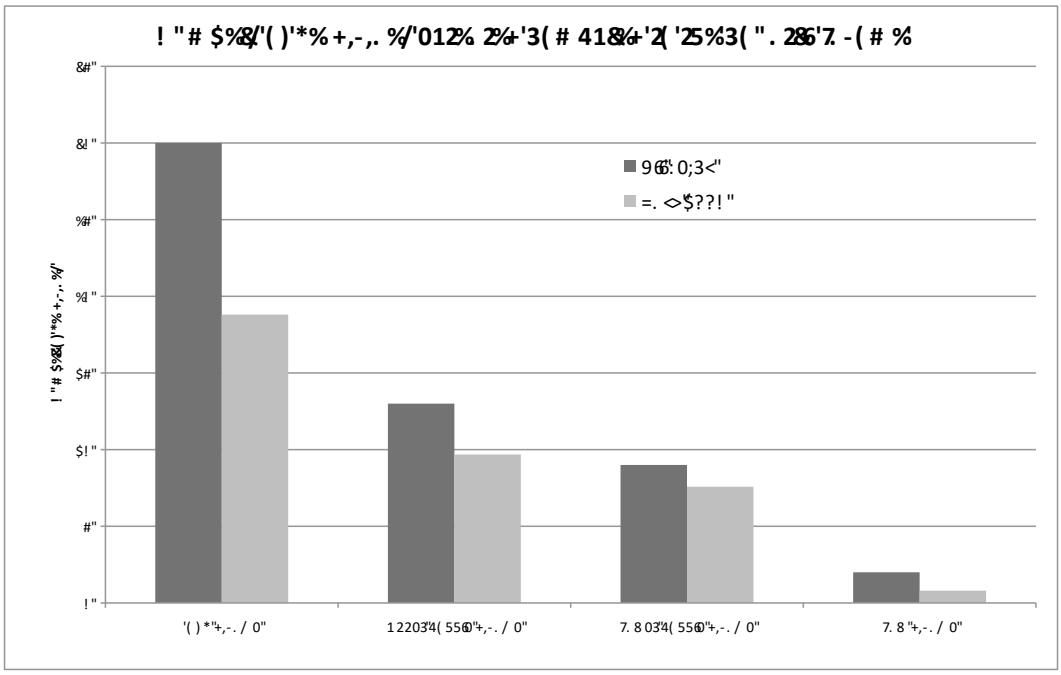


Figure 3: Essential Medicines and Their Relationship to World Bank National Income Levels – Post 1990. Data is cumulative of patent filings arising from Base Patents, Orange Book Patents, and Family Patents. The number of medicines represents the combined total number of patent filings in each country (representative medicines in the graph are from a binary analysis. That is a 1 designates if any patent document is filed in a particular jurisdiction, therefore counting the medicine as patented in that income level, and a 0 designates if no patent documents are filed in a particular jurisdiction). A medicine patented in multiple countries was counted a single time regardless of the number of jurisdictions the medicine was patented. Income levels are derived from World Bank.

Similar disparity can be seen between organizations like the EPO and ARIPO (See Figure 2 legend).[20] The EPO has considerable more patent filings than ARIPO, suggesting that many EML pharmaceutical patentees do not seek protection in Africa other than a few nations, for example South Africa.

Lastly, analyzing the current assignees to the unique 166 patents identified as either base patents or Orange Book patents reveals that three dominant companies; Abbott, Merck, and GSK appear to actively and aggressively pursue patent rights for their medicines (see Figure 3). Companies shown in Figure 3 should be approached to discuss patents and other protections for their medicines listed on the EML.

[20] Number of filings in each organization: EPO = 43, WIPO = 30, AIPO = 17, ARIPO = 14, EAPO = 11, GCC = 0.

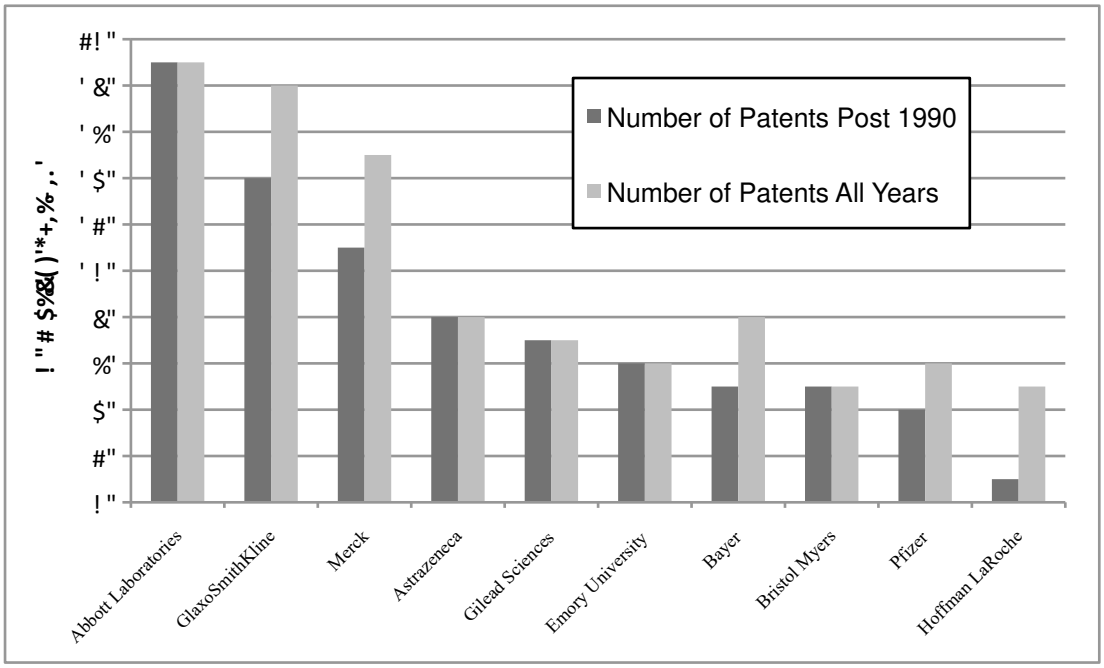


Figure 4: Comparison of Assignee Companies. Assignees were determined from the 166 unique patent documents found on the Master Patent Spreadsheet.

Caveats

While the overall data suggest that the prevailing trend for filing of patent applications for EML pharmaceuticals has been in countries with developed economies, established healthcare plans and market potential for pharmaceuticals, caution should temper hasty conclusions vis-à-vis patent protection in countries outside of the developed and industrialized categories. Countries with apparent lack of patent filing activity should not automatically be discounted as countries EML pharmaceutical patentees ignore for patent protection.

There are several reasons for caution. First, as the data presented herein suggests, global patent filing trends for EML pharmaceuticals appear to be correlated with emerging economies. Hence, countries that might not have been considered as filing jurisdictions in 1995, e.g., Brazil, India and China, are now increasingly jurisdictions wherein patent protection is sought. Assuming that this global economic development extends into the 21st century, additional national jurisdictions will likely also become attractive for filing. Hence, ascertaining likely filing jurisdictions needs to be conditioned on the dynamism of global development and, if recent trends are indicative, there will be a gradual increase in both the amount and global distribution of patent filings.

Second, many national jurisdiction patent filing authorities have likely not yet made their complete patent information available through web-based and electronic resources, amenable to patent searching tools and platforms. Theoretically, such jurisdictions may have patent protection for EML pharmaceuticals that is not readily detectable. In other words, electronic patent searching cannot locate documents from these jurisdictions. Further, there are many national jurisdictions that are not yet included in the patent family databases used to assemble data, e.g., INPADOC, Derwent and Lexis Total Patent (as used in this report).[21] And even when included in these databases, as well as on the WIPO PCT website, reporting of data by the

[21] INPADOC – 96 countries; DWPI – 41 countries (Data obtained from Dialog® bluesheets – database numbers 345 and 351). LexisNexis® TotalPatent™ – ~100 countries.

national jurisdiction might be slow, incomplete or incorrect. Hence, as stated already, when carefully considering the freedom to operate (FTO) status in a national jurisdiction, the more conservative/methodical/standard approach to consult with patent professionals in said jurisdiction and/or regional patent offices to identify potential patents should be carefully considered.[22]

Finally, any patent search strategy is limited by the very parameters that yield results. For example, both the ITTI and the Attaran protocols have strengths and weaknesses that must be weighed against efficiency and precision. The ITTI protocol was largely based on Orange Book information, which derives from U.S. patent filings and is also only a restricted data set based upon FDA approval and innovator filed information. Whereas the disproportionate number of patentees for EML pharmaceuticals file in the U.S., an increasingly large number of emerging economy entities may begin to seek patent rights; if these entities do not file U.S. patent applications on relevant EML pharmaceuticals, then they could fall outside of the search parameters of this report. Similarly, the Attaran protocol relied on data supplied by top assignees, which, although providing highly useful information on patent filing in developing countries, could also possibly miss other, perhaps more recent, EML pharmaceutical patentees, particularly those filing patents solely in national offices, *e.g.*, India, China and Brazil.

Conclusions and Key Implications

EML medicines, intended to be available in functioning health systems in all countries, are among the most cost-effective ways to treat infectious (e.g., respiratory infections, diarrhea, tuberculosis, malaria, AIDS) and chronic (e.g., asthma, cancer, diabetes) diseases in developing countries.[23] Yet, availability of EML medicines is hampered by poor supply and distribution systems, insufficient health facilities and staff, low investment in health, and high cost (particularly in developing countries where pharmaceuticals can literally consume household finances to the point of poverty).

Whether patents have complicated the efforts of WHO to implement its global EML agenda is an issue that has been the subject of discussion and debate. However, informed discussion and debate will be facilitated when the existence and/or extent of such potential patent complications is quantified and thereby better understood with empirical data. This report provides WHO with both representative data and a preliminary protocol for assessing global patenting with regard to additions to the EML.

Key implications of this report include:

- A standardized protocol is a critical tool for periodic identification and analyses of patents appurtenant to updates of the WHO EML. Said protocol should be made available, and indeed taught to, all Member States, with particular focus on the developing nations.
- Of the 91 medicines evaluated, 74 were added to the EML since 2003, and 17 were previously identified by Attaran in his 2004 paper. A total of 17 were identified from the evaluated list as possibly still being under patent protection in different jurisdictions, including in several developing countries.
- Caution in assessing FTO in any given jurisdiction should be the *modus operandi*; a stepwise approach which proceeds from a standardized protocol to more diligent research, e.g., analyzing patentee portfolios or in-country paper-based patent searches,

[22] See Appendix D for a full country coverage list of the three patent databases (INPADOC, DWPI, TotalPatent) used in this report.
[23] Model List of Essential Medicines, *supra* 14-15.

is strongly recommended. Hasty assumptions based on preliminary data are neither judicious nor prudent.

- ∞ Data presented in the ITTI EML patent study support the proposition that global patenting trends follow economic development and markets; this is a dynamic and fluid situation across the world; patentees will likely file patent applications in more countries as viable economic markets expand accordingly.
- ∞ Patents *per se* might not be a primary obstacle for access to EML pharmaceuticals in many developing countries, as they are consistently not detected in patent family data from developing nations and regions; yet caution in assessing FTO is always necessary.
- ∞ More recent EML pharmaceuticals appear to have greater global patent filings, which is not inconsistent with generally increasing global trends in patenting activity.

In conclusion, debates and discussion on patents and access to EML pharmaceuticals needs to be based on empirical data, otherwise they will likely continue in circles, dominated by ideology sans evidence.

Disclaimer and Scope of Project

This is solely an educational report and is neither inclusive nor comprehensive. The information provided in this report serves as a resource for initiating a search strategy aimed at providing a survey of relevant patent literature with regard to medicines listed on the WHO Essential Medicines List. This report is not a freedom-to-operate opinion (FTO), and the International Technology Transfer Institute (ITTI) Clinic at the Franklin Pierce Center for Intellectual Property (FPCIP) at the University of New Hampshire School of Law (UNH-Law) draws no conclusions, makes no opinions or representations either explicitly or implicitly, including but not limited to patent term and expiration dates, and geographic coverage.

Neither the ITTI Clinic nor UNH-Law are responsible for any errors, omissions, and limitations of data or search parameters of any data source used within this report. The patent searching platforms utilized in this report are limited to English language searching of full text patent documents and abstracts using machine translated national and bibliographic records including but not limited to those arising from DWPI and INPADOC.

Neither the ITTI Clinic nor UNH-Law are experts in the field of pharmaceutical patent law. Therefore no guarantees or opinions are expressed herein with respect to the evaluation of patents as ITTI Clinic members did not perform claim interpretation or determine the validity of claims. The tight time frame for report preparation, overall demands faced by the ITTI Clinic Student Team, and limitations imposed by both the search methodology and patent search platforms used affected the level of sophistication and the number of patents found and evaluated. As such, additional patents whether inside or outside the confines of the methodology herein, were not considered. The ITTI Clinic also aware of the now available online ARV database provided by Medicines Patent Pool Foundation in collaboration with WIPO.[24] This database became available after the data for this report was generated and therefore was not used in the methodology in this report.

The confines of the methodology used in this report limit the data to medicines having a US patent or US patent application either as the parent document or within a base patent family and is limited to updates to the EML between 2003 and 2009. Medicines lacking a US Patent or US Patent Application remain unidentified by all searches performed in this report. Finally, with regard to any national or regional jurisdiction patent filing, whether within or outside of the defined scope of this project, it is imperative to appreciate the difficulties of locating patents in national jurisdictions that do not report, or report infrequently, to electronic or internet patent databases. All users of this report should engage a patent professional in all jurisdictions of interest to evaluate any patents listed within this report.

[24] The Patent Status Database for Selected HIV Medicines. (Accessed May 22, 2011.) http://www.medicinespatentpool.org/LICENSING/PatentStatusOfARVs.

Abbreviations

AIDS:	Acquired Immune Deficiency Syndrome
ANDA:	Abbreviated New Medicine Application
ARIPO:	African Regional Intellectual Property Authority
ARV:	Anti-retroviral medicine
Base Patent:	Earliest identified patent for the active pharmaceutical ingredient, formulation, or method of use
CAS:	Chemical Abstract Service
DTP:	Decision Tree Protocol
DWPI:	Derwent World Patent Database
EAPO:	Eurasian Patent Organization
EFV:	Efavirenz
EPIDSD:	European Patent Information Documentation Systems Directorate
EPO:	European Patent Organization
EPC:	European Patent Convention
Exclusivity:	Exclusive marketing right granted and valid in the US by the FDA upon approval of a medicine product
FDA:	United States Food and Drug Administration
FTC:	Emtricitabine
GCC:	Gulf Cooperation Council
HIV:	Human Immunodeficiency Virus
ITTI Clinic:	International Technology Transfer Institute | Franklin Pierce Center for Intellectual Property | University of New Hampshire School of Law
INPADOC:	International Patent Document
IUPAC:	International Union of Pure and Applied Chemistry
EML:	Model List of Essential Medicines
NCE:	New Chemical Entity
NDA:	New Medicine Application
OAPI/AIPO:	Organisation Africaine de la Propriété Intellectuelle/African Intellectual Property Organization
OB:	FDA Orange Book
ODE:	Orphan Medicine Exclusivity
PAIR:	Patent Application Information Retrieval
PCE:	Patent Challenge Exclusivity
PCT:	Patent Cooperation Treaty
PED:	Pediatric Exclusivity
PUC:	Patent Use Code
TDF:	Tenofovir Disproxol Fumarate
USPTO:	United States Patent and Trademark Office
WIPO:	World Intellectual Property Organization
WHO:	World Health Organization
WTO:	World Trade Organization

Introduction

WHO Essential Medicines List (EML) Background

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends. In 1975, WHO was commissioned with the task of identifying a list of medicines that were "of the utmost importance, basic, indispensable, and necessary for the health and needs of the population." The first list identified 205 medicines that were selected after consideration of safety, quality, efficacy, and total cost.[25] The goal of the initial list was to provide guidelines for the rational use of pharmaceuticals, both in the developed and developing world, by establishing a principle that some medicines were more essential than others to meet the needs of the population.[26] That principle quickly gained global favor, resulting in shift beyond mere selection of drugs to a list that is beneficial to procurement, distribution, and quality assurance.

Today, WHO continues to develop the Essential Medicines List (EML), releasing new guidelines approximately every two years.[27] While the list has remained structurally unchanged, the definition of what constitutes an essential medicine has evolved.[28] WHO now defines essential medicines as medicines that satisfy the priority health care needs of the population.[29] Each medicine is selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms with assured quality and adequate information, and at a price the individual and the community can afford.[30]

The EML consists of two categories, the core medicines and the supplemental medicines.[31] The core medicines are essential medicines that meet the selection criteria by being efficacious, safe, and cost effective.[32] In contrast, the supplemental medicines, while still satisfying the healthcare needs of the population, do not meet all the selection criteria and are typically costly or require specialized facilities or services for administration.[33] Though the EML guidelines propagated to assist national procurement offices contain the entire set of core medicines, the supplemental medicines should not be overlooked for inclusion on national lists.

The EML began as a selection of medicines by WHO programme staff and expert committees who used little to no evidence to support inclusion of medicines on the EML.[34] In response to the growing need to provide support for the choices on the list, today, an evidence-based approach is now used that provides support for each of the selection criteria for inclusion of the medicine on the list.[35] What began as an idea to advocate the essentiality of particular medicines has now blossomed into a vital tool for implementing the procurement and distribution of pharmaceuticals to developing countries.

[25] Lancet 1991; 338, 743-45.
[26] Id.
[27] Lancet 2003; 361, 1723-29.
[28] Id.
[29] Id.
[30] Id.
[31] Id.
[32] Id.
[33] Id.
[34] Lancet 2003, 361, 1723-29.
[35] Id.

The EML is intended to serve as a guide to national procurement officers in establishing national lists unique to the needs of each specific jurisdiction.[36] Essential medicines are intended to be flexible and adaptable to many different situations and exactly which medicines are regarded as essential remains a national responsibility. Thus some differences between the WHO EML and national lists are present and expected.[37] The EML is designed as a broad-spectrum solution to aid in determining essential medicines for the majority of disease indications. However, because every nation's needs and morbidity patterns differ, inclusion and deletion of medicines on the national list with respect to the needs of its population is justified.[38]

Since its development in 1975, the EML has guided the interpretation of national lists and medicines essential for maintaining a healthy population. Its popularity as a guideline for countries to establish their own lists is universal as virtually every country has some form of a national list. This report focuses solely on the WHO EML and does not consider national lists in any respect.

Previous Work

The growing concern about safeguarding patent protection of medicines on the EML has been at the forefront of national procurement offices for many years. Since the EML serves as the guide to many nations developing national lists, before beginning any importation or manufacturing strategies, each medicine listed on the EML should be evaluated for existing patent protection. Patent protection for medicines can limit the availability of medicines on the EML within certain jurisdictions and therefore may require interaction with pharmaceutical manufacturers for importation or manufacture of qualified generics within these regions.

Recently, the biggest concern has been access to HIV/AIDS medications within the poorest of African countries.[39] Essential medicines are listed in the EML as cost-effective solutions for individuals and countries to promote healthcare options that cultivate healthy populations. As early as 2001, HIV/AIDS antiretrovirals (ARV) were analyzed to determine the extent of patent coverage and the possible impact on impeding access to patent protected medications.[40] While the results of such studies were met with much controversy, an initial methodology was developed that was later expanded to analyze the entire WHO EML list in 2004.[41]

In 2004, the 13th edition of the EML was evaluated for the extent of products listed on the list that had existing patent coverage.[42] The list was initially evaluated to identify generic therapies, defined as products that were considered "ancient or nonpharmacological" or had descriptions that did not correspond to a singly patentable product.[43] These products were removed from the list due to the likelihood of expired or non-existent patent protection. The remaining products were then subjected to searches using printed and electronic databases to determine "basic patents" for each product, where the basic patent was considered to be the earliest identified patent covering either the active pharmaceutical ingredient or method of use.[44]

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[36] Id.
[37] Id.
[38] Id.
[39] Attaran, Amir; Gillespie-White, Lee. "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" JAMA, 286(15), 1886-92, 2001.
[40] Id.
[41] Id.; Editorial Remarks to Attaran & Gillespie. JAMA, 287(7), 840-43, 2002.
[42] Attaran, Amir. "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" Health Affairs, 23(3), 155-66, 2003.
[43] Id.
[44] Id.

Once the initial patent searches were finished, the assignees for each basic patent were compiled.[45] Surveys were then issued to each of the assignees listed on the patents to supplant omissions inherently found in patent databases.[46] In the surveys, each assignee was asked for a disclosure of current patents and pending applications that covered WHO EML specified doses. The majority of companies responded with information to the queries, providing information regarding current patent coverage for the list of medicines.

Ultimately, and in line with previous analyses, approximately 6% of the list had at least one unexpired basic patent (19 of 319 products).[47] Most of the products having existing patent coverage were ARV medications for HIV/AIDS that could limit importation and manufacture into developing nations depending on the patent status of medicines in these jurisdictions. Because they provide an information base for making rational and informed strategic determinations, analyses like this are a necessity to facilitate access to quality medicines in all nations. This study suggested that even in the face of highly complex and costly pharmaceutical development, many medicines on the EML that are essential to promoting global health appear to be unprotected by patents.

The Orange Book

Purpose of the Orange Book

The publication *Approved Medicine Products with Therapeutic Equivalence Evaluation* is commonly known as the Orange Book. The purpose of the Orange Book is to list all the medicine products approved through New Medicine Applications (NDAs) and Abbreviated New Medicine Applications (ANDAs), by the United States Food and Drug Administration (FDA) on the basis of safety and effectiveness, in a single place.[48] State health agencies, prescribers, and pharmacists use the Orange Book to help make medicine product selection decisions.[49] In practice, the Orange Book allows prescribers and pharmacists to make generic medicine substitutions for brand name medicines, or reference medicine products, by providing therapeutic equivalence evaluations of each approved prescription medicine product.[50] By encouraging medicine product substitutions, the FDA seeks to contain healthcare costs.[51]

History

By the late 1970s, the FDA struggled to meet the requests of individual states asking for assistance in preparing medicine equivalence lists.[52] The FDA distributed the first embodiment of the Orange Book in January of 1979 as an attempt to solve this administrative issue.[53] The list, officially known as the list of *Approved Medicine Products with Therapeutic Equivalence Evaluations*, included currently marketed FDA approved prescription medicines.[54] The official policy for therapeutic equivalence evaluation can be found in the *Federal Register*.[55] Generally, a pharmaceutically equivalent medicine product is an FDA approved medicine that has no known or suspected bioequivalence issues, has been manufactured in accordance with current

[45] Id.
[46] Id.
[47] Id.
[48] U.S. Dept. of Health & Human Servs., Approved Medicine Products with Therapeutic Equivalence Evaluations i (30th ed. 2010).
[49] Id.
[50] Id.
[51] Id.
[52] Id.
[53] Id.
[54] Id.
[55] *See* Therapeutically Equivalent Medicines; Availability of List, 45 Fed. Reg. 72582 (Oct. 31, 1980).

good manufacturing practices, and meets necessary standards.[56] A final version of the list was published in October of 1980.[57] The FDA used the Orange Book to fulfill the 1984 Medicine Price Competition and Patent Term Restoration Act's requirement to make a list of approved medicine products publicly available.[58]

What Patents Are Included in the Orange Book

Anyone who submits an NDA, an NDA amendment, an ANDA, or a supplement to an approved medicine application must submit patent information to the FDA.[59] The types of patents required for reporting include medicine substance (active ingredient) patents when the subject of the patent is the same as the subject of the application or the same as the active ingredient in the application.[60] Patents claiming a polymorph of a reference compound can be reported if sufficient testing information is submitted proving that the polymorph is bioequivalent to the reference compound.[61] Additionally, the formulation, composition, and method-of-use patents for the medicine in the application must be reported.[62] Also, any patented change regarding a medicine's method of use, submitted in supplements to the approved medicine applications, must be reported. For example, patents regarding a change in formulation, addition of a new indication or condition of use, or a change of strength, are required to be submitted in supplements.[63]

What Patents Are Not Included in the Orange Book

The FDA does not require submission of information regarding process patents or patents claiming packaging, metabolites, or intermediates.[64] Additionally, the Orange Book does not include patent information regarding medicines approved strictly on the basis of safety or medicines available prior to 1938.[65]

Exclusivities

Exclusivity, in the United States, is an exclusive marketing right granted by the FDA upon approval of a medicine product and is different from Patent Term Extension (PTE) as provided for in 35 U.S.C. § 156.[66] Exclusivities are statutory provisions and are granted to NDA applicants if the statutory requirements are met.[67] Exclusivities are distinct and different from rights granted by patents and can run concurrently with a patent.[68] For example, if both a patent and a granted exclusivity protect a particular medicine compound, and the patent is invalidated through litigation, the exclusivity will still provide the medicine protection, or exclusive marketing rights, for the duration of the exclusivity period. Some medicines have

[56] Id. at 72600.
[57] U.S. Dept. of Health & Human Servs., *supra*, at iii.
[58] *Id.* at i.
[59] 21 C.F.R. § 314.53 (2009).
[60] *Id.*
[61] *See* 21 C.F.R. § 314.53(b)(2) (discussing the requirements for submitting polymorph patent information).
[62] 21 C.F.R. § 314.53 (2009).
[63] *Id.*
[64] Id.
[65] Id.
[66] http://www.fda.gov/Medicines/DevelopmentApprovalProcess/ucm079031.htm (Accessed Oct. 1, 2010) [hereinafter Frequently asked Questions on Patents and Exclusivity]. ; See 35 U.S.C. § 156 (PTE actually extends the term of the patent whereas exclusivity does not).
[67] *See* 21 C.F.R. § 314.108 (1994); 21 C.F.R. § 316.31 (1997); 21 C.F.R. § 316.34 (1997).
[68] Frequently asked Questions on Patents and Exclusivity, *supra*. note 20.

both patent and exclusivity protection while others have just one type or no protection.[69] There are 5 types of exclusivities:

- ∞ Orphan Medicine Exclusivity (ODE) which grants a 7-year exclusivity,
- ∞ New Chemical Exclusivity (NCE) which grants a 5-year exclusivity,
- ∞ Pediatric Exclusivity (PED) which grants a 6 month exclusivity, and
- ∞ "Other" Exclusivity that grants a 3-year exclusivity for a "change" if criteria are met.[70] One example of this "Other" Exclusivity is if an NDA applicant submits a supplemental application to the FDA that contains reports of clinical investigations, unrelated to bioavailability studies, which were essential to the supplemental application's approval.[71]
- ∞ Patent Challenge Exclusivity (PC) which grants 180 days of exclusivity to the first ANDA applicant, or generic medicine manufacturer, to file a "Paragraph IV" challenge to a NDA applicant's patents for a particular medicine product listed in the Orange Book.[72] An ANDA applicant's "Paragraph IV" challenge to an Orange Book patent generally leads to patent litigation involving the challenged patent.

Patent Use Codes

Patent use codes (PUCs) are listed in the Orange Book with the format being a number and a descriptor.[73] The purpose of the PUC is to designate a code for a patent that covers the approved indication or use of a medicine product.[74] It is important to note that the NDA applicants provide the FDA with the exact patent use code description to be published in the Orange Book.[75] The FDA has no role in determining the appropriateness of patent use codes assigned to particular medicine products by NDA applicants.[76]

Potential Issues with Patents Listed in the Orange Book

NDA applicants are solely responsible for submitting appropriate patent information to the FDA. Currently, NDA applicants are required to submit patent information as part of the NDA application process.[77] That patent information, exactly as submitted by the NDA applicant, is then listed in the Orange Book.[78] Although NDA applicants are required to submit specific patent information as part of the NDA application process, it is possible that NDA applicants may strategically choose to include some patent information initially and include other patent information at a later date.[79] This strategy could potentially delay the entry of a bioequivalent generic medicine product into the market and prevent generic competition. The FDA, however, maintains a purely ministerial role regarding the listing of patent information submitted by NDA applicants.[80]

[69] *Id.* (follow "Why does the exclusivity expire before the patent?" hyperlink).
[70] *Id.* (follow "How long is exclusivity granted for?" hyperlink).
[71] *See* 21 C.F.R. § 314.108 (1994).
[72] Frequently asked Questions on Patents and Exclusivity, *supra.* note 20.
[73] *See* http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm (Accessed Oct. 1, 2010).
[74] *See* 21 C.F.R. § 314.53 (providing that a NDA applicant is required to provide a description for each method of use patent).
[75] *Id.*
[76] *See* Applications for FDA Approval to Market a New Medicine: Patent Submission and Listing Requirements and Application of 30 Month Stays on Approval of Abbreviated New Medicine Applications Certifying That a Patent Claiming a Medicine Is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36,676, at 36,682-83 (June 18, 2003) (to be codified at 21 C.F.R. pt. 314).
[77] 21 C.F.R. § 314.53.
[78] *Id.*
[79] *See* 68 Fed. Reg. 36,373 at 36,683.
[80] *Id.*

No administrative process exists for evaluating patent information submitted by NDA applicants. As mentioned, the NDA applicant is solely responsible for determining what patents should be included in the NDA application and, ultimately, what patents will be listed in the Orange Book. Currently, the FDA does not have the authority to declare any patent submitted by a NDA applicant invalid.[81] The FDA's position is that questions regarding the issuance and validity of patents are left to the USPTO and the courts.[82]

No administrative process exists for challenging patent listings or for seeking removal of patents listed in the Orange Book. Once a patent expires, it is no longer included in the Orange Book.[83] Other than waiting for a patent to expire, generic medicine manufacturers have no other way, outside of invalidating a patent through litigation, to get a potentially improperly listed patent removed from the Orange Book. Because there is currently no administrative procedure for challenging patent listings, a fear exists that NDA applicants could submit inappropriate patent information to the FDA to delay generic competition.[84] The FDA's position is that the current system sufficiently addresses this concern because NDA applicants are required to submit specific detailed information regarding a medicine product's patents and are required to certify that the information is correct.[85] The FDA will relay questions about the accuracy of a patent submission to the NDA holder, but will not perform its own investigation.[86]

Conclusion

The Orange Book, in addition to being a valuable tool utilized by health care providers making decisions about whether or not a specific medicine is therapeutically equivalent to a reference medicine product, lists patent information for medicine products approved and marketed in the United States. Although the possibility exists that all the patents relating to a specific medicine product will not be listed in the Orange Book, it can be a good starting point for finding relevant patents relating to specific medicine products in the United States. While the patents listed for a specific medicine product in the Orange Book cannot answer the broader question, i.e., if a specific medicine product is under patent in a specific jurisdiction outside of the United States, the patent information one obtains in the Orange Book, for example key words and/or INPADOC family data, can be used to facilitate a jurisdiction specific patent search.

Patent Families

Background

A patent family in its simplest form is a collection of patents from different jurisdictions that share a priority date with a single parent document. The concept for a patent family first emerged from the Paris Convention for the Protection of Industrial Property in 1883, which recognized the need to systematically analyze patents in different jurisdictions.[87] When filing patent applications in multiple jurisdictions, an inventor must follow the individual procedures of each jurisdiction.[88] Without patent families, searches are complicated because the multiple different jurisdictional applications are shown as independent results, making quick viewing

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and analysis of the patent landscape confusing and difficult. Therefore, using patent families eliminates the multiplicity of foreign and domestic filings when searching for patents, because a single representative member will be displayed in the results and all foreign filings of the same invention will be displayed in an organized, easy to read format.

However, while solving difficulties with multiplicity while searching, patent families are not infallible. Currently there is no single convention for defining a patent family.[89] Thus different patent family generating services create families using different strategies. Due to the lack of a single convention, to ensure complete coverage, it may be necessary to search multiple sources of patent families.

Importance

The rapid development of search technology has greatly advanced the capability of researchers to find patents. However, without an organized system categorizing patent activity, even the best searches quickly become unmanageable. The importance of patent families lies in the indexing of multiple patents, consequently showing global patent activity in a fairly straightforward and more manageable system.[90] Because patent families show global activity of an invention, corporations can detail factors like marketing strategies in a multitude of jurisdictions.

Types of Patent Families

The World Intellectual Property Organization (WIPO) defines patent families as a collection of patent documents sharing a common aspect that are published at different times in different jurisdictions.[91] The patents all share priority to an originating member of the family. However, because priority rights of patents are not always linear relationships, different types of patent families exist to cope with the multitude of different priority relationships.[92] WIPO has defined six patent family types that describe all potential priority relationships:[93]

- ∞ Simple Patent Families
- ∞ Complex Patent Families
- ∞ Extended Patent Families
- ∞ National Patent Families
- ∞ Domestic Patent Families
- ∞ Artificial Patent Families.

The first five families are considered natural families since the members all share a true priority with one another.

Of the natural families, the simple, complex, and extended families are the most commonly used family priority schemes and grow in complexity from simple families to extended families.[94] The simple patent family is the most basic of the patent families. In a simple patent family, all members of the family have the same priority to exactly the same originating application(s) (Figure 1).[95] The simple family classification, while being the most straightforward

[89] EUROPEAN PATENT OFFICE. http://www.epo.org/patents/patent-information/about/families.html. (last visited Dec. 29, 2010).
[90] *Id.*
[91] WIPO HANDBOOK ON INDUSTRIAL PROPERTY INFORMATION AND DOCUMENTATION, GLOSSARY OF TERMS CONCERNING INDUSTRIAL PROPERTY INFORMATION AND DOCUMENTATION Section 8.1.1, 8.1.18-8.1.19 (2008).
[92] WIPO HANDBOOK, *supra* 8.1.18.
[93] WIPO HANDBOOK, *supra* 8.1.19.
[94] WIPO HANDBOOK, *supra* 8.1.19.
[95] WIPO HANDBOOK, *supra* 8.1.19; Tom Wolf, *PIUG Knowledge Base Page on Patent Families*, (Dec. 13, 2007, 12:20 PM), http://wiki.piug.org/display/PIUG/Patent+Families.

application of the family concept, also is the least informative of the patent landscape as it relates directly to a single originating document that all the family members share.

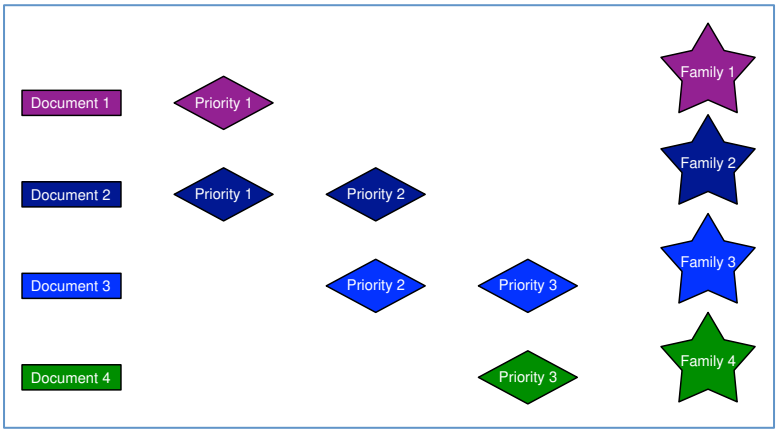


Figure 1: Simple Patent Families. In purple, Family 1 consists of Document 1 only. In navy blue, Family 2 consists of Document 2. In light blue, Family 3 consists of Document 3. Lastly, in Green, Family 4 consists of Document 4. Here, though some documents have shared priorities (i.e. Document 1 and Document 2 share Priority 1), Document 2 has an additional priority, Priority 2. Thus Document 2 is in a different Simple Family than Document 1 because the priority data does not match exactly between the documents.

Complex families expand family data to include all the members of the family related to the same invention or inventions sharing common aspects.[96] Each family member has at least one priority document in common with each other (Figure 2).[97] Thus complex families provide a broader perspective of the patent landscape than simple families but are still limited in their capacity to provide complete patent family analysis.

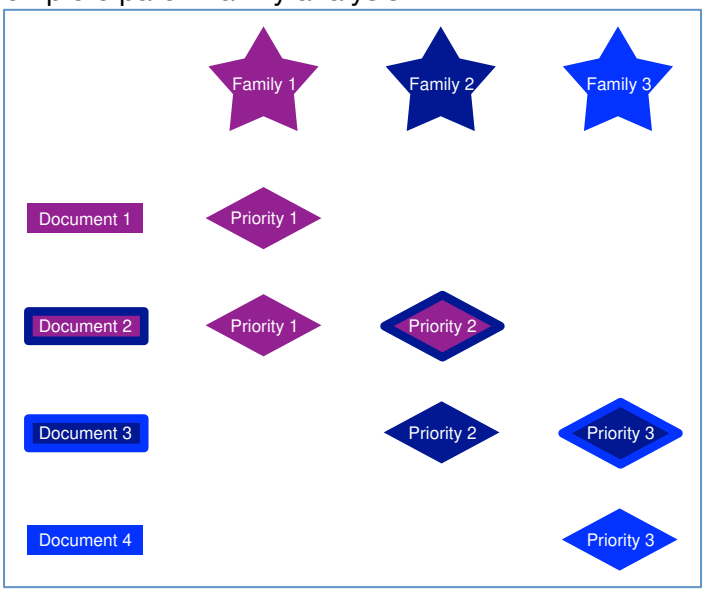


Figure 2: Complex Patent Families. Complex patent families extend the family members to documents having a shared priority document. Here, Family 1 consists of Document 1 and Document 2 because of shared Priority 1. Family 2 consist of Document 2 and Document 3 because of shared Priority 2. Family 3 consists of Document 3 and Document 4 because of shared Priority 3.

[96] WIPO HANDBOOK, *supra* 8.1.19.

[97] Tom Wolf, *PIUG Knowledge Base*, *supra* "Patent Families in INPADOC".

Extended families are the broadest of the non-artificial patent families and are commonly used by patent searchers for priority searches. In an extended patent family, all members of the family relate to one or more inventions, and each member has at least one originating application in common with another member of the family.[98] The difference between the extended patent family and the complex patent family is that each patent in an extended family need not relate to the same invention or even to inventions that share common aspects.

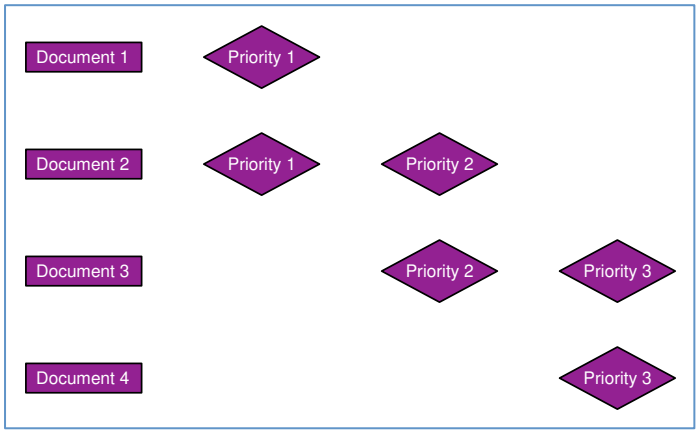


Figure 3: Extended Patent Families. All of the priority documents are in the same family because they all share at least a one priority with all the other documents. Document 1 shares Priority 1 with Document 2. Document 2 shares Priority 2 with Document 3. Document 4 shares Priority 3 with Document 3. All the documents are in the same family because priority can be traced back to Priority 1.

The national patent family and domestic patent family refer to patents generated from the same office. In a national patent family, the members must be distinct from each other and have priority to at least one originating application in common with the family.[99] The relationship between family members in a national patent family exists because of additions, continuations, continuations-in-part, or divisions of the parent application. In contrast to a national patent family, a domestic patent family member originates from a single office's different procedural publications for the same parent application.

The last and broadest patent family is the artificial patent family.[100] Artificial families are created by categorizing equivalent disclosures and matching documents that, while sharing common aspects, do not share priority to originating application(s) in the family.[101] Artificial families therefore expand families far beyond the original priority data for natural patent families. The features of artificial families are value-added because artificial families provide more in depth analysis of patent relationships.[102]

Generating patent family data differs substantially, depending on the search parameters used and the construction of the families from the search service used. There are currently three primary family building services available, INPADOC, DWPI, and the TotalPatent™ families from LexisNexis®.

INPADOC

International Patent Document (INPADOC) families are of the extended family type. They were introduced in 1972 through an agreement between the Austrian patent office and the

[98] WIPO HANDBOOK, *supra* 8.1.19.
[99] WIPO HANDBOOK, *supra* 8.1.19.
[100] WIPO HANDBOOK, *supra* 8.1.19.
[101] DWPI REFERENCE MANUAL, DERWENT WORLD PATENT INDEX 7G10 (Thomson Reuters Scientific, STN Online User Guide, Apr. 2009).
[102] DWPI REFERENCE MANUAL, *supra* 7.

World Patent Organization.[103] INPADOC was incorporated into the European Patent Office (EPO) in 1989 and is now incorporated into the EPO's European Patent Information and Documentation Systems Directorate (EPIDSD).[104]

INPADOC families were created in the infancy of patent families and thus were designed to be very broad to encompass a large amount of family data.[105] As a consequence of its breadth, and because the members in each family need only share at least one priority document with at least one patent in the family, INPADOC families can become quite large. Large INPADOC families are especially prevalent in the chemical and biological arts.[106] Recently, INPADOC has integrated older patent documents into the family system to create artificial families, sometimes showing family members back to the 1830s. These artificial families provide a source of searching for remotely extended family members that would be lost before the integration of family data.

DWPI

The Derwent World Patent Index (DWPI) families are of the artificial family type. The system was developed in 1951 to facilitate quicker prior art searches for the chemical and pharmaceutical arts.[107] DWPI differs substantially from other patent family systems because human intervention forms artificial families through codes, rewritten abstracts, and rewritten titles. Because of labor intensive rewriting and indexing, DWPI costs are substantially higher than INPADOC and are value-added.[108]

It is important to understand how DWPI divides patent priority data to understand family structure. DWPI divides data in basic records, those patents that appear to have unique priority data, and conventional equivalents, patents that share priority with the basic record. Together, the basic and conventional equivalent patents create simple patent families.[109] However because of the value-added features of DWPI, such as rewritten abstracts and rewritten titles, patents that share subject matter or applicants can be added to pre-established patent families. These additional unrelated patents are termed non-equivalents and under normal family schemes cannot be included in any natural patent family because they lack the necessary priority. By combining non-equivalent patents with pre-established families, DWPI creates artificial families that extend patent data to a useful, more expansive view of patent activity. DWPI families are typically smaller than INPADOC families with some, but not complete, overlap.

LexisNexis® TotalPatent™

TotalPatent™ is a tool developed by LexisNexis® for patent searching that extends country coverage beyond that of INPADOC. TotalPatent™ families are generated using only priority information matching and do not include artificial family members. TotalPatent™ currently has three primary family generation strategies: Main Families, INPADOC Families, and Extended Families.[110] TotalPatent™ Main Families are simple families generated with single priorities

[103] EUROPEAN PATENT OFFICE. http://www.epo.org/patents/patent-information/about/families.html (last visited Dec. 1, 2010).
[104] *supra*.
[105] *supra*.
[106] *supra*.
[107] DERWENT WORLD PATENTS INDEX. DERWENT WORLD PATENTS INDEX EXTENSION – Bluesheets File 280, http://library.dialog.com/bluesheets/html/bl0351.html (last visited Dec 1, 2010).
[108] Derwent World Patents Index Bluesheets File 280, *supra* "File Description"; DWPI REFERENCE MANUAL, *supra* 7. http://thomsonreuters.com/products_services/legal/legal_products/intellectual_property/dwpi/ (last visited Dec 3, 2010).
[109] Derwent World Patents Index Bluesheets File 280, *supra* "File Description".
[110] E-mail from Jonathan Grant, LexisNexis Global IP Education Specialist Manager, to Dr. Kevin Clark (Nov. 8, 2010, 8:26 EST) (on file with receiver).

between family members to the exact same originating document (see Figure 1). TotalPatent™ Main Families have single priority to a parent member and therefore provide the least amount of family information of the three TotalPatent™ strategies.[111]

The remaining two strategies, the INPADOC and Extended families are of the extended family type. Both families have at least one priority document in common with each other. However, the families differ in two keys ways. First, while both are of the extended family type, the Extended family strategy of TotalPatent™ has additional country coverage beyond that reported by INPADOC.[112] Therefore, TotalPatent™ Extended families provide a broader coverage of filings in jurisdictions not found in any other family generating service. The INPADOC TotalPatent™ Family mirrors the methodology provided by INPADOC but excludes and members generated through human intervention.[113] Second, while the TotalPatent™ Extended families broaden country coverage, TotalPatent™ currently provides no legal status for those members. In contrast, while the TotalPatent™ INPADOC family has fewer members, the reported INPADOC legal status is available but still excludes any priority generated through human intervention.

Conclusions

While various strategies exist to generate patent families, it is readily apparent that each strategy has advantages and disadvantages, which must be weighed and analyzed to determine which service to use. No single service or combination thereof can guarantee finding every potential patent available for a given invention. Therefore, an experienced attorney should perform as in-depth search as possible with the resources available and seek additional help from offices on a jurisdiction-by-jurisdiction basis to mitigate concerns about prior art.

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How to Use This Report

Division of Data

This report is designed as a layered approach to identify patents for a subset of medicines listed in the EML. By layering the data into successively more in-depth analyses, a user can quickly and efficiently locate pertinent information. However, it should be duly noted that this report is not a Freedom-to-Operate analysis nor is it fully comprehensive to the availability of patent data outside current standardized patent databases. The data is limited to patents and patent families having at least one US patent document and are current as of late 2010, and new data may well be available since that time. The data is further limited by the inherent limitations of the FDA Orange Book as described in the Orange Book Section. Thus, medicines lacking a US document may be missing patent documents that cover the medicine. Because no analysis can fully cover all available patent data in non-reporting jurisdictions, or jurisdictions that report infrequently, it is necessary for the user to verify the reported data in jurisdictions outside those reported by many electronic patent resources. Therefore, individuals should seek patent professionals in jurisdictions of interest to search national patent libraries and investigate regional patent offices.

The least in-depth of the analyses in this report is the Quick Reference Data Sheets, the printed sheets provided in the results section for each medication searched. Designed as a cursory overview, this data presents an encapsulated view of what the EML medicine is and its intended use, together with relevant patent information such as the presence or absence of a base patent, basic filing information, and available globe filing trends through generation of family data. The ITTI Clinic defines the base patent as the earliest identified patent covering either the active pharmaceutical ingredient or method of use. A total of 240 patents are found within the Quick Reference Data Sheets. These 240 patents represent the identified base patents (88) and Orange Book patents (152) without removing redundancies. Redundancies were not removed to represent the entire patent information identified for each medicine's base patent(s) and Orange Book patent(s).

Quick Reference Data Sheets

Include:

- Medicine name, Dose, and/or formulation, and Uses
- Chemical name, Abstract number, and Formula
- Base Patent information, including: Patent number, Original and Current assignee and country, and the Date filed
- Orange Book Patent information, including: Patent number, Original and Current assignee and country, and the Date filed
- A world map showing patent trends for patents, including: Patents having filing dates prior to 1980, Patents having filing dates between 1980-1989, and Patents having filing dates after 1990.

***For quick reference purposes and for ease of use, the Quick Reference Data sheets are printed within this report and have been arranged in alphabetical order by medicine name.

Because the intent of the WHO EML is to provide recommendations globally for national lists, locating patent family members was necessary to illustrate patent trends in jurisdictions outside the United States. Therefore, all ascertained base patents and patents located in the FDA Orange Book were subjected to searches to generate families using Derwent, INPADOC, and Lexis TotalPatent™. A total of 27,568 patents, including the base patents and Orange Book patents are listed in the Family Data Sheet. However, to reduce data redundancies in the family data, redundant Base Patents and Orange Book patents were removed before generating the family patent data. The Family Data Sheets present all the available generated family data and users can utilize this data to help analyze global patent trends for a particular EML medicine (DVD Electronic File Name: WHO_EML_Family Data.xlsx).

Family Data Sheets
Include:

- Medicine name
- Base Patent number
- Orange Book patent number
- Derwent World Patent Index (DWPI) family members
- INPADOC family members
- LexisNexis® TotalPatent™ family members

***For quick reference purposes, the Family Data Sheets are placed in an electronic spreadsheet available on DVD (Electronic file name: WHO_EML_Family Data.xlsx) and have been arranged in alphabetical order by medicine name.

The third and most comprehensive of the spreadsheets is the Master Patent Data Sheet (DVD Electronic File Name: WHO_EML_Master Patent Data.xlsx. This spreadsheet contains all patent information extracted from Thompson Reuters Innovation (including all of the Base Patents and Orange Book Patents) and represents what may be useful patent information for the user of this report by providing all available information of Thompson Reuters in a single spreadsheet. This spreadsheet contains 166 unique patent documents derived from removing the redundancies found in the 240 base patents and Orange Book patents in the Quick Reference Sheets.

Master Patent Data Sheet
Includes:

- Medicine name
- Base Patent and Orange Book Patent information, including but not limited to: Application data, Publication data, priority data, family data, patent classification, and INPADOC legal status
- Other patent information including but not limited to: Title, Abstract, Claims, Assignees, and Inventors
- Hyperlinks to Adobe® pdf documents for all listed patents and patent applications

***For quick reference purposes and for ease of use, the Master Patent Data Sheet is a single electronic spreadsheet available on DVD (Electronic file name: WHO EML Master Patent Data.xlsx).

Together, the three data sheets provide a comprehensive overview of the current known status for each EML listed medicine provided by WHO. By providing layers of data, the user can quickly and efficiently find desired pertinent information for the task at hand by systematically providing increasingly complex layers of information in the successive data sheets. Refer to Figure 9 page 28 for a flowchart diagram of how each set of data is related.

Application to Global Maps

The identified base patents for each medicine were reduced to the US patent when possible to simplify analysis. Using the family data, a series of global maps were created identifying patent filing trends. Countries colored in red show patent filings identified within the confines of the ITTI methodology that had filing dates from 1990 onward. Countries colored in orange show patent filings identified that had filing dates between 1980 and 1989. Countries colored in yellow show patent filings identified having a filing date prior to 1980.[114] Countries colored in grey had no identified patent filings as defined by the confines of the methodology at any time. Though no patent filings were identified in these countries, this neither guarantees that no patent filings have been or are still valid within these jurisdictions nor does it alleviate users of this report from further investigation of these jurisdictions might be needed.

Important to note on the maps are the regional filing tables. Of particular interest are EPO filings. Members of the EPC who file regional patent applications must still undergo validity analysis in each designated jurisdiction before patent rights may be granted in each nation.[115] Thus while an EPO filing can cover all parties to the EPC, it is necessary for applicants to diligently pursue their rights in all nations.[116] The importance of this necessity is shown in the apparent lack of patenting activity in France and Italy for example, for many of the products on the list having filing dates later than 1990. The EPO INPADOC legal status for these documents can be overwhelming and within the limited time frame for this project, it was simply impossible for student researchers to investigate each patent and application for all legal status. In addition, PCT national phase filings from France and Italy only proceed via the EPO. Thus, while some maps show no activity within European nations such as France and Italy, the presence of EPO filings corresponding to similar dates suggests with a high likelihood that regional filings exist and are patent databases are awaiting either prosecution of those filings or the prosecuted applications have yet to be reported. Therefore, to further investigate the status of any given patent in a EPO filing, additional research is necessary.

Limitations may also exist with the African regional offices, OAPI and ARIPO. However, the regional offices of these organizations work differently than the EPC. There are currently 16 member states of OAPI: Benin, Cameroon, Central African Republic, Chad, Congo, Gabon, Cote d'Ivoire, Mauritania, Niger, Senegal, Republic of Togo, Burkina Faso, Guinea, Guinea-Bissau, Mali, and Equatorial Guinea.[117] Unlike the EPC where the applicant must seek verification within each designated member state, under OAPI, once the regional office grants a patent, the patent is immediately effective in all member states.[118] Similarly, there are currently 16 member states of ARIPO: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia,

[114] The filing dates were determined from the latest filing date of the most recent family member.

[115] European Patent Convention art 66, 79. 1973; PCT Applicant's Guide – National Phase – National Chapter – European Patent Office. WIPO, Jan. 14, 2010. 37 Pages.

[116] European Patent Convnetion art 66, 79.

[117] PCT Applicant's Guide – National Phase – National Chapter – Office of the African Regional Intellectual Property Organization (ARIPO). WIPO, Jan. 14, 2010. 8 Pages.

[118] Id.

and Zimbabwe.[119] Similar to OAPI, under ARIPO, once the ARIPO office grants a patent, the patent is immediately effective in all member states.[120] Thus, while both of these organizations provide for immediate patenting in each member state, both organizations still appear to lack the means to consistently report patents to international patent databases.

Methods

Comparative Approach Between ITTI and Former Methodologies

The previous approach developed by Attaran in 2004 was an effective methodology to evaluating existing patent coverage for medicines on the WHO EML.[121] However, as with any methodology, limitations generate opportunities for further developments to create a better, more efficient system. When approached by the WIPO Global Strategies to create a new methodology, built upon the established system by Attaran, the ITTI Clinic sought three key elements. First, the methodology should serve as an educational model for member states to ascertain existing patent coverage. As an educational facility, FPCIP encourages innovative learning in the field of intellectual property and supports efforts to educate member states to develop their own capabilities. Second, the methodology should be cost-effective as member states may not have every conceivable resource available at their disposal. Lastly, the methodology should be reproducible and highly transferrable so member states can readily access and utilize data for their own purposes. With these goals in mind, the ITTI Clinic set out to adapt the Attaran methodology to reasonably meet these goals.

Generally, similar to the Attaran methodology, the ITTI Clinic first scanned a subset of the 16th edition of the EML provided by WHO for products that were unlikely to have existing patent protection or were generalized therapies that likely had did not correspond to a single patentable product.[122] Following the elimination of products meeting the above elements, the list was searched using the DTP. Briefly, and also similar to the Attaran approach, each medicine was subjected to searches using available patent databases and additional resources to determine a base patent.[123] The ITTI definition of a base patent was the earliest identified patent covering either the active pharmaceutical ingredient or method of use. These patents were compiled and the medicines were subjected to additional searches using FDA online drug repository to identify additional patents reported to the FDA that covered the EML products. Once these patents were identified, each patent was subjected to an analysis of family members to generate a listing of patents covering each medicine globally.

The Attaran methodology continued after this point to send surveys to each of the assignees on all identified basic patents to obtain omissions inherent in the patent databases.[124] The goal of the Attaran methodology, which was predominantly of an academic nature, was to identify, as comprehensively as possible, all existing patent coverage for EML products within the confines of the African continent.[125] Among the conclusions arrived at, was the suggestion that patents were not an impedance to access to medicines within poorer

[119] PCT Applicant's Guide – National Phase – National Chapter – African Intellectual Property Organization (OAPI). WIPO, Jan. 14, 2010. 8 Pages.

[120] Id.

[121] Attaran, Amir. "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" Health Affairs, 23(3), 155-66, 2003.

[122] Id. See Results section and Appendix B for complete table of the subset of medicines given to the ITTI Clinic. Includes updates to the EML between 2003 and 2009.

[123] Id.

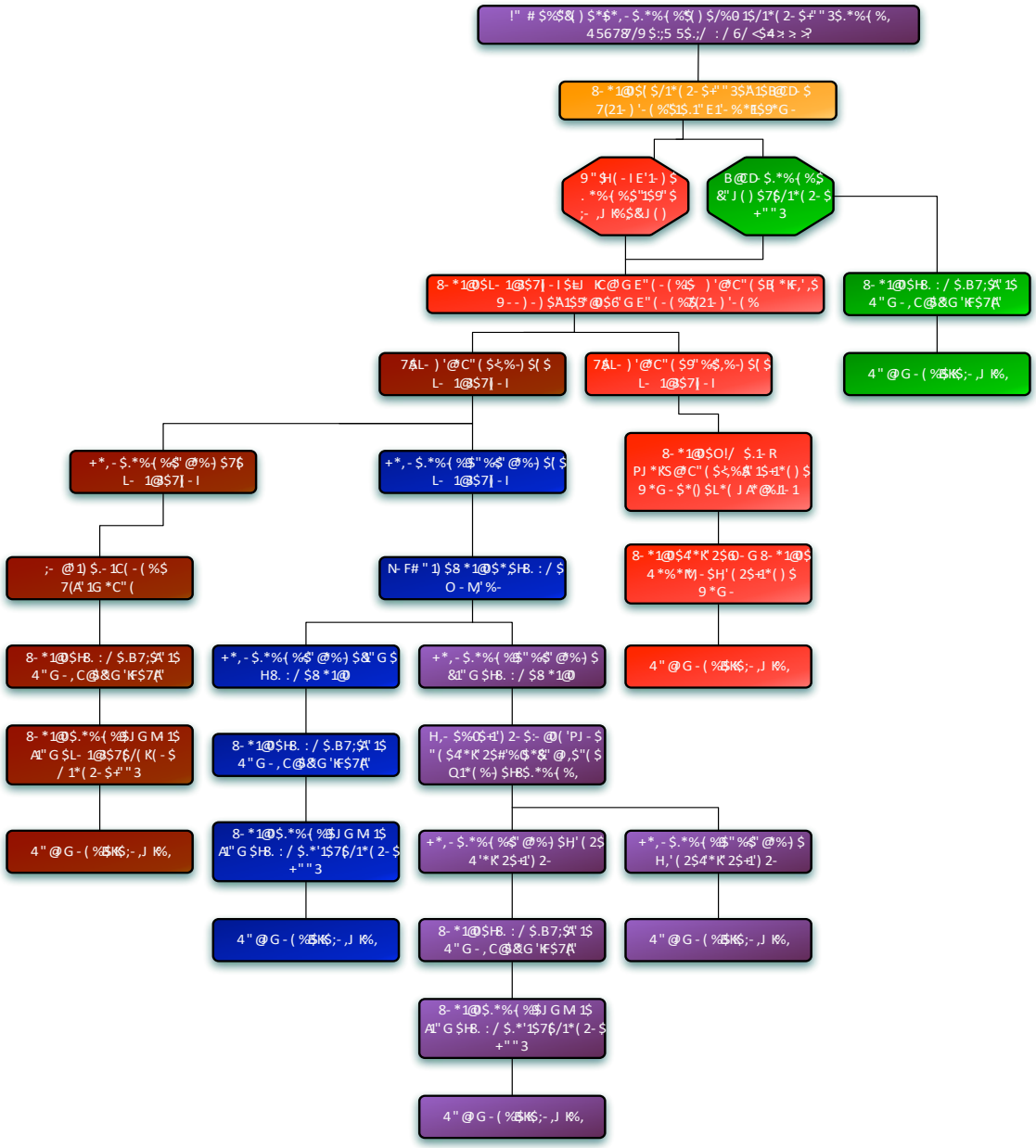
[124] Id.

[125] Id.

member states.[126] In contrast, this report was designed as a research project to devise an initial protocol and methodology to instead create a methodology that member states could learn from and adapt for their needs. Thus the ITTI Clinic methodology provides patent trends rather than factual, discrete patent data. The trend data provides users with a broader view of both past and present patent activity for medicines on the EML, globally and not just within the confines of the African continent. Unlike in the Attaran methodology, here, no surveys were issued to assignees of identified patents; however, WHO as a future step in continuing this research may decide to issue such surveys.

[126] Id.

