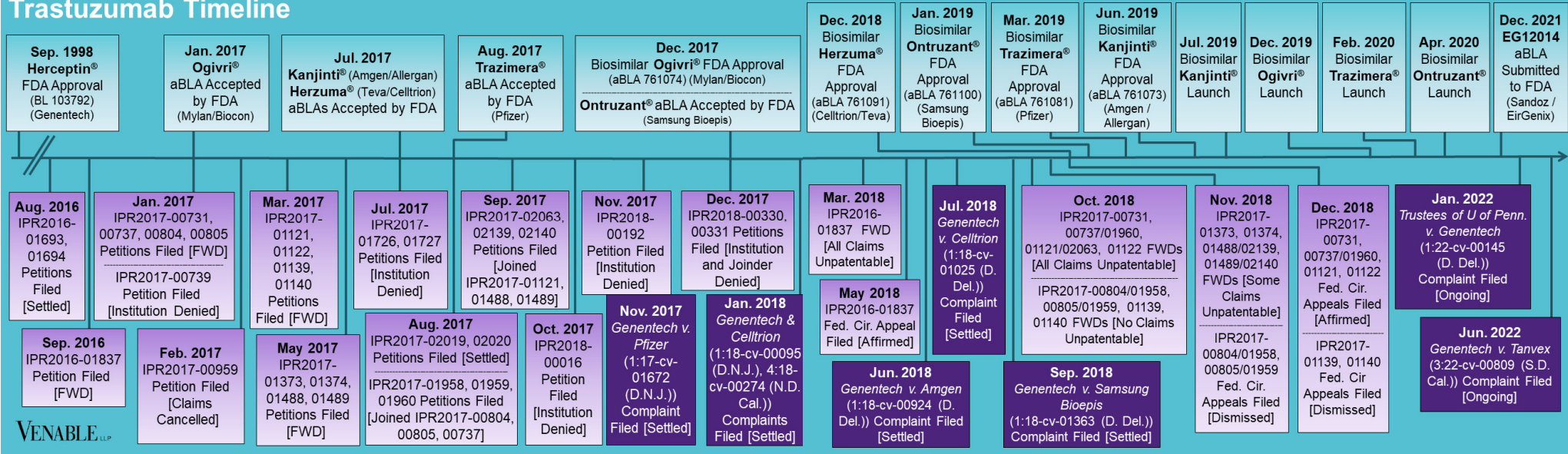
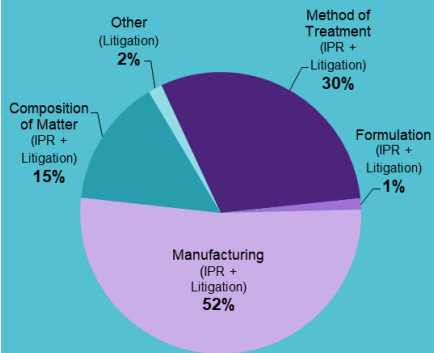


## Trastuzumab Timeline



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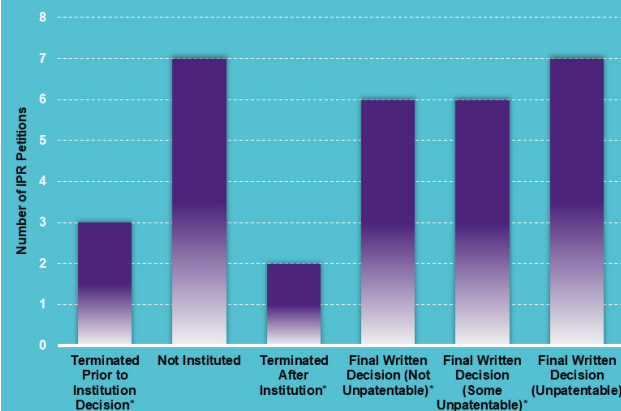
### Trastuzumab Challenged Claim Types in IPR and Litigation\*



\*In litigations, it has been alleged that at least these claims will be infringed or are invalid.

