# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

, Individually and On Behalf of All Others Similarly Situated,	) ) ) Case No.
Plaintiff,	)
v.	) CLASS ACTION COMPLAINT
INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI and SANDIP S. KAPADIA,	) JURY TRIAL DEMANDED ) )
Defendants.	) _)

# **CLASS ACTION COMPLAINT**

Plaintiff \_\_\_\_\_\_\_\_, individually and on behalf of all other personssimilarly situated, by her undersigned attorneys, for her complaint against Defendants, alleges the following based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through her attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

## NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Intercept securities between May 31,

2016 and September 20, 2017, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

- 2. Intercept Pharmaceuticals, Inc. manufactures and markets biopharmaceutical products. The Company focuses on the development and commercialization of therapeutics to treat chronic liver diseases utilizing proprietary bile acid chemistry.
- 3. Founded in 2002, the Company is headquartered in New York, New York. Intercept's stock trades on the NASDAQ stock market under the ticker symbol "ICPT."
- 4. The Company's lead product candidate, Ocaliva (obeticholic acid, or OCA), is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid, that selectively binds to and activates the farnesoid X receptor, or FXR.
- 5. On May 31, 2016, Intercept announced that the U.S. Food and Drug Administration ("FDA") had approved Ocaliva for the treatment of patients with primary biliary cholangitis ("PBC").
- 6. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Ocaliva entailed undisclosed safety risks, including death, to patients suffering from PBC; and (ii) as a result of the foregoing, Intercept's public statements were materially false and misleading at all relevant times.

- 7. On September 12, 2017, Intercept issued a letter warning physicians against overdosing patients with Ocaliva, advising them that the drug has been tied to liver injuries and death among patients suffering from PBC.
- 8. On this news, Intercept's share price fell \$15.36, or 13.53%, to close at \$98.12 on September 12, 2017.
- 9. On September 21, 2017, the U.S. Food and Drug Administration ("FDA") issued a safety announcement entitled "FDA Drug Safety Communication: FDA warns about serious liver injury with Ocaliva for rare chronic liver disease," warning doctors after reports of multiple deaths linked to the drug. In the safety announcement, the FDA stated in relevant part:

[09-21-2017] The Food and Drug Administration (FDA) is warning that the liver disease medicine Ocaliva is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. *Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose*. The recommended dosing and monitoring for patients on Ocaliva are described in the current drug label. We are working with the drug manufacturer, Intercept Pharmaceuticals, to address these safety concerns.

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In the 13 months after Ocaliva was approved in May 2016, FDA received reports of serious liver injury or death associated with Ocaliva.\* The FDA's Adverse Event Reporting System (FAERS) includes only reports submitted to FDA, so there may be additional cases about which we are unaware.

Nineteen cases of death were identified, of which eight provided information about the patient's cause of death. The cause of death was reported to be worsening of PBC disease in seven cases, with cardiovascular disease cited in the other case. Seven of these eight cases described patients with moderate to severe decreased liver function who received Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly as recommended in the label prescribing information for patients with this extent of decreased liver function.

FDA also identified 11 cases of serious liver injury with Ocaliva use. Six of the patients who had moderate or severe decreases in liver function at baseline and developed serious liver injury were receiving Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly as recommended by FDA in the drug label.

Three of these six patients died, which were included in the 19 death cases mentioned previously. Ocaliva was discontinued in four of six cases, which resulted in one patient experiencing symptom resolution and an improvement in a liver blood test. The remaining three cases did not report the response after discontinuation. The other five cases of serious liver injury were reported in patients with no or mild decreases in liver function prior to initiating Ocaliva. Four of these five patients received Ocaliva 5 mg daily, and one did not report the dose. Ocaliva was discontinued in all five cases, which resulted in one patient experiencing symptom resolution and one patient experiencing improved liver blood tests and symptom resolution. The remaining three cases did not report the response after discontinuation.

(Emphases added.)

