EDITION NO. 3A

NEW SURVEY

POST GRANT HQ® PHARMA REPORTER

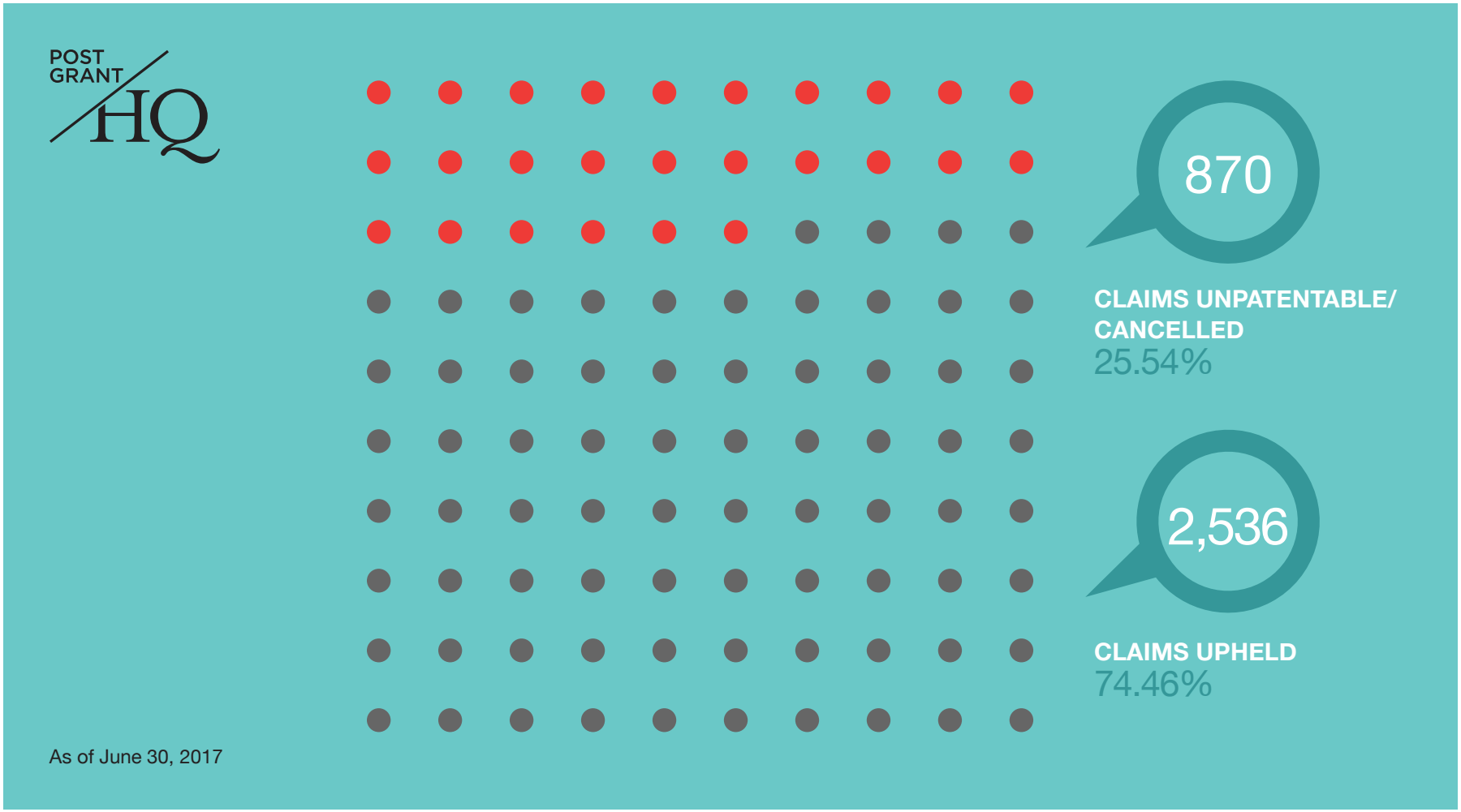
2017 ANALYSIS ON INTER PARTES REVIEW OF PHARMACEUTICAL PATENTS

INTRODUCTION

Fitzpatrick, Cella, Harper & Scinto undertook this Report on Patent Trial and Appeal Board (PTAB) Contested Proceedings to provide objective information on the results of Inter Partes Review (IPR) proceedings on pharmaceutical patents. The analysis is based on a review of all final written decisions issued through June 2017 and all decisions denying institution issued through June 2016. Because final written decisions issue about one year after institution decisions, we did not include decisions denying institution after June 2016 to avoid improper skewing.

