EXHIBIT A-1

**Invalidity Claim Chart of Sigg, alone or in combination with any of Boulange, Lam, Reuter, Scypinski, M
Schoenknecht, Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, USP789
Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier against U.S. Patent No. 9,220,**

Charted Reference:

PCT Patent Publication No. WO 2011/006877 to Sigg *et al.* ("Sigg"), alone or in view of Boulange, Lam, Reuter
Shah, Fries, Schoenknecht, Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, US
DC365, Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier, render obvious claims 1-26 of U.S. Patent N

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 S
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,	Sigg 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 Terminal sterilization of prefilled containers in secondary packaging is on the device to an end user with a low bio-burden and low risk of contamina application of the product by the end user. Moreover there is a strong mar terminally antimicrobially-treated medical devices, such as prefilled syrin intravitreal injections. **Sigg at 2:15-19.** Described herein is a terminal sterilization and surface decontamination tr prefilled containers, specifically for sterilization of prefilled containers co sensitive solutions, such as a drug product or biological therapeutic, withi packaging. In one embodiment, terminal sterilization is achieved by treati containers within secondary packaging with controllable vaporized-hydro (VHP). **Sigg at 3:8-13.** The method and system described herein decontaminate or, more preferab an outside surface of primary packaged drug products within a secondary improving safety of products for critical administration (e.g. use in a surgi intravitreal injections) **Sigg at 4:12-15.** In one embodiment, the prefilled container is a syringe. Other suitable pre include vials, bottles, bags and other medical devices capable of containin solution or a solution requiring sterilization.

Claim Language	Corresponding Disclosure
	In one embodiment, the syringe is filled with a drug product, such as in th solution, powder or solid. In another embodiment the drug product is a sol drug solution or protein solution that is otherwise sensitive to exposure to temperatures, such as those used in steam sterilization, and ionizing energ gamma or beta rays and oxidizing gasses. In yet another embodiment the one that has been lyophilized, in other words a solid, and requires reconsti or solution prior to use. In another embodiment, a solution is any drug product having requirement for sterility of the drug product container surface. In one particular embod product is a protein solution, such as ranibizumab (e.g. 6mg/ml or 10 mg/ intravitreal injection. **Sigg at 9:1-14.** Example 1 In the following experiment, prefilled syringes were treated with a vaporiz peroxide sterilization treatment in a chamber, either by a single pass throu sterilization procedure or two passes (shown in the table below as 2 x) thr sterilization procedure. Syringes containing protein solutions treated by V compared to control syringes treated with VHP to determine if the integrit present in solution was maintained. A formulation as described in U.S. Patent No. 7,060,269 was tested for pr degradation following treatment by VHP. Approximately 10 mL of solution was filtered through a 0.22 µm syringe GV filter available from Millipore, Billerica, MA USA.) Filling of 0.5 mL performed in a sterile lab for hydrogen peroxide treatment.

Claim Language	Corresponding Disclosure
	Analysis after the treatment with VHP revealed the following protein cont by HPLC analysis: byproducts and degradation products by HPLC (IEC) a and degradation products by HPLC (SEC). **Table 1: Protein Stability Following Treatment with VHP** 	Batch	IEC (% main peak)	IEC (% basic peak)	SEC (%
---	---	---	---
Control			
9823.01 CSi	98	2	1
9823.02 CSi	98	2	1
1 x treatment			
9823.04 CSi	98	2	1 | | 9823.05 CSi	98	2	1
2 x treatment			
9823.07	98	2	1
9823.08	98	2	1
				 The results seen were within the requirement; there were no differences be results of the untreated syringes and with hydrogen-peroxide treated syring can also be carried out at different time points following treatment, such a months and six months following treatment by VHP, or over the shelf-life of the prefilled container. Analysis can be carried out to determine continu the protein solution, including tests by HPLC for presence of by-products HPLC laboratory protocols. Analysis can also be carried out by the presen changes, such as measuring the concentration of H2O2 in solution by a flu using an over-the-counter commercially available kit in conjunction with a with fluorescence detection. **Sigg at 20:10-21:11.**

<table>
<tr><th>Claim Language</th><th>Corresponding Disclosure</th></tr>
<tr><td></td><td>To the extent Novartis alleges this limitation is not met by any of the disclosur
would have been obvious in view of Boulange, Lam, Reuter, Scypinski, Metzn
Schoenknecht, Chacornac, Nema, D’Souza, Furfine, Badkar, Macugen, Eylea,
USP789, Liu, Hioki, DC365, Hagen, Khandke, Wittland, Shams, Dixon, and/o
Exhibits A-2–A-13, B-1–B-3 and all references cited therein.</td></tr>
<tr><td>[1.b] the syringe comprising a glass body forming a barrel, a stopper and a plunger</td><td>Sigg discloses the syringe comprising a glass body forming a barrel, a stopper

For example, see the following passages and/or figures, as well as all related d

Further, sterilizing doses of gamma rays cause a brown discoloration of gl
device, and is prone to damage elastomeric materials like plunger stoppers
destruction of the elastomers leads to increased stickiness of the componer
impairing the functionality of the system. Thus radiation is not an appropr
sterilizing prefilled containers, such as syringes, containing a biotech drug

Sigg at 2:1-6.

Additionally, the oxidative stress exerted on a 0.5% Polysorbate 20 soluti
glass syringes (1 mL long, ISO) was investigated by measurement of pero
to standard protocols. The total amount of peroxides was measured by the
Oxidation (FOX) test, according to a standard protocol.

Table 3: Peroxide Levels Following Beta Irradiation of Prefilled Cont
<table>
<tr><td>Number of passes through E-beam tunnel</td><td>Peroxide content of 0.5% Polysorbate 20 s
in water in 1mL long glass syringe (ISO) [µ</td></tr>
<tr><td>Reference (not treated)</td><td>0.04</td></tr>
<tr><td>1 pass</td><td>0.04</td></tr>
<tr><td>3 passes</td><td>0.03</td></tr>
<tr><td>5 passes</td><td>0.05</td></tr>
</table>
</td></tr>
</table>

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.