- 10. On this news, Intercept's share price fell \$24.42, or 24.88%, to close at \$73.70 on September 21, 2017.
- 11. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

#### **JURISDICTION AND VENUE**

- 12. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).
- 13. This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. §§ 1331 and Section 27 of the Exchange Act.
- 14. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). Intercept's principal executive offices are located within this Judicial District.
- 15. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

#### **PARTIES**

- 16. Plaintiff, as set forth in the attached Certification, acquired Intercept securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.
- 17. Defendant Intercept is incorporated in Delaware, with principal executive offices located at 450 W 15<sup>th</sup> Street, Suite 505, New York, New York 10011. Intercept's shares trade on the NASDAQ under the ticker symbol "ICPT."
- 18. Defendant Mark Pruzanski ("Pruzanski") founded and has served at all relevant times as the Company's Chief Executive Officer ("CEO"), President and Director.
- 19. Defendant Sandip Kapadia ("Kapadia") has served at all relevant times as the Company's Chief Financial Officer ("CFO").
- 20. The Defendants referenced above in ¶¶ 18-19 are sometimes referred to herein as the "Individual Defendants."

## **SUBSTANTIVE ALLEGATIONS**

#### **Background**

- 21. Intercept manufactures and markets biopharmaceutical products. The Company focuses on the development and commercialization of therapeutics to treat chronic liver diseases utilizing proprietary bile acid chemistry.
- 22. The Company's lead product candidate, Ocaliva, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid, that selectively binds to and activates the farnesoid X receptor, or FXR.

# Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on May 31, 2016, when Intercept issued a press release, also attached as Exhibit 99.1 to a Current Report on Form 8-K filed with the SEC, announcing FDA approval of Ocaliva for the treatment of patients with PBC (the "May 2016 Press Release"). The Company made material misrepresentations in the press release, including, in pertinent part:

# FDA Grants Accelerated Approval to Ocaliva<sup>TM</sup> (Obeticholic Acid) for the Treatment of Patients with PBC

First new medicine for PBC in nearly 20 years

Investor conference call Tuesday May 31 at 8:30 a.m. ET

NEW YORK, NY, May 27, 2016 – Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to Ocaliva for the treatment of primary biliary cholangitis, previously known as primary biliary cirrhosis (PBC), in combination with ursodeoxycholic (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. Ocaliva is an agonist of the farnesoid X receptor (FXR), a nuclear receptor expressed in the liver and intestine and a key regulator of bile acid, inflammatory, fibrotic and metabolic pathways.

"Intercept was founded on the belief that targeting FXR would benefit patients with liver diseases for which there are limited or no treatment options, and Ocaliva's approval marks the culmination of more than a decade of work," said Mark Pruzanski, M.D., Chief Executive Officer and President of Intercept. "We are very pleased that the FDA has approved Ocaliva for PBC and would like to thank all the patients and investigators around the world who participated in our clinical trials to make this possible."

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

"Ocaliva fills an important unmet need for the many patients with PBC who have an inadequate response to or are intolerant of UDCA, which until now has been the only approved treatment," said John Vierling, M.D., F.A.C.P., F.A.A.S.L.D., Professor of Medicine and Surgery at Baylor College of Medicine and Past President of the American Association for the Study of Liver Diseases (AASLD).

"Ocaliva has demonstrated a clinically meaningful improvement in lowering ALP, a liver enzyme and biomarker that is used to track disease progression in patients with PBC. Importantly, Ocaliva maintained durable ALP reductions, which is critical for treatment of a chronic disease like PBC."

In Intercept's Phase 3 POISE trial, Ocaliva administration in combination with UDCA (or as monotherapy in UDCA-intolerant patients) met the primary composite endpoint in 46% of patients in the titration group, as compared to 10% of those receiving placebo added to UDCA (p<0.0001). Pruritus (itching), a common symptom of PBC that is unrelated to disease stage or outcomes, was the most common side effect observed in Ocaliva-treated patients. However, pruritus associated with Ocaliva treatment was generally less in patients who were on the dose titration regimen (5 mg once-daily increasing to 10 mg once-daily); one patient (1%) in the titration group discontinued from the study due to pruritus. Additional side effects observed during the trial included fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality and eczema.

