EXHIBIT A-3

Invalidity Claim Chart of Lam, alone or in combination with any of Sigg, Boulange, Reuter, Scypinski, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, USP789, Liu, Hioki, DC365, Khan against U.S. Patent No. 9,220,631.

Charted Reference:

PCT Patent Publication No. WO 2008/077155 to Lam *et al.* ("Lam"), in view of Sigg, Boulange, Reuter, Scypin Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, USP789, Liu, Hioki, DC365, Khandke, an obvious claims 1-26 of U.S. Patent No. 9,220,631.

This claim chart is based on Regeneron's current understanding of the asserted claims, and Regeneron's investig Regeneron is not admitting to the accuracy of any particular construction. Regeneron reserves all rights to amend chart in light of any claim construction developments or any amendments to Novartis's infringement contentions contentions, should such developments occur or amendments be allowed. Further, as discovery is ongoing and R seek discovery from third parties regarding the references identified in Regeneron's invalidity contentions as wel prior art, Regeneron reserves the right to revise its invalidity contentions as appropriate in view of any ongoing d

The claim chart below identifies where each limitation of each asserted claim of the 631 Patent can be found in I provided below are exemplary, rather than exhaustive, and Regeneron reserves the right to rely upon any other p references. Where Regeneron identifies a portion of a reference's text, the identification should be understood as corresponding figure or diagram, and vice versa.

Claim Language	Corresponding Disclosure
[1.a-pre] A pre-filled, terminally sterilized syringe for intravitreal injection	Lam discloses a pre-filled, terminally sterilized syringe for intravitreal injectio For example, see the following passages and/or figures, as well as all related d Objects used in medical applications are generally sterilized before use. St be accomplished by a variety of methods including, e.g., steam sterilizatio sterilization, gas sterilization (e.g. with ethylene oxide), and chemical ster However, these treatments cannot be used for objects containing pharmace compositions because their active ingredients are typically sensitive to the steam and gas sterilization are generally performed at high temperatures (a to 55 0 C or higher) that damage certain active ingredients in pharmaceuti compositions. Similarly, the agents used for radiation or chemical steriliza cause chemical damage to the active ingredients. Consequently, pharmace compositions are generally sterilized by an alternative method, e.g. by filtr packaged into separately sterilized objects. Because of the complexity of t difficult to also ensure the sterility of the surfaces of the objects. In many circumstances it would be advantageous to sterilize the surfaces o in order to reduce the risk of contamination during subsequent handling. F there is an increased risk of endophthalmitis after intraocular injection if th syringe used for injection is not sterilized. Thus, there remains a need for e cost-effective methods of surface-sterilizing objects containing ethylene-o temperature-sensitive compounds, such as biological molecules, without a adverse effect on their activity or integrity. **Lam at 1:14-32.** The invention relates to methods for surface-sterilizing objects containing oxide-sensitive, temperature-sensitive compounds, such as biological mol invention is based, in part, on the surprising discovery of ethylene-oxide -h sterilization conditions that will effectively sterilize the surface of an objec

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	not significantly damage ethylene-oxide-sensitive, temperature-sensitive c contained inside. In one aspect, the invention provides a method for surface-sterilizing an ob ethylene-oxide(EtO)-impermeable interior space containing a compound v temperature-sensitive and EtO-sensitive activity by exposing the object to conditions such that the object is surface-sterilized and the compound reta of said activity. In some embodiments, the conditions comprise: a) temper 25 0 C and 35 0 C; b) EtO concentration of between 300 mg/L and 800 mg relative humidity between 45% and 60%; for between 1 and 6 hours. In so embodiments, the conditions comprise: a) temperature between 27 0 C and concentration of between 300 mg/L and 600 mg/L; and c) relative humidit and 52%; for between 1 and 6 hours. In some embodiments, the condition temperature of 3O 0 C; b) EtO concentration of 600 mg/L; and c) relative 50%; for 1, 1.5 or 2 hours. In some embodiments, the compound retains at least 90% of said activity. embodiments, the compound is a polypeptide, e.g. an antibody, which incl monoclonal antibodies, chimeric antibodies, humanized antibodies or hum In some embodiments where the compound is a polypeptide, the percent a polypeptide is not statistically different from a control polypeptide not exp some embodiments, the antibody is an antigen-binding fragment, e.g. a Fa some embodiments, the Fab fragment binds VEGF, e.g. ranibizumab (LUC some embodiments, the compound is present in an aqueous pharmaceutica e.g. a composition comprising at least one of: an amino acid, a disaccharid ionic surfactant. In some embodiments the pharmaceutical composition co histidine, trehalose and polysorbate 20. In some embodiments, the object is a syringe. In some embodiments the sy comprises glass and comprises a stopper comprising D777-7 laminated wi and a tip cap comprising D777-7 laminated with FluroTec® or D21-7H la

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	FluroTec®. In some embodiments, the object is contained within a packag EtO-permeable material, e.g. TYVEK®. **Lam at 2:3-33.** In some embodiments, the pharmaceutical composition is designed for int injection. **Lam at 11:30-31.** The methods of the invention are typically used to sterilize objects contain pharmaceutical formulations. For example, the methods of the invention n syringes, vials or cartridges (such as are used in devices designed for mult In addition, the method of the invention may be used with a syringe with c needle. In the latter case, some sort of cap or needle shield is generally pos the needle will subsequently be attached. The following example is intend illustrate the practice of the present invention and is not provided by way o The disclosures of all patent and scientific literatures cited herein are expr incorporated in their entirety by reference. **Lam at 12:31-13:6.** We performed experiments to identify whether there were parameters for that would effectively sterilize the surface of an object but which do not d ethylene-oxide-sensitive, temperature-sensitive compound contained insid performed EtO sterilization runs on syringes containing a ranibizumab sol protein concentration indicated in Table 2 in a solution with 10 mM histid α - trehalose dehydrate, 0.01% polysorbate 20, pH 5.5) where each run ha standard EtO sterilization steps: (1) set temperature; (2) evacuate chamber HgA; (3) leak test; (4) wash twice with nitrogen; (5) humidify chamber an about 30 min; (6) inject EtO gas and incubate for dwell time; (7) evacuate about 5.0" HgA; and (8) wash four times with nitrogen (each wash cycle i

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	min). In addition to the syringe, each run also included a paper strip with a 1.9 x 10 6 Bacillus subtilis spores, which was used to monitor the steriliza the strip was soaked in media, vortexed vigorously and then serial dilution and grown for one week. We then varied the following sterilization-critica indicated in Table 1 : temperature, relative humidity, time of exposure (ga EtO concentration **Lam at 13:12-26.** We also tested several different syringe components: where the stopper or comprised D777-7 laminated with a 125 µm coating of FluroTec® barrier the tip cap comprised either D777-7 or D21-7H laminated on both the surf with the tip of the syringe and the exterior surface with a 125 µm coating o barrier film (all components from West Pharmaceutical Services / Daikyo measured the residual EtO in the syringe and the stability of ranibizumab l day as the treatment and at various monthly time points thereafter. For IEC the percentage of protein in the main peak and in the acidic and basic peak protein in the basic peak representative of alkylation which may have been EtO treatment. As shown in Table 3, under all conditions tested the percen in the basic peaks was at most approximately 1% over control. Further, wh FluroTec® barrier film was used on the syringe components, the percentag the basic peak was not statistically different from control. **Lam at 15:12-24.**

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