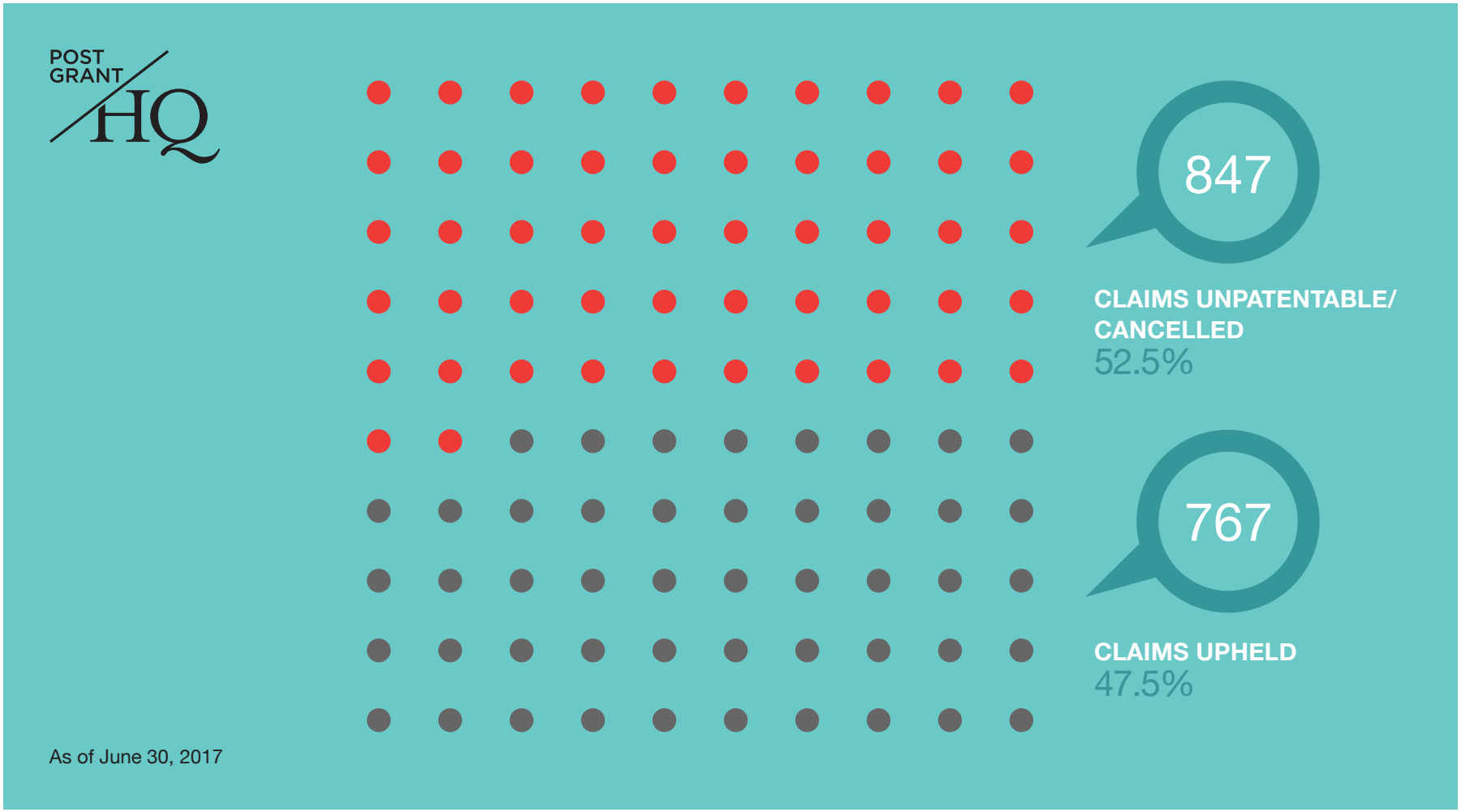
This report provides perspective on the effects of IPRs in pharmaceutical patents based on a rigorous methodology. We believe this report provides valuable insights regarding both the usefulness of these proceedings to challengers and effective lines of defense for patent owners.

