

# Patent Listing Disputes

Current through January 14, 2022

| Established Drug Product Name | NDA Number | NDA Holder         | Strength(s)                                                          | Relevant U.S. Patent Number(s)                          | Type of Patent Claim             | Original Use Code (if applicable)                                                                                                                                                                                                                              | Revised Use Code (if applicable)                                                                                                                                                                                                                               | Due Date for NDA Holder Response | NDA Holder Response Date | Dispute Outcome        |
|-------------------------------|------------|--------------------|----------------------------------------------------------------------|---------------------------------------------------------|----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------|------------------------|
| metaxalone                    | 013217     | King Pharms        | 800 mg                                                               | 7122566                                                 | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 12/17/2021                       | 12/3/2021                | No Orange Book Changes |
| epinephrine                   | 205029     | Belcher            | 1mg/mL                                                               | 10004700 and 10039728                                   | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 7/24/2021                        | Pending                  | Pending                |
| memantine hydrochloride       | 22525      | Allergan Sales LLC | 7 mg<br>14 mg<br>21 mg<br>28 mg                                      | 8168209, 8173708, 8283379, 8329752, 8362085 and 8598233 | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 5/28/2021                        | 5/28/2021                | Patent Listing Updated |
| epinephrine                   | 201739     | Kaleo Inc          | 0.1 mg<br>0.15 mg<br>0.3 mg                                          | 10824938                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 2/28/2021                        | 2/3/2021                 | Patent Listing Updated |
| netarsudil and latanoprost    | 208259     | Aerie Pharms Inc   | 0.02%/0.005%                                                         | 10654844                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 11/18/2020                       | 10/30/2020               | Patent Listing Updated |
| netarsudil                    | 208254     | Aerie Pharms Inc   | 0.02%                                                                | 10654844                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 11/18/2020                       | 10/30/2020               | Patent Listing Updated |
| cangrelor                     | 204958     | Chiesi             | 50 mg/vial                                                           | 8680052                                                 | Method of Use                    | U-2869: IV Administration of cangrelor before PCI and continuous infusion for at least 2 hours or the duration of the PCI and, during or after the continuous infusion, administration of a loading dose of ticagrelor or an equivalent therapy (per labeling) | U-2979: Method comprising IV administration of cangrelor before PCI then continuous infusion for at least 2 hours or the duration of PCI and, during or after continuous infusion, administration of a loading dose of ticagrelor, or an equivalent method     | 11/8/2020                        | 11/3/2020                | Patent Listing Updated |
| dapagliflozin and metform HCl | 205649     | AstraZeneca        | 5mg/500mg<br>5mg/1000mg<br>10mg/500mg<br>10mg/1000mg<br>2.5mg/1000mg | 6515117                                                 | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 10/29/2020                       | 10/1/2020                | Patent Listing Updated |
| cangrelor                     | 204958     | Chiesi             | 50 mg/vial                                                           | 8680052                                                 | Method of Use                    | U-1715: P2Y12 Platelet Inhibitor for use as adjunct to percutaneous coronary intervention to reduce risk of various diseases/conditions in patients not treated with a P2Y12 platelet inhibitor and not given a glycoprotein IIb/IIIa inhibitor                | U-2869: IV Administration of cangrelor before PCI and continuous infusion for at least 2 hours or the duration of the PCI and, during or after the continuous infusion, administration of a loading dose of ticagrelor or an equivalent therapy (per labeling) | 8/9/2020                         | 8/7/2020                 | Patent Listing Updated |
| fingolimod hydrochloride      | 022527     | Novartis           | EQ 0.5mg Base                                                        | 9187405                                                 | Method of Use                    | U-2613: Treatment of Relapsing-Remitting Sclerosis (MS)                                                                                                                                                                                                        | N/A                                                                                                                                                                                                                                                            | 6/15/2020                        | 6/10/2020                | No Orange Book Changes |
| paliperidone palmitate        | 022264     | Janssen Pharms     | 39 mg/0.25 mL,<br>78 mg/0.5 mL,<br>117 mg/0.75 mL,<br>156 mg/mL      | 9439906                                                 | Method of Use                    | U-543: Treatment of Schizophrenia                                                                                                                                                                                                                              | U-2757: Dosing regimen for the treatment of schizophrenia in adults by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)                                                                                               | 3/21/2020                        | 3/20/2020                | Patent Listing Updated |
| paliperidone palmitate        | 022264     | Janssen Pharms     | 39 mg/0.25 mL,<br>78 mg/0.5 mL,<br>117 mg/0.75 mL,<br>156 mg/mL      | 9439906                                                 | Method of Use                    | U-1901: Treatment of Schizoaffective Disorder as a Monotherapy and as an adjunct to mood stabilizers or antidepressants                                                                                                                                        | U-2758: Dosing regimen for the treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)          | 3/21/2020                        | 3/20/2020                | Patent Listing Updated |
| glatiramer acetate            | 020622     | Teva Pharms USA    | 40mg/ml                                                              | 8232250, 8399413, 8969302, 9155776, and 9402874         | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                                                                            | N/A                                                                                                                                                                                                                                                            | 2/15/2020                        | 2/6/2020                 | Patent Listing Updated |