VENABLE LLP

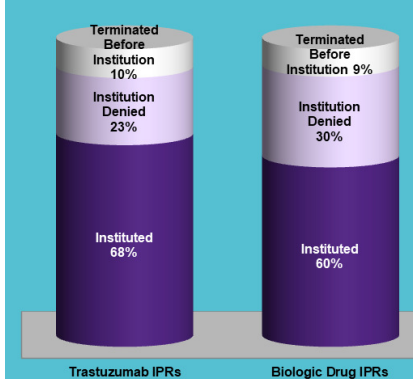
### Trastuzumab IPR Status



\*Joinder counted as separate decisions

VENABLE LLP

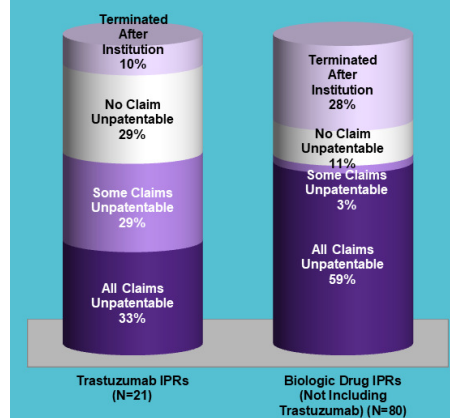
### IPR Institution Rates\*



\*Joinder counted as separate decisions

VENABLE LLP

### Outcomes After Institution\*



\*Joinder counted as separate decisions

VENABLE LLP

FWD = Final Written Decision

# Spotlight On: Trastuzumab

December 31, 2022

**Technology:** Trastuzumab is a humanized monoclonal antibody that targets the HER2/neu receptor, which is overexpressed in some types of cancer. The HER2 pathway is involved in cell growth and division.