PHARMA IPR: SURVIVAL RATE OF CHALLENGED CLAIMS



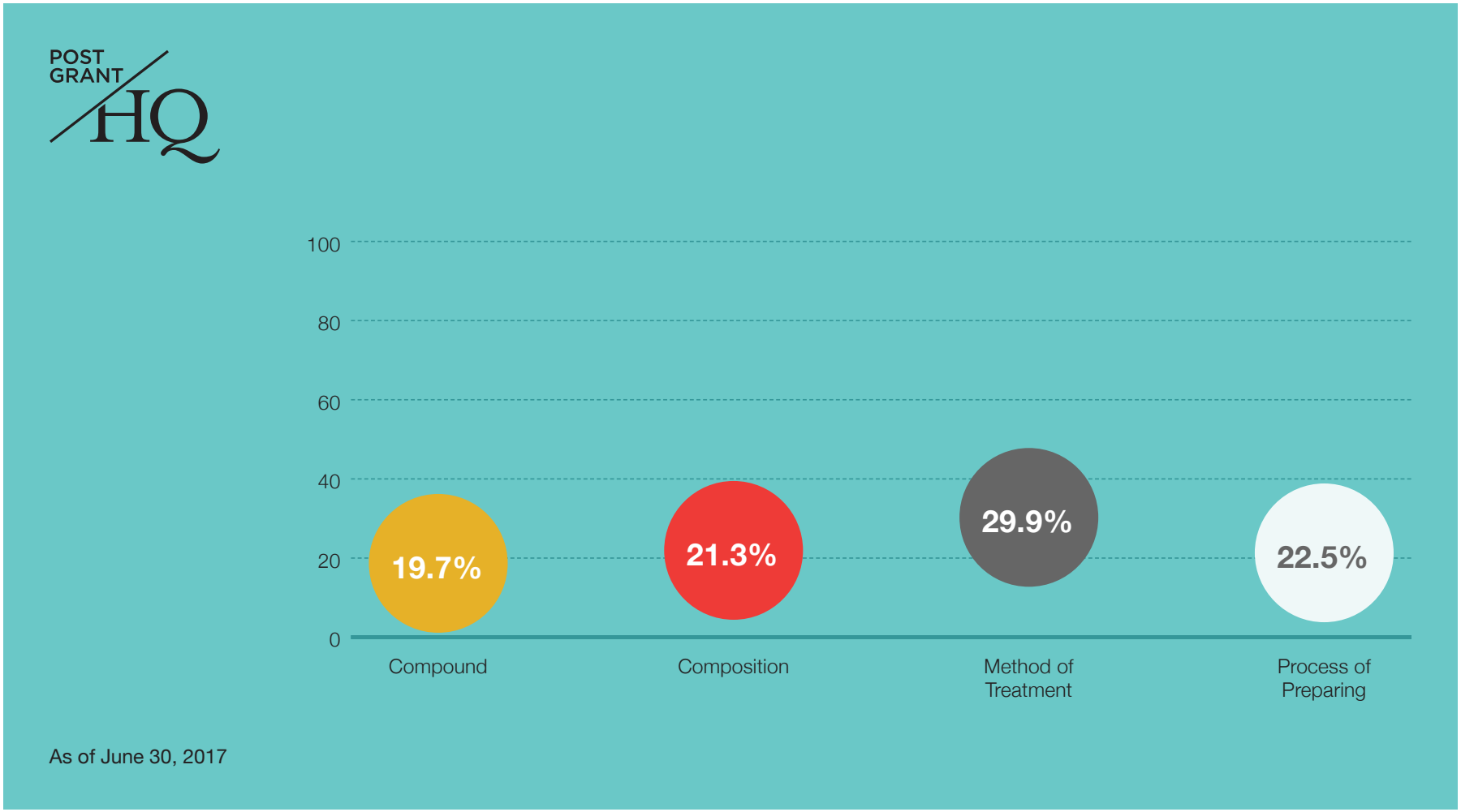
Key Finding: In pharmaceutical cases that reached final written decisions or were substantively denied institution, about 26% of claims that were originally *challenged* in the IPR petitions were cancelled or found unpatentable. This rate is about half that for overall IPR proceedings (about 54%). This statistic accounts for challenged claims that were denied institution for substantive reasons, as opposed to procedural reasons. This analysis does not factor in challenges that did not reach a decision on the merits because of settlement, or redundancies (which were deemed immaterial).