**Patent Listing Disputes**  
Current through January 14, 2022

| Established Drug Product Name | NDA Number | NDA Holder           | Strength(s)               | Relevant U.S. Patent Number(s)                       | Type of Patent Claim             | Original Use Code (if applicable)                                                                                                                                                                         | Revised Use Code (if applicable) | Due Date for NDA Holder Response | NDA Holder Response Date | Dispute Outcome        |
|-------------------------------|------------|----------------------|---------------------------|------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------|--------------------------|------------------------|
| empagliflozin and linagliptin | 206073     | Boehringer Ingelheim | 10mg;5mg, 25mg;5mg        | 10406172                                             | Method of Use                    | U-1652: Method of Treating Type 2 Diabetes Mellitus by administering Linagliptin in combination with empagliflozin and metformin                                                                          | N/A                              | 1/18/2020                        | 1/17/2020                | Patent Listing Updated |
| empagliflozin                 | 204629     | Boehringer Ingelheim | 10 mg, 25 mg              | 10406172                                             | Method of Use                    | U-1652: Method of Treating Type 2 Diabetes Mellitus by administering Linagliptin in combination with empagliflozin and metformin                                                                          | N/A                              | 1/18/2020                        | 1/17/2020                | Patent Listing Updated |
| sodium oxybate                | 021196     | Jazz Pharms          | 500 mg/mL                 | 10213400                                             | Method of Use                    | U-2499: Method of reducing adverse effects in patients suffering from excessive daytime sleepiness and/or cataplexy in narcolepsy who are concomitantly administered sodium oxybate and divalproex sodium | N/A                              | 10/30/2019                       | 10/29/2019               | No Orange Book Changes |
| sodium oxybate                | 021196     | Jazz Pharms          | 500 mg/mL                 | 8772306, 9050302, 9486426                            | Method of Use                    | U-1532: Method of treating excessive daytime sleepiness and/or cataplexy in narcolepsy patients with sodium oxybate when divalproex sodium is concomitantly administered                                  | N/A                              | 10/30/2019                       | 10/29/2019               | No Orange Book Changes |
| sodium oxybate                | 021196     | Jazz Pharms          | 500 mg/mL                 | 8731963                                              | Method of Use                    | U-1110: Method of treating a patient with a prescription drug using a computer database in a computer system for distribution                                                                             | N/A                              | 10/30/2019                       | 10/29/2019               | No Orange Book Changes |
| abaterone acetate             | 202379     | Janssen Biotech      | 250 mg, 500 mg            | 8822438                                              | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 9/22/2019                        | 9/19/2019                | Patent Listing Updated |
| sodium oxybate                | 021196     | Jazz Pharms          | 500 mg/mL                 | 7668730, 7765106, 7765107, 7895059, 8457988, 8589182 | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 9/22/2019                        | 9/19/2019                | Patent Listing Updated |
| ramelteon                     | 021782     | Takeda Pharms USA    | 8 mg                      | 10098866                                             | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 7/18/2019                        | 7/11/2019                | No Orange Book Changes |
| fexofenadine hydrochloride    | 201373     | Sanofi Aventis US    | 30 mg/5 mL                | 8933097                                              | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 6/15/2019                        | 6/12/2019                | Patent Listing Updated |
| cyclosporine                  | 050790     | Allergan             | 0.05%                     | 9669974, 9676525                                     | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 4/26/2019                        | 4/19/2019                | No Orange Book Changes |
| nateglinide                   | 021204     | Novartis             | 60 mg, 120 mg             | 6559188, 6878749                                     | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 1/25/2019                        | 1/22/2019                | Patent Listing Updated |
| avibactam sodium; ceftazidime | 206494     | Allergan Sales LLC   | EQ 0.5 gm base; 2 gm/vial | 8969566                                              | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 1/6/2019                         | 1/7/2019                 | No Orange Book Changes |
| trospium chloride             | 022103     | Allergan             | 60 mg                     | 7410978, 7759359, 7763635, 7781448, 7781449          | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 11/18/2018                       | 10/31/2018               | Patent Listing Updated |
| metformin hydrochloride       | 021748     | Santarus Inc         | 500 mg, 1 gm              | 6723340                                              | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 8/25/2018                        | 8/23/2018                | No Orange Book Changes |
| pirfenidone                   | 208780     | Genentech Inc        | 267 mg, 534 mg, 801 mg    | 8383150                                              | Disputes Not Related to Use Code | N/A                                                                                                                                                                                                       | N/A                              | 8/23/2018                        | 8/24/2018                | Patent Listing Updated |