|           | <i>Genentech v. Pfizer</i><br>1:17-cv-01672 (D. Del.)<br>Settled<br>Cont'd below | <i>Celltrion v. Genentech</i><br>4:18-cv-00274 (N.D. Cal.)<br>Dismissed;<br>Fed. Cir. 18-2160<br>Dismissed<br>Cont'd below | <i>Genentech v. Celltrion</i><br>1:18-cv-00095 (D. Del.)<br>Settled<br>Cont'd below | <i>Genentech v. Amgen</i><br>1:18-cv-00924 (D. Del.)<br>Settled;<br>Fed. Cir. 19-2156<br>TRO/PI<br>Denied<br>Cont'd below | <i>Genentech v. Celltrion</i><br>1:18-cv-01025 (D. Del.)<br>Settled<br>Cont'd below | <i>Genentech v. Samsung Bioepis</i><br>1:18-cv-01363 (D. Del.)<br>Settled<br>Cont'd below | <i>Pfizer v. Genentech</i><br>IPR2017-02019<br>Settled after institution;<br>IPR2018-00330<br>Institution and joinder denied                                   | <i>Celltrion v. Genentech</i><br>IPR2017-01373<br>IPR2017-01374<br>FWD- Some claims unpatentable               | <i>Pfizer &amp; Samsung Bioepis v. Genentech</i><br>IPR2017-01488<br>IPR2017-02139<br>(joined)<br>FWD- Some claims unpatentable                       | <i>Pfizer &amp; Samsung Bioepis v. Genentech</i><br>IPR2017-01489<br>IPR2017-02140<br>(joined)<br>FWD- Some claims unpatentable   | <i>Pfizer &amp; Samsung Bioepis v. Genentech</i><br>IPR2017-00804<br>IPR2017-01958<br>(joined)<br>FWD- No claims unpatentable,<br>Fed. Cir. 19-1174<br>Settled | <i>Celltrion v. Genentech</i><br>IPR2017-01139<br>FWD- No claims unpatentable,<br>Fed. Cir. 19-1258<br>Settled | <i>Hospira v. Genentech</i><br>IPR2016-01837<br>FWD- All claims unpatentable,<br>Fed. Cir. 18-1933<br>Affirmed (US as Intervenor,<br>Hospira settled) |
|-----------|--|--|---|---|---|---|--|--|---|---|--|--|---|
| 6,121,428 | x  |  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 6,242,177 | x  |  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 6,331,415 | x  | x  | x   | x   | x   | x   |  |  |   |   |  |  |   |
| 6,339,142 | x  | x  | x   |   | x   | x   | x  |  |   |   |  |  |   |
| 6,407,213 | x  | x  | x   | x   | x   | x   |  | x  | x   | x   |  |  |   |
| 6,417,335 | x  | x  | x   | x   | x   | x   |  |  |   |   |  |  |   |
| 6,489,447 | x  | x  | x   | x   | x   |   | <i>Pfizer &amp; Samsung Bioepis v. Genentech</i><br>IPR2017-00805<br>IPR2017-01959<br>(joined)<br>FWD- No claims unpatentable,<br>Fed. Cir. 19-1173<br>Settled | <i>Celltrion v. Genentech</i><br>IPR2017-01140<br>FWD- No claims unpatentable,<br>Fed. Cir. 19-1259<br>Settled | <i>Hospira v. Genentech</i><br>IPR2017-00731<br>FWD- All claims unpatentable,<br>Fed. Cir. 19-1263<br>Affirmed (US as Intervenor,<br>Hospira settled) | <i>Celltrion &amp; Pfizer v. Genentech</i><br>IPR2017-01121<br>IPR2017-02063<br>(joined)<br>FWD- All claims unpatentable,<br>Fed. Cir. 19-1267<br>Affirmed (US as Intervenor,<br>Other parties settled) |  |  |   |
| 6,586,206 | x  | x  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 6,610,516 | x  | x  | x   |   | x   | x   |  |  |   |   |  |  |   |
| 6,620,918 | x  | x  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 6,627,196 | x  | x  | x   | x   | x   | x   |  |  |   |   | x  | x  |   |
| 6,716,602 | x  | x  | x   |   | x   |   |  |  |   |   |  |  |   |
| 6,870,034 |  |  |   | x   |   |   |  |  |   |   | <i>Pfizer v. Genentech</i><br>IPR2018-00016<br>Institution denied  | <i>Samsung Bioepis v. Genentech</i><br>IPR2018-00192<br>Institution denied                                     | <i>Trustees of U of Penn. v. Genentech</i><br>1:22-cv-00145 (D. Del.)<br>Ongoing  |
| 7,371,379 | x  | x  | x   | x   | x   | x   | x  | x  |   |   |  |  |   |
| 7,390,660 | x  | x  | x   |   | x   | x   |  |  |   |   |  |  |   |
| 7,449,184 | x  | x  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 7,485,704 | x  | x  | x   |   | x   | x   |  |  |   |   |  |  |   |
| 7,501,122 | x  | x  | x   | x   | x   |   |  |  |   |   |  |  |   |
| 7,625,558 |  |  |   |   |   |   |  |  |   |   |  |  | x   |
| 7,807,799 | x  | x  | x   |   | x   | x   |  |  |   |   |  |  |   |
| 7,846,441 | x  | x  | x   | x   | x   | x   |  |  | x   | x   | x  | x  |   |