PHARMA IPR: SURVIVAL RATE OF INSTITUTED CLAIMS



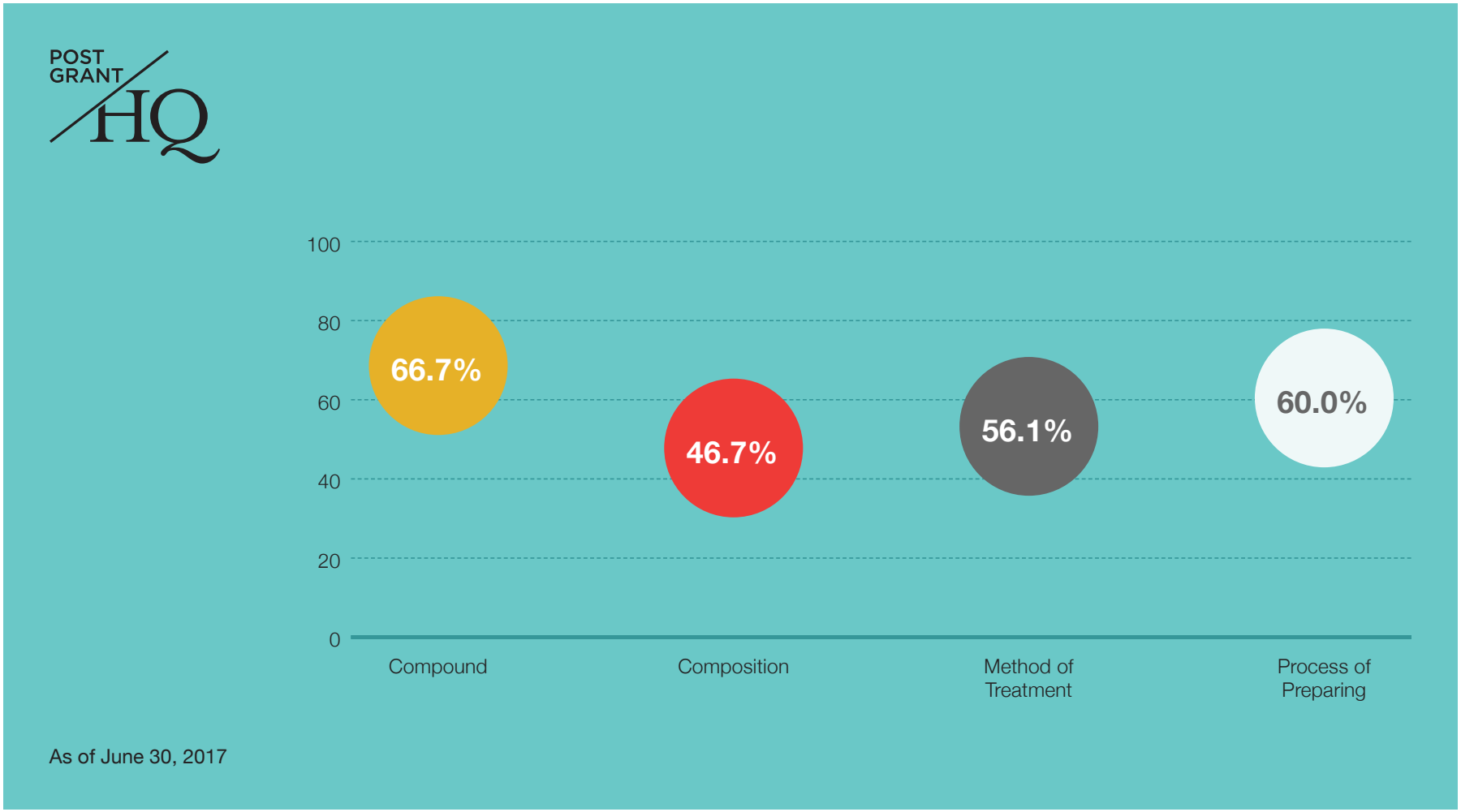
Key Finding: This chart shows the survival rate of *instituted* claims in pharmaceutical IPR proceedings that reached a final written decision. While survival rate drops by roughly half compared to pre-institution pharmaceutical cases, the post-institution survival rate shown here (about 48%) is significantly higher than the overall post-institution survival rate for IPR proceedings across all technology areas (about 19%). This analysis does not factor in challenges that did not reach a decision on the merits because of settlement, or redundancies (which were deemed immaterial).