- 24. On August 9, 2016, Intercept filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2016 (the "Q2 2016 10-Q"). For the quarter, the Company reported a net loss of \$77.30 million, or \$3.14 per diluted share, on revenue of \$5.52 million, compared to a net loss of \$47.89 million, or \$1.99 per diluted share, on revenue of \$450,000 for the same period in the prior year.
- 25. The Q2 2016 10-Q contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, stating that the financial information contained in the Q2 2016 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 26. On November 9, 2016, Intercept filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended September 30, 2016 (the "Q3 2016 10-Q"). For the quarter, the Company reported a net loss of \$88.82 million, or \$3.59 per diluted share, on revenue of \$5.18 million.
- 27. The Q3 2016 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q3 2016 10-Q was

accurate and disclosed any material changes to the Company's internal control over financial reporting.

28. On March 1, 2017, Intercept filed an annual report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and fiscal year ended December 31, 2016 (the "2016 10-K"). For the quarter, the Company reported a net loss of \$120.04 million, or \$4.84 per diluted share, on revenue of \$13.81 million, compared to a net loss of \$88.25 million, or \$3.62 per diluted share, on revenue of \$450,000 for the same period in the prior year. For 2016, the Company reported a net loss of \$412.83 million, or \$16.74 per diluted share, on revenue of \$24.95 million, compared to a net loss of \$226.43 million, or \$9.56 per diluted share, on revenue of \$2.78 million for 2015.

## 29. In the 2016 10-K, the Company stated, in relevant part:

Our lead product candidate, obeticholic acid, or OCA, is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid, that selectively binds to and activates the farnesoid X receptor, or FXR. We believe OCA has broad liver-protective properties and may effectively counter a variety of chronic insults to the liver that cause fibrosis, or scarring, which can eventually lead to cirrhosis, liver transplant and death.

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OCA achieved the primary endpoint in a Phase 2b clinical trial for the treatment of NASH, known as the FLINT trial, which was sponsored by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, a part of the National Institutes of Health. The FLINT trial was completed in late July 2014. We have an ongoing Phase 3 clinical trial in non-cirrhotic NASH patients with liver fibrosis, known as the REGENERATE trial. REGENERATE includes a preplanned histology-based interim analysis after 72 weeks of treatment. We are targeting completion of enrollment of the cohort of patients needed for this analysis by mid-2017, with results from the interim analysis anticipated in 2019. We also have an ongoing Phase 2 clinical trial, known as the CONTROL trial, to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. We completed enrollment of the targeted number of patients for our CONTROL trial in October 2016 and expect top-line results in 2017. We continue to work towards expanding our overall NASH development program with additional trials and studies, including a Phase 3 trial in NASH patients with cirrhosis, which we expect to initiate in 2017.

OCA was generally well tolerated in the FLINT trial. Adverse events were generally mild to moderate in severity and the incidence in the OCA and placebo treatment groups was similar for all symptoms except pruritus. Pruritus in the OCA treatment group occurred more frequently (23% versus 6%, p < 0.0001), at a higher grade (predominantly moderate pruritus) but resulted in only one patient discontinuation. The incidence of severe or life threatening events was not different between the two treatment groups and most of the events in both groups were deemed to be unrelated to treatment, including all severe or life threatening cardiovascular events. As previously disclosed, two deaths occurred in the OCA treatment group, but neither was considered related to OCA treatment.

(Emphases added.)

- 30. The 2016 10-K contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the 2016 10-K was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 31. On May 10, 2017, Intercept filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended March 31, 2017 (the "Q1 2017 10-Q"). For the quarter, the Company reported a net loss of \$89.93 million, or \$3.61 per diluted share, on revenue of \$21.05 million, compared to a net loss of \$126.67 million, or \$5.17 per diluted share, on revenue of \$450,000 for the same period in the prior year.
- 32. The Q1 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q1 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 33. On July 31, 2017, the Company held an earnings call with investors for the quarter ended June 30, 2017. During the conference call, Defendant Pruzanski discussed its lead product OCA, stating in relevant part:

Consistent with our previous experience, pruritus was the most commonly observed adverse event in the study, with all such events reported by patients as mild or

moderate. While there is no difference in incidents between placebo and the 5 and 10 milligrams OCA groups, just over half of the 25 milligrams OCA patients reported pruritus, resulting in two treatment discontinuations.