Decision Tree Protocol



Decision Tree Protocol - Explanation

The Decision Tree Protocol (DTP) was established to ascertain the base patent for each medicine using a systematic methodology. The ITTI Clinic defines a base patent as the earliest identified patent covering either the active pharmaceutical ingredient or method of use.

The first step in finding a base patent for a given medicine involved searching the online Orange Book database using either the “active ingredient” or the “proprietary name” search fields. The results of this search determined the extent of further research necessary. If active patents were found using the online Orange Book database, then those active patents were further explored within the United States Patent and Trademark Office (USPTO) Patent Application Information Retrieval (PAIR) website. PAIR displays issued or published patent

application statuses, and includes domestic family information for a patent.[127] The PAIR website provides additional patent information by including the relationship between patent documents (i.e. continuation, continuation in part, or divisional) along with priority information – information that was vital in confirming whether the base patent retrieved from the Orange Book database was most likely the earliest available patent. After researching the base patent with PAIR, the base patent was evaluated and the procedure and results documented. For further precision, the medicine was researched in the latest available Merck Index to provide a secondary verification of the base patent.

If no results were found in the initial Orange Book, or if only "unexpired patents", as listed by the online Orange Book database, the Merck Index was searched. The Merck Index was also cross-checked for patents identified using the Orange Book database. If the medicine was located in the Merck Index with a listed base patent, then the name of the medicine, formula, CAS number, medicine code, brand name, synonyms and the base patent number were recorded. If additional derivatives of the medicine were listed in the Merck Index, the additional derivative information was also documented. After obtaining information from the Merck Index, PAIR was used to research domestic family information. All base patents retrieved from the Merck Index were redundantly searched in the online Orange Book and all results were documented.

If the medicine was listed in the Merck Index without base patent information, a United States Patent and Trademark Office (USPTO, http://www.uspto.gov) keyword search was performed using the searching capabilities of the USPTO website. If a base patent was located using search strings, the domestic family information was researched through the PAIR website to obtain priority information and redundantly checked through the online Orange Book database.

If a base patent is not found at this point, then the Bridge technique using ProQuest® Dialog™ should be applied to the medicine (see Appendix C).[128] The Bridge technique is an advanced patent searching technique in that uses searches across multiple Dialog™ databases to pinpoint information. The ITTI Clinic used the Bridge technique, to focus on locating granted US patents only. If a base patent was found using the Bridge technique, then the base patent was researched on the PAIR website for domestic family information and subjected to a redundant check through the online Orange Book database. If no base patent was found using the Bridge technique, search options to locate a base patent were apparently exhausted, and search results were documented.

If the medicine was unlisted in the Merck Index, the WHO pre-qualification list for essential medicines was searched.[129] The WHO pre-qualification of medicines is a list of medicines that have passed the quality, safety and efficacy standards of WHO.[130] The Dialog™ ChemSearch database was then searched using keywords obtained from the pre-qualification list to obtain CAS numbers, molecular formulas and synonyms of the essential medicine searched. The information was then crosschecked with the Merck Index, a USPTO search, and a search through the online Orange Book database as detailed above.

Combinational therapies (such as many ARV) were searched using the DTP for each component active ingredient and for patents covering the combination itself using the strategy detailed above. Following the DTP closely is not only vital in determining the base patent for a medicine, but is also vital to maintaining an accurate and systematic methodology of searching for base patents.

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Orange Book Searches

Orange Book patents were found using the FDA online Orange Book data repository.[131] The ITTI Clinic searched by prescription active ingredient, entering the essential medicine ingredient into the search field. This search would result in a listing of all FDA applications pertaining to the searched medicine. The ITTI Clinic searched each application, recording all patents listed for the searched essential medicine, taking note of WHO EML suggested dosages and formulations. The screenshots below illustrate an example search for Indinavir:

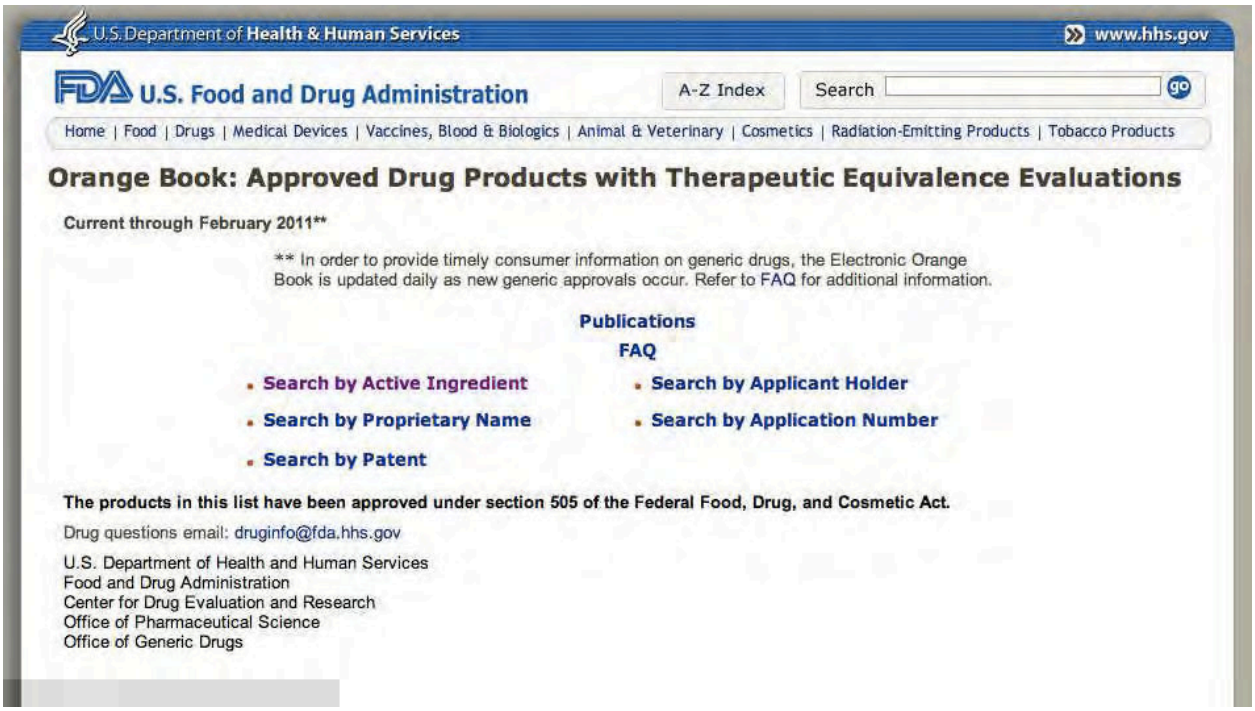


Figure 4: The Orange Book homepage at the FDA website.

[131] http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

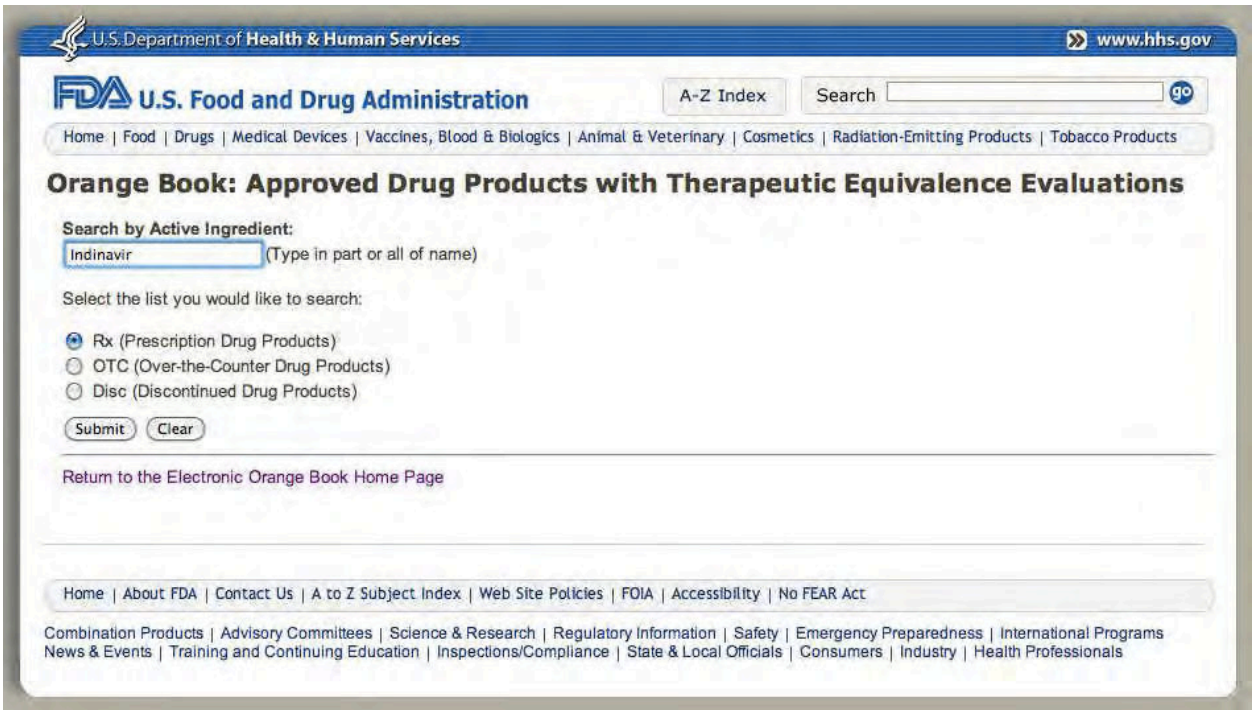


Figure 5: Active Ingredient search page, with Prescription Medicine option highlighted.



Figure 6: Search results for Indinavir, showing two FDA Orange Book applications.

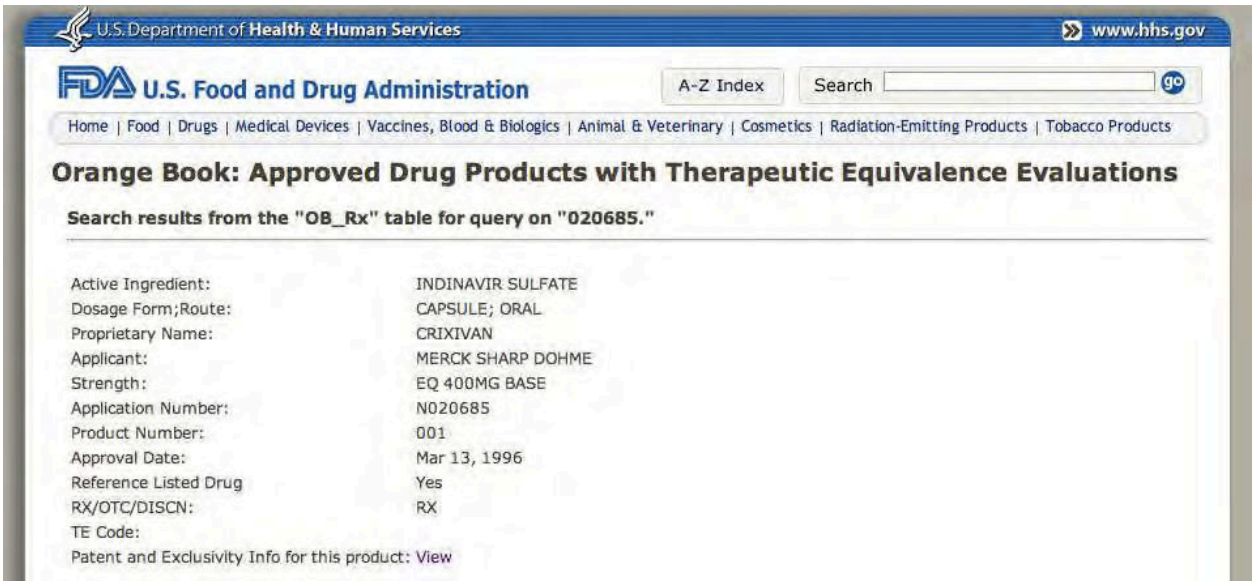


Figure 7: Application page for Application number N020685, one of the two applications on the results page. Next ITTI Clinic members select the “View” link for Patent and Exclusivity info.



Figure 8: Listed patent information for Indinavir for application N020685, showing no patents with FDA exclusivity. ITTI Clinic members would then perform the same sequence for all applications.

Patent Family Generation

The ITTI Clinic collected family data for each base patent and Orange Book patent for the subset of medicine identified by WHO on the EML and provided to the ITTIC Clinic. Three sets of family data were created for each identified patent:

- ∞ DWPI Family
- ∞ INPADOC Family
- ∞ TotalPatent Expanded Family

DWPI and INPADOC families were obtained using the Thomson Innovation patent database. Data for the TotalPatent Expanded Family came from the LexisNexis® TotalPatent database. The family patents were placed into an Excel® spreadsheet in a uniform format so that the data could be automatically reformatted into a grid using the ITTI designed Excel® macro as described subsequently, to create a grid that displays patent filings for each medicine or patent by respective country.

Patent Family Data Spreadsheet Generation – Excel Macro Development

The preformatted set of base patent and Orange Book family data were reformatted into an x-y coordinate grid system with the x-coordinate corresponding to the essential medicine and the y-coordinate corresponding to nation of activity, using an automated macro (a script for automating activity in Microsoft Excel using the VisualBASIC programming language).

Multiple x-y co-ordinate grid systems were created to display world-wide patent trends for essential medicines and their individual patents. These grids are included in the DVD accompanying the report.

The preformatted columns of base patent and Orange Book family data were reformatted into an x-y coordinate grid system with the x-coordinate corresponding to either the essential medicine or its individual patents and the y-coordinate corresponding to the jurisdiction of activity. An automated macro (a script for automating activity in Microsoft Excel® using the VisualBASIC programming language) was developed to facilitate this sorting process. !

First, a lookup table was created containing the name of each nation and its WIPO country code.[132] Second, a grid was created containing the name of the essential medicine or the individual patent comprising the x-axis, and the individual nations comprising the y-axis was created. Third, for each column of family patent data in the preformatted sheet, the program looked up the country code prefix for that patent in the lookup table from Step (1) and placed that patent into the grid corresponding to the essential medicine or individual patent on the x-axis and its country (determined through the lookup scheme) on the y-axis. If a patent already occupied the relevant cell, then the current patent was added after the first patent. The final value for each grid cell was the consolidated, de-duplicated data from the three family sources: DWPI, INPADOC, and TotalPatent™.

This process was repeated in further grids for which the patent inputs were limited to patents filed within specific time periods. One such set of grids was made for families created from base and orange book patents filed before January 1, 1980. Another set of grids was made based on patents filed between January 1, 1980 and December 31, 1989. A final set of grids was made based on patents filed on or after January 1, 1990.

Finally, the values in the x-y coordinate grid system were transformed from a list of patents to a four-value system. A value of “Y” (Yellow) for a medicine grid cell indicated the most the most recent patent document was filed before January 1, 1980. A value of “O” (Orange) for a

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medicine grid cell indicated the most recent patent document was filed between January 1, 1980 and December 31, 1989. A value of “R” (Red) for a medicine grid cell indicated the most the most recent patent document was filed on or after January 1, 1990.

The values from this grid served as input data for the world map generation.

World Map Generation

World maps were generated from patent family data using the Mapland™ Basic software package from Software Illustrated®. For each essential medicine a world map was generated indicating countries with a history of patent document filings. In addition, the world map employs yellow as corresponding to patent documents filed before 1980, orange corresponding to patent documents filed between 1980 and 1989, and red corresponding to patent documents filed after 1990. Overall patent trends having world maps use the identical color scheme to individual maps and were generated using the same software.

Chemical Structure Generation

All chemical structures were ascertained from medicinal package inserts using provided International Union of Pure and Applied Chemistry (IUPAC) nomenclature. The structures were generated using Cambridgesoft® Chemdraw™ Ultra version 12.0 software package and verified for correct stereochemistry using built-in structure verification and cross-checked against structures provided in the package insert.

Results

Medicines and Base Patents

A subset of 91 essential medicines added to the WHO EML since 2003 was assigned to the ITTI Clinic for analysis. (See Appendix Table A for the complete list of products from analyzed from the EML). Dr. Attaran had cleared much of this list in his 2003 study of the entire 13th Edition of the EML.[133] Thus, building upon the work of Dr. Attaran, this subset consisted of the 17 medicines identified in 2003 having existing patent protection and 74 medicines added to the EML since 2003.[134] Similar to the previous strategy, products on the EML with high probability of non-existing patent protection and products that did not correspond to a singly patentable product were removed from the analysis: thirteen such products were removed from the list.[135] These products included: Cholera, haemophilus influenxae type B, hepatitis A, Japanese encephalitis, pneumococcal, rotavirus, and varicella vaccines, human immunoglobulin, nicotine gum, oral rehydration therapy, surfactant, xylometazoline, and zinc sulfate. The remaining products (78) were subjected to the searches using the Decision Tree Protocol (DTP) methodology described herein to identify base patents.

Table 1: Products identified as having existing base patent protection in the 2004 Attaran study.[136] All of these medicines were again analyzed using the methodology described in this report. (Medicines in Red, according to the methodology used here, appear to no longer have active base patents)

Medicine Name	Medicine Name
Abacavir	Lopinavir-ritonavir
Artemether-lumefantrine	Mefloquine
Azithromycin	Nelfinavir
Ciprofloxacin	Nevirapine
Didanosine	Ritonavir
Efavirenz	Saquinavir
Fluconazole	Stavudine
Indinavir	Zidovudine
Lamivudine	

From the 78 analyzed products, 88 base patents were identified, where the base patent is considered as the earliest identified patent for the active pharmaceutical ingredient or method of use. Removing redundancies in the data yielded 70 unique base patents. Because many of these products have earlier patent filing dates, the ITTI team chose to use a cutoff date of 1990 to identify products that might still have existing patent protection. Of the 70 unique identified ***base patents***, 53 patents had filing dates prior to 1990 leaving 17 base patents having filing dates post January 1, 1990. These 17 patents constitute approximately 5% of the analyzed list, a value that is consistent with the previous results of Dr. Attaran's research.[137] Additionally, also like the previous study, the majority of products having existing patent protection were ARV medications for HIV/AIDS treatment.[138]

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Table 2: Products with base patents filed after 1990. Lumefantrine appears to not have a US family member of the identified Chinese base patent. Abbreviations: EFV = Efavirenz, FTC = Emtricitabine, TDF = tenofovir disproxol fumarate, NVP = Nevirapine, d4T = Stavudine, 3TC = Lamuvidine

Medicine	Patent Document	Medicine	Patent Document
Arthemether	US5677331	Nevirapine(NVP)	US5366972
Atazanavir	US5849911	Ritonavir	US5541206
Efavirenz(EFV)	US5519021	Omeprazole	US5693818
EFV/FTC/TDF	US20070099902A1	Saquinavir	US5196438
Emtricitabine(FTC)	US5210085	Stavudine(d4T)	US5130421
FTC/TDF	US20040224917A1	Tenofovir (TDF)	US5922695
Indinavir	US5413999	3TC/NVP/d4T	US20080241265A1
Lopinavir	US5914332	Nelfinavir	US5484926
Lumefantrine	CN10425335		

The ITTI Clinic searched the FDA Orange Book to provide additional details about existing patent coverage that could prohibit importation or manufacture. From the Orange book an additional set of 152 patents were identified, yielding a total of 166 unique patent documents. (Redundancies were identified between the base patents and patents located using the online Orange Book database. Removing the redundancies reduced the total number of patent documents to 166 unique documents from the originally located 222 documents). All of the base patent documents are listed as US documents when possible in this report to simplify the analysis.

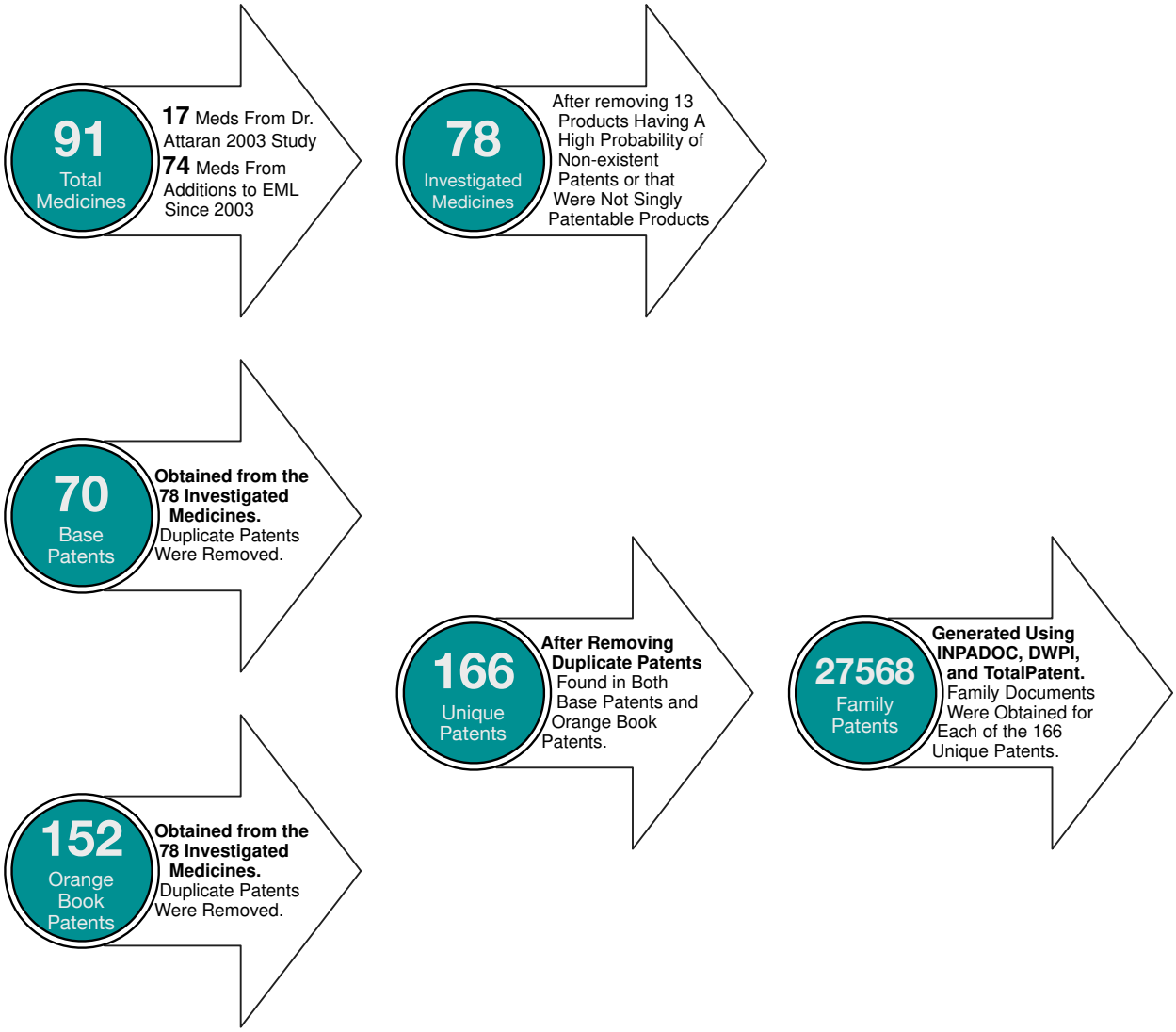


Figure 9: Flowchart for Results and How the Data was Generated for this Report as described above. 91 total medicines were reduced to 78 after removing products that likely did not have existing patent coverage because of the age of the drug or because they were not singly patentable products. From the 78 investigated medicines, 70 base patents and 152 orange book patents were obtained that were reduced to 166 unique documents after removing redundancies. The 166 unique documents were expanded using family data to 27568 patent documents.

WHO Therapeutic Groups

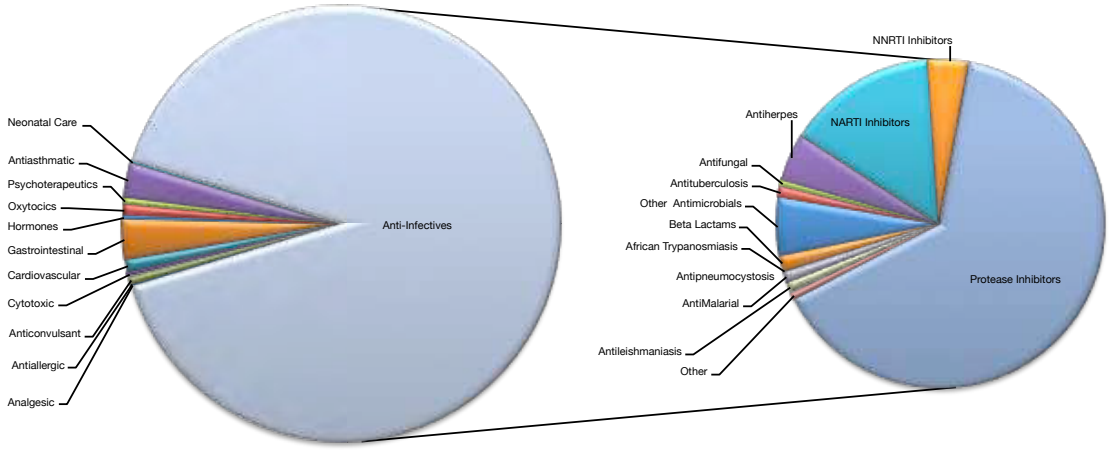
It is also important to identify the number of patents in each WHO therapeutic group. By comparing the number of patents in each therapeutic group to total number of patents, a user of this report can quickly identify which groups may have patent protection. Tables 3 and 4 compare the total number of patents to WHO therapeutic groups that have representative medicines in the subset provided by the WHO. As can be seen in both Table 3 and Table 4, the overwhelming numbers of patent documents lie within the anti-infective WHO therapeutic group. This group represents all of the ARVs along with any antibiotics and antifungal medications. Because the subset provided to the ITTI Clinic was not a full representation of the entire WHO EML not all therapeutic groups are represented in the table. The pie charts below each table are graphical representations of the data in each table.

Table 3: Patent Trends and Its Relation to WHO Therapeutic Groups – All Years. The number of patent is cumulative of all Base Patents (70), Orange Book Patents (152), and Patents identified via Family analysis (27,568). The pie chart is a graphical representation of the data in the table.

WHO Therapeutic Group Number	WHO Therapeutic Group Name	Number of Patents
2	Analgesic Medicines	54
3	Antiallergic Medicines	1
5	Anticonvulsant Medicines	160
6	Anti-Infective Medicines	25099
6.2.1	Beta Lactam Medicines	399
6.2.2	Other Antibacterials	1394
6.2.4	Antituberculosis Medicines	271
6.3	Antifungal Agents	173
6.4.1	Antiherpes Medicines	1181
6.4.2.1	NARTI Inhibitors	3730
6.4.2.2	NNRTI Inhibitors	973
6.4.2.3	Protease Inhibitors	16167
6.4.3	Other Antivirals	168
6.5.2	Antileishmaniasis Medicines	275
6.5.3	AntiMalarial Medicines	268
6.5.4	Antipneumocystosis Medicines	3
6.5.5.1	African Trypanosmiasis	11
8.2	Cytotoxic Medicines	86
12	Cardiovascular Medicines	260
17	Gastrointestinal Medicines	808
18	Hormones and other Endocrine Medicines	77
22.1	Oxytocics and Antioxytocics	215
24.5	Psychoterapeutic Medicines	152
25.1	Antiasthmatic Medicines	701
29	Specific Medicines for Neonatal Care	41

*!

Number of Patents Per WHO Therapeutic Group - All Years



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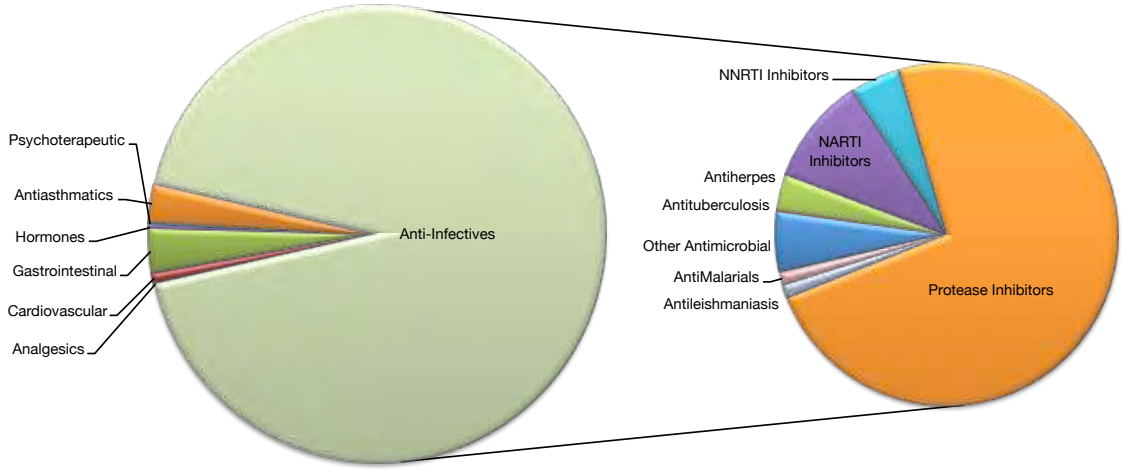
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Table 4: Patent Trends and Its Relation to WHO Therapeutic Groups – Post 1990. The number of patent is cumulative of all Base Patents (70), Orange Book Patents (152), and Patents identified via Family analysis (27,568).

WHO Therapeutic Group Number	WHO Therapeutic Group Name	Number of Patents
2	Analgesic Medicinces	26
3	Antiallergic Medicines	0
5	Anticonvulsant Medicines	0
6	Anti-Infective Medicines	26
6.2.1	Beta Lactam Medicines	0
6.2.2	Other Antibacterials	1165
6.2.4	Antituberculosis Medicines	39
6.3	Antifungal Agents	0
6.4.1	Antiherpes Medicines	707
6.4.2.1	NARTI Inhibitors	2107
6.4.2.2	NNRTI Inhibitors	973
6.4.2.3	Protease Inhibitors	15267
6.4.3	Other Antivirals	0
6.5.2	Antileishmaniasis Medicines	273
6.5.3	AntiMalarial Medicines	240
6.5.4	Antipneumocystosis Medicines	0
6.5.5.1	African Trypanosmiasis	0
8.2	Cytotoxic Medicines	0
12	Cardiovascular Medicines	161
17	Gastrointestinal Medicines	685
18	Hormones and other Endocrine Medicines	63
22.1	Oxytocics and Antioxytocics	0
24.5	Psychoterapeutic Medicines	43
25.1	Antiasthmatic Medicines	598
29	Specific Medicines for Neonatal Care	0

Number of Patents Per WHO Therapeutic Group - Post 1990



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WHO Regional Analysis

The WHO divides the Member States into 6 regions that are not the same as the United Nations designations. The regions individually develop strategies to control and prevent chronic and noncommunicable diseases. The regional division helps to reduce the overall burden on the WHO headquarters while also creating offices with more intimate knowledge and contact within each region. Because the regions are imperative to the WHO health mission to ensure that medicines on the EML satisfy the priority health care needs of the population, an analysis of potential patent protection for medicines on the list is crucial to understanding how innovators may develop patent strategies for new medications.

Tables 5 and 6 show the number medicines patented in each region. Because many medicines are patented in numerous countries within the same region, the numbers shown are much higher than the number of medicines listed in the subset. However, most important to the analysis is the average per country since this represents the overall impact patents for EML medicines may have for each region. As can be seen in Tables 5 and 6, the European region has the most patent document per country whereas the African region has the least. Surprisingly, the American region as the third highest average number demonstrating that only a two major countries, the US and Canada, are primary places for apply for patents.

Table 5: Patent Filing Trends and Relations to WHO Regions – All Years. Data is cumulative of patent filings arising from Base Patents, Orange Book Patents, and Family Patents. The number of medicines represents the combined total number of patent filings in each country. A medicine patented in multiple countries was counted each time it is patented in a different jurisdiction.

WHO Region	Number of Medicines Per Region	Number of Countries per Region	Average Per Country
African Region	109	46	2
American Region	245	35	7
Eastern Mediterranean Region	50	21	2
European Region	939	53	18
South-East Asia Region	61	11	6
Western Pacific Region	336	27	12

!

Table 6: Patent Filing Trends and Relations to WHO Regions – Post 1990. Data is cumulative of patent filings arising from Base Patents, Orange Book Patents, and Family Patents. The number of medicines represents the combined total number of patent filings in each country. A medicine patented in multiple countries was counted each time it is patented in a different jurisdiction.

WHO Region	Number of Medicines Per Region	Number of Countries per Region	Average Per Country
African Region	59	46	1
American Region	161	35	5
Eastern Mediterranean Region	22	21	1
European Region	624	53	12
South-East Asia Region	81	11	7
Western Pacific Region	276	27	10

!

Assignee Analysis

Which innovators are filing for patent protection is important to determine which companies need to be approached when making decisions regarding use or manufacture of EML medicines in certain jurisdictions. Figure 10 compares number of patents in relation to the top 10 patenting companies. The top patenting companies have 10 or more patents with filing dates post 1990. As expected, the largest pharmaceutical companies also have the largest number of patents for medicines on the EML.

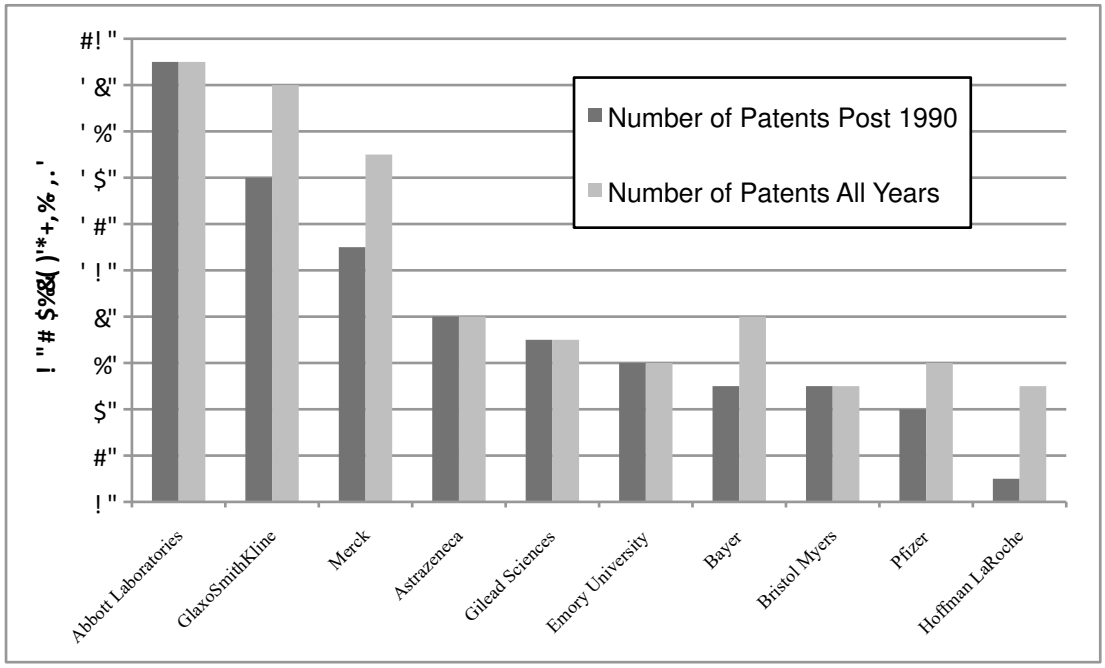


Figure 10: Comparison of Assignee Companies. Assignees were determined from the 166 unique patent documents found on the Master Patent Spreadsheet.

Patents and Country Income Analysis

Finally, it is important to understand the importance of national income in relation to the number of patents filed in differing income level countries. Traditionally, countries that have little resources and fall within the lower and low income WTO income brackets are less likely to be pursued by innovator companies for patent protection as the manufacturing capacity may not likely exist in these jurisdictions. As seen in Figures 10 and 11, regardless of the time frame looked at, nations classified by the WTO as high-income nations have significantly higher numbers of medicines on the EML protected by patents. In contrast, nations classified as low-income nations, regardless of the time period analyzed, have very little numbers of medicines on the EML protected by patents. Such analysis suggests that procurement officers in countries with more wealth should more diligently investigate the patent status of medicines on the EML to ensure they abide by international patent laws.

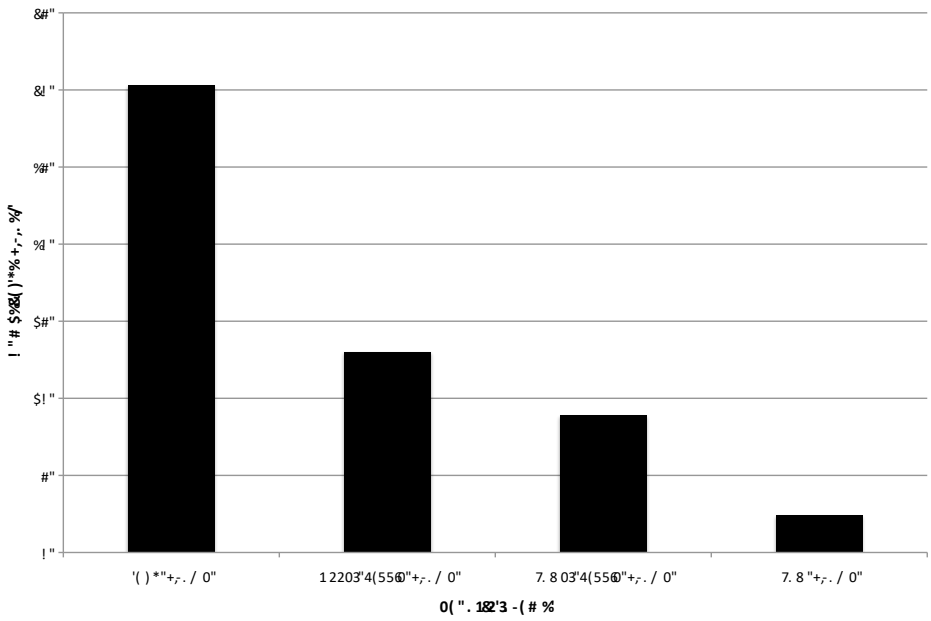


Figure 11: Essential Medicines and Their Relationship to World Bank National Income Levels – All Years. Data is cumulative of patent filings arising from Base Patents, Orange Book Patents, and Family Patents. The number of medicines represents the average of the combined total number of patent filings in each country (representative medicines in the graph are from a binary analysis. That is a 1 designates if any patent document is filed in a particular jurisdiction, thus counting the medicine as patented in that income level, and a 0 designates if no patent documents are filed in a particular jurisdiction). A medicine patented in multiple countries was counted a single time regardless of the number of jurisdictions the medicine was patented. Income levels are derived from World Bank.

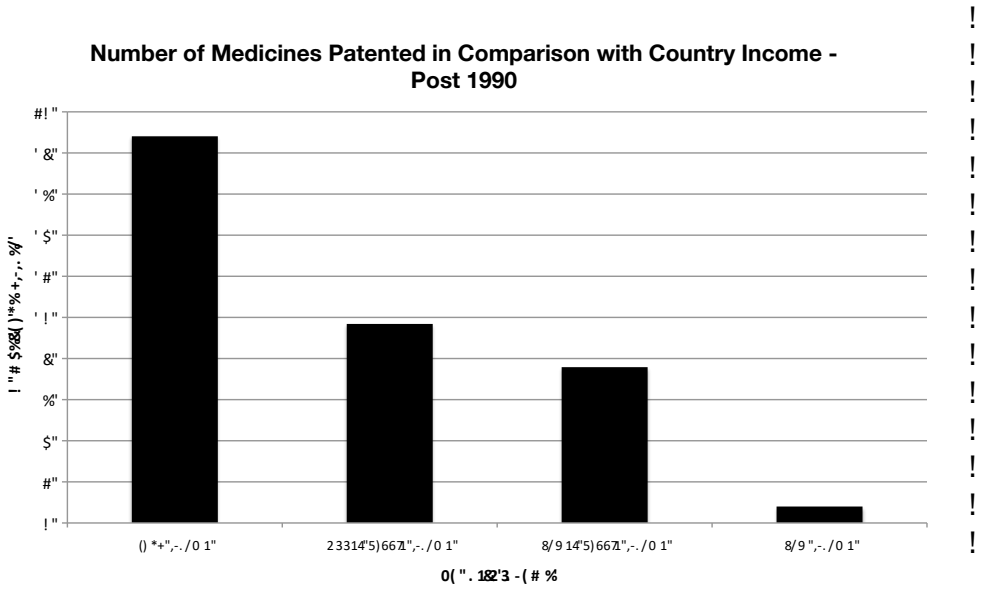


Figure 12: Essential Medicines and Their Relationship to World Bank National Income Levels – Post 1990. Data is cumulative of patent filings arising from Base Patents, Orange Book Patents, and Family Patents. The number of medicines represents the average of the combined total number of patent filings in each country (representative medicines in the graph are from a binary analysis. That is a 1 designates if any patent document is filed in a particular jurisdiction, thus counting the medicine as patented in that income level, and a 0 designates if no patent documents are filed in a particular jurisdiction). A medicine patented in multiple countries was counted a single time regardless of the number of jurisdictions the medicine was patented. Income levels are derived from World Bank.

Discussion and Conclusions

With respect to the subset of the WHO EML analyzed for patent coverage, this report represents a temporal continuation of the Attaran analysis in that it is based on his findings, accepting and incorporating these as a starting point and proceeding therefrom.[139] Therefore, building on the analysis that Attaran undertook, this report analyzes what he identified as potentially/likely still under patent protection plus the additions to the EML since 2003. Nevertheless, while similar in some respects, the ITTI approach differed from that of the Attaran group in several key features. The ITTI goal was to develop a comprehensive yet readily *transferrable* methodology to identify patent filings for medications on the WHO EML, with a preliminary presentation of patent data to illustrate consistency with the previous Attaran study, robustness of the methodology and protocol and as a foundation for subsequent research, analyses and refinements. Somewhat in contrast, in the Attaran study, the overall goal was to assemble patent data in order to empirically test the policy presumption that patents are a primary block, particularly in developing countries, for access to medicines on the WHO EML. In this report, we provide, in addition to an update of the Attaran analysis, a more thorough pool of patent data and information and a methodically detailed protocol. Both of these value-added features can then be used and refined in subsequent iterations of the EML patent analysis project.

The aggregate findings presented in this report and those of the previous work of Attaran are not inconsistent:[140] we estimate that approximately 5-6% of the 355 medicines on the WHO Essential Medicines List (EML) are still under patent (base patents for medicines), close to the Attaran estimate. It is important to note though, that this estimation is qualified, taking into account several assumptions that are outlined in the report. For example, ITTI was provided with a subset of the EML that followed the Attaran study, culling non-patented medicines and generating the group most likely to still be under patent; it was from this point that ITTI proceeded, reasonably relying on the integrity of this previous work. In addition, ITTI did not analyze the most recent updates to the EML, which became available in April 2011. It is also important to emphasize that solid research generally generates more questions than it answers, *e.g*., in this case, it would be interesting to know more about where, *i.e*., in which national jurisdictions, this subset of 5-6% are still under patent; that indeed is the challenge.

Although the data presented herein both builds on that of Dr. Attaran and supports his general conclusions, other aspects differ, in terms of methodology, presentation and availability of data, from this earlier work.[141] Whereas the Attaran and ITTI methodologies both initially analyzed the EML medicines for patents via searching of patent database platforms, Attaran subsequently assembled patent data and then approach the various patent portfolio owners (assignees) in order to procure a more complete data set; this served to solidify and verify core data. ITTI, however, did not take this step, albeit it was discussed and considered as a possible future addition to the overall methodology and protocol developed. However, unlike Attaran, ITTI has presented a highly detailed protocol for analyzing patent information related to the WHO EML; this can serve as a tool for subsequent development as well as an educational template for building capacity in the member states, particularly the developing countries of Asia, Africa and Latin America. Furthermore, the Attaran study did not provide highly in depth patent data; however the ITTI report provides layers of data that can be

[139] Attaran, Amir. "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" Health Affairs, 23(3), 155-66, 2003.
[140] Id.
[141] Id.

accessed, mined, analyzed and thereby utilized for many purposes, from policy to strategy to implementation.

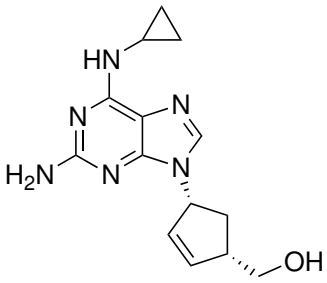
The results presented herein corroborate and support Attaran's general conclusion that patents, *per se*, might not be the principal, or even the secondary, obstacles for developing country access to the WHO EML medicines (with the possible exception of anti-retroviral medicines in some jurisdictions).[142] Perhaps there are other challenges conditioning global access that require more urgent attention, including, as Attaran pointed out, poverty.[143] In addition, investment and capacity building in domestic R&D capabilities, production capacity, delivery, storage infrastructure, as well as technology transfer will certainly serve to create sustainable systems for WHO EML access and distribution. Finally, if patents indeed are not the principal obstacle, then perhaps patent information, when assembled and analyzed, will in fact facilitate strategic management of patents towards accelerating global access to the EML medicines. Hence, and perhaps paradoxically, patents might not be part of the problem but rather a critical component of the solution.

[142] Attaran, Amir. "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?" Health Affairs, 23(3), 155-66, 2003.
[143] Id.

Individual Medicine Patent Information and Global Patent Trends[144]

Abacavir

Tablet: 300 mg (as sulfate)
Oral Liquid: 100 mg/5 mL (as sulfate)



Uses:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	{(1*S*,4*R*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]cyclopent-2-en-1-yl}methanol
CAS Number:	136470-78-5
Chemical Formula:	$C_{14}H_{18}N_6O$

Base Patent Info:

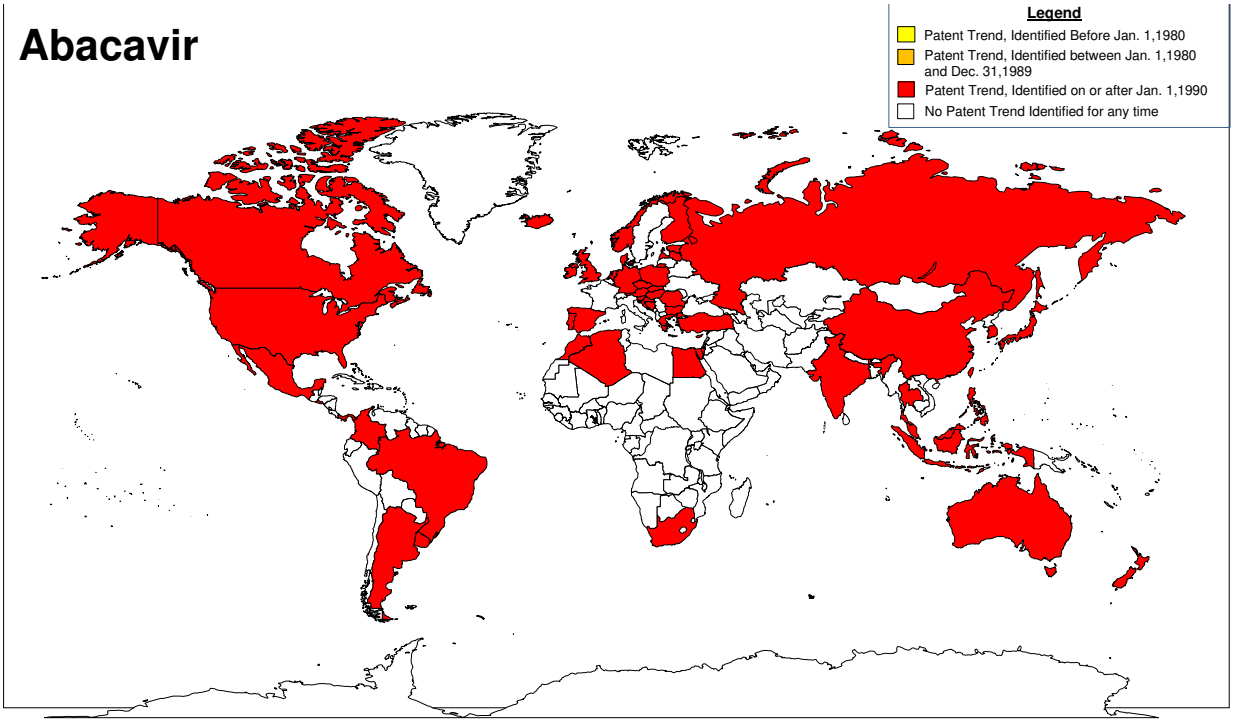
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5034394	Burroughs Wellcome, Co./USA	Burroughs Wellcome, Co./USA	Dec. 22, 1989

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5034394	Burroughs Wellcome, Co./USA	Smithkline Beecham Corp./USA	Dec. 22, 1989
US5047407	IAF BioChem International Inc./USA	Glaxo Wellcome Inc./USA	Feb. 8, 1989
US5089500	Burroughs Wellcome, Co./USA	Smithkline Beecham Corp./USA	May 8, 1991
US5905082	Glaxo Group LTD/GB	Glaxo Group LTD/GB	Jun. 2, 1992
US6294540	Glaxo Wellcome Inc./USA	Smithkline Beecham Corp./USA	Dec. 1, 1999
US6417191	GlaxoSmithKline/USA	Smithkline Beecham Corp./USA	Sept. 30, 1997
US6641843	GlaxoSmithKline/USA	Smithkline Beecham Corp./USA	Aug. 4, 2000
US7119202	Glaxo Wellcome Inc./USA	Glaxo Wellcome Inc./USA	Jun. 6, 1995

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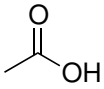
World Map Generated from Abacavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Acetic Acid

Topical: 2% in alcohol



Uses:	Irrigation of the bladder; periodic irrigation of indwelling catheters; treatment of superficial bacterial infections of the external auditory canal*
IUPAC Name:	Ethanoic Acid
CAS Number:	64-19-7
Chemical Formula:	$C_2H_4O_2$

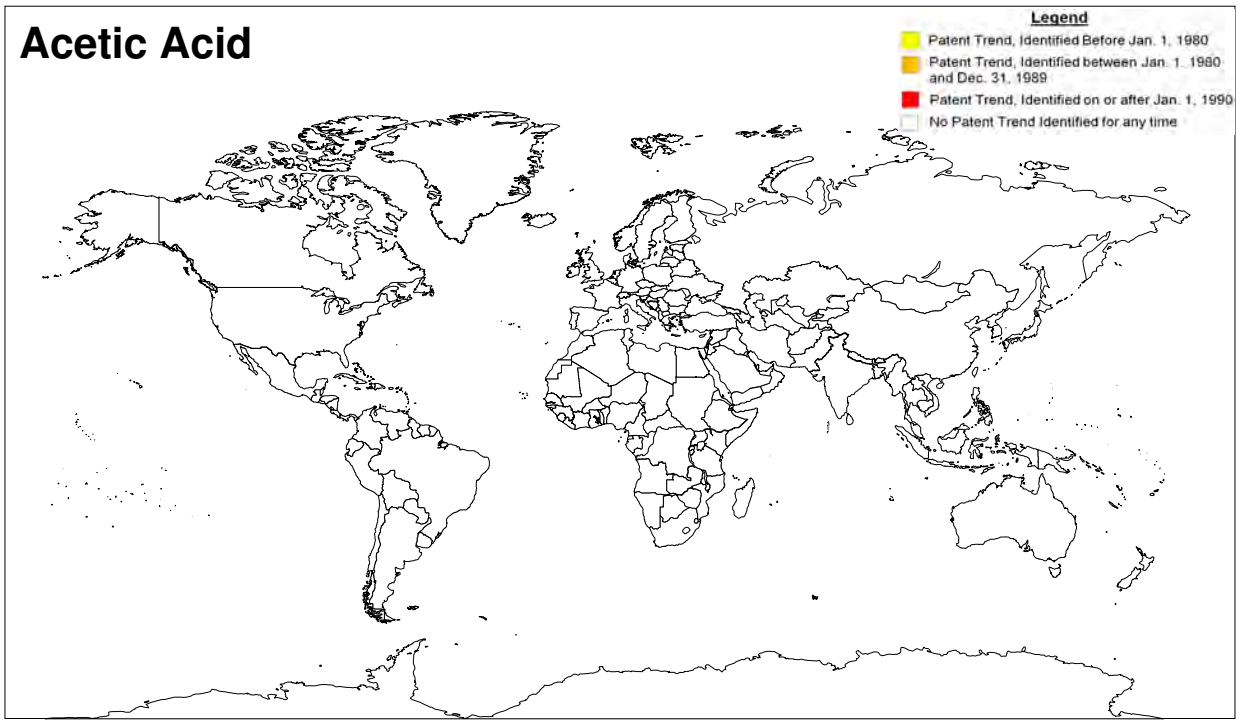
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Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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Orange Book Patent Info:

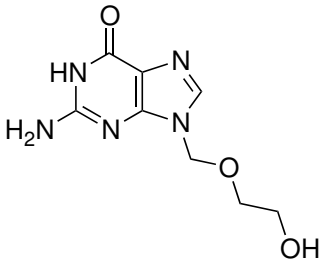
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Acetic Acid Family Data



Acyclovir

Ointment: 3%



Uses:	Treatment of genital herpes simplex virus (HSV), herpes labialis (cold sores), herpes zoster (shingles), HSV encephalitis, neonatal HSV, mucocutaneous HSV in immunocompromised patients, varicella-zoster (chickenpox)*
IUPAC Name:	2-amino-9-((2-hydroxyethoxy)methyl)-1H-purin-6(9H)-one
CAS Number:	64-19-7
Chemical Formula:	$C_8H_{11}N_5O_3$

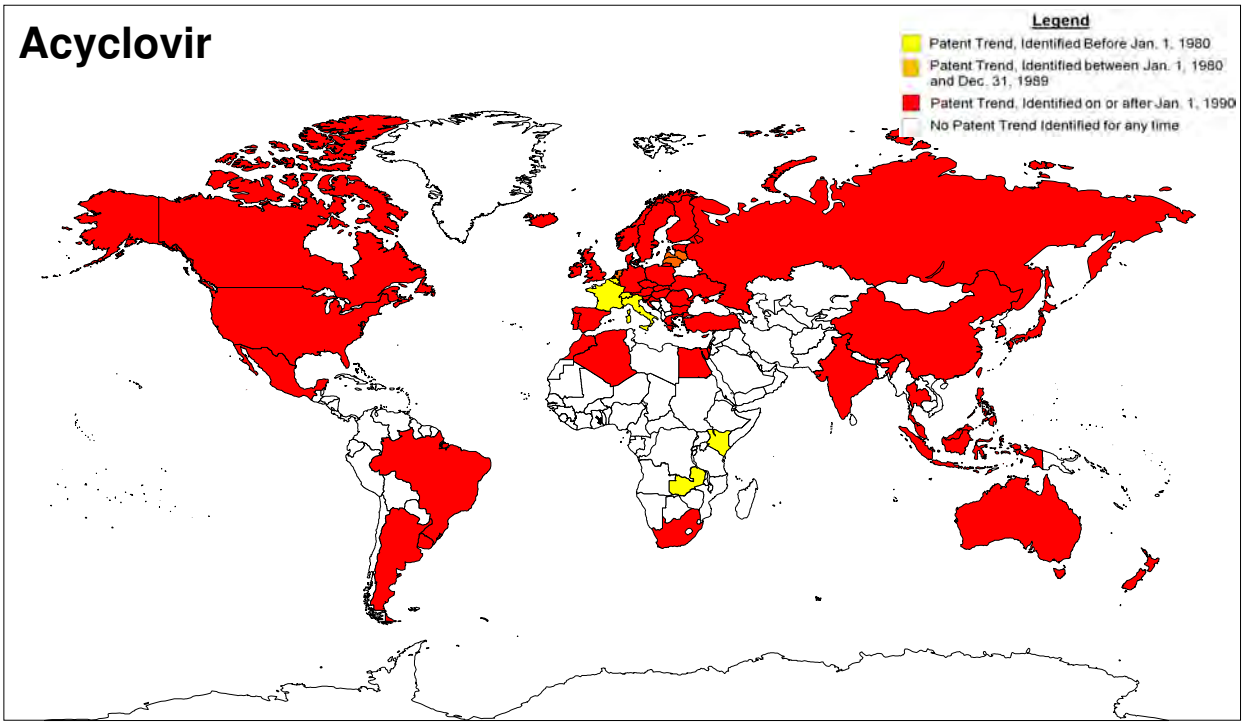
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Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4199574	Burroughs Wellcome Co./USA	Burroughs Wellcome Co./USA	Mar. 1, 1976

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4957924	Burroughs Wellcome Co./USA	Burroughs Wellcome Co./USA	Aug. 4, 1988
US5879706	Glaxo Wellcome Inc./USA	Glaxo Wellcome Inc./USA	Aug. 29, 1997
US6107302	Glaxo Wellcome Inc./USA	Glaxo Wellcome Inc./USA	Sept. 22, 1997
US6514980	Smithkline Beecham P.L.C./USA	Novartis International Pharmaceutical LTD/Bermuda	Jul. 26, 2000
US7223387	Medivir AB/Sweden	Medivir AB/Sweden	Dec. 30, 2002

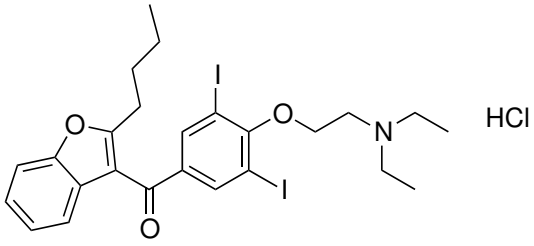
World Map Generated from Acyclovir Family Data



Regional Office	Patent Trend
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African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Amiodarone

Injection: 50 mg/mL, 100 mg/mL



Uses:	Management of life-threatening recurrent ventricular fibrillation (VF) or hemodynamically-unstable ventricular tachycardia (VT) refractory to other antiarrhythmic agents or in patients intolerant of other agents used for these conditions*
IUPAC Name:	(2-{4-[(2-butyl-1-benzofuran-3-yl)carbonyl]-2,6-diiodophenoxy}ethyl)diethylamine
CAS Number:	1951-25-3
Chemical Formula:	$C_{25}H_{29}I_2NO_3$