PHARMA IPR: BREAKDOWN BY CLAIM TYPE & UNPATENTABILITY RATE OF CHALLENGED CLAIMS



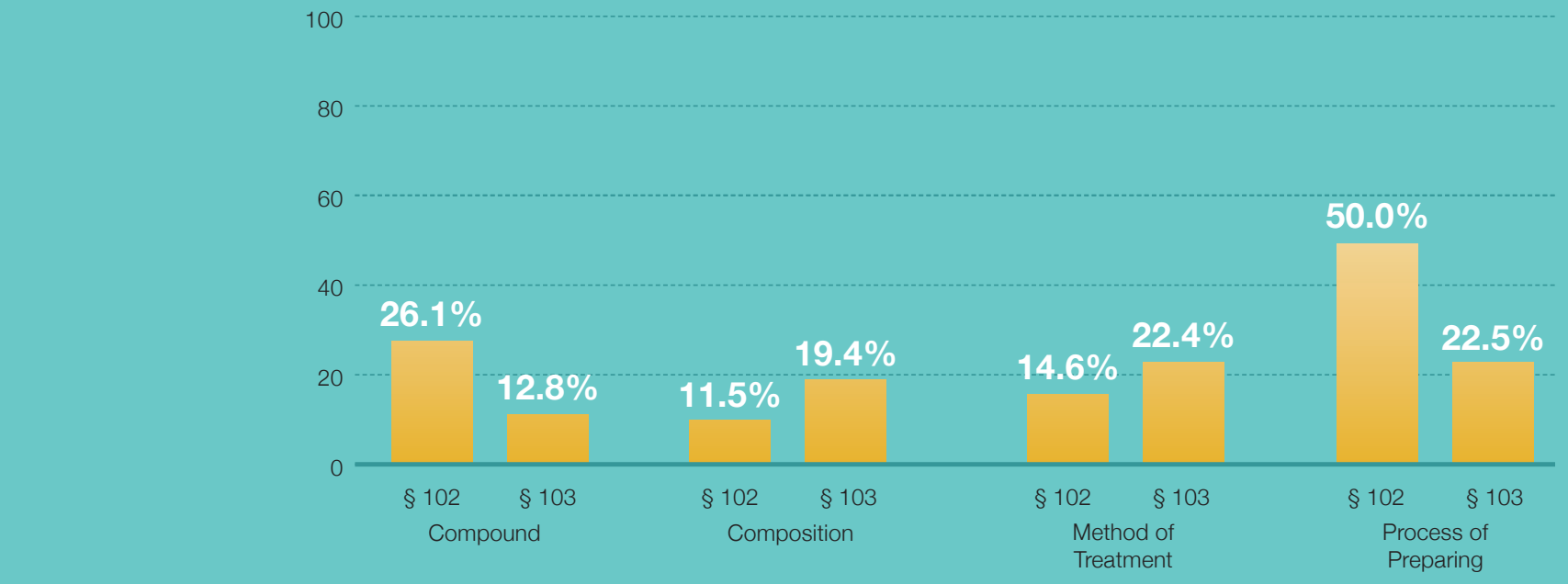
Key Finding: Pharmaceutical claims may be generally categorized into four groups: compound, composition (which includes formulation), method of treatment, and process of preparing. This chart evaluates rates of unpatentability/cancellation for each group relative to claims originally *challenged* in petitions. While still a small sample size (particularly for compound and process-of-preparing claims), the relative success rates reflect conventional wisdom – compound claims fare best, with composition claims not far behind and method of treatment claims trailing more significantly. These statistics do not account for redundancies (which were deemed immaterial). The claims were categorized based on the class as claimed, rather than attempting to determine a likely key feature recited (e.g., whether a particular composition was recited in a claimed method of treatment).