Other treatment-emergent adverse events were similar across all groups, *with no unexpected safety findings*. Overall, 97% of patients who completed the double-blind phase opted to continue on treatment in the two-year LTSE phase.

(Emphasis added.)

- 34. On August 3, 2017, Intercept filed a quarterly report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarter ended June 30, 2017 (the "Q2 2017 10-Q"). For the quarter, the Company reported a net loss of \$86.56 million, or \$3.46 per diluted share, on revenue of \$30.89 million, compared to a net loss of \$77.30 million, or \$3.14 per diluted share, on revenue of \$5.52 million for the same period in the prior year.
  - 35. In the Q2 2017 10-Q, the Company stated, in relevant part:

The most common side effects observed in clinical trials of OCA in PBC were pruritus, or itching, fatigue, headaches, nausea, constipation and diarrhea. In our POISE trial, pruritus, generally mild to moderate, was the most frequently reported adverse event associated with OCA treatment and was observed in 38% of patients on placebo, 70% of patients in the 10 mg OCA group and 56% of patients in the OCA titration group (5 mg to 10 mg). Eight patients discontinued due to pruritus, of whom none were in the placebo group, seven (10%) patients were in the 10 mg OCA group and one (1%) patient was in the OCA titration group. Pruritus also has been observed in other clinical trials of OCA. Decreases in HDL cholesterol were also observed during treatment in the POISE trial. In our Phase 2 trials for OCA in PBC, a dose-response relationship was observed for the occurrence of liver-related adverse reactions, including jaundice, ascites and primary biliary cholangitis flare with dosages of OCA of 10 mg once daily to 50 mg once daily (up to 5-times the highest recommended dosage), as early as one month after starting treatment with OCA. The European label for Ocaliva also notes that elevations in alanine amino transferase and aspartate aminotransferase were observed in patients treated with OCA.

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During the ongoing long-term safety extension, or LTSE, phase of CONTROL, there has been one patient death...

The principal investigator determined that the events leading to the patient's death were unlikely related to OCA. Despite the numerous confounding factors in this

case, given the contemporaneous administration of OCA during the patient's ongoing deterioration, we determined that it could not be ruled out that these events were possibly related to treatment. Subsequent to our determination, the independent data safety monitoring committee separately evaluated the case and determined that the events leading to the patient's death were unlikely related to OCA.

(Emphasis added.)

- 36. The Q2 2017 10-Q contained signed certifications pursuant to SOX by the Individual Defendants, stating that the financial information contained in the Q2 2017 10-Q was accurate and disclosed any material changes to the Company's internal control over financial reporting.
- 37. The statements referenced in ¶¶ 23-36 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Ocaliva entailed undisclosed safety risks, including death, to patients suffering from PBC; and (ii) as a result of the foregoing, Intercept's public statements were materially false and misleading at all relevant times.

## **The Truth Begins to Emerge**

- 38. On September 12, 2017, Intercept issued a letter warning physicians against overdosing patients with Ocaliva, advising them that the drug has been tied to liver injuries and death among patients suffering from PBC.
- 39. On this news, Intercept's share price fell \$15.36, or 13.53%, to close at \$98.12 on September 12, 2017.
- 40. On September 21, 2017, the FDA issued a safety announcement entitled "FDA Drug Safety Communication: FDA warns about serious liver injury with Ocaliva for rare chronic

liver disease," warning doctors after reports of multiple deaths linked to the drug. In the safety announcement, the FDA stated in relevant part:

[09-21-2017] The Food and Drug Administration (FDA) is warning that the liver disease medicine Ocaliva is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. *Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose*. The recommended dosing and monitoring for patients on Ocaliva are described in the current drug label. We are working with the drug manufacturer, Intercept Pharmaceuticals, to address these safety concerns.