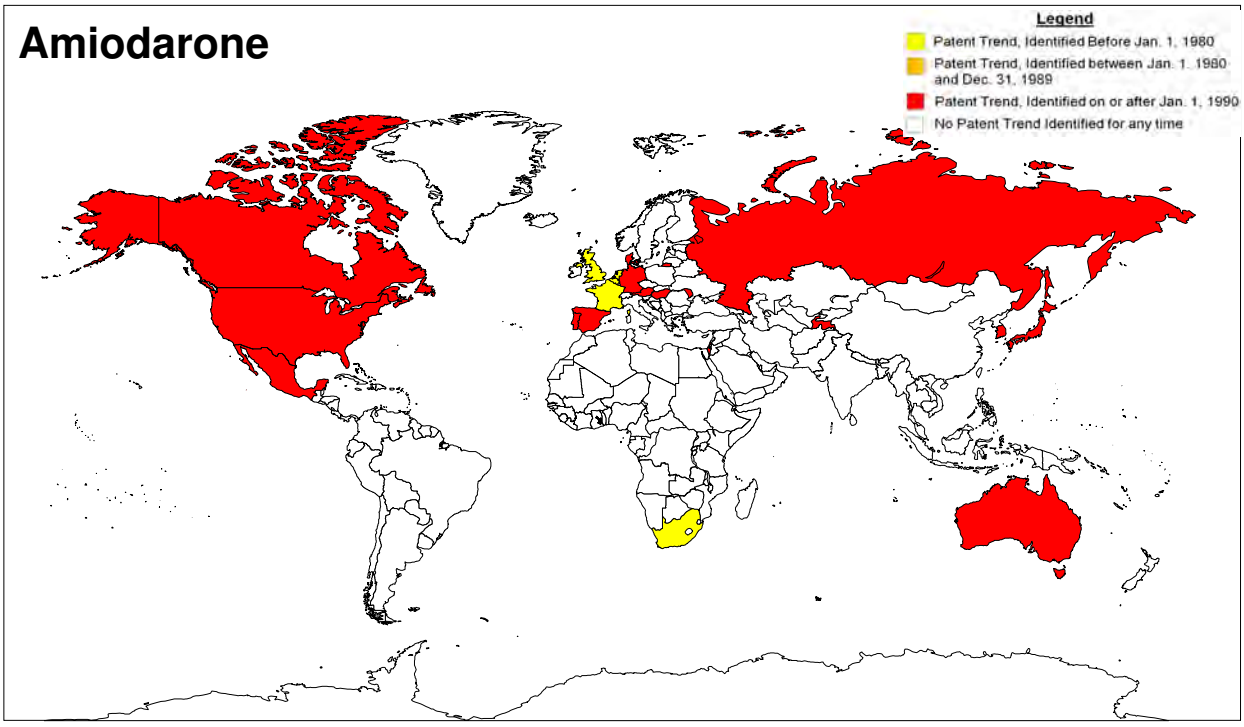
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3248401	Sodefe Beige de 1'Azate/Belgium	Sodefe Beige de 1'Azate/Belgium	Nov. 14, 1962

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5134127	University of Kansas/USA	National Institutes of Health/USA	Jan. 23, 1990
US5376645	University of Kansas/USA	University of Kansas/USA	Jul. 27, 1992
US6869939	Cydex, Inc./USA	CardioVascular Holdings, LLC/USA	May 4, 2002
US7635773	Cydex Pharmaceuticals, Inc./USA	Cydex Pharmaceuticals, Inc./USA	Mar. 13, 2009

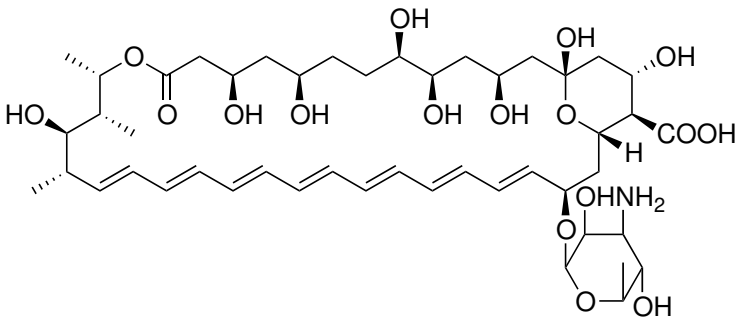
World Map Generated from Amiodarone Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Amphotericin B

Liposomal Formation



Uses:	life-threatening fungal infections including histoplasmosis, coccidioidomycosis, paracoccidioidomycosis, blastomycosis, aspergillosis, cryptococcosis, mucormycosis, sporotrichosis, and candidosis; leishmaniasis
IUPAC Name:	(1*R*,3*S*,5*R*,6*R*,9*R*, 11*R*,15*S*,16*R*,17*R*,18*S*,19*E*,21*E*, 23*E*,25*E*,27*E*,29*E*,31*E*,33*R*,35*S*,36*R*,37*S*)- 33-[(3-amino- 3,6-dideoxy- β-D-mannopyranosyl)oxy]- 1,3,5,6,9,11,17,37-octahydroxy- 15,16,18-trimethyl- 13-oxo- 14,39-dioxabicyclo [33.3.1] nonatriaconta-19,21,23,25,27,29,31-heptaene- 36-carboxylic acid
CAS Number:	1397-89-3
Chemical Formula:	$C_{47}H_{73}NO_{17}$

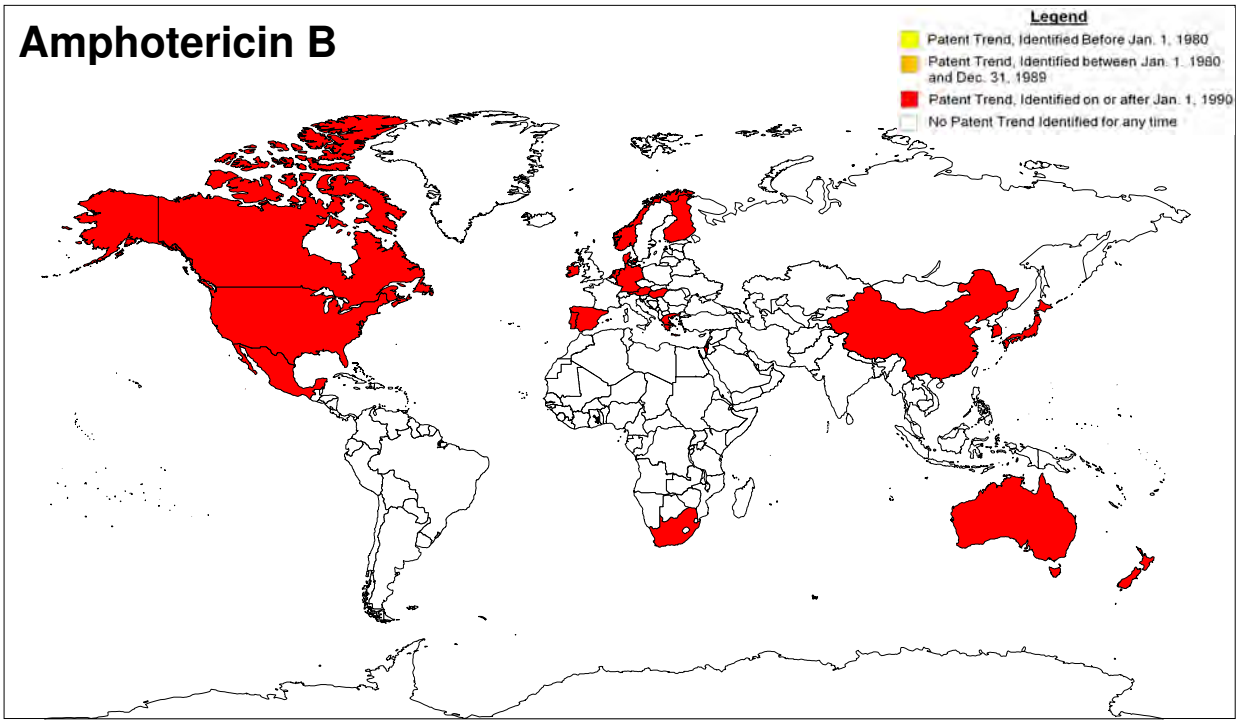
Base Patent Info:

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US2908611	Olin Mathieson/ USA	Olin Mathieson/ USA	Dec. 28, 1954

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5616334	Liposome Company, Inc./USA	Enzon, Inc./USA	Apr. 28, 1995
US5874104	Vestar, Inc./USA	Nexstar Pharmaceuticals, Inc./USA	Jun. 6, 1995
US5965156	Vestar, Inc./USA	Nexstar Pharmaceuticals, Inc./USA	Jun. 6, 1995
US6406713	Liposome Company, Inc./USA	Defiante Farmaceutica, S.A./Portugal	Apr. 28, 1995

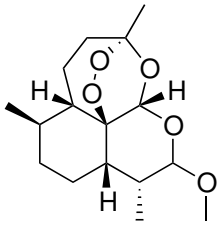
World Map Generated from Amphotericin B Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Artemether

Injection: 80 mg/mL in mL ampoule



Uses:	Treatment of severe *P. falciparum* malaria in areas where quinine is Ineffective
IUPAC Name:	(+)-(3-alpha,5a-beta,6-beta,8a-beta, 9-alpha,12-beta,12aR)-decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano(4,3-j)-1,2-benzodioxepin
CAS Number:	71963-77-4
Chemical Formula:	$C_{16}H_{26}O_5$

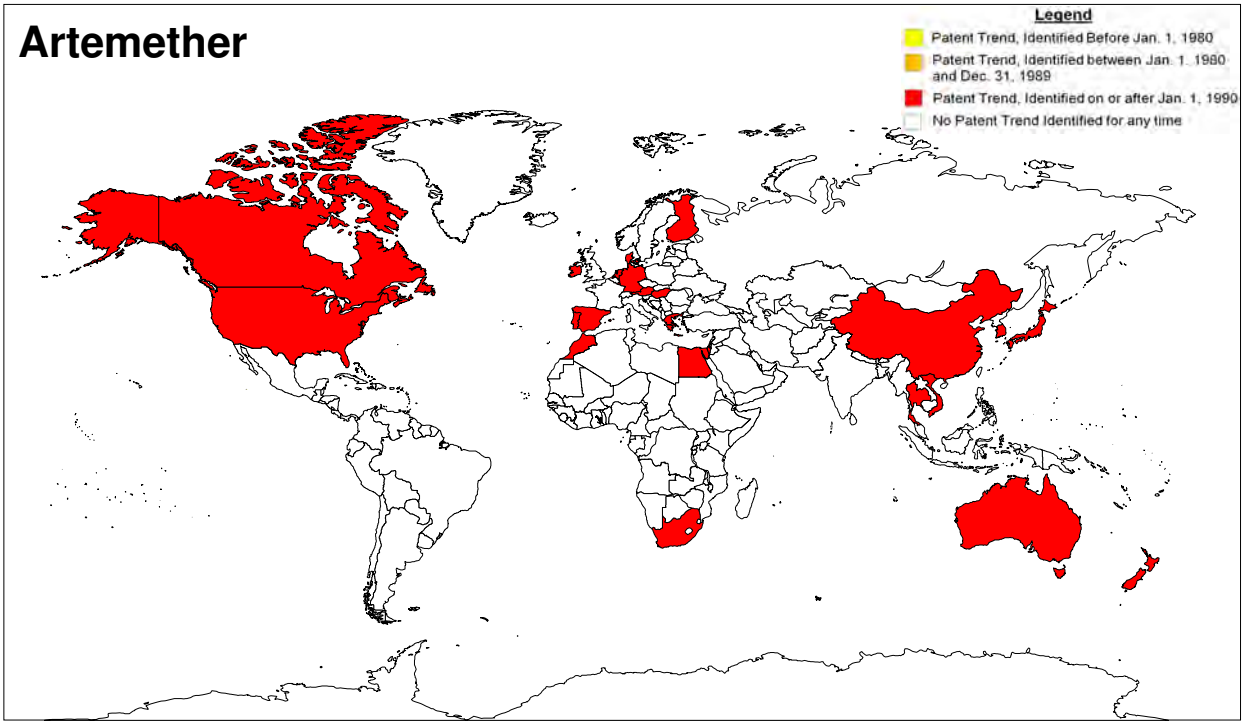
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5677331	Institute of Microbiology and Epidemiology, China/ Ciba-Geigy, AG	Novartis AG/Switzerland	Mar. 23, 1994

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5677331	Institute of Microbiology and Epidemiology/China; Ciba-Geigy, AG/Switzerland	Novartis AG/Switzerland	Mar. 23, 1994

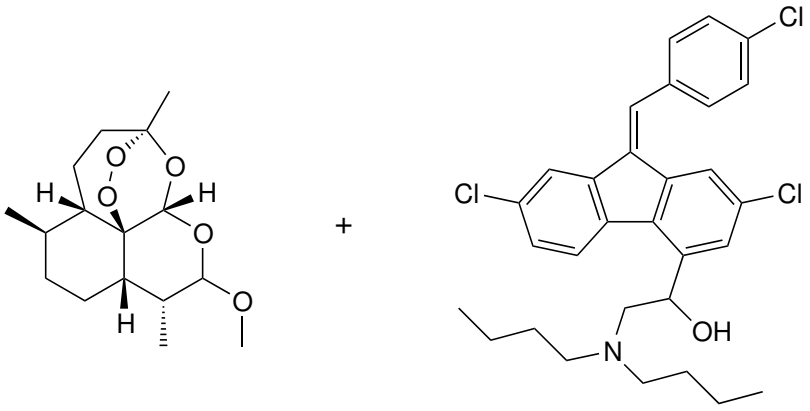
World Map Generated from Artemether Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Artemether + Lumefantrine

Tablet: 20 mg + 120 mg



Uses:	Treatment of uncomplicated malaria caused by *P. falciparum* alone or with other *Plasmodium* spp. in areas with significant medicine resistance
IUPAC Name:	(+)-(3-alpha,5a-beta,6-beta,8a-beta, 9-alpha,12-beta,12aR)-decahydro-10-methoxy-3,6,9-trimethyl-3,12-epoxy-12H-pyrano(4,3-j)-1,2-benzodioxepin; 2-(dibutylamino)-1-[(9*E*)-2,7-dichloro-9-(4-chlorobenzylidene)-9*H*-fluoren-4-yl]ethanol
CAS Number:	71963-77-4; 82186-77-4
Chemical Formula:	$C_{16}H_{26}O_5$; $C_{30}H_{32}C_{l3}NO$

Base Patent For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

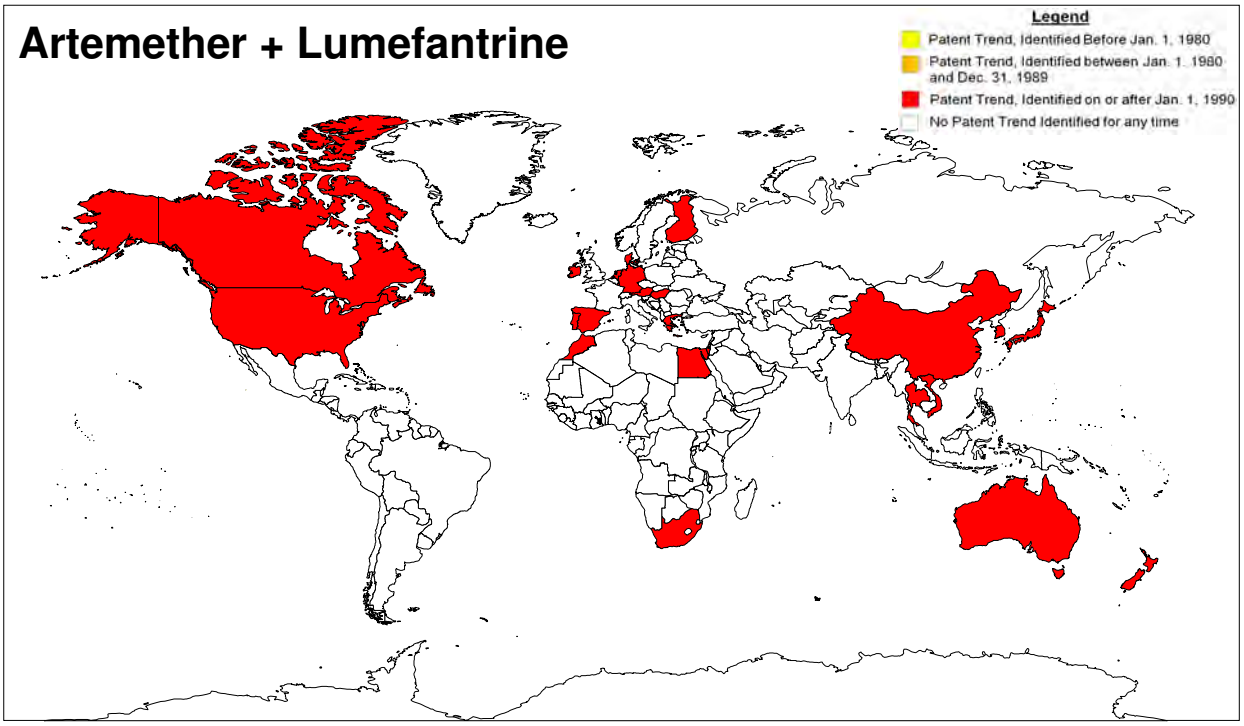
Base Patents For Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
Artemether: US5677331	Institute of Microbiology and Epidemiology, China/ Ciba-Geigy, AG	Novartis AG/Switzerland	Mar. 23, 1994
Lumefantrine: CN1042535C	Eli Lilly & Co.	Eli Lilly & Co.	Feb. 7, 1994

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5677331	Institute of Microbiology and Epidemiology, China; Ciba-Geigy, AG/Switzerland	Novartis AG/Switzerland	Mar. 23, 1994

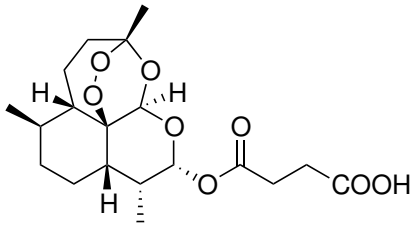
World Map Generated from Artemether + Lumefantrine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Artesunate

Tablet: 50 mg
Injection: 60 mg with separate ampoule of 5% sodium bicarbonate
Rectal Capsule: 50 mg, 200 mg



Uses:	Treatment of uncomplicated malaria caused by *P. falciparum* in combination with other antimalarials; Treatment of severe malaria in areas where quinine is ineffective.
IUPAC Name:	4-oxo-4-(((3*R*,5a*S*,6*R*,8a*S*,9*R*,10*R*,12*R*,12a*R*)-3,6,9-trimethyldecahydro-3*H*-3,12-epoxy[1,2]dioxepino[4,3-*i*]isochromen-10-yl)oxy)butanoic acid
CAS Number:	88495-63-0
Chemical Formula:	$C_{19}H_{28}O_8$

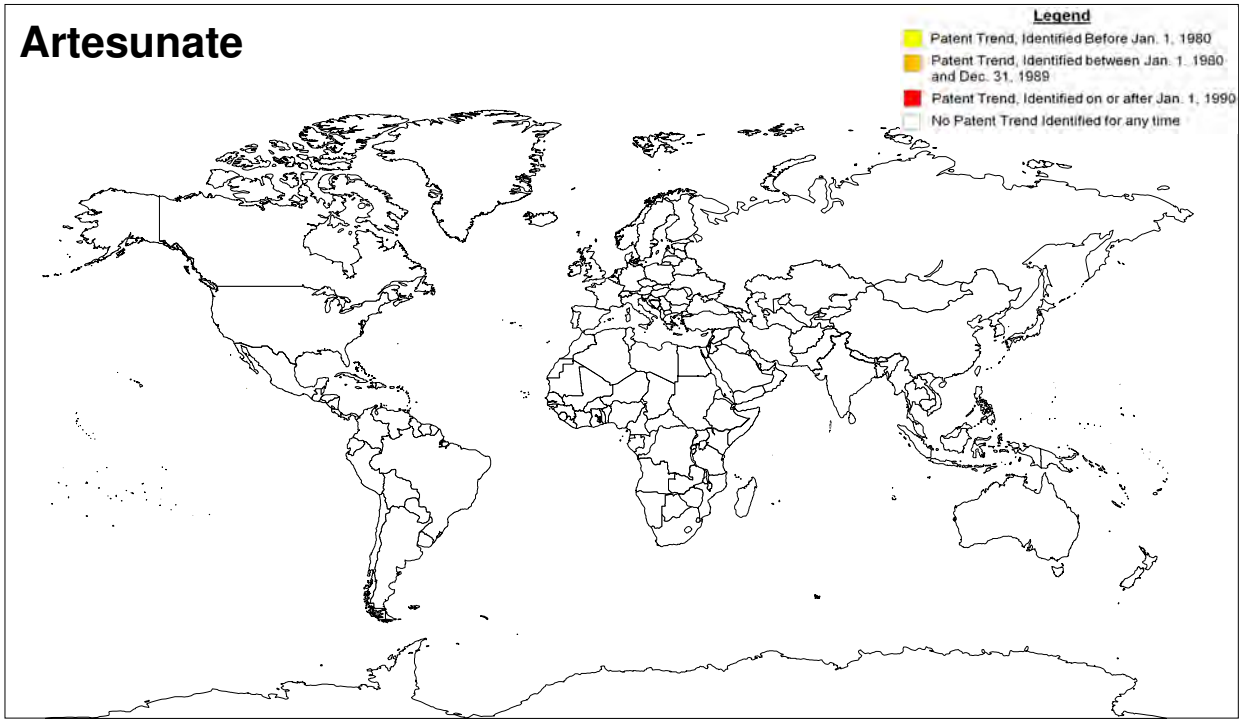
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Orange Book Patent Info:

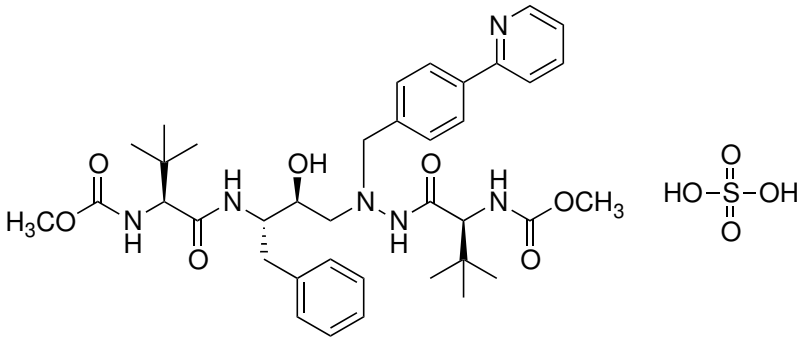
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Artesunate Family Data



Atazanavir

Solid Oral Form: 100 mg, 150 mg, 300 mg



Uses:	Treatment of HIV-1 infections in combination with at least two other antiretroviral agents*
IUPAC Name:	methyl *N*-[(1*S*)-1-{[(2*S*,3*S*)-3-hydroxy-4-[(2*S*)-2-[(methoxycarbonyl)amino]-3,3-dimethyl-*N*'-{[4-(pyridin-2-yl)phenyl]methyl}butanehydrazido]-1-phenylbutan-2-yl]carbamoyl}-2,2-dimethylpropyl]carbamate
CAS Number:	198904-31-3
Chemical Formula:	$C_{38}H_{52}N_6O_7$

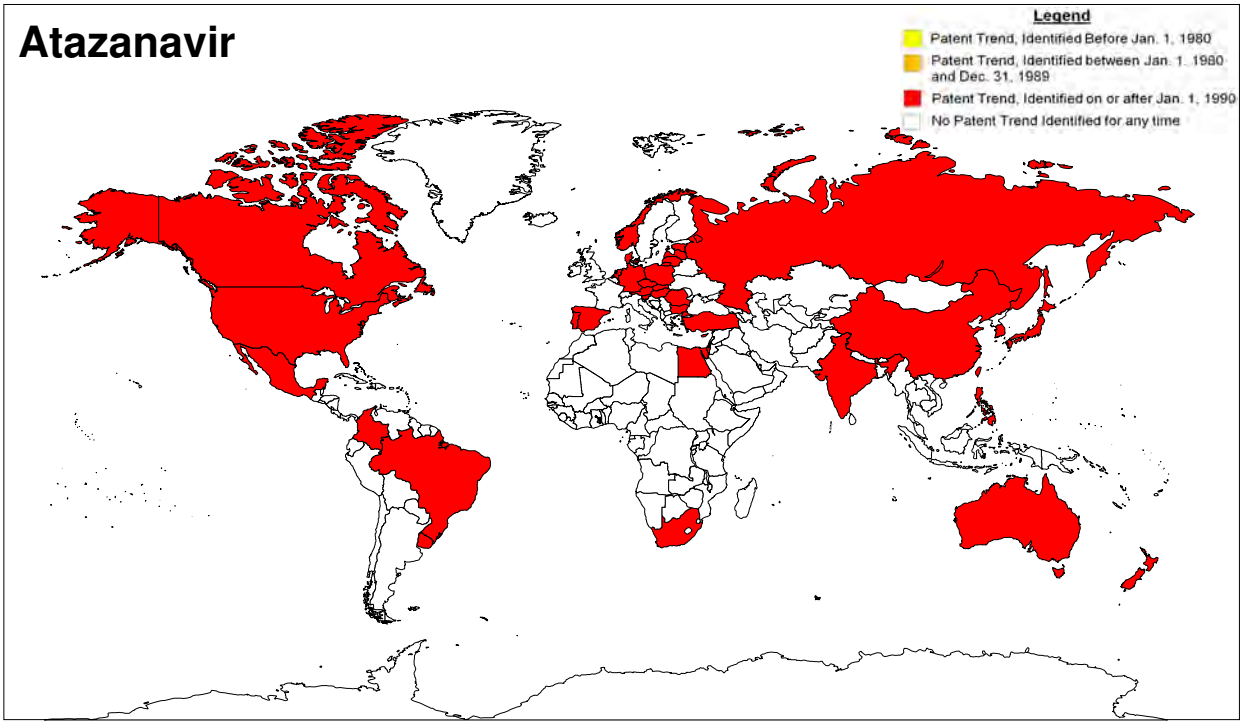
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5849911	Novartis Finance Corp/USA	Novartis Finance Corp/USA	Apr. 9, 1997

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5849911	Novartis Finance Corp/USA	Novartis Finance Corp/USA	Apr. 9, 1997
US6087383	Bristol-Myers Squibb Co./USA	Bristol-Myers Squibb Co./USA	Dec. 21, 1998

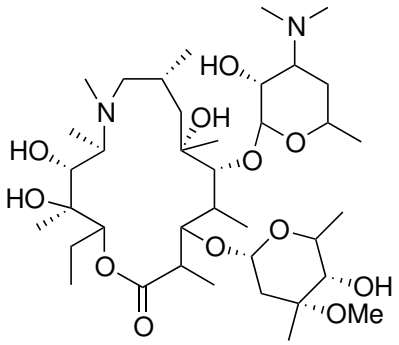
World Map Generated from Atazanavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Azithromycin

Zithromax



Uses:	Uncomplicated genital chlamydial infections and trachoma.
IUPAC Name:	(2*R*,3*S*,4*R*,5*R*,8*R*,10*R*,11*R*,12*S*,13*S*,14*R*)-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-15-oxo- 11-{[3,4,6-trideoxy-3-(dimethylamino)-β-D-*xylo*-]oxy}-1-oxa-6-azacyclopentadec-13-yl 2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranoside
CAS Number:	83905-01-5
Chemical Formula:	$C_{38}H_{72}N_2O_{12}$

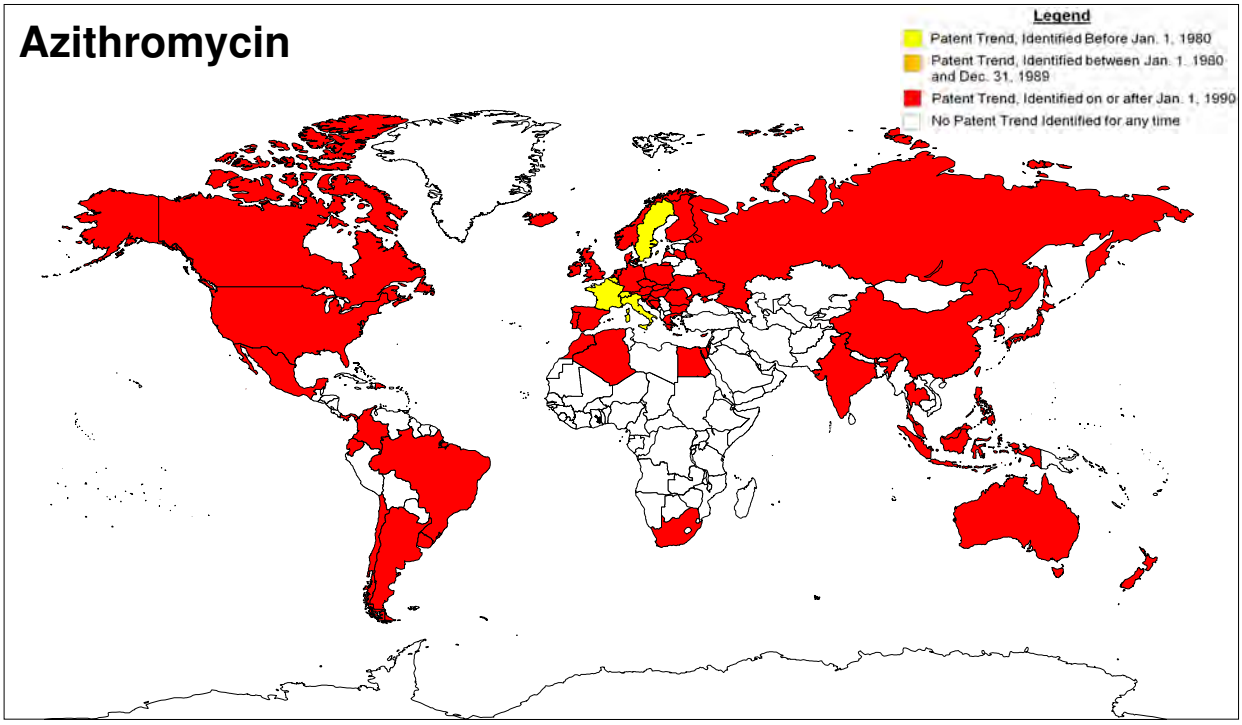
Base Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4517359	Sour Pliva farmaceutska	Pliva Pharm. & Chem. Works	Sept. 22, 1981

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5192535	Insite Vision Inc./USA	Insite Vision Inc./USA	Jun. 27, 1990
US6068859	Pfizer, Inc./USA	Pfizer, Inc./USA	Nov. 4, 1996
US6159458	Insite Vision/ USA	Insite Vision Inc./USA	Nov. 4, 1997
US6239113	Insite Vision Inc./USA	Insite Vision Inc./USA	Jul. 2, 1999
US6268489	Pfizer, Inc./USA	Pfizer, Inc./USA	Dec. 21, 1992
US6569443	Insite Vision Inc./USA	Insite Vision Inc./USA	Jan. 24, 2001
US6861411	Pfizer, Inc./USA	Pfizer, Inc./USA	Nov. 25, 1998
US6984403	Pfizer, Inc./USA	Pfizer, Inc./USA	Jan. 23, 2004
US7056893	Insite Vision Inc./USA	Insite Vision Inc./USA	Jun. 4, 2002

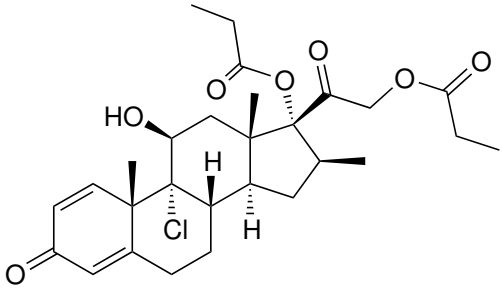
World Map Generated from Azithromycin Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Beclomethasone

10 ∝g/inhaled dose



Uses:	Mild, moderate, or severe persistent asthma relief
IUPAC Name:	(8*S*,9*R*,10*S*,11*S*,13*S*,14*S*,16*S*,17*R*)-9-chloro-11-hydroxy-10,13,16-trimethyl-3-oxo-17-[2-(propionyloxy)acetyl]-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3*H*-cyclopenta[*a*]phenanthren-17-yl propionate
CAS Number:	4419-39-0
Chemical Formula:	$C_{28}H_{37}ClO_7$

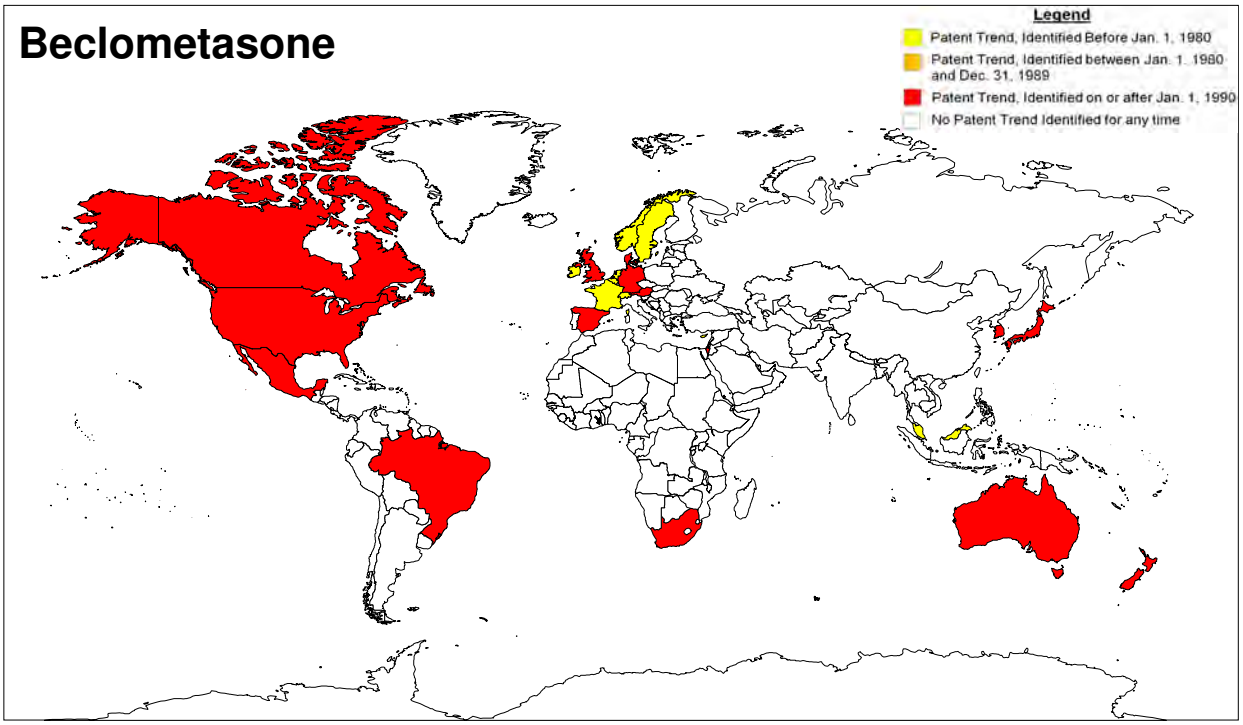
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3312590	Glaxo Labs Ltd./U.S.	Glaxo Labs, Ltd./U.S.	Jun. 9, 1964

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5605674	Riker Laboratories, Inc./USA	3M Innovative Properties Co./USA	May 31, 1995
US5683677	Riker Laboratories, Inc./USA	3M Innovative Properties Co./USA	May 31, 1995
US5695743	Riker Laboratories, Inc./USA	3M Innovative Properties Co./USA	Mar. 4, 1993
US5766573	Riker Laboratories, Inc./USA	3M Innovative Properties Co./USA	Jan. 16, 1997
US5776432	3M Innovative Properties Co./USA	Ivax Corp./USA	May 31, 1995
US6352684	Riker Laboratories, Inc./USA	3M Innovative Properties Co./USA	Apr. 28, 1998

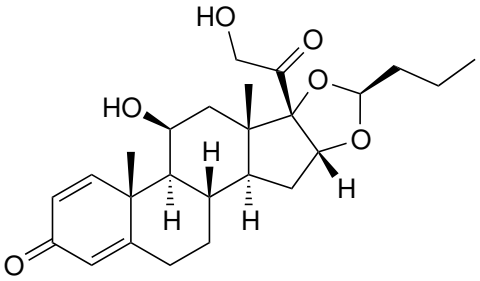
World Map Generated from Beclomethasone Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Budesonide

Nasal spray/100 µg per dose



Use:	Management of symptoms of seasonal or perennial rhinitis.
IUPAC Name:	16,17-(butylidenebis(oxy))-11,21-dihydroxy-, (11-β,16-α)-pregna-1,4-diene-3,20-dione
CAS Number:	51333-22-3
Chemical Formula:	$C_{25}H_{34}O_6$

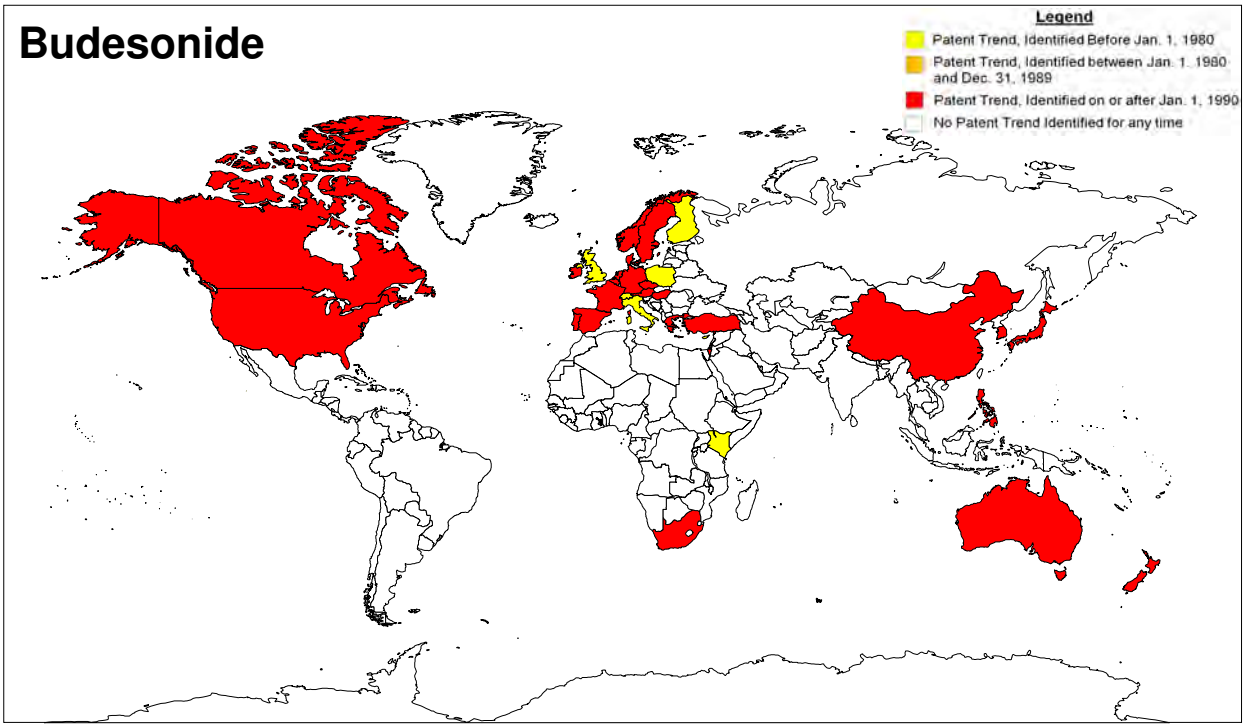
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3929768	Aktiebolaget Bofors/Sweden	Aktiebolaget Bofors/Sweden	May 14, 1973

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US6291445	Astrazeneca / Sweden	Astrazeneca / Sweden	Apr. 29, 1997
US6686346	Astra Aktiebolag / Sweden	Astra Aktiebolag / Sweden	Aug. 20, 2001
US6986904	Astra Aktiebolag / Sweden	Astra Aktiebolag / Sweden	Nov. 17, 2003

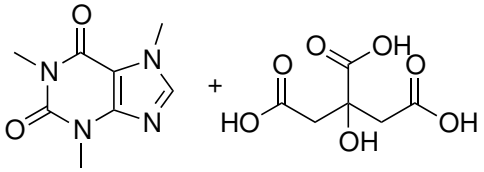
World Map Generated from Budesonide Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Caffeine Citrate

Injection/20mg per ml; oral liquid/20mg per ml



Use:	Neonatal apnoea in preterm infants
IUPAC Name:	1,3,7-trimethylpurine-2,6-dione; 2-hydroxypropane-1,2,3-tricarboxylic acid
CAS Number:	62-22-7, 58-08-2, 77-92-9
Chemical Formula:	$C_8H_{10}N_4O_2*C_6H_8O_7$

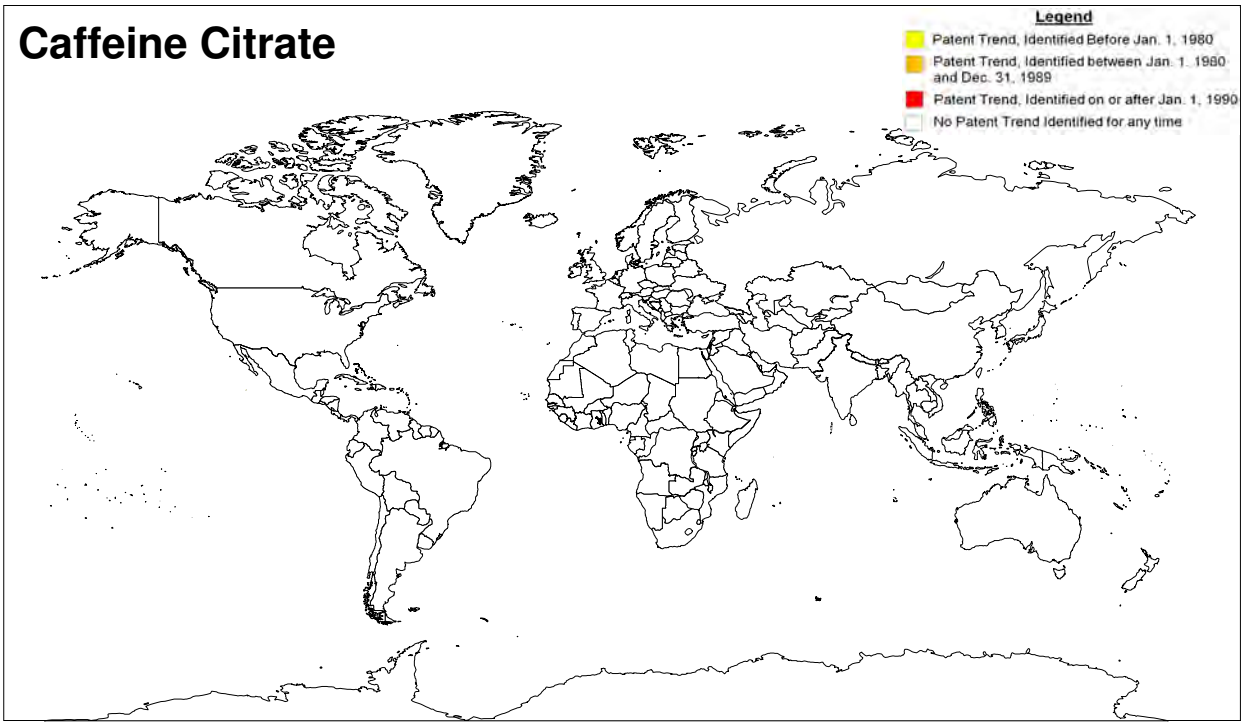
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

Orange Book Patents:

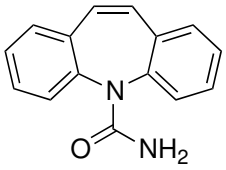
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Caffeine Citrate Family Data



Carbamazepine

Tablets: 100 mg, 200 mg
Oral liquid: 100 mgl 5 ml



Use:	Generalized tonic-clonic and partial seizures; trigeminal neuralgia; bipolar disorder
IUPAC Name:	5H-dibenzazepine-5-carboxamide
CAS Number:	298-46-4
Chemical Formula:	$C_{15}H_{12}N_2O$

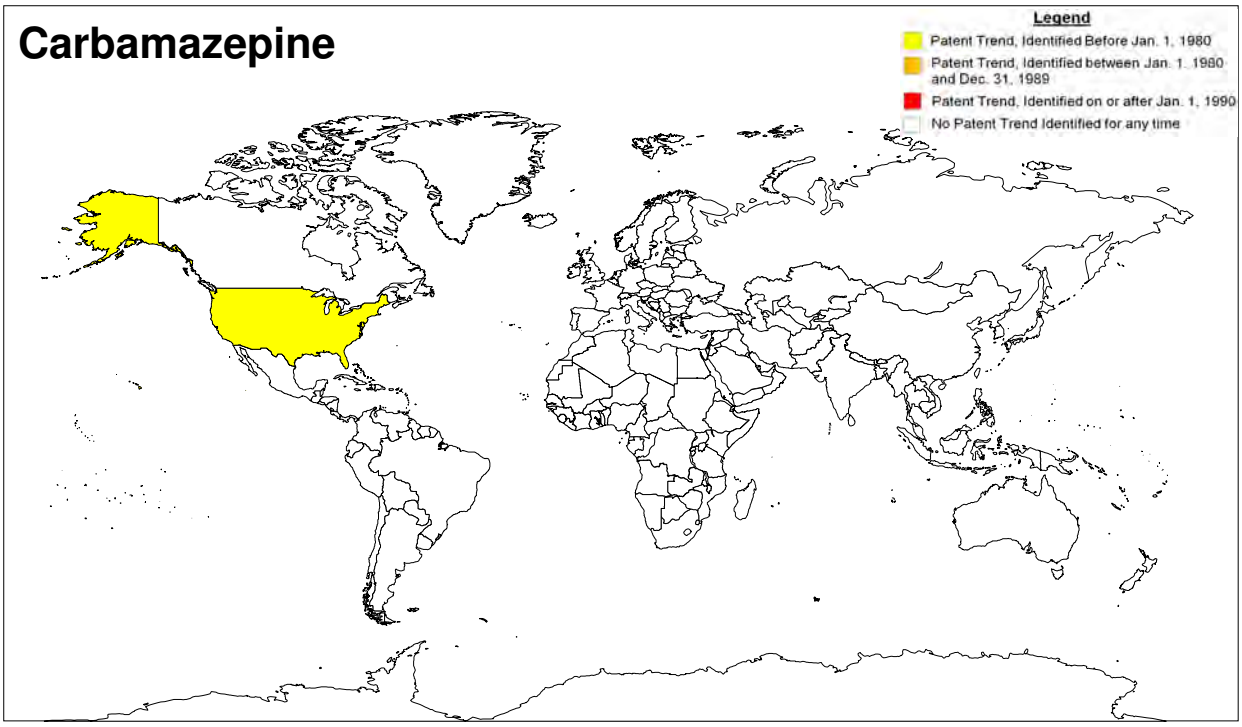
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2948718	Gelgy Chemical Corp./U.S.	Gelgy Chemical Corp./U.S.	Nov. 20, 1958

Orange Book Patents:

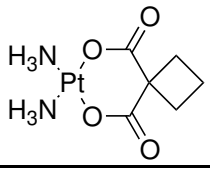
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Carbamazepine Family Data



Carboplatin

Injection: 50 mg/ ml, 150 mg/15 ml, 450 mg/45 ml,
600 mg/60 ml



Use:	Treatment of advanced ovarian cancer.
IUPAC Name:	*cis*-diammine(cyclobutane-1,1-dicarboxylate-*O*,*O*')platinum(II)
CAS Number:	41575-94-9
Chemical Formula:	$C_6H_{12}N_2O_4$

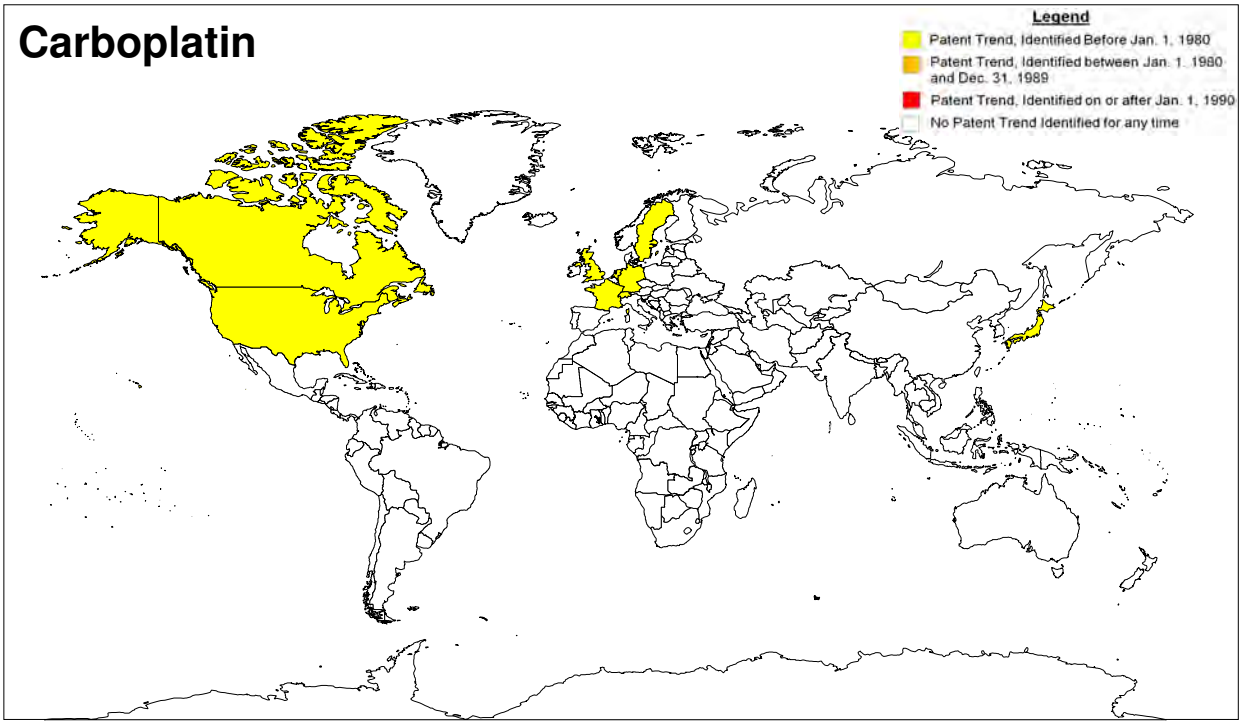
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4140707	Research Corp./U.S.	Research Corp. Technologies, Inc./U.S.	Mar. 18, 1977

Orange Book Patents:

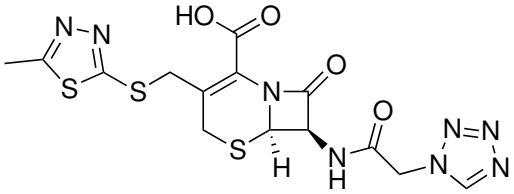
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Carboplatin Family Data



Cefazolin

Injection / 1g (as sodium salt) in vial



Use:	Prophylaxis of infection in surgery
IUPAC Name:	(6*R*,7*R*)-3-{[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl}-8-oxo-7-[(1*H*-tetrazol-1-ylacetyl)amino]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid
CAS Number:	25953-19-9
Chemical Formula:	$C_{14}H_{14}N_8O_4S_3$

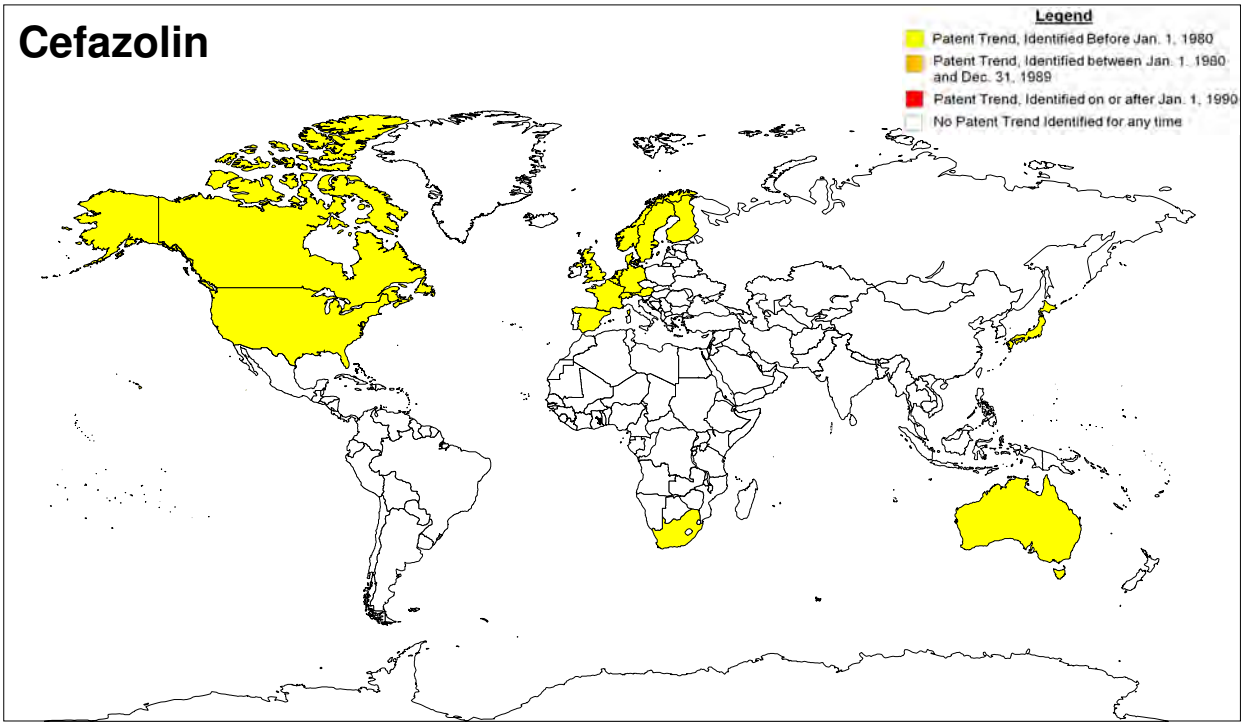
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3516997	Fujisawa Pharmaceutical Co./Japan	Fujisawa Pharmaceutical Co./Japan	Apr. 12, 1968

Orange Book Patents:

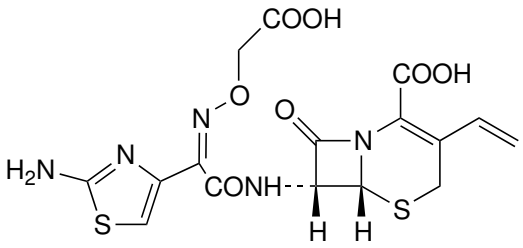
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Cefazolin Family Data



Cefixime

Capsule: 400 mg
Tablet: 400 mg



Use:	Cefalosporin hypersensitivity
IUPAC Name:	(6*R*,7*R*)-7-{[2-(2-amino-1,3-thiazol-4-yl)-2-(carboxymethoxyimino)acetyl]amino}-3-ethenyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid
CAS Number:	79350-37-1
Chemical Formula:	$C_{16}H_{15}N_5O_7S_2$

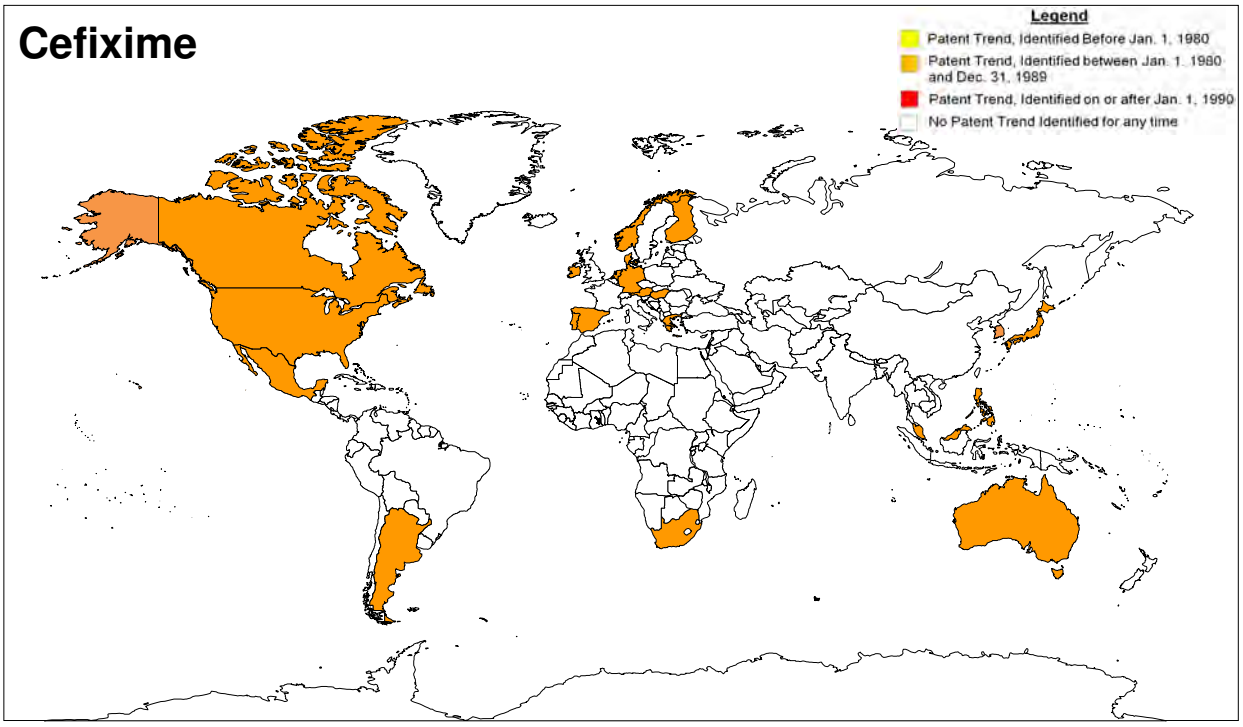
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4409214	Fujisawa Pharmaceutical Co./Japan	Fujisawa Pharmaceutical Co./Japan	Nov. 10, 1980

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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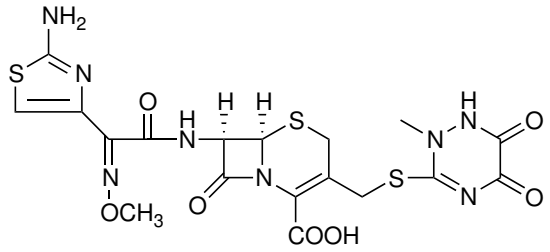
World Map Generated from Cefixime Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Ceftriaxone

Capsule: 400 mg



Use:	Serious infections due to sensitive bacteria, including septicaemia, pneumonia, and meningitis; osteomyelitis, septic arthritis; *Haemophilus influenzae* epiglottis; surgical prophylaxis; prophylaxis of meningococcal meningitis; shigellosis, invasive salmonellosis; endocarditis; gonococcal conjunctivitis; gonorrhoea; pelvic inflammatory disease; Lyme disease
IUPAC Name:	(6*R*,7*R*)-7-{[(2*Z*)-2-(2-amino-1,3-thiazol-4-yl)->2-(methoxyimino)acetyl]amino}-3-{[(2-methyl-5,6-dioxo-1,2,5,6-tetrahydro-1,2,4-triazin-3-yl)thio]methyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid
CAS Number:	73384-59-5
Chemical Formula:	$C_{18}H_{18}N_8O_7S_3$