PHARMA IPR: BREAKDOWN BY CLAIM TYPE & UNPATENTABILITY RATE OF INSTITUTED CLAIMS



Key Finding: This chart also categorizes pharmaceutical claims into four groups: compound, composition (which includes formulation), method of treatment, and process of preparing. However, this chart evaluates unpatentability/cancellation rates relative to claims *instituted*. Interestingly, unlike the results for claims challenged, compound claims fare worst post institution. Again, note that the sample size for compound claims is still small (142 claims). These statistics do not account for redundancies (which were deemed immaterial). Again, the claims were categorized based on the class as claimed, rather than attempting to determine a likely key claim feature in the body of the claim.

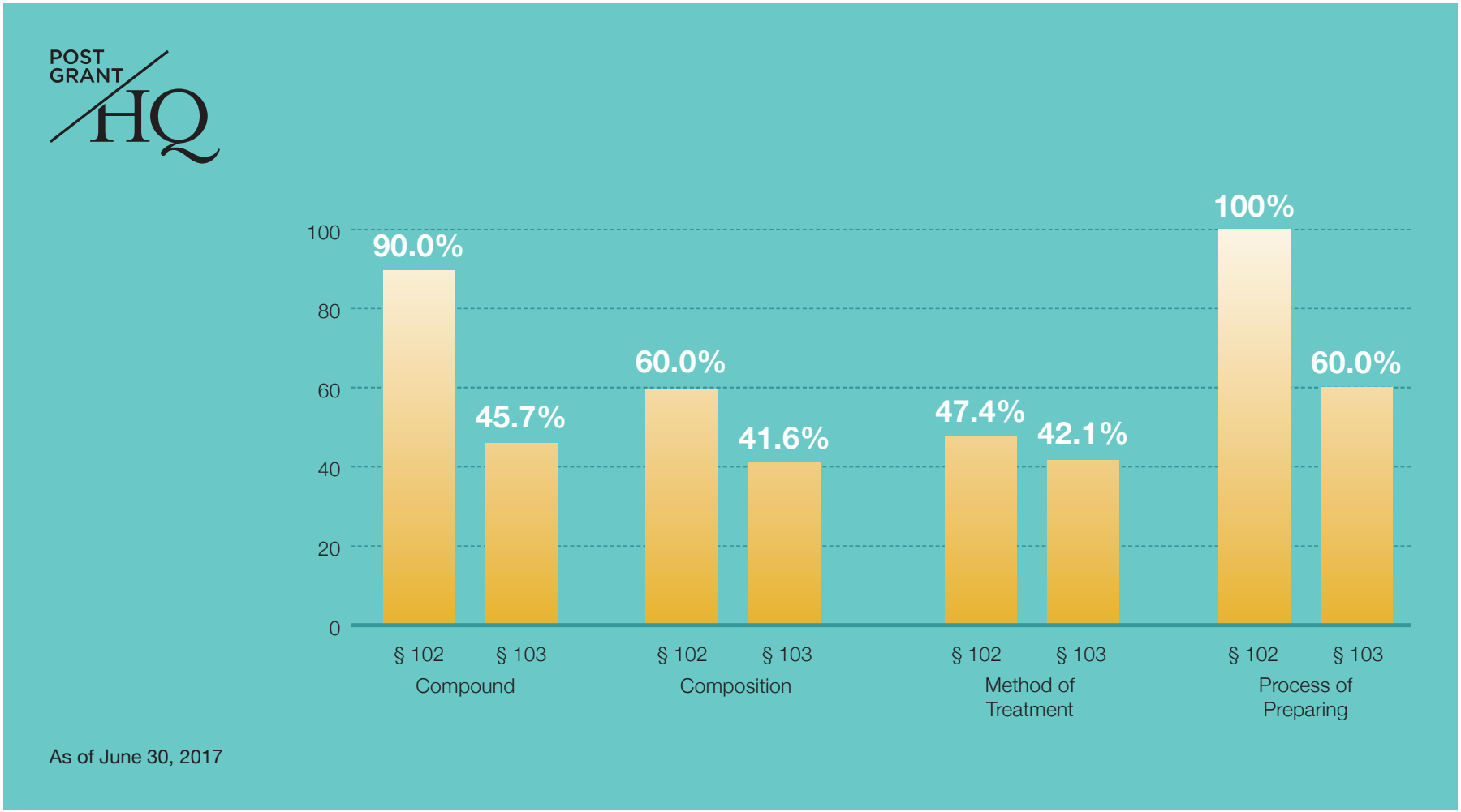
PHARMA IPR: BREAKDOWN BY CLAIM AND CHALLENGE TYPES AND UNPATENTABILITY RATE OF CHALLENGED CLAIMS