FWD = Final Written Decision

Spotlight On:  
Trastuzumab

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|            | <i>Genentech v. Pfizer</i><br>1:17-cv-01672<br>(D. Del.)<br><br>Cont'd from above | <i>Celltrion v. Genentech</i><br>4:18-cv-00274<br>(N.D. Cal.)<br><br>Cont'd from above | <i>Genentech v. Celltrion</i><br>1:18-cv-00095<br>(D. Del.)<br><br>Cont'd from above | <i>Genentech v. Amgen</i><br>1:18-cv-00924<br>(D. Del.)<br><br>Cont'd from above | <i>Genentech v. Celltrion</i><br>1:18-cv-01025<br>(D. Del.)<br><br>Cont'd from above | <i>Genentech v. Samsung Bioepis</i><br>1:18-cv-01363<br>(D. Del.)<br><br>Cont'd from above | <i>Genentech v. Tanvex</i><br>3:22-cv-00809<br>(S.D. Cal.)<br>Ongoing | <i>Pfizer &amp; Samsung Bioepis v. Genentech</i><br>IPR2017-00737<br>IPR2017-01960 (joined)<br>FWD- All claims unpatentable,<br>Fed. Cir. 19-1265 Affirmed (US as<br>Intervenor, Other parties settled) | <i>Pfizer v. Genentech</i><br>IPR2017-00739<br>Institution denied  | <i>Celltrion v. Genentech</i><br>IPR2017-01122<br>FWD- All claims unpatentable, Fed. Cir.<br>19-1270 Affirmed (US as<br>Intervenor, Celltrion settled) |
|------------|---|--|--|--|--|--|---|---|--|--|
| 7,892,549  | x   | x  | x  | x  | x  | x  |   | x   | x  | x  |
| 7,923,221  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 7,993,834  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 8,044,017  | x   |  |  | x  |  |  |   |   |  |  |
| 8,076,066  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 8,314,225  | x   |  |  | x  |  |  |   |   |  |  |
| 8,357,301  |   | x  | x  | x  | x  |  |   |   |  |  |
| 8,425,908  | x   | x  | x  | x  | x  | x  |   | <i>Pfizer v. Genentech</i><br>IPR2017-02020<br>Settled after institution;<br>IPR2018-00331 Institution and<br>joinder denied  | <i>Celltrion v. Genentech</i><br>IPR2017-00959<br>Terminated<br>before institution<br>(claims cancelled) | <i>Pfizer v. Genentech</i><br>IPR2017-01726<br>IPR2017-01727<br>Institution denied<br>(claims previously cancelled)                                    |
| 8,440,402  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 8,460,895  | x   | x  | x  | x  | x  |  |   |   |  |  |
| 8,512,983  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 8,574,869  | x   | x  | x  | x  | x  | x  | x   |   |  |  |
| 8,591,897  |   |  |  |  |  |  |   | x   | x  |  |
| 8,633,302  | x   | x  | x  |  | x  |  |   |   |  |  |
| 8,691,232  | x   | x  | x  | x  | x  |  |   |   |  |  |
| 8,710,196  | x   |  |  | x  |  |  |   |   |  |  |
| 8,771,988  | x   | x  | x  | x  | x  |  |   |   |  |  |
| 8,822,655  | x   | x  | x  |  | x  |  |   |   |  |  |
| 9,047,438  |   | x  | x  | x  | x  |  |   |   |  |  |
| 9,080,183  |   | x  | x  | x  | x  |  |   |   |  |  |
| 9,249,218  | x   | x  | x  | x  | x  | x  |   | x   |  |  |
| 9,428,548  |   | x  | x  |  | x  |  |   |   |  |  |
| 9,428,766  | x   | x  | x  | x  | x  |  |   |   |  |  |
| 9,487,809  | x   | x  | x  | x  | x  |  |   |   |  |  |
| 9,493,744  | x   |  |  | x  |  |  |   |   |  |  |
| 9,714,293  | x   | x  | x  | x  | x  | x  |   |   |  |  |
| 9,868,760  |   |  |  | x  |  |  |   |   |  |  |
| 10,160,811 |   |  |  | x  |  |  |   |   |  |  |
| 10,662,237 |   |  |  |  |  |  | x   |   |  |  |
| 10,808,037 |   |  |  |  |  |  | x   |   |  |  |