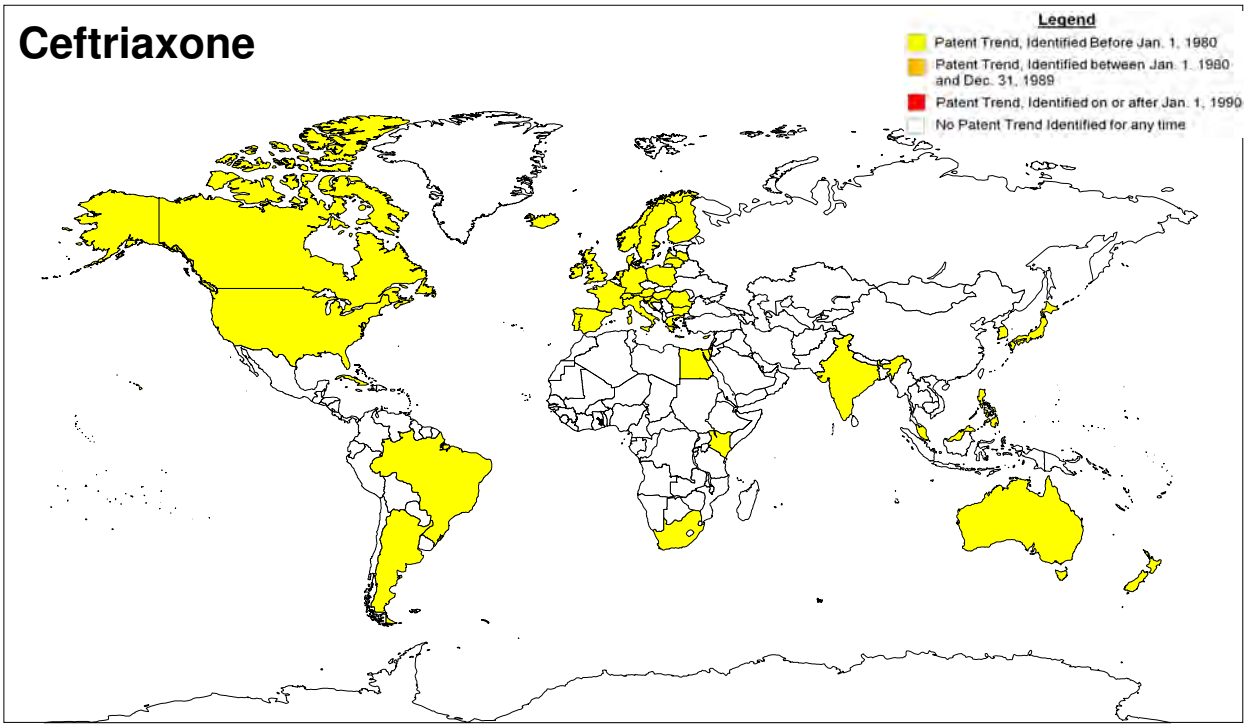
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4327210	Hoffman-LaRoche, Inc/U.S.	Hoffman-LaRoche, Inc./U.S.	Nov. 24, 1978

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

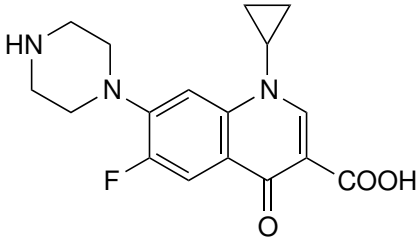
World Map Generated from Ceftriaxone Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan.1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified before Jan.1,1980
Gulf Cooperation Council	
World Intellectual Property Organization	

Ciprofloxacin

Topical: 0.3% drops



Use:	Gastroenteritis—including cholera, shigellosis, travellers' diarrhoea, campylobacter and salmonella enteritis; typhoid; gonorrhoea; chancroid; pelvic inflammatory disease (with doxycycline and metronidazole); legionnaires' disease; meningitis (including meningococcal meningitis prophylaxis); respiratory-tract infections—including pseudomonal infections in cystic fibrosis, but not pneumococcal pneumonia; urinary-tract infections; bone and joint infections; septicaemia; anthrax; skin infections; otitis externa; prophylaxis in surgery
IUPAC Name:	1-cyclopropyl- 6-fluoro- 4-oxo- 7-piperazin- 1-yl- quinoline- 3-carboxylic acid
CAS Number:	85721-33-1
Chemical Formula:	$C_{17}H_{18}FN_3O_3$

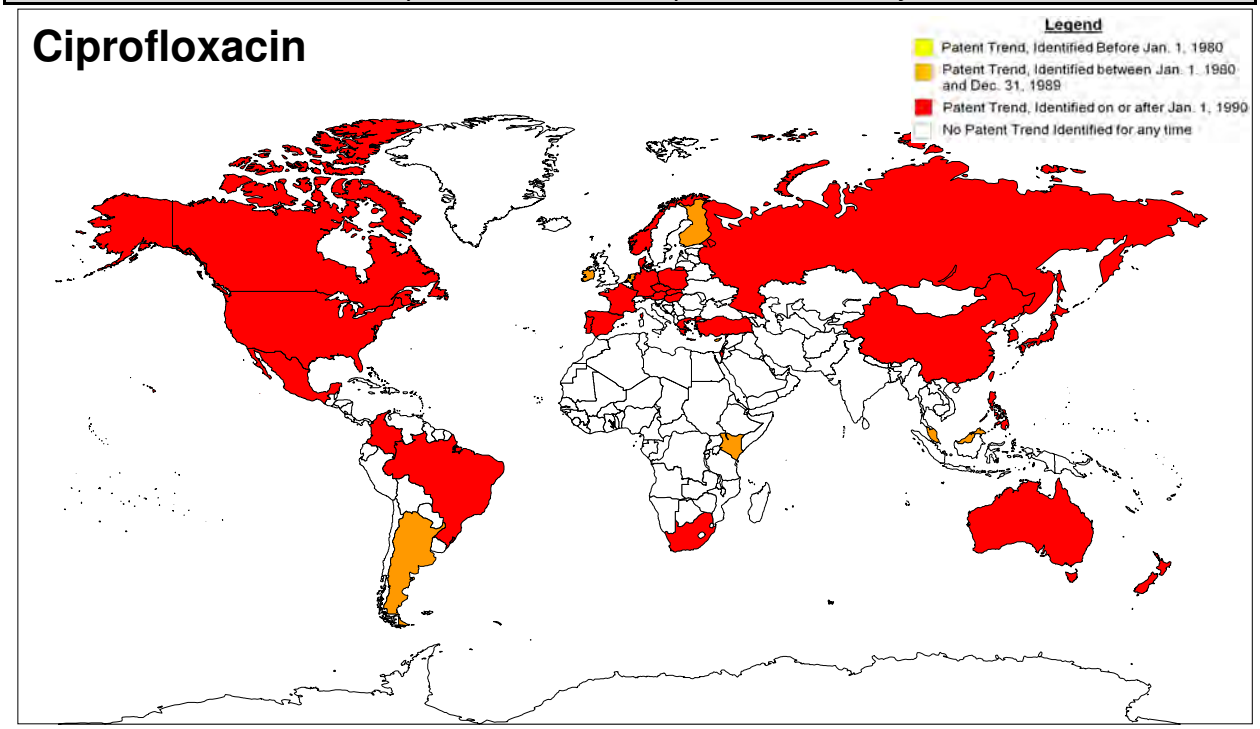
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4670444	Bayer Aktiengesellschaft/Germany	Bayer Aktiengesellschaft/Germany	May 29, 1984

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5843930	Bayer Corp./U.S.	Bayer Corp./U.S.	Apr. 7, 1997
US5965549	Bayer Healthcare/Germany	Bayer Healthcare/Germany	Feb. 18, 1997
US6284804	Alcon/Switzerland	Alcon/Switzerland	Aug. 10, 2000
US6359016	Alcon/Switzerland	Alcon/Switzerland	May 25, 2001
US5695784	Bayer AG/Germany	Bayer AG/Germany	Feb. 4, 1994
US6136347	Bayer Healthcare/Germany	Bayer Healthcare/Germany	May 4, 1996

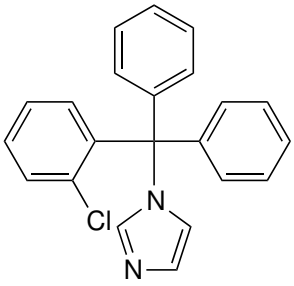
World Map Generated from Ciprofloxacin Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Clotrimazole

Powder for injection: 250 mg, 1 g (as sodium salt) in vial
Cream: 1%, 10%
Tablet: 100 mg, 500 mg



Use:	Anogenital candidosis
IUPAC Name:	1-[(2-chlorophenyl)(diphenyl)methyl]-1*H*-imidazole
CAS Number:	23593-75-1
Chemical Formula:	$C_{22}H_{17}ClN_2$

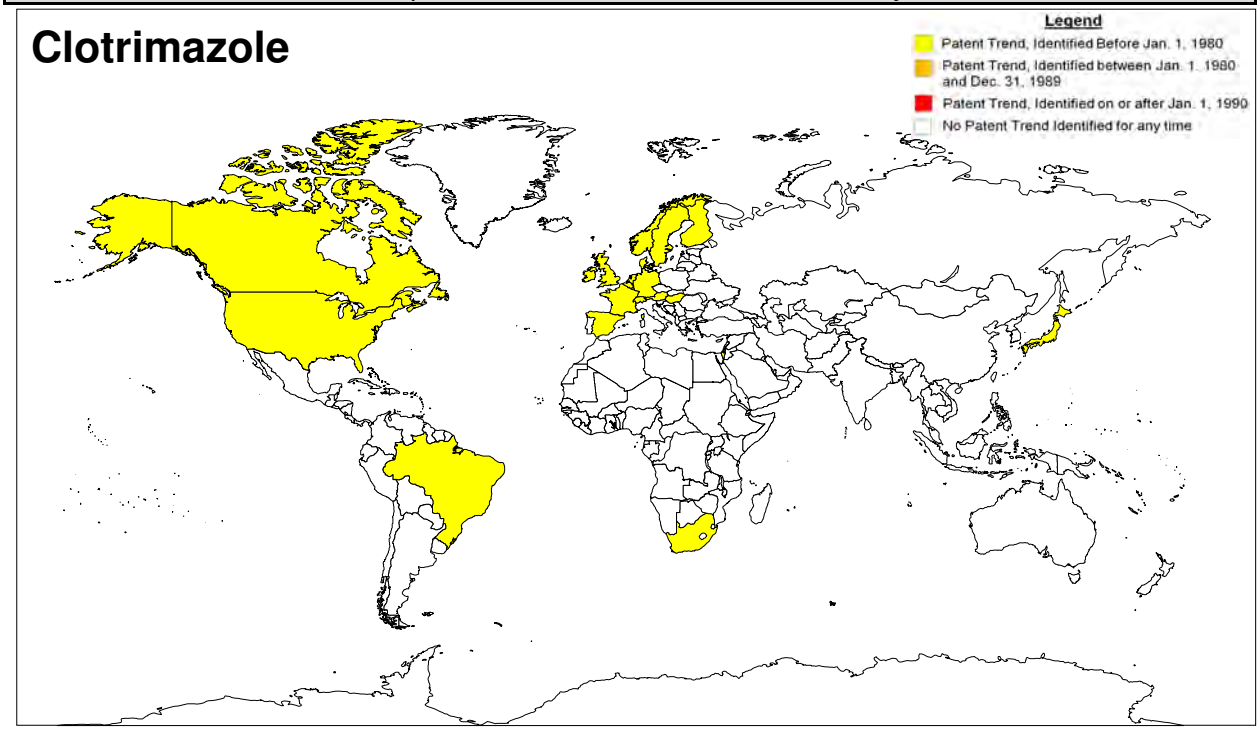
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3660577	Bayer AG/Germany	Bayer AG/Germany	Sept. 1, 1968

Orange Book Patents:

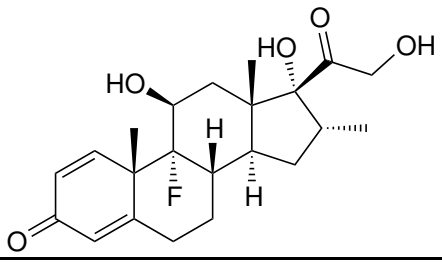
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Clotrimazole Family Data



Dexamethasone

Oral Solid: 0.5 mg, 1.5 mg, 4 mg;
Oral Liquid: 0.5 mg/5 mL;
Injection: 4 mg/mL



Use:	adjunct in the emergency treatment of anaphylaxis; short-term suppression of inflammation in allergic disorders; for other indications, treatment of malignant neoplasms.
IUPAC Name:	(8*S*,9*R*,10*S*,11*S*,13*S*,14*S*,16*R*,17*R*)-9-fluoro-11,17-dihydroxy-17-(2-hydroxyacetyl)-10,13,16-trimethyl-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-3*H*-cyclopenta[*a*]phenanthren-3-one
CAS Number:	50-02-2
Chemical Formula:	$C_{22}H_{29}FO_5$

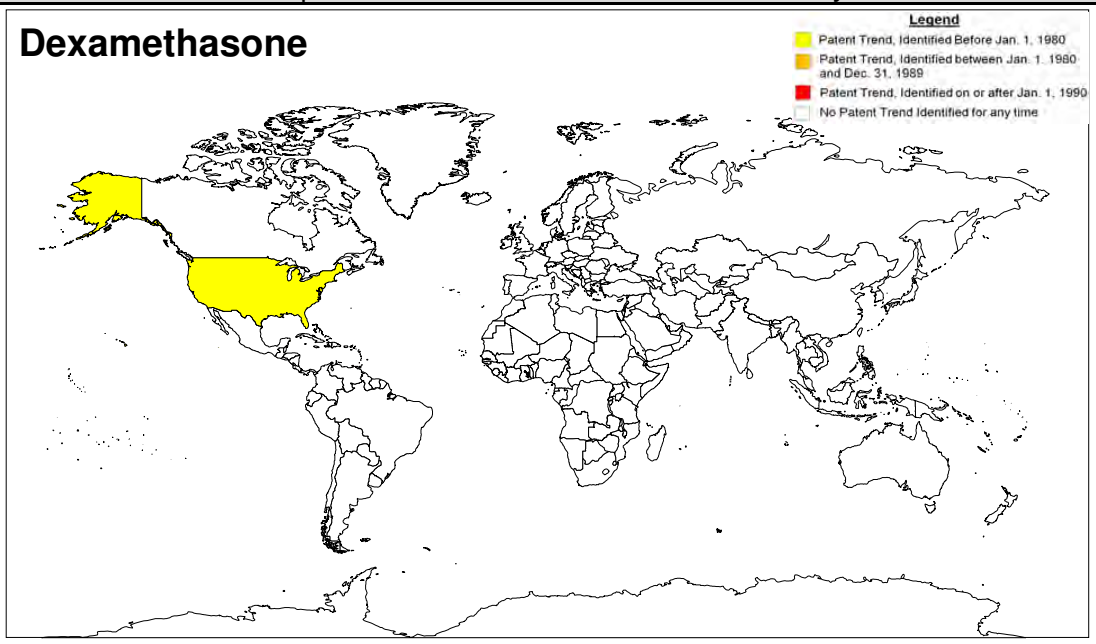
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/ Country	Date Filed
US2939873	Merck & Co., Inc	N/A	Jan. 26, 1959

Orange Book Patents:

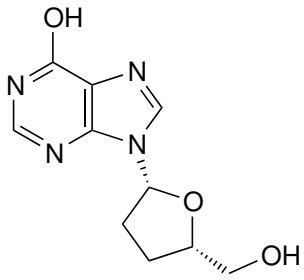
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Dexamethasone Family Data



Didanosine

Oral Capsule: 125 mg, 250 mg, 400 mg;
Oral Solution: 10 mg/mL;



Uses:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	9-((2*R*,5*S*)-5-(hydroxymethyl)tetrahydrofuran-2-yl)-9*H*-purin-6-ol
CAS Number:	69655-05-6
Chemical Formula:	$C_{10}H_{12}N_4O_3$

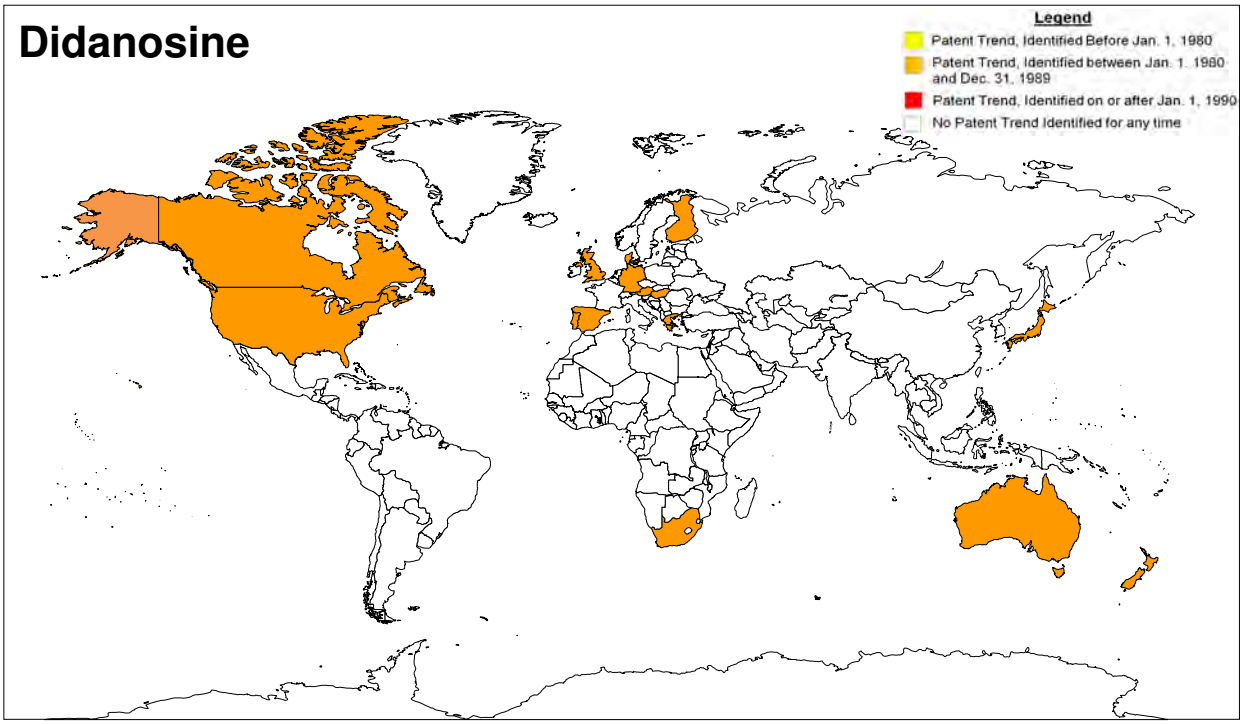
Base Patent:

Base Patent	Patent Listed Assignee/ Country	Current Listed Assignee/ Country	Date Filed
US4920210	Burroughs Welcome Co.	Glaxo Wellcome, Inc.	May 15, 1986

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

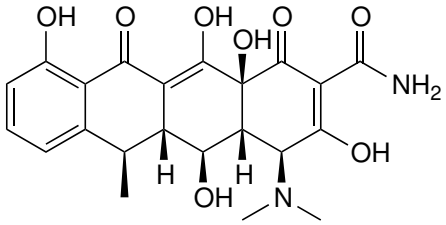
World Map Generated from Didanosine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Doxycycline

Oral Capsule: 50 mg, 75 mg, 100 mg, 150 mg;
Oral Tablet: 20 mg, 50 mg, 75 mg, 100 mg, 150 mg



Uses:	supplement to quinine or artesunate treatment for multimedicine-resistant *P. falciparum* malaria; short-term prophylaxis of multimedicine-resistant *P. falciparum* malaria (section 6.5.3.1; see also introductory note above); bacterial infections (section 6.2.2); moderate acne (section 13.5).
IUPAC Name:	(4*S*,4a*R*,5*S*,5a*R*,6*R*,12a*S*)-4-(dimethylamino)-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-1,4,4a,5,5a,6,11,12a-octahydrotetracene-2-carboxamide
CAS Number:	564-25-0
Chemical Formula:	$C_{22}H_{24}N_2O_8$

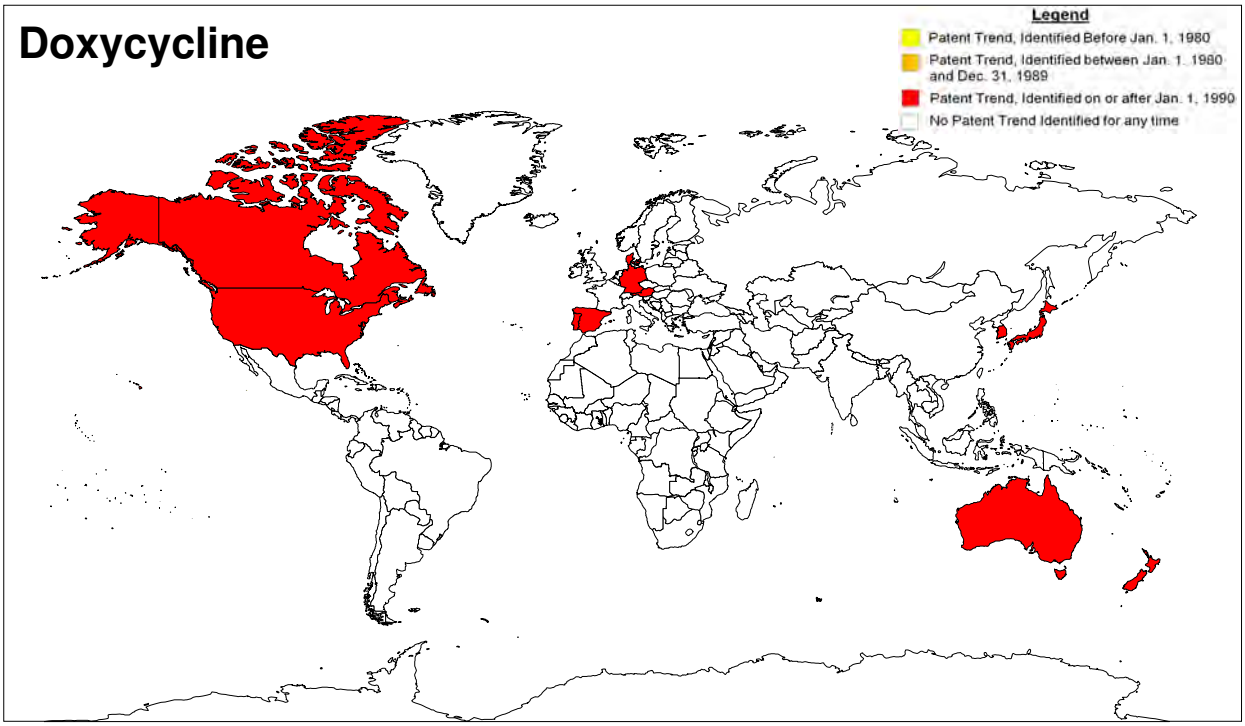
Base Patent Info:

Base Patent	Patent Listed Assignee/ Country	Current Listed Assignee/ Country	Date Filed
US3019260	American Cyanamide Company/USA	American Cyanamide Company/USA	May 13, 1959

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5789395	The Research Foundation of State University of New York/USA	The Research Foundation of State University of New York/USA	Aug. 30, 1996
US5919775	The Research Foundation of State University of New York/USA	The Research Foundation of State University of New York/USA	Apr. 16, 1998
US7211267	CollaGenex Pharmaceuticals Inc/USA	CollaGenex Pharmaceuticals Inc/USA	Apr. 5, 2002
US7232572	CollaGenex Pharmaceuticals Inc/USA	CollaGenex Pharmaceuticals Inc/USA	Feb. 18, 2005
US7749532	Supernus Pharmaceuticals Inc/USA	Supernus Pharmaceuticals Inc/USA	Apr. 7, 2004
US6958161	F H Faulding & Co Limited/AU	F H Faulding & Co Limited/AU	Apr. 12, 2002

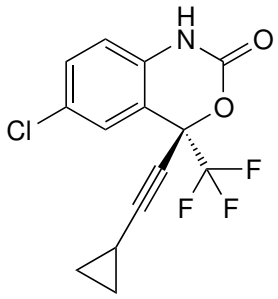
World Map Generated from Doxycycline Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Efavirenz (EFV or EFZ)

Oral Capsule: 50 mg, 200 mg;
Oral Tablet: 600 mg



Uses:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	(*S*)-6-chloro-4-(cyclopropylethynyl)-4-(trifluoromethyl)-1*H*-benzo[*d*][1,3]oxazin-2(4*H*)-one
CAS Number:	154598-52-4
Chemical Formula:	$C_{14}H_9ClF_3NO_2$

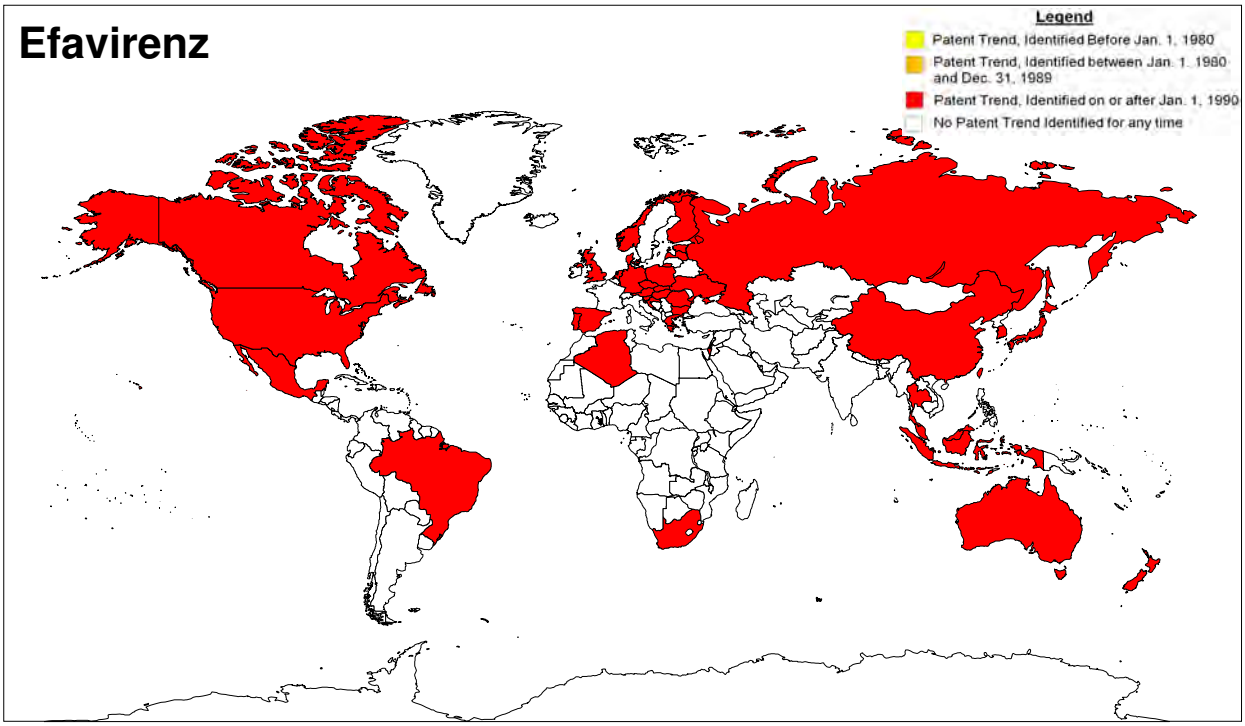
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5519021	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5519021	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995
US5663169	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995
US5811423	Merck & Co./USA	Merck Sharp Dohme/USA	Mar. 12, 1997
US6238695	DuPont Pharmaceuticals/USA	DuPont Pharmaceuticals/USA	Apr. 6, 1999
US6555133	Bristol Myers Squibb Co./USA	Bristol Myers Squibb Co./USA	Apr. 2, 1001
US6639071	Merck & Co./USA	Merck Sharp Dohme/USA	Oct. 19, 2001
US6939964	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 24, 2004

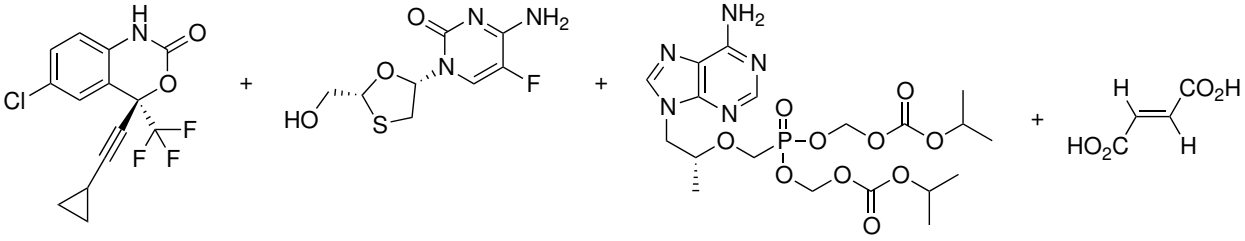
World Map Generated from Efavirenz Family Data



Regional Office	Patent Trend
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Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Efavirenz (EFV) + Emtricitabine (FTC) + Tenofovir (TDF)

Oral Tablet, 600 mg EFV, 200 mg FTC, 300 mg TDF



Uses:	HIV infection alone as a complete regimen or in combination with other antiretroviral medicines.
IUPAC Name:	*EFV/FTC/TDF:* (*S*)-6-chloro-4-(cyclopropylethynyl)-4-(trifluoromethyl)-1*H*-benzo[*d*][1,3]oxazin-2(4*H*)-one • 4-amino-5-fluoro-1-((2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1*H*)-one • 9-[(R)-2-[[bis[[(isopropoxycarbonyl)oxy]methoxy] phosphinyl]methoxy]propyl] • adenine fumarate *EFV*: (*S*)-6-chloro-4-(cyclopropylethynyl)-4-(trifluoromethyl)-1*H*-benzo[*d*][1,3]oxazin-2(4*H*)-one *FTC*: 4-amino-5-fluoro-1-((2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1*H*)-one *TDF*: 9-[(R)-2-[[bis[[(isopropoxycarbonyl)oxy]methoxy]phosphinyl]methoxy] propyl] adenine fumarate (1:1)
CAS Number:	*EFV/FTC/TDF*: 731772-50-2 *EFV*: 154598-52-4 *FTC*: 143491-57-0 *TDF*: 201341-05-1
Chemical Formula:	*EFV/FTC/TDF*: $C_{14}H_9ClF_3NO_2 \bullet C_8H_{10}FN_3O_3S \bullet C_9H_{14}N_5O_4P \bullet C_4H_4O_4$ *EFV*: $C_{14}H_9ClF_3NO_2$ *FTC*: $C_8H_{10}FN_3O_3S$ *TDF*: $C_{19}H_{30}N_5O_{10}P \bullet C_4H_4O_4$

Base Patent Info:

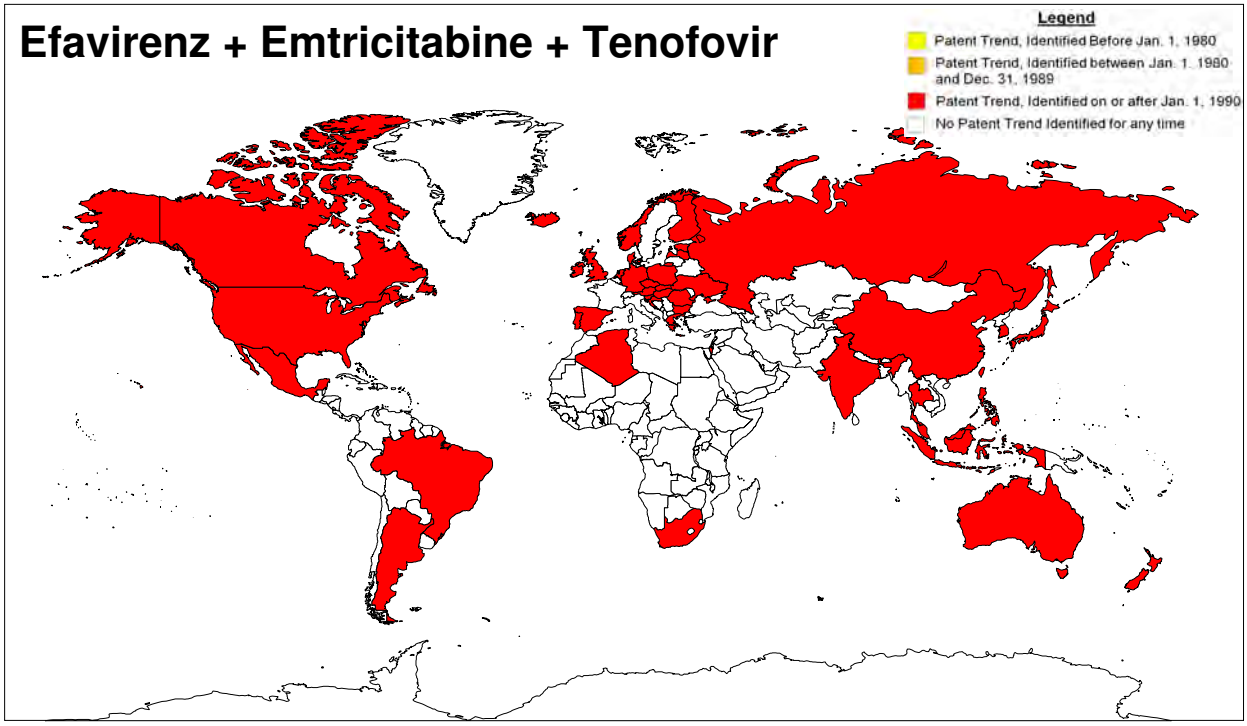
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US20070099902A1	Bristol Myers Squibb & Gilead Sciences Inc.	Bristol Myers Squibb & Gilead Sciences Inc.	Jun. 13, 2006
US5519021	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995
US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991
US5922695	Gilead Sciences, Inc/USA	Gilead Sciences, Inc/USA	Jul. 25, 1997

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991
US5814639	Emory University/USA	Emory University/USA	Feb. 16, 1993
US5914331	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6642245	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6703396	Emory University/USA	Emory University/USA	Mar. 13, 1995

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US7402588	Emory University/USA	Emory University/USA	Mar. 28, 2006
US5519021	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995
US5663169	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 2, 1995
US5811423	Merck & Co./USA	Merck Sharp Dohme/USA	Mar. 12, 1997
US6639071	Merck & Co./USA	Merck Sharp Dohme/USA	Oct. 19, 2001
US6939964	Merck & Co./USA	Merck Sharp Dohme/USA	Jun. 24, 2004
US5922695	Gilead Sciences/USA	Gilead Sciences/USA	Jul. 25, 1997
US5935946	Gilead Sciences/USA	Gilead Sciences/USA	Jul. 25, 1997
US5977089	Gilead Sciences/USA	Gilead Sciences/USA	Nov. 6, 1998
US6043230	Gilead Sciences/USA	Gilead Sciences/USA	May 19, 1999

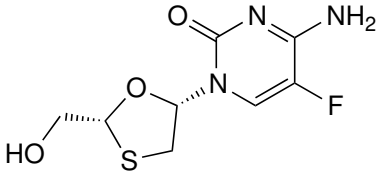
World Map Generated from Efavirenz + Emtricitabine + Tenofovir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Emtricitabine

Oral Capsule: 200 mg;
Oral Solution: 10 mg/mL



Uses:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	4-amino-5-fluoro-1-((2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1*H*)-one
CAS Number:	143491-57-0
Chemical Formula:	$C_8H_{10}FN_3O_3S$

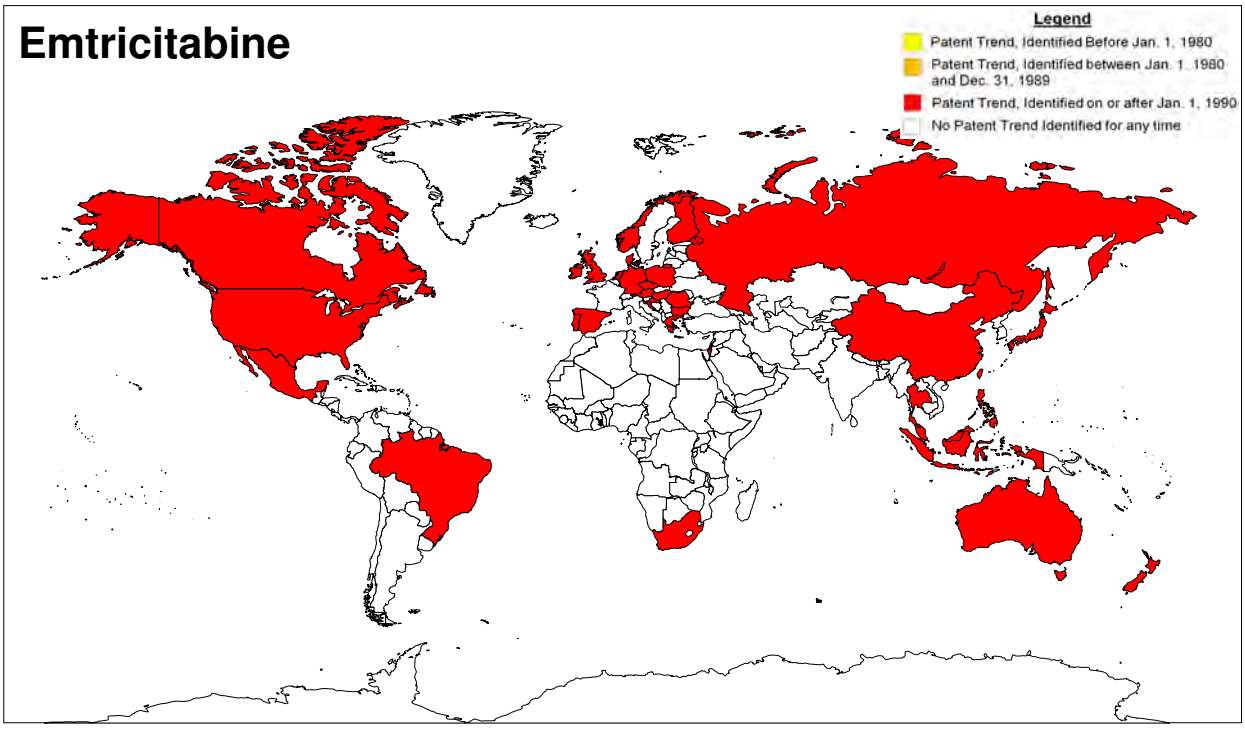
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US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991
US5814639	Emory University/USA	Emory University/USA	Feb. 16, 1993
US5914331	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6642245	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6703396	Emory University/USA	Emory University/USA	Mar. 13, 1995
US7402588	Emory University/USA	Emory University/USA	Mar. 28, 2006

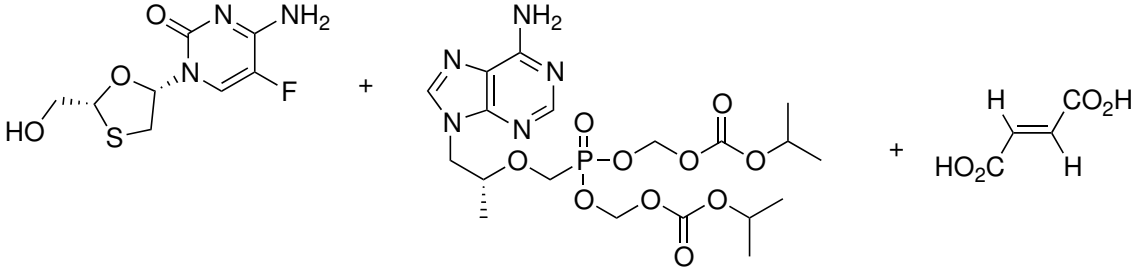
World Map Generated from Emtricitabine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Emtricitabine (FTC) + Tenofovir (TDF)

Oral Tablet: 200 mg FTC, 300 mg TDF



Uses:	HIV infection alone as a complete regimen or in combination with other antiretroviral medicines.
IUPAC Name:	*FTC/TDF:* 4-amino-5-fluoro-1-((2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1*H*)-one • 9-[(R)-2-[[bis[[(isopropoxycarbonyl)oxy]methoxy]phosphinyl]methoxy]propyl] • adenine fumarate *FTC*: 4-amino-5-fluoro-1-((2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1*H*)-one *TDF*: 9-[(R)-2-[[bis[[(isopropoxycarbonyl)oxy]methoxy]phosphinyl]methoxy]propyl] adenine fumarate (1:1)
CAS Number:	*FTC/TDF*: 731772-45-5 *FTC*: 143491-57-0 *TDF*: 201341-05-1
Chemical Formula:	*FTC/TDF*: $C_8H_{10}FN_3O_3S \bullet C_{19}H_{30}N_5O_{10}P \bullet C_4H_4O_4$ *FTC*: $C_8H_{10}FN_3O_3S$ *TDF*: $C_{19}H_{30}N_5O_{10}P \bullet C_4H_4O_4$

Base Patent Info:

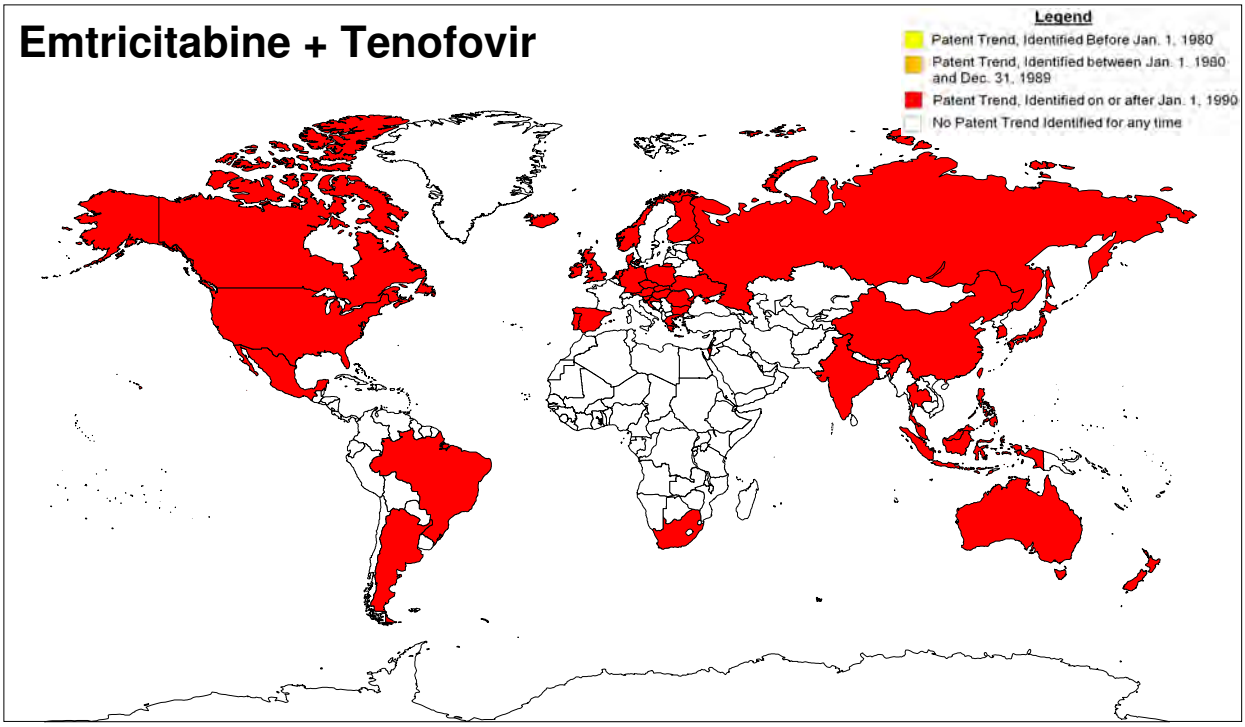
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US20040224917A1	Gilead Sciences, Inc	Gilead Sciences, In	Jan. 13, 2004
US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991
US5922695	Gilead Sciences, Inc/USA	Gilead Sciences, Inc/USA	Jul. 25, 1997

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5210085	Emory University/USA	Emory University/USA	Feb. 22, 1991
US5814639	Emory University/USA	Emory University/USA	Feb. 16, 1993
US5914331	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6642245	Emory University/USA	Emory University/USA	Jun. 7, 1995
US6703396	Emory University/USA	Emory University/USA	Mar. 13, 1995
US7402588	Emory University/USA	Emory University/USA	Mar. 28, 2006
US5922695	Gilead Sciences/USA	Gilead Sciences/USA	Jul. 25, 1997
US5935946	Gilead Sciences/USA	Gilead Sciences/USA	Jul. 25, 1997

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5977089	Gilead Sciences/USA	Gilead Sciences/USA	Nov. 6, 1998
US6043230	Gilead Sciences/USA	Gilead Sciences/USA	May 19, 1999

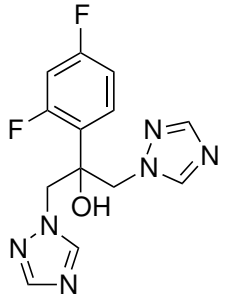
World Map Generated from Emtricitabine + Tenofovir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Fluconazole

Oral Tablet: 50 mg, 100 mg, 150 mg, 200 mg;
Oral Suspension: 50 mg/5 mL, 200 mg/5 mL;
Injectable Solution: 200 mg/100 mL, 400 mg/ 200 mL



Uses:	systemic mycoses including histoplasmosis, non-meningeal coccidioidomycosis, paracoccidioidomycosis, and blastomycosis; treatment and, in AIDS and other immunosuppressed patients, prophylaxis of cryptococcal meningitis; prevention of fungal infections in immunocompromised patients; oesophageal and oropharyngeal candidosis, vaginal candidosis and systemic candidosis; ringworm where topical treatment has failed).
IUPAC Name:	2-(2,4-difluorophenyl)-1,3-di(1*H*-1,2,4-triazol-1-yl)propan-2-ol
CAS Number:	86386-73-4
Chemical Formula:	$C_{13}H_{12}F_2N_{6O}$

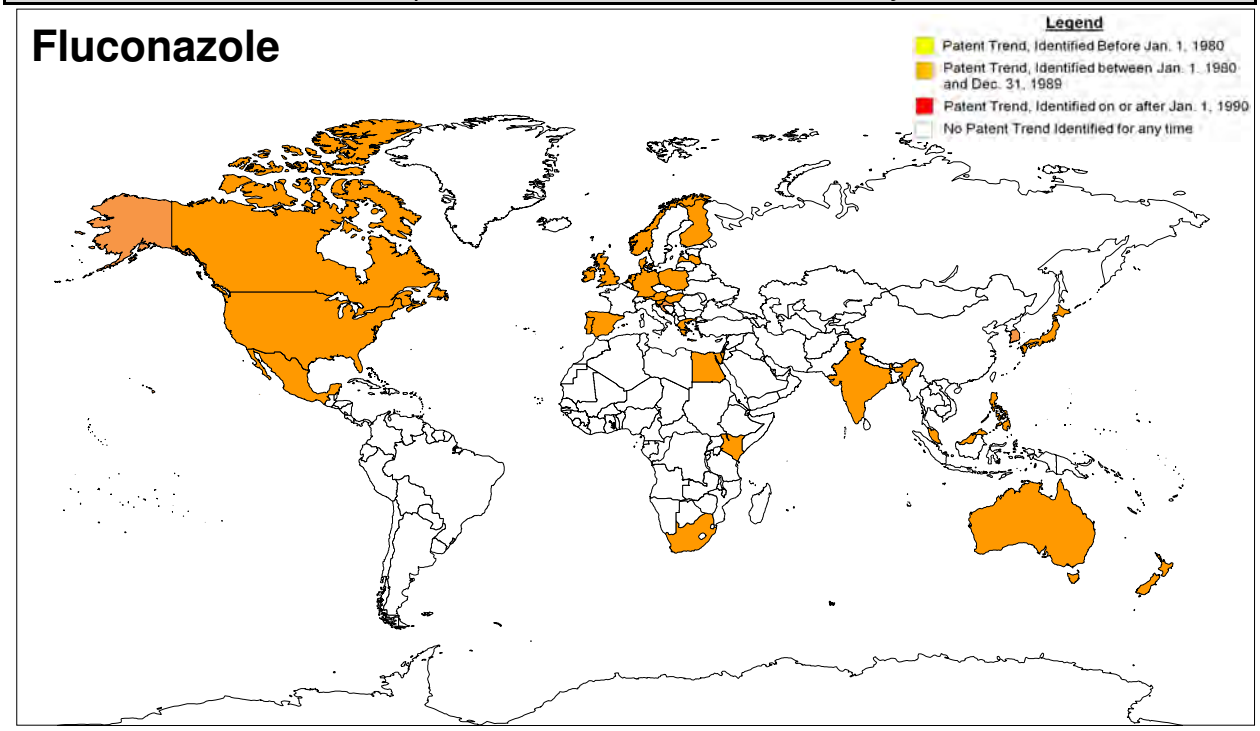
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4404216	Pfizer, Inc/USA	Pfizer, Inc/USA	Jun. 1, 1982

Orange Book Patents:

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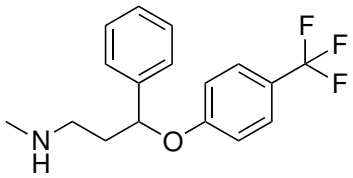
World Map Generated from Fluconazole Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Fluoxetine HCl

Oral Capsule: 20 mg



Uses:	moderate to severe major depression.
IUPAC Name:	*N*-methyl-3-phenyl-3-(4-(trifluoromethyl)phenoxy)propan-1-amine
CAS Number:	59333-67-4
Chemical Formula:	$C_{17}H_{18}F_3N_O$

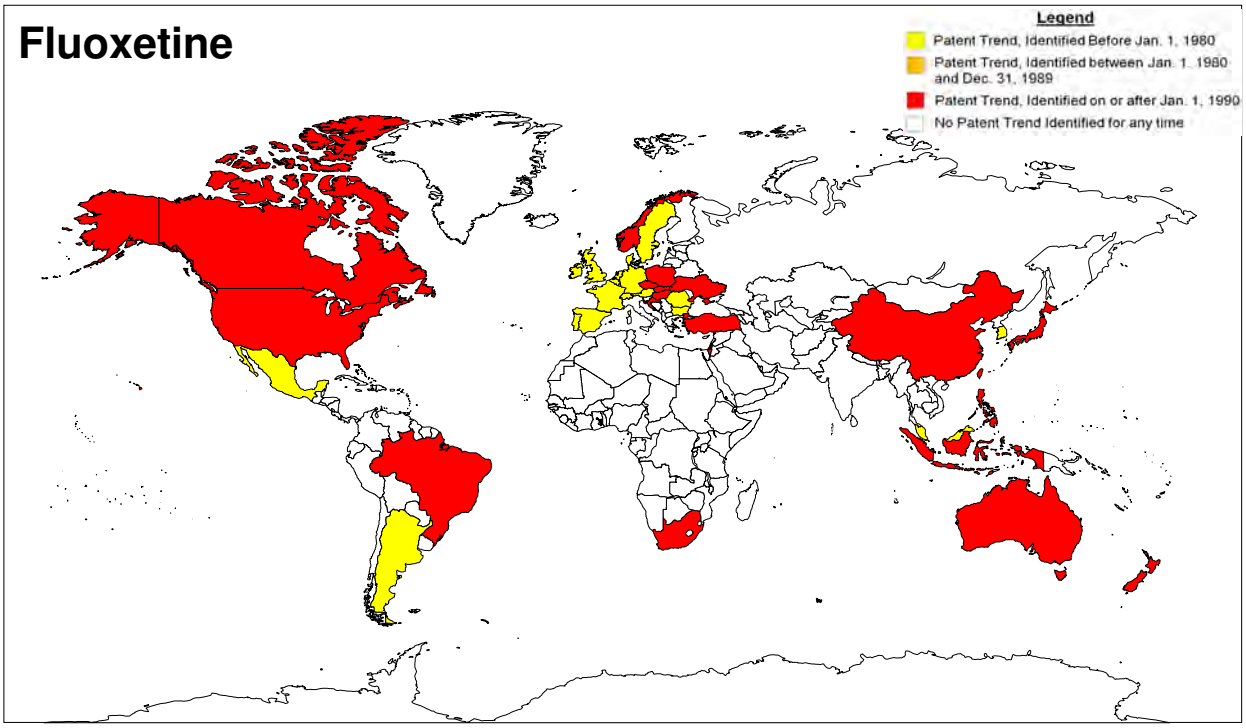
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/ Country	Date Filed
US4314081	Eli Lilly & Co./USA	Eli Lilly & Co./USA	Jan. 10 1974

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/ Country	Date Filed
US6960577	Eli Lilly/USA	Eli Lilly/USA	May 10, 2002

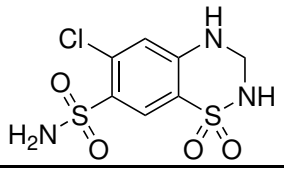
World Map Generated from Fluoxetine HCl Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Hydrochlorothiazide

Tablet: 12.5 mg;
Oral Liquid: 50 mg/5 mL



Uses:	Alone in mild hypertension, and in combination with other medicines in moderate to severe hypertension; heart failure; oedema.
IUPAC Name:	6-chloro-1,1-dioxo-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide
CAS Number:	8049-49-8
Chemical Formula:	$C_7H_8ClN_3O_4S_2$

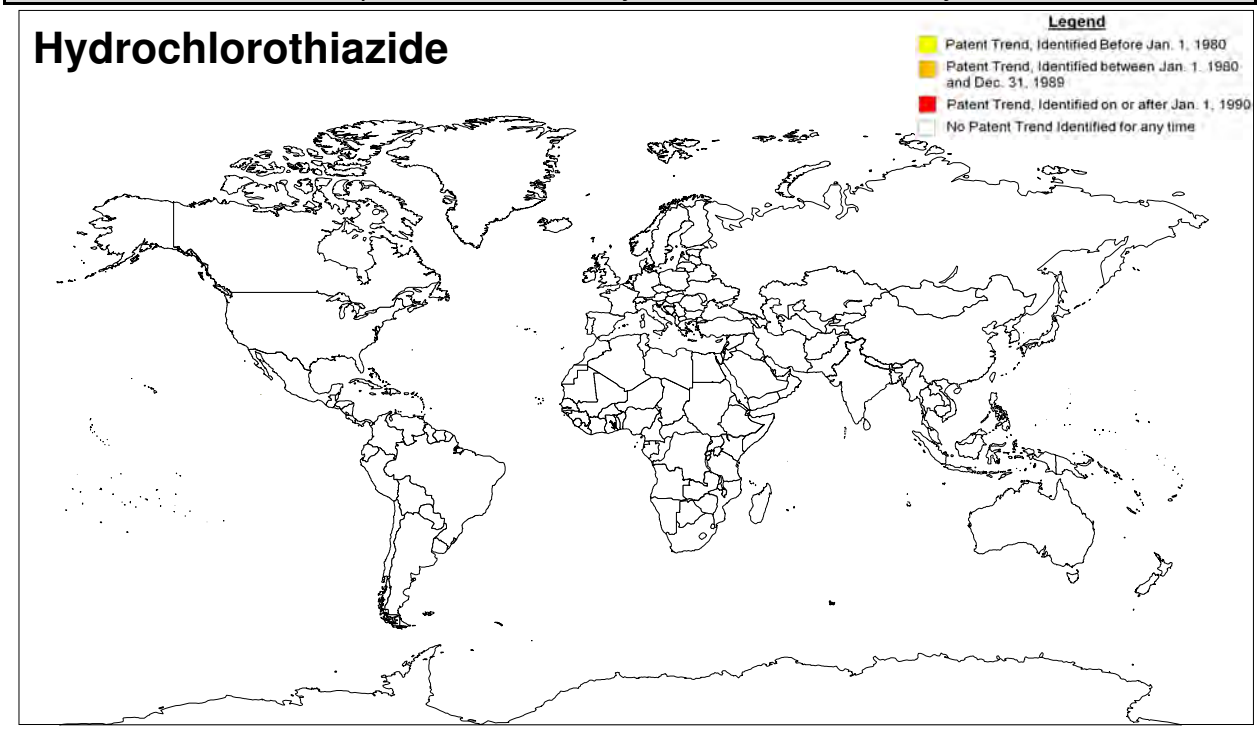
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3025292	Merck & Co., Inc./USA	Merck & Co., Inc./USA	Nov. 26, 1958

Orange Book Patent:

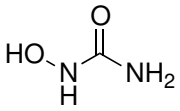
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Hydrochlorothiazide Family Data



Hydroxycarbamide

Capsule: 200 mg, 250 mg, 300 mg, 400 mg, 500 mg;
Tablet: 1 g



Uses:	Not Listed on the WHO Model Formulary
IUPAC Name:	Hydroxyurea
CAS Number:	8029-68-3
Chemical Formula:	$CH_4N_2O_2$

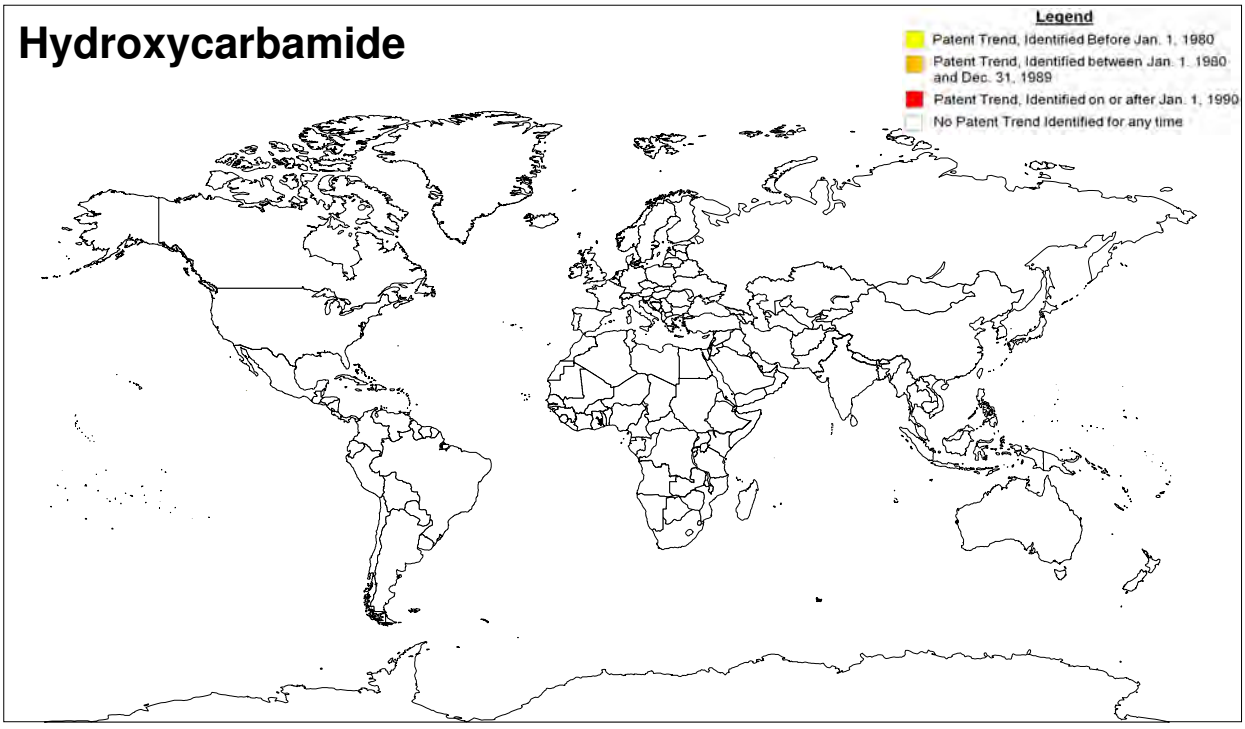
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