As of June 30, 2017

Key Finding: This chart presents the percentage of claims found unpatentable under Sections 102 and 103 for the different categories of pharmaceutical claims, out of the claims originally *challenged*. Compound claims were found unpatentable more often under Section 102. However, for composition claims, the opposite held true. The low level of success for obviousness attacks against compound claims may be a reason for the overall low success rate of challenges against those claims.

PHARMA IPR: BREAKDOWN BY CLAIM AND CHALLENGE TYPES AND UNPATENTABILITY RATE OF INSTITUTED CLAIMS



Key Finding: This chart presents the percentage of claims found unpatentable under Sections 102 and 103 for the different categories of pharmaceutical claims, out of the claims for which trial was *instituted*. Interestingly, after the PTAB makes the initial determination to move forward with trial, the likelihood of compound claims being found unpatentable under either Section 102 or 103 rises more dramatically than in other claim categories. As can be seen, an initial determination that a compound claim is unpatentable under Section 102 is unlikely to change with the final written decision. Composition claims fare better than compound claims post-institution. Process-of-preparing claims see high rates of unpatentability across the board, which may relate to the very small sample size for that category (80 claims).

ABOUT US

At Fitzpatrick, IP is not just a practice area—it is our sole focus. We cover the spectrum of intellectual property services for clients from virtually every industry. Our offices in New York, NY, Washington, D.C. and Costa Mesa, CA, serve a diverse national and international clientele from Fortune 500 companies to Internet start-ups. Founded in 1971, we have continually kept pace with the complex world of new technologies and the strategies required for protecting knowledge, vision and ideas. We have one of the premier patent litigation practices and consistently appear in the list of top patent prosecution firms. We have decades of experience in complex proceedings before the PTAB—the foundation for IPRs, PGRs, and CBMs. Since the inception of these AIA review proceedings, we have shepherded clients to victory before the PTAB in cases spanning a broad spectrum of technologies.

OUR METHODOLOGY

Our analysis for this report considers all of the final written decisions issued by the PTAB for pharma IPR proceedings through June 2017 and all decisions denying institution through June 2016. A few things to note:

1. In gathering statistics, we evaluated only the original claims in the patents at issue. We did not account for amended claims that were subsequently allowed by the PTAB. The number of cases in which motions to amend were granted is quite small.
2. For cases in which the patent owner requested adverse judgment against itself, we considered the claims to be cancelled.
3. For the charts that show the percentage of claims in IPR proceedings found unpatentable under Sections 102 and 103, please note that, in some instances, the PTAB found claims unpatentable based on both grounds.
4. We did not include in our analysis petitions that did not reach either a final written decision or decision denying institution (*e.g.,* settlements).
5. We analyzed substantive decisions not to institute. We did not include in our analysis denials that were procedural in nature (*e.g.,* time barred petitions).
6. Although care has been taken to ensure the data's accuracy, these statistics should be viewed as estimates.

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