5 Drugs Facing Key Patent Expirations and Potential Generic Entry from December 2021 – February 2022

A challenge in anticipating generic entry is elucidating which patents and regulatory protections constrain generic entry.

Presented here is a set of estimated loss of exclusivity dates for five drugs, from December 2021 through February 2022. These estimated drug patent expiration dates and generic entry opportunity dates are calculated from analysis of known patents and US regulatory protections covering drugs.[1] This methodology can be extended to ex-US jurisdictions by leveraging these estimates and tracking patent family members in other patent offices.

LICART (diclofenac epolamine)
Estimated US Loss of Exclusivity Date: 19 December 2021[2]*
Generic Entry Controlled by: FDA Regulatory Exclusivity
LICART is marketed by Ibsa Inst Bio and is included in one NDA. By analysing the patents and regulatory protections it appears that the earliest date for generic entry in the US will be December 19th, 2021, when FDA Regulatory Exclusivity expires.

VAZALORE (aspirin)
Estimated US Loss of Exclusivity Date: 19 December 2021[3]*
Generic Entry Controlled by: US Patent 9351984
Title: Compositions comprising lecithin oils and NSAIDs for protecting the gastrointestinal tract and providing enhanced therapeutic activity
Abstract: "A novel pharmaceutical composition is provided by which nonsteroidal anti-inflammatory drugs (NSAIDs) are added directly to phospholipid-containing oil such as lecithin oils or to a bio-compatible oil to which a phospholipid has been added to make a NSAID-containing formulation that possess low gastrointestinal (GI) toxicity and enhanced therapeutic activity to treat or prevent inflammation, pain, fever, platelet aggregation, tissue ulcerations and/or other tissue disorders. The composition of the invention is in the form of a non-aqueous solution, paste, suspension, dispersion, colloidal suspension or in the form of an aqueous emulsion or microemulsion for internal, oral, direct or topical administration."[4]

VAZALORE is marketed by Plx Pharma and is included in one NDA. There are five US patents protecting this drug, and forty-two patent family members in eighteen other countries/regional patent offices.

By analysing the patents and regulatory protections it appears that the earliest date for generic entry in the US will be December 19th, 2021, when US Patent 9,351,984 expires. Patent 9,351,984 describes'compositions comprising lecithin oils and NSAIDs for protecting the gastrointestinal tract and providing enhanced therapeutic activity', and is assigned to The Board of Regents of the University of Texas System (Austin, TX).[3,4]

FEMTRACE (estradiol acetate)
Estimated US Loss of Exclusivity Date: 21 December 2021[5]*
Generic Entry Controlled by: US Patent 6962908
Title: Oral pharmaceutical products containing 17 .beta. -estradiol-3-lower alkanoate, method of administering the same and process of preparation
Abstract: "A pharmaceutical dosage unit for oral administration to a human female comprising a therapeutically effective amount of 17.beta.-estradiol-3-lower alkanoate, most preferably 17.beta.-estradiol-3-acetate, and a pharmaceutically acceptable carrier is disclosed. Also disclosed is a method for treating a human female in need of 17.beta.-estradiol and a contraceptive method by oral administration of the pharmaceutical dosage unit and a method of preparing a pharmaceutical composition that may be used to form the pharmaceutical dosage unit of the invention."[6]

FEMTRACE is marketed by Apil and is included in one NDA. There are three US patents protecting this drug, and eleven patent family members in ten other countries/regional patent offices.

By analysing the patents and regulatory protections it appears that the earliest date for generic entry in the US will be December 21st, 2021, when US Patent 6,962,908 expires. Patent 6,962,908 describes Oral pharmaceutical products containing 17 .beta.-estradiol-3-lower alkanoate, method of administering the same and process of preparation, and is assigned to Warner Chilcott Company Inc. (Fajardo, PR).[5,6]

PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER (calcium chloride; magnesium chloride; potassium chloride; sodium bicarbonate; sodium chloride; sodium phosphate)
Estimated US Loss of Exclusivity Date: 13 January 2022[7]*
Generic Entry Controlled by: FDA Regulatory Exclusivity
PHOXILLUM B22K 4/0 IN PLASTIC CONTAINER is marketed by Baxter Hlthcare Corp and is included in one NDA. By analysing the patents and regulatory protections it appears that the earliest date for generic entry in the US will be January 13th, 2022, when FDA Regulatory Exclusivity expires.

SPIRIVA RESPIMAT (tiotropium bromide)
Estimated US Loss of Exclusivity Date: 4 February 2022[8]*
Generic Entry Controlled by: US Patent 7988001
Title: Container provided with a pressure equalization opening
Abstract: "A process for producing a container comprising an outer container, an inner bag disposed therein and a pressure equalisation opening disposed in the outer container, and a container produced according to this process, is described, wherein a pre-moulding, comprising two coaxial tubes, is first produced by co-extrusion with the help of a blow mould and with an outwardly-projecting base seam being formed. The process forms a pressure equalisation opening in the outer container without endangering the integrity of the container, wherein a lower wastage rate and higher productivity are achieved. To do this, the base seam is partially cut off and a force

which acts in the direction of the seam is introduced into the pre-moulding, which has a temperature of 40°C to 70°C, which force breaks open and plastically deforms the base seam so that a pressure equalisation opening is formed in the base area."[9]

SPIRIVA RESPIMAT is marketed by Boehringer Ingelheim and is included in one NDA. There are seven US patents protecting this drug, and one hundred and sixty-nine patent family members in forty-four other countries/regional patent offices.

By analysing the patents and regulatory protections it appears that the earliest date for generic entry in the US will be February 4th, 2022, when US Patent 7,988,001 expires. Patent 7,988,001 describes'Container provided with a pressure equalisation opening,' and is assigned to Boehringer Ingelheim Pharma GmbH & Co. KG (Ingelheim am Rhein, DE).[8,9]

Disclaimer

* Generic entry predictions are estimates. Drugs may be covered by multiple patents and regulatory protections. Although great care is taken in the proper and correct provision of this information, the author does not accept any responsibility for possible consequences of errors or omissions in the provided data. The data presented herein is for information purposes only. There is no warranty that the data contained herein is error free.

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Financial & competing interests' disclosure

Y Friedman is the CEO of DrugPatentWatch. The author has no other relevant affiliations or financial involvement with any organisation or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed. No writing assistance was utilised in the production of this manuscript.

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