Orange Book Patent Info:

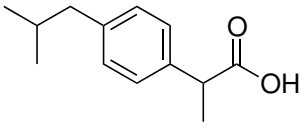
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Hydroxycarbamide Family Data



Ibuprofen

Injection: 5 mg/mL



Uses:	Pain and inflammation in rheumatic disease and other musculoskeletal disorders including juvenile arthritis; mild to moderate pain including dysmenorrhoea and headache; pain in children; acute migraine attack.
IUPAC Name:	(RS)-2-(4-(2-methylpropyl)phenyl)propanoic acid
CAS Number:	79261-49-7
Chemical Formula:	$C_{13}H_{18}O_2$

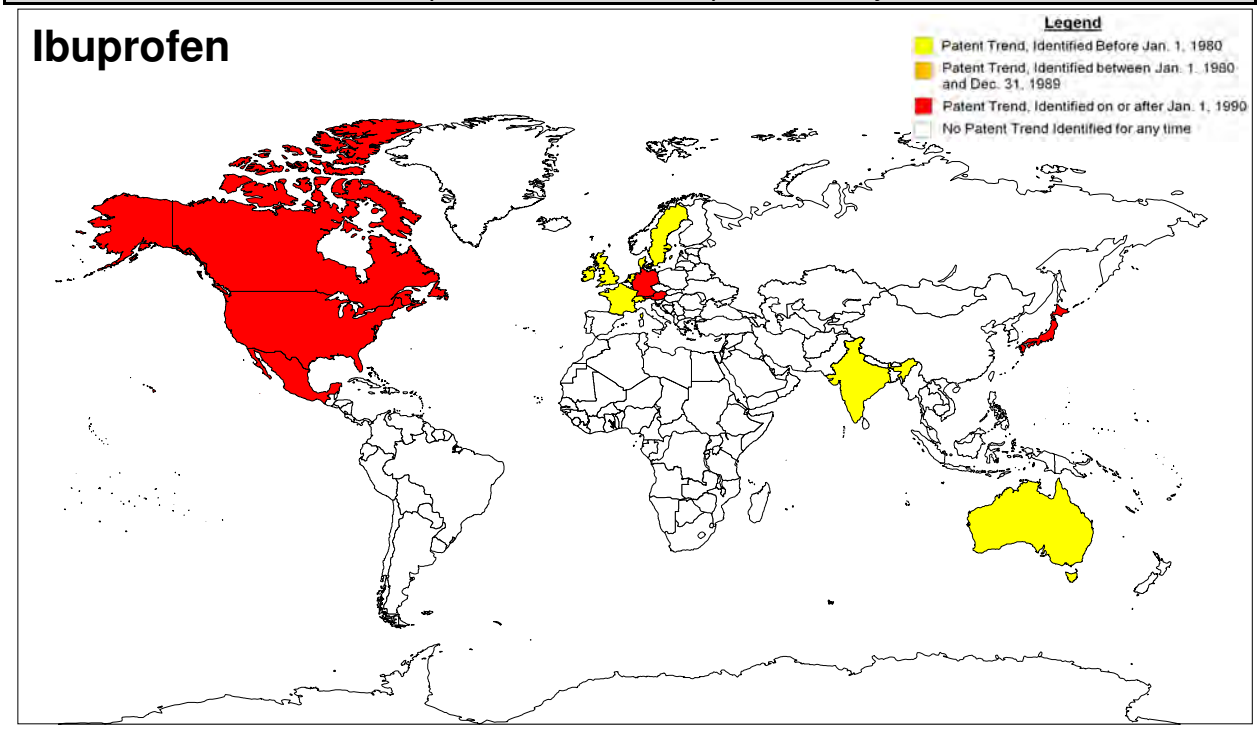
Base Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3385886	The Boots Co., PLC/GB	Boots Pure Medicine Co., Lt. (Boots)/GB	Jul. 23, 1963

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US6342530	Farmacon, LLC/USA	Farmacon, LLC/USA	Nov. 14, 2000
US6344479	Farmacon, LLC/USA	Farmacon, LLC/USA	Mar. 20, 2001

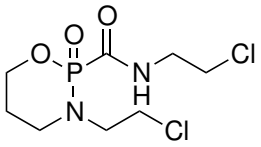
World Map Generated from Ibuprofen Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	

Ifosfamide

Powder for Injection: 1 g, 2 g vials



Uses:	Not Listed on the WHO Model Formulary
IUPAC Name:	N,3-bis(2-chloroethyl)-1,3,2-oxazaphosphinane-2-carboxamide 2-oxide
CAS Number:	84711-20-6
Chemical Formula:	$C_7H_{15}Cl_2N_2O_2P$

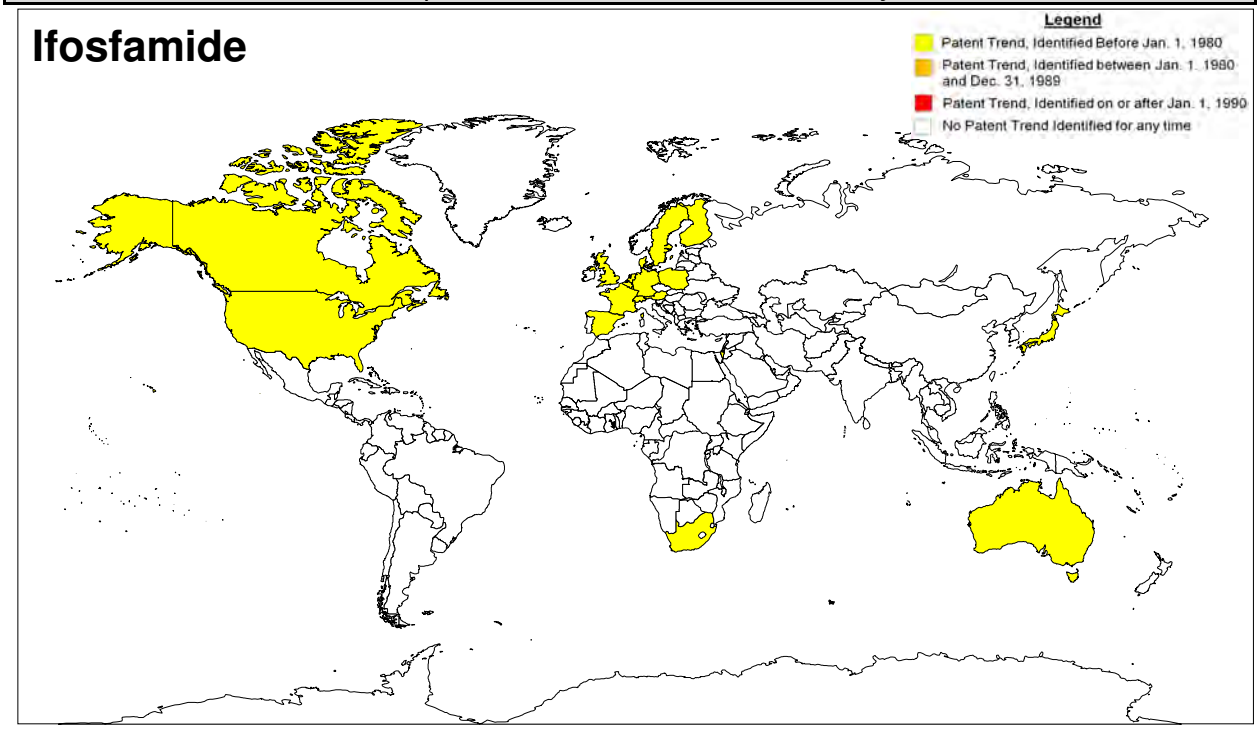
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3732340	Asta Werke Chemische Fabrik, AG	Asta Werke Chemische Fabrik, AG	Jan. 11, 1971

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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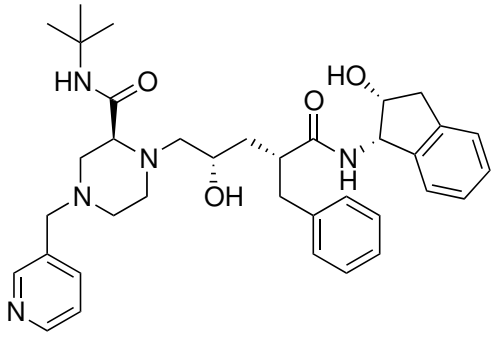
World Map Generated from Ifosfamide Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan. 1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	
Gulf Cooperation Council	
World Intellectual Property Organization	

Indinavir

Capsule: 200 mg, 333 mg, 400 mg (as sulfate)



Uses:	HIV infection usually in combination with two nucleoside reverse transcriptase inhibitors and a low-dose ritonavir booster.
IUPAC Name:	(S)-1-((2S,4R)-4-benzyl-2-hydroxy-5-(((1S,2R)-2-hydroxy-2,3-dihydro-1H-inden-1-yl)amino)-5-oxopentyl)-N-(tert-butyl)-4-(pyridin-3-ylmethyl)piperazine-2-carboxamide
CAS Number:	216884-06-9
Chemical Formula:	$C_{36}H_{47}N_5O_4$

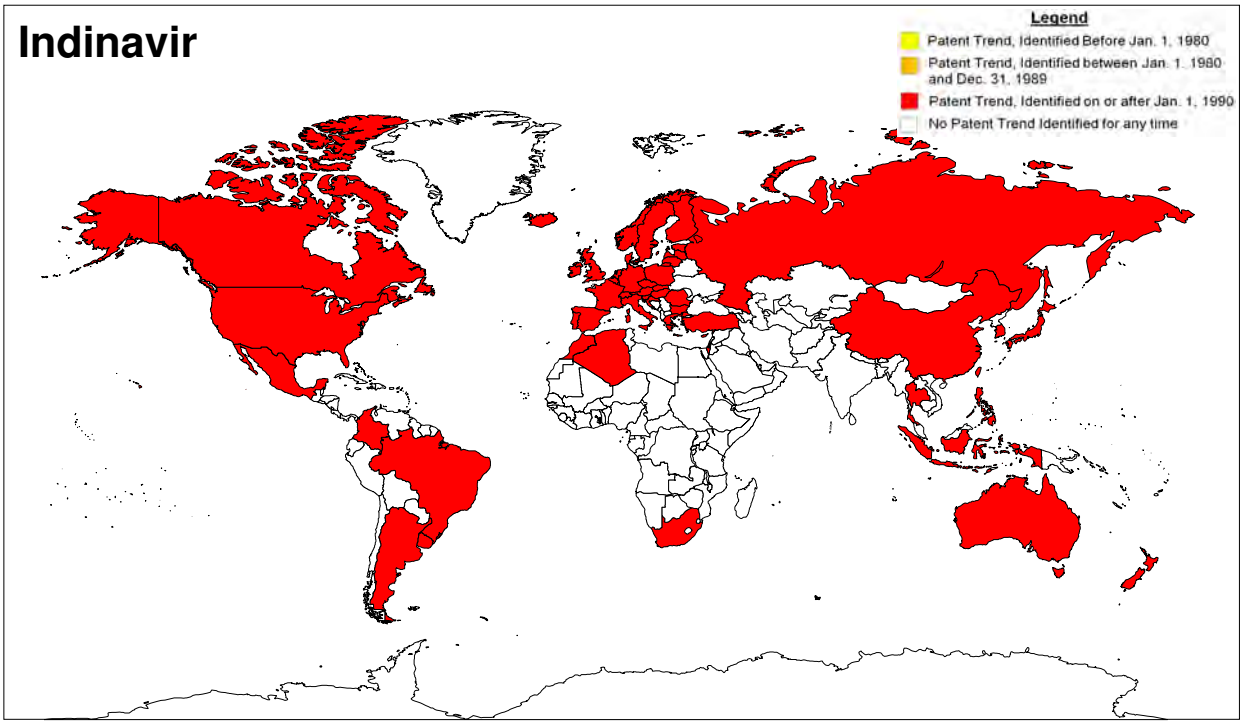
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5413999	Merck & Co. Inc./U.S.	Merck Sharp & Dohme Corp./U.S.	May 7, 1993

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5413999	Merck Sharp & Dohme/USA	Merck Sharp & Dohme/USA	May 7, 1993
US6645961	Merck Sharp & Dohme/USA	Merck Sharp & Dohme/USA	Mar. 4, 1998
US6689761	Merck Sharp & Dohme/USA	Merck Sharp & Dohme/USA	Feb. 1, 1995

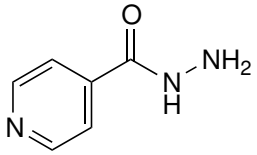
World Map Generated from Indinavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Isoniazid

Tablet: 50 mg (scored)



Uses:	Tuberculosis treatment, in combination with other medicines; tuberculosis prophylaxis.
IUPAC Name:	Isonicotinohydrazide
CAS Number:	7640-37-1
Chemical Formula:	$C_6H_7N_3O$

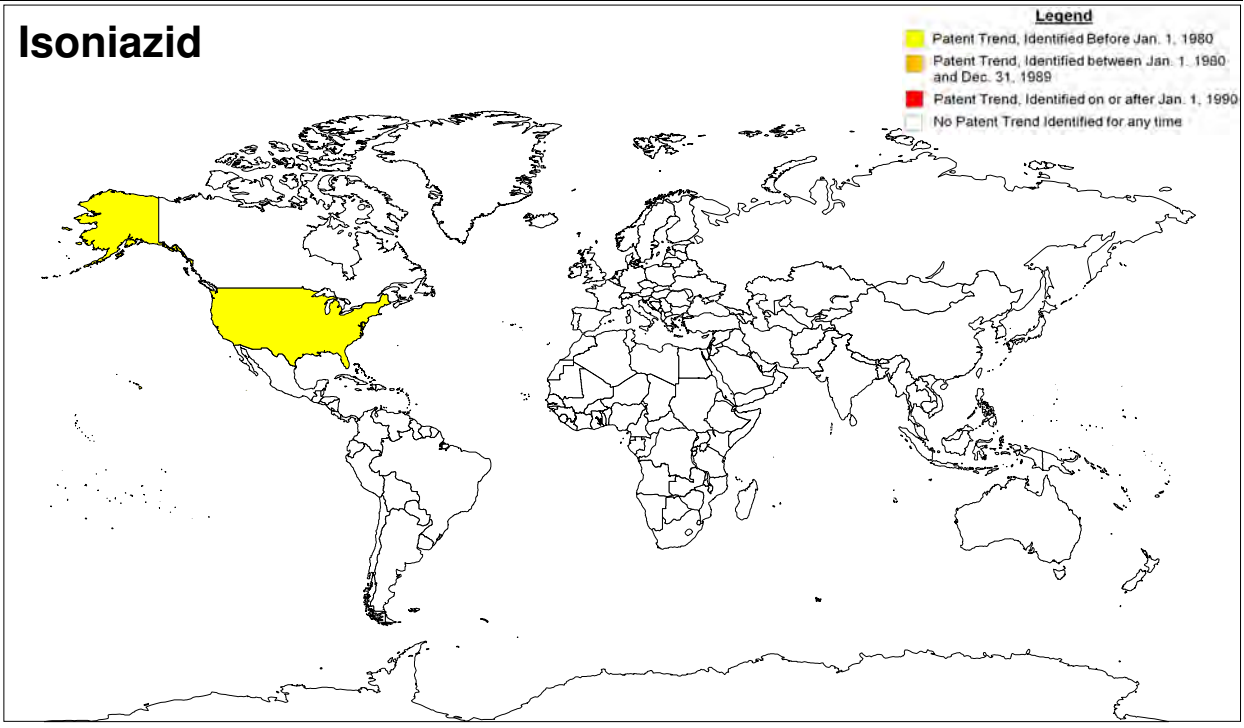
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2596069	Hoffman La Roche/USA	Hoffman La Roche/USA	Mar. 7, 1952

Orange Book Patent Info:

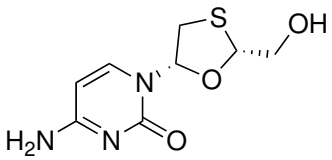
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Isoniazid Family Data



Lamivudine

Tablet: 150 mg;
Oral Liquid: 50 mg/5 mL



Uses:	HIV infection in combination with at least 2 other antiretroviral medicines; prevention of mother-to-child HIV transmission.
IUPAC Name:	4-amino-1-((2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1H)-one
CAS Number:	480434-79-5
Chemical Formula:	$C_8H_{11}N_3O_3S$

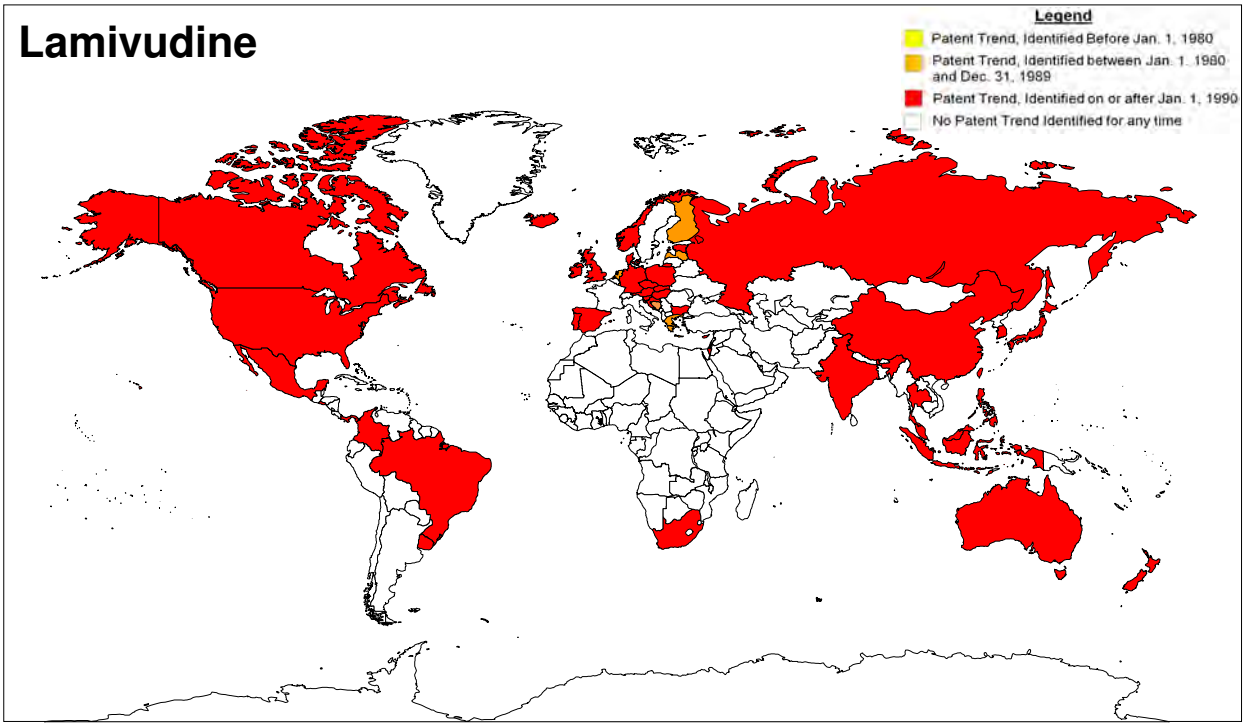
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5047407	IAF Biochem International, Inc./Canada	Glaxo Wellcome Inc./Canada	Feb. 8, 1989

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5047407	IAF Biochem Intl, Inc./CA	Glaxo Wellcome Inc./CA	Feb. 8, 1989
US5905082	Glaxo Group Limited, GB	Glaxo Group Limited, GB	Jun. 2, 1992
US6004968	Glaxo Wellcome, Inc./USA	Glaxo Wellcome, Inc./USA	Mar. 20, 1998

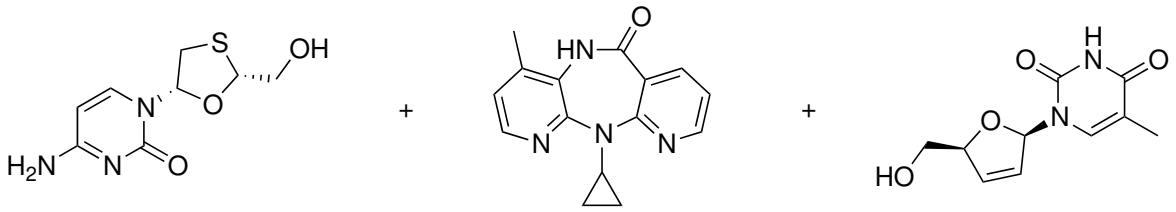
World Map Generated from Lamivudine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Lamivudine + Nevirapine + Stavudine

Tablet: 30 mg + 50 mg + 6 mg, 60 mg + 100 mg + 12 mg,
150 mg + 200 mg+ 30 mg



Uses:	HIV infection alone as a complete regimen or in combination with other antiretroviral medicines.
IUPAC Name:	None for the compound Lamivudine = 4-amino-1-((2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl)pyrimidin-2(1H)-one Nevirapine = 11-cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido [3,2-b:2',3'-e][1,4] diazepin-6-one Stavudine = 1-((2R,5S)-5-(hydroxymethyl)-2,5-dihydrofuran-2-yl)-5-methylpyrimidine-2,4(1H,3H)-dione
CAS Number:	Lamivudine = 480434-79-5 Nevirapine = 129618-40-2 Stavudine = 3056-17-5
Chemical Formula:	Lamivudine = $C_8H_{11}N_3O_3S$ Nevirapine = $C_{15}H_{14}N_4O$ Stavudine = $C_{10}H_{12}N_2O_4$

Base Patent For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US20080241265A1	CIPLA Ltd. / IN	CIPLA Ltd. / IN	Aug. 31, 2005

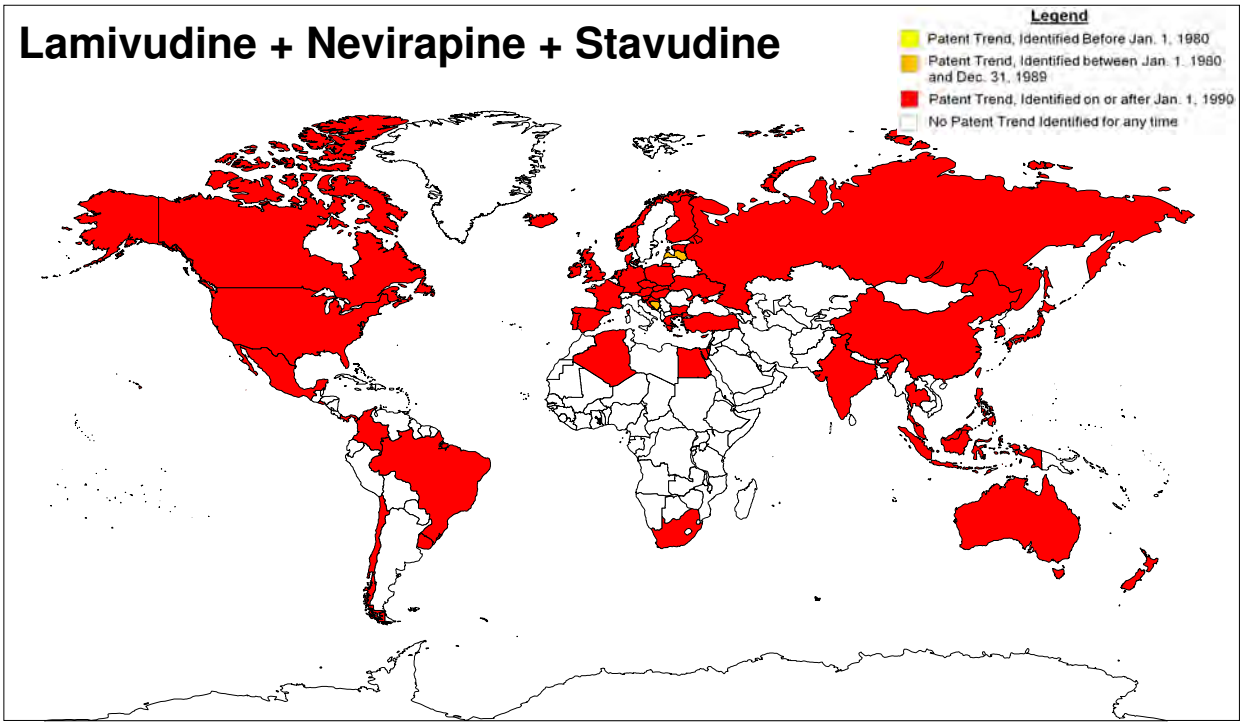
Base Patents For Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5047407A	CIPLA Ltd. / IN	CIPLA Ltd. / IN	Feb. 8, 1989
US5130421	Bristol-Meyers Company/USA	Bristol-Meyers Company/USA	Apr. 29, 1991
US5366972	Boehringer Ingelheim Pharmaceuticals, Inc./USA	Boehringer Ingelheim Pharmaceuticals, Inc./USA	July 13, 1993

Orange Book Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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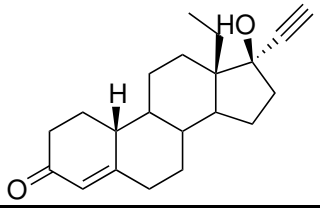
World Map Generated from Lamivudine + Nevirapine + Stavudine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Levonorgestrel-Releasing Implant

2-rod implant: Releasing 75 mg (150 mg in total)



Uses:	Contraception (particularly when estrogens are contraindicated); emergency hormonal contraception.
IUPAC Name:	(10R,13S,17R)-13-ethyl-17-ethynyl-17-hydroxy-6,7,8,9,10,11,12,13,14,15,16,17-dodecahydro-1H-cyclopenta[a]phenanthren-3(2H)-one
CAS Number:	797-63-7
Chemical Formula:	$C_{21}H_{28}O_2$

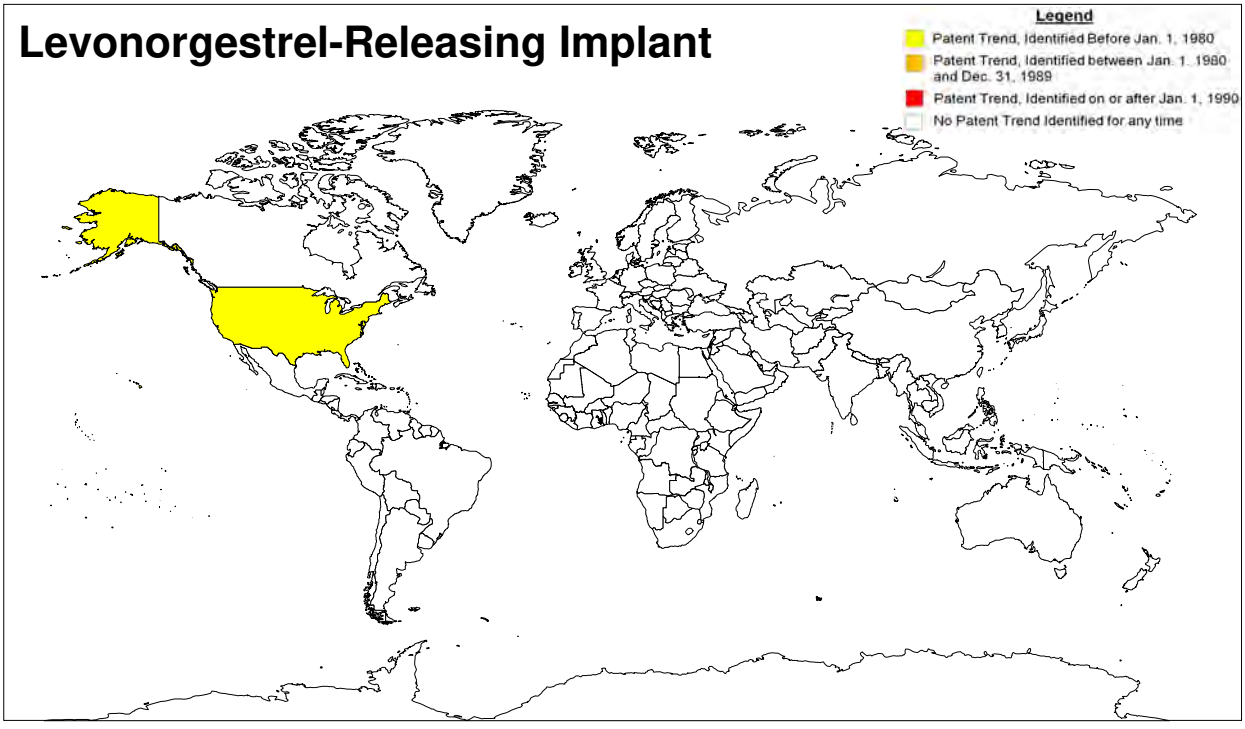
Base Patent Info:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4244949	The Population Council Inc./US	The Population Council Inc./US	Apr. 6, 1978

Orange Book Patent Info:

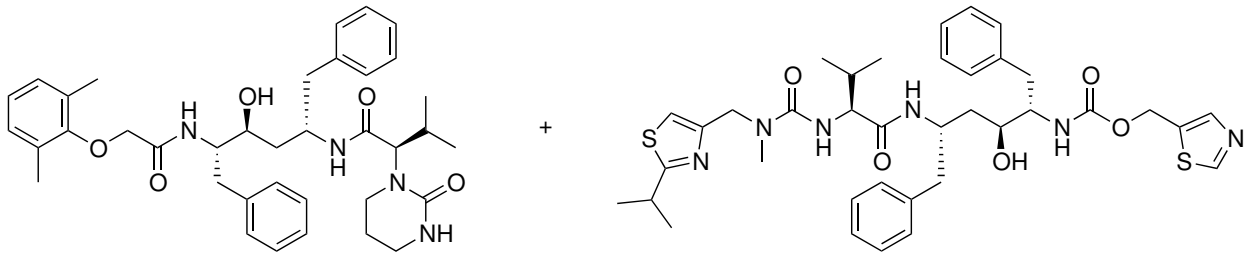
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Levonorgestrel-Releasing Implant Family Data



Lopinavir + Ritonovir

Tablet: 100 mg + 25 mg, 200 mg + 50 mg;
Capsule: 133.3 mg + 33.3 mg;
Oral Liquid: (400 mg + 100 mg)/5 ml



Uses:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	None for compound Lopinavir = [1S-[1R*,(R*), 3R*, 4R*]]-N-[4-[[(2,6-dimethylphenoxy)acetyl]amino]-3-hydroxy-5-phenyl-1-(phenylmethyl)pentyl]tetrahydro-alpha-(1-methylethyl)-2-oxo-1(2H)-pyrimidineacetamide Ritonavir = 10-hydroxy-2-methyl-5-(1- methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11- bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid, 5-thiazolylmethyl ester, [5S-(5R*,8R*,10R*,11R*)]
CAS Number:	Lopinavir = 192725-17-0 Ritonovir = 155213-67-5
Chemical Formula:	Compound = $C_{37}H_{48}N_4O_5 + C_{37}H_{48}N_6O_5S_2$ Lopinavir = $C_{37}H_{48}N_4O_5$ Ritonavir = $C_{37}H_{48}N_6O_5S_2$

Base Patents For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

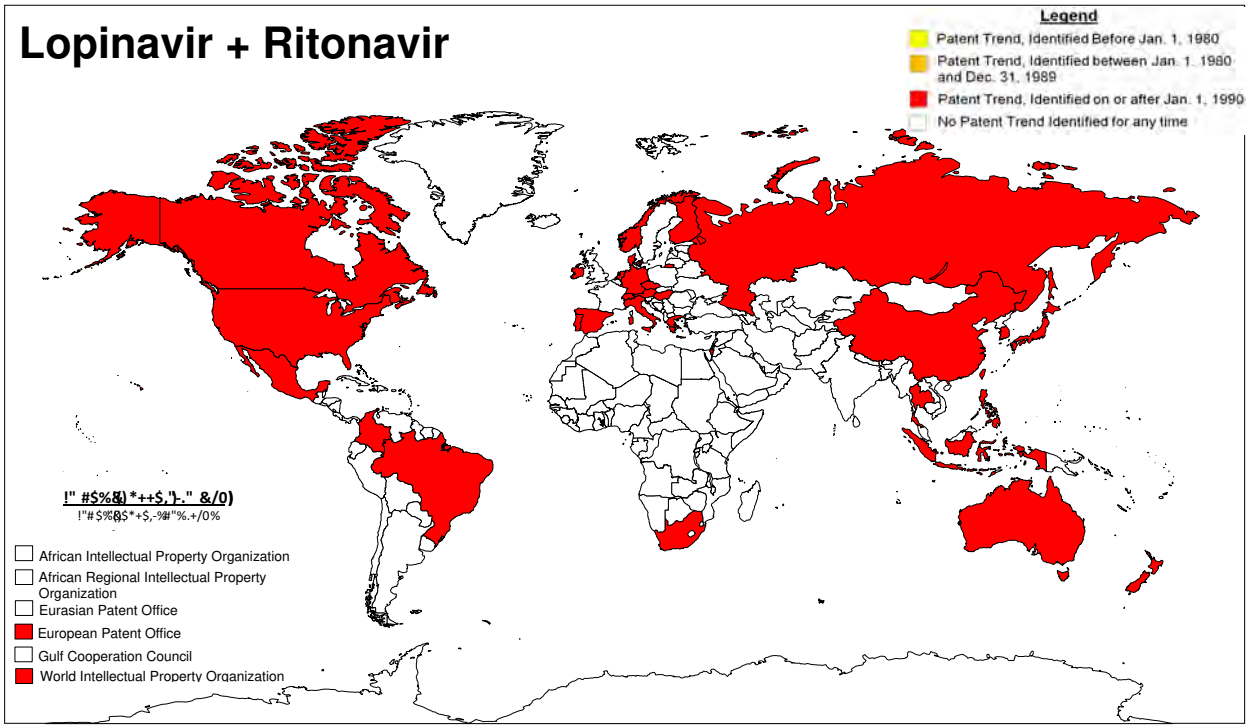
Base Patents For Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5914332	Abbott Laboratories/U.S.	Abbott Laboratories/U.S.	Nov. 21, 1996
US5541206	Abbott Laboratories / USA	Abbott Laboratories / USA	May 25, 1995

Orange Book Patent Info:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5142056	Abbott Laboratories / USA	Abbott Laboratories / USA	May 9, 1990
US5484801	Abbott Laboratories / USA	Abbott Laboratories / USA	May 12, 1995
US5541206	Abbott Laboratories / USA	Abbott Laboratories / USA	May 25, 1995
US5635523	Abbott Laboratories / USA	Abbott Laboratories / USA	Apr. 6, 1995
US5648497	Abbott Laboratories / USA	Abbott Laboratories / USA	Mar. 24, 1995
US5674882	Abbott Laboratories / USA	Abbott Laboratories / USA	Mar. 29, 1995
US5886036	Abbott Laboratories / USA	Abbott Laboratories / USA	Mar. 20, 1997
US5914332	Abbott Laboratories / USA	Abbott Laboratories / USA	Nov. 21, 1996
US5948436	Abbott Laboratories / USA	Abbott Laboratories / USA	Mar. 13, 1995
US6037157	Abbott Laboratories / USA	Abbott Laboratories / USA	Jun. 26, 1996
US6232333	Abbott Laboratories / USA	Abbott Laboratories / USA	Nov. 7, 1997
US6284767	Abbott Laboratories / USA	Abbott Laboratories / USA	Dec. 8, 1998
US6458818	Abbott Laboratories / USA	Abbott Laboratories / USA	Jul. 2, 1999
US6521651	Abbott Laboratories / USA	Abbott Laboratories / USA	Sept. 10, 1999
US6703403	Abbott Laboratories / USA	Abbott Laboratories / USA	Sept. 20, 2001
US6911214	Abbott Laboratories / USA	Abbott Laboratories / USA	Sept. 4, 2001
US7141593	Abbott Laboratories / USA	Abbott Laboratories / USA	May 22, 2000
US7432294	Abbott Laboratories / USA	Abbott Laboratories / USA	Oct. 12, 2006

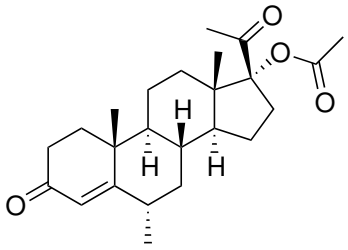
World Map Generated from Lopinavir + Ritonovir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Medroxyprogesterone Acetate

Depot injection: 150 mg/ml in 1 ml vial



Use:	Parenteral progestogen contraception (short-term)
IUPAC Name:	(6S,8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-3-oxo-2,3,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl acetate
CAS Number:	71-58-9
Chemical Formula:	$C_{24}H_{34}O_4$

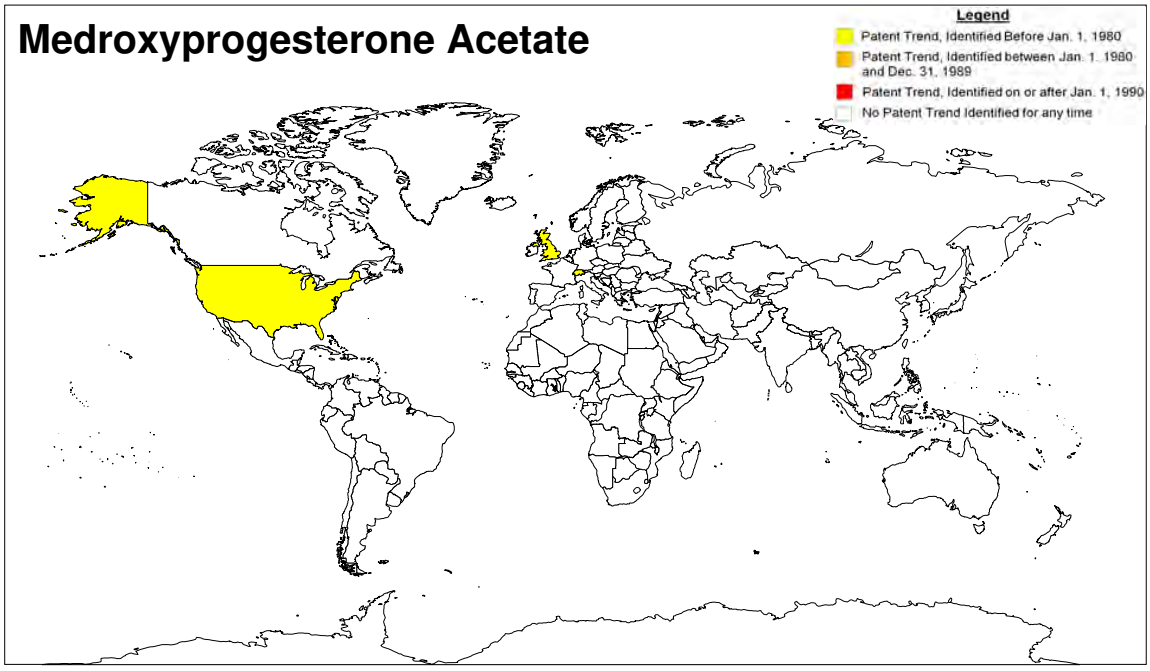
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3377364	Upjohn Co./U.S.	Upjohn Co./U.S.	Sept. 23, 1957

Orange Book Patents:

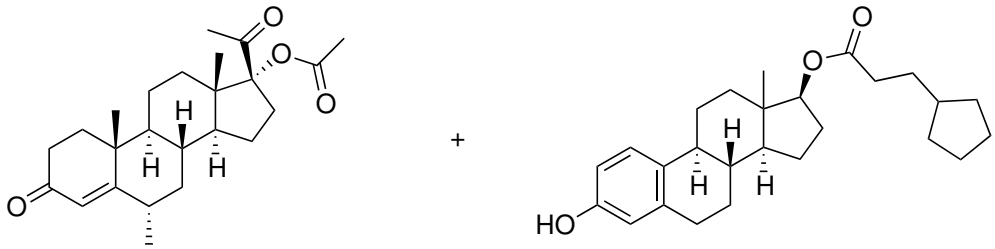
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Medroxyprogesterone Acetate Family Data



Medroxyprogesterone Acetate + Estradiol Cypionate

Injection: 25 mg + 5 mg



Use:	Parenteral combined progestogen-estrogen contraception (short-term)
IUPAC Name:	(6S,8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-3-oxo-2,3,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl acetate + (8R,9S,14S,17S)-3-hydroxy-13-methyl-7,8,9,11,12,13,14,15,16,17-decahydro-6H-cyclopenta[a]phenanthren-17-yl 3-cyclopentylpropanoate (6S,8R,9S,10R,13S,14S,17R)-17-acetyl-6,10,13-trimethyl-3-oxo-2,3,6,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl acetate (8R,9S,14S,17S)-3-hydroxy-13-methyl-7,8,9,11,12,13,14,15,16,17-decahydro-6H-cyclopenta[a]phenanthren-17-yl 3-cyclopentylpropanoate
CAS Number:	71615-27-5 71-58-9 313-06-4
Chemical Formula:	$C_{24}H_{34}O_4$ + $C_{26}H_{36}O_3$ $C_{24}H_{34}O_4$ $C_{26}H_{36}O_3$

Base Patent For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

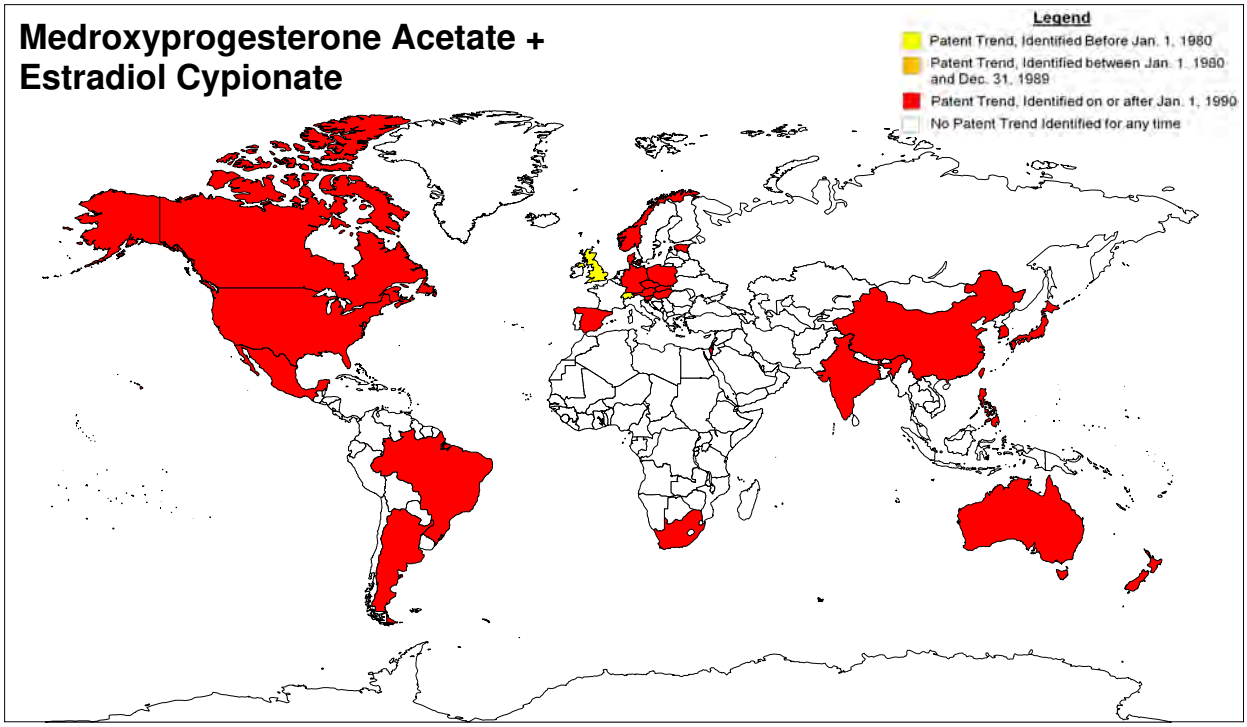
Base Patents For Components:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2096744	Schering Corp./U.S.	Schering Corp./U.S.	Oct. 21, 1933
US3377364	Upjohn Co./U.S.	Upjohn Co./U.S.	Sept. 23, 1957
US6495534	Pharmacia & Upjohn SpA/Italy; Pharmacia & Upjohn Company/USA	Pharmacia & Upjohn SpA/Italy; Pharmacia & Upjohn Company/USA	May 15, 2000

Orange Book Patents:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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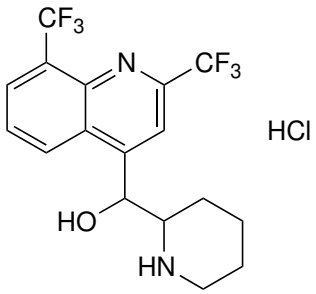
World Map Generated from Medroxyprogesterone Acetate + Estradiol Cypionate Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Mefloquine

Tablet: 250 mg



Use:	Treatment of uncomplicated malaria due to multimedicine-resistant *P. falciparum* in combination with other antimalarials
IUPAC Name:	(2,8-bis(trifluoromethyl)quinolin-4-yl)(piperidin-2-yl)methanol hydrochloride
CAS Number:	53230-10-7
Chemical Formula:	$C_{17}H_{16}F_6N_2O$

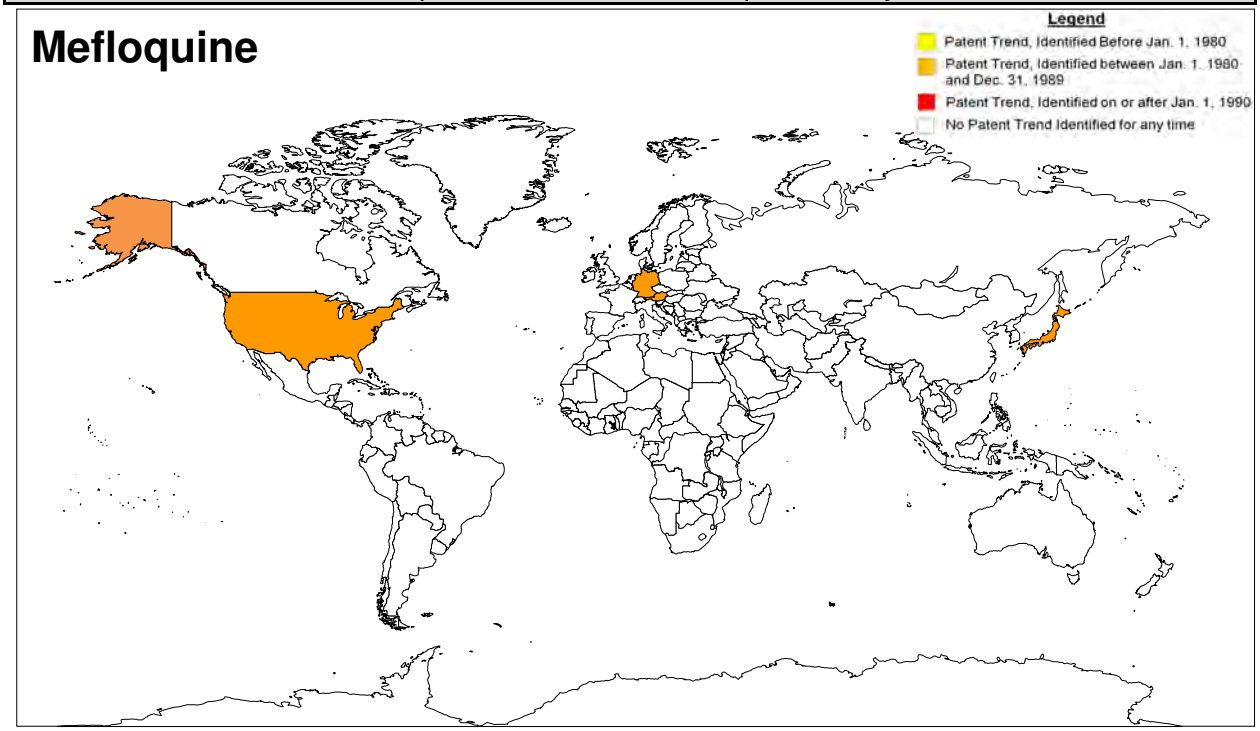
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4507482	Hoffman-LaRoche Inc./U.S.	Hoffman-LaRoche Inc./U.S.	Apr. 4, 1983

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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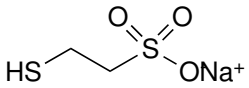
World Map Generated from Mefloquine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Mesna

Injection: 100 mg/ml;
Tablet: 400 mg, 600 mg



Use:	Detoxifying agent to inhibit the hemorrhagic cystitis induced by fosfamide
IUPAC Name:	sodium 2-mercaptoethanesulfonate
CAS Number:	19767-45-4
Chemical Formula:	$C_2H_5NO_3S_2$

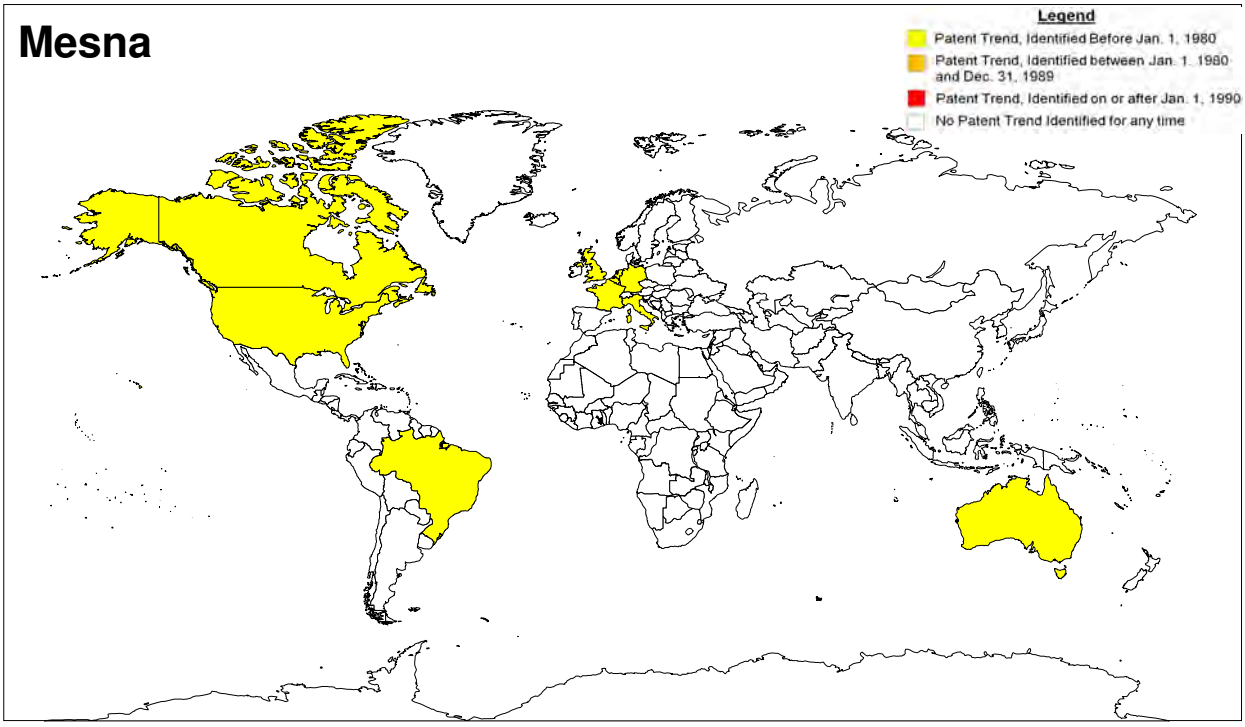
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US3567835	UCB SA/Belgium	UCB SA/Belgium	Dec. 13, 1968

Orange Book Patents:

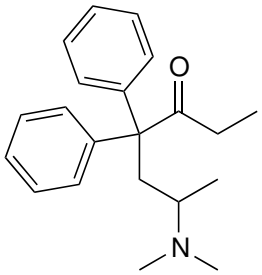
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Mesna Family Data



Methadone

Oral Liquid: 5 mg/5 ml, 10 mg/5 ml;
Concentrate for Oral Liquid: 5 mg/ml, 10 mg/ml



Use:	Adjunct in treatment of opioid dependence.
IUPAC Name:	6-(dimethylamino)-4,4-diphenyl-3-hepatanone hydrochloride
CAS Number:	76-99-3
Chemical Formula:	$C_{21}H_{27}NO$

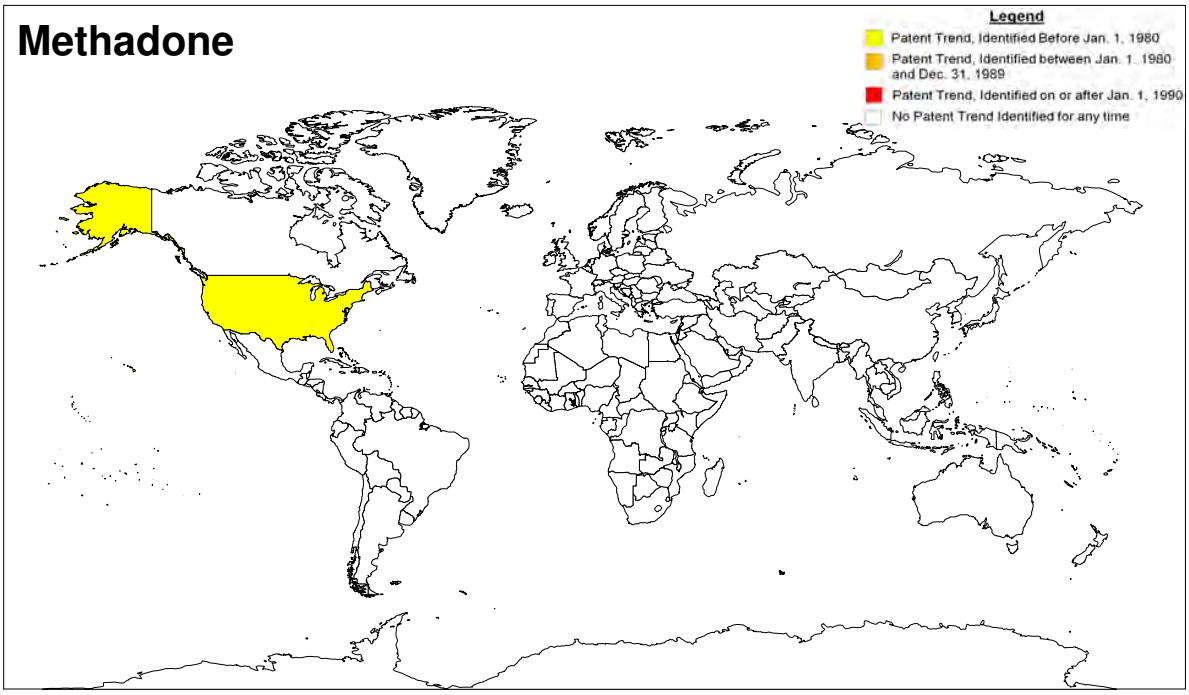
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2644010	Merck & Co. Inc./U.S.	Merck & Co. Inc./U.S.	Oct. 24, 1947

Orange Book Patents:

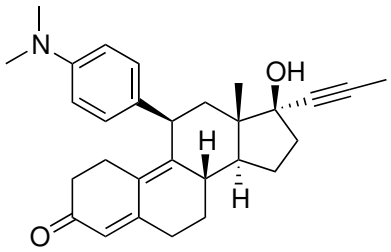
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Methadone Family Data



Mifepristone

Oral Tablet; 200 mg



Use:	Medical termination of intrauterine pregnancy
IUPAC Name:	11ß-[p- (Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one
CAS Number:	84371-65-3
Chemical Formula:	$C_{29}H_{35}NO_2$

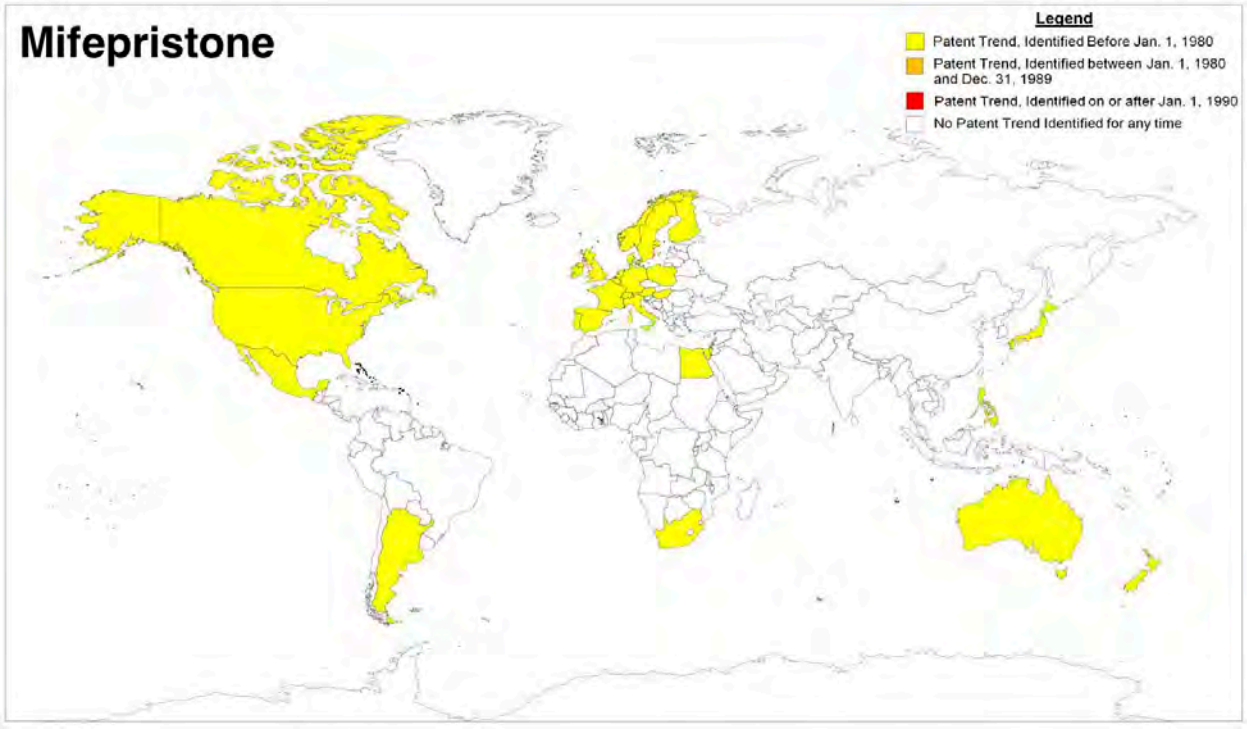
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4160027	Sterling Drug, Inc.	Sterling Drug, Inc.	Dec. 20, 1977

Orange Book Patents:

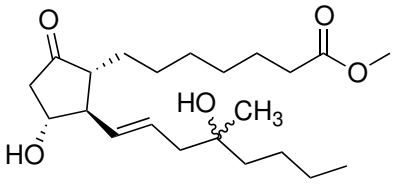
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Mifepristone Family Data