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In the 13 months after Ocaliva was approved in May 2016, FDA received reports of serious liver injury or death associated with Ocaliva.\* The FDA's Adverse Event Reporting System (FAERS) includes only reports submitted to FDA, so there may be additional cases about which we are unaware.

Nineteen cases of death were identified, of which eight provided information about the patient's cause of death. The cause of death was reported to be worsening of PBC disease in seven cases, with cardiovascular disease cited in the other case. Seven of these eight cases described patients with moderate to severe decreased liver function who received Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly as recommended in the label prescribing information for patients with this extent of decreased liver function.

FDA also identified 11 cases of serious liver injury with Ocaliva use. Six of the patients who had moderate or severe decreases in liver function at baseline and developed serious liver injury were receiving Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly as recommended by FDA in the drug label. Three of these six patients died, which were included in the 19 death cases mentioned previously. Ocaliva was discontinued in four of six cases, which resulted in one patient experiencing symptom resolution and an improvement in a liver blood test. The remaining three cases did not report the response after discontinuation. The other five cases of serious liver injury were reported in patients with no or mild decreases in liver function prior to initiating Ocaliva. Four of these five patients received Ocaliva 5 mg daily, and one did not report the dose. Ocaliva was discontinued in all five cases, which resulted in one patient experiencing symptom resolution and one patient experiencing improved liver blood tests and symptom resolution. The remaining three cases did not report the response after discontinuation.

(Emphases added.)

- 41. On this news, Intercept's share price fell \$24.42, or 24.88%, to close at \$73.70 on September 21, 2017.
- 42. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

# PLAINTIFF'S CLASS ACTION ALLEGATIONS

- 43. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Intercept securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.
- 44. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Intercept securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Intercept or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 45. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 46. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 47. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
  - whether the federal securities laws were violated by Defendants' acts as alleged herein;
  - whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Intercept;
  - whether the Individual Defendants caused Intercept to issue false and misleading financial statements during the Class Period;
  - whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
  - whether the prices of Intercept securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
  - whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 48. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

- 49. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-the-market doctrine in that:
  - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
  - the omissions and misrepresentations were material;
  - Intercept securities are traded in an efficient market;
  - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
  - the Company traded on the NASDAQ and was covered by multiple analysts;
  - the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
  - Plaintiff and members of the Class purchased, acquired and/or sold Intercept securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 50. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 51. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

#### **COUNT I**

# (Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

52. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

- 53. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Intercept securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Intercept securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.
- Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Intercept securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Intercept's finances and business prospects.
- 56. By virtue of their positions at Intercept, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended

thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

- 57. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Intercept, the Individual Defendants had knowledge of the details of Intercept's internal affairs.
- 58. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Intercept. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Intercept's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Intercept securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Intercept's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Intercept securities at artificially inflated prices and relied upon the price of the securities,

the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

- 59. During the Class Period, Intercept securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Intercept securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Intercept securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Intercept securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.
- 60. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 61. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

#### **COUNT II**

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

- 62. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.
- 63. During the Class Period, the Individual Defendants participated in the operation and management of Intercept, and conducted and participated, directly and indirectly, in the conduct of Intercept's business affairs. Because of their senior positions, they knew the adverse non-public information about Intercept's misstatement of income and expenses and false financial statements.
- 64. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Intercept's financial condition and results of operations, and to correct promptly any public statements issued by Intercept which had become materially false or misleading.
- Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Intercept disseminated in the marketplace during the Class Period concerning Intercept's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Intercept to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Intercept within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Intercept securities.
- 66. Each of the Individual Defendants, therefore, acted as a controlling person of Intercept. By reason of their senior management positions and/or being directors of Intercept, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Intercept to engage in the unlawful acts and conduct complained of herein. Each of the

Individual Defendants exercised control over the general operations of Intercept and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

67. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Intercept.

## PRAYER FOR RELIEF

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and postjudgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
  - D. Awarding such other and further relief as this Court may deem just and proper.

## **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

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