

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-307

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

**PATENT INFORMATION SUBMITTED WITH THE
FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT**

**For Each Patent That Claims a Drug Substance
(Active Ingredient), Drug Product (Formulation and
Composition) and/or Method of Use**

NDA NUMBER

NAME OF APPLICANT / NDA HOLDER
ELI LILLY AND COMPANY

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
EFFIENT

ACTIVE INGREDIENT(S)
Prasugrel hydrochloride

STRENGTH(S)
5 mg and 10 mg

DOSAGE FORM
Tablets

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4). Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number 5,288,726	b. Issue Date of Patent 02/22/1994	c. Expiration Date of Patent 09/08/2012
d. Name of Patent Owner Daiichi Sankyo Company, Limited	Address (of Patent Owner) 3-5-1, Nihonbashi Honcho	
	City/State Chuo-ku, Tokyo, Japan	
	ZIP Code 103-8426	FAX Number (if available) +81-3-5696-8773
	Telephone Number +81-3-5696-8270	E-Mail Address (if available) N/A
d. Name of Patent Owner UBE Industries, Ltd.	Address (of Patent Owner) Seavans North Building, 1-2-1, Shibaura	
	City/State Minato-Ku, Tokyo, Japan	
	ZIP Code 105-8449	FAX Number (if available) +81-3-5419-6237
	Telephone Number +81-3-5419-6112	E-Mail Address (if available) N/A

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address (of agent or representative named in 1.e.) P.O. Box 6288	
	City/State Indianapolis, IN	
General Patent Counsel, Eli Lilly and Company	ZIP Code 46206-6288	FAX Number (if available) 317-276-3861
	Telephone Number 317-276-2958	E-Mail Address (if available) patents@lilly.com
f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? <input type="checkbox"/> Yes <input type="checkbox"/> No		
For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.		
2. Drug Substance (Active Ingredient)		
2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21.CFR 314.53(b). <input type="checkbox"/> Yes <input type="checkbox"/> No		
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.		
2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
2.6 Does the patent claim only an intermediate? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
2.7 If the patent referenced in 2.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) <input type="checkbox"/> Yes <input type="checkbox"/> No		
3. Drug Product (Composition/Formulation)		
3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
3.2 Does the patent claim only an intermediate? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
3.3 If the patent referenced in 3.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) <input type="checkbox"/> Yes <input type="checkbox"/> No		
4. Method of Use		
<i>Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:</i>		
4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		

4.2 Patent Claim Number (as listed in the patent) 48	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none">patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI)patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 49	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none">patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI)patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 50	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none">patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI)patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 51	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none">patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI)patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 52	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none">patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI)patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 53	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

<p>4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.</p>	<p>Use: (Submit indication or method of use information as identified specifically in the approved labeling.)</p> <p>EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows:</p> <ul style="list-style-type: none"> • patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI) • patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
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5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. Yes

6. Declaration Certification

6.1 *The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.*

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)	Date Signed
	December 5, 2007

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

<input type="checkbox"/> NDA Applicant/Holder	<input checked="" type="checkbox"/> NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
<input type="checkbox"/> Patent Owner	<input type="checkbox"/> Patent Owner's Attorney, Agent (Representative) or Other Authorized Official
Name Mr. Douglas K. Norman	
Address P. O. Box 6288	City/State Indianapolis, IN
ZIP Code 46206-6288	Telephone Number 317-276-2958
FAX Number (if available) 317-276-3861	E-Mail Address (if available) patents@lilly.com

**PATENT INFORMATION SUBMITTED WITH THE
FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT**

*For Each Patent That Claims a Drug Substance
(Active Ingredient), Drug Product (Formulation and
Composition) and/or Method of Use*

NDA NUMBER

NAME OF APPLICANT / NDA HOLDER
ELI LILLY AND COMPANY

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For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number
6,693,115

b. Issue Date of Patent
02/17/2004

c. Expiration Date of Patent
07/03/2021

d. Name of Patent Owner
Daiichi Sankyo Company, Limited

Address (of Patent Owner)
3-5-1, Nihonbashi Honcho

City/State
Chuo-ku, Tokyo, Japan

ZIP Code
103-8426

FAX Number (if available)
+81-3-5696-8773

Telephone Number
+81-3-5696-8270

E-Mail Address (if available)
N/A

d. Name of Patent Owner

UBE Industries, Ltd.

Address (of Patent Owner)
Seavans North Bldg, 1-2-1, Shibaura

City/State
Minato-Ku, Tokyo, Japan

ZIP Code
105-8449

FAX Number (if available)
+81-3-5419-6237

Telephone Number
+81-3-5419-6112

E-Mail Address (if available)
N/A

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States) General Patent Counsel, Eli Lilly and Company	Address (of agent or representative named in 1.e.) P.O. Box 6288	
	City/State Indianapolis, IN	
	ZIP Code 46206-6288	FAX Number (if available) 317-276-3861
	Telephone Number 317-276-2958	E-Mail Address (if available) patents@lilly.com

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? Yes No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? Yes No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement? Yes No

2.2 Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement? Yes No

2.3 If the answer to question 2.2 is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b). Yes No

2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in 2.3.

2.5 Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.) Yes No

2.6 Does the patent claim only an intermediate? Yes No

2.7 If the patent referenced in 2.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

3. Drug Product (Composition/Formulation)

3.1 Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement? Yes No

3.2 Does the patent claim only an intermediate? Yes No

3.3 If the patent referenced in 3.1 is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.) Yes No

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? Yes No

4.2 Patent Claim Number (as listed in the patent) 8	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none"> patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI) patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
4.2 Patent Claim Number (as listed in the patent) 9	Does the patent claim referenced in 4.2 claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4.2a If the answer to 4.2 is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: (Submit indication or method of use information as identified specifically in the approved labeling.) EFFIENT (prasugrel hydrochloride) is indicated for the reduction of atherothrombotic events (cardiovascular death, nonfatal myocardial infarction, nonfatal stroke) and the reduction of stent thrombosis in acute coronary syndromes (ACS) as follows: <ul style="list-style-type: none"> patients with unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) who are managed with percutaneous coronary intervention (PCI) patients with ST-segment elevation myocardial infarction (STEMI) who are managed with primary or delayed PCI.
5. No Relevant Patents	
For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. <input type="checkbox"/> Yes	
6. Declaration Certification	
<p>6.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.</p> <p>Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.</p>	
6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)	Date Signed December 5, 2007
NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).	

Check applicable box and provide information below.

NDA Applicant/Holder

NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official

Patent Owner

Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name

Mr. Douglas K. Norman

Address

P. O. Box 6288

City/State

Indianapolis, IN

ZIP Code

46206-6288

Telephone Number

317-276-2958

FAX Number (if available)

317-276-3861

E-Mail Address (if available)

patents@lilly.com

The public reporting burden for this collection of information has been estimated to average 9 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDER (HFD-007)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.