Misoprostol

Oral Tablet: 200 µg;
Vaginal Tablet: 25 µg



Use:	Induction of labour; medical termination of intrauterine pregnancy of up to 63 days gestation with mifepristone.
IUPAC Name:	methyl 7-((1R,2R,3R)-3-hydroxy-2-((E)-4-hydroxy-4-methyloct-1-en-1-yl)-5-oxocyclopentyl)heptanoate
CAS Number:	59122-46-2
Chemical Formula:	$C_{22}H_{38}O_5$

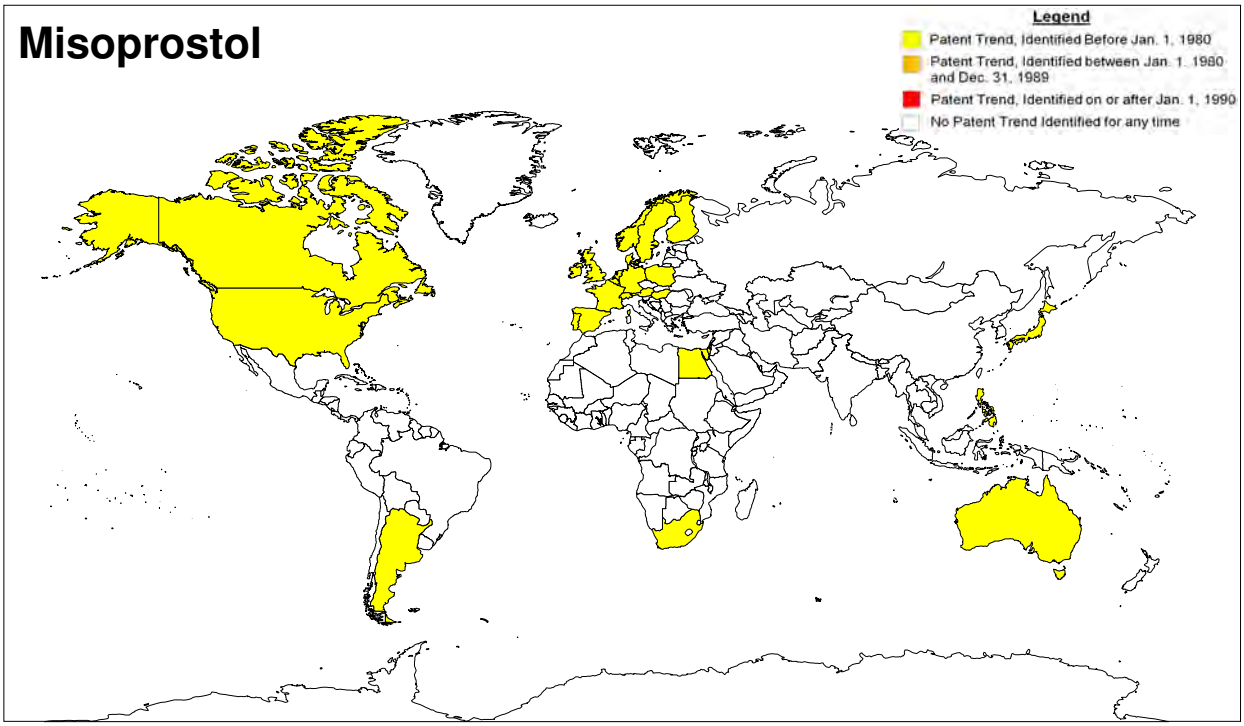
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3965143	G.D. Searle & Co./U.S.	G.D. Searle & Co./U.S.	Mar. 26, 1974

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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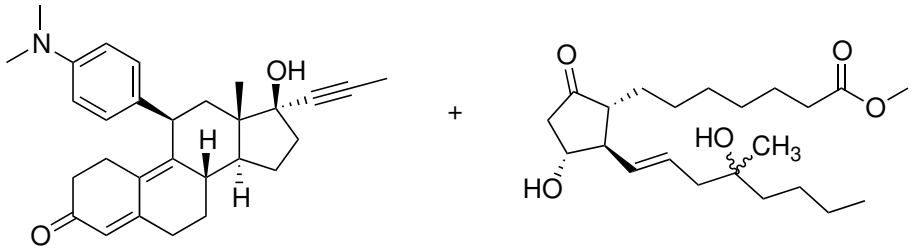
World Map Generated from Misoprostol Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan. 1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	
Gulf Cooperation Council	
World Intellectual Property Organization	

Misoprostol + Mifepristone

Oral Tablet: 200 mg;
Vaginal Tablet: 200 µg



Use:	Medical termination of intrauterine pregnancy of up to 63 days gestation with misoprostol.
IUPAC Name:	11ß-[p- (Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one + methyl 7-((1R,2R,3R)-3-hydroxy-2-((E)-4-hydroxy-4-methyloct-1-en-1-yl)-5-oxocyclopentyl)heptanoate 11ß-[p- (Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one methyl 7-((1R,2R,3R)-3-hydroxy-2-((E)-4-hydroxy-4-methyloct-1-en-1-yl)-5-oxocyclopentyl)heptanoate
CAS Number:	84371-65-3 + 59122-46-2 84371-65-3 59122-46-2
Chemical Formula:	$C_{29}H_{35}NO_2 + C_{22}H_{38}O_5$ $C_{29}H_{35}NO_2$ $C_{22}H_{38}O_5$

Base Patent for Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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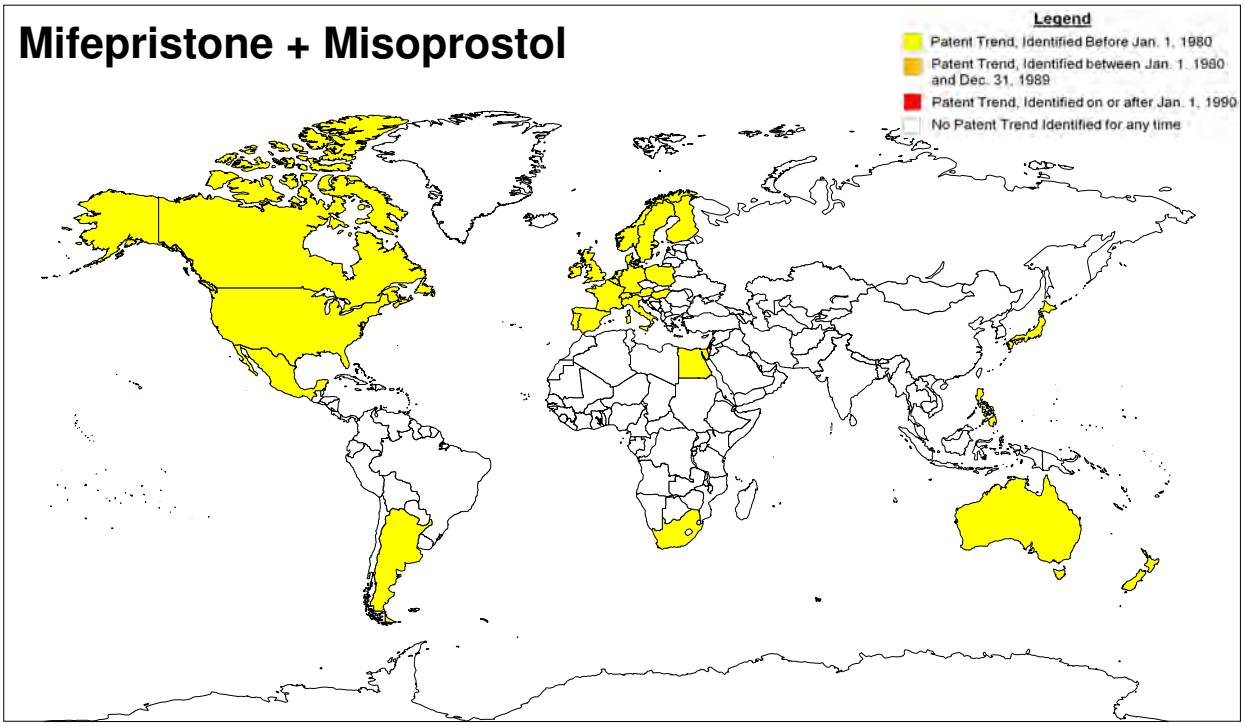
Base Patents for Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4160027	Sterling Drug, Inc.	Sterling Drug, Inc.	Dec. 20, 1977
US3965143	G.D. Searle & Co./U.S.	G.D. Searle & Co./U.S.	Mar. 26, 1974

Orange Book Patents:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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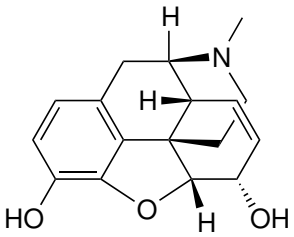
World Map Generated from Mifepristone + Misoprostol Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan. 1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	
Gulf Cooperation Council	
World Intellectual Property Organization	

Morphine

Time Release Oral Tablet: 10 mg, 30 mg, 60 mg



Use:	Severe pain (acute and chronic); myocardial infarction, acute pulmonary oedema; adjunct during major surgery and postoperative analgesia
IUPAC Name:	7,8 didehydro-4,5 α-epoxy-17-methylmorphinan-3,6 α-diol
CAS Number:	57-27-2
Chemical Formula:	$C_{27}H_{29}NO_3$

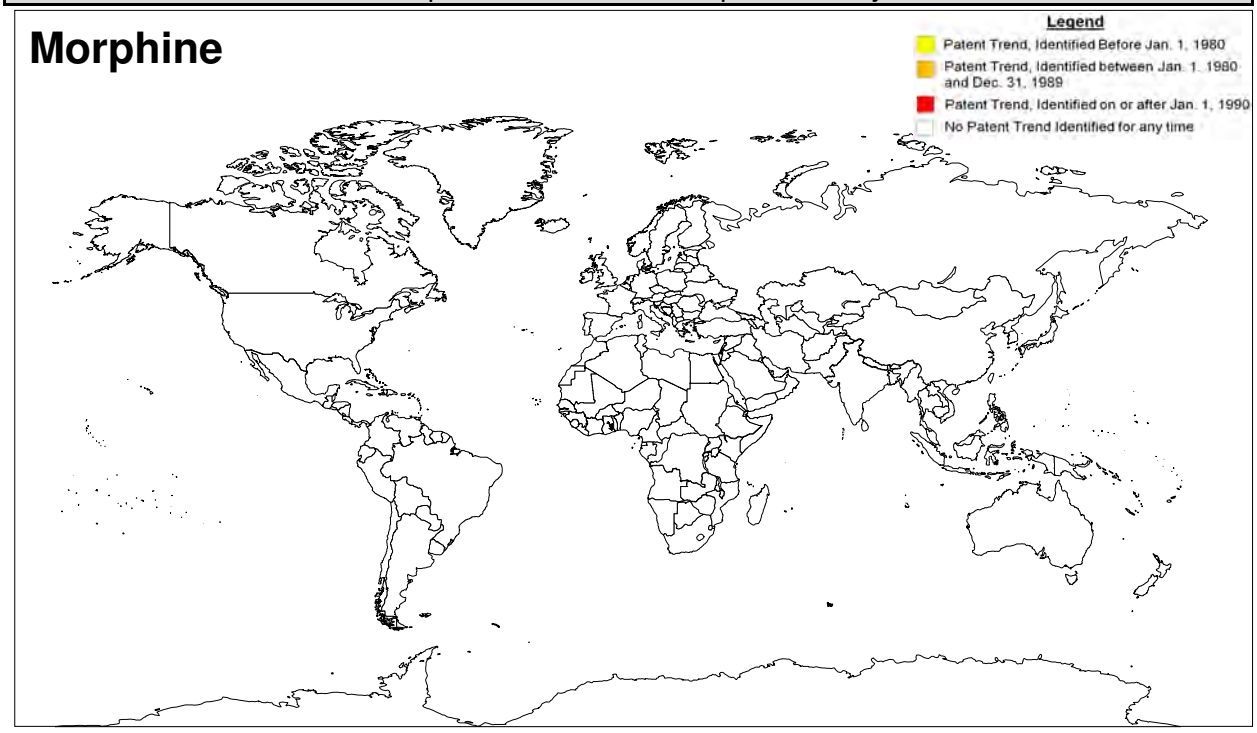
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Orange Book Patents:

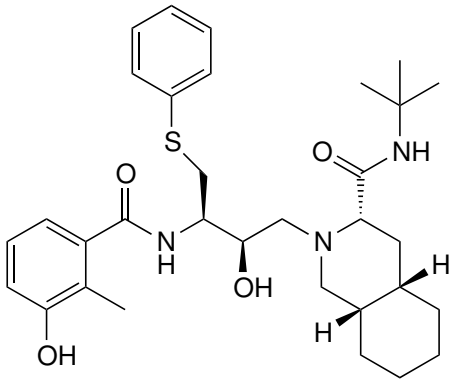
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Morphine Family Data



Nelfinavir

Tablet: 250mg (as mesilate);
Oral Powder: 50 mg/g



Use:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	(3S,4aS,8aS)-N-(1,1-Dimethylethyl)decahydro-2-((2R,3R)-2-hydroxy-3-((3-hydroxy-2-methylbenzoyl)amino)-4-(phenylthio)butyl)-3-isoquinolinecarboxamide
CAS Number:	159989-64-7
Chemical Formula:	$C_{32}H_{45}N_3O_4S$

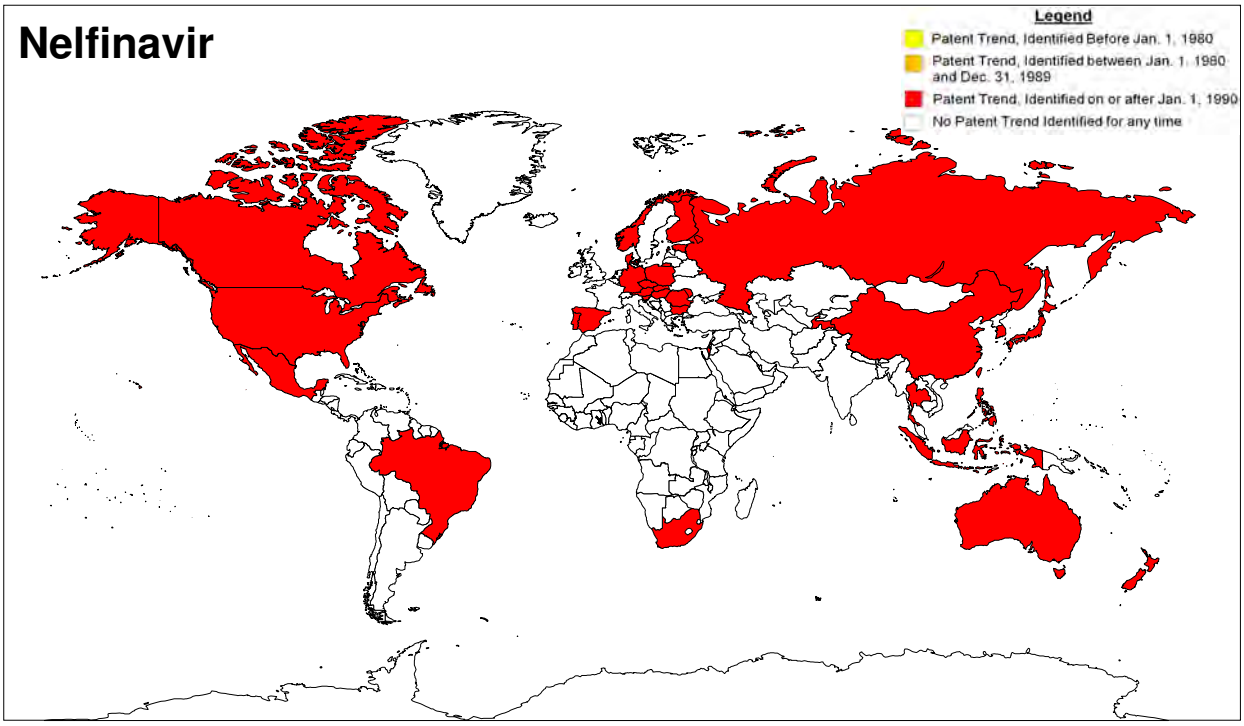
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5484926	Agouron Pharma/U.S.	Agouron Pharma/U.S.	Feb. 2, 1994

Orange Book Patents:

Patent	Patent Listed Assignee /Country	Current Listed Assignee/ Country	Date Filed
US5484926	Agouron Pharma/United States	Agouron Pharma/United States	Feb 2, 1994
US5952343	Agouron Pharmaceuticals/United States	Agouron Pharmaceuticals/United States	Jun. 7, 1995
US6162812	Agouron Pharma/United States	Agouron Pharma/United States	Apr. 1, 1999

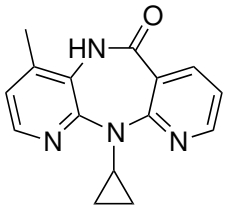
World Map Generated from Nelfinavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Nevirapine

Tablet: 200 mg;
Oral Solution: 50 mg/5 ml;
Oral Liquid: 50 mg/5 ml



Use:	HIV infection in combination with at least two other antiretroviral medicines; prevention of mother-to-child HIV transmission.
IUPAC Name:	11-Cyclopropyl-5,11-dihydro-4-methyl-6H-dipyrido(3,2-b:2',3'-e)(1,4)diazepin-6-one
CAS Number:	129618-40-2
Chemical Formula:	$C_{15}H_{14}N_4O$

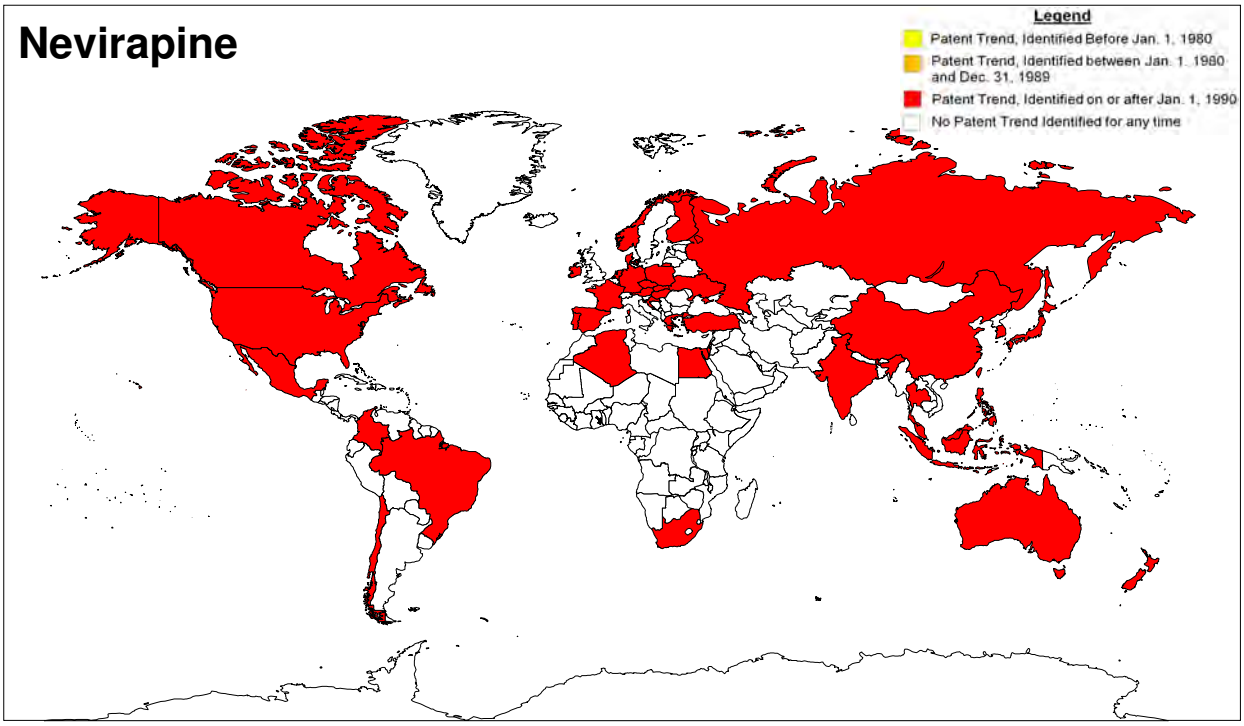
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5366972	Boehringer Ingelheim Pharma/Germany	Boehringer Ingelheim Pharma/Germany	Jul. 13, 1993

Orange Book Patents:

Patent	Patent Listed Assignee/ Country	Current Listed Assignee /Country	Date Filed
US5366972	Boehringer Ingelheim Pharma/ Germany	Boehringer Ingelheim Pharma/ Germany	Jul. 13, 1993

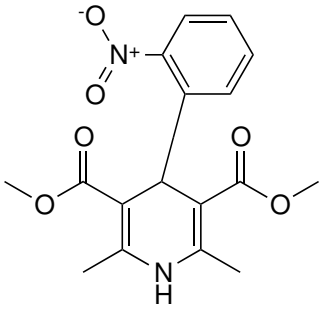
World Map Generated from Nevirapine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Nifedipine

Immediate Release Capsule: 10mg



Use:	Uncomplicated premature labour
IUPAC Name:	1,4-Dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridinedicarboxylic acid dimethyl ester
CAS Number:	21829-25-4
Chemical Formula:	$C_{17}H_{18}N_2O_6$

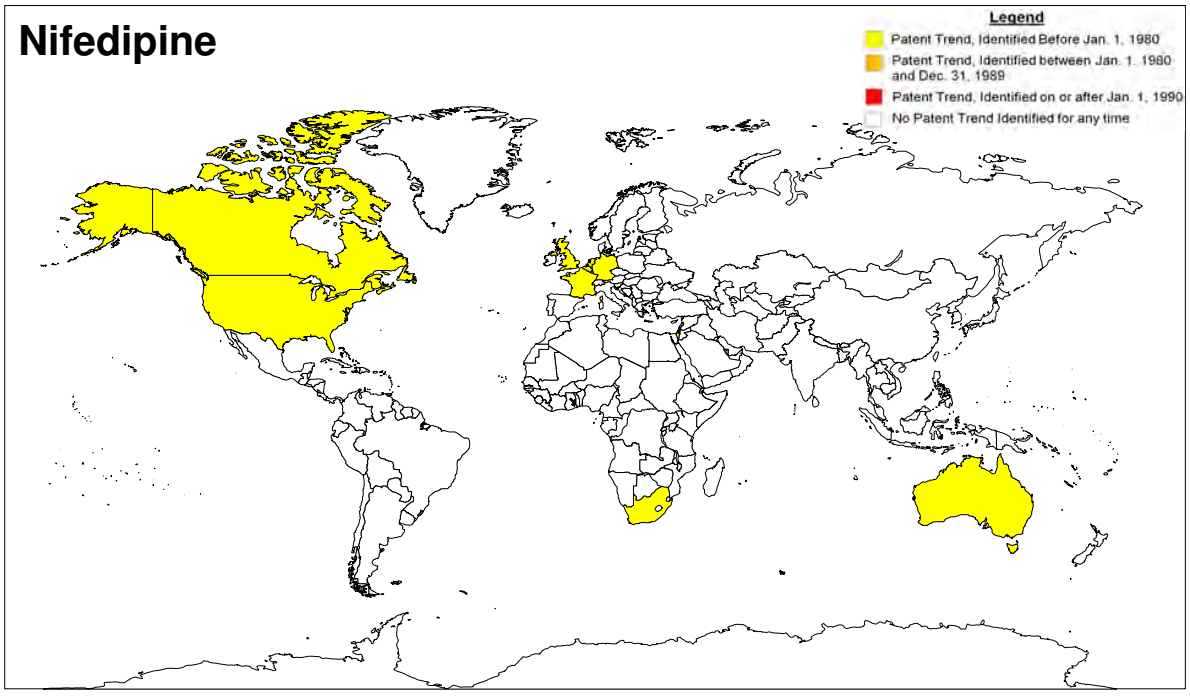
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Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3485847	Bayer AG/Germany	Bayer AG/Germany	Mar. 13, 1968

Orange Book Patents:

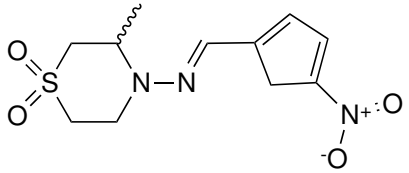
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Nifedipine Family Data



Nifurtimox

Tablet: 30 mg, 120 mg, 250 mg



Use:	Acute American trypanosomiasis (Chagas disease).
IUPAC Name:	3-Methyl-N-((5-nitro-2-furanyl)methylene)-4-thiomorpholinamine 1,1-dioxide
CAS Number:	23256-30-6
Chemical Formula:	$C_{10}H_{13}N_3O_5S$

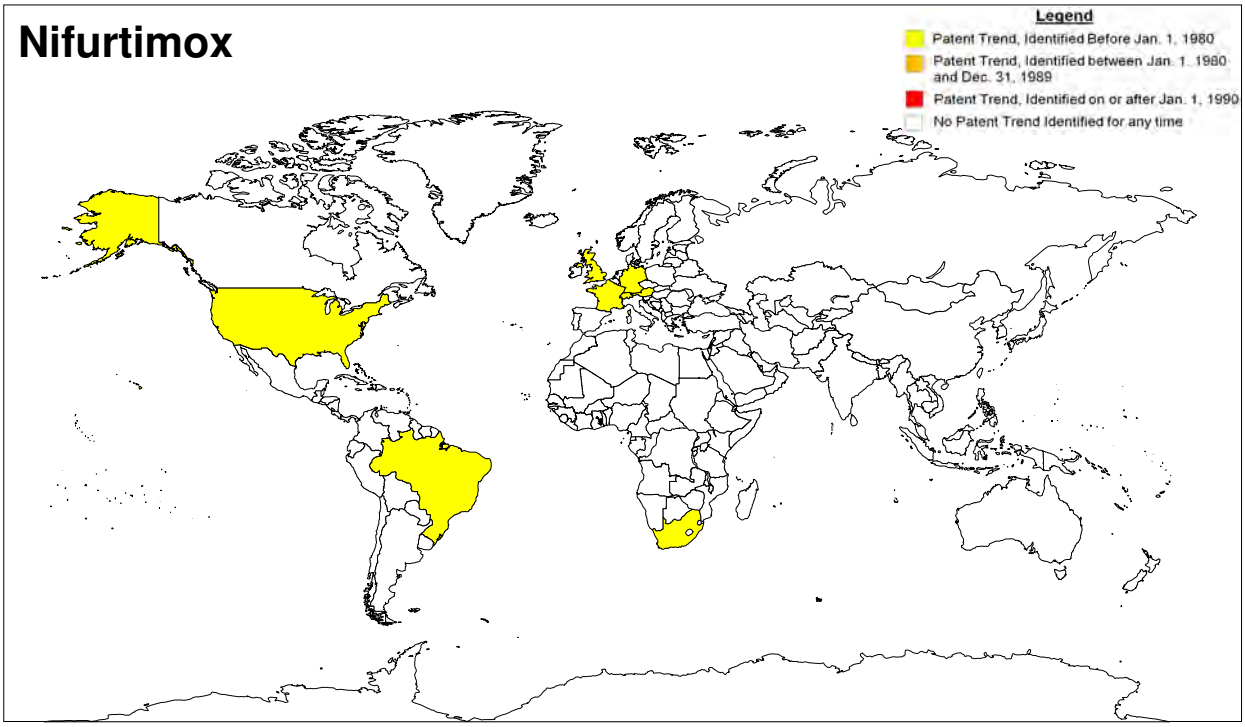
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3262930	Bayer AG/German	Bayer AG/Germany	Nov. 13, 1963

Orange Book Patents:

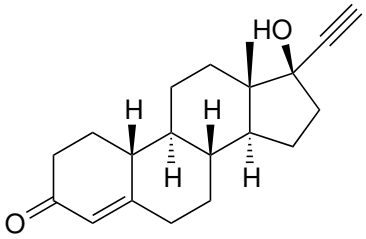
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Nifurtimox Family Data



Norethisterone Enantate

Solution: 200 mg/ml in 1-ml ampoule



Use:	Parenteral progestogen-only contraception (short-term)
IUPAC Name:	(17alpha)-17-Hydroxy-19-norpregn-4-en-20-yn-3-one
CAS Number:	68-22-4
Chemical Formula:	$C_{20}H_{26}O_2$

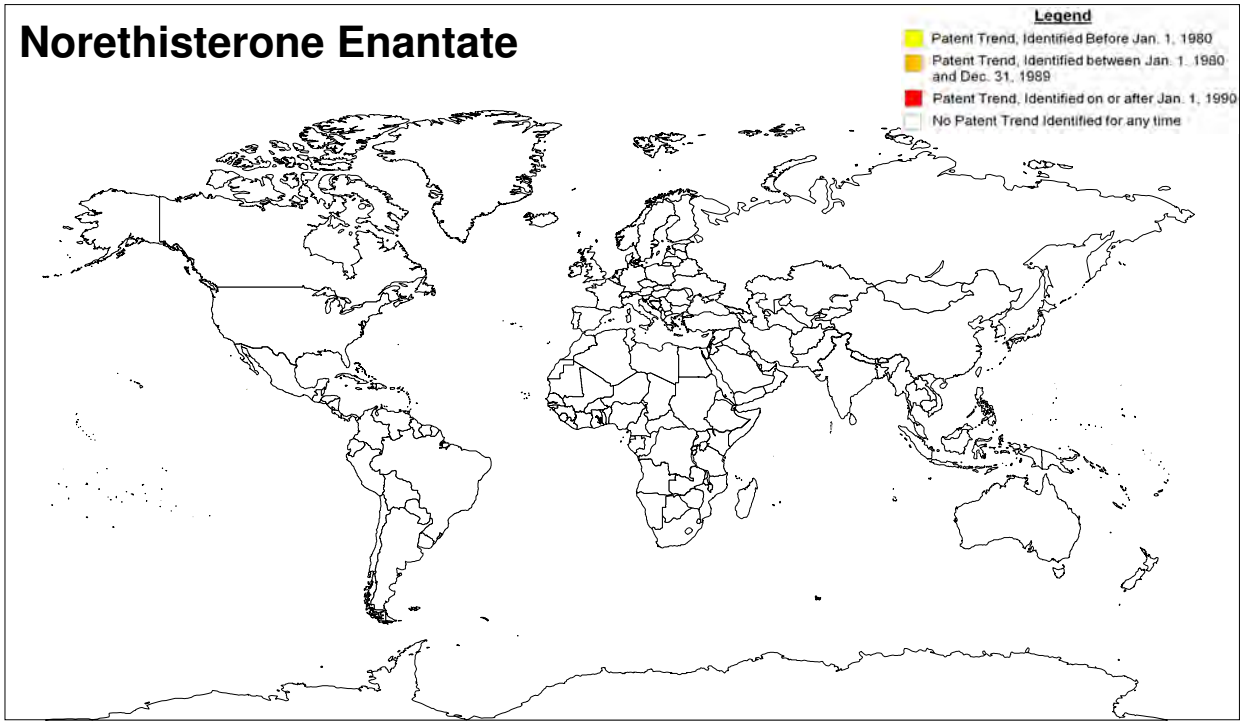
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2744122	Syntex SA/Switzerland	Syntex SA/Switzerland	Nov. 12, 1952

Orange Book Patents:

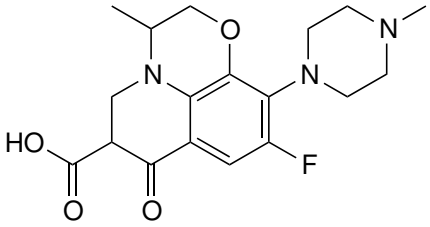
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Norethisterone Enantate Family Data



Ofloxacin

Tablet: 200 mg, 400 mg.



Use:	Treatment of multimedicine-resistant tuberculosis which should be used in specialized centres adhering to WHO standards for tuberculosis control.
IUPAC Name:	9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido(1,2,3-de)-1,4-benzoxazine-6-carboxylic acid
CAS Number:	82419-36-1
Chemical Formula:	$C_{18}H_{20}FN_3O_4$

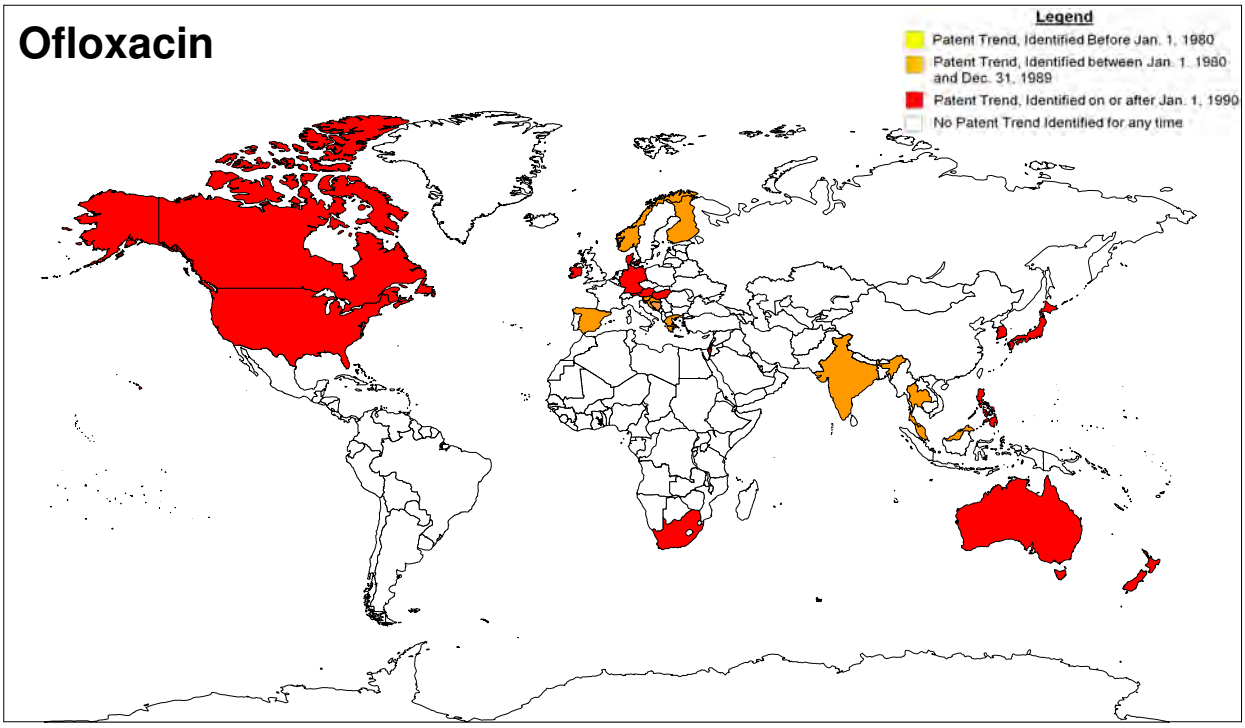
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4382892	Daiichi Seiyaku Co./Japan	Daiichi Seiyaku Co./Japan	Sept. 2, 1981

Orange Book Patents:

Patent	Patent Listed Assignee/ Country	Current Listed Assignee/ Country	Date Filed
US5401741	Daiichi Seiyaku Co/Japan	Daiichi Seiyaku Co/Japan	Apr. 12, 1993

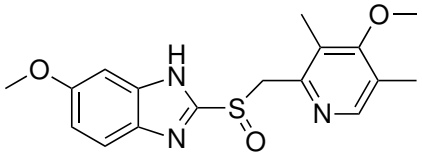
World Map Generated from Ofloxacin Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	

Omeprazole

Powder for Oral Liquid: 20 mg, 40 mg;
Solid oral Dosage Form: 10 mg, 20 mg, 40 mg



Use:	Treatment of peptic ulcers
IUPAC Name:	5-Methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl)-1H-benzimidazole
CAS Number:	73590-58-6
Chemical Formula:	$C_{17}H_{19}N_3O_3S$

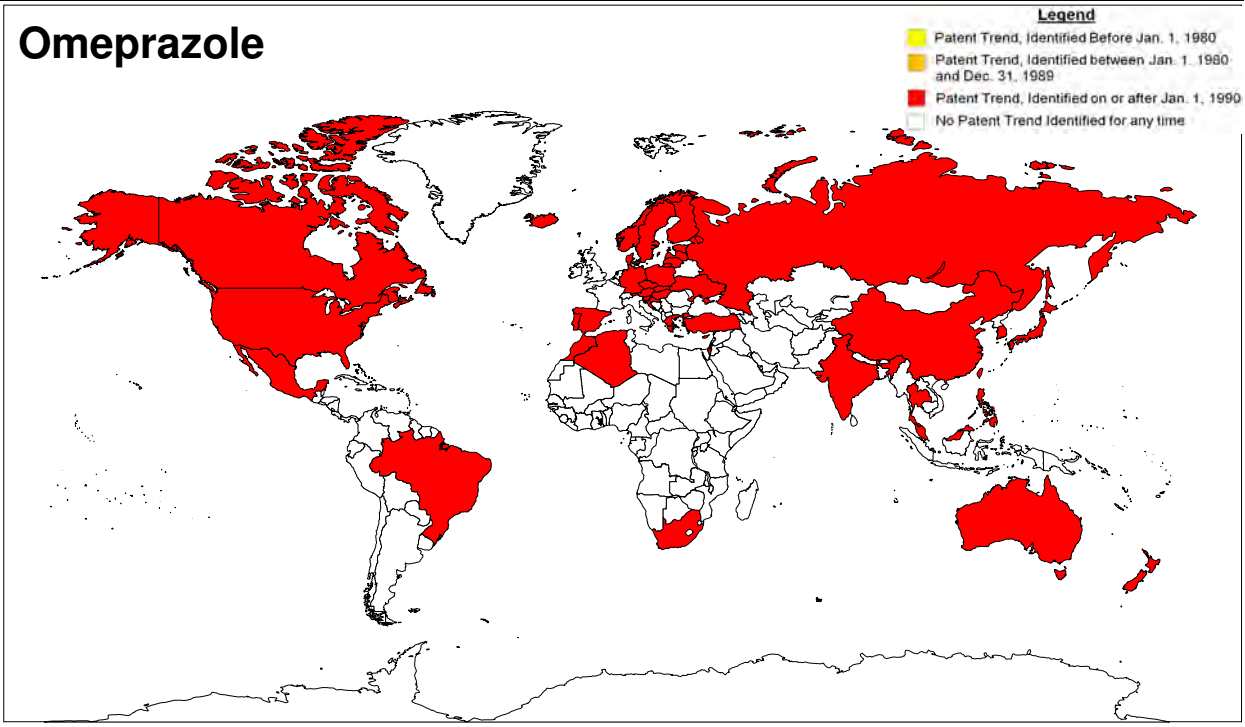
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5693818	Astra AB/Sweden	Astrazeneca/Sweden	Jun. 28, 1994

Orange Book Patents:

Patent	Patent Listed Assignee/ Country	Current Listed Assignee/ Country	Date Filed
US6147103	Merck & Co, Inc./United States	Merck & Co, Inc./United States	Sep. 1, 1999
US6150380	Astra AB/Sweden	Astrazeneca AB/Sweden	Dec. 10, 1998
US6166213	Merck & Co., Inc./United States	Merck & Co., Inc./United States	Oct. 9, 1998
US6191148	Merck & Co., Inc./United States	Merck & Co., Inc./United States	Dec. 15, 1999

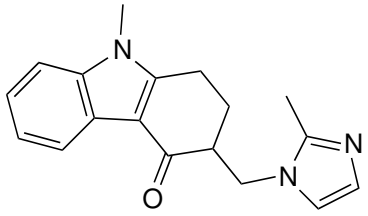
World Map Generated from Omeprazole Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Ondansetron

Injection: 2 mg base/ml in 2 mL ampoule (as hydrochloride);
Oral Liquid, 4 mg base/5 mL;
Solid Oral Dosage Form: 4 mg, 8 mg, 24 mg



Use:	Prevention of nausea and vomiting associated with moderately- to highly-emetogenic cancer chemotherapy; radiotherapy; prevention of postoperative nausea and vomiting (PONV); treatment of PONV if no prophylactic dose of ondansetron received.*
IUPAC Name:	1,2,3,9-Tetrahydro-9-methyl-3-((2-methyl-1H-imidazol-1-yl)methyl)-4H-carbazol-4-one
CAS Number:	99614-02-5
Chemical Formula:	$C_{18}H_{19}N_3O$

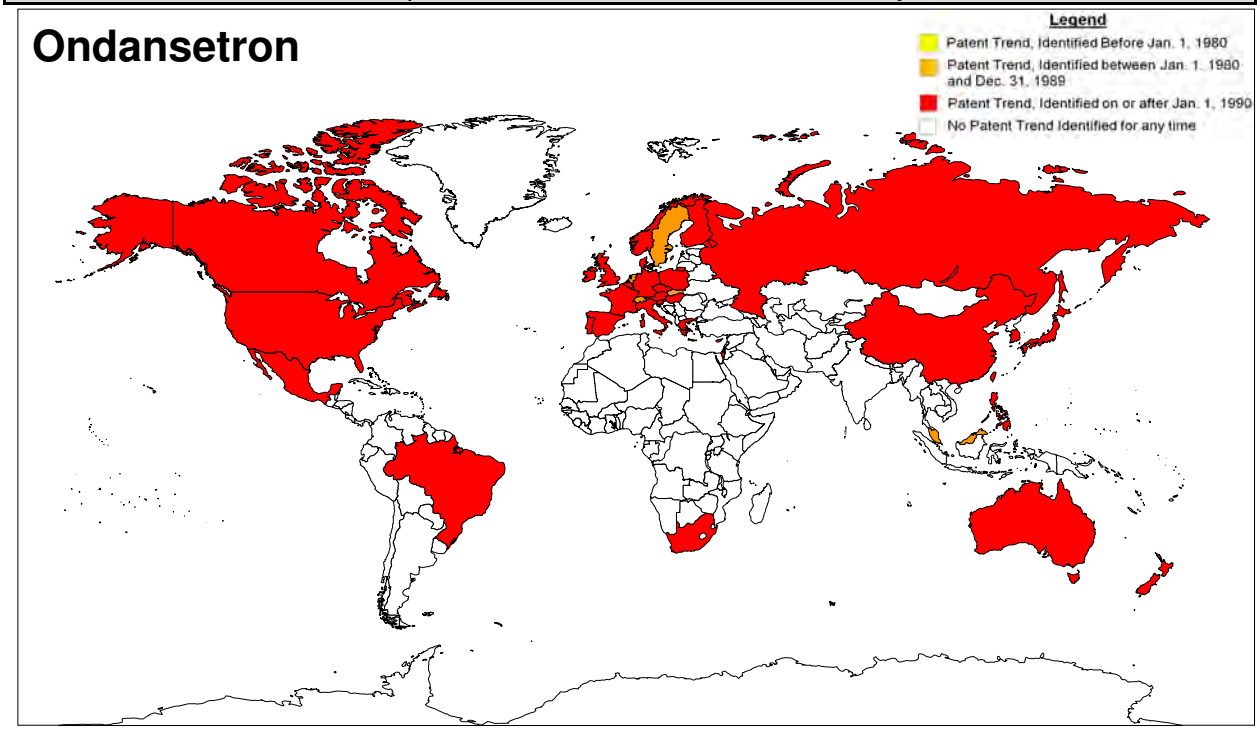
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4695578	Glaxo Grp. Ltd./England	Glaxo Grp. Ltd./England	Nov. 17, 1986

Orange Book Patents:

Patent	Patent Listed Assignee/ Country	Current Listed Assignee/ Country	Date Filed
US5955488	Glaxo Wellcome, Inc./England	Glaxo Wellcome, Inc./England	Apr. 8, 1998
US6063802	Glaxo Wellcome, Inc./England	Glaxo Wellcome, Inc./England	Jan. 28, 1999

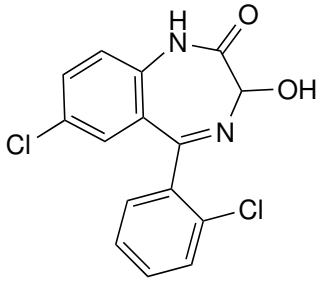
World Map Generated from Ondansetron Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Parenteral Lorazepam

Liquid: 2 mg/mL, 4 mg/mL in 1 mL ampoule



Use:	Status epilepticus, amnesia, sedation.*
IUPAC Name:	7-Chloro-5-(2-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2- one
CAS Number:	846-49-1
Chemical Formula:	$C_{15}H_{10}C_{l2}N_2O_2$

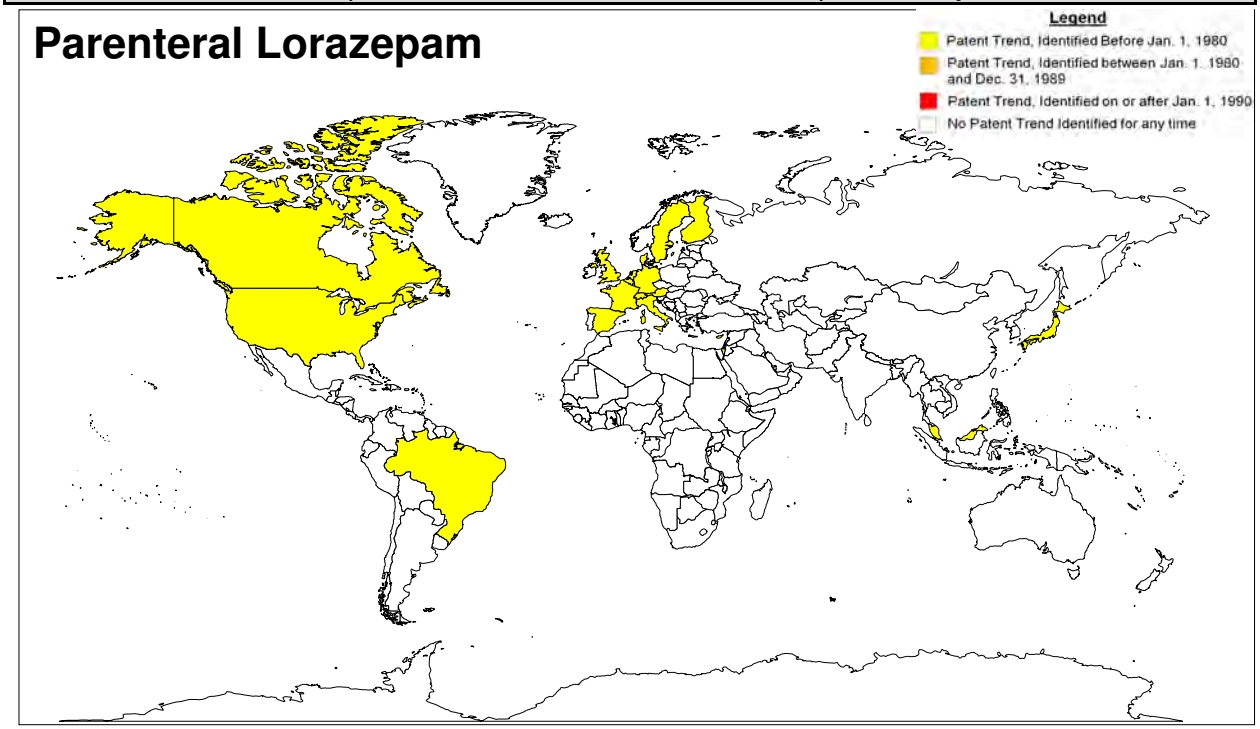
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3296249	American Home Prod./U.S.	American Home Prod./U.S.	Jun. 4, 1963

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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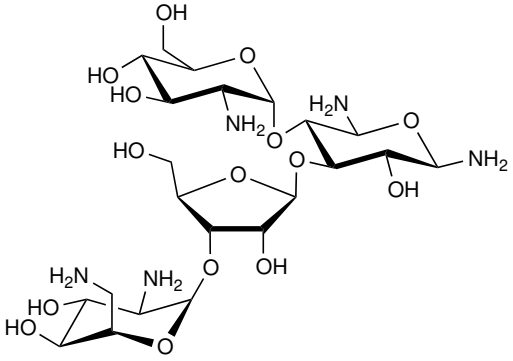
World Map Generated from Parenteral Lorazepam Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan. 1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	
Gulf Cooperation Council	
World Intellectual Property Organization	

Paromomycin

Injection: 750 mg of paromomycin base (as sulfate)



Use:	Visceral leishmaniasis unresponsive to antimonial compounds.
IUPAC Name:	O-2-Amino-2-deoxy-alpha-D-glucopyranosyl-(1-->4)-O-(O-2,6-diamino-2,6-dideoxy-beta-L-idopyranosyl-(1-->3)-beta-D-ribofuranosyl-(1-->5))-2-deoxy-D-streptamine
CAS Number:	7542-37-2
Chemical Formula:	$C_{23}H_{45}N_5O_{14}$

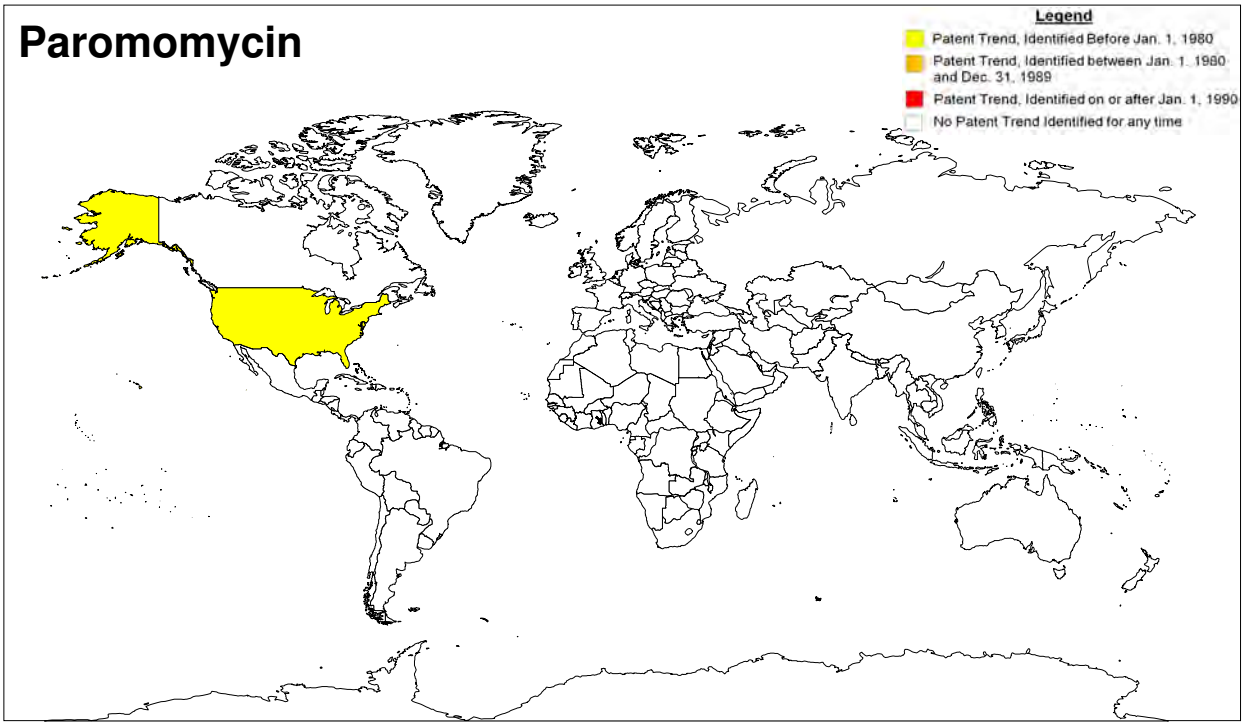
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2895876	Pfizer & Co./U.S.	Pfizer and Co./U.S.	Mar. 11, 1954

Orange Book Patents:

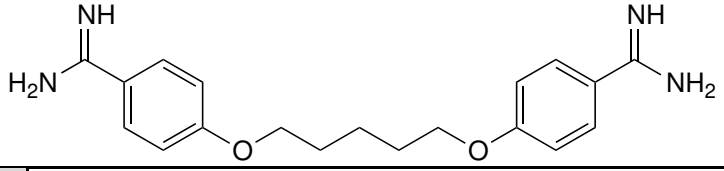
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Paromomycin Family Data



Pentamidine

Powder for Injection: 200 mg (pentamidine isetionate) in vial



Use:	Leihmaniasis; African trypanosomiasis; Pneumocystis carinii (Pneumocystis jiroveci) pneumonia
IUPAC Name:	4,4'-(pentamethylenedioxy)dibenzamidine ; 4,4'-diamidino-alpha,omega-diphenoxypentane
CAS Number:	100-33-4
Chemical Formula:	$C_{19}H_{24}N_4O_2$

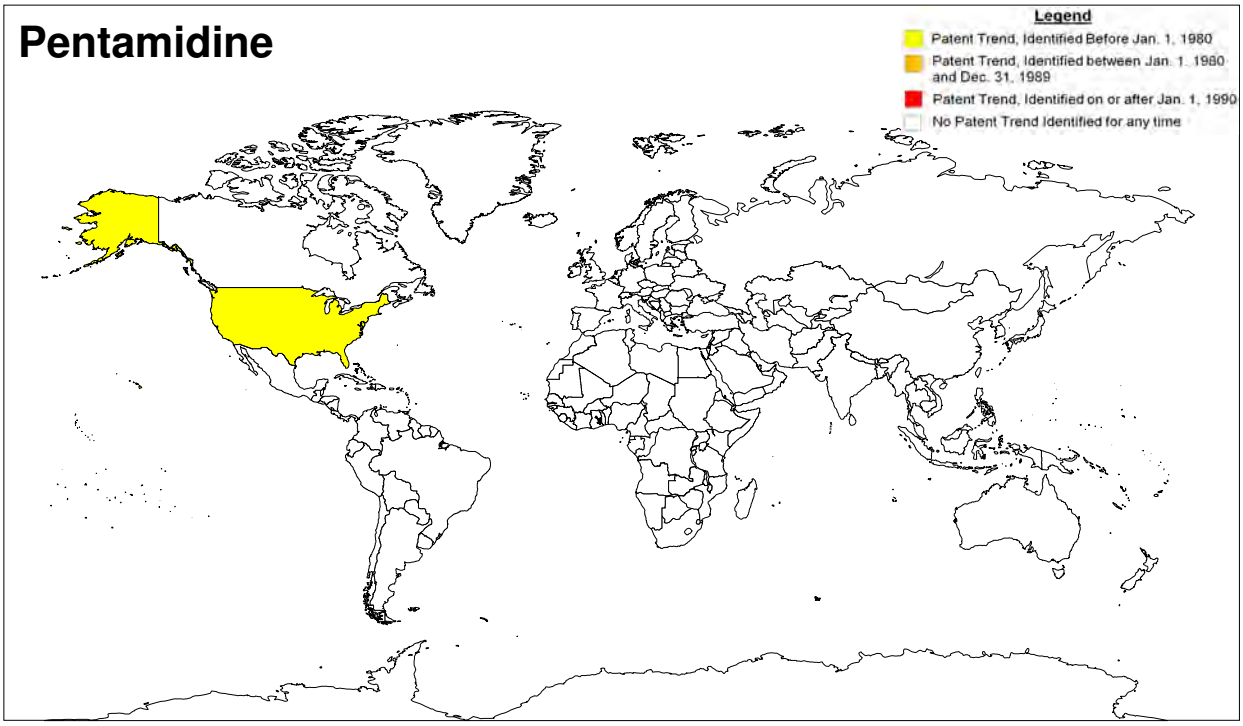
Base Patent:

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US2394003	May & Baker Ltd./England	May & Baker Ltd./England	Apr. 11, 1942

Orange Book Patents:

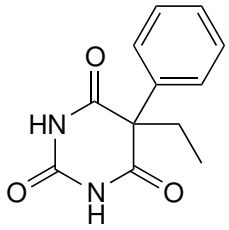
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Pentamidine Family Data



Phenobarbital

Phenobarbital Sodium Injection: 200 mg/ml



Use:	generalized tonic–clonic seizures; partial seizures; neonatal seizures; febrile convulsions; status epilepticus.
IUPAC Name:	5-ethyl-5-phenylpyrimidine-2,4,6(1H,3H,5H)-trione
CAS Number:	50-06-6
Chemical Formula:	$C_{12}H_{12}N_2O_3$

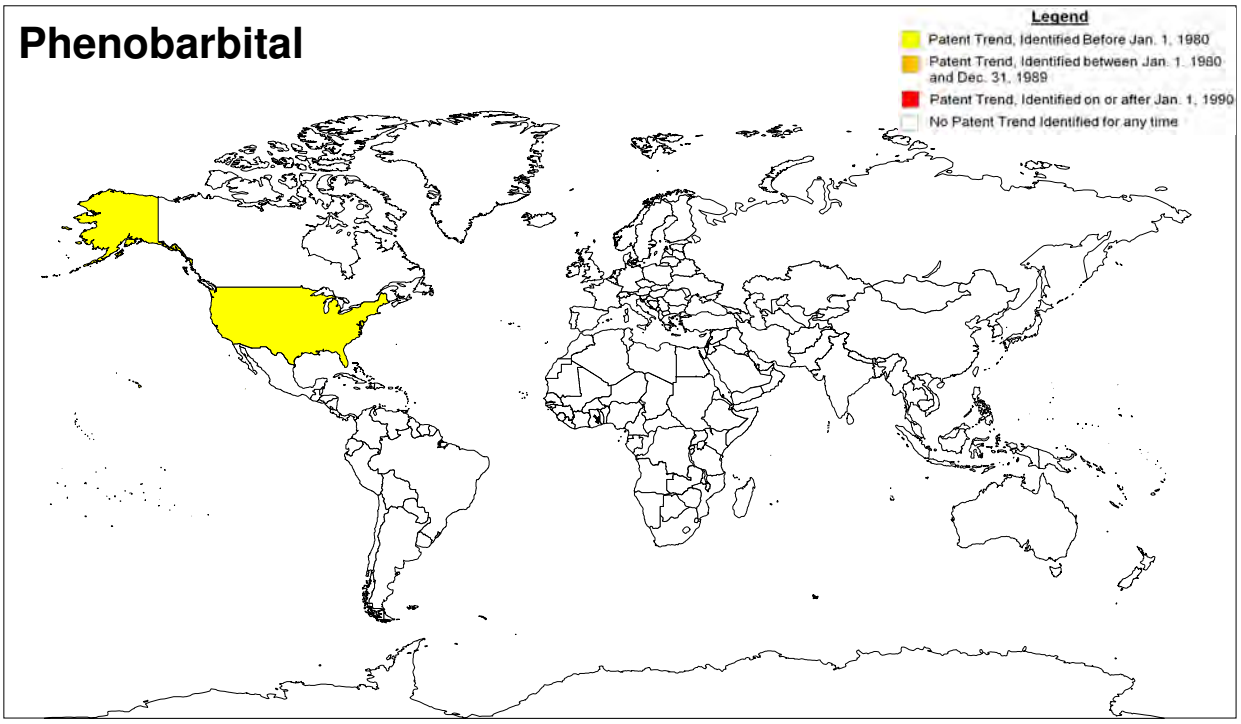
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US1025872	Farbenfabriken Vorm. Friedr. Bayer & Co./ Germany	Farbenfabriken Vorm. Friedr. Bayer & Co./Germany	Sep. 6, 1911

Orange Book Patents:

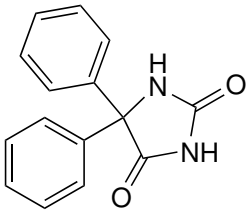
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Phenobarbital Family Data



Phenytoin

Chewable tablet: 50 mg
Oral liquid 25–30 mg/5 ml



Use:	generalized tonic–clonic seizures; partial seizures; status epilepticus.
IUPAC Name:	5,5-diphenylimidazolidine-2,4-dione
CAS Number:	57-41-0
Chemical Formula:	$C_{15}H_{12}N_2O_2$

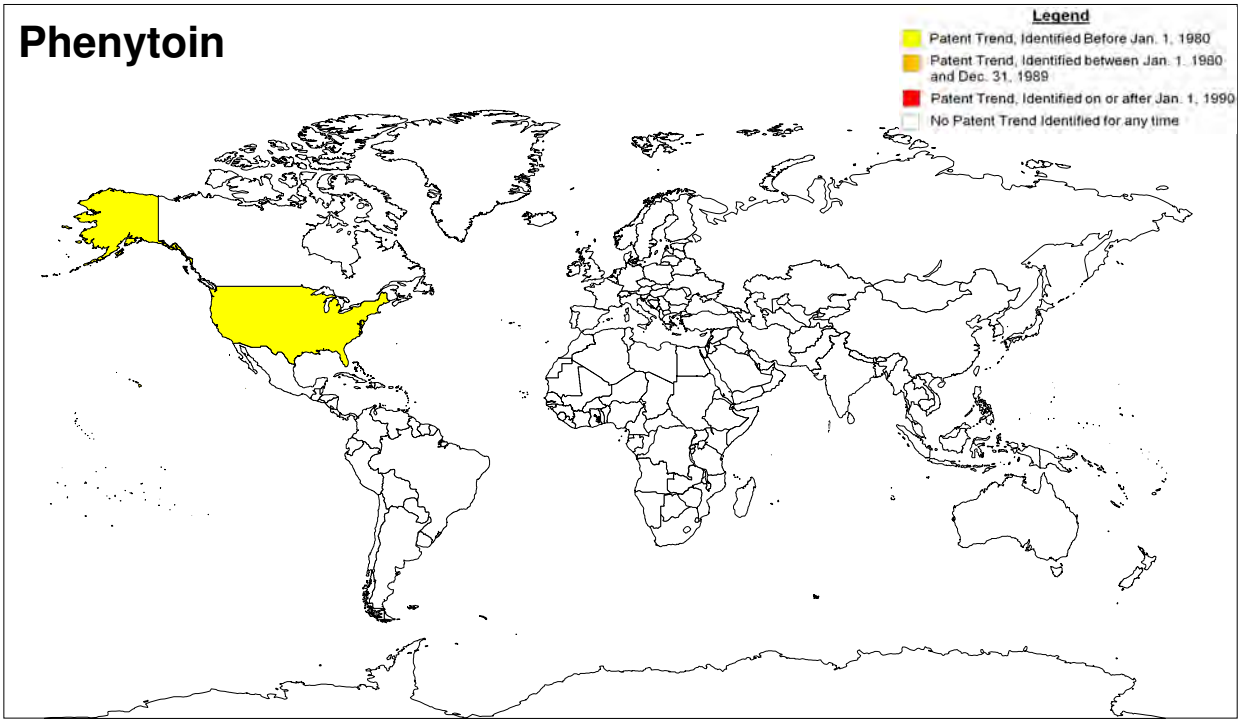
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2409754	Park Davis and Co./USA	Park Davis and Co./USA	Sept. 9, 1940

Orange Book Patents:

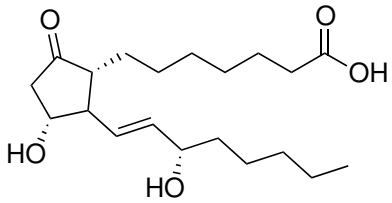
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Phenytoin Family Data



Prostaglandin E1/alprostadil

0.5 mg/ml in alcohol



Use:	temporary maintenance of patency of ductus arteriosus in neonates with ductal-dependent congenital heart disease until surgery can be performed.*
IUPAC Name:	7-((1R,3R)-3-hydroxy-2-((S,E)-3-hydroxyoct-1-en-1-yl)-5-oxocyclopentyl)heptanoic acid
CAS Number:	745-65-3
Chemical Formula:	$C_{20}H_{34}O_5$

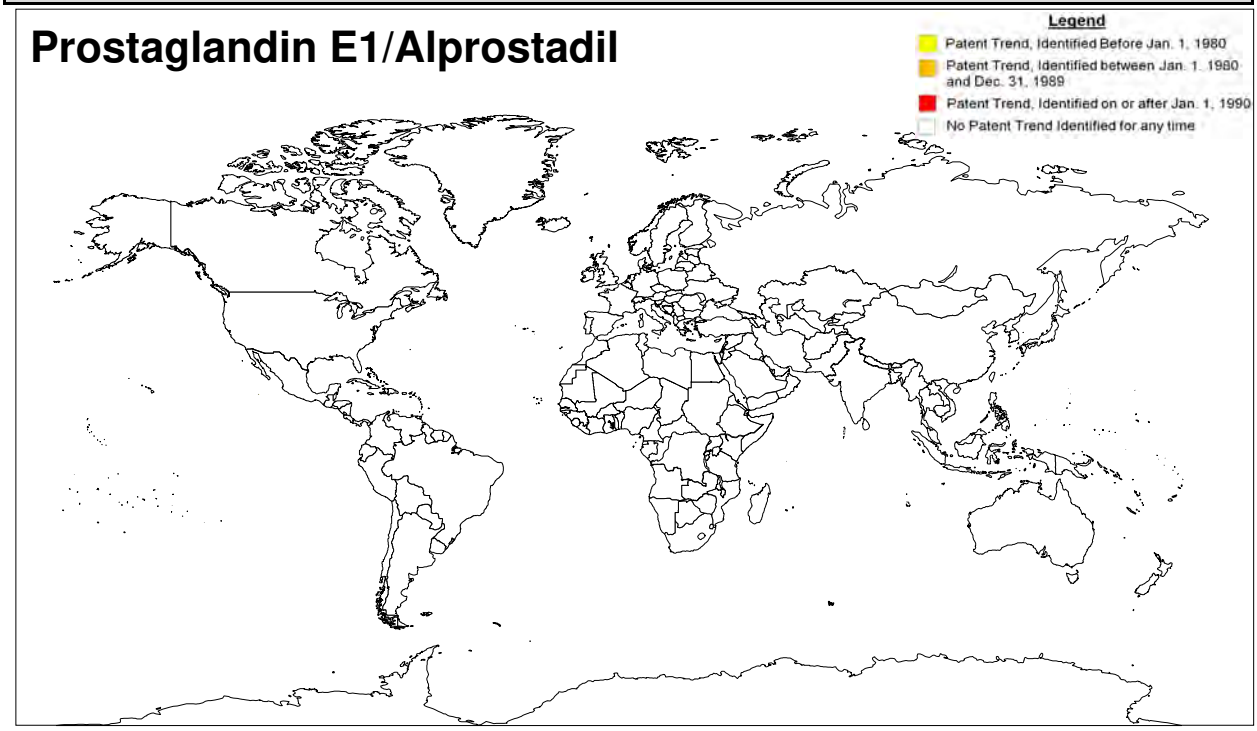
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Orange Book Patents:

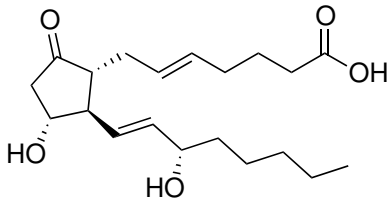
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Prostaglandin E1/alprostadil Family Data



Prostaglandin E2/dinoprostone

Solution for Injection: 1mg/ml



Use:	induction of labour.*
IUPAC Name:	(E)-7-((1R,2R,3R)-3-hydroxy-2-((S,E)-3-hydroxyoct-1-en-1-yl)-5-oxocyclopentyl)hept-5-enoic acid
CAS Number:	363-24-6
Chemical Formula:	$C_{20}H_{32}O_5$

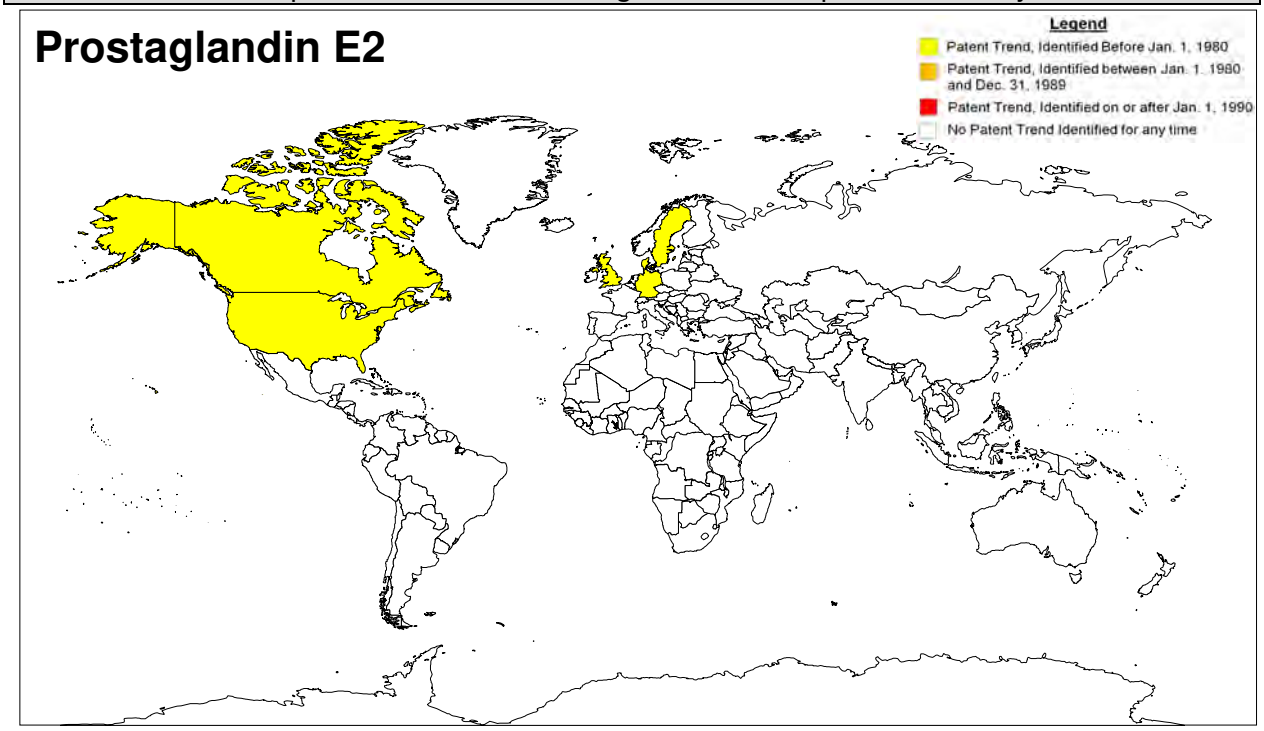
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3598858	JAN SJOVALL; SUNE BERGSTROM/GB	JAN SJOVALL; SUNE BERGSTROM/GB	Jun. 1, 1962

Orange Book Patents:

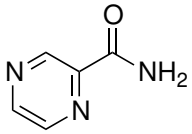
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Prostaglandin E2/dinoprostone Family Data



Pyrazinamide

Dispersible tablet: 150 mg;
Scored tablet: 150 mg



Use:	tuberculosis, in combination with other medicines.
IUPAC Name:	pyrazine-2-carboxamide
CAS Number:	98-96-4
Chemical Formula:	$C_5H_5N_3O$

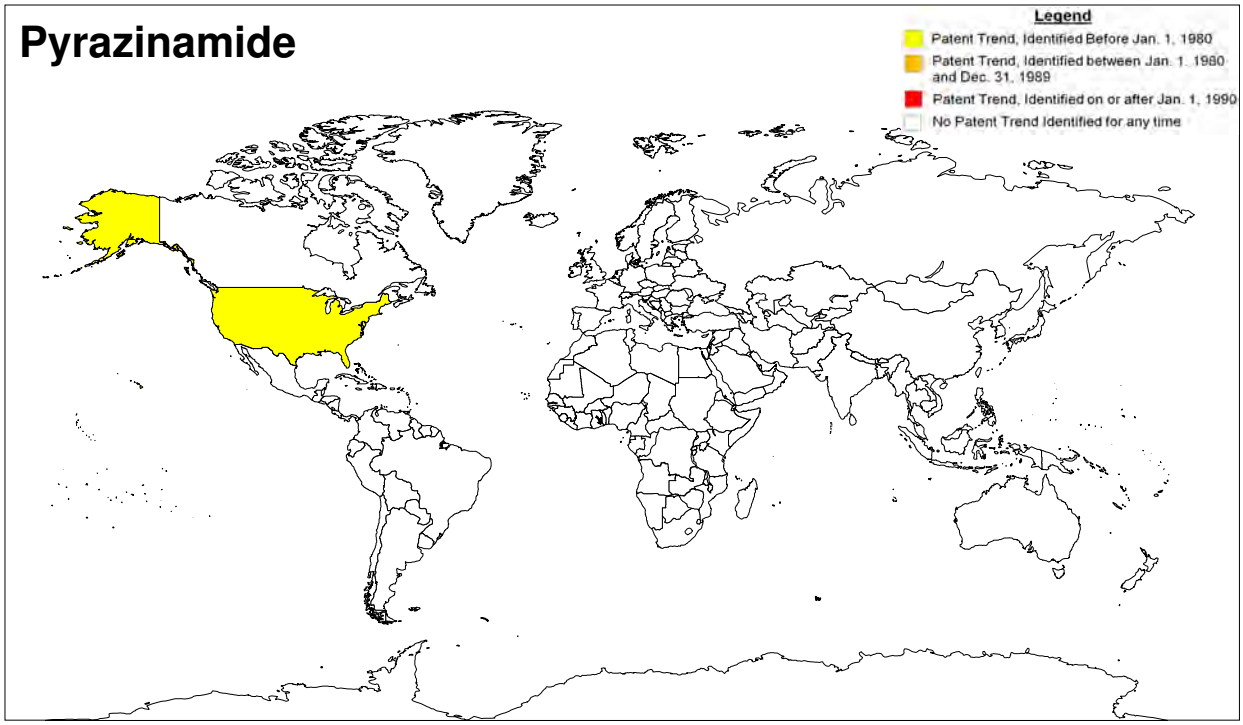
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US2149279	MERCK/Sweden	MERCK/Sweden	Jul. 5, 1935

Orange Book Patents:

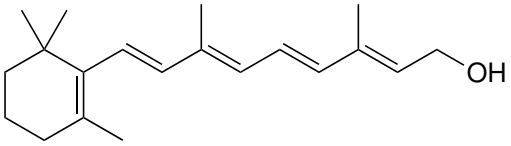
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Pyrazinamide Family Data



Retinol

Capsule: 50,000 IU, 100,000 IU (as palmitate)



Use:	prevention and treatment of vitamin A deficiency; prevention of complications of measles.
IUPAC Name:	(2E,4E,6E,8E)-3,7-dimethyl-9-(2,6,6-trimethylcyclohex-1-en-1-yl)nona-2,4,6,8-tetraen-1-ol
CAS Number:	68-26-8
Chemical Formula:	$C_{20}H_{30}O$

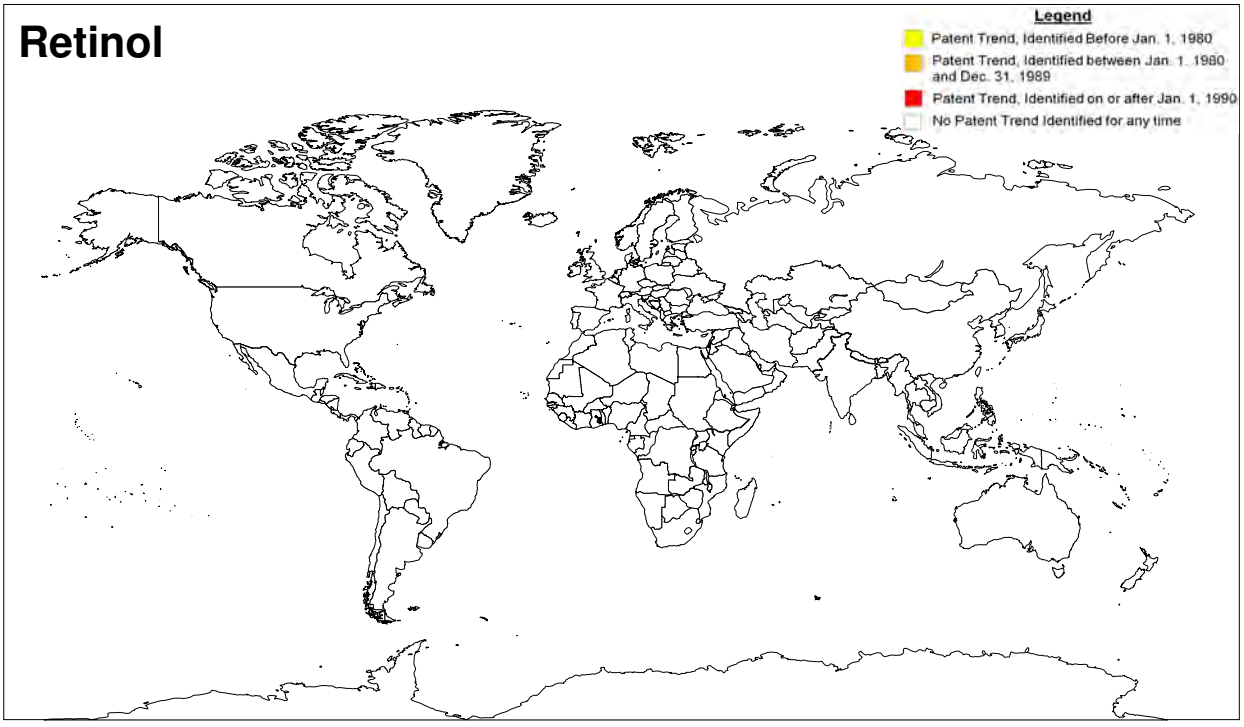
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

Orange Book Patents:

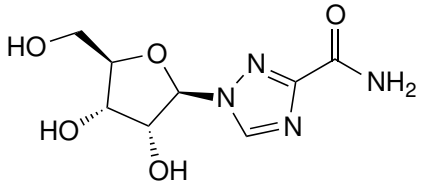
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Retinol Family Data



Ribavirin

Injection: 1000 mg/10 mL, 800 mg/10 ml (phosphate buffer solution);
Oral Solid Dosage Form: 200 mg, 400 mg, 600 mg



Use:	treatment of haemorrhagic fever, including Lassa fever, Argentine haemorrhagic fever, and Crimean–Congo haemorrhagic fever; haemorrhagic fever with renal syndrome.
IUPAC Name:	1-((2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)tetrahydrofuran-2-yl)-1H-1,2,4-triazole-3-carboxamide
CAS Number:	36791-04-5
Chemical Formula:	$C_8H_{12}N_4O_5$

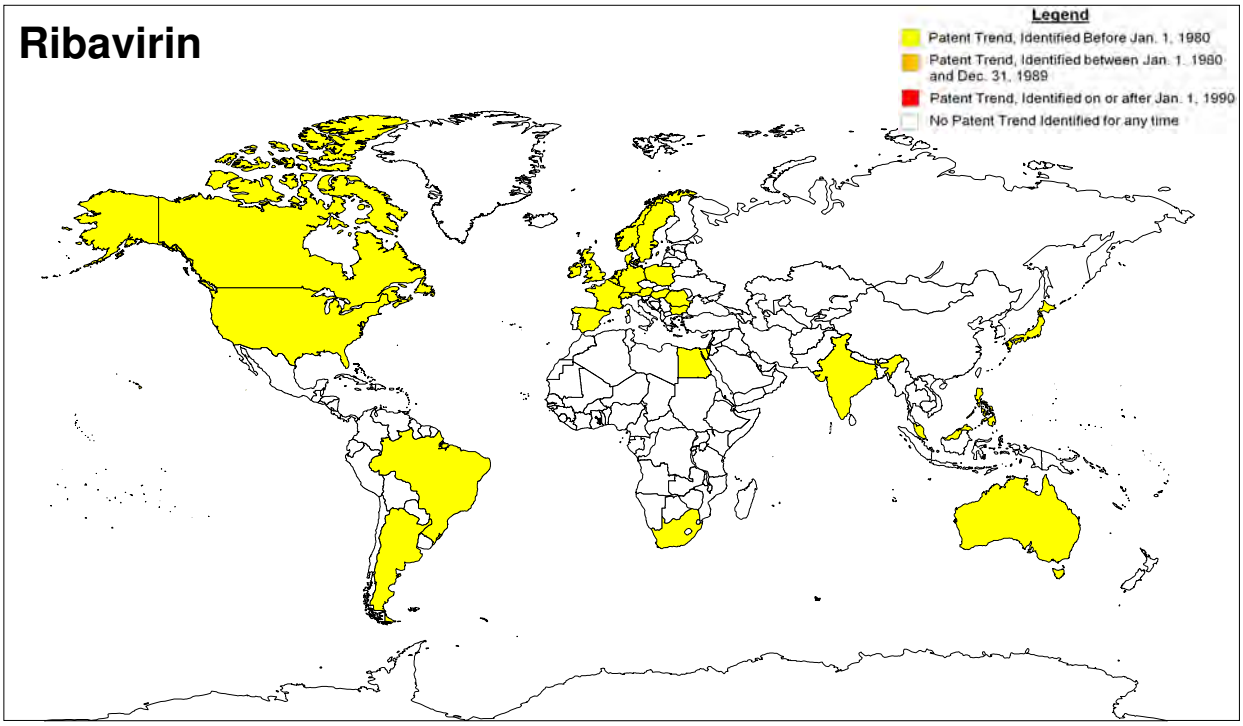
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US3798209	ICN PHARMACEUTICALS INC./USA	ICN PHARMACEUTICALS INC./USA	Mar. 1, 1972

Orange Book Patents:

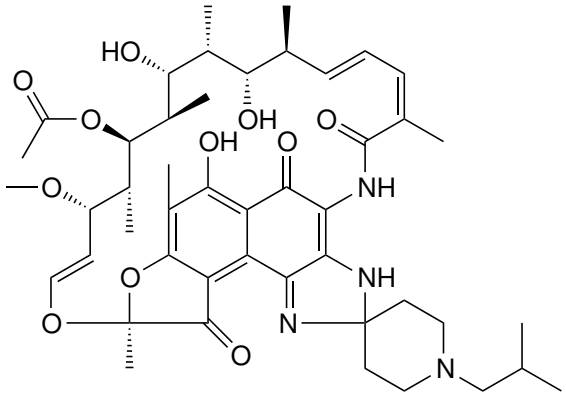
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Ribavirin Family Data



Rifabutin

Capsule: 150 mg



Use:	prevention of disseminated *Mycobacterium avium* complex (MAC) in patients with advanced HIV infection.*
IUPAC Name:	(9S, 12E, 14S, 15R, 16S, 17R, 18R, 19R, 20S, 21S, 22E, 24Z)-6,16,18,20- tetrahydroxy-1'-isobutyl-14-methoxy-7,9,15,17,19,21,25-heptamethyl-spiro [9,4-(epoxypentadeca[1,11,13]trienimino)-2H-furo[2',3':7,8]naphth[1,2-d]imidazole-2,4'- piperidine]-5,10,26-(3H,9H)-trione-16-acetate
CAS Number:	98-96-4
Chemical Formula:	$C_{46}H_{62}N_4O_1$

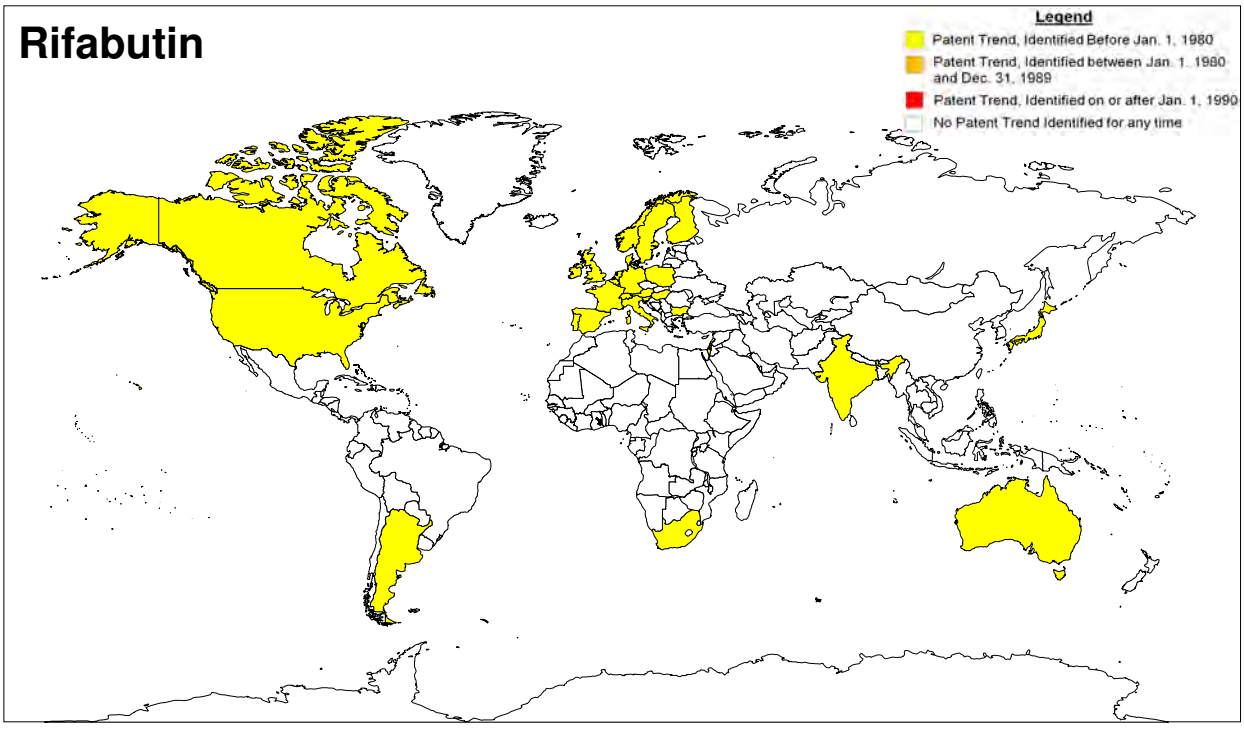
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4086225	Archifar Industrie Chimiche del Trentino S.p.A./Italy	Archifar Industrie Chimiche del Trentino S.p.A./Italy	Jun. 10, 1976

Orange Book Patents:

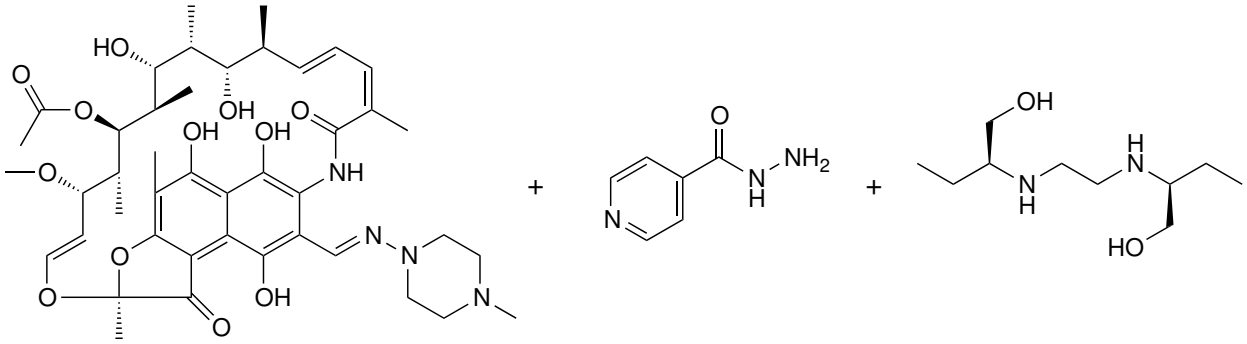
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Rifabutin Family Data



Rifampicin + Isoniazid + Ethambutol

Tablet: 150 mg + 75 mg + 275 mg



Use:	tuberculosis.
IUPAC Name:	3-[[(4-Methyl-1-piperazinyl)imino]methyl]rifamycin; isonicotinohydrazide; (2S,2'S)-2,2'-(ethane-1,2-diylbis (azanediyl))bis(butan-1-ol)
CAS Number:	Combination: 402507-77-1 (MIXTURE)
	Rifampicin: 13292-46-1
	Isoniazid: 54-85-3
	Ethambutol: 74-55-5
Chemical Formula:	Rifampicin: $C_{43}H_{58}N_4O_{12}$
	Isoniazid: $C_6H_7N_3O$
	Ethambutol: $C_{10}H_{24}N_2O_2$

Base Patent for Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
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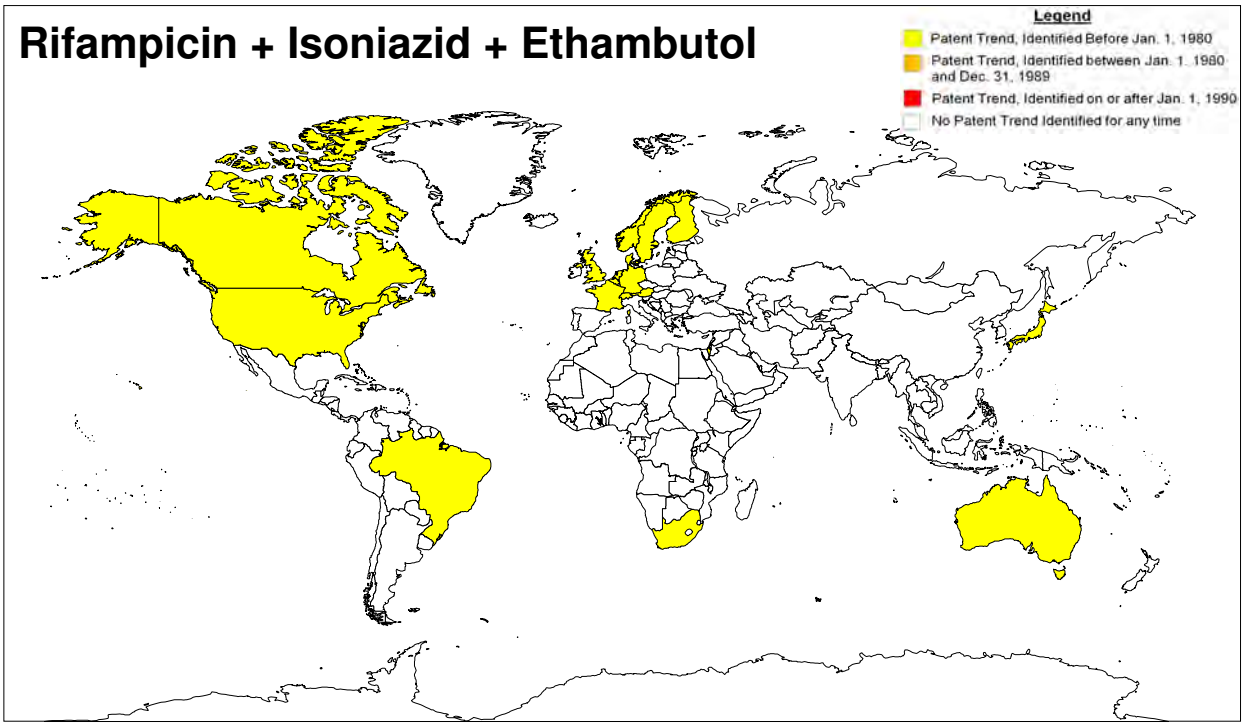
Base Patents for Components:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
Rifampicin: US3342810	Lepetit S.p.A., Italy	Lepetit S.p.A., Italy	Jul. 9, 1965
Isoniazid: US2596069A	Hoffman LaRoche/U.S.	Hoffman LaRoche/U.S.	Mar. 7, 1952
Ethambutol: US3943247	Taito Co., Ltd./Japan	Taito Co., Ltd./Japan	Jul. 11, 1973

Orange Book Patents:

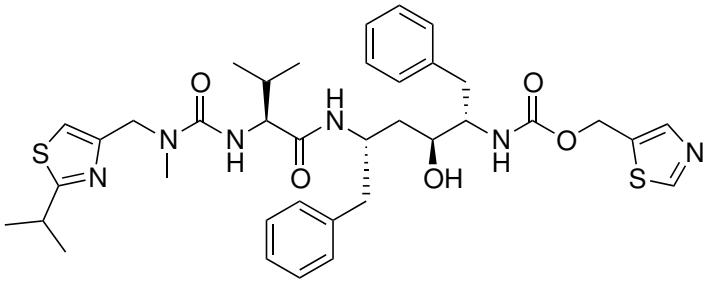
Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Rifampicin + Isoniazid + Ethambutol Family Data



Ritonavir

Oral Solid Dosage Form: 100 mg;
Oral Liquid: 400 mg/5 ml;
Tablet (heat stable): 25 mg, 100 mg



Use:	HIV infection, as a booster to increase the effect of indinavir, lopinavir or saquinavir, in combination with at least two other antiretroviral medicines.
IUPAC Name:	10-hydroxy-2-methyl-5-(1- methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11- bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid, 5-thiazolylmethyl ester, [5S-(5R*,8R*,10R*,11R*)]
CAS Number:	155213-67-5
Chemical Formula:	$C_{37}H_{48}N_6O_5S_2$

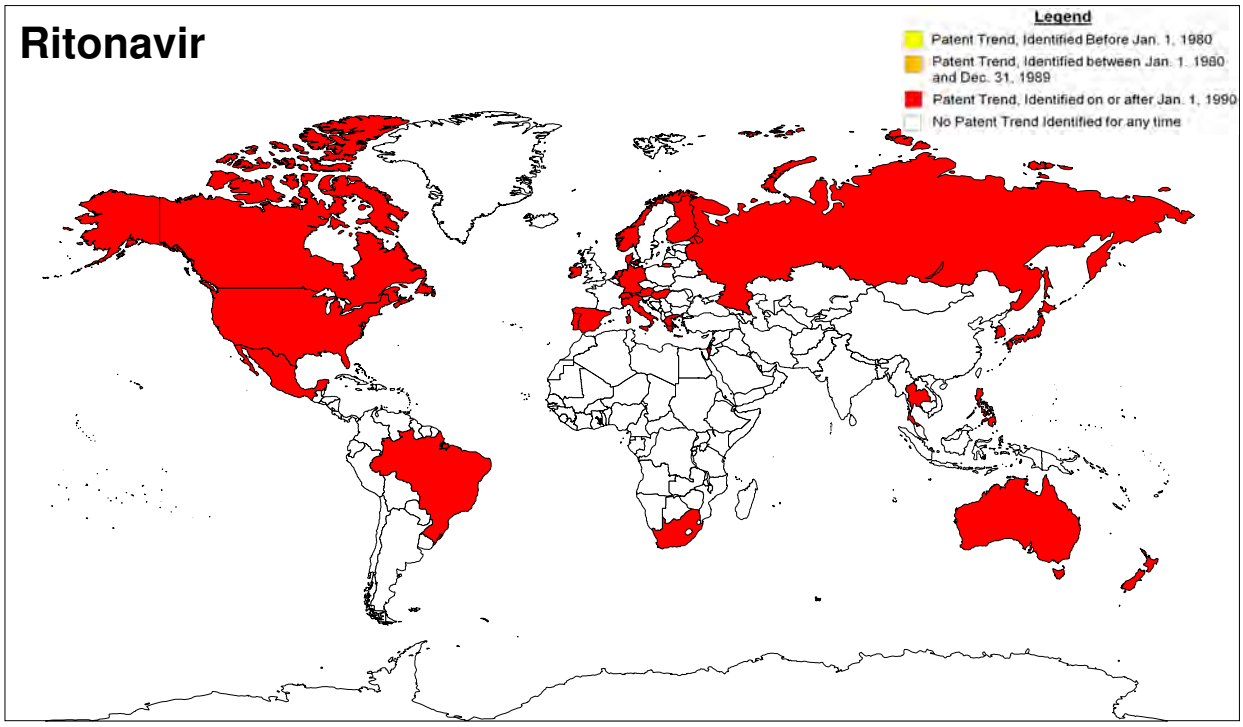
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5541206	ABBOTT LABORATORIES, US	ABBOTT LABORATORIES, US	Mar. 25, 1995

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5635523	ABBOTT LABS, US	ABBOTT LABS, US	Apr. 6, 1995
US5648497	ABBOTT LABS, US	ABBOTT LABS, US	Mar. 24, 1995
US5674882	ABBOTT LABS, US	ABBOTT LABS, US	Mar. 29, 1995
US6037157	ABBOTT LABS, US	ABBOTT LABS, US	Jun. 26, 1996
US6703403	ABBOTT LABS, US	ABBOTT LABS, US	Sep. 20, 2001
US7148359	ABBOTT LABS, US	ABBOTT LABS, US	May 4, 2005
US7364752	ABBOTT LABS, US	ABBOTT LABS, US	Nov. 10, 2000

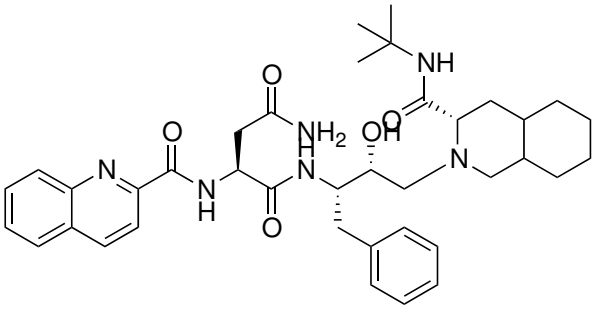
World Map Generated from Ritonavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Saquinavir

Solid Oral Dosage Form: 200 mg, 500 mg



Use:	HIV infection in combination with at least two other antiretroviral medicines and usually a low-dose ritonavir booster.
IUPAC Name:	(2S)-N-[(2S,3R)-4-[(3S)-3-(tert-butylcarbamoyl)-decahydroisoquinolin-2-yl]-3-hydroxy-1-phenylbutan-2-yl]-2-(quinolin-2-ylformamido)butanediamide
CAS Number:	127779-20-8
Chemical Formula:	$C_{38}H_{50}N_6O_5$

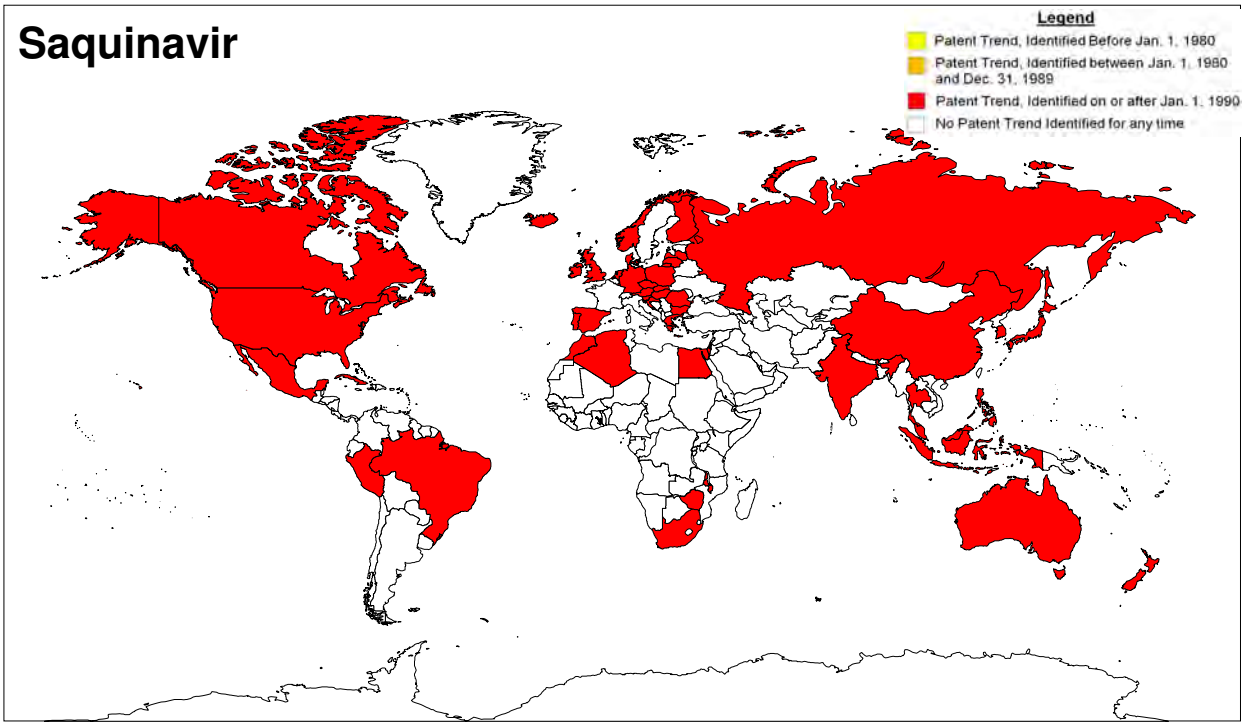
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5196438	Hoffmann-La Roche Inc./US	Hoffmann-La Roche Inc./US	Nov. 19, 1990

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5196438	Hoffmann-La Roche Inc./US	Hoffmann-La Roche Inc./US	Nov. 19, 1990

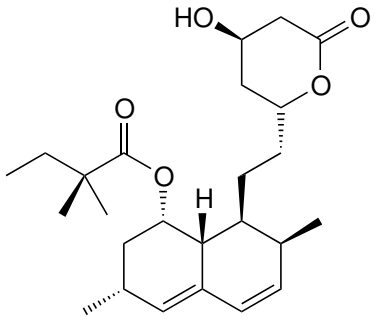
World Map Generated from Saquinavir Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	

Simvastatin

Tablet: 5 mg, 10 mg, 20 mg, 40 mg



Use:	prevention of cardiovascular events in patients with high cardiovascular risk due to atherosclerotic cardiovascular disease or diabetes mellitus.
IUPAC Name:	2,2-dimethyl-,1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4- hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1S-[1α,3α,7β,8β(2S*,4S*),-8aβ]]
CAS Number:	79902-63-9
Chemical Formula:	$C_{25}H_{38}O_5$

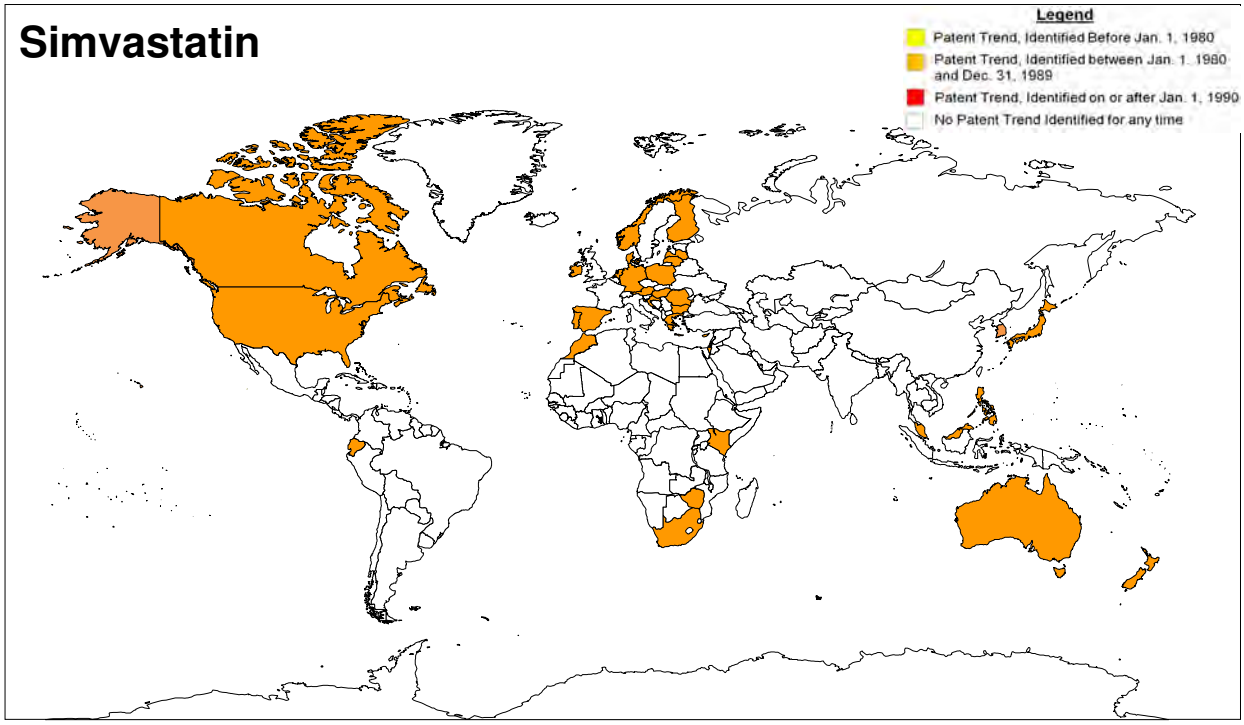
Base Patent:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4444784	Merck & Co., Inc., US	Merck & Co., Inc., US	Dec. 18, 1980

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Simvastatin Family Data

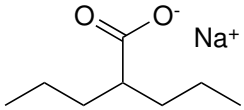


Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Sodium Valproate/Valproic Acid

Tablet: 100mg (Crushable)

Oral Liquid: 200 mg/5 ml



Use:	acute mania; epilepsy (section 5)
IUPAC Name:	2-propylpentanoic acid
CAS Number:	99-66-1
Chemical Formula:	$C_8H_{16}O_2$

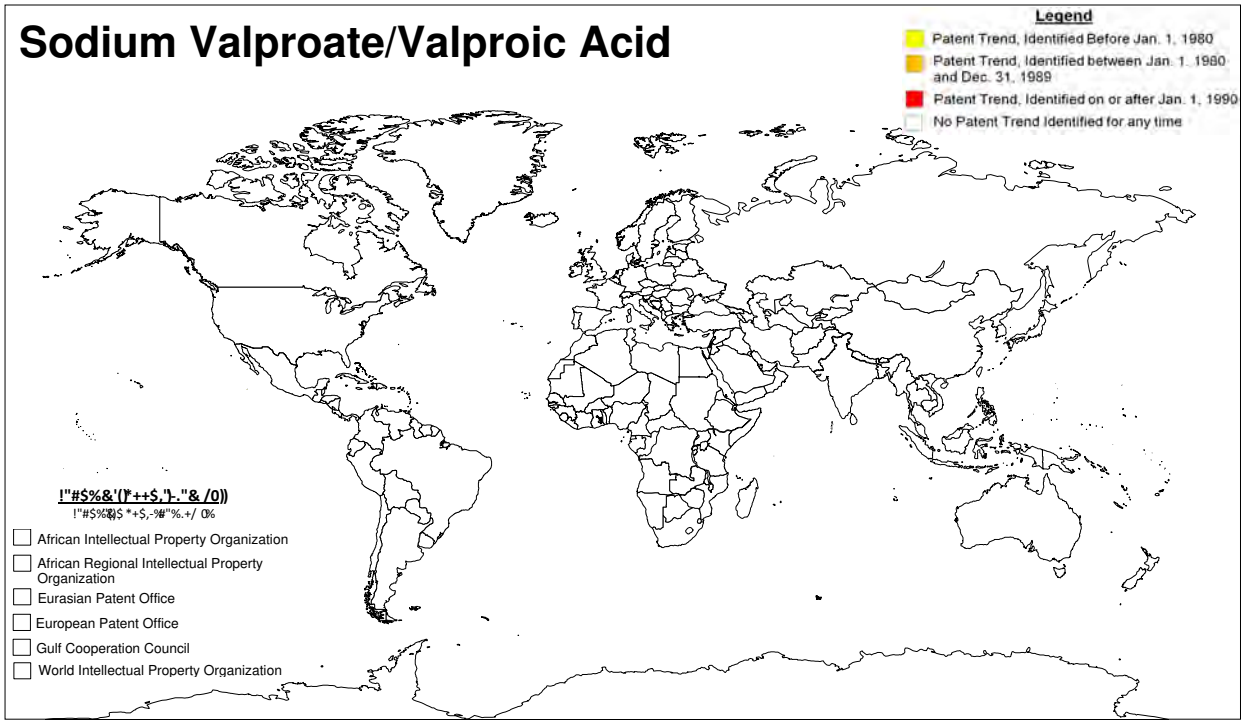
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

Orange Book Patents:

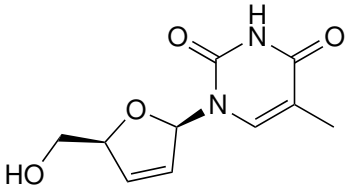
Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Sodium Valproate/Valproic Acid Family Data



Stavudine

Zerit: 15 mg, 20 mg, 30 mg, 40 mg;
Powder for Oral Liquid: 5 mg/5 ml



Use:	HIV infection in combination with at least two other antiretroviral medicines.
IUPAC Name:	1-[(2*R*,5*S*)-5-(hydroxymethyl)-2,5-dihydrofuran-2-yl]-5-methyl-1,2,3,4-tetrahydropyrimidine-2,4-dione
CAS Number:	3056-17-5
Chemical Formula:	$C_{10}H_{12}N_2O_4$

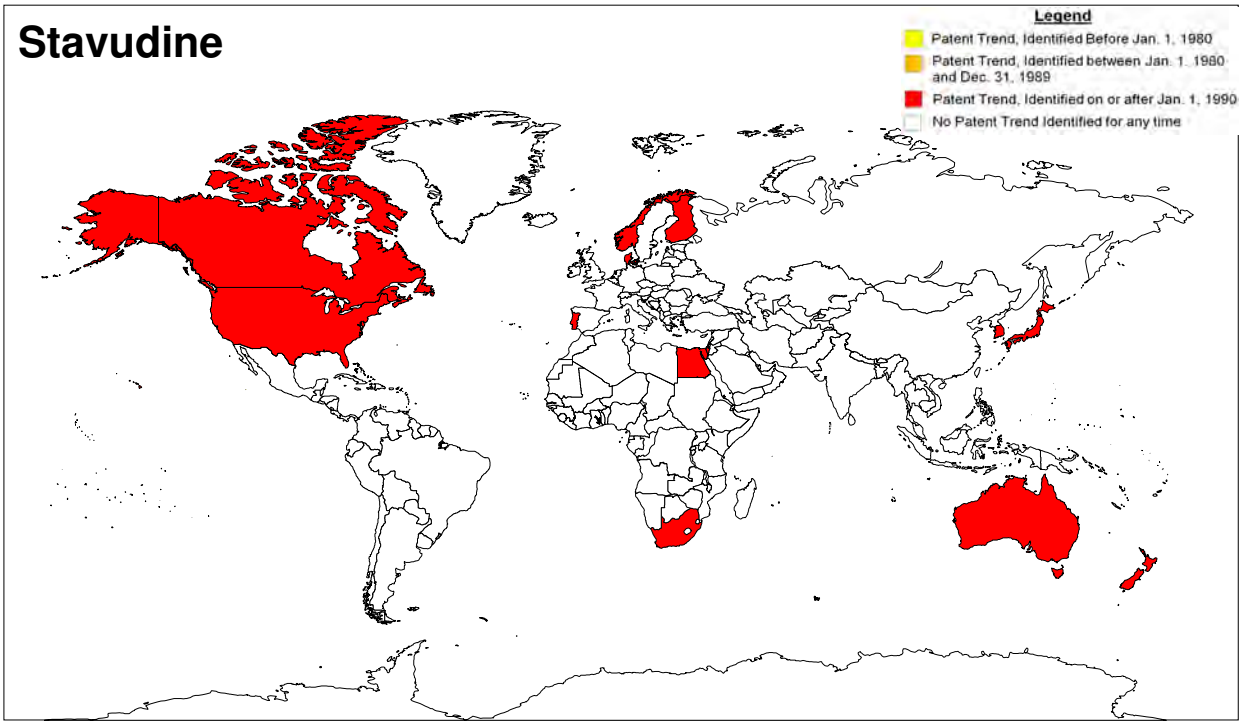
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5130421	Bristol-Myers Co./U.S.	Bristol-Myers Co./U.S.	Apr. 29, 1991

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

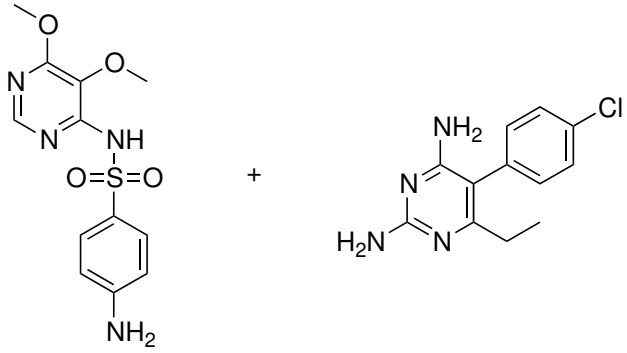
World Map Generated from Stavudine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	

Sulfadoxine + Pyrimethamine

Tablet: 500 mg + 25 mg



Use:	Treatment of falciparum malaria in combination with other antimalarials.
IUPAC Name:	4-Amino-*N*-(5,6-dimethoxy-4-pyrimidinyl)benzenesulfonamide ! 5-(4-chlorophenyl)-6-ethyl- 2,4-pyrimidinediamine
CAS Number:	2447-57-6 58-14-0
Chemical Formula:	$C_{12}H_{14}N_4O_4S + C_{12}H_{13}ClN_4$

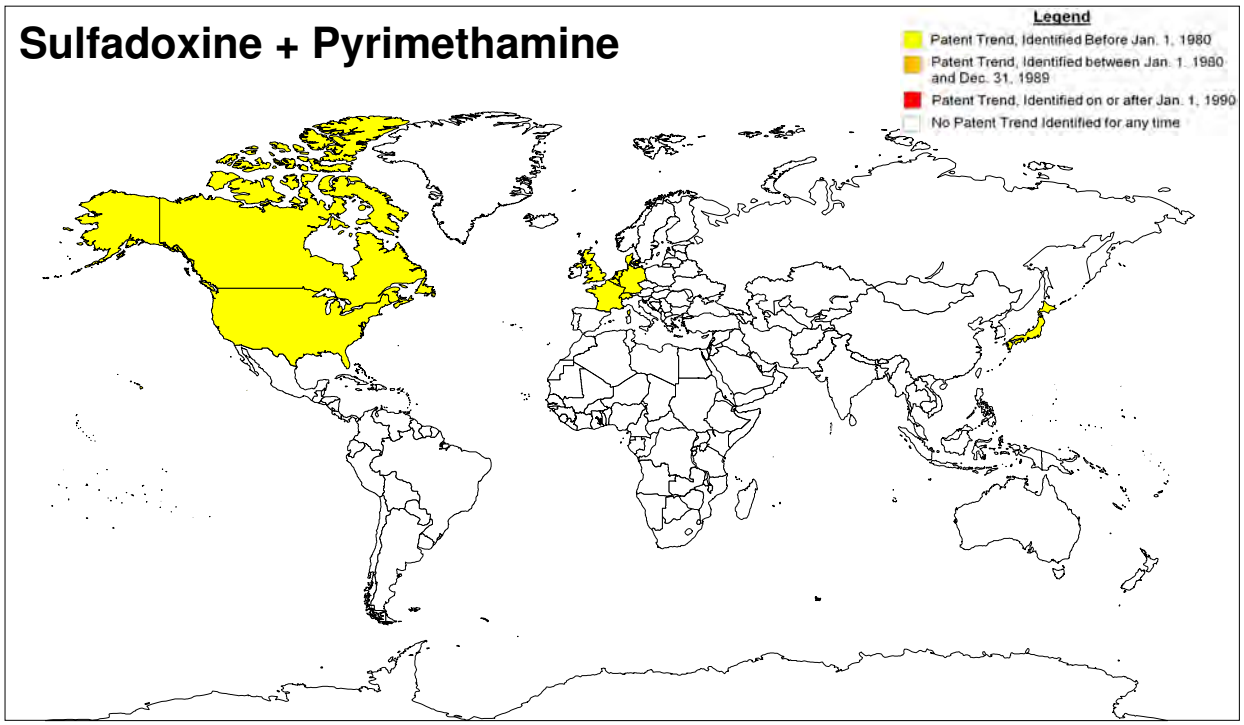
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
Pyrimethamine: US2680740	Societe des Itsines Chimiques Rhone/France	Societe des Itsines Chimiques Rhone/France	Jun. 19, 1952
Sulfadoxine: US3132139	Hoffman-LaRoche Inc./U.S.	Hoffman-LaRoche Inc./U.S.	Jun. 8, 1962

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

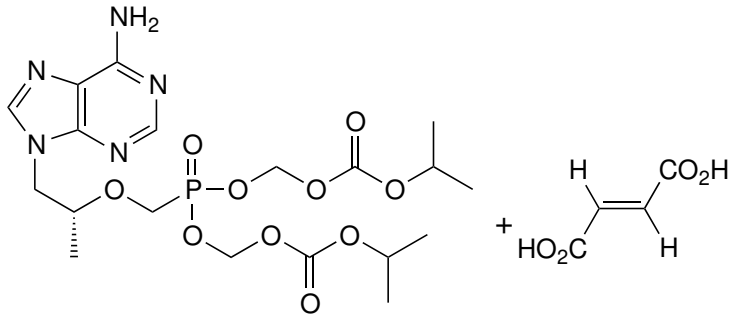
World Map Generated from Sulfadoxine + Pyrimethamine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified before Jan. 1,1980
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	
Gulf Cooperation Council	
World Intellectual Property Organization	

Tenofovir Disoproxil Fumarate

Tablet: 300 mg



Use:	HIV infection in combination with other antiretroviral medicines.
IUPAC Name:	({[(2*R*)-1-(6-amino-9*H*-purin-9-yl)propan-2-yl]oxy}methyl)phosphonic acid
CAS Number:	147127-20-6
Chemical Formula:	$C_9H_{14}N_5O_4P$

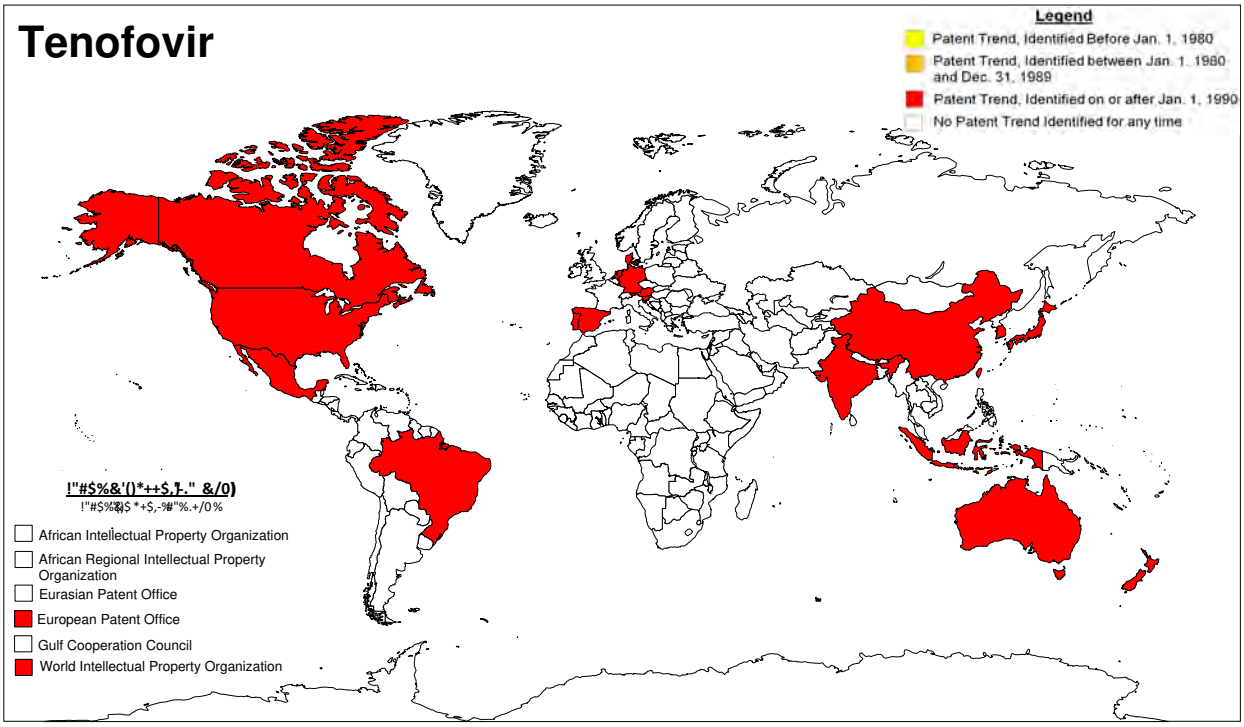
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5922695	Gilead Sciences, Inc./U.S.	Gilead Sciences, Inc./U.S.	Jul. 25, 1997

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5922695	Gilead Sciences, Inc./US	Gilead Sciences, Inc./US	Jul. 25, 1997
US5935946	Gilead Sciences, Inc./US	Gilead Sciences, Inc./US	Jul. 25, 1997
US5977089	Gilead Sciences, Inc./US	Gilead Sciences, Inc./US	Nov 6, 1998
US6043230	Gilead Sciences, Inc./US	Gilead Sciences, Inc./US	May 19, 1999

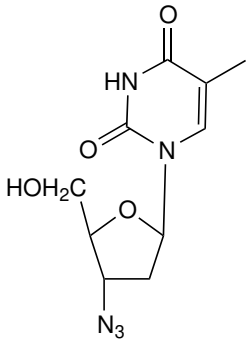
World Map Generated from Tenofovir Disoproxil Fumarate Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	
Eurasian Patent Office	
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Zidovudine

Tablet: 100 mg, 250 mg, 300 mg;
Solution for IV Infusion Injection: 10 mg/ml in 20 ml vial;
Oral Liquid: 50 mg/5 ml



Use:	HIV infection in combination with at least one other antiretroviral medicine.
IUPAC Name:	1-[(2*R*,4*S*,5*S*)-4-azido-5-(hydroxymethyl)oxolan-2-yl]-5-methyl-1,2,3,4-tetrahydropyrimidine-2,4-dione
CAS Number:	30516-87-1
Chemical Formula:	$C_{10}H_{13}N_5O_4$

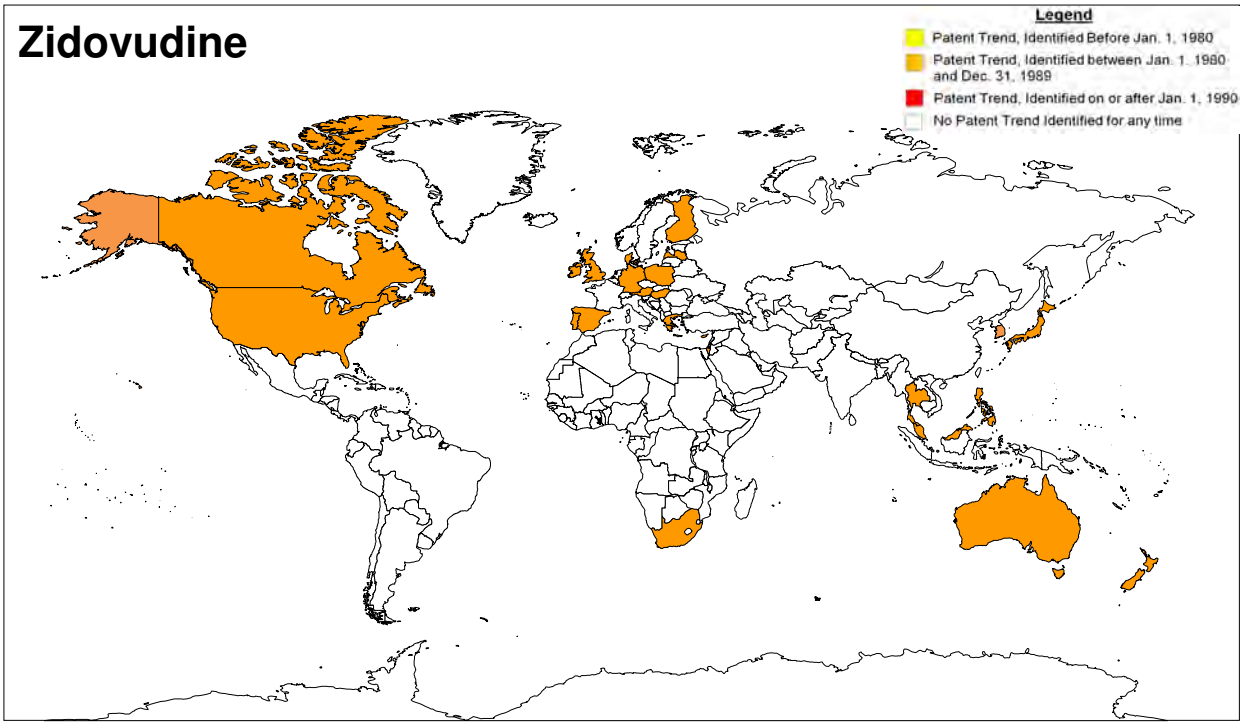
Base Patent:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4724232	Burroughs Welcome/U.S.	Burroughs Welcome/U.S.	Sept. 17, 1985

Orange Book Patents:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

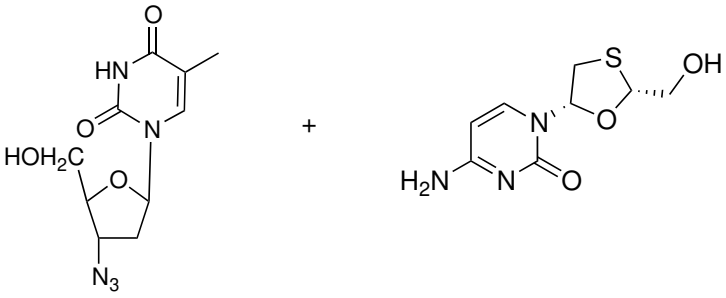
World Map Generated from Zidovudine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	
African Regional Intellectual Property Organization	Identified between Jan.1,1980 and Dec.31,1989
Eurasian Patent Office	
European Patent Office	Identified between Jan.1,1980 and Dec.31,1989
Gulf Cooperation Council	
World Intellectual Property Organization	

Zidovudine + Lamivudine

Tablet: 60 mg + 30 mg, 300 mg +150 mg



Use:	HIV infection in combination with at least one other antiretroviral medicine.
IUPAC Name:	1-[(2*R*,4*S*,5*S*)-4-azido-5-(hydroxymethyl)oxolan-2-yl]-5-methyl-1,2,3,4-tetrahydropyrimidine-2,4-dione + 4-amino-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one
CAS Number:	30516-87-1 + 134678-17-4
Chemical Formula:	$C_{10}H_{13}N_5O_4$ + $C_8H_{11}N_3O_3S$

Base Patent For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

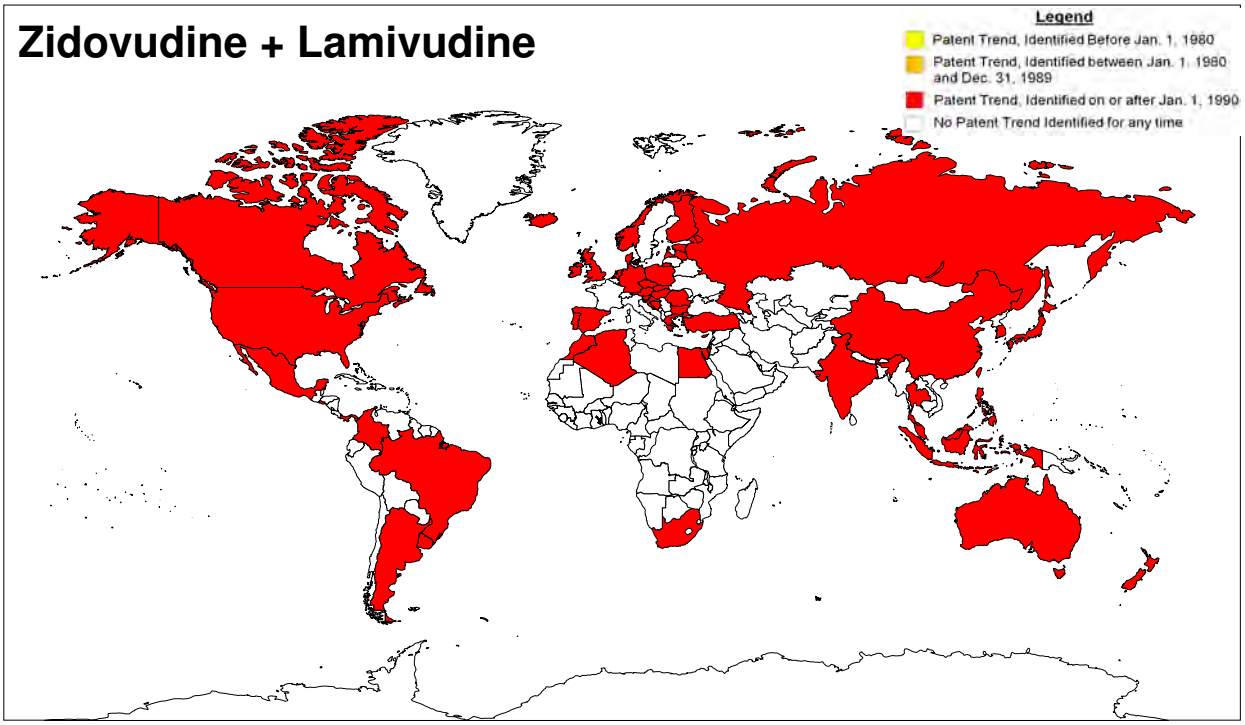
Base Patents For Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4724232	Burroughs Welcome/U.S.	Burroughs Welcome/U.S.	Sept. 17, 1985
US5047407	IAF BioChem Intl., Inc./Canada	IAF BioChem Intl. Inc./Canada	Feb. 8, 1989

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US5859021	Glaxo Group Ltd./USA	Glaxo Group Ltd./USA	Feb 22, 1996
US7119202	Glaxo Wellcome Inc./USA	Glaxo Wellcome Inc. /USA	Jun 6, 1995
US5034394	Burroughs Wellcome Co./USA	Burroughs Wellcome Co./USA	Dec 22, 1989
US5047407	IAF BioChem Intl., Inc./CA	IAF BioChem Intl, Inc./CA	Feb 8, 1989
US5089500	Burroughs Wellcome Co./USA	Burroughs Wellcome Co./USA	May 8, 1991
US5905082	Glaxo Group Ltd./UK	Glaxo Group Ltd./UK	Jun 2, 1992
US6294540	Glaxo Wellcome Inc./USA	Glaxo Wellcome Inc./USA	Dec 1, 1999
US6417191	GlaxoSmithKline/USA	GlaxoSmithKline/USA	Sep 30, 1997

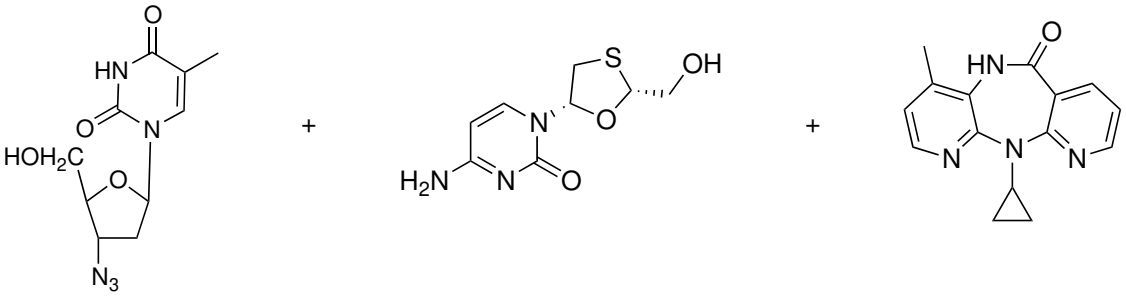
World Map Generated from Zidovudine + Lamivudine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

Zidovudine + Lamivudine + Nevirapine

Tablet: 60 mg + 30 mg + 50 mg, 300 mg + 150 mg + 200 mg



Use:	HIV infection alone as a complete regimen or in combination with other antiretroviral medicines.
IUPAC Name:	1-[(2*R*,4*S*,5*S*)-4-azido-5-(hydroxymethyl)oxolan-2-yl]-5-methyl-1,2,3,4-tetrahydropyrimidine-2,4-dione ! 4-amino-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-1,2-dihydropyrimidin-2-one ! 11-cyclopropyl-4-methyl-5,11-dihydro-6*H*- dipyrido[3,2-*b*:2′,3′-*e*][1,4]diazepin-6-one
CAS Number:	30516-87-1 + 134678-17-4 + 129618-40-2
Chemical Formula:	$C_{10}H_{13}N_5O_4$ + $C_8H_{11}N_3O_3S$ + $C_{15}H_{14}N_4O$

Base Patent For Combination:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

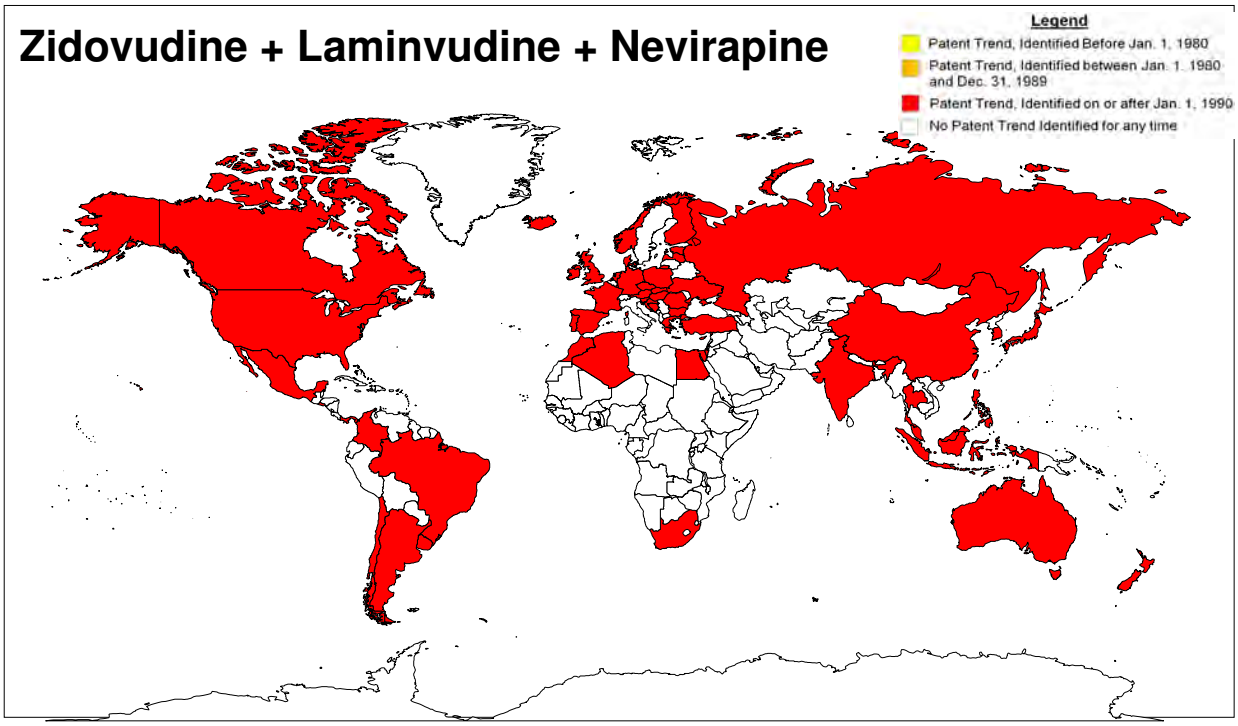
Base Patents For Components:

Base Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
US4724232	Burroughs Welcome/U.S.	Burroughs Welcome/U.S.	Sept. 17, 1985
US5047407	IAF BioChem Intl. Inc./Canada	IAF BioChem Intl. Inc./Canada	Feb. 8, 1989
US5366972	Boehringer Ingelheim Pharmaceuticals Inc./U.S.	Boehringer Ingelheim Pharmaceticals Inc./U.S.	Jul. 13, 1993

Orange Book Patents:

Patent	Patent Listed Assignee/Country	Current Listed Assignee/Country	Date Filed
N/A	N/A	N/A	N/A

World Map Generated from Zidovudine + Lamivudine + Nevirapine Family Data



Regional Office	Patent Trend
African Intellectual Property Organization	Identified on or after Jan. 1,1990
African Regional Intellectual Property Organization	Identified on or after Jan. 1,1990
Eurasian Patent Office	Identified on or after Jan. 1,1990
European Patent Office	Identified on or after Jan. 1,1990
Gulf Cooperation Council	
World Intellectual Property Organization	Identified on or after Jan. 1,1990

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Appendix

Appendix A: Income Breakdown for Medicines.[145]

Medicine Name	Total Number of Patents	Hign Income Nations	Upper Middle Income Nations	Lower Middle Income Nations	Low Income Nations	ARIPO or OAPI Activity?	EPO Activity?
Abacavir	8	32	14	8	0	Yes	Yes
Acetic Acid	0	0	0	0	0	No	No
Acyclovir	6	39	12	8	2	Yes	Yes
Amiodarone	5	16	3	1	1	No	Yes
Amphotericin B	5	20	2	1	0	No	Yes
Artemether	1	19	1	5	0	Yes	Yes
Artemether + Lumefantrine	2	19	1	5	0	Yes	Yes
Artesunate	0	0	0	0	0	No	No
Atazanavir	2	25	10	4	0	No	Yes
Azithromycin	10	36	15	9	0	Yes	Yes
Beclometasone	7	21	4	0	0	No	Yes
Budesonide	4	28	2	2	1	No	Yes
Caffeine Citrate	0	0	0	0	0	No	No
Carbamazepine	1	1	0	0	0	No	No
Carboplatin	1	9	0	0	0	No	No
Cefazolin	1	16	1	0	0	No	No
Cefixime	1	18	4	1	0	No	Yes
Ceftriaxone	1	35	8	3	1	Yes	Yes
Ciprofloxacin	7	28	8	2	1	No	Yes
Clotrimazole	1	19	2	0	0	No	No
Dexamethasone	1	1	0	0	0	No	No
Didanosine	1	14	1	0	0	No	Yes
Doxycycline	6	11	0	0	0	No	Yes
Efavirenz	7	29	8	4	0	No	Yes
Efavirenz + Emtricitabine + Tenofovir	16	32	9	6	0	Yes	Yes
Emtricitabine	6	27	7	4	0	No	Yes
Emtricitabine + Tenofovir	11	30	8	6	0	Yes	Yes
Fluconazole	1	26	4	3	1	No	Yes
Fluoxetine	2	27	8	4	0	No	Yes
Hydrochlorothiazide	1	1	0	0	0	No	No
Hydroxycarbamide	0	0	0	0	0	No	No
Ibuprofen	3	13	1	1	0	No	Yes
Ifosfamide	1	18	1	0	0	Yes	No
Indinavir	3	38	12	5	0	Yes	Yes
Isoniazid	1	1	0	0	0	No	No
Lamivudine	3	32	10	6	0	Yes	Yes
Lamivudine + Nevirapine + Stavudine	4	33	13	8	0	Yes	Yes
Levonorgestrel-Releasing Implant	1	1	0	0	0	No	No
Lopinavir + Ritonavir	20	24	5	4	0	No	Yes
Medroxyprogesterone Acetate	1	3	0	0	0	No	No
Medroxyprogesterone Acetate + Estradiol Cypio	4	22	4	3	0	No	Yes
Mefloquine	1	4	0	0	0	No	Yes
Mesna	1	9	1	0	0	No	No
Methadone	1	1	0	0	0	No	No
Mifepristone + Misoprostol	2	25	3	2	0	Yes	No
Misoprostol	1	21	2	2	0	Yes	No
Morphine	0	0	0	0	0	No	No
Nelfinavir	3	23	7	5	1	Yes	Yes
Nevirapine	1	27	9	7	0	Yes	Yes
Nifedipine	1	9	1	0	0	No	No
Nifurtimox	1	6	2	0	0	No	No
Norethisterone Enantate	1	1	0	0	0	No	No
Ofloxacin	2	19	3	3	0	No	Yes
Omeprazole	5	29	8	6	0	No	Yes
Ondansetron	3	34	5	2	0	No	Yes
Parenteral Lorazepam	1	18	2	0	0	Yes	No
Paromomycin	1	1	0	0	0	No	No
Pentamidine	1	1	0	0	0	No	No
Phenobarbital	1	1	0	0	0	No	No
Phenytoin	1	1	0	0	0	No	No
Prostaglandin E1/Alprostadil	0	0	0	0	0	No	No
Prostaglandin E2	1	6	0	0	0	No	No
Pyrazinamide	1	1	0	0	0	No	No
Retinol	0	0	0	0	0	No	No
Ribavirin	1	22	6	3	0	No	No
Rifabutin	1	25	3	1	0	No	No
Rifampicin + Isoniazid + Ethambutol	3	16	2	0	0	No	No
Ritonavir	8	22	4	2	0	No	Yes
Saquinavir	1	31	11	7	2	Yes	Yes
Simvastatin	1	25	5	3	2	No	Yes
Sodium Valproate/Valproic Acid	0	0	0	0	0	No	No
Stavudine	1	11	1	1	0	No	Yes
Sulfadoxine + Pyrimethamine	2	10	0	0	0	Yes	No
Tenofovir	4	17	2	3	0	No	Yes
Zidovudine	1	24	2	2	0	Yes	Yes
Zidovudine + Lamivudine + Nevirapine	3	35	15	9	0	Yes	Yes
Zidovudine + Lamivudine	9	34	14	8	0	Yes	Yes

[145] Figures 11 and 12 are averages of all the data here. Any medicine with a patent document in each country were counted and summed. These summations were aggregated to yield a total number of patented medicines. The total number of patented medicines was then divided by the number of countries in each representative income designation to yield the values for the graph.

Appendix B: Medicines Assigned to the ITTI Clinic.

Medicines in red were removed due to the high likelihood of non-existing patent coverage or due to the apparent lack of a singly patentable product.

Abacavir	Mesna
Acetic acid	Methadone
Acyclovir	Mifepristone
Amiodarone	Mifepristone - misoprostol
Amphotericin B	Misoprostol
Artemether	Morphine
Artemether + lumefantrine	Nelfinavir
Artesunate	Nevirapine
Atazanavir	Nicotine gum
Azithromycin	Nifedipine
Beclometasone	Nifurtimox
Budesonide (D)	Norethisterone enantate
Caffeine citrate	Ofloxacin
Carbamazepine	Omeprazole
Carboplatin	Ondansetron
Cefalozin (a)	Parenteral lorazepam
Cefixime	Paromomycin
Ceftriaxone (a)	Pentamidine
Ciprofloxacin (D)	Phenobarbital
Clotrimazole	Phenytoin
Dexamethasone (D)	Prostaglandin E
Didanosine	Pyrazinamide
Doxycycline	Retinol
Efavirenz	Ribavirin
Efavirenz + emtricitabine + tenofovir	Rifabutin
Emtricitabine (FTC) (a)	Rifampicin + isoniazid + ethambutol
Emtricitabine + tenofovir	Ritonavir
Fluconazole	Saquinavir (SQV) (a)
Fluoxetine	Simvastatin
Human immunoglobulin	Sodium valproate
Hydrochlorothiazide	Stavudine
Hydroxycarbamide	Stavudine + lamivudine + nevirapine
Ibuprofen (D)	Sulfadoxine + pyrimethamine
Ifosfamide	Surfactant
Indinavir	Tenofovir
Isoniazid	Tenofovir disoproxil fumarate (TDF)
Lamivudine	Xylometazoline
Lamivudine + neviparine + stavudine	Zidovudine (ZDV or AZT)
Levonorgestrel-releasing implant (D)	Zidovudine + lamivudine
Lopinavir + ritonavir	Zidovudine + lamivudine + nevirapine
Medroxyprogesterone acetate (D)	Zinc sulfate
Medroxyprogesterone acetate + estradiol cypionate	
Mefloquine	

Appendix C: Database Techniques Used in the DTP Methodology

TotalPatent™

LexisNexis® TotalPatent™ is a full-text based comprehensive database for patent-family based research, retrieval and analysis. TotalPatent™ combines the patent family information from INPADOC with LexisNexis® proprietary patent family information. This database not only includes full-text coverage for a number of foreign countries, but also provides machine translation coverage for a number of countries.

The TotalPatent™ platform is easy to navigate, and it allows users to limit their search criteria to narrow regions of the patent such as the title, claims, abstract, full-text, or a combination of the above. It also offers additional search features within the advanced search option. The advanced search option allows the user to search for Assignee/Applicants, Normalized Assignee, Inventors, Kind Code, Publication Country, Priority Number, US Class, Patent Citation, ECLA, IPC 1-8, and Priority Date. Searches done within the advanced search option may also be saved and used again at a later time.

Although advantages of TotalPatent™ include the easy searching interface and the ease through which results are viewed, there are quite a few disadvantages. First, TotalPatent™ limits the number of search results to 3,000, and such a limit could eliminate important patents from the search results. In addition, it is difficult to export data from TotalPatent™ in a form that is easily manipulated or presented.

The Bridge

The Bridge is a technique used through ProQuest® Dialog™. Dialog™ is an online information service, providing access to articles and reports from thousands of real-time news feeds, newspapers, broadcast transcripts and trade publications, plus market research reports and analyst notes providing support for financial decision-making, as well as in-depth repositories of scientific and technical data, patents, trademarks and other intellectual property data. Dialog™ contains over 900 databases organized by source.[146] Because each database is different, each may not contain the same data for identical searches. As a result, it may be necessary to import search result data from one database to another.

The Bridge is a technique that allows the user to save result data from one database and use the result data in another database. This idea of "bridging" across two databases allowed the ITTI Clinic to search for medicines by patents and patents by medicines, for example, by bridging data between granted patent databases and non-patent literature databases such as the Merck Index. Below is an example of The Bridge technique, provided to the ITTI Clinic by Mr. Ron Kaminecki, M.S., J.D., Director of Intellectual Property Market, and reproduced here with his permission:

[146] Dialog and the invention of online information services, http://www.dialog.com/about/ (last visited Dec. 2, 2010).

Searching chemical patents by CAS® Registry number

CAS Registry numbers cannot be searched in patent files, but they can be searched in a patent-intensive file, namely, CA SEARCH® (File 399). So, find the CAS Registry Number for the substance, grab the registry numbers and synonyms using the MAP command, and then search these terms in CA SEARCH. Restrict the retrieval to patents (S S1/PAT) and use MAP again to extract the patent numbers from CA SEARCH and run them in Derwent World Patents Index. Not a perfect search due to indexing, date and country coverage and other differences, but a good one nonetheless.

Topic: Find patents related to the brand name Claritin.

Open the chemical dictionary Chemsearch.

```
?b 398

File 398:CHEMSEARCH(TM) 1957-2000/Aug
     (c) 2000 Amer.Chem.Soc.
```

EXPANDing NA= (name) finds the term as either a CAS Systematic Name or as a common or trade name.

Output a record to insure it's correct. Skip this step to save money, but first make sure that you found the right substance.

```
  Set Items Description
  --- ----- -----------
?e na=claritin

Ref  Items Index-term
E1     1 NA=CLARITHROMYCIN-LANSOPRAZOLE-METRONIDAZOLE MIXT
E2     1 NA=CLARITHROMYCIN-OMEPRAZOLE MIXT.
E3     1 *NA=CLARITIN
E4     1 NA=CLARITY
E5     1 NA=CLARK I
E6     1 NA=CLARK II
E7     1 NA=CLARK N-11
E8     1 NA=CLARK 1
E9     1 NA=CLARK 2
E10    2 NA=CLARKEANIDINE
E11    1 NA=CLARKEITE
E12    1 NA=CLARKINOL

    Enter P or PAGE for more

?s e3
  S1     1 NA="CLARITIN"

?t s1/9/1

 1/9/1
DIALOG(R)File 398:CHEMSEARCH(TM)
(c) 2000 Amer.Chem.Soc. All rts. reserv.
```

CAS REGISTRY NUMBER: 79794-75-5
MOLECULAR FORMULA: C22H23ClN2O2
RING SYSTEM DATA:
(01) (nr=01; sr=6; ar=C5N.01; fr=NC5.01; ir=46-156-1)
(01) (nr=03; sr=6,6,7; ar=C5N.01-C6.01-C7.01; fr=NC5.01-C6.01-C7.01;ir=3068-10-3)
CA NAME(S):
HP=1-Piperidinecarboxylic acid (9CI)
SB=4-(8-chloro-5,6-dihydro-11H-benzo(5,6)cyclohepta(1,2-b)pyridin-11-ylidene)-
NM=ethyl ester
OTHER CA NAMES:
HP=11H-Benzo(5,6)cyclohepta(1,2-b)pyridine
NM=1-piperidinecarboxylic acid deriv.
SYNONYMS: Claritin; Klaritin; Loratadine; Loratidine; Sch 29851

Use MAP to extract the synonyms (SY) and the registry numbers (RN) temporarily (T). The result is a SearchSave that contains both terms. Note that some substances may have multiple registry numbers; this command picks them all up.

EXS will execute steps using the last SearchSave. If the MAP command created more than one SearchSave, make sure to EXS each one (e.g., exs td100, then exs td101, etc.) and then OR them together (e.g., s s97 or s180, where s97 is the final set of td100 and s180 is the final set of td101).

Note that the registry number picked up the most hits.

Limit the retrieval to just patents.

The search yielded 117 patent numbers. Now, search these patent numbers in Derwent WPI.

SUBFILE: CHEMNAME 211 LITERATURE REFERENCE(S) IN FILE 399.
LAST UPDATE: 199902

?**map syrn t**

1 Select Statement(s), 6 Search Term(s)
Serial#TD100

?**b 399**

File 399:CA SEARCH(R) 1967-2000/UD=13318
(c) 2000 American Chemical Society

Set Items Description
--- ----- -----------
?**exs**

Executing TD100
3 CLARITIN
1 KLARITIN
166 LORATADINE
11 LORATIDINE
1291 SCH
5 29851
5 SCH(W)29851
308 RN=79794-75-5
S1 320 CLARITIN + KLARITIN + LORATADINE +
LORATIDINE + SCH()29851 + RN=70794-75-5

?**s s1/pat**

S2 115 S1/PAT

?**map pn t**

Processing MAP
Processing MAP
Processing MAP

10 Select Statement(s), 117 Search Term(s)

Seria

?**b 351**

File 351:Derwent WPI 1963-2000/UD,UM &UP=200054
(c) 2000 Derwent Info Ltd

Set Items Description
--- ----- -----------
?**exs**

Executing TD101
0 PN=JP 86289087
1 PN=JP 61289087
1 PN=CA 2134128
1 PN=CA 2166179
1 PN=CH 688412
0 PN=CN 1151987
1 PN=DE 19814392
1 PN=DE 4333190
1 PN=DE 4442999
1 PN=EP 396083
1 PN=EP 396404
1 PN=EP 433766
1 PN=EP 459387
1 PN=EP 556813
1 PN=EP 704206
S1 13 PN=(JP 86289087 + JP 61289087) + PN=CA 2134128 + PN=CA 2166179 + PN=CH 688412 + PN=CN 1151987 + PN=DE 19814392 + PN=DE 4333190 + PN=DE 4442999 + PN=EP 396083 + PN=EP 396404 + PN=EP 433766 + PN=EP 459387 + PN=EP 556813 + PN=EP 704206
1 PN=EP 719548
1 PN=EP 719549
1 PN=EP 780127
1 PN=EP 875245
1 PN=EP 890358
1 PN=EP 903151
1 PN=EP 968715
1 PN=ES 2009465
1 PN=ES 2009466
1 PN=ES 2040177
1 PN=ES 2042421
1 PN=ES 2080699
1 PN=ES 2080700
1 PN=ES 2087818
1 PN=JP 61289087
S2 15 PN=EP 719548 + PN=EP 719549 + PN=EP 780127 + PN=EP 875245 + PN=EP 890358 + PN=EP 903151 + PN=EP 968715 + PN=ES 2009465 + PN=ES 2009466 + PN=ES 2040177 + PN=ES 2042421 + PN=ES 2080699
.

.
.
S8 14 PN=WO 9837889 + PN=WO 9838166 + PN=WO 9839005
+ PN=WO 9848803 + PN=WO 9852540 + PN=WO
9853802 + PN=WO 9858685 + PN=WO 9901450 +
PN=WO 9908676 + PN=WO 9909962 + PN=WO 9915173
+ PN=WO 9919322 + PN=WO 9921556 + PN=WO
9925328
1 PN=WO 9930690
1 PN=WO 9962516

Now TYPE out the records. Note how highly relevant they are.

1 PN=WO 9966919
S9 3 PN=WO 9930690 + PN=WO 9962516 + PN=WO 9966919
S10 108 S1:S9

?**t s10/19/1-5**

1/19/1
DIALOG(R)File 351:Derwent WPI
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012746122
WPI Acc No: 1999-552239/*199947*
Orally administrable effervescent tablets containing antihistamines
Patent Assignee: HERMES FAB PHARM PRAEPARATE GRADINGER (HERM-N)
Inventor: DANDL K; HEIN T; ROTHENBERGER S
Number of Countries: 025 Number of Patents: 002
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
DE 19814392 A1 19991007 DE 1014392 A 19980331 199947 B
EP 948961 A2 19991013 EP 99106452 A 19990329 199947

Priority Applications (No Type Date): DE 1014392 A 19980331
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
DE 19814392 A1 3 A61K-045/00
EP 948961 A2 G A61K-009/20
Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI

Abstract (Basic): *DE 19814392* A1
NOVELTY - Effervescent tablets containing antihistamines also contain calcium.
ACTIVITY - Antihistaminic; antiallergic.
MECHANISM OF ACTION - None given.
USE - For treatment of allergies.
ADVANTAGE - The tablets provide rapid release and good bioavailability, have good organoleptic properties and can be administered without problems, even to children. Simultaneous administration of calcium is stated to increase the efficacy of the antihistamine (no data given).
pp; 3 DwgNo 0/0
Technology Focus:
TECHNOLOGY FOCUS - PHARMACEUTICALS - Preferred Tablets: The tablets contain an acid and an alkali or alkaline earth metal carbonate or bicarbonate. The calcium content is 100-1500 (especially 400-1200) mg/tablet. The calcium is in carbonate and/or citrate form. The antihistamine content is 1-150 mg/tablet.
The tablet also comprises colors, flavorings, disintegrants, fillers, binders, antioxidants, surfactants and lubricants.
Preferred Antihistamines: The antihistamine is cetirizine, fexofenadine, azelastine, loratadine, clemastine hydrogen fumarate, terfenadine, astemizole, dimetindene maleate and/or doxyamine succinate, especially cetirizine.
Title Terms: ORAL; ADMINISTER; EFFERVESCENT; TABLET; CONTAIN; ANTIHISTAMINE

Derwent Class: B05; B07
International Patent Class (Main): A61K-009/20; A61K-045/00
International Patent Class (Additional): A61K-009/46; A61K-031/495
File Segment: CPI
Chemical Fragment Codes (M2):
01 F011 F014 F553 G010 G013 G100 H1 H182 H2 H202 H5 H581 H6 H602 H641 H8 J0
Ring Index Numbers: ; 41641; 41641
Derwent Registry Numbers: 1278-U
Specific Compound Numbers: R14937-K; R14937-T; R14937-M; R16291-K; R16291-T;

1/19/2
DIALOG(R)File 351:Derwent WPI
(c) 2000 Derwent Info Ltd. All rts. reserv.

011493546 **Image available**
WPI Acc No: 1997-471459/*199744*
XRAM Acc No: C97-149841
Preparation of 1,4-disubstituted piperidine derivatives - with H1
anti-histamine properties, e.g. loratadin, by reaction of ketone parent with 1,4-piperidone
Patent Assignee: CILAG AG (CILA)
Inventor: GLADOW S; REY M
Number of Countries: 081 Number of Patents: 004
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
CH 688412 A5 19970915 CH 97571 A 19970311 199744 B
WO 9840376 A1 19980917 WO 98CH91 A 19980306 199843
AU 9860869 A 19980929 AU 9860869 A 19980306 199906
SK 9901249 A3 20000516 WO 98CH91 A 19980306 200036
SK 991249 A 19980306

Priority Applications (No Type Date): CH 97571 A 19970311
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
CH 688412 A5 G 8 C07D-519/00
WO 9840376 A1 G C07D-401/04
Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GE GH GM GW HU ID IL IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG US UZ VN YU ZW
Designated States (Regional): AT BE CH DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SZ UG ZW
AU 9860869 A C07D-401/04 Based on patent WO 9840376
SK 9901249 A3 C07D-401/04

Abstract (Basic): CH 688412 A
Preparation of 1,4-disubstituted piperidine compounds of formula (I) comprises reaction of a ketone of formula (II) with a piperidone of formula (III) in the presence of a finely divided group (IV), (V) and/or (VI) metal or one in a lower oxidation state, in an inert solvent (ether, N-containing unsaturated heteroaromatic or tertiary amine) and a reducing agent (group II alkali metals, their alloys, compounds with carbon, metal hydrides, naphthalide anions or higher polycyclic aromatics). R = H, F, Cl, Br or 1-5C alkyl or 2-5C alkenyl (optionally substituted by F, Cl, Br, 1-5C alkylether and/or phenyl), phenyl (optionally substituted by F, Cl, Br, 1-5C alkyl, COOH, 1-5C alkyl ester, NH2 and/or mono- or di-(1-5C alkyl)amino), 5-6 membered heteroaromatic bonded either directly or via a 1-5C alkylene to the pyridine and/or phenyl ring (containing 1-3 N, 1 O and/or 1 S atoms and optionally substituted by F, Cl, Br, 1-5C alkyl, COOH, 1-5C alkylester, NH2 and/or mono- or di-1-5C alkylamino); or 2 R's bonded to the same ring form a 5-6 membered aromatic or heteroaromatic (optionally substituted by F, Cl, Br, 1-5C alkyl, COOH, 1-5C alkylester, NH2, or mono- or di-1-5C alkyl); Y = (CH2)n, O, S, vinyl, CH2O, OCH2 , CH2S or SCH2; Z = H, COR1, COOR1, OSOR2 or R1; R1 = as R (but not H, Cl, Br or F); R2 = R1 or a bridged, saturated, isocyclic system (especially camphor sulphonic acid). Also claimed are compounds prepared using this process.
USE - (I) (especially 4-(8-chloro-5,6-dihydro-11H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-yliden)-1- piperidine carboxylic acid ethyl ester (loratadin) (Ia)) are useful as H1-antihistamines.
ADVANTAGE - Unlike prior art processes (see e.g. US4731447), the process uses few reagents, needs no intermediate protecting groups on the piperidine N and gives good yields. It does not use toxic reagents or solvents, uses conventional temperatures and equipment, all products precipitate out and it does not use or form environmentally damaging compounds.

Dwg.0/0
{INSERT IMAGE BMP "W0AF60AA.bmp"}

Title Terms: PREPARATION; DI; SUBSTITUTE; PIPERIDINE; DERIVATIVE; ANTI; HISTAMINE; PROPERTIES; REACT; KETONE; PARENT; PIPERIDONE
Derwent Class: B02
International Patent Class (Main): C07D-401/04; C07D-519/00
File Segment: CPI
Manual Codes (CPI/A-N): B06-H; B14-L10
Chemical Fragment Codes (M2):
01 C316 D011 D012 D013 D019 D021 D022 D023 D029 E160 E520 E820 F010 F011
Generic Compound Numbers: 9744-00501-N; 9744-00501-P; 9744-00502-N; 9744-00502-P

1/19/3
DIALOG(R)File 351:Derwent WPI
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010838870
WPI Acc No: 1996-335823/199634
XRAM Acc No: C96-106055
Compsns. for treating sensitive skin - contain at least one histamine, interleukin-1 or alpha-TNF antagonist
Patent Assignee: L'OREAL SA (OREA)
Inventor: BRETON L; COHEN C; DE LACHARRIERE O
Number of Countries: 020 Number of Patents: 006
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
FR 2728793 A1 19960705 FR 9415796 A 19941228 199634 B
EP 729750 A1 19960904 EP 95402677 A 19951128 199640
CA 2166179 A 19960629 CA 2166179 A 19951227 199642
JP 8231432 A 19960910 JP 95341294 A 19951227 199646
US 5658581 A 19970819 US 95580291 A 19951228 199739
US 5993833 A 19991130 US 95580291 A 19951228 200003
US 97879889 A 19970620

Priority Applications (No Type Date): FR 9415796 A 19941228
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
FR 2728793 A1 21 A61K-031/41
US 5993833 A A61K-007/48 Div ex application US 95580291
Div ex patent US 5658581
EP 729750 A1 F 16 A61K-031/00
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE
CA 2166179 A F A61K-007/40
JP 8231432 A 11 A61K-045/00
US 5658581 A 7 A61K-007/48

Abstract (Basic): FR 2728793 A
Use of at least one cpd. (I) which may be a histamine, interleukin-1 or alpha-TNF antagonist or a mixt. of (I) in the treatment of sensitive skin, is new. Also claimed is the use of (I) or a mixt. of (I) in a compsn. contg. an irritant.
The antagonist is pref. a heterocycle or a nitrogen-contg. cpd including at least one benzene ring, pref. tetrazolyl-benzofuran carboxamides, tetrazolyl-benzothiophene carboxamides, or diethylenediamine, aminopropane or phenothiazine derivs.
USE - (I) are used in compsns. for preventing or treating skin irritations and/or scurf patches and/or erythema and/or pain and/or heat sensations and/or pruritus of the skin and mucous membranes. The compsns. are for topical application to the skin, scalp and/or the mucous membranes (all claimed). The compsns. may be formulated as face creams, handcreams, body lotions, day creams, night creams, make-up removing creams, foundations, sunscreens, cleaning lotions or milks, artificial tanning lotions, bath products, deodorants contg. bactericide, after-shave gels or lotions, depilatory creams, insect repellent compsns., analgesic preparations or compsns. for treating skin irritations, erythema, pain, prickly heat or pruritus. They may also be formulated as soaps, aerosols, shampoos, mouthwashes or toothpastes.
Dwg.0/0
Abstract (Equivalent): US 5658581 A

Composition for pharmaceutical, cosmetic or dermatological usage comprises at least 1 compound which produces an irritant side effect and also contains at least 1 agent to antagonize this side effect which is selected from auranofin, lactoferrin, lisophylline, sulphasalazine, a compound of formula(I),
6,7-dihydro-2-[4-(methylsulfinyl)phenyl]-3-(4-pyridinyl)-5H-pyrrolo[1,2-a]im idazole and their combinations.
Method for producing a topical composition for cosmetic, pharmaceutical or dermatological usage comprises adding a composition containing at least 1 product which produces an irritant side effect and at least 1 compound to antagonize the side effect which is selected from the above compounds. Dwg.0/0
Title Terms: COMPOSITION; TREAT; SENSITIVE; SKIN; CONTAIN; ONE; HISTAMINE; INTERLEUKIN; ALPHA; TNF; ANTAGONIST
Derwent Class: B04; B05; D21
International Patent Class (Main): A61K-007/40; A61K-007/48; A61K-031/00; A61K-031/41; A61K-045/00
International Patent Class (Additional): A61K-007/00; A61K-007/02; A61K-007/075; A61K-031/38; A61K-031/395; A61K-031/40; A61K-031/44; A61K-031/445; A61K-031/495
File Segment: CPI
Manual Codes (CPI/A-N): B03-G; B06-H; B07-H; B14-L06; B14-L07; B14-L09; B14-N17; D08-B08; D08-B09
Chemical Fragment Codes (M1):
13 H4 H401 H481 H5 H521 H8 M280 M313 M321 M332 M342 M383 M391 M423 M431 M782 9634-04701-M P330 P412 P420 P617 P930 P942 Q252 Q262 R03221-M 06384
Ring Index Numbers: 06384; 41641; 01391
Derwent Registry Numbers: 0007-U; 0122-U; 1117-U; 1211-U; 1279-U; 1871-U
Specific Compound Numbers: R18538-M; R14937-M; R01279-M; R03221-M; R14939-M; R04592-M; R21322-M; R12996-M; R00007-M; R04912-M; R00122-M; R03005-M; R01871-M
Generic Compound Numbers: 9634-04701-M

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DIALOG(R)File 351:Derwent WPI
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010837418 **Image available**
WPI Acc No: 1996-334371/*199634*
XRAM Acc No: C96-105653
Prodn. of loratadine - from N-t-butyl-3-methyl-pyridine-2-carboxamide via new intermediates.
Patent Assignee: APOTEX INC (APOT-N)
Inventor: IYER R; JACKSON W P; KARIMIAN K; LEE S
Number of Countries: 001 Number of Patents: 001
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
CA 2134128 A 19960425 CA 2134128 A 19941024 199634 B

Priority Applications (No Type Date): CA 2134128 A 19941024
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
CA 2134128 A 21 C07D-401/02

Abstract (Basic): CA 2134128 A
Prodn. of loratadine e.g. 8-chloro-11-(1-ethoxycarbonyl-4-piperidylidene)-6,11-dihydro-5H-benzo(5,6)cyclohepta(1,2-b)pyridine of formula (I), comprises: (a) reacting N-t-butyl-3-methylpyridine-2- carboxamide of formula (VI) with a 2-halo-5-chlorobenzyl bromide of formula (VII); (b) hydrolysing the prod. of formula (VIII) to give a carboxylic acid of formula (IX); (c) converting (IX) to an alcohol of formula (X) by carboxylic derivatisation and redn.; (d) converting (X) to a halide of formula (III) by OH/halogen exchange; (e) converting (III) to a phosphonate of formula (V); (f) reacting (V) with ethyl 4-oxo-2-piperidinecarboxylate; and (g) subjecting the prod. of formula
(II) to intramolecular cyclisation in a catalysed medium. X,X'=halo.
USE - (I) is a non-sedating histamine H1 receptor antagonist.
ADVANTAGE - Problems associated with the use of strong acids, namely toxicity, expense, corrosion and isomer formation, are avoided (cf. CA1272480 and EP396083).
Dwg.0/0
{INSERT IMAGE BMP "W0A55DAA.bmp"}

Title Terms: PRODUCE; N; BUTYL; METHYL; PYRIDINE; CARBOXAMIDE; NEW; INTERMEDIATE
Derwent Class: B02
International Patent Class (Main): C07D-401/02

International Patent Class (Additional): C07D-213/30; C07D-213/78
File Segment: CPI
Manual Codes (CPI/A-N): B06-D13; B14-L09; N02-F01
Chemical Fragment Codes (M2):
01 A546 A960 M411 M730 M903 Q421
Ring Index Numbers: 41641
Derwent Registry Numbers: 1738-U; 1830-U
Specific Compound Numbers: R14939-P
Generic Compound Numbers: 9634-00201-N; 9634-00202-N; 9634-00203-N; 9634-00204-N; 9634-00205-N

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DIALOG(R)File 351:Derwent WPI
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010780502
WPI Acc No: 1996-277455/199628
XRAM Acc No: C96-087998
Transdermal compsn. with antihistamine activity comprising active loratadine metabolite - is administered e.g. in salve or transdermal plaster, shows improved antihistaminic activity
Patent Assignee: HEXAL AG (HEXA-N); HEXAL PHARMA GMBH (HEXA-N)
Inventor: FISCHER W; KLOKKERS K
Number of Countries: 027 Number of Patents: 005
Patent Family:
Patent No Kind Date Applicat No Kind Date Week
WO 9616641 A1 19960606 WO 95EP4761 A 19951204 199628 B
DE 4442999 A1 19960605 DE 4442999 A 19941202 199629
AU 9643015 A 19960619 AU 9643015 A 19951204 199640
ZA 9510234 A 19961129 ZA 9510234 A 19951201 199702
EP 794770 A1 19970917 EP 95941659 A 19951204 199742
WO 95EP4761 A 19951204

Priority Applications (No Type Date): DE 4442999 A 19941202
Cited Patents: 2.Jnl.Ref; US 4910205
Patent Details:
Patent No Kind Lan Pg Main IPC Filing Notes
WO 9616641 A1 G 12 A61K-009/70
Designated States (National): AU CA CZ FI JP NO PL SK US
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LU MC NL PT SE
DE 4442999 A1 4 A61K-031/445
AU 9643015 A A61K-009/70 Based on patent WO 9616641
ZA 9510234 A 7 A61K-000/00
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EP 794770 A1 G A61K-009/70 Based on patent WO 9616641
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU NL PT SE

Abstract (Basic): WO 9616641 A
Pharmaceutical compsn. for systemic transdermal admin. comprises an active loratadine metabolite as active agent.
USE - The active cpd. is useful as an antihistamine. It may be administered, e.g. in a salve or a transdermal plaster.
ADVANTAGE - Loratadine is metabolised in the body. It is normally available as a soln. or in tablet form. The new compsn. shows improved antihistamine effect.
Dwg.0/0
Title Terms: TRANSDERMAL; COMPOSITION; ANTIHISTAMINE; ACTIVE; COMPRISE; ACTIVE; METABOLITE; ADMINISTER; SALVE; TRANSDERMAL; PLASTER; SHOW; IMPROVE; ANTIHISTAMINE; ACTIVE
Derwent Class: B02; B07; D22
International Patent Class (Main): A61K-000/00; A61K-009/70; A61K-031/445
File Segment: CPI
Manual Codes (CPI/A-N): B06-D13; B12-M02F; B14-L09; D09-C04B

Chemical Fragment Codes (M2):
01 D021 D022 E160 F014 F433 H6 H602 H641 H7 H720 M1 M116 M119 M280 M320 M412 M431 M511 M521 M530 M540 M782 M903 M904 P432 9628-26001-M 41641
Ring Index Numbers: 41641
Generic Compound Numbers: 9628-26001-M

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Appendix D: Country Coverage of Databases Used

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Consolidated Countries		Total Patent Countries		DWPI Countries		INPADOC Countries	
Code	Consolidated Country	Code	Total Patent Country	Code	DWPI Country	Code	INPADOC Country
AP	African Regional Intellectual Property Organization	OA	African Intellectual Property Organization	AP	ARIPO	AP	ARIPO
AR	Argentina	AP	African Regional Intellectual Property Organization	AR	Argentina	AR	Argentina
AT	Austria	DZ	Algeria	AU	Australia	AT	Austria
AU	Australia	AR	Argentina	AT	Austria	AU	Australia
BA	Bosnia and Herzogovina	AU	Australia	BE	Belgium	BA	Bosnia
BE	Belgium	AT	Austria	BR	Brazil	BE	Belgium
BG	Bulgaria	BY	Belarus	CA	Canada	BG	Bulgaria
BN	Brunei	BE	Belgium	CN	China	BR	Brazil
BO	Bolivia	BO	Bolivia	CZ	Czech Republic	BY	Belarus
BR	Brazil	BA	Bosnia and Herzogovina	CS	Czechoslovakia	CA	Canada
BY	Belarus	BR	Brazil	DK	Denmark	CH	Switzerland
CA	Canada	BN	Brunei	EP	European Patent Office	CL	Chile
CH	Switzerland	BG	Bulgaria	FI	Finland	CN	China
CL	Chile	CA	Canada	FR	France	CO	Colombia
CN	China	CL	Chile	DE	Germany	CR	Costa Rica
CO	Columbia	CN	China	DE	German	CS	Czechoslovakia
CR	Costa Rica	CO	Columbia	DD	German Dem. Rep	CU	Cuba
CS	Czechoslovakia	CR	Costa Rica	HU	Hungary	CY	Cyprus
CU	Cuba	HR	Croatia	IN	India	CZ	Czech Republic
CY	Cyprus	CU	Cuba	IE	Ireland	DD	Germany (EX_GDR)
CZ	Czech Republic	CY	Cyprus	IL	Israel	DE	Germany
DD	East Germany	CZ	Czech Republic	IT	Italy	DK	Denmark
DE	Germany	CS	Czechoslovakia	JP	Japan	DO	Dominican Republic
DK	Denmark	DK	Denmark	KR	Rep. of Korea	DZ	Algeria
DO	Dominican Republic	DO	Dominican Republic	LU	Luxembourg	EA	Eurasian Patent Office
DZ	Algeria	DD	East Germany	MX	Mexico	EC	Ecuador
EA	Eurasian Patent Office	EC	Ecuador	NL	Netherlands	EE	Estonia

Consolidated Countries		Total Patent Countries		DWPI Countries		INPADOC Countries	
Code	Consolidated Country	Code	Total Patent Country	Code	DWPI Country	Code	INPADOC Country
EC	Ecuador	EG	Egypt	NZ	New Zealand	EG	Egypt
EE	Estonia	SV	El Salvador	NO	Norway	EP	European Patent Office
EG	Egypt	EE	Estonia	WO	Patent Cooperation Treaty	ES	Spain
EP	European Patent Office	EA	Eurasian Patent Office	PH	Philippines	FI	Finland
ES	Spain	EP	European Patent Office	PT	Portugal	FR	France
FI	Finland	FI	Finland	RO	Romania	GB	United Kingdom
FR	France	FR	France	RU	Russian Federation	GC	Gulf Coop. Council
GB	United Kingdom	DE	Germany	SG	Singapore	GR	Greece
GC	Gulf Cooperation Council	GR	Greece	SK	Slovakia	GT	Guatemala
GR	Greece	GT	Guatemala	ZA	South Africa	HK	Hong Kong
GT	Guatemala	GC	Gulf Cooperation Council	SU	Soviet Union	HR	Croatia
HK	Hong Kong	HN	Honduras	ES	Spain	HU	Hungary
HN	Honduras	HK	Hong Kong	SE	Sweden	ID	Indonesia
HR	Croatia	HU	Hungary	CH	Switzerland	IE	Ireland
HU	Hungary	IS	Iceland	TW	Taiwan	IL	Israel
ID	Indonesia	IN	India	GB	United Kingdom	IN	India
IE	Ireland	ID	Indonesia	UK	United Kingdom	IS	Iceland
IL	Israel	IE	Ireland	US	United States	IT	Italy
IN	India	IL	Israel	PCT	Patent Cooperation Treaty	JP	Japan
IS	Iceland	IT	Italy	##	##	KE	Kenya
IT	Italy	JP	Japan	##	##	KR	Republic of Korea
JP	Japan	KZ	Kazakhastan	##	##	KZ	Kazakhstan
KE	Kenya	KE	Kenya	##	##	LT	Lithuania
KR	South Korea	KR	Korea, Republic of	##	##	LU	Luxembourg
KZ	Kazakhastan	LV	Latvia	##	##	LV	Latvia
LT	Lithuania	LT	Lithuania	##	##	MA	Morocco
LU	Luxembourg	LU	Luxembourg	##	##	MC	Monaco
LV	Latvia	MW	Malawi	##	##	MD	Moldova
MA	Morocco	MY	Malaysia	##	##	MN	Mongolia

Consolidated Countries		Total Patent Countries		DWPI Countries		INPADOC Countries	
Code	Consolidated Country	Code	Total Patent Country	Code	DWPI Country	Code	INPADOC Country
MC	Monaco	MT	Malta			MT	Malta
MD	Moldova	MX	Mexico			MW	Malawi
MN	Mongolia	MD	Moldova			MX	Mexico
MT	Malta	MC	Monaco			MY	Malaysia
MW	Malawi	MN	Mongolia			NI	Nicaragua
MX	Mexico	MA	Morocco			NL	Netherlands
MY	Malaysia	NL	Netherlands			NO	Norway
NI	Nicaragua	NZ	New Zealand			NZ	New Zealand
NL	Netherlands	NI	Nicaragua			OA	OAPI
NO	Norway	NO	Norway			PA	Panama
NZ	New Zealand	PA	Panama			PE	Peru
OA	African Intellectual Property Organization	PY	Paraguay			PH	Philippines
PA	Panama	PE	Peru			PL	Poland
PCT	Patent Cooperation Treaty	PH	Philippines			PT	Portugal
PE	Peru	PL	Poland			RO	Romania
PH	Philippines	PT	Portugal			RU	Russia
PL	Poland	RO	Romania			SE	Sweden
PT	Portugal	RU	Russia			SG	Singapore
PY	Paraguay	SG	Singapore			SI	Slovenia
RO	Romania	SK	Slovak Republic			SK	Slovakia
RU	Russia	SI	Slovenia			SM	San Marino
SE	Sweden	ZA	South Africa			SU	U.S.S.R.
SG	Singapore	SU	Soviet Union			SV	El Salvador
SI	Slovenia	ES	Spain			TJ	Tajikistan
SK	Slovak Republic	SE	Sweden			TR	Turkey
SM	San Marino	CH	Switzerland			TW	Taiwan
SU	Soviet Union	TW	Taiwan			UA	Ukraine
SV	El Salvador	TJ	Tajikistan			US	U.S.A.
TH	Thailand	TH	Thailand			UY	Uruguay
TJ	Tajikistan	TT	Trinidad and Tobago			VN	Viet Nam

Consolidated Countries		Total Patent Countries		DWPI Countries		INPADOC Countries	
Code	Consolidated Country	Code	Total Patent Country	Code	DWPI Country	Code	INPADOC Country
TR	Turkey	TR	Turkey			WO	W.I.P.O (P.C.T.)
TT	Trinidad and Tobago	UA	Ukraine			YU	Yugoslavia
TW	Taiwan B39	GB	United Kingdom			YU	SERBIA and MONTENEGRO
UA	Ukraine	US	United States			ZA	South Africa
UK	United Kingdom	UY	Uruguay			ZM	Zambia
US	United States	UZ	Uzbekistan			ZW	Zimbabwe
UY	Uruguay	VN	Vietnam				
UZ	Uzbekistan	WO	World Intellectual Property Organization				
VN	Vietnam	YU	Yugoslavia				
WO	World Intellectual Property Organization	ZM	Zambia				
YU	Yugoslavia	ZW	Zimbabwe				
ZA	South Africa						
ZM	Zambia						
ZW	Zimbabwe						