# Patent Listing Disputes

Current through January 14, 2022

| Established Drug Product Name | NDA Number | NDA Holder           | Strength(s)                                | Relevant U.S. Patent Number(s)                                                                                                                                                                                         | Type of Patent Claim             | Original Use Code (if applicable)                                                                                                                                                    | Revised Use Code (if applicable)                                                                                                                                                                                      | Due Date for NDA Holder Response | NDA Holder Response Date | Dispute Outcome        |
|-------------------------------|------------|----------------------|--------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------|------------------------|
| empagliflozin and linagliptin | 206073     | Boehringer Ingelheim | 10 mg; 5 mg, 25 mg; 5 mg                   | 8673927                                                                                                                                                                                                                | Method of Use                    | U-1772: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin                                                                   | None                                                                                                                                                                                                                  | 8/9/2018                         | 8/10/2018                | No Orange Book Changes |
| empagliflozin and linagliptin | 206073     | Boehringer Ingelheim | 10 mg; 5 mg, 25 mg; 5 mg                   | 9173859                                                                                                                                                                                                                | Method of Use                    | U-1652: Method of treating type 2 diabetes mellitus by administering linagliptin in combination with empagliflozin and metformin                                                     | None                                                                                                                                                                                                                  | 8/9/2018                         | 8/10/2018                | No Orange Book Changes |
| tadalafil                     | 022332     | Eli Lilly Co         | 20 mg                                      | 6821975, 7182958                                                                                                                                                                                                       | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 7/27/2018                        | 7/23/2018                | Patent Listing Updated |
| ropivacaine hydrochloride     | 020533     | Fresenius Kabi USA   | 200mg/100mL (2mg/mL), 400mg/200mL (2mg/mL) | 7828787, 7857802, 8118802, 8162915                                                                                                                                                                                     | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 6/20/2018                        | 6/7/2018                 | No Orange Book Changes |
| metformin hydrochloride       | 021748     | Santarus Inc         | 500 mg, 1 gm                               | 6488962                                                                                                                                                                                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 6/17/2018                        | 6/19/2018                | Patent Listing Updated |
| metaxalone                    | 013217     | King Pharms          | 880 mg                                     | 7122566                                                                                                                                                                                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 6/7/2018                         | 6/6/2018                 | No Orange Book Changes |
| colchicine                    | 204820     | Hikma Intl Pharms    | 0.6 mg                                     | 8927607, 9399036, 9555029, 9675613, 9789108                                                                                                                                                                            | Method of Use                    | U-1020: Method of using colchicine for the prophylaxis of gout flares                                                                                                                | None                                                                                                                                                                                                                  | 5/12/2018                        | 5/10/2018                | No Orange Book Changes |
| acetaminophen                 | 022450     | Mallinckrodt IP      | 1gm/100mL (10mg/mL)                        | 9610265                                                                                                                                                                                                                | Method of Use                    | U-2000: Management of moderate to severe pain as an adjunct to opioid analgesics                                                                                                     | U-2263: Modified dosing regimen for the management of moderate to severe pain with adjunctive opioid analgesics                                                                                                       | 4/4/2018                         | 4/4/2018                 | Patent Listing Updated |
| acetaminophen                 | 022450     | Mallinckrodt IP      | 1 gm/100 mL (10 mg/mL)                     | 9399012                                                                                                                                                                                                                | Method of Use                    | U-1882: Management of mild to moderate pain, management of moderate to severe pain as an adjunct to opioid analgesics, reduction in fever through analgesic and antipyretic activity | U-2261: Modified dosing regimen for the management of mild to moderate pain or management of moderate to severe pain as an adjunct to opioid analgesics<br>U-2262: Modified dosing regimen for the reduction of fever | 4/4/2018                         | 4/4/2018                 | Patent Listing Updated |
| dimethyl fumarate             | 204063     | Biogen Idec Inc      | 120 mg, 240 mg                             | 7320999, 8759393                                                                                                                                                                                                       | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 4/4/2018                         | 3/30/2018                | No Orange Book Changes |
| tofacitinib citrate           | 208246     | Pfizer Inc           | EQ 11 mg base                              | RE41783                                                                                                                                                                                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 3/13/2018                        | 3/8/2018                 | No Orange Book Changes |
| metformin hydrochloride       | 021748     | Santarus Inc         | 500 mg, 1 gm                               | 8323692                                                                                                                                                                                                                | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 3/10/2018                        | 2/21/2018                | Patent Listing Updated |
| dapagliflozin propanediol     | 202293     | Astrazeneca AB       | 5 mg, 10 mg                                | 6479065, 6495164, 6667061, 6824822, 6872700, 6956026, 7223440, 7456254, 7563871, 7612176, 7741269, 8216180, 8329648, 8431685, 8439864, 8461105, 8690837, 8712615, 8758292, 8827963, 8906851, 8998876, 9238076, 9320853 | Disputes Not Related to Use Code | N/A                                                                                                                                                                                  | N/A                                                                                                                                                                                                                   | 1/11/2018                        | 1/5/2018                 | Patent Listing Updated |

**Patent Listing Disputes**  
*Current through January 14, 2022*

| Established Drug Product Name | NDA Number | NDA Holder           | Strength(s)                    | Relevant U.S. Patent Number(s) | Type of Patent Claim             | Original Use Code (if applicable)                                                                                                                                                             | Revised Use Code (if applicable) | Due Date for NDA Holder Response | NDA Holder Response Date | Dispute Outcome        |
|-------------------------------|------------|----------------------|--------------------------------|--------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------|--------------------------|------------------------|
| eslicarbazepine acetate       | 022416     | Sunovion Pharms Inc  | 200 mg, 400 mg, 600 mg, 800 mg | 9750747                        | Method of Use                    | U-2041: Treatment of partial-onset seizures                                                                                                                                                   | None                             | 12/8/2017                        | 12/5/2017                | No Orange Book Changes |
| dabigatran etexilate mesylate | 022512     | Boehringer Ingelheim | 75 mg, 110 mg, 150 mg          | 7866474                        | Disputes Not Related to Use Code | N/A                                                                                                                                                                                           | N/A                              | 9/7/2017                         | 9/1/2017                 | Patent Listing Updated |
| dapagliflozin propanediol     | 202293     | Astrazeneca AB       | 5 mg, 10 mg                    | 8685934                        | Method of Use                    | U-1522: Treatment of type 2 diabetes mellitus in a patient, wherein glycemic control (HbA1c < 7.0%) is not achievable using one or more of insulin, metformin, pioglitazone, or rosiglitazone | None                             | 9/6/2017                         | 9/5/2017                 | No Orange Book Changes |
| metaxalone                    | 013217     | King Pharms          | 800 mg                         | 7122566                        | Disputes Not Related to Use Code | N/A                                                                                                                                                                                           | N/A                              | 6/25/2017                        | 6/23/2017                | No Orange Book Changes |
| dabigatran etexilate mesylate | 022512     | Boehringer Ingelheim | 75 mg, 110 mg, 150 mg          | 9034822                        | Disputes Not Related to Use Code | N/A                                                                                                                                                                                           | N/A                              | 5/28/2017                        | 5/26/2017                | No Orange